
Harmonization of Transportation Safety Requirements with International Atomic Energy Agency

Proposed Rule—Regulatory Analysis

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Abstract

The U.S. Nuclear Regulatory Commission (NRC), in consultation with the U.S. Department of Transportation (DOT), is proposing to amend its regulations for the packaging and transportation of radioactive material. The NRC has historically been consistent in harmonizing its transportation safety regulations with the International Atomic Energy Agency (IAEA) standards. These changes are necessary to maintain a consistent regulatory framework with the DOT for the domestic packaging and transportation of radioactive material and to ensure general accord with these standards. Concurrently, the NRC is issuing for public comment draft regulatory guide (DG) DG-7011 “Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material,” which is Revision 3 to Regulatory Guide (RG) 7.9. The guidance identifies the information to be provided for package approval and establishes a uniform format for presenting that information.

This document presents a regulatory analysis of the proposed rule, “Harmonization of Transportation Safety Requirements with International Atomic Energy Agency,” and DG-7011. The rule would result in a net incremental cost of (\$542,909). The proposed rule cost estimate represents the following estimated costs and savings for licensees, certificate of compliance (CoC) holders, Agreement States, and the NRC:

- The licensees are estimated to save \$5,929,424.
- The CoC holders are expected to incur a cost of (\$2,574,442).
- The NRC is expected to incur a cost of (\$1,489,808), which includes the rulemaking development and implementation costs (\$1,169,291) and an operational cost of (\$320,517).
- Agreement States are expected to incur a net cost of (\$2,408,083) to implement the rule and revise procedures. This estimate includes the implementation cost of the rule by the Agreement States of (\$2,242,429). The rulemaking action will also result in a marginal operational cost of (\$165,654) to the Agreement States.
- The proposed rule is not cost-justified in that the total net incremental quantitative costs are estimated to exceed the incremental “averted” costs or savings by (\$543,000). However, the rulemaking represents the best option that can address all the issues and could result in net savings of \$3,354,982 in averted costs to industry. Furthermore, the proposed rule is expected to have important qualitative benefits, including: (1) harmonization of the NRC regulations in Part 71 of Title 10 of the *Code of Federal Regulations*, “Packaging and Transportation of Radioactive Material,” with the IAEA’s safety standards, thereby reducing the regulatory burden on the licensees by eliminating conflicting requirements; (2) assurance that the NRC’s regulations continue to be consistent with the DOT regulations for domestic transportation of radioactive materials; and (3) consistency with the NRC’s response to previous revisions and updates of IAEA standards, without any broad programmatic requirements or significant negative impacts on the NRC’s licensees or CoC holders. For these reasons, the qualitative benefits of the rule outweigh its costs.

To improve the credibility of the NRC’s cost estimates for this regulatory action, the NRC conducted an uncertainty analysis to consider the effects of input uncertainty on the cost estimate, and a sensitivity analysis to identify the variables that most affect the cost estimate

(i.e., the cost drivers). The NRC's analysis demonstrates that the proposed rule would result in a net increase in cost to the industry and the NRC of approximately \$543,000 using a 7 percent discount rate.

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Abbreviations and Acronyms

ACRS	Advisory Committee on Reactor Safeguards
ADAMS	Agencywide Documents Access and Management System
Bq	Becquerel
°C	degrees Celsius
CFR	<i>Code of Federal Regulations</i>
Ci	Curie
CoC	Certificate of Compliance
CSI	Criticality Safety Index
DOE	U.S. Department of Energy
DOT	U.S. Department of Transportation
EA	Environmental Assessment
°F	degrees Fahrenheit
FR	<i>Federal Register</i>
g	Gram
g cal/cm ²	Gram-calories per square centimeter
HMR	Hazardous Materials Regulations
IAEA	International Atomic Energy Agency
ISO	International Organization for Standardization
LDM	Low Dispersible Material
LSA	Low Specific Activity
MOU	Memorandum of Understanding
NRC	U.S. Nuclear Regulatory Commission
NPV	Net Present Value
NUREG	Nuclear Regulatory Publication
Pa	Pascal
psi	Pounds Per Square Inch
QAP	Quality Assurance Program
Rem	Roentgen Equivalent Man
SCO	Surface Contaminated Object
SI	International System of Units
SOC	statement of consideration
SRM	Staff Requirements Memorandum
SRP	Standard Review Plan

SSR-6	IAEA Specific Safety Requirements Number SSR-6, "Regulations for the Safe Transport of Radioactive Material"
Sv	Sievert
TRANSSC	Transportation Safety Standards Committee
UF ₆	Uranium Hexafluoride
W/m ²	Watts per square meter

Executive Summary

On June 12, 2015, the U.S. Nuclear Regulatory Commission (NRC), in consultation with the U.S. Department of Transportation (DOT), published a final rule that amended the NRC's regulations for the packaging and transportation of radioactive material (80 FR 33988; June 12, 2015) [1]. These amendments made conforming changes to the NRC's regulations based on the standards of the International Atomic Energy Agency (IAEA). That final rule, in combination with a DOT final rule (79 FR 40589; July 11, 2014) [3] amending Title 49 of the *Code of Federal Regulations* (49 CFR), brought U.S. regulations into general accord with the 2009 edition of the IAEA's "Regulations for the Safe Transport of Radioactive Material" (TS-R-1) [4]. The IAEA has since updated its standards for the transport of radioactive material in Specific Safety Requirements No. 6 (SSR-6) (2012 and 2018 Editions) [5,7]. In that final rule, the Commission stated that the NRC will consider any necessary changes related to SSR-6 in a future rulemaking after consulting with the DOT.

In SECY-16-0093, dated July 28, 2016 [8], the NRC staff requested Commission approval to initiate a rulemaking related to harmonizing Part 71 of Title 10 of the *Code of Federal Regulations* (10 CFR), "Packaging and Transportation of Radioactive Material," with the updated IAEA standards in SSR-6, 2012 Edition, along with the then-anticipated 2018 Edition, and DOT regulations. The Commission approved the NRC staff recommendation via a staff requirements memorandum, SRM-SECY-16-0093, dated August 19, 2016 [9]. This rulemaking harmonizing NRC regulations with the 2018 Edition of SSR-6 includes changes made in the 2012 Edition of SSR-6 that have been carried forward to the 2018 Edition.

The DOT and the NRC coregulate transportation of radioactive materials in the United States. The roles of the DOT and the NRC in the coregulation of the transportation of radioactive materials are documented in a Memorandum of Understanding (44 FR 38690; July 2, 1979) [10]. The NRC and the DOT have historically coordinated to harmonize their respective regulations to the IAEA revisions through the rulemaking process.

The NRC reviewed the updated IAEA standards [5,7] and identified 15 regulatory issues to be analyzed during the rulemaking development process. Issues 1–14 were previously documented in an "issues paper" [11]. In addition to the harmonization issues, NRC staff identified administrative and editorial changes that are needed to clarify certain regulations. The NRC staff also identified additional items to consider in the rulemaking that were not covered in the issues paper (reporting requirements, definition for low specific activity (LSA), advance notification of shipments of irradiated reactor fuel and nuclear waste, Tables A-1 and A-2 in Appendix A to 10 CFR Part 71, and the changes to Agreement State compatibility categories); these items have been grouped under a new issue that was designated as Issue 15.

The NRC issued a notice of the issues paper, public meeting, and request for comment in the *Federal Register* on November 21, 2016 [12], and held a public meeting December 5-6, 2016, to discuss the issues paper. The NRC subsequently issued a summary of the public meeting [13]. After the public meeting, the NRC received 49 comment letters on the issues paper, identified comments that are pertinent to the rulemaking action, and considered these comments in the development of the draft regulatory basis [22].

In this regulatory analysis, the NRC considers and evaluates two alternative actions to align the NRC's regulations with the IAEA standards and DOT regulations: a no-action option maintaining

the status quo (Alternative 1), and an action to initiate a rulemaking to revise 10 CFR Part 71 (Alternative 2).

The alternatives were analyzed based on their viability to resolve the regulatory issues of concern and estimates of their costs and potential benefits. The NRC determined that the rulemaking action (Alternative 2), represents the best approach to accomplish the goal of harmonization with SSR-6 and it is the recommended action by the NRC. Other alternatives that were considered in the draft regulatory basis and then rejected included issuing generic communications and regulatory guidance and issuing license-specific conditions and exemptions. These were rejected because they would not address all the regulatory issues of concern or would result in higher costs to the NRC and industry.

Table ES-1 below lists the 15 regulatory issues identified and analyzed by the NRC, including the recommended action and net present value (NPV) estimates of cost and potential benefits by issue. All costs are in 2020 dollars and are calculated using a 7-percent discount rate.

Table ES-1 Net Benefits (Costs) by Issue

Issue No.	Description	Net Benefits (Costs) (2020 dollars at 7% NPV) ^{a,b,c,d,e}
1	Revision of Fissile Exemptions	\$3,678,000
2	Revision of Reduced External Pressure Test for Normal Conditions of Transport ^d	\$0
3	Type C Package Standards ^d	Not Analyzed
4	Revision of Insulation Requirements for Package Evaluations	(\$1,399,000)
5	Inclusion of Definition for Radiation Level ^e	\$0
6	Deletion of the Low Specific Activity-III Leaching Test	\$73,000
7	Inclusion of New Definition for Surface Contaminated Object	\$1,174,000
8	Revision of Uranium Hexafluoride Package Requirements (UF ₆ Cylinder Plugs)	(\$82,000)
9	Inclusion of Evaluation of Aging Mechanisms and a Maintenance Program	\$0
10	Revision of Transitional Arrangements	(\$1,987,000)
11	Inclusion of Head Space for Liquid Expansion	(\$8,000)
12	Revision of Quality Assurance Program Biennial Reporting Requirements	(\$31,000)
13	Deletion of Type A Package Limitations in Fissile Material General Licenses	\$23,000
14	Deletion of ²³³ U Restriction in Fissile General License	\$1,592,000
15	Other Recommended Changes to 10 CFR Part 71.95	(\$166,000)
<i>Operation Costs (By Issue) Total</i>		\$2,869,000
Non-Issue Specific Benefits (Costs)		
NRC Rulemaking Implementation Costs		(\$1,169,000)
Agreement States Implementation Costs		(\$2,242,000)
Total Benefits (Costs)		(\$543,000)

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b The values are rounded to the nearest thousand dollars.

^c Benefits and averted costs are positive. Costs are (negative).

^d The NRC did not analyze the costs for Issue 3 because NRC is not proposing to adopt Type C standards in NRC regulations for domestic transport. The NRC did analyze the costs for Issue 2, and decided to not propose reduced external pressure test requirements.

- ^e The costs for issue 5 are solely for performing the rulemaking which are calculated in the NRC implementation costs.

The NRC proposes to conduct rulemaking to address and resolve all issues except for Issues 2 and 3 (no-action to harmonize with SSR-6):

1. IAEA harmonization issues (Issues 1, 4, 5, 6, 7, 8, 9, 10, 11, and 15 (in part)): Staff assessments of these issues identified potential revisions to harmonize the existing regulations with the IAEA standards.
2. DOT compatibility issues (Issues 6, 7, 10, 11, and 15 (in part)): NRC assessments of these issues identified potential revisions to ensure compatibility between revisions to the NRC regulations in 10 CFR Part 71 and amendments to the DOT regulations.
3. Administrative, editorial, or clarification issues (Issues 12, 13, 14, and 15 (in part)). NRC assessments of these issues identified potential changes to clarify the regulations and improve 10 CFR Part 71 implementation.

The total cost in Table ES-2 includes estimates of the NRC implementation costs for 2 years (2020 and 2021), and the operational costs, where applicable, during the first 11 years after the effective date of the rule (2022 through 2032, inclusive). The NRC chose this time frame because, on average, the NRC rulemaking to harmonize 10 CFR Part 71 with the IAEA standards has followed an 11-year cycle. The total cost is the net present value of costs and benefits in 2020 dollars. Averted costs are costs of activities and actions performed under the existing regulations that would no longer be required if the proposed revision to the regulations is implemented, and they are assigned positive values. Costs are new or additional actions associated with the rule, if approved, and they are assigned negative values and displayed in parentheses. For example, the Agreement States rule development cost of (\$2,242,429) and the net cost of (\$542,909) are both negative values and are displayed in parentheses.

The estimated costs for the rule, including its associated guidance development, are:

- The NRC would incur a cost of (\$1,489,808), which includes the rulemaking development and implementation costs of (\$1,169,291) and a cost of (\$320,517) for operation.
- The Agreement States would incur a total net cost of (\$2,408,083) to implement the rule, to adopt equivalent requirements, and revise procedures. This estimate includes the implementation cost of the rule by the Agreement States of (\$2,242,429) and a small operational cost of (\$165,654).
- The rule would result in a net savings to industry of \$3,354,982. This is comprised of a savings of \$5,929,424 to fissile material licensees and nuclear power plant licensees that ship LSA-III material. However, the NRC expects that certificate holders would incur costs of (\$2,574,442) for changes to regulations that affect their package preparation and approval.

Table ES-2 provides a summary of the net benefits that would result from this rule to the NRC, Agreement States, and the industry licensees and CoC holders. The estimate is reported in 2020 dollars and based on a 7-percent discount rate.

Table ES-2 Net Benefits (Costs) by Affected Entity

Issue No.	Description	Alternative 2 Net Benefits (Costs)—2020 dollars at 7% NPV				
		NRC	Industry (Licensee)	Industry (CoC Holder)	Agreement States	Total ^{a b}
1	Revision of Fissile Exemptions	\$3,561	\$3,674,423	\$0	\$0	\$3,677,984
2	Revision of Reduced External Pressure Test for Normal Conditions of Transport	\$0	\$0	\$0	\$0	\$0
3	Type C Package Standards	\$0	\$0	\$0	\$0	\$0
4	Revision of Insolation Requirements for Package Evaluations	(\$168,222)	\$0	(\$1,230,879)	\$0	(\$1,399,102)
5	Inclusion of Definition for Radiation Level	\$0	\$0	\$0	\$0	\$0
6	Deletion of the Low Specific Activity-III Leaching Test	\$0	\$73,106	\$0	\$0	\$73,106
7	Inclusion of New Definition for Surface Contaminated Object	\$600,913	\$573,391	\$0	\$0	\$1,174,304
8	Revision of Uranium Hexafluoride Package Requirements (UF ₆ Cylinder Plugs)	(\$13,221)	\$0	(\$69,019)	\$0	(\$82,241)
9	Inclusion of Evaluation of Aging Mechanisms and a Maintenance Program	\$0	\$0	\$0	\$0	\$0
10	Revision of Transitional Arrangements	(\$746,713)	\$0	(\$1,240,161)	\$0	(\$1,986,874)
11	Inclusion of Head Space for Liquid Expansion	(\$2,003)	\$0	(\$5,734)	\$0	(\$7,737)
12	Revision of Quality Assurance Program Biennial Reporting Requirements	(\$1,926)	\$0	(\$28,649)	\$0	(\$30,575)
13	Deletion of Type A Package Limitations in Fissile Material General Licenses	\$7,094	\$16,137	\$0	\$0	\$23,231
14	Deletion of ²³³ U Restriction in Fissile General License	\$0	\$1,592,368	\$0	\$0	\$1,592,368
15	Other Recommended Changes to 10 CFR 71.95	\$0	\$0	\$0	(\$165,654)	(\$165,654)
Operational (Costs) (By Issue) Total		(\$320,517)	\$5,929,424	(\$2,574,442)	(\$165,654)	\$2,868,811
Non-Issue Specific Benefits (Costs)						
NRC Rulemaking Implementation (Costs)		(\$1,169,291)	\$0	\$0	\$0	(\$1,169,291)
Agreement States Implementation (Costs)		\$0	\$0	\$0	(\$2,242,429)	(\$2,242,429)
Total Benefit (Cost)		(\$1,489,808)	\$5,929,424	(\$2,574,442)	(\$2,408,083)	(\$542,909)

^a NPV = net present value^b Averted cost = positive, normal cost is (negative)

The estimated net cost of the rule is approximately (\$542,909). These costs are dominated by NRC rulemaking costs and costs by Agreement States to promulgate and implement the rule and revise procedures accordingly. However, the staff determined that rulemaking is the only option that can meet all regulatory objectives and that it would result in net savings to the industry. Furthermore, the rule is expected to have important qualitative benefits, including harmonization of the NRC regulations in 10 CFR Part 71 with the IAEA's safety standards, which minimizes potential international commerce disruption and helps to ensure that international obligations are met (e.g., for air transport, the IAEA transport standards serve as the basis for the International Civil Aviation Organization Technical Instructions, as they relate to radioactive material, with which the U.S. must comply according to the Convention on International Civil Aviation - also known as the Chicago Convention), and assurance that the NRC's regulations continue to be consistent with DOT regulations for the domestic transportation of radioactive materials. For these reasons, the qualitative benefits of the rule outweigh its costs.

1 Introduction

In SECY-16-0093, dated July 28, 2016 [8], the U.S. Nuclear Regulatory Commission (NRC) staff requested Commission approval of a rulemaking plan to initiate a rulemaking to: (1) harmonize Part 71 of Title 10 of the *Code of Federal Regulations* (10 CFR), “Packaging and Transportation of Radioactive Material,” with the International Atomic Energy Agency’s (IAEA) transportation safety standards and the U.S. Department of Transportation’s (DOT) standards and (2) make staff-initiated administrative, editorial, or clarifying changes to 10 CFR Part 71. More specifically, the rulemaking would revise and harmonize the NRC’s regulations for packaging and transportation with the 2018 Edition of the IAEA’s Specific Safety Requirements No. 6 (SSR-6) [7], ensure compatibility with DOT regulations, and make NRC staff-initiated changes. Harmonizing NRC regulations with the 2018 Edition of SSR-6 includes changes made in the 2012 Edition of SSR-6 that have been carried forward to the 2018 Edition. The Commission approved the NRC staff recommendation via a staff requirements memorandum (SRM) to SECY-16-0093, dated August 19, 2016 [9].

The DOT is undertaking a similar rulemaking to harmonize its regulations for the transportation of radioactive material in Parts 107 and 171-180 of Title 49 of the *Code of Federal Regulations* (49 CFR) with the IAEA’s standards in the 2018 Edition of SSR-6.

2 Statement of the Problem and Objective

2.1 Background

The IAEA establishes safety standards to protect public health and safety and to minimize the danger to life and property. The IAEA has developed international safety standards for the safe transport of radioactive material. The IAEA safety standards are developed in consultation with the competent authorities of Member States, so they reflect an international consensus on what is needed to provide for a high-level of safety. The U.S. is a Member State and the DOT is the competent U.S. authority before the IAEA for radioactive material transportation matters. By providing a global framework for the consistent regulation of the transport of radioactive material, SSR-6 [7] facilitates international commerce and contributes to the safe conduct of international trade involving that material. By periodically revising NRC regulations to be compatible with IAEA standards and DOT regulations, the NRC is able to remove inconsistencies that could impede international commerce for NRC licensees.

The roles of the DOT and the NRC in the coregulation of the transportation of radioactive materials are documented in a Memorandum of Understanding (44 FR 38690; July 2, 1979) [10]. Because the DOT and the NRC coregulate transportation of radioactive materials in the U.S., the two agencies have historically coordinated to harmonize their respective regulations to the IAEA revisions through the rulemaking process. In the NRC’s previous 10 CFR Part 71 harmonization rulemaking, published in the *Federal Register* on June 12, 2015 [1], the Commission stated that the NRC will consider any necessary changes related to SSR-6 in a future rulemaking after consulting with the DOT.

The NRC staff engaged with the DOT staff in the development of this proposed rule to identify and evaluate gaps between 10 CFR Part 71 regulations and the updated IAEA standards in SSR-6, 2018 Edition. The DOT is undertaking a similar initiative to harmonize its regulations for the transportation of radioactive material in 49 CFR Parts 107 and 171-180 with the 2018 Edition of SSR-6.

The NRC reviewed the 2018 Edition of the IAEA standard and identified 10 regulatory issues for harmonization with IAEA and another 4 NRC-initiated changes to 10 CFR Part 71 to be evaluated during the rulemaking development process. Fourteen of these issues were documented in the issues paper [11]. A notice of the issues paper, public meeting, and request for comment was published in the *Federal Register* (81 FR 83171; November 21, 2016) [12]. The NRC held a public meeting on December 5-6, 2016, to discuss the issues paper, and the DOT participated in that public meeting. A summary of the public meeting, including the attendance list, was prepared [13]. After the public meeting, the NRC received 49 comment submissions on the issues paper and identified comments that are pertinent to the rulemaking action. More recently, the NRC identified other potential changes to clarify the regulations and ensure compatibility with the DOT and Agreement State regulations, and these potential changes were grouped under a new issue that was designated as Issue 15.

On April 12, 2019, the NRC noticed the draft regulatory basis for this rulemaking in the *Federal Register* and requested public comments (84 FR 14898; April 12, 2019) [23]. The NRC held a public meeting on April 30, 2019, to discuss the draft regulatory basis and answer questions. The NRC received seven public comment submissions on the draft regulatory basis. Because none of the comments would result in significant changes to the draft regulatory basis, the NRC decided against preparing a final regulatory basis. Instead, the NRC has considered these comments in preparing the proposed rule.

In the draft regulatory basis, the NRC evaluated four alternative actions for each issue. These were: (1) a no-action option that would maintain the status quo (Alternative 1); (2) issue generic communications and regulatory guidance (Alternative 2); (3) issue license-specific conditions and exemptions (Alternative 3); and (4) initiate a rulemaking action to revise 10 CFR Part 71 (Alternative 4). The alternatives were evaluated based on their viability to resolve the regulatory issues of concern and estimates of their costs and potential benefits. The NRC determined that the rulemaking action (Alternative 4) for Issues 1 (in part), 2, 4, and 6-15, in combination with the no-action alternative (Alternative 1) for Issue 3, is the NRC-recommended action because it represents the best and least costly option. Alternatives 2 and 3 would not address all the regulatory issues or would result in higher costs to the NRC and industry and, therefore, have not been carried forward to the proposed rule. As a result, this regulatory analysis renames Alternative 4 as Alternative 2. While the NRC is not proposing to adopt IAEA changes for Issue 5, the NRC is proposing to clarify the meaning of radiation level. After subsequent evaluation during the development of the proposed rule, the NRC determined that the no-action alternative (Alternative 1) for Issue 2 is appropriate.

2.2 Statement of the Problem

Compatibility of the U.S. domestic regulations with the international standards provides a consistent basis for safe packaging and transportation of radioactive material, reduces impediments to trade, facilitates international cooperation, reduces safety risk associated with the import and export of radioactive material, and can be expected to have safety benefits. If the NRC does not pursue rulemaking it will result in inconsistencies and differences between the NRC's regulations and the IAEA's standards, as well as the DOT's regulations. Such inconsistencies and differences can cause uncertainty because of conflicting or duplicative requirements and have negative impacts on both existing and new licensees for domestic transport. Conflicting or duplicative requirements between NRC and foreign competent authorities can impede international transport. Also, the IAEA has periodically changed its standards to take advantage of increased knowledge and industry experience, and without this

proposed harmonization, 10 CFR Part 71 regulations would continue to diverge from the international standards. A decision not to harmonize at this time may make harmonization of the NRC regulations with the international standards (and possibly DOT regulations) increasingly difficult over time.

The NRC evaluated two alternative actions to align the NRC's regulations with the IAEA standards: a no-action option that would maintain the status quo (Alternative 1); and a rulemaking option that would revise 10 CFR Part 71 (Alternative 2) and issue DG-7011 to update Regulatory Guide 7.9, "Standard Format and Content of 10 CFR Part 71 Applications for Approval of Packages for Radioactive Material."

2.3 Objectives

Consistent with the rulemaking process, this regulatory analysis describes and documents the results of assessments and analyses performed by the NRC in support of the proposed rule. The regulatory analysis addresses the regulatory issues (Section 2); alternative actions (Section 3); cost estimates (Section 4 and Appendix A); uncertainty analysis (Section 5); other impacts and regulatory considerations (Section 6); and summary and conclusions (Section 7). The regulatory analysis is supported by Appendix A, which provides supporting information for the uncertainty analysis.

3 Discussion of Alternatives

3.1 Action the NRC is Proposing to Take

The NRC is proposing to amend its regulations to harmonize them with SSR-6, 2018 Edition. These revisions also would be consistent with the DOT's hazardous materials regulations, as DOT is undertaking a similar rulemaking to maintain a consistent framework for the domestic packaging and transportation of radioactive material.

In addition to harmonization with SSR-6, 2018 Edition, the proposed rule would revise 10 CFR Part 71 to include administrative, editorial, and clarification changes, including changes to Agreement State compatibility category designations of certain regulations in order to allow the Agreement States to adopt equivalent requirements.

3.2 Applicability of the Proposed Action

This action would affect: (1) NRC licensees authorized by a specific or general license issued by the Commission to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, or transports the material outside of the site of usage as specified in the NRC license, or transports that material on public highways; (2) holders of, and applicants for, a CoC under 10 CFR Part 71; and (3) holders of a 10 CFR Part 71 quality assurance program (QAP) approval. This action also would change regulations that are a matter of compatibility with the Agreement States. Therefore, the Agreement States would need to update their regulations, as appropriate, at which time those licensees located within Agreement States would need to meet the compatible Agreement State regulations.

3.3 Proposed Changes to NRC Transportation Regulations

The NRC is proposing to revise its regulations under 10 CFR Part 71 to: (1) harmonize and ensure general accord with the IAEA international transportation standards in SSR-6; (2) be compatible with the DOT regulations; and (3) include NRC staff-initiated changes. These changes would also improve or maintain consistency between 10 CFR Part 71 and DOT regulations under 49 CFR to maintain a consistent domestic framework for the packaging and transportation of radioactive material. To accomplish these goals, the NRC is proposing to revise 10 CFR Part 71 as described in the following sections.

For each of the issues, this regulatory analysis considers two options: Alternative 1, the No-Action alternative, and Alternative 2, to pursue rulemaking to amend 10 CFR Part 71, and describes the advantages and disadvantages of each alternative.

3.3.1 Issue 1. Revision of Fissile Exemptions

In 2012, the IAEA modified the fissile exception provisions in SSR-6 paragraph 417 to include three new per-package mass limit options, with associated mass limits on the consignment and/or conveyance.

The NRC proposes to incorporate SSR-6 paragraph 417(c) into a new provision under 10 CFR 71.15 for 3.5 grams or less ²³⁵U, provided the uranium is enriched in ²³⁵U to a maximum of 5 percent by weight, and the total plutonium and ²³³U content does not exceed 1 percent of the mass of ²³⁵U. The NRC is not proposing to incorporate the associated consignment limit of IAEA SSR-6 paragraph 570(c). The NRC also proposes to incorporate SSR-6 paragraph 417(e), with its associated exclusive use restriction in paragraph 570(e), but with a higher mass limit of 140 grams of fissile material, as an additional fissile exemption under 10 CFR 71.15(g). The NRC is not proposing to incorporate the IAEA SSR-6 fissile exception in paragraph 417(d).

Alternative 1: No-Action Alternative

Under the no-action alternative, the two proposed additions to the 10 CFR Part 71 fissile exemptions described in Issue 1a would not be made, and licensees wishing to ship the amounts of fissile material described in these proposed changes would have to submit an application for a Type AF or B(U)F/B(M)F package and demonstrate that the package meets the criticality safety requirements of 10 CFR 71.55 and 71.59. This alternative would leave the fissile exempt material requirements in 10 CFR 71.15 unchanged and these requirements would not be harmonized with similar requirements in SSR-6, 2018 Edition.

Alternative 2: Revise 10 CFR Part 71

If the NRC were to complete the proposed rulemaking, the fissile exemption changes in 10 CFR 71.15 would be codified, and it would be clear to all current and future licensees, applicants, and staff that the NRC considers this material to be subcritical without a demonstration of compliance with 10 CFR 71.55 and 71.59. Additionally, the changes would meet the intent of the fissile exemptions, in that licensees could self-certify packages for shipping the amount of material described in the two proposed changes. If the NRC were to move forward with the proposed rulemaking, the fissile exemptions in 10 CFR 71.15 would be more consistent with similar provisions in IAEA SSR-6 paragraph 417. Since harmonization with IAEA SSR-6, to the extent described above, facilitates the safe transportation of fissile material internationally, performing the rulemaking as proposed is the staff-recommended alternative.

3.3.2 Issue 2. Revision of Reduced External Pressure Test for Normal Conditions of Transport

The NRC has decided not to further pursue any changes to the reduced external pressure test requirement under 10 CFR Part 71.71(c)(3). As a result, no further discussion or analysis is presented in this regulatory analysis on that issue.

3.3.3 Issue 3. Type C Package Standards

The NRC has decided not to further pursue any changes to 10 CFR Part 71 to adopt Type C package standards. As a result, no further discussion or analysis is presented in this regulatory analysis on that issue.

3.3.4 Issue 4. Revision of Insolation Requirements for Package Evaluations

During transport, a package is subjected to heating by the sun (i.e., insolation). The effect of insolation is to increase the package temperature. The NRC is proposing changes to the regulatory requirements for: (1) the unit of measure for the values of insolation in the “Insolation Data” table in 10 CFR 71.71(c)(1) for the heat test for normal conditions of transport; and (2) the initial conditions for the tests for hypothetical accident conditions in 10 CFR 71.73(b).

3.3.4.1 Issue 4.1 Unit of Measure for Insolation for Normal Conditions of Transport

The NRC previously harmonized its regulations with the 1985 Edition of Safety Series No. 6 (60 FR 50248; September 28, 1995). That final rule neither discussed nor proposed changing the units on the heat test for normal conditions of transport in 10 CFR 71.71(c)(1). Consequently, the current units for insolation in 10 CFR Part 71 are “g cal/cm².” This is inconsistent with IAEA standards in the 2018 Edition of SSR-6. As a result, NRC package approvals are evaluated for less insolation than that prescribed by IAEA standards and required by foreign competent authorities.

In order to be used for international transport, NRC-approved packages must be issued a certificate of competent authority from the DOT. For NRC-approved packages, the DOT issues certificates of competent authority based on the NRC CoC. The amount of insolation evaluated in the thermal evaluation for packages approved by the DOT for international transport, as reviewed by the NRC, is less than the values in the 2018 Edition of SSR-6.

Alternative 1: No-Action Alternative

In considering the no-action alternative, since the NRC values for insolation are lower than the equivalent values in IAEA’s SSR-6, 2018 Edition, applicants for a transportation CoC can voluntarily use the IAEA values and still meet NRC requirements. However, absent a rule change, the NRC cannot require certificate holders to use the higher IAEA values. Evaluating a package to the lower values may necessitate a different thermal evaluation using the higher IAEA values in SSR-6, 2018 Edition, if requested by a foreign competent authority when reviewing a DOT certificate of competent authority for revalidation for international transportation.

Alternative 2: Revise 10 CFR Part 71

Under this alternative, the NRC would revise the units for insolation for the heat test for normal conditions of transport in 10 CFR 71.71(c)(1) to be consistent with those of the IAEA. Performing the rulemaking would ensure that thermal analyses performed for package approval in the U.S. have the same conditions as those that use IAEA standards for normal conditions of transport. Since regulatory consistency would be achieved, performing the rulemaking is the preferred alternative.

3.3.4.2 Issue 4.2 Initial Conditions for Hypothetical Accident Conditions

In Safety Series No. 6, "Regulations for the Safe Transport of Radioactive Material, 1985 Edition (as amended in 1990)" [24], paragraph 628 stated:

With respect to the initial conditions for the thermal test, the demonstration of compliance shall be based upon the assumption that the package is in equilibrium at an ambient temperature of 38°C. The effects of radiation may be neglected prior to and during the tests but must be taken into account in the subsequent evaluation of the package response.

The thermal test, previously in paragraph 628, was moved to paragraph 728 in the 1996 Edition of TS-R-1 [25] and revised to state:

The specimen shall be in thermal equilibrium under conditions of an ambient temperature of 38 °C, subject to the insolation conditions specified in Table XI and subject to the design maximum rate of internal heat generation within the package from the radioactive contents.

When the NRC revised its regulations in 2004 to harmonize with the 1996 IAEA standard (69 FR 3697; January 26, 2004) [26], the NRC did not revise the initial conditions of the fire test listed in 10 CFR 71.73(b) to explicitly require evaluation of insolation as an initial condition.

Alternative 1: No-Action Alternative

In the no-action alternative, the NRC would not move forward with the proposed rule but would continue to confirm during application review that applicants for a CoC evaluate insolation as a precursor to the fire test. The disadvantage is that the regulations would not explicitly state that insolation is an initial condition to the fire test and NRC regulations would not be harmonized with the IAEA standards for transport of radioactive material.

Alternative 2: Revise 10 CFR Part 71

Under this alternative, the NRC would undertake rulemaking to require insolation as an initial condition to the fire test in 10 CFR 71.73(b) for hypothetical accident conditions. The regulation would be consistent with the IAEA's SSR-6, 2018 Edition, and with requirements in use by other foreign competent authorities, obviating the need for questions about whether insolation was considered in the initial conditions of the tests for hypothetical accident conditions. Since regulatory consistency would be achieved, performing the rulemaking is the preferred alternative.

3.3.5 Issue 5. Inclusion of Definition for Radiation Level

In the 2018 Edition of SSR-6, the IAEA replaced the term “radiation level” with the term “dose rate” and defined the dose rate to be the dose-equivalent per unit time. However, such a change would result in cost impacts to licensees to change documentation and potentially training programs, with no safety benefit. Therefore, in order to minimize the burden to licensees, the NRC is proposing to clarify the term radiation level by adding a definition to 10 CFR 71.4. The NRC is not expecting any licensees to change their documentation due to this new definition.

Alternative 1: No-Action Alternative

The no-action alternative would not change the regulations or guidance. Since this is solely an issue of what to name the dose rate measurements and calculations, there would be no impact to safety by choosing this option.

Alternative 2: Revise 10 CFR Part 71

Rulemaking would add a definition for “radiation level” to state that it means “the radiation dose equivalent rate expressed in millisieverts per hour or mSv/h (millirems per hour or mrem/h)” to ensure that it is clear that the dose rates for NRC-approved packages will meet the dose rate criteria in SSR-6 for approval by foreign competent authorities. Since regulatory consistency would be achieved, performing the rulemaking is the preferred alternative.

3.3.6 Issue 6. Deletion of the Low Specific Activity-III Leaching Test

The qualification tests in 10 CFR 71.77 for low specific activity category III (i.e., LSA-III) material include a leaching test with immersion of the specimen material for 7 days. The IAEA eliminated the LSA-III leaching test in SSR-6, 2018 Edition. Consequently, the NRC is proposing to remove 10 CFR 71.77 and make corresponding revisions to 10 CFR 71.4 and 71.100 to remove reference to the leaching test.

Alternative 1: No-Action Alternative

The no-action alternative would not change the regulations and the leaching test would remain in 10 CFR 71.77. Retaining the status quo would result in an inconsistency between the NRC regulations and the international standard in SSR-6 for this issue. Additionally, the DOT is undertaking a rulemaking to remove the LSA-III leaching test from its regulations under 49 CFR. If the DOT removes the leaching test and the NRC retains the test, an inconsistency would result for this issue. Such an outcome would have a negative impact on the users of the collective domestic transportation regulations (i.e., 10 CFR and 49 CFR).

Alternative 2: Revise 10 CFR Part 71

In an effort to assure international transportation of all types of radioactive material, especially LSA material, the NRC is proposing to harmonize 10 CFR Part 71 with both the DOT regulations and SSR-6 international standards. Through harmonization with the DOT and the IAEA, the LSA-III leaching test would be removed from 10 CFR Part 71. Revising 10 CFR Part 71 to remove the LSA-III leaching test would also result in a reduction in burden and an averted cost to shippers of radioactive material due to the regulatory relief that is achieved by deleting this test requirement for LSA-III material.

An international working group concluded that the then-currently required leaching test for LSA-III material did not contribute to the 50 mSv effective dose transport safety limit. Therefore, the working group recommended to the Transport Safety Standards Committee (TRANSSC) 30 that the leaching test is not necessary or justified and its removal from the transport requirements is appropriate. Thus, the removal of the LSA-III leaching test from SSR-6 benefited from technical and health physics considerations, and TRANSSC made the decision to remove the test from the transport regulations. The NRC recognizes the working group's information and is recommending harmonizing the NRC's regulations with SSR-6, 2018 Edition, and remove the leaching test from 10 CFR Part 71.

3.3.7 Issue 7. Inclusion of New Definition for Surface Contaminated Object (SCO-III)

Decommissioning activities can include transporting large radioactive objects (e.g., steam generators, coolant pumps, and pressurizers). Although 10 CFR 71.41(d) allows for special package authorization of one-time type shipments, the NRC also recognizes that it needs time to complete such an authorization. Efficiencies would be gained for the NRC and for licensees by having a regulatory definition for a third category of large surface contaminated objects. Currently, the regulations in 10 CFR 71.4 contain two definitions for SCO: SCO-I and SCO-II. Harmonization with SSR-6, 2018 Edition, would add the new SCO-III category and the associated definition.

The NRC is proposing to include a definition of SCO-III in 10 CFR 71.4. The NRC is coordinating with the DOT to align on a definition for SCO-III that the DOT would similarly adopt as part of their harmonization rulemaking.

Alternative 1: No-Action Alternative

The no-action alternative would not add a definition for SCO-III to 10 CFR Part 71. This would create a discrepancy between the NRC regulations and SSR-6. Furthermore, the DOT is undertaking a rulemaking to add SCO-III to 49 CFR. If the DOT adds an SCO-III definition and the NRC does not, a regulatory inconsistency would result for this issue necessitating NRC review under 10 CFR 71.41(d) of shipments that can be self-certified and transported under DOT regulations. Additionally, the NRC already includes definitions for the related categories SCO-I and SCO-II, consistent with DOT and IAEA.

Alternative 2: Revise 10 CFR Part 71

In an effort to ensure domestic and international transportation of all types of radioactive material, and most especially of large radioactive objects, the NRC proposes to harmonize 10 CFR Part 71 with SSR-6 and DOT regulations by adding the definition of SCO-III to 10 CFR 71.4.

The 1979 NRC/DOT Memorandum of Understanding (MOU) delineates that DOT has regulatory authority for LSA material. At the time this MOU was signed, the SCO categories did not exist. However, within the DOT regulations at that time, provisions existed for transporting items that were externally contaminated. Currently, the DOT is the lead agency for both LSA material and SCO. Within 49 CFR 173.427, the DOT provides the transportation requirements for LSA material and SCO. The DOT is undertaking a rulemaking to update 49 CFR (specifically 49 CFR 173.403 and 173.427) to include the SCO-III definition and transportation requirements.

3.3.8 Issue 8. Revision of Uranium Hexafluoride Package Requirements

In 2004, the NRC added a new provision in 10 CFR 71.55(g) to provide a specific exception for certain uranium hexafluoride (UF₆) packages from the requirements of 10 CFR 71.55(b). The exception allows UF₆ packages to be evaluated for criticality safety without considering in-leakage of water into the containment system provided certain conditions are met, including that the uranium is enriched to not more than 5 weight percent in ²³⁵U. In order to use this exception, the applicant must demonstrate that, following the tests for hypothetical accident conditions in 10 CFR 71.73, there is “no physical contact between the valve body and any other component of the packaging, other than at its original point of attachment, and the valve remains leak tight.”

In the SSR-6, 2018 Edition, the IAEA added the same requirement for the plug as was added in the 1996 Edition of TS-R-1 for the valve to ensure that the entire cylinder remains leak tight. In order to ensure criticality safety, both the plug and the valve must remain leak tight after the tests for hypothetical accident conditions, to prevent ingress of water into the cylinder.

Alternative 1: No-Action Alternative

In the no-action alternative, under the existing requirements in 10 CFR 71.55(g), the NRC would not require that the plug remain leak tight after the tests for hypothetical accident conditions. In this alternative, the NRC criticality safety requirement for moderator exclusion for UF₆ cylinders would be different from that of the IAEA and other IAEA Member States who have adopted the IAEA requirement; therefore, foreign competent authorities may question certificate holders about whether the plug on NRC-approved packages remains leak tight after the tests for hypothetical accident conditions.

Alternative 2: Revise 10 CFR Part 71

The preferred alternative is to perform the rulemaking and revise 10 CFR 71.55(g)(1) to require that there is no contact between the cylinder plug and any other part of the package, other than at its original attachment point, and that the cylinder plug remains leak tight after the tests for hypothetical accident conditions. This would ensure that the 30B cylinder in NRC-approved packages, which is used world-wide for transport of large quantities of UF₆ enriched up to 5 weight percent, will be consistent with SSR-6 and have the same approval basis as required by other competent authorities.

3.3.9 Issue 9. Inclusion of Evaluation of Aging Mechanisms and a Maintenance Program

In paragraph 613A of SSR-6, the IAEA added that package design evaluations should evaluate aging mechanisms. Paragraph 809 of SSR-6 requires that the application for package approval contain a maintenance program. While NRC regulations do not specifically require evaluation of aging, because the effects of aging are due to a reaction (e.g., oxidation-, chemical-, or radiation-induced reactions), NRC regulations at 10 CFR 71.43(d) require no significant reactions that would affect package aging. The evaluation in the application of whether package components degrade over time and the quantified effect of that degradation on package performance can determine whether a periodic test to evaluate the components efficacy or a replacement/repair schedule, or both, is included in the maintenance program chapter of the application.

The maintenance program chapter in the application includes periodic testing requirements, inspections, and replacement criteria and schedules for replacement and repair of components,

on an as-needed basis to ensure that the package components meet the requirements in 10 CFR 71.43(d). Following the maintenance program contained in the application provides assurance that the effects of aging will be minimized, and the packaging will perform as intended throughout its time in service.

Alternative 1: No-Action Alternative

In the no-action alternative, the NRC would not move forward with the rulemaking and, consistent with NRC regulations in 10 CFR 71.43(d), would continue to verify in package certificate reviews that applicants for a CoC appropriately evaluate aging effects and ensure that the applicants describe the maintenance program as part of their applications. The disadvantage to this alternative is that the regulations would not explicitly require evaluation of aging management and a description of the maintenance program in the application.

Alternative 2: Revise 10 CFR Part 71

Under this alternative, the NRC would make its regulations consistent with SSR-6 by requiring applications for package approval to contain a description of the maintenance program and how the effects of aging of package components are evaluated. While these items are already reviewed as part of a package approval, consistent regulations would ensure that there is a consistent world-wide regulatory framework for radioactive material transport. Since regulatory consistency would be achieved, performing the rulemaking is the preferred alternative.

3.3.10 Issue 10. Transitional Arrangements

Historically, IAEA, DOT, and NRC regulations have included transitional arrangements or "grandfathering" provisions whenever the regulations have undergone revision. The purpose is to minimize the costs and impacts of implementing changes in the regulations, since package designs compliant with the existing regulations do not become "unsafe" when the regulations are revised (unless a significant safety issue is corrected in the revision).

Typically, the transitional arrangements include provisions that allow for: (1) continued use of existing package designs and packagings already fabricated; and completion of packagings in the process of being fabricated, although some restrictions on fabrication of packages approved to earlier editions of the regulations may be imposed; (2) restriction on modifications to package designs without the need to demonstrate full compliance with the revised regulations; (3) changes in packaging identification numbers; and (4) changes to the manufacture and use of special form sources approved to earlier versions of the regulations.

The IAEA updated its transitional arrangements in paragraphs 819 through 823 of SSR-6, 2018 Edition. In addition, DOT is undertaking a rulemaking to harmonize its transitional arrangements with those of the IAEA.

Alternative 1: No-Action Alternative

In the no-action alternative, the NRC would not make any rule changes. Packages approved to the NRC's regulations harmonized with the 1973 Edition of Safety Series No. 6 standard would not be phased out; there would be no further restrictions to packages with a "-85" or "-96" in the package identification number; and the NRC would not be able to issue CoCs that are consistent with IAEA SSR-6, 2018 Edition.

While the NRC would continue to authorize use of packages approved to regulations that are harmonized with the 1973 version of IAEA standards for domestic use (i.e., packages without a “-85” or “-96” in the package identification number), assuming the DOT completes its rulemaking, these packages would not be able to be transported internationally without the need to obtain a special package authorization from the DOT, the country of origin or destination (depending on whether it is an import or export shipment to or from the U.S.) and, as appropriate, all countries that the package would pass through. It is not clear whether other countries would be willing to issue a special authorization for every one of these shipments using older package designs.

The NRC would not add the restriction on fabrication for packages after December 31, 2028, for packages that have a “-96” in the package identification number. The result would be that there may be identical packages that, depending on the date of fabrication (before or after December 31, 2028), would have different international transport requirements. Packages fabricated before December 31, 2028 would be able to be transported internationally, with multilateral approval. The same package fabricated after December 31, 2028 would need a special package authorization from the DOT, the country of origin or destination (depending on whether it is an import or export shipment to or from the U.S.) and, as appropriate, all countries that the package would pass through.

The NRC would not revise its definition of “special form radioactive material,” resulting in inconsistent regulations on manufacture and use of special form radioactive material between the NRC and the DOT. Under this alternative, special form radioactive material that was approved after September 30, 2004, and fabricated after December 31, 2025, would be authorized for transport under NRC regulations but would not be authorized for transport under DOT regulations.

Finally, for existing certificates issued by the NRC, consistent with 10 CFR 71.19(d), the package identification number would continue to have a “-96” in it, even if the applicant evaluated the package against the standards in SSR-6, 2018 Edition. If the NRC were to continue to add a “-96” in the package identification, this would place restrictions on the ability of the certificate holder to fabricate and use these packages in international shipment as described above.

As the competent authority in the U.S. for transportation of radioactive material, if the DOT harmonizes its regulations for transitional arrangements with those of the IAEA and the NRC did not, then the NRC regulations for domestic transport of radioactive material would not be consistent with DOT regulations. This inconsistency could cause confusion among NRC licensees as to whether their package is authorized for only domestic transport, international transport, or both, and whether it can be fabricated and used domestically. If the regulations in 10 CFR 71.19(d) are not revised and the NRC is not able to issue certificates to NRC regulations harmonized with the SSR-6, 2018 Edition, after December 31, 2025, then any licensee, who desires to ship radioactive material internationally would have to request a special permit from DOT and NRC licensees would have to request an exemption from NRC. (State licensees would need to request an exemption from its state regulatory body.) The NRC licensee would request an exemption from the NRC requirements in 10 CFR 71.19(d) to obtain package approvals to the latest version of SSR-6. These actions would be needed for each package, from each licensee using the package for import/export, rather than from certificate holders.

Alternative 2: Revise 10 CFR Part 71

The rulemaking would make transitional arrangements in 10 CFR Part 71 consistent with the IAEA standards, as follows:

1. Phase out the use of packages approved to NRC regulations that were harmonized with the IAEA's Safety Series No. 6, 1973 Revised Edition, [27], 8 years after the effective date of this rulemaking. These packages would be required to be re-certified, removed from service, or used via exemption.
2. Discontinue the use of packages with a "-96" in the package identification number for those packages fabricated after December 31, 2028, and for packages to be used for international shipment, require multilateral approval, as defined in 49 CFR 173.403, "Definitions." Revise § 71.17(e) to state that packages with a "-96" in the package identification number would become previously approved packages and subject to the current 71.19(c).
3. Coordinate with the DOT and make appropriate changes to 10 CFR 71.4 to align with the definition of "special form radioactive material" that the DOT is proposing to adopt as part of their harmonization rulemaking, since DOT is the lead for certifying special form sources.
4. Revise 10 CFR 71.19(e) to allow for previously approved package designs (i.e., packages with an "-96" or earlier identification number) to be resubmitted to the NRC for review against the current standards. If the package design described in the resubmitted application meets the current standards, the NRC may issue a new CoC for that package design without a year designation.

Performing the rulemaking is the preferred alternative since it would ensure consistent regulations between the NRC and the DOT, and with the IAEA standard, for domestic and international transport of radioactive material.

3.3.11 Issue 11. Inclusion of Head Space for Liquid Expansion

The NRC's regulations in 10 CFR 71.87, "Routine determinations," require, in part, that "Before each shipment of licensed material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this part and of the license. The licensee shall determine that—(d) Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid." The NRC does not have a design requirement for Type AF and Type B packages in 10 CFR Part 71 comparable to that in DOT's regulations in 49 CFR 173.412(k) for Type A packages and SSR-6 paragraph 649 for Type A packages and paragraphs 652 and 667 for Type B(U) and Type B(M) packages, respectively, in SSR-6, 2018 Edition.

The NRC does not have a design requirement for Type AF and Type B packages in 10 CFR Part 71 comparable to that in DOT's regulations in 49 CFR 173.412(k) for Type A packages and SSR-6 paragraph 649 for Type A packages and paragraphs 652 and 667 for Type B(U) and Type B(M) packages, respectively, in SSR-6, 2018 Edition.

The NRC is proposing to add a design requirement to ensure that package components that contain liquid have sufficient head space for liquid expansion under the tests for normal conditions of transport and hypothetical accident conditions.

Alternative 1: No-Action Alternative

In the no-action alternative, the NRC would not modify its regulations to add a design requirement in 10 CFR Part 71 to ensure sufficient head space for systems containing liquid. The NRC would continue to ensure that package operating procedures complied with the requirements in 10 CFR 71.87(d) to include provisions to allow adequate head space for liquid expansion. The disadvantage to this alternative is that the NRC regulations would not have a compatible regulation for adequate head space for Type AF packages and Type B packages as DOT does for Type A packages. Therefore, this is not the desired option, since NRC design regulations for Type AF and Type B packages containing liquids would be different from DOT regulations and IAEA standards.

Alternative 2: Revise 10 CFR Part 71

Rulemaking would revise 10 CFR 71.43, "General standards for all packages," to add a design requirement for a package designed to contain liquids to ensure adequate ullage is maintained during evaluation of the tests and conditions for normal conditions of transport and hypothetical accident conditions. Rulemaking would ensure that during the design phase, the NRC staff would have consistent regulations between the NRC and the DOT, and with the IAEA standard, for domestic and international transport of packages containing liquids and not have to rely on operational regulations to ensure adequate volume for filling containers holding liquids.

3.3.12 Issue 12. Revision of Quality Assurance Program Biennial Reporting Requirements

On June 12, 2015, the NRC issued a final rule to amend 10 CFR Part 71 regulations and 10 CFR 71.106 was added to establish requirements that applied to changes to QAPs and included associated reporting requirements to the NRC. According to the language provided in the preamble of the 2015 final rule (80 FR 33988; June 12, 2015), if no changes were made to the QAP in the preceding 24 months, the NRC would expect a report to be submitted stating no changes were made. In addition, the NRC's guidance document for 10 CFR Part 71 QAPs, Regulatory Guide (RG) 7.10 [28], states that if no changes were made to the QAP, a QAP approval holder would indicate to the NRC that no changes were made. The requirement for a report if no changes were made during the preceding 24-month period was intended to be included in 10 CFR 71.106 as part of the 2015 final rule, but it was silent on this point.

The NRC is proposing to revise 10 CFR 71.106(b) to achieve NRC's stated intent in the 2015 final rule: a biennial report must be submitted to the NRC if no changes are made to the QAP during the reporting period.

Alternative 1: No-Action Alternative

In the no-action alternative, the NRC would not modify its regulations in 10 CFR 71.106(b) to clarify that a biennial report must be submitted to the NRC if no changes are made to the QAP during the reporting period. The regulatory uncertainty would continue to exist because of the inconsistency between the current regulatory language in 10 CFR 71.106(b) and RG 7.10 guidance.

Alternative 2: Revise 10 CFR Part 71

Under this alternative, the NRC would perform the rulemaking as proposed to remove regulatory uncertainty, achieve the NRC's stated intent in the 2015 final rule, and ensure consistency between the rule language in 10 CFR Part 71 and regulatory guidance. The NRC inspection program for Part 71 QAP approval holders also relies on having current information about the QAP available to the NRC so the 24-month reporting period for either changes or no changes made to the QAP is considered to provide an appropriate balance between the burden placed on the QAP approval holders and the need to ensure that the NRC has that current information. Another benefit is that the revised QAP reporting requirements in Part 71 would be consistent with those in 10 CFR 50.54(a)(3) and 50.71(e)(2) for Part 50 QAPs.

3.3.13 Issue 13. Deletion of Type A Package Limitations in Fissile Material General Licenses

The general license criteria in 10 CFR 71.22 and 10 CFR 71.23 are intended to allow NRC licensees to ship small quantities of fissile material in packages that have been assigned a criticality safety index (CSI) to ensure accumulation control for packages on a conveyance. The provisions of 10 CFR 71.22 and 10 CFR 71.23 require that the material is in a Type A package meeting the requirements of 49 CFR 173.417(a) and that there is no more than a Type A quantity of radioactive material. The limitation to a Type A quantity of radioactive material in a Type A package, however, is not consistent with the mass limits for some fissile nuclides in some cases.

The NRC is proposing to remove the restriction in 10 CFR 71.22 and 71.23 to ship Type A material in only a Type A package (i.e., allowing shipment in a Type B package), which would correct the inconsistencies between the mass limits and package restrictions discussed above. Additionally, the NRC is proposing to clarify language in 10 CFR 71.23 to ensure that it is clear that this regulation only applies to special form plutonium-beryllium sources. The existing rule language refers to "sealed sources." While all special form sources are sealed sources, not all sealed sources meet the definition of special form material in 10 CFR 71.4. For example, 10 CFR 71.23 only applies to sealed sources that meet this definition.

Alternative 1: No-Action Alternative

Under the no-action alternative, the NRC would not make the proposed change to 10 CFR 71.22 and 10 CFR 71.23, and licensees would continue to be limited to shipping less than the mass limits cited in these regulations for some fissile radionuclides because of the Type A quantity and packaging limitation. Additionally, it may continue to be unclear that sealed sources which do not meet the definition of special form material in 10 CFR 71.4 are not authorized under 10 CFR 71.23.

Alternative 2: Revise 10 CFR Part 71

If the NRC were to complete the rulemaking, licensees could ship higher amounts of material under the general licenses in 10 CFR 71.22 and 10 CFR 71.23, up to the amounts already determined to be safe in calculations that support the existing mass limits. Additionally, the proposed change would meet the intent of the general license provisions, which is that the amount of material represented by the mass limits in 10 CFR 71.22 and 10 CFR 71.23 is safe to ship with a package CSI determined via the equations in each provision. The three new paragraphs in §§ 71.22 and 71.23, and the conforming changes to § 71.0(d)(1) would also

ensure similar requirements for licensees using these general licenses as in § 71.17(c), (d), and (e). If the NRC were to move forward with the rulemaking and allow general license quantities of fissile material to be shipped in a Type B package, then 10 CFR 71.22 and 10 CFR 71.23 would be consistent with the intent of the general licenses. Because this change would facilitate the safe transportation of small quantities of fissile material without explicit NRC approval, thereby enhancing regulatory efficiency, performing the rulemaking is the staff recommended alternative. Additionally, the intent of 10 CFR 71.23 would be clarified to ensure that sealed sources that do not meet the definition of special form material in 10 CFR 71.4 are not authorized for shipment under this provision.

3.3.14 Issue 14. Deletion of ^{233}U Restriction in Fissile General License

Users of the general license in 10 CFR 71.22 assign a CSI for a fissile material package based on the equation in 10 CFR 71.22(e)(1), and the fissile mass limits in either Table 71-1 or 71-2. Table 71-2 contains mass limits for shipping uranium enriched to various weight percent levels in ^{235}U . However, 10 CFR 71.22(e)(5) states that the lower mass values of Table 71-1 must be used if the enrichment level of uranium is unknown, if the amount of plutonium exceeds one percent of the mass of ^{235}U , or if ^{233}U is present in the package.

The isotope ^{233}U is not present in natural uranium but may be present in very low concentrations in some facilities which may have handled ^{233}U in the past. These contamination-level concentrations, while detectable with modern isotopic assay methods and physically “present,” are not important for criticality safety of ^{235}U transportation. The calculations used to support the enrichment limit for 10 CFR 71.15(d), for up to 1.0 weight percent enriched uranium, demonstrate that this limit is safe provided the plutonium and ^{233}U are limited to less than one percent of the ^{235}U . The same limitation could be applied to the use of Table 71-2 limits for shipping enriched uranium under 10 CFR 71.22, without affecting criticality safety. The NRC is proposing to revise 10 CFR 71.22 to limit the ^{233}U to less than one percent of the mass of ^{235}U , similar to the provision limiting plutonium in 10 CFR 71.22(e)(5)(ii).

Alternative 1: No-Action Alternative

Under the no-action alternative, the NRC would not make the proposed change to 10 CFR 71.22, and licensees would continue to be limited to shipping lower masses of enriched uranium under the Table 71-1 limits, even though the amount of ^{233}U in the material is negligible (but physically detectable).

Alternative 2: Revise 10 CFR Part 71

If the NRC were to complete the rulemaking, licensees could ship larger amounts of material under the general license in 10 CFR 71.22, up to the amounts determined to be safe in calculations that support the mass limits in Table 71-2. Additionally, the proposed change would meet the intent of the general license provisions, which is that the amount of ^{233}U in the package should be low enough to maintain the validity of the enrichment limits in Table 71-2, which were based on calculations with ^{235}U systems. If the NRC were to proceed with the rulemaking and allow Table 71-2 mass limits to be used for uranium with ^{233}U mass up to one percent of the mass of ^{235}U , 10 CFR 71.22 would remain consistent with the intent of the general license, while allowing greater quantities of fissile material to be shipped under this provision. This change would facilitate the safe transportation of small quantities of fissile material without explicit NRC approval, thereby enhancing regulatory efficiency.

3.3.15 Issue 15. Other Recommended Changes to 10 CFR Part 71

3.3.15.1 Issue 15.1 Delete Duplicative Reporting Requirements in 10 CFR 71.95

In a 2004 final rule (69 FR 3698; January 26, 2004) [26], the NRC added paragraph (a)(3) to 10 CFR 71.95, which introduced duplicative language between paragraph (a)(3) and paragraph (b). The NRC is proposing to delete the text in paragraph (a)(3).

Alternative 1: No-Action Alternative

Under the no-action alternative, the NRC would not delete the requirements in 10 CFR 71.95(a)(3). NRC licensees would be required by both 10 CFR 71.95(a)(3) and 10 CFR 71.95(b) to submit a report when shipments occurred and the conditions of approval in the CoC were not followed.

Alternative 2: Revise 10 CFR Part 71

Revising 10 CFR Part 71 to delete 10 CFR 71.95(a)(3) would not change the reporting requirements for licensees who perform a shipment that is not in accordance with the regulations, since reporting would still be required under 10 CFR 71.95(b). However, this alternative would remove the duplicative requirement.

3.3.15.2 Issue 15.2 Revise the Definition of LSA in 10 CFR 71.4

The NRC is considering modifying the first sentence in the definition of “low specific activity (LSA) material” in 10 CFR 71.4 to change “excepted under 10 CFR 71.15” to “exempted under 10 CFR 71.15.” This change would make the definition of LSA in 10 CFR 71.4 consistent with the title and intent of 10 CFR 71.15, “Exemption from classification as fissile material.”

Alternative 1: No-Action Alternative

Under the no-action alternative, the definition of LSA material would continue to be inconsistent with the title and intent of 10 CFR 71.15, “Exemption from classification as fissile material.” This inconsistency could lead to confusion over the difference in terms.

Alternative 2: Revise 10 CFR Part 71

If the NRC were to complete the rulemaking, the definition of LSA would be consistent with the title of 10 CFR 71.15 and 10 CFR Part 71 would be more internally consistent. Also, there would be less potential confusion regarding the intent of the definition of LSA regarding fissile exempt material.

3.3.15.3 Issue 15.3 Revise the A₁ and A₂ Values and the Exempt Material Activity Concentrations and Exempt Consignment Activity Limits

The IAEA has made changes in SSR-6, 2018 Edition, related to the A₁ and A₂ activity values and the exempt material activity concentrations and exempt consignment activity limits. The DOT is the lead agency for information related to the A₁ and A₂ values and for the exempt material activity concentrations and exempt consignment activity limits, as provided in 49 CFR 173.435 and 49 CFR 173.436, respectively. The NRC has corresponding information in 10 CFR Part 71, Appendix A, Tables A-1 and A-2.

In its concurrent harmonization rulemaking, the DOT is proposing to make changes to 49 CFR 173.435 and 173.436 by adding seven radionuclides, including Barium-135m, Germanium-69, Iridium-193m, Nickel-57, Strontium-83, Terbium-149 and Terbium-161. The NRC is proposing to make corresponding changes to Tables A-1 and A-2 to add these radionuclides. The NRC is proposing to revise the specific activity of natural rubidium to correct an error that was introduced in the 1995 version of the rule. Table A-1 of Appendix A to 10 CFR Part 71 gives the specific activity as 6.7×10^6 TBq/g, 1.8×10^8 Ci/g. The A_1 and A_2 values were not impacted by this error and remain correct. The NRC is also proposing to revise Footnote c at the end of Table A-2 to state that in the case of thorium-natural, the parent radionuclide is ^{232}Th , and in the case of uranium-natural, the parent radionuclide is ^{238}U . Further, the NRC is proposing to editorially revise several other radionuclides to move the name of the element and its atomic number (shown in the second column of each table) to the first instance of that element alphabetically in the tables.

Alternative 1: No-Action Alternative

Under the no-action alternative, if the DOT adds the seven radionuclides to its regulations and the NRC does not, then there would be inconsistent regulations for domestic transport. It is possible that under DOT regulations, a shipment of one of the seven new radionuclides may need to take place in a Type A package under DOT regulations. But if the NRC does not have one of the radionuclides in Table A-1, then a licensee would use the more restrictive A values in Table A-3 and have to make the shipment in an NRC-approved Type B package.

Similarly, if the DOT adds the seven radionuclides to its regulations for the exempt material activity concentrations and exempt consignment activity limits and the NRC does not, then under DOT regulations, a shipment containing one or more of the radionuclides may not be subject to the hazardous materials regulations in 49 CFR Parts 171–180. However, under NRC regulations, it may be subject to the hazardous material regulations based on the more restrictive values in Table A-3 in 10 CFR Part 71.

Alternative 2: Revise 10 CFR Part 71

The NRC would revise Tables A-1 and A-2 in Appendix A to 10 CFR Part 71 to add seven radionuclides ($^{135\text{m}}\text{Ba}$, ^{69}Ge , $^{193\text{m}}\text{Ir}$, ^{57}Ni , ^{83}Sr , ^{149}Tb and ^{161}Tb) to ensure consistent domestic regulations for transport of radioactive material. This would preclude the use of a Type B package for shipments involving certain quantities of any of these seven radionuclides.

3.3.15.4 Issue 15.4 Revision to Agreement State Compatibility Categories

Revise the compatibility category designations for the regulations containing QAP requirements for those Agreement States that have licensees who use Type B packages for shipping radioactive materials, other than for industrial radiography operations, or have licensees that ship using the general license in § 71.21, § 71.22 or § 71.23, which also requires an approved QAP. This would give the Agreement States the appropriate authority to approve, inspect, and enforce against all the necessary regulations that specify the criteria for a QAP required for those licensees that use Type B packages, other than for industrial radiography use, or for those that ship using the general license in § 71.21, § 71.22 or § 71.23.

The NRC is considering changing the compatibility category for 10 CFR 71.95(a) to Compatibility Category C in order to have Agreement State regulations require their licensees to notify the NRC if a package is found to have a defect or significant reduction in effectiveness so

that others using the package can be made aware of the situation. The NRC is proposing to revise the compatibility category for 10 CFR 71.95(b), to Compatibility Category C, so that Agreement States would get feedback on the effectiveness of the QAPs that they approve. In addition, since 10 CFR 71.95(c) and (d) include requirements for the content and legibility of the report, NRC is proposing to revise them to Compatibility Category C, so that the reports sent to the Agreement States and NRC contain the same information.

Alternative 1: No-Action Alternative

Under the no-action alternative, the Agreement States would not have the appropriate authority to approve, inspect and enforce the regulations related to a QAP for those licensees that use Type B packages, other than for industrial radiography, or for those licensees that ship using the general license in § 71.21, § 71.22 or § 71.23. This has potential health and safety consequences. For example, if the licensee does not have an adequate QAP, a shipment of Type B quantities of radioactive material could be sent in a defective package, causing exposures to personnel and the public. The use of these packages would not be fully inspectable and the Agreement State radiation control program could not enforce against all the necessary regulations. There also could be potential conflicts, duplications and gaps in the regulation of the use of these packages across the nation.

In addition, Agreement State licensees would not be required to send reports required by 10 CFR 71.95(a) to the NRC of instances in which a package is found to have a defect or significant reduction in effectiveness. The NRC would not know whether a package being used by an Agreement State licensee had a defect or significant reduction in its effectiveness, without the State licensee voluntarily reporting it. Agreement State regulators would not receive reports required by 71.95(b) of instances in which their licensees used an NRC-approved package in a manner that does not comply with the NRC certificate of compliance. This would not give Agreement State regulators feedback on the effectiveness of QAPs that it approves for its licensees.

Alternative 2: Revise 10 CFR Part 71

The NRC would revise the Agreement State compatibility categories and State licensees would be required to send reports required by 10 CFR 71.95(a) to the NRC for instances in which an NRC-approved package, including industrial radiography devices, is found to have a defect or significant reduction in effectiveness. The NRC would be able to assess the issue and discuss with the certificate holder if other users should be notified of the issue to ensure safe transport of NRC-approved packages. In addition, the NRC would revise the compatibility category for 71.95(b) from a Compatibility Category D to a C so that Agreement State regulators would be able to evaluate the effectiveness of QAPs it approves for its licensees since it would receive reports required by 71.95(b) of instances in which their licensees used an NRC-approved package in a manner that does not comply with the NRC certificate of compliance.

In addition, Agreement States would be able to approve and inspect those shipments against all the applicable QA requirements and perform enforcement actions, as necessary.

3.3.15.5 Issue 15.5—Address Redundancies in Advance Notification Requirements of 10 CFR 71.97 with Requirements of 10 CFR Parts 37 and 73.

The NRC is proposing to modify 10 CFR 71.97 to remove references to irradiated reactor fuel to delete duplicative reporting requirements between it and 10 CFR 73.37 or 73.35, depending on the quantity of spent fuel being transported.

Alternative 1: No-Action Alternative

Under the no-action alternative, the NRC would not delete the requirements in 10 CFR 71.97. NRC licensees would be required by both 10 CFR 71.97, and either 10 CFR 73.35 or 10 CFR 73.37, to submit advance notification of shipments of spent fuel. It is possible that a shipment could meet the advance notification requirements of 10 CFR 71.97 and 73.37 or 10 CFR 73.35, thus presenting the licensee with a requirement to provide two similar reports to the same agencies (State and Federal agencies) to describe a single shipment.

Alternative 2: Revise 10 CFR Part 71

The NRC would revise 10 CFR 71.97 to remove the requirement for advance notification of shipment of irradiated reactor fuel but would not change the requirements for advance notification of nuclear waste, thus deleting the duplicative reporting requirements for irradiated reactor fuel.

3.4 **Impacted Regulatory Guidance Documents**

If this rule is implemented, RG 7.9, “Standard Format and Content of 10 CFR Part 71 Applications for Approval of Packages for Radioactive Material,” will be updated to make conforming changes.

4 **Estimates of Costs and Savings**

This section provides estimates of the costs and savings associated with the alternatives described in the previous section.

4.1 **Basis for Cost and Savings Estimates**

The costs were determined based on estimates of normal costs (real costs) and potential savings (averted costs). Averted costs are costs of activities and actions performed under the existing regulations that would no longer be required if a revision to 10 CFR Part 71 is implemented. Averted costs are considered as benefits (savings) and they are assigned positive values. Normal costs are real costs of new or additional actions (i.e., if Alternative 2 is implemented in whole or in part) and they are assigned negative values (in parentheses). The net present value (NPV) is the discounted normal and averted cost estimates in 2020 dollars.

The following is a summary of the implementation and operational costs to industry (licensees and CoC holders), the NRC, and the Agreement States.

Industry Implementation. This attribute accounts for the projected net economic effect on the affected licensees to implement the mandated changes. Costs include procedural and administrative activities related to establishing plans and revising procedures. Additional costs

above the regulatory baseline are considered negative, and cost savings and averted costs are considered positive.

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 which 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 implemented. It includes NRC implementation costs and potential savings relative to those expected under the regulatory baseline.

NRC Operation. This attribute accounts for the projected net economic effect on the NRC after the rule is developed and implemented.

Agreement State Implementation. This attribute accounts for the projected net economic effect on the Agreement States to implement all of the mandated changes in Part 71. Costs include procedural and administrative activities related to harmonizing State regulations with NRC policy and other guidance documents. The NRC regulations or equivalent legally binding requirements should be adopted and implemented within a 3-year timeframe from the effective date of the NRC's final rule as stated in the *Federal Register* notice. The Agreement State implementation costs were estimated based on the following considerations:

- The number of Agreement States is 39.
- On average, 756 productive hours would be required to update State regulations. This average includes Agreement States that are promulgating the minimum number of requirements and those promulgating the maximum, i.e., those Agreement States with licensees that ship using one of the general licenses (in 10 CFR 71.17 or 71.21-71.23) other than industrial radiography.
- The average hourly rate range for a State employee is \$101/hour (\$32 to \$161 range).
- The NRC regulations or equivalent legally binding requirements would be adopted and implemented within 3 years of the effective date of the NRC's final rule.

Agreement State Operation. The NRC determined that there are operational costs incurred by the Agreement States as a result of the proposed rule as shown in Section 4.2.15.4.

4.2 Evaluation of Alternative 2 (NRC Transportation Regulations)

Tabulated cost estimates for the NRC, industry and Agreement States are provided in the tables beginning in Section 4.2.1 by respective issue. For estimating purposes, the three input values were used in the Monte Carlo sensitivity analysis and yielded the results shown. The following subsections describe how the costs were developed for each issue.

4.2.1 Revision of Fissile Exemptions

4.2.1.1 Add Fissile Exemption for Packages Containing 3.5 Grams ²³⁵U per Package

If this change is adopted, it would represent a new option under the fissile exemption provisions in 10 CFR 71.15. Consignors who wish to ship more than 2.0 grams of up to 5.0 weight percent enriched uranium, but less than 3.5 grams of ²³⁵U enriched up to 5.0 weight percent, currently

either have to break this material into two shipments of 2.0 grams or less of ²³⁵U (10 CFR 71.15(a)) or ship in a package where there is at least 200 grams nonfissile material per gram of fissile material (700 grams nonfissile material; 10 CFR 71.15(b)). Any of these shipments would have to be in a Type A package (exempt quantity of ²³⁵U is less than 0.123 grams), and there is no associated consignment or other accumulation limit.

The averted cost for this change would be from a decreased number of shipments compared to the 2.0-gram provision in 10 CFR 71.15(a). The affected licensees consist primarily of enrichment and fuel fabrication facilities, and other facilities undergoing decommissioning.

Currently there are six uranium fuel fabrication plant licensees and five enrichment plant licensees that would be expected to make shipments under this provision. Each affected licensee would be expected to make a low number of shipments under this provision, from several to dozens per year. This provision could also affect several Department of Energy (DOE) facilities, but these effects are not being considered for this impact assessment.

For cost analysis considerations, the staff estimates an average of 20 averted shipments per year, per licensee, over the 11-year period considered for the cost analysis. Each shipment is estimated to have an average averted cost of \$1,083 as shown in Table 1.

Table 1 Estimated Averted Cost of Making Shipments with New Fissile Exemption

Year	Description	Number of affected fissile material licensees	Number of shipments per year	Cost per shipment	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2022	Averted cost to ship under this exemption	20	23	\$1,083	\$487,500	\$425,801	\$459,516
2023	Averted cost to ship under this exemption	20	23	\$1,083	\$487,500	\$397,945	\$446,132
2024	Averted cost to ship under this exemption	20	23	\$1,083	\$487,500	\$371,911	\$433,137
2025	Averted cost to ship under this exemption	20	23	\$1,083	\$487,500	\$347,581	\$420,522
2026	Averted cost to ship under this exemption	20	23	\$1,083	\$487,500	\$324,842	\$408,274
2027	Averted cost to ship under this exemption	20	23	\$1,083	\$487,500	\$303,590	\$396,382
2028	Averted cost to ship under this exemption	20	23	\$1,083	\$487,500	\$283,729	\$384,837
2029	Averted cost to ship under this exemption	20	23	\$1,083	\$487,500	\$265,168	\$373,628
2030	Averted cost to ship under this exemption	20	23	\$1,083	\$487,500	\$247,820	\$362,746
2031	Averted cost to ship under this exemption	20	23	\$1,083	\$487,500	\$231,608	\$352,180
2032	Averted cost to ship under this exemption	20	23	\$1,083	\$487,500	\$216,456	\$341,923
Total Benefit (Cost)					\$5,362,500	\$3,416,452	\$4,379,276

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

4.2.1.2 Up to 140 Grams Fissile Nuclides, Shipped Exclusive Use

This change would provide a new option under the fissile exemption provisions in 10 CFR 71.15. Licensees who wish to ship up to 140 grams (g) fissile material currently either have to break this material into as many as 10 packages, each containing 14 grams of fissile material and at least 200 grams nonfissile material per gram of fissile material in order to ship under the general licenses in 10 CFR 71.22 or 71.23, or transport all 140 grams in an NRC-certified

Type AF or a B(U)F/B(M)F package. This new option would affect primarily ²³⁵U shipments, as small quantities of ²³³U or plutonium require shipment in a Type B package.

However, there could still be averted costs from new or amended Type B package certificates including up to 140 grams fissile material as allowable contents, as the applicant would not have to perform, and the NRC would not have to evaluate, a criticality safety evaluation per 10 CFR 71.55 and 71.59.

For ²³³U and plutonium shipments, 140 grams of fissile material would still have to be in an NRC-certified Type B package, although it could be in one that did not have an approved criticality safety analysis (i.e., did not have an “F” certification). The staff estimates that this cost savings would be small for such a small quantity of fissile material, for which subcriticality would be easy to demonstrate in a certificate application. The averted cost in this case would be not having to demonstrate criticality safety for a new or previously certified Type B(U) or B(M) package (without the “F” fissile certification). Because this is a specialized type of shipment, the staff estimates that one applicant might design a new package or modify an existing package to take advantage of this rule change, over the 11-year period considered for the cost analysis. For this design, the applicant could simply refer to the mass limit in this exemption, and limit such shipments to exclusive use, rather than providing a demonstration of criticality safety per 10 CFR 71.55 and 71.59. The staff estimates that a demonstration of criticality safety to support certification of this amount of material would take 87 hours on average, at an average averted cost of \$203 per hour as shown in Table 2.

Table 2 Averted Cost to Licensees Using New 140 Gram Fissile Exemption

Year	Description	No. of Exemptions	No. of Hours	Hourly Cost	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2022	Averted cost to prepare and submit an application	0.09	87	\$203	\$1,602	\$1,399	\$1,510
2023	Averted cost to prepare and submit an application	0.09	87	\$203	\$1,602	\$1,308	\$1,466
2024	Averted cost to prepare and submit an application	0.09	87	\$203	\$1,602	\$1,222	\$1,423
2025	Averted cost to prepare and submit an application	0.09	87	\$203	\$1,602	\$1,142	\$1,382
2026	Averted cost to prepare and submit an application	0.09	87	\$203	\$1,602	\$1,067	\$1,342
2027	Averted cost to prepare and submit an application	0.09	87	\$203	\$1,602	\$998	\$1,303
2028	Averted cost to prepare and submit an application	0.09	87	\$203	\$1,602	\$932	\$1,265
2029	Averted cost to prepare and submit an application	0.09	87	\$203	\$1,602	\$871	\$1,228
2030	Averted cost to prepare and submit an application	0.09	87	\$203	\$1,602	\$814	\$1,192
2031	Averted cost to prepare and submit an application	0.09	87	\$203	\$1,602	\$761	\$1,157
2032	Averted cost to prepare and submit an application	0.09	87	\$203	\$1,602	\$711	\$1,124
Total		1.00			\$17,622	\$11,227	\$14,391

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

The NRC modeled this as a one-time action over the 11-year cycle. The staff estimates that NRC review of an applicant's criticality safety demonstration would take approximately 40 hours on average, at an average averted cost of \$131 per hour as shown in Table 3.

Table 3 Averted NRC Review Cost for 140 Gram Fissile Exemption

Year	Description	No. of NRC Review of Exemptions per Year	Hours to Review Exemptions	Hourly Rate	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2022	NRC Operational Averted Costs	0.09	43	\$131	\$508	\$444	\$479
2023	NRC Operational Averted Costs	0.09	43	\$131	\$508	\$415	\$465
2024	NRC Operational Averted Costs	0.09	43	\$131	\$508	\$388	\$451
2025	NRC Operational Averted Costs	0.09	43	\$131	\$508	\$362	\$438
2026	NRC Operational Averted Costs	0.09	43	\$131	\$508	\$339	\$426
2027	NRC Operational Averted Costs	0.09	43	\$131	\$508	\$316	\$413
2028	NRC Operational Averted Costs	0.09	43	\$131	\$508	\$296	\$401
2029	NRC Operational Averted Costs	0.09	43	\$131	\$508	\$276	\$389
2030	NRC Operational Averted Costs	0.09	43	\$131	\$508	\$258	\$378
2031	NRC Operational Averted Costs	0.09	43	\$131	\$508	\$241	\$367
2032	NRC Operational Averted Costs	0.09	43	\$131	\$508	\$226	\$356
Total		1.00			\$5,589	\$3,561	\$4,565

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

The affected licensees consist primarily of enrichment and fuel fabrication facilities and reactor facilities undergoing decommissioning. Currently there are six uranium fuel fabrication plant licensees, five enrichment plant licensees, and 18 reactor units undergoing decommissioning that would be expected to make shipments under the proposed 140-gram limitation. Under this proposal, each affected licensee would be expected to make a low number of shipments from several to dozens per year. This provision could also affect several U.S. DOE facilities, but these effects are not being considered for this impact assessment because DOE does not utilize NRC regulations for shipments between its facilities. Under DOT regulations, DOE self-certifies shipments between its facilities. For cost analysis considerations, the staff estimates an average of 11 shipments per year that would be made under this new provision, per licensee, over the 11-year period considered for the cost analysis. The staff estimates that the cost savings of shipping in a Type A or B package, as opposed to a Type AF or BF package, is an average of \$108 per shipment as shown in Table 4.

Table 4 Licensee Shipping Benefit Using the 140 Gram Fissile Exemption

Year	Description	Number of Licensees	Number of Shipments	Cost per Shipment	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2022	Licensee averted shipping cost under this exemption	30	11	\$108	\$35,208	\$30,752	\$33,187
2023	Licensee averted shipping cost under this exemption	30	11	\$108	\$35,208	\$28,740	\$32,221
2024	Licensee averted shipping cost under this exemption	30	11	\$108	\$35,208	\$26,860	\$31,282
2025	Licensee averted shipping cost under this exemption	30	11	\$108	\$35,208	\$25,103	\$30,371
2026	Licensee averted shipping cost under this exemption	30	11	\$108	\$35,208	\$23,461	\$29,486

Year	Description	Number of Licensees	Number of Shipments	Cost per Shipment	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2027	Licensee averted shipping cost under this exemption	30	11	\$108	\$35,208	\$21,926	\$28,628
2028	Licensee averted shipping cost under this exemption	30	11	\$108	\$35,208	\$20,492	\$27,794
2029	Licensee averted shipping cost under this exemption	30	11	\$108	\$35,208	\$19,151	\$26,984
2030	Licensee averted shipping cost under this exemption	30	11	\$108	\$35,208	\$17,898	\$26,198
2031	Licensee averted shipping cost under this exemption	30	11	\$108	\$35,208	\$16,727	\$25,435
2032	Licensee averted shipping cost under this exemption	30	11	\$108	\$35,208	\$15,633	\$24,694
Total		121			\$387,292	\$246,744	\$316,281

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

4.2.2 Revision of Reduced External Pressure Test for Normal Conditions of Transport

The NRC has decided not to further pursue any changes to the reduced external pressure test requirement under 10 CFR Part 71.71(c)(3).

4.2.3 Type C Package Standards

The NRC has decided not to pursue any changes to Type C package standards in this rulemaking.

4.2.4 Revision of Insolation Requirements for Package Evaluations

4.2.4.1 Cost Impacts for Insolation for Normal Conditions of Transport

Cost Impact to Existing Certificate Holders

The staff estimates that all holders of the 14 certificates that do not have an “-85” or “-96” in the package identification number will request a revision for their certificate to show they meet the revised NRC requirements in the first 4 years after the rule change to ensure the packages are approved within the 8-year timeframe for package phaseout. In addition, the staff estimates that certificate holders will revise an additional four certificates of compliance that contain either a “-85” or “-96” in the package identification number to show they meet revised NRC requirements. Therefore, the NRC estimates that certificate holders will revise an average of 7.5 certificates per year over a 11-year period (14 certificates that will be phased out in the first 4 years of the rulemaking and another four certificate revisions for those with a “-85” and “-96” every year after the rulemaking is effective) following the rulemaking effective date to show compliance with the revised NRC requirements.

The costs to evaluate this change in insolation to current certificate holders would only be incurred if they were to request a revision of their CoC to show compliance with the revised NRC regulations. The cost to an existing certificate holder to evaluate the new insolation values would vary depending on the complexity of the thermal evaluation. Certificate holders may use reasoned arguments to evaluate the insolation increase of some smaller packages with significant margin, whereas, for larger more complex packages (i.e., spent fuel and Type B

waste packages), the certificate holders would likely revise their finite element thermal models. The staff estimates that the cost to evaluate the new insolation values and to submit an application including the result has a mean value of (\$8,667) and would range from a low value of \$2,000 to a high value of \$20,000 per package, depending on the complexity of the package design as shown in the table below.

Table 5 Cost for Certificate Holders to Prepare an Application Evaluating New Insolation Value

Year	Description	No. of Certificates Revision	Certification Request Preparation Cost	Net Benefit (Cost) [2020\$] ^{a b}		
				Undiscounted	7% NPV	3% NPV
2022	Cost to submit certificate for new insolation	7.5	(\$8,667)	(\$65,000)	(\$56,774)	(\$61,269)
2023	Cost to submit certificate for new insolation	7.5	(\$8,667)	(\$65,000)	(\$53,059)	(\$59,484)
2024	Cost to submit certificate for new insolation	7.5	(\$8,667)	(\$65,000)	(\$49,588)	(\$57,752)
2025	Cost to submit certificate for new insolation	7.5	(\$8,667)	(\$65,000)	(\$46,344)	(\$56,070)
2026	Cost to submit certificate for new insolation	4	(\$8,667)	(\$34,667)	(\$23,100)	(\$29,033)
2027	Cost to submit certificate for new insolation	4	(\$8,667)	(\$34,667)	(\$21,589)	(\$28,187)
2028	Cost to submit certificate for new insolation	4	(\$8,667)	(\$34,667)	(\$20,176)	(\$27,366)
2029	Cost to submit certificate for new insolation	4	(\$8,667)	(\$34,667)	(\$18,856)	(\$26,569)
2030	Cost to submit certificate for new insolation	4	(\$8,667)	(\$34,667)	(\$17,623)	(\$25,795)
2031	Cost to submit certificate for new insolation	4	(\$8,667)	(\$34,667)	(\$16,470)	(\$25,044)
2032	Cost to submit certificate for new insolation	4	(\$8,667)	(\$34,667)	(\$15,392)	(\$24,315)
Total		58		(\$502,667)	(\$338,971)	(\$420,883)

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

The staff estimates that time required to review these applications would vary depending on the complexity of the package. The staff estimates that the time required to review an update to the value for insolation would range from a low of 5 hours to a maximum of 24 hours, with the most likely review time of 15 hours. Table 6 shows that the estimated review cost is (\$76,000) using a 7-percent discount rate and (\$94,000) using a 3-percent discount rate.

Table 6 NRC Cost to Review Applications for Revised Certificates of Compliance

Year	Description	Number of Revised Certificates	Number of Review Hours	Labor Rate	Net Benefit (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2022	NRC review costs	7.5	15	\$131	(\$14,574)	(\$12,729)	(\$13,737)
2023	NRC review costs	7.5	15	\$131	(\$14,574)	(\$11,897)	(\$13,337)
2024	NRC review costs	7.5	15	\$131	(\$14,574)	(\$11,118)	(\$12,949)
2025	NRC review costs	7.5	15	\$131	(\$14,574)	(\$10,391)	(\$12,571)
2026	NRC review costs	4.0	15	\$131	(\$7,773)	(\$5,179)	(\$6,509)
2027	NRC review costs	4.0	15	\$131	(\$7,773)	(\$4,840)	(\$6,320)
2028	NRC review costs	4.0	15	\$131	(\$7,773)	(\$4,524)	(\$6,136)
2029	NRC review costs	4.0	15	\$131	(\$7,773)	(\$4,228)	(\$5,957)

Year	Description	Number of Revised Certificates	Number of Review Hours	Labor Rate	Net Benefit (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2030	NRC review costs	4.0	15	\$131	(\$7,773)	(\$3,951)	(\$5,784)
2031	NRC review costs	4.0	15	\$131	(\$7,773)	(\$3,693)	(\$5,615)
2032	NRC review costs	4.0	15	\$131	(\$7,773)	(\$3,451)	(\$5,452)
Total		58			(\$112,704)	(\$76,001)	(\$94,367)

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

Impact to Applicants for a New Certificate of Compliance

For new certificates of compliance there would be a small additional accrued cost because of this rulemaking. Although applicants for a CoC already are required to evaluate insolation, increasing the value by approximately 3 percent will increase the cost to perform a review by a small margin. The staff estimates that for small packages where material properties have margin to their operating limits the increased additional charge would be approximately \$500. Larger, more complex packages (i.e., spent fuel and Type B waste packages) would require more complex computer modeling, so that the NRC review cost would be approximately \$2,000. The staff estimates that one new package per year for the 11 years following the final rule effective date will be submitted for review and approval. The staff estimates that the averted cost for this review would be approximately \$1,000 per package.

Table 7 Licensee Averted Costs to Submit Certificate for New Certificate of Compliance

Year	Description	Number of New Certificates	Certification Request Preparation Cost	Net Benefits (Cost) [2020\$] ^{a b}		
				Undiscounted	7% NPV	3% NPV
2022	Averted cost to submit certificate for new certificate of compliance	1	\$1,083	\$1,083	\$946	\$1,021
2023	Averted cost to submit certificate for new certificate of compliance	1	\$1,083	\$1,083	\$884	\$991
2024	Averted cost to submit certificate for new certificate of compliance	1	\$1,083	\$1,083	\$826	\$963
2025	Averted cost to submit certificate for new certificate of compliance	1	\$1,083	\$1,083	\$772	\$934
2026	Averted cost to submit certificate for new certificate of compliance	1	\$1,083	\$1,083	\$722	\$907
2027	Averted cost to submit certificate for new certificate of compliance	1	\$1,083	\$1,083	\$675	\$881
2028	Averted cost to submit certificate for new certificate of compliance	1	\$1,083	\$1,083	\$631	\$855
2029	Averted cost to submit certificate for new certificate of compliance	1	\$1,083	\$1,083	\$589	\$830
2030	Averted cost to submit certificate for new certificate of compliance	1	\$1,083	\$1,083	\$551	\$806
2031	Averted cost to submit certificate for new certificate of compliance	1	\$1,083	\$1,083	\$515	\$783
2032	Averted cost to submit certificate for new certificate of compliance	1	\$1,083	\$1,083	\$481	\$760
Total		11		\$11,917	\$7,592	\$9,732

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

The staff estimates that on average, the cost to the NRC to review and provide the safety evaluation for an application for a new certificate with the increased value for insolation would be approximately 3 hours for small packages, 10 hours for large, complex packages and, on average, approximately 5.5 hours.

Table 8 NRC Incremental Costs to Review New Certificates of Compliance

Year	Description	No. of New Certificate Submittals	No. of Review Hours	Labor Rate	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2022	NRC costs to review submitted certificates	1.0	(5.5)	\$131	(\$721)	(\$629)	(\$679)
2023	NRC costs to review submitted certificates	1.0	(5.5)	\$131	(\$721)	(\$588)	(\$659)
2024	NRC costs to review submitted certificates	1.0	(5.5)	\$131	(\$721)	(\$550)	(\$640)
2025	NRC costs to review submitted certificates	1.0	(5.5)	\$131	(\$721)	(\$514)	(\$622)
2026	NRC costs to review submitted certificates	1.0	(5.5)	\$131	(\$721)	(\$480)	(\$603)
2027	NRC costs to review submitted certificates	1.0	(5.5)	\$131	(\$721)	(\$449)	(\$586)
2028	NRC costs to review submitted certificates	1.0	(5.5)	\$131	(\$721)	(\$419)	(\$569)
2029	NRC costs to review submitted certificates	1.0	(5.5)	\$131	(\$721)	(\$392)	(\$552)
2030	NRC costs to review submitted certificates	1.0	(5.5)	\$131	(\$721)	(\$366)	(\$536)
2031	NRC costs to review submitted certificates	1.0	(5.5)	\$131	(\$721)	(\$342)	(\$521)
2032	NRC costs to review submitted certificates	1.0	(5.5)	\$131	(\$721)	(\$320)	(\$505)
Total		11.0			(\$7,926)	(\$5,049)	(\$6,472)

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

Table 8 estimates that the incremental NRC review costs are \$5,000 using a 7-percent discount rate and \$6,500 using a 3-percent discount rate.

4.2.4.2 Cost Impacts for Insolation for Hypothetical Accident Conditions

Cost Impact to Existing Certificate Holders

Similar to the cost for impacts of insolation for normal conditions of transport, above, the cost to an existing certificate holder to evaluate the insolation as an initial condition to the fire test would vary depending on the complexity of the thermal evaluation. Some smaller packages with significant margin may use reasoned argument to evaluate the revised initial condition, whereas larger, more complex packages (i.e., spent fuel and Type B waste packages) would likely revise their finite element thermal models.

The staff estimates that for smaller packages, the cost to a certificate holder to evaluate the new insolation condition and include the result in an application is approximately \$1,000. Larger, more complex packages would cost approximately \$50,000, depending on the number of analyses that have to be reevaluated. The staff estimates that the average cost to its certificate holders would be approximately \$20,000, assuming more than one analysis must be reevaluated. The staff estimates that all 14 certificate holders would revise their package designs to the revised regulations, from the package designs approved without a “-85” or “-96” in the package identification number. In addition, for the certificates approved with either a “-85” or “-96” in the package identification number, the staff estimates that certificate holders will want to revise an additional four certificates per year, over an 11-year period. Therefore, the staff estimates that certificate holders will revise an average of 7.5 certificates per year over the 11-year period following the final rule effective date to show compliance with the revised NRC regulations.

The staff estimated that the average cost to prepare and submit an application to the NRC is \$21,833 for each application submitted for the next 11 years after the rule change. Since NRC expects on average 7.5 applications each year for the first four years after the rule change and

4 applications for years 5 to 11, the undiscounted cost to certificate holders would total to \$655,000 for years 2022 to 2025 and costs of \$611,331 for years 2026 to 2032 for a total cost of \$1,266,333.

Table 9 Certificate Holder Cost to Evaluate Insolation as an Initial Condition

Year	Description	Number of Certificates Submitted	Certification Request Preparation Cost	Net Benefits (Cost) [2020\$] ^{a b}		
				Undiscounted	7% NPV	3% NPV
2022	Cost to evaluate insolation as an initial condition	7.5	(\$21,833)	(\$163,750)	(\$143,026)	(\$154,350)
2023	Cost to evaluate insolation as an initial condition	7.5	(\$21,833)	(\$163,750)	(\$133,669)	(\$149,854)
2024	Cost to evaluate insolation as an initial condition	7.5	(\$21,833)	(\$163,750)	(\$124,924)	(\$145,490)
2025	Cost to evaluate insolation as an initial condition	7.5	(\$21,833)	(\$163,750)	(\$116,751)	(\$141,252)
2026	Cost to evaluate insolation as subsequent condition	4	(\$21,833)	(\$87,333)	(\$58,194)	(\$73,140)
2027	Cost to evaluate insolation as subsequent condition	4	(\$21,833)	(\$87,333)	(\$54,387)	(\$71,010)
2028	Cost to evaluate insolation as subsequent condition	4	(\$21,833)	(\$87,333)	(\$50,829)	(\$68,942)
2029	Cost to evaluate insolation as subsequent condition	4	(\$21,833)	(\$87,333)	(\$47,504)	(\$66,934)
2030	Cost to evaluate insolation as subsequent condition	4	(\$21,833)	(\$87,333)	(\$44,396)	(\$64,984)
2031	Cost to evaluate insolation as subsequent condition	4	(\$21,833)	(\$87,333)	(\$41,491)	(\$63,081)
2032	Cost to evaluate insolation as subsequent condition	4	(\$21,833)	(\$87,333)	(\$38,777)	(\$61,254)
Total		83		(\$1,266,333)	(\$853,947)	(\$1,060,302)

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

The staff estimates that time required to review these applications would vary depending on the complexity of the package. The staff estimates that the time required to review an update to the value for insolation would range from a low of 5 hours to a maximum of 24 hours, with the most likely review time of 15 hours.

Table 10 NRC Cost to Review Applications for Revised Certificates of Compliance

Year	Description	No. of Certificates Submitted	Hours to Review Applications	Labor Rate	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2022	NRC review of revised certificates	7.5	(15)	\$131	(\$14,574)	(\$12,729)	(\$13,737)
2023	NRC review of revised certificates	7.5	(15)	\$131	(\$14,574)	(\$11,897)	(\$13,337)
2024	NRC review of revised certificates	7.5	(15)	\$131	(\$14,574)	(\$11,118)	(\$12,949)
2025	NRC review of revised certificates	7.5	(15)	\$131	(\$14,574)	(\$10,391)	(\$12,571)
2026	NRC review of revised certificates	4	(15)	\$131	(\$7,773)	(\$5,179)	(\$6,509)
2027	NRC review of revised certificates	4	(15)	\$131	(\$7,773)	(\$4,840)	(\$6,320)
2028	NRC review of revised certificates	4	(15)	\$131	(\$7,773)	(\$4,524)	(\$6,136)
2029	NRC review of revised certificates	4	(15)	\$131	(\$7,773)	(\$4,228)	(\$5,957)
2030	NRC review of revised certificates	4	(15)	\$131	(\$7,773)	(\$3,951)	(\$5,784)

Year	Description	No. of Certificates Submitted	Hours to Review Applications	Labor Rate	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2031	NRC review of revised certificates	4	(15)	\$131	(\$7,773)	(\$3,693)	(\$5,615)
2032	NRC review of revised certificates	4	(15)	\$131	(\$7,773)	(\$3,451)	(\$5,452)
Total		58			(\$112,704)	(\$76,001)	(\$94,367)

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

Cost Impact to Applicants for a New Certificate of Compliance

The staff estimates that there would be an additional accrued cost for new certificates of compliance. Although not explicitly required, most applicants for a CoC already have included insolation as an initial condition to the fire test. Adding this as an initial condition in 10 CFR 71.73(b) would increase the applicant's cost to prepare and submit an application by a small margin. The staff estimates that for small packages where material properties have margin to their material temperature limits, the increased cost would be approximately \$1,000 per package for an applicant to prepare and submit an application. Larger, more complex packages (i.e., spent fuel and Type B waste packages) would require more complex computer modeling, therefore the increased cost would be approximately \$30,000 per package for an applicant to prepare and submit an application. The high estimate is for the package or two which has material properties that are very close to the upper limit for use. The staff estimates that the average cost for a certificate holder to evaluate the new solar insolation quantity would be approximately \$6,500.

Table 11 Licensee Costs to Submit Certificate for New Certificate of Compliance

Year	Description	No. of Applications per Year	Cost to Prepare and Submit Certification Request	Net Benefits (Cost) [2020\$] ^{a b}		
				Undiscounted	7% NPV	3% NPV
2022	Licensee costs to prepare and submit revised certificates	1	(\$6,500)	(\$6,500)	(\$5,677)	(\$6,127)
2023	Licensee costs to prepare and submit revised certificates	1	(\$6,500)	(\$6,500)	(\$5,306)	(\$5,948)
2024	Licensee costs to prepare and submit revised certificates	1	(\$6,500)	(\$6,500)	(\$4,959)	(\$5,775)
2025	Licensee costs to prepare and submit revised certificates	1	(\$6,500)	(\$6,500)	(\$4,634)	(\$5,607)
2026	Licensee costs to prepare and submit revised certificates	1	(\$6,500)	(\$6,500)	(\$4,331)	(\$5,444)
2027	Licensee costs to prepare and submit revised certificates	1	(\$6,500)	(\$6,500)	(\$4,048)	(\$5,285)
2028	Licensee costs to prepare and submit revised certificates	1	(\$6,500)	(\$6,500)	(\$3,783)	(\$5,131)
2029	Licensee costs to prepare and submit revised certificates	1	(\$6,500)	(\$6,500)	(\$3,536)	(\$4,982)
2030	Licensee costs to prepare and submit revised certificates	1	(\$6,500)	(\$6,500)	(\$3,304)	(\$4,837)
2031	Licensee costs to prepare and submit revised certificates	1	(\$6,500)	(\$6,500)	(\$3,088)	(\$4,696)
2032	Licensee costs to prepare and submit revised certificates	1	(\$6,500)	(\$6,500)	(\$2,886)	(\$4,559)
Total		11		(\$71,500)	(\$45,553)	(\$58,390)

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

The staff estimates that it will receive one new package per year, over the 11-year period following the final rule effective date. The staff estimates that its review cost to evaluate these submittals would depend on the package type and how the applicant evaluated the package for the fire test. The staff estimates that, for smaller packages, the time needed to perform the application review and to document the review in a safety evaluation report would take approximately 3 hours and larger, more complex package design reviews would take approximately 30 hours. The staff estimates that the average review time for this change would be 12 hours.

Table 12 NRC Incremental Costs to Review New Certificates of Compliance

Year	Description	No. of New Certificates	No. of Hours to Review New Application	NRC Labor Rate	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2022	NRC costs to review new certificate of compliance	1	(12)	\$131	(\$1,594)	(\$1,392)	(\$1,502)
2023	NRC costs to review new certificate of compliance	1	(12)	\$131	(\$1,594)	(\$1,301)	(\$1,459)
2024	NRC costs to review new certificate of compliance	1	(12)	\$131	(\$1,594)	(\$1,216)	(\$1,416)
2025	NRC costs to review new certificate of compliance	1	(12)	\$131	(\$1,594)	(\$1,136)	(\$1,375)
2026	NRC costs to review new certificate of compliance	1	(12)	\$131	(\$1,594)	(\$1,062)	(\$1,335)
2027	NRC costs to review new certificate of compliance	1	(12)	\$131	(\$1,594)	(\$993)	(\$1,296)
2028	NRC costs to review new certificate of compliance	1	(12)	\$131	(\$1,594)	(\$928)	(\$1,258)
2029	NRC costs to review new certificate of compliance	1	(12)	\$131	(\$1,594)	(\$867)	(\$1,222)
2030	NRC costs to review new certificate of compliance	1	(12)	\$131	(\$1,594)	(\$810)	(\$1,186)
2031	NRC costs to review new certificate of compliance	1	(12)	\$131	(\$1,594)	(\$757)	(\$1,151)
2032	NRC costs to review new certificate of compliance	1	(12)	\$131	(\$1,594)	(\$708)	(\$1,118)
Total		11			(\$17,533)	(\$11,170)	(\$14,318)

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

4.2.5 Inclusion of Definition for Radiation Level

For cost analysis considerations, the staff estimates that no licensees would prepare revised applications or revise facility documentation. The staff estimates no costs to licensees or certificate holders for this issue.

4.2.6 Deletion of the Low Specific Activity-III Leaching Test

The staff estimates there would be an averted cost impact of this proposed change to licensees or CoC holders because removing the leaching test requirement would provide regulatory relief. The test would be removed from 10 CFR 71.77 and would no longer be required. Five licensees are expected to perform this test over the next 11 years if the test is not removed during this rulemaking. The NRC estimates that the mean averted cost for each test would be \$21,667, with a minimum test cost of \$10,000, a most likely cost of \$20,000, and the maximum test cost of \$40,000. The total averted cost over the 11 years following the rulemaking is \$73,106, using a 7-percent discount factor.

Table 13 Averted Cost for Deletion of Leaching Test

Year	Description	No. of Low Specific Activity-III Leaching Tests	Cost for Low Specific Activity-III Leaching Test	Net Benefits (Cost) [2020\$] ^{a b}		
				Undiscounted	7% NPV	3% NPV
2022	Licensee preparation to assess impact of Deletion of the Low Specific Activity-III Leaching Test	0.45	\$21,667	\$9,848	\$8,602	\$9,283
2023	Licensee preparation to assess impact of Deletion of the Low Specific Activity-III Leaching Test	0.45	\$21,667	\$9,848	\$8,039	\$9,013
2024	Licensee preparation to assess impact of Deletion of the Low Specific Activity-III Leaching Test	0.45	\$21,667	\$9,848	\$7,513	\$8,750
2025	Licensee preparation to assess impact of Deletion of the Low Specific Activity-III Leaching Test	0.45	\$21,667	\$9,848	\$7,022	\$8,495
2026	Licensee preparation to assess impact of Deletion of the Low Specific Activity-III Leaching Test	0.45	\$21,667	\$9,848	\$6,562	\$8,248
2027	Licensee preparation to assess impact of Deletion of the Low Specific Activity-III Leaching Test	0.45	\$21,667	\$9,848	\$6,133	\$8,008
2028	Licensee preparation to assess impact of Deletion of the Low Specific Activity-III Leaching Test	0.45	\$21,667	\$9,848	\$5,732	\$7,774
2029	Licensee preparation to assess impact of Deletion of the Low Specific Activity-III Leaching Test	0.45	\$21,667	\$9,848	\$5,357	\$7,548
2030	Licensee preparation to assess impact of Deletion of the Low Specific Activity-III Leaching Test	0.45	\$21,667	\$9,848	\$5,006	\$7,328
2031	Licensee preparation to assess impact of Deletion of the Low Specific Activity-III Leaching Test	0.45	\$21,667	\$9,848	\$4,679	\$7,115
2032	Licensee preparation to assess impact of Deletion of the Low Specific Activity-III Leaching Test	0.45	\$21,667	\$9,848	\$4,373	\$6,908
Total Benefit (Cost)				\$118,182	\$73,106	\$95,177

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

4.2.7 Inclusion of New Definition for Surface Contaminated Object

The staff estimates there will be no costs to CoC holders with the addition of the SCO-III definition to the regulations, as the proposed new SCO-III material would not be packaged in Type B packages. Therefore, when licensees apply the SCO-III definition, the staff estimates that licensees will benefit because they will not have to get a Type B package approved in accordance with 10 CFR 71.41(d). The NRC estimates that licensees' costs to prepare an application for an approval under 10 CFR 71.41(d) range from \$25,000 for smaller packages to \$75,000 for much larger or more complex packages, with an average cost of \$50,000. To date, the NRC has approved one package authorization under the provisions of 10 CFR 71.41(d), which required 400 hours. The NRC estimates that the time required to review these packages could range from 200 hours to 600 hours. There are 18 nuclear power plants in the active process of decommissioning that may use the new SCO-III provisions the first 11 years after issuance of the rulemaking. As shown in Table 14, the averted cost to apply the SCO-III definition for the 18 plants over the 11 years following the rulemaking is \$573,000, using a 7-percent discount rate.

Table 14 Averted Cost for Licensees using SCO-III Package

Year	Description	No. of Licensees that Apply New Definition	Hours To Perform a SCO-III Assessment	Cost to Prepare Application	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2022	Licensee assessment of material to qualify as SCO-III	1.6	1	\$50,000	\$81,818	\$62,419	\$72,694
2023	Licensee assessment of material to qualify as SCO-III	1.6	1	\$50,000	\$81,818	\$58,335	\$70,577
2024	Licensee assessment of material to qualify as SCO-III	1.6	1	\$50,000	\$81,818	\$54,519	\$68,521
2025	Licensee assessment of material to qualify as SCO-III	1.6	1	\$50,000	\$81,818	\$50,952	\$66,526
2026	Licensee assessment of material to qualify as SCO-III	1.6	1	\$50,000	\$81,818	\$47,619	\$64,588
2027	Licensee assessment of material to qualify as SCO-III	1.6	1	\$50,000	\$81,818	\$44,504	\$62,707
2028	Licensee assessment of material to qualify as SCO-III	1.6	1	\$50,000	\$81,818	\$41,592	\$60,880
2029	Licensee assessment of material to qualify as SCO-III	1.6	1	\$50,000	\$81,818	\$38,871	\$59,107
2030	Licensee assessment of material to qualify as SCO-III	1.6	1	\$50,000	\$81,818	\$36,328	\$57,386
2031	Licensee assessment of material to qualify as SCO-III	1.6	1	\$50,000	\$81,818	\$71,463	\$77,121
2032	Licensee assessment of material to qualify as SCO-III	1.6	1	\$50,000	\$81,818	\$66,788	\$74,875
Total Benefit (Cost)					\$900,000	\$573,391	\$734,983

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

Table 15 shows the averted cost to the NRC for the 11 years is \$601,000, based on a 7-percent discount rate.

Table 15 Averted Cost for NRC Review for Licensees using SCO-III

Year	Description	No. of Decommissioned Power Plants That Apply New Definition	No. of Hours to Review and Issue an Exemption Request	NRC Labor Rate	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2022	NRC harmonize with DOT regulation	1.6	400	\$131	\$85,745	\$74,893	\$80,823
2023	NRC harmonize with DOT regulation	1.6	400	\$131	\$85,745	\$69,994	\$78,469
2024	NRC harmonize with DOT regulation	1.6	400	\$131	\$85,745	\$65,415	\$76,184
2025	NRC harmonize with DOT regulation	1.6	400	\$131	\$85,745	\$61,135	\$73,965
2026	NRC harmonize with DOT regulation	1.6	400	\$131	\$85,745	\$57,136	\$71,810
2027	NRC harmonize with DOT regulation	1.6	400	\$131	\$85,745	\$53,398	\$69,719
2028	NRC harmonize with DOT regulation	1.6	400	\$131	\$85,745	\$49,905	\$67,688
2029	NRC harmonize with DOT regulation	1.6	400	\$131	\$85,745	\$46,640	\$65,717
2030	NRC harmonize with DOT regulation	1.6	400	\$131	\$85,745	\$43,589	\$63,803
2031	NRC harmonize with DOT regulation	1.6	400	\$131	\$85,745	\$40,737	\$61,944
2032	NRC harmonize with DOT regulation	1.6	400	\$131	\$85,745	\$38,072	\$60,140
Total Benefit (Cost)					\$943,200	\$600,913	\$770,263

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

4.2.8 Revision of Uranium Hexafluoride Package Requirements

Currently the NRC has two certificates of compliance to transport UF₆ in 30B cylinders, one of which has already shown that the plug meets the requirements in SSR-6, 2018 Edition. If the certificate holder desires to revise the CoC to the new NRC requirements harmonized with SSR-6, 2018 Edition, then the certificate holder would have to demonstrate that the cylinder plug remains leaktight after the tests for hypothetical accident conditions listed in 10 CFR 71.73 and doesn't contact any other part of the package other than at its point of attachment to the cylinder. The NRC estimates the cost to the existing certificate holder to evaluate the change would depend on the currently available information to the certificate holder. The NRC estimates that if existing drop tests or analyses could be used to demonstrate compliance with the proposed regulations, the cost to compile and submit an application to the NRC would be \$50,000. However, if the applicant cannot use existing data, and would need to perform calculations to provide a demonstration of the plug performance, then the NRC estimates the cost to the applicant to be approximately \$100,000. If, instead of additional calculations, the certificate holder performed additional drop tests to demonstrate performance of the cylinder plug, then the cost estimate is \$200,000, resulting in a mean cost of (\$108,333). This cost would be a single, one-time cost to the current certificate holder; however, it is unclear to the NRC in which year to include this one-time cost. Therefore, the NRC has averaged the cost over each of the 11 years following the rulemaking.

Table 16 Cost to Prepare Application for Revised UF₆ Certificate of Compliance

Year	Description	No. of Certificates	Cost to Prepare and Submit Certification Request	Net Benefits (Cost) [2020\$] ^{a b}		
				Undiscounted	7% NPV	3% NPV
2022	Number of certificates to be revised to current (2018) IAEA regs	0.09	(\$108,333)	(\$9,848)	(\$8,602)	(\$9,283)
2023	Number of certificates to be revised to current (2018) IAEA regs	0.09	(\$108,333)	(\$9,848)	(\$8,039)	(\$9,013)
2024	Number of certificates to be revised to current (2018) IAEA regs	0.09	(\$108,333)	(\$9,848)	(\$7,513)	(\$8,750)
2025	Number of certificates to be revised to current (2018) IAEA regs	0.09	(\$108,333)	(\$9,848)	(\$7,022)	(\$8,495)
2026	Number of certificates to be revised to current (2018) IAEA regs	0.09	(\$108,333)	(\$9,848)	(\$6,562)	(\$8,248)
2027	Number of certificates to be revised to current (2018) IAEA regs	0.09	(\$108,333)	(\$9,848)	(\$6,133)	(\$8,008)
2028	Number of certificates to be revised to current (2018) IAEA regs	0.09	(\$108,333)	(\$9,848)	(\$5,732)	(\$7,774)
2029	Number of certificates to be revised to current (2018) IAEA regs	0.09	(\$108,333)	(\$9,848)	(\$5,357)	(\$7,548)
2030	Number of certificates to be revised to current (2018) IAEA regs	0.09	(\$108,333)	(\$9,848)	(\$5,006)	(\$7,328)
2031	Number of certificates to be revised to current (2018) IAEA regs	0.09	(\$108,333)	(\$9,848)	(\$4,679)	(\$7,115)

Year	Description	No. of Certificates	Cost to Prepare and Submit Certification Request	Net Benefits (Cost) [2020\$] ^{a b}		
				Undiscounted	7% NPV	3% NPV
2032	Number of certificates to be revised to current (2018) IAEA regs	0.09	(\$108,333)	(\$9,848)	(\$4,373)	(\$6,908)
Total		1.00		(\$108,333)	(\$69,019)	(\$88,470)

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

The NRC estimates that the cost to the NRC to perform the review would depend on the evaluation the certificate holder chooses to submit. The NRC estimates that if the applicant submits existing data and did not need to perform additional calculations or drop tests, the NRC review would take approximately 158 hours to review one certificate, which the staff expects to be submitted within the 11-year period analysis period.

Table 17 NRC Cost to Review Application for Certificate Revision

Year	Description	No. of Certificates Revised to 2018 IAEA Standards	No. of Hours to Review Application	NRC Labor Rate	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2022	NRC review of revised certificates	0.09	(158)	\$131	(\$1,887)	(\$1,648)	(\$1,778)
2023	NRC review of revised certificates	0.09	(158)	\$131	(\$1,887)	(\$1,540)	(\$1,727)
2024	NRC review of revised certificates	0.09	(158)	\$131	(\$1,887)	(\$1,439)	(\$1,676)
2025	NRC review of revised certificates	0.09	(158)	\$131	(\$1,887)	(\$1,345)	(\$1,627)
2026	NRC review of revised certificates	0.09	(158)	\$131	(\$1,887)	(\$1,257)	(\$1,580)
2027	NRC review of revised certificates	0.09	(158)	\$131	(\$1,887)	(\$1,175)	(\$1,534)
2028	NRC review of revised certificates	0.09	(158)	\$131	(\$1,887)	(\$1,098)	(\$1,489)
2029	NRC review of revised certificates	0.09	(158)	\$131	(\$1,887)	(\$1,026)	(\$1,446)
2030	NRC review of revised certificates	0.09	(158)	\$131	(\$1,887)	(\$959)	(\$1,404)
2031	NRC review of revised certificates	0.09	(158)	\$131	(\$1,887)	(\$896)	(\$1,363)
2032	NRC review of revised certificates	0.09	(158)	\$131	(\$1,887)	(\$838)	(\$1,323)
Total		1.00			(\$20,753)	(\$13,221)	(\$16,948)

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

Cost Impact to an Applicant for a New Certificate of Compliance

The NRC is not aware of any new packages for transport of UF₆ enriched to a maximum of 5-weight percent ²³⁵U. However, presuming that a new package is evaluated by testing, then the NRC estimates that the cost for a new CoC would be approximately \$10,000 to perform the additional drop tests on the plug end. If calculations were performed to evaluate the performance of the plug, the NRC estimates the cost to perform the calculations and document their results in an application would be \$25,000.

The NRC estimates that its cost to review and document the soundness of the cylinder plug after the tests for hypothetical accident conditions would be 50 hours for a cost of \$6,500, if the applicant evaluated the plug by drop tests, and 250 hours of review time at a cost of \$32,750, if the new package is evaluated by analysis.

4.2.9 Inclusion of Evaluation of Aging Mechanisms and a Maintenance Program

The proposed changes to the packaging requirements to add evaluation of aging effects and a maintenance program would not impact the applications for transport of package design approval or NRC reviews. These changes ensure consistency with IAEA standards and conform to approaches already taken by certificate holders to evaluate aging effects and inclusion of a maintenance program. Consequently, no changes to packages or costs—for either the NRC or current or future certificate holders—are anticipated from implementing this change to the regulation.

4.2.10 Revision of Transitional Arrangements

After the effective date of the rulemaking, the change would result in implementation costs to industry, but the magnitude of the costs depends upon the type of package and the required actions. For example, some previously approved package designs may already meet current safety regulations but lack the documentation for the NRC to make this determination. These packages would have fewer costs to recertify than packages that cannot be shown to meet current safety regulations. In general, the types of costs industry would bear include costs to: (1) develop applications to show previously approved package designs meet the revised regulations; (2) develop new package design(s) or package modification(s); (3) analyze and/or physically test these new package design(s) or modification(s); (4) generate and submit revised package applications; and (5) implement these new design(s) or package modification(s). The NRC costs are to review and approve the new package designs or package modifications.

The NRC reviewed the changes to the NRC regulations starting with the rule change effective on April 1, 1996 (60 FR 50248; September 28, 1995) [29], and the NRC-approved packages whose certificate is based on the NRC regulations harmonized with SS No. 6, 1973 Edition, in the final rule effective on September 6, 1983 (48 FR 35600; August 5, 1983) [30]. Based on this review, the NRC estimated that the cost to develop and provide an application to the NRC to update a certificate to the NRC regulations harmonized with SSR-6, 2018 Edition, would range from a low estimate of approximately \$10,000, to a most likely estimate of \$20,000, to a high estimate of \$30,000. This estimate excludes the costs for other changes that the certificate holder may voluntarily make to the package as a result of this rule change. The NRC estimates that the average cost would be approximately \$20,000 per package, excluding the costs estimated for other changes incorporated due to this rule change.

The NRC estimates that all certificate holders will revise the 14 certificates that were approved to the NRC regulations in effect prior to April 1, 1996 (i.e., packages that do not have a “-85” or “-96” in their package identification number). The NRC estimates that, for packages with a “-85” or “-96” in the package identification number, certificate holders would revise an additional four certificates per year to SSR-6, 2018 Edition of IAEA standards. Therefore, certificate holders would revise an average of 7.5 certificates per year, for the first 4 years and 4 certificates per year for the next 7 years following the final rule effective date to show compliance with the NRC regulations in effect at the time.

Table 18 Certificate Holder Cost to Revise Certificates

Year	Description	Number of Revised Certificates	Cost to Prepare and Submit Certification Request	Net Benefits (Cost) [2020\$] ^{a b}		
				Undiscounted	7% NPV	3% NPV
2022	Licensee preparation of revised certificates	7.5	(\$20,000)	(\$150,000)	(\$131,016)	(\$141,389)
2023	Licensee preparation of revised certificates	7.5	(\$20,000)	(\$150,000)	(\$122,445)	(\$137,271)
2024	Licensee preparation of revised certificates	7.5	(\$20,000)	(\$150,000)	(\$114,434)	(\$133,273)
2025	Licensee preparation of revised certificates	7.5	(\$20,000)	(\$150,000)	(\$106,948)	(\$129,391)
2026	Licensee preparation of revised certificates	4	(\$20,000)	(\$80,000)	(\$53,307)	(\$66,999)
2027	Licensee preparation of revised certificates	4	(\$20,000)	(\$80,000)	(\$49,820)	(\$65,047)
2028	Licensee preparation of revised certificates	4	(\$20,000)	(\$80,000)	(\$46,561)	(\$63,153)
2029	Licensee preparation of revised certificates	4	(\$20,000)	(\$80,000)	(\$43,515)	(\$61,313)
2030	Licensee preparation of revised certificates	4	(\$20,000)	(\$80,000)	(\$40,668)	(\$59,528)
2031	Licensee preparation of revised certificates	4	(\$20,000)	(\$80,000)	(\$38,007)	(\$57,794)
2032	Licensee preparation of revised certificates	4	(\$20,000)	(\$80,000)	(\$35,521)	(\$56,110)
Total		58.0		(\$1,160,000)	(\$782,242)	(\$971,269)

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

Table 19 NRC Review Time for Revised Certificates Cost

Year	Description	No. of Certificates Revised to 2018 IAEA Standards	No. of Hours to Review Licensee Report	NRC Labor Rate	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2022	NRC review certificate revision cost	7.5	130	(\$131)	(\$127,725)	(\$111,560)	(\$120,393)
2023	NRC review certificate revision cost	7.5	130	(\$131)	(\$127,725)	(\$104,262)	(\$116,886)
2024	NRC review certificate revision cost	7.5	130	(\$131)	(\$127,725)	(\$97,441)	(\$113,482)
2025	NRC review certificate revision cost	7.5	130	(\$131)	(\$127,725)	(\$91,066)	(\$110,177)
2026	NRC review certificate revision cost	4	130	(\$131)	(\$68,120)	(\$45,391)	(\$57,049)
2027	NRC review certificate revision cost	4	130	(\$131)	(\$68,120)	(\$42,422)	(\$55,388)
2028	NRC review certificate revision cost	4	130	(\$131)	(\$68,120)	(\$39,646)	(\$53,775)
2029	NRC review certificate revision cost	4	130	(\$131)	(\$68,120)	(\$37,053)	(\$52,208)
2030	NRC review certificate revision cost	4	130	(\$131)	(\$68,120)	(\$34,629)	(\$50,688)
2031	NRC review certificate revision cost	4	130	(\$131)	(\$68,120)	(\$32,363)	(\$49,211)
2032	NRC review certificate revision cost	4	130	(\$131)	(\$68,120)	(\$30,246)	(\$47,778)
Total		58.0			(\$987,740)	(\$666,079)	(\$827,035)

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

If a package design that does not have a “-85” or “-96” in its package identification number cannot be shown to meet current safety standards, the NRC estimated the cost to design, receive NRC certification, and fabricate a replacement package. This estimate is based on updating the similar information in NUREG/CR-6713, “Regulatory Analysis of Major Revision of 10 CFR Part 71,” Section 3.3.8, “Grandfathering of Previously Approved Packages” [31]. The staff’s estimates for the cost to design, obtain NRC approval, and fabricate new packages ranges between \$387,612 and \$893,967 with an average cost of \$597,500.

Table 20 Certificate Holder Cost to Prepare an Application for a Replacement Package

Year	Description	No. of Certificates Revised to 2018 IAEA Standards	Cost to Prepare and Submit Certification Request	Net Benefits (Cost) [2020\$] ^{a b}		
				Undiscounted	7% NPV	3% NPV
2022	Licensee cost to prepare an application	0.2	(\$597,500)	(\$119,500)	(\$104,376)	(\$112,640)
2023	Licensee cost to prepare an application	0.2	(\$597,500)	(\$119,500)	(\$97,548)	(\$109,359)
2024	Licensee cost to prepare an application	0.2	(\$597,500)	(\$119,500)	(\$91,166)	(\$106,174)
2025	Licensee cost to prepare an application	0.2	(\$597,500)	(\$119,500)	(\$85,202)	(\$103,082)
2026	Licensee cost to prepare an application	0.2	(\$597,500)	(\$119,500)	(\$79,628)	(\$100,079)
2027	Licensee cost to prepare an application	0	(\$0)	(\$0)	(\$0)	(\$0)
2028	Licensee cost to prepare an application	0	(\$0)	(\$0)	(\$0)	(\$0)
2029	Licensee cost to prepare an application	0	(\$0)	(\$0)	(\$0)	(\$0)
2030	Licensee cost to prepare an application	0	(\$0)	(\$0)	(\$0)	(\$0)
2031	Licensee cost to prepare an application	0	(\$0)	(\$0)	(\$0)	(\$0)
2032	Licensee cost to prepare an application	0	(\$0)	(\$0)	(\$0)	(\$0)
Total		1.0		(\$597,500)	(\$457,919)	(\$531,335)

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

The NRC estimates that the NRC’s cost to review these new package design applications would take a mean of 1,056 hours per certificate. In addition, one package over a three-year period (2027 to 2029), at \$131 per staff-hour, excluding any review time for costs associated with other changes in this rulemaking, results in a cost of (\$80,634) at 7%.

Table 21 NRC Review Cost for Reviewing an Application for a Replacement Package

Year	Description	No. of Certificates Revisions to 2018 IAEA Standards	No. of Hours to Review Licensee Reports	NRC Labor Rate	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2022	NRC cost to review new package design	0	1,056	(\$131)	(\$0)	(\$0)	(\$0)
2023	NRC cost to review new package design	0	1,056	(\$131)	(\$0)	(\$0)	(\$0)
2024	NRC cost to review new package design	0	1,056	(\$131)	(\$0)	(\$0)	(\$0)
2025	NRC cost to review new package design	0	1,056	(\$131)	(\$0)	(\$0)	(\$0)
2026	NRC cost to review new package design	0	1,056	(\$131)	(\$0)	(\$0)	(\$0)

Year	Description	No. of Certificates Revisions to 2018 IAEA Standards	No. of Hours to Review Licensee Reports	NRC Labor Rate	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2027	NRC cost to review new package design	0.3	1,056	(\$131)	(\$46,111)	(\$28,716)	(\$37,493)
2028	NRC cost to review new package design	0.3	1,056	(\$131)	(\$46,111)	(\$26,837)	(\$36,401)
2029	NRC cost to review new package design	0.3	1,056	(\$131)	(\$46,111)	(\$28,081)	(\$35,340)
2030	NRC cost to review new package design	0	1,056	(\$131)	(\$0)	(\$0)	(\$0)
2031	NRC cost to review new package design	0	1,056	(\$131)	(\$0)	(\$0)	(\$0)
2032	NRC cost to review new package design	0	1,056	(\$131)	(\$0)	(\$0)	(\$0)
Total		1.0		Total	(\$138,333)	(\$80,634)	(\$109,233)

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

4.2.11 Inclusion of Head Space for Liquid Expansion

The NRC currently has six certificates of compliance that authorize liquid contents. The NRC estimates that, when an existing certificate holder desires to revise its certificate to the latest version of the regulations, the certificate holder would have to review its application to ensure that it adequately addresses expansion of liquid due to thermal variations that may occur during normal conditions of transport and hypothetical accident conditions. The NRC estimates that this review would cost the applicant approximately \$1,500 per application.

Table 22 Licensee Cost to Prepare and Evaluate Liquid Expansion

Year	Description	No. of Certificates Revised to 2018 IAEA Standards	Cost to Prepare and Submit Certification Request	Net Benefits (Cost) [2020\$] ^{a b}		
				Undiscounted	7% NPV	3% NPV
2022	Licensee preparation of revised certificates	0.55	(\$1,500)	(\$818)	(\$715)	(\$771)
2023	Licensee preparation of revised certificates	0.55	(\$1,500)	(\$818)	(\$668)	(\$749)
2024	Licensee preparation of revised certificates	0.55	(\$1,500)	(\$818)	(\$624)	(\$727)
2025	Licensee preparation of revised certificates	0.55	(\$1,500)	(\$818)	(\$583)	(\$706)
2026	Licensee preparation of revised certificates	0.55	(\$1,500)	(\$818)	(\$545)	(\$685)
2027	Licensee preparation of revised certificates	0.55	(\$1,500)	(\$818)	(\$510)	(\$665)
2028	Licensee preparation of revised certificates	0.55	(\$1,500)	(\$818)	(\$476)	(\$646)
2029	Licensee preparation of revised certificates	0.55	(\$1,500)	(\$818)	(\$445)	(\$627)
2030	Licensee preparation of revised certificates	0.55	(\$1,500)	(\$818)	(\$416)	(\$609)
2031	Licensee preparation of revised certificates	0.55	(\$1,500)	(\$818)	(\$389)	(\$591)
2032	Licensee preparation of revised certificates	0.55	(\$1,500)	(\$818)	(\$363)	(\$574)
Total		6.00		(\$9,000)	(\$5,734)	(\$7,350)

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

The NRC estimates that there would be no additional cost to applicants for a new CoC because the NRC regulations in 10 CFR 71.87 already include an operational requirement to ensure that the container includes sufficient head space for the liquid contents.

The NRC estimates that its review of an application for revision of an existing certificate would take approximately 4 hours. The NRC estimates that the cost to evaluate six package applications to revise an existing CoC to revised NRC regulations that are harmonized with SSR-6, 2018 Edition, over an 11-year period would be \$2,000 based on a 7-percent discount rate.

Table 23 NRC Cost to Evaluate Application for Liquid Expansion

Year	Description	No. of Certificates Revisions to 2018 IAEA Standards for Liquid Expansion	NRC Time to Perform the Review of Licensee Application (Hours) for Liquid Expansion	NRC Labor Rate	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2022	NRC review of revised certificates	1	(4)	\$131	(\$286)	(\$250)	(\$269)
2023	NRC review of revised certificates	1	(4)	\$131	(\$286)	(\$233)	(\$262)
2024	NRC review of revised certificates	1	(4)	\$131	(\$286)	(\$218)	(\$254)
2025	NRC review of revised certificates	1	(4)	\$131	(\$286)	(\$204)	(\$247)
2026	NRC review of revised certificates	1	(4)	\$131	(\$286)	(\$190)	(\$239)
2027	NRC review of revised certificates	1	(4)	\$131	(\$286)	(\$178)	(\$232)
2028	NRC review of revised certificates	1	(4)	\$131	(\$286)	(\$166)	(\$226)
2029	NRC review of revised certificates	1	(4)	\$131	(\$286)	(\$155)	(\$219)
2030	NRC review of revised certificates	1	(4)	\$131	(\$286)	(\$145)	(\$213)
2031	NRC review of revised certificates	1	(4)	\$131	(\$286)	(\$136)	(\$206)
Total		11			(\$3,144)	(\$2,003)	(\$2,568)

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

4.2.12 Revision of Quality Assurance Program Biennial Reporting Requirements

The proposed rulemaking alternative would currently affect 41 QAP approval holders under 10 CFR Part 71. Each affected QAP approval holder would need to reconcile the change with their own procedures and processes which would be a one-time implementation cost once the final rule is issued. The NRC estimates that this review and update would cost on average \$800 per QAP approval holder. The majority of the QAP approval holders will not have to make any changes to their current processes because 38 of the 41 current QAP holders have already submitted biennial reports. Therefore, they would only incur the costs of performing the verification of their current processes. The NRC assumes the remaining three QAP approval holders did not send in a biennial report because no changes have been made to their QAP. They would need to make conforming changes to their current processes to ensure a biennial report is issued to the NRC at future reporting intervals if no changes were made to their QAP during the previous 24 months.

Table 24 Licensee Cost to Evaluate Program Change for Biennial Report

Year	Description	No. of QAPs Clarified	No. of Hours to Revise QAP	Labor Rate	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2022	Licensee/Certificate holder cost to evaluate QAP	(41)	10	\$80	(\$32,800)	(\$28,649)	(\$30,917)
2023	Licensee/Certificate holder cost to evaluate QAP	0	10	\$80	\$0	\$0	\$0
2024	Licensee/Certificate holder cost to evaluate QAP	0	10	\$80	\$0	\$0	\$0
2025	Licensee/Certificate holder cost to evaluate QAP	0	10	\$80	\$0	\$0	\$0
2026	Licensee/Certificate holder cost to evaluate QAP	0	10	\$80	\$0	\$0	\$0
2027	Licensee/Certificate holder cost to evaluate QAP	0	10	\$80	\$0	\$0	\$0
2028	Licensee/Certificate holder cost to evaluate QAP	0	10	\$80	\$0	\$0	\$0
2029	Licensee/Certificate holder cost to evaluate QAP	0	10	\$80	\$0	\$0	\$0
2030	Licensee/Certificate holder cost to evaluate QAP	0	10	\$80	\$0	\$0	\$0
2031	Licensee/Certificate holder cost to evaluate QAP	0	10	\$80	\$0	\$0	\$0
2032	Licensee/Certificate holder cost to evaluate QAP	0	10	\$80	\$0	\$0	\$0
2033	Licensee/Certificate holder cost to evaluate QAP	0	10	\$80	\$0	\$0	\$0
Total					(\$32,800)	(\$28,649)	(\$30,917)

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

In addition, the three QAP approval holders discussed above that have not submitted a biennial report would incur the operational costs of issuing those biennial reports stating no changes were made every 24 months. The NRC estimates that QAP approval holder operational costs for issuance of their QAP biennial report every 24 months would be approximately 1 hour for each issuance occurrence at a rate of \$80 per hour. The NRC assumes that an additional four QAP approval holders would need to submit a report in each future 24-month reporting interval if no changes were made to their QAP.

Table 25 Licensee Cost to Submit Biennial Report

Year	Description	No. of QAP Biennial Report Submitted	No. of Hours to Develop and Submit Biennial Report	Labor Rate	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2022	Licensees and certificate holders cost to submit QAP biennial report	4	(1)	\$80	(\$307)	(\$268)	(\$289)
2023	Licensees and certificate holders cost to submit QAP biennial report	0	(1)	\$80	\$0	\$0	\$0
2024	Licensees and certificate holders cost to submit QAP biennial report	4	(1)	\$80	(\$307)	(\$234)	(\$272)
2025	Licensees and certificate holders cost to submit QAP biennial report	0	(1)	\$80	\$0	\$0	\$0
2026	Licensees and certificate holders cost to submit QAP biennial report	4	(1)	\$80	(\$307)	(\$204)	(\$257)

Year	Description	No. of QAP Biennial Report Submitted	No. of Hours to Develop and Submit Biennial Report	Labor Rate	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2027	Licensees' and certificate holders' cost to submit QAP biennial report	0	(1)	\$80	\$0	\$0	\$0
2028	Licensees' and certificate holders' cost to submit QAP biennial report	4	(1)	\$80	(\$307)	(\$178)	(\$242)
2029	Licensees' and certificate holders' cost to submit QAP biennial report	0	(1)	\$80	\$0	\$0	\$0
2030	Licensees' and certificate holders' cost to submit QAP biennial report	4	(1)	\$80	(\$307)	(\$156)	(\$228)
2031	Licensees' and certificate holders' cost to submit QAP biennial report	0	(1)	\$80	\$0	\$0	\$0
2032	Licensees' and certificate holders' cost to submit QAP biennial report	4	(1)	\$80	(\$307)	(\$136)	(\$215)
Total		24			(\$1,839)	(\$1,176)	(\$1,503)

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

The NRC estimates that its review of additional QAP biennial reports every 2 years would take approximately 1 hour each for every review occurrence at a rate of \$131 per staff-hour. The NRC assumed four additional QAP biennial reports would be reviewed based on three QAP approval holders who have not submitted a report as described above.

Table 26 NRC Cost to Review Biennial Report

Year	Description	No. of Biennial Report Submittals	No. of Hours to Review Biennial QAP Report	NRC Labor Rate	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2022	NRC review of biennial report submittals	4	(1)	\$131	(\$502)	(\$438)	(\$473)
2023	NRC review of biennial report submittals	0	(1)	\$131	\$0	\$0	\$0
2024	NRC review of biennial report submittals	4	(1)	\$131	(\$502)	(\$383)	(\$446)
2025	NRC review of biennial report submittals	0	(1)	\$131	\$0	\$0	\$0
2026	NRC review of biennial report submittals	4	(1)	\$131	(\$502)	(\$334)	(\$420)
2027	NRC review of biennial report submittals	0	(1)	\$131	\$0	\$0	\$0
2028	NRC review of biennial report submittals	4	(1)	\$131	(\$502)	(\$292)	(\$396)
2029	NRC review of biennial report submittals	0	(1)	\$131	\$0	\$0	\$0
2030	NRC review of biennial report submittals	4	(1)	\$131	(\$502)	(\$255)	(\$373)
2031	NRC review of biennial report submittals	0	(1)	\$131	\$0	\$0	\$0

Year	Description	No. of Biennial Report Submittals	No. of Hours to Review Biennial QAP Report	NRC Labor Rate	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2032	NRC review of biennial report submittals	4	(1)	\$131	(\$502)	(\$223)	(\$352)
Total		24			(\$3,012)	(\$1,926)	(\$2,461)

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

4.2.13 Deletion of Type A Package Limitations in Fissile Material General Licenses

The staff is of the view that a licensee who wished to ship up to 37 grams of plutonium previously would have done so in an NRC-certified Type B(U)F package, rather than splitting the material up into a large number of shipments. The averted cost for this requirement, therefore, arises from not having to perform a demonstration of criticality safety for a new or previously certified Type B(U) package (without the “F” fissile certification). Because this is a specialized type of shipment, the staff estimates that two applicants might design a new package or modify an existing package to take advantage of this rule change. For this design, the applicant could simply refer to 10 CFR 71.22 for a CSI calculation and mass limits, rather than providing a demonstration of criticality safety per 10 CFR 71.55 and 71.59. The NRC estimates that a criticality safety assessment to support certification of this amount of material would take an average of 40 hours, at an average cost of \$200/hour. The NRC estimates that the time needed to perform a typical criticality safety assessment review would take 43 hours, on average, at an average cost of \$131 per hour. The staff estimates that two certificates may be revised to take advantage of the new general license requirements, over the next 10 years.

Table 27 Averted Licensee Cost to Obtain Approval for Shipment in Type BF Package

Year	Description	No. of Certificate Holders Adopting 10 CFR 71.22 Limit	Certificate Holder Labor Rate	No. of Hours to Prepare Criticality Safety Evaluation	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2022	Certificate holder averted cost by adopting 10 CFR 71.22 limit for Pu	0.18	\$203	43	\$1,602	\$1,399	\$1,510
2023	Certificate holder averted cost by adopting 10 CFR 71.22 limit for Pu	0.18	\$203	43	\$1,602	\$1,308	\$1,466
2024	Certificate holder averted cost by adopting 10 CFR 71.22 limit for Pu	0.18	\$203	43	\$1,602	\$1,222	\$1,424
2025	Certificate holder averted cost by adopting 10 CFR 71.22 limit for Pu	0.18	\$203	43	\$1,602	\$1,142	\$1,382
2026	Certificate holder averted cost by adopting 10 CFR 71.22 limit for Pu	0.18	\$203	43	\$1,602	\$1,068	\$1,342
2027	Certificate holder averted cost by adopting 10 CFR 71.22 limit for Pu	0.18	\$203	43	\$1,602	\$998	\$1,303
2028	Certificate holder averted cost by adopting 10 CFR 71.22 limit for Pu	0.18	\$203	43	\$1,602	\$933	\$1,265
2029	Certificate holder averted cost by adopting 10 CFR 71.22 limit for Pu	0.18	\$203	43	\$1,602	\$872	\$1,228
2030	Certificate holder averted cost by adopting 10 CFR 71.22 limit for Pu	0.18	\$203	43	\$1,602	\$815	\$1,192

Year	Description	No. of Certificate Holders Adopting 10 CFR 71.22 Limit	Certificate Holder Labor Rate	No. of Hours to Prepare Criticality Safety Evaluation	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2031	Certificate holder averted cost by adopting 10 CFR 71.22 limit for Pu	0.18	\$203	43	\$1,602	\$761	\$1,158
2032	Certificate holder averted cost by adopting 10 CFR 71.22 limit for Pu	0.18	\$203	43	\$1,602	\$711	\$1,124
Total		2.00			\$17,625	\$11,229	\$14,393

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

Table 28 Averted NRC Cost to Review Application for Approval for Shipment in Type BF Package

Year	Description	No. of Certificate Holders Adopting 71.22 Limit	No. of Hours to Review of Criticality Evaluation	NRC Labor Rate	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2022	NRC review criticality evaluation	0.18	43	\$131	\$1,012	\$884	\$954
2023	NRC review criticality evaluation	0.18	43	\$131	\$1,012	\$826	\$926
2024	NRC review criticality evaluation	0.18	43	\$131	\$1,012	\$772	\$899
2025	NRC review criticality evaluation	0.18	43	\$131	\$1,012	\$722	\$873
2026	NRC review criticality evaluation	0.18	43	\$131	\$1,012	\$675	\$848
2027	NRC review criticality evaluation	0.18	43	\$131	\$1,012	\$630	\$823
2028	NRC review criticality evaluation	0.18	43	\$131	\$1,012	\$589	\$799
2029	NRC review criticality evaluation	0.18	43	\$131	\$1,012	\$551	\$776
2030	NRC review criticality evaluation	0.18	43	\$131	\$1,012	\$515	\$753
2031	NRC review criticality evaluation	0.18	43	\$131	\$1,012	\$481	\$731
2032	NRC review criticality evaluation	0.18	43	\$131	\$1,012	\$449	\$710
Total Benefit (Cost)					\$11,135	\$7,094	\$9,093

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

There may also be averted costs associated with this proposed change because licensees would be able to ship a Type B package, as opposed to a Type BF. The NRC estimates that there would be three affected shipments per year, on average, that would be made under this revised provision. The staff estimates that the average averted cost per shipment of shipping in a Type B versus a Type BF package would be \$200.

Table 29 Averted Licensee Cost to Make Shipment Using New Type B Package Limits

Year	Description	No. of Shipments	Incremental Cost of Shipping a Type B Versus a Type BF Package	No. of Licensees	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2022	Averted licensee cost to ship under new Type B package limits	3	\$233	1	\$700	\$612	\$660
2023	Averted licensee cost to ship under new Type B package limits	3	\$233	1	\$700	\$572	\$641
2024	Averted licensee cost to ship under new Type B package limits	3	\$233	1	\$700	\$534	\$622
2025	Averted licensee cost to ship under new Type B package limits	3	\$233	1	\$700	\$499	\$604

Year	Description	No. of Shipments	Incremental Cost of Shipping a Type B Versus a Type BF Package	No. of Licensees	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2026	Averted licensee cost to ship under new Type B package limits	3	\$233	1	\$700	\$467	\$587
2027	Averted licensee cost to ship under new Type B package limits	3	\$233	1	\$700	\$436	\$569
2028	Averted licensee cost to ship under new Type B package limits	3	\$233	1	\$700	\$408	\$553
2029	Averted licensee cost to ship under new Type B package limits	3	\$233	1	\$700	\$381	\$537
2030	Averted licensee cost to ship under new Type B package limits	3	\$233	1	\$700	\$356	\$521
2031	Averted licensee cost to ship under new Type B package limits	3	\$233	1	\$700	\$333	\$506
2032	Averted licensee cost to ship under new Type B package limits	3	\$233	1	\$700	\$311	\$491
Total		33			\$7,704	\$4,908	\$6,292

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

4.2.14 Deletion of ²³³U Restriction in Fissile General License

For cost analysis considerations, the staff estimates an average of 11 averted shipments per year, per licensee, over the 11-year period considered for the cost analysis. The staff estimates an average cost of \$1,850 per shipment. Costs are higher in this case than in Issue 1, as these packages require a fissile CSI label and associated accumulation restrictions.

Table 30 Licensee Averted Cost for Transporting Using General License in 10 CFR 71.22

Year	Description	No. of Fissile Material Licensees	No. of Shipments of Low-Enriched ²³⁵ U	Cost per Shipment	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2022	Licensee averted shipment costs shipping under 10 CFR 71.22	11	11	\$1,850	\$227,218	\$198,461	\$214,175
2023	Licensee averted shipment costs shipping under 10 CFR 71.22	11	11	\$1,850	\$227,218	\$185,478	\$207,937
2024	Licensee averted shipment costs shipping under 10 CFR 71.22	11	11	\$1,850	\$227,218	\$173,343	\$201,880
2025	Licensee averted shipment costs shipping under 10 CFR 71.22	11	11	\$1,850	\$227,218	\$162,003	\$196,000
2026	Licensee averted shipment costs shipping under 10 CFR 71.22	11	11	\$1,850	\$227,218	\$151,405	\$190,291
2027	Licensee averted shipment costs shipping under 10 CFR 71.22	11	11	\$1,850	\$227,218	\$141,500	\$184,749
2028	Licensee averted shipment costs shipping under 10 CFR 71.22	11	11	\$1,850	\$227,218	\$132,243	\$179,368
2029	Licensee averted shipment costs shipping under 10 CFR 71.22	11	11	\$1,850	\$227,218	\$123,592	\$174,144
2030	Licensee averted shipment costs shipping under 10 CFR 71.22	11	11	\$1,850	\$227,218	\$115,506	\$169,071

Year	Description	No. of Fissile Material Licensees	No. of Shipments of Low-Enriched ²³⁵ U	Cost per Shipment	Net Benefits (Cost) [2020\$] ^{a b}		
					Undiscounted	7% NPV	3% NPV
2031	Licensee averted shipment costs shipping under 10 CFR 71.22	11	11	\$1,850	\$227,218	\$107,950	\$164,147
2032	Licensee averted shipment costs shipping under 10 CFR 71.22	11	11	\$1,850	\$227,218	\$100,887	\$159,366
Total)		121	121		\$2,499,397	\$1,592,368	\$2,041,128

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

4.2.15 Other Recommended Changes to 10 CFR Part 71

4.2.15.1 Issue 15.1. Deletion of Duplicative Reporting Requirements

Since the NRC is proposing to delete duplicative requirements, reporting instances in which licensees perform a shipment that is not in accordance with the regulations would still be reportable under 10 CFR 71.95(b) and there would be no change in costs.

4.2.15.2 Revision of the Definition of Low Specific Activity

There is no cost impact expected from clarifying the definition of “LSA.” Revising the definition of “LSA” to make it consistent with the fissile exemptions in 10 CFR 71.15 to ensure licensees know that LSA packages may contain up to an exempt quantity of fissile material does not change the meaning of the definition.

4.2.15.3 Revision of Tables Containing A₁ and A₂ Values and Exempt Material Activity and Consignment Limits

There is no cost impact expected from revising the values in Table A-1 and A-2 in Appendix A to 10 CFR Part 71. Revising the items in the tables would align the information with the values in the DOT regulations and would be consistent with SSR-6, 2018 Edition. Since the values for A₁ and A₂ are either remaining the same or increasing, and currently there are no packages approved to transport Type B quantities of the seven new radionuclides, the NRC does not expect any new Type B package approvals.

4.2.15.4 Revision to Agreement State Compatibility Categories

The NRC is proposing to revise the compatibility category designations for the reporting requirements in 10 CFR 71.95 and the regulations containing QAP review criteria for Agreement State review, approval, and inspection of the use of Type B packages, other than industrial radiography use, or the use of the general licenses in § 71.21, § 71.22 or § 71.23, which also requires an approved QAP.

The NRC has not received any reports over the past several years of a significant reduction in the effectiveness of an NRC-approved Type B or Type AF packaging during use, or defects with safety significance in any NRC-approved Type B or fissile material packaging, after first use. Therefore, the NRC does not expect to get any reports from Agreement State licensees pursuant to 10 CFR 71.95(a) over the next 11-year period. The NRC expects that Agreement States that incorporate these changes will get approximately two reports per Agreement State

per year pursuant to 10 CFR 71.95(b) reporting of instances in which the CoC was not followed during shipment. The NRC estimates that licensees submitting these reports will take approximately 3 hours to complete the report and submit it to an Agreement State. The NRC estimates on the amount of time to review the report ranges from a low of 1 hour, for reading and digesting the content of the report, to a high of 5 hours to review the report and write a report summarizing the licensees report, with an average of approximately 3 hours. For the revised compatibility category designations to the QAP review criteria, the NRC does not expect any additional operational costs for Agreement States, as this is only a clarification of a previous change.

Table 31 Agreement States Costs to Review Reports

Year	Description	No. of Agreement States	No. of 10 CFR 71.95 Reports per Year	No. of Hours to Review Reports	Labor Rate	Net Benefits (Cost) [2020\$] ^{a b}		
						Undiscounted	7% NPV	3% NPV
2022	Agreement State cost to review 10 CFR 71.95 reports	(39)	2	3	\$101	(\$23,637)	(\$20,646)	(\$22,281)
2023	Agreement State cost to review 10 CFR 71.95 reports	(39)	2	3	\$101	(\$23,637)	(\$19,295)	(\$21,632)
2024	Agreement State cost to review 10 CFR 71.95 reports	(39)	2	3	\$101	(\$23,637)	(\$18,033)	(\$21,002)
2025	Agreement State cost to review 10 CFR 71.95 reports	(39)	2	3	\$101	(\$23,637)	(\$16,853)	(\$20,390)
2026	Agreement State cost to review 10 CFR 71.95 reports	(39)	2	3	\$101	(\$23,637)	(\$15,751)	(\$19,796)
2027	Agreement State cost to review 10 CFR 71.95 reports	(39)	2	3	\$101	(\$23,637)	(\$14,720)	(\$19,219)
2028	Agreement State cost to review 10 CFR 71.95 reports	(39)	2	3	\$101	(\$23,637)	(\$13,757)	(\$18,660)
2029	Agreement State cost to review 10 CFR 71.95 reports	(39)	2	3	\$101	(\$23,637)	(\$12,857)	(\$18,116)
2030	Agreement State cost to review 10 CFR 71.95 reports	(39)	2	3	\$101	(\$23,637)	(\$12,016)	(\$17,589)
2031	Agreement State cost to review 10 CFR 71.95 reports	(39)	2	3	\$101	(\$23,637)	(\$11,230)	(\$17,076)
2032	Agreement State cost to review 10 CFR 71.95 reports	(39)	2	3	\$101	(\$23,637)	(\$10,495)	(\$16,579)
Total			22			(\$260,012)	(\$165,654)	(\$212,339)

^a The results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

^b There may be differences between tables due to rounding.

4.2.15.5 Deletion of Redundant Advance Notification Requirements for Shipment of Spent Fuel

Revising 10 CFR 71.97 to remove the requirement for advance notification of shipment of irradiated reactor fuel would not change the requirements for advance notification of nuclear waste. Since reporting would still be required by either 10 CFR 73.35 or 10 CFR 73.37 there would not be an increase or decrease in licensee costs for this rule clarification.

5 Uncertainty Analysis

The NRC completed a Monte Carlo sensitivity analysis for this regulatory analysis using the specialty software @Risk®.¹ The Monte Carlo approach answers the question, “What distribution of net benefits results from multiple draws of the probability distribution assigned to key variables?”

5.1 Uncertainty Analysis Assumptions

As this regulatory analysis uses estimates of values that are sensitive to unique certificate holders’ situations, the staff analyzed the variables that have the greatest amount of uncertainty. To perform this analysis, the staff used 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 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 (in other words, 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 staff’s professional judgment. When defining the probability distributions for use in a Monte Carlo simulation, summary statistics are used to characterize the distributions. These summary statistics include the minimum, most likely, and maximum values of a program evaluation and review technique (PERT) distribution.² The staff used the PERT distribution to reflect the relative spread and skewness of the distribution defined by the three estimates, the minimum, most likely, and maximum. Appendix A, Table A-1 of this document provides the probability distribution function and the descriptive statistics of the inputs used in the uncertainty analysis.

5.2 Uncertainty Analysis Results

The NRC performed the Monte Carlo simulation by repeatedly calculating the results 10,000 times. Appendix A provides the inputs used in the uncertainty analysis and additional information regarding the uncertainty analysis results.

For each iteration, the variable values in Appendix A 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 resulting output variable values were used to define the resultant probability distribution.

¹ Information about this software is available at <http://www.palisade.com>.

² 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, as 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 it is desired to capture tail or extreme events.

The results of the uncertainty analysis are provided graphically in Figures A-1 through A-12 located in Appendix A. These figures display the histograms of the incremental net benefit between the identified alternatives to address that issue. The uncertainty analysis graph results are reported in 2020 dollars using a 7-percent discount rate.

The estimates for several issues were not included in the uncertainty analysis for the following reasons. Issue 2 has no graph because there are no incremental costs or benefits. Issue 3 has no graph because it was not analyzed as NRC licensees are not transporting Type C packages (large quantities of nonfissile, radioactive material by air). Issue 5 has no graph because the NRC determined that the cost to make a definition change is negligible and included in the NRC rulemaking cost.

Figure A-13, shown on page A-8, is reproduced here and shows a tornado diagram that identifies the key variables whose uncertainty drives the largest impact on the net benefits for the combined recommended alternative—that is, the recommended alternative for each issue taken together and calculated as an aggregate. Figure A-13 ranks the variables based on their contribution to cost uncertainty.

The proposed approach to addressing Issues 1, 14, and 4 drives the most uncertainty in the expected benefits.

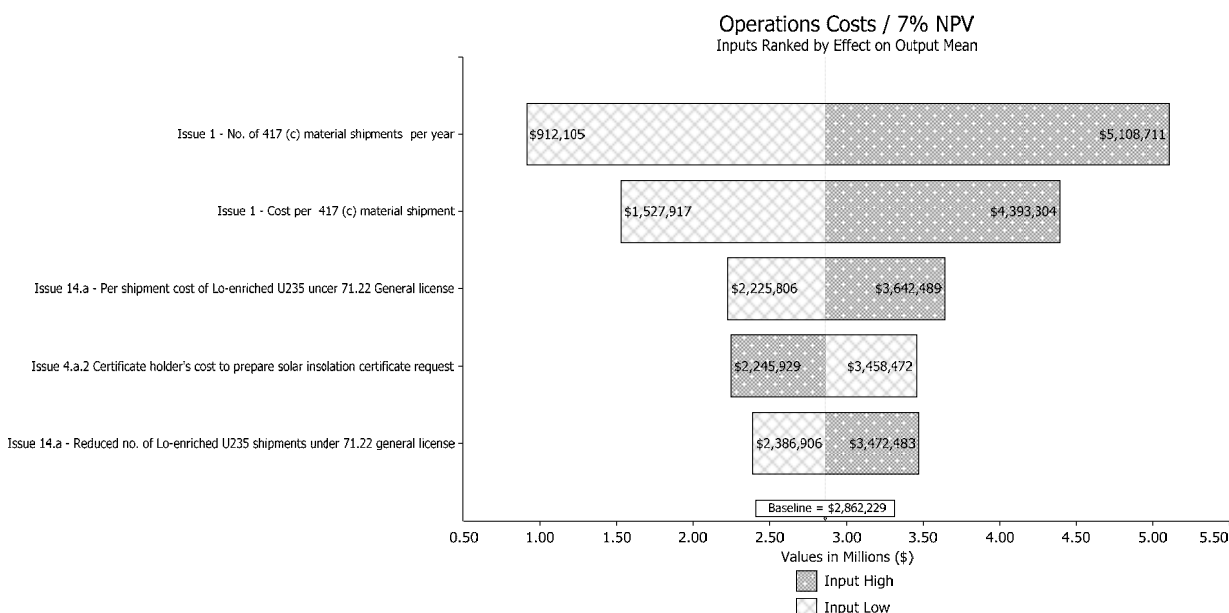


Figure A-13 Tornado Diagram of Rulemaking–7-Percent NPV

The estimate for Issue 1 has two variables that contribute to the greatest variation in the overall results. The two variables are the number of material shipments per year and the costs for these shipments. The uncertainty in the number of shipments results in a change in Issue 1 that would result in a change to the mean of \$4.20 million, the difference in averted costs that ranges between \$0.91 million to \$5.11 million with a 90-percent confidence level. The uncertainty in material shipment cost ranges could result in a change in Issue 1 that would result in a change to the mean of \$2.86 million (the difference in averted costs that ranges between \$1.53 million to \$4.39 million with a 90-percent confidence level). However, Table A-2 shows that even with these two large variable uncertainties, the minimum Issue 1 averted costs is \$712,000.

Issue 14 also has two variables that contribute to the greatest variation in the overall results. The two variables are the cost per shipment of low-enriched ²³⁵U under 10 CFR 71.22, General license: fissile material, and the number of shipments. The uncertainty in shipment costs would result in a change to the mean of \$1.41 million, the difference between \$2.23 million and \$3.64 million with a 90-percent confidence level. The uncertainty in the number of low-enriched ²³⁵U shipments would result in a change to the mean of \$1.08 million (the difference between \$2.39 million and \$3.47 million). However, Figure A-11 shows that even with these two variable uncertainties, the minimum Issue 14 averted costs is \$521,000.

The fourth variable that causes the greatest variation in the incremental costs is the Issue 4 variable for the certificate holders' cost to prepare and submit insolation certification requests. As shown in Figure A-13, this level of variation could change the mean by up to (\$1.21 million) (the difference between (\$2.25 million) and (\$3.46 million)) with a 90-percent confidence level. As shown in Figure A-3, the mean cost to implement Issue 4 is (\$1.4 million) with a minimum cost of (\$2.7 million) and a maximum cost of (\$383 thousand)

6 Other Impacts and Regulatory Considerations

This section discusses potential non-cost impacts of the proposed action, including impacts on licensees and Agreement States.

6.1 Impacts on Licensees and Certificate Holders

The NRC's recommended revisions to 10 CFR Part 71 would not impose new broad programmatic requirements on licensees and certificate holders; however, licensees and certificate holders would need to review any resulting final rule amending 10 CFR Part 71 and update their internal procedures and provide additional training to their staff, as appropriate. Some of the proposed changes may require certificate holders to submit applications for certificate amendments in order to continue using a certificate design, as evaluated in the cost model. Applicants for a new certificate would have to meet the regulations in effect at the time.

Harmonization of NRC regulations with those of the IAEA would provide greater regulatory certainty, remove multiplicity of regulations, facilitate international commerce, and reduce costs of importing and exporting radioactive material for both existing and new licensees and certificate holders.

6.2 Impacts on Agreement States

In accordance with the Commission's "Agreement State Program Policy Statement; Correction" [17], this rulemaking would provide compatibility between the radiation control programs of the NRC and the Agreement States, thereby providing consistency among the Agreement States' and the NRC transportation regulations. Implementation costs to the Agreement States would include activities for rule promulgation, public and NRC comment disposition, and codification of the rule through the State's legislative process. The rule also changes requirements that are a matter of compatibility with the Agreement States, so Agreement States would need to update their regulations, as appropriate, at which time those licensees located within Agreement States would need to meet the compatible Agreement State regulations. Agreement States would need to add requirements to their state regulations that are compatible with existing NRC regulations in 10 CFR 71.95(a), (b), (c) and (d). Once added, for reports required under 10 CFR 71.95(b), Agreement States would receive and review reports of instances in which the NRC certificate of

compliance was not following during transportation to gauge the efficacy of their licensees' QAPs. These report reviews will result in operational costs of (\$165,654).

There are no additional operational costs expected for the changes to the QAP compatibility categories since the Agreement States were already performing the review, approval, inspection and enforcement of their licensees' QAPs; the proposed rule would provide them the proper authority to carry out these regulatory functions.

During the rule development, the NRC has analyzed the proposed rule in accordance with the procedure established within Section III, "Categorization Process for NRC Program Elements," of Handbook 5.9 to Management Directive 5.9, "Adequacy and Compatibility of Program Elements for Agreement State Programs," [18] and coordinated the rulemaking, consistent with NRC policy and other guidance documents. The NRC regulations or equivalent legally binding requirements should be adopted and implemented in a timeframe such that the effective date of the Agreement State requirement for its licensees is not later than 3 years after the effective date of the NRC's final rule. Certain circumstances (e.g., adoption of a basic radiation protection standard or other rule that will have significant impact on the regulation of Agreement States on a nationwide basis) may warrant that the effective dates for both NRC licensees and Agreement State licensees be the same.

6.3 Compliance with the National Environmental Policy Act

The NRC has made an initial determination that a rulemaking to revise and align 10 CFR Part 71 with the IAEA's and the DOT's regulations would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not likely to be required. A draft environmental assessment (EA) was performed to identify and evaluate potential environmental impacts, and that draft assessment concludes that no environmental impact statement would be required. Accordingly, since there are no significant environmental impacts as evaluated in the EA, any costs for the EA are captured by NRC implementation costs, there are no additional operational costs associated with the EA for licensees, applicants for a certificate of compliance, and certificate holders.

6.4 Compliance with the Regulatory Flexibility Act

The Regulatory Flexibility Act, enacted in September 1980, requires agencies to consider the effect of their regulatory proposals on small entities, analyze alternatives that minimize effects on small entities, and make their analyses available for public comment. This proposed rule would affect NRC licensees, including operators of nuclear power plants, who transport or deliver to a carrier for transport, relatively large quantities of radioactive material in a single package; holders of a QAP issued under 10 CFR part 50, 71, or 72; and holders of a certificate of compliance for a transportation package. Except for certain QAP holders and certificate holders, these companies do not typically fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards adopted by the NRC at 10 CFR 2.810. Reviewing records of these affected entities (QAP holders and certificate holders), the NRC found that only 10 of 86 of those are small entities. Further, of these 10, the NRC expects that only 7 would be negatively affected by the proposed rule, given these companies' lines of business and day-to-day operations. For these reasons, there will not be a significant economic impact on a substantial number of small entities.

7 Cost Analysis Summary and Conclusions

Table 32 provides a summary of the results.

Table 32 Alternative 2 Summary Table by Cost Type and Impacted Organization

Issue	Description	Alternative 2 Net Benefits (Costs)–2020 dollars at 7% NPV				
		NRC	Industry (Licensee)	Industry (CoC Holder)	Agreement States	Total ^{a b}
1	Revision of Fissile Exemptions	\$3,561	\$3,674,423	\$0		\$3,677,984
2	Revision of Reduced External Pressure Test for Normal Conditions of Transport	\$0	\$0	\$0		\$0
3	Type C Package Standards	Not Analyzed	Not Analyzed	Not Analyzed		Not Analyzed
4	Revision of Insolation Requirements for Package Evaluations	(\$168,222)	\$0	(\$1,230,879)		(\$1,399,102)
5	Inclusion of Definition for Radiation Level ^c	\$0	\$0	\$0		\$0
6	Deletion of the Low Specific Activity-III Leaching Test	\$0	\$73,106	\$0		\$73,106
7	Inclusion of New Definition for Surface Contaminated Object	\$600,913	\$573,391	\$0		\$1,174,304
8	Revision of Uranium Hexafluoride Package Requirements (UF ₆ Cylinder Plugs)	(\$13,221)	\$0	(\$69,019)		(\$82,241)
9	Inclusion of Evaluation of Aging Mechanisms and a Maintenance Program	\$0	\$0	\$0		\$0
10	Revision of Transitional Arrangements	(\$746,713)	\$0	(\$1,240,161)		(\$1,986,874)
11	Inclusion of Head Space for Liquid Expansion	(\$2,003)	\$0	(\$5,734)		(\$7,737)
12	Revision of Quality Assurance Program Biennial Reporting Requirements	(\$1,926)	\$0	(\$28,649)		(\$30,575)
13	Deletion of Type A Package Limitations in Fissile Material General Licenses	\$7,094	\$16,137	\$0		\$23,231
14	Deletion of ²³³ U Restriction in Fissile General License	\$0	\$1,592,368	\$0		\$1,592,368
15	Other Recommended Changes to 10 CFR Part 71.95	\$0	\$0	\$0	(\$165,654)	(\$165,654)
Operation Costs (By Issue)		(\$320,517)	\$5,929,424	(\$2,574,442)	(\$165,654)	\$2,868,811
Non-Issue Specific Benefits (Costs)						
NRC Rulemaking Implementation		(\$1,169,291)	\$0	\$0	\$0	(\$1,169,291)
Agreement States Implementation Costs		\$0	\$0	\$0	(\$2,242,429)	(\$2,242,429)
Total Benefit (Cost)		(\$1,489,808)	\$5,929,424	(\$2,574,442)	(\$2,408,083)	(\$542,909)

^a NPV = net present value

^b Averted cost = positive, normal cost is (negative)

^c Issue 5 costs to change the definition for radiation level are included in the rulemaking estimate in NRC implementation costs.

Based on this evaluation, the NRC has reached the following conclusions:

Alternative 1 maintains the status quo, results in no new direct costs or benefits to the NRC or the licensees but does not achieve the stated regulatory objective.

Alternative 2 achieves the following benefits.

1. The rulemaking option for Issues 1, 4 through 15, in combination with the no-action alternative (Alternative 1) for Issues 2 and 3, would address and resolve all of the regulatory issues of concern and accomplish the goals of the harmonization initiative:
 - Resolution of Issues 1, 4, 6, 7, 8, 9, 10, 11, and 15 (in part) by a rulemaking action would harmonize the NRC's existing regulations with the current IAEA standards in SSR-6, 2018 Edition.
 - Resolution of Issues 6, 7, 10, 11, and 15 (in part) by a rulemaking action would maintain compatibility between the NRC's regulations in 10 CFR Part 71 and DOT's regulations in 49 CFR Parts 107 and 171-180.
 - Resolution of Issues 12, 13, 14, and 15 (in part) by a rulemaking action would improve 10 CFR Part 71 implementation.
2. The rulemaking option would reduce the regulatory burden on licensees and certificate holders by maintaining consistency between NRC and DOT regulations and compatibility with IAEA standards, and thereby eliminating conflicting requirements.
3. The rulemaking option is consistent with the NRC's response to earlier revisions and updates of the international standards by the IAEA. Rulemaking represents the least costly viable option and would result in savings to the industry.

The analysis shows that Alternative 2 recommended by the NRC staff would result in a total net incremental cost of (\$542,909). The estimate has the following quantified costs and benefits for licensees, certificate of compliance (CoC) holders, Agreement States, and the NRC:

- The licensees would save an estimated \$5,929,424.
- The CoC holders would incur a cost of (\$2,574,442).
- The NRC would incur a net cost of (\$1,489,808), which includes the rulemaking development and implementation costs of (\$1,169,291) and operational costs of (\$320,517).
- Agreement States would incur a net cost of (\$2,408,083) to implement the rule and revise procedures. This estimate includes the implementation cost of the rule by the Agreement States of (\$2,242,429). The rulemaking action would also result in marginal operational cost of (\$165,654) to the Agreement States.
- The rulemaking represents the best option that can address all the issues and could result in net savings of \$3,354,982 in averted costs to the industry licensees and CoC holders. Furthermore, the proposed rule is expected to have important qualitative benefits, including harmonization of the NRC regulations in 10 CFR Part 71 with the IAEA's safety standards, which minimizes potential international commerce disruption and helps to ensure that international obligations are met (e.g., for air transport, the IAEA transport standards serve as the basis for the International Civil Aviation Organization Technical Instructions, as they relate to radioactive material, with which the U.S. must comply according to the Convention on International Civil Aviation - also known as the Chicago Convention) and assurance that the NRC's regulations continue to be consistent with the DOT regulations for the domestic transportation of radioactive materials. For these reasons, the qualitative benefits of the rule outweigh its costs.

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Appendix A - Cost Uncertainty Analysis

Uncertainty Analysis Approach

The probability distributions chosen to represent the different variables in the analysis were bounded by the range-referenced input and the 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. The staff used the PERT distribution to reflect the relative spread and skewness of the distribution defined by the minimum, most likely, and maximum. The input variables used in the uncertainty analysis are provided in Table A-1, which is located at the end of this appendix.

Uncertainty Analysis Results

Figures A-1 through A-12 display the key statistical results, including the 90-percent confidence interval in which the net benefits would fall between the 5-percent and 95-percent percentile values. The 5-percent and 95-percent values (in other words, the bands marked "5.0%" on either side of the 90.0-percent confidence interval) that appear as numerical values on the top of the vertical lines of the uncertainty figures provided are shown in the next section.

Figures A-1 through A-12 show the probability density functions of the incremental net benefit for different issues and alternatives. All graphs are shown based on 7-percent NPV calculations. Figure A-13 shows a tornado diagram that identifies the key variables whose uncertainty drives the largest impact on net benefits for this recommended alternative. Figure A-13 ranks the variables based on their contribution to cost uncertainty.

Issue 2 has no graph because there are no costs or benefits. Issue 3 has no graph because it was not analyzed because of a lack of need by the licensees and Issue 5 has no graph because the costs for making this definition change in the regulations are included in the NRC implementation costs.

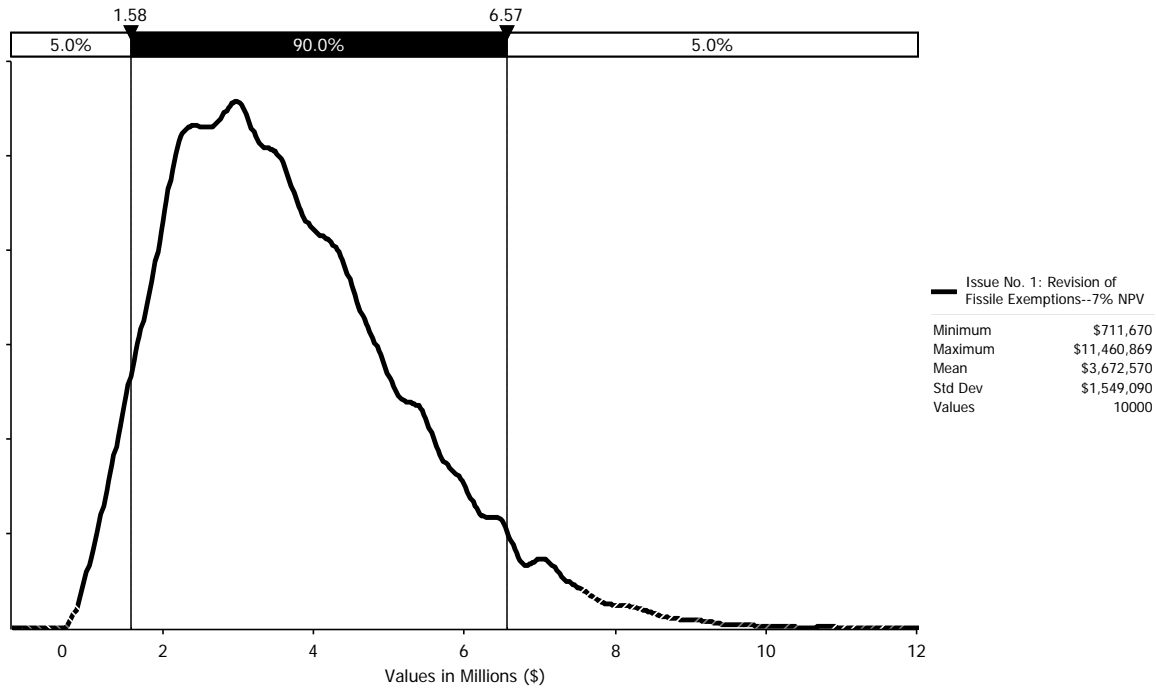


Figure A-1 Issue 1—Revision of Fissile Exemptions—7-Percent NPV

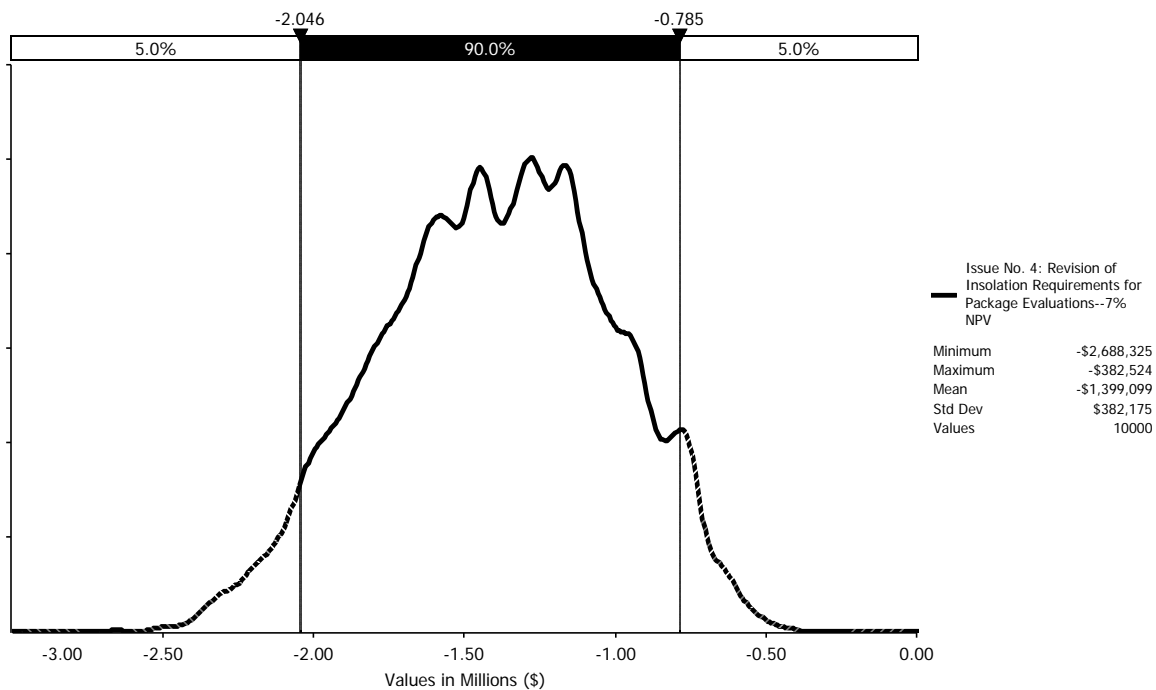


Figure A-2 Issue 4—Revision of Insolation Requirements for Package Evaluations—7-Percent NPV

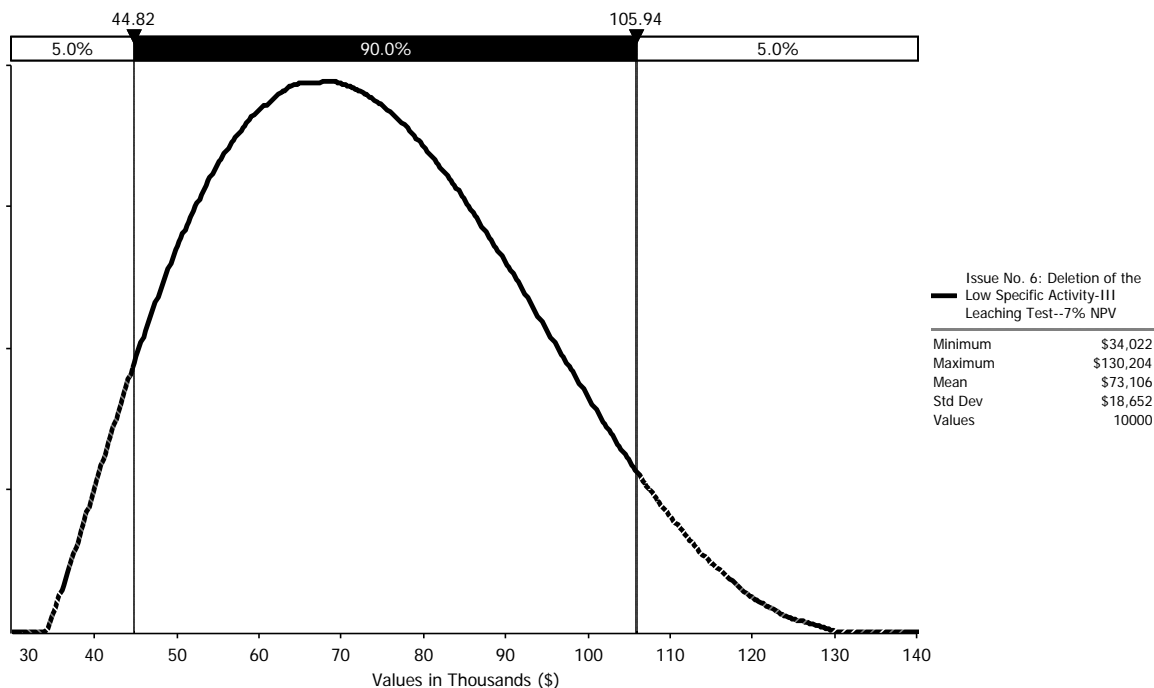


Figure A-3 Issue 6—Deletion of the Low Specific Activity-III Leaching Test—7-Percent NPV

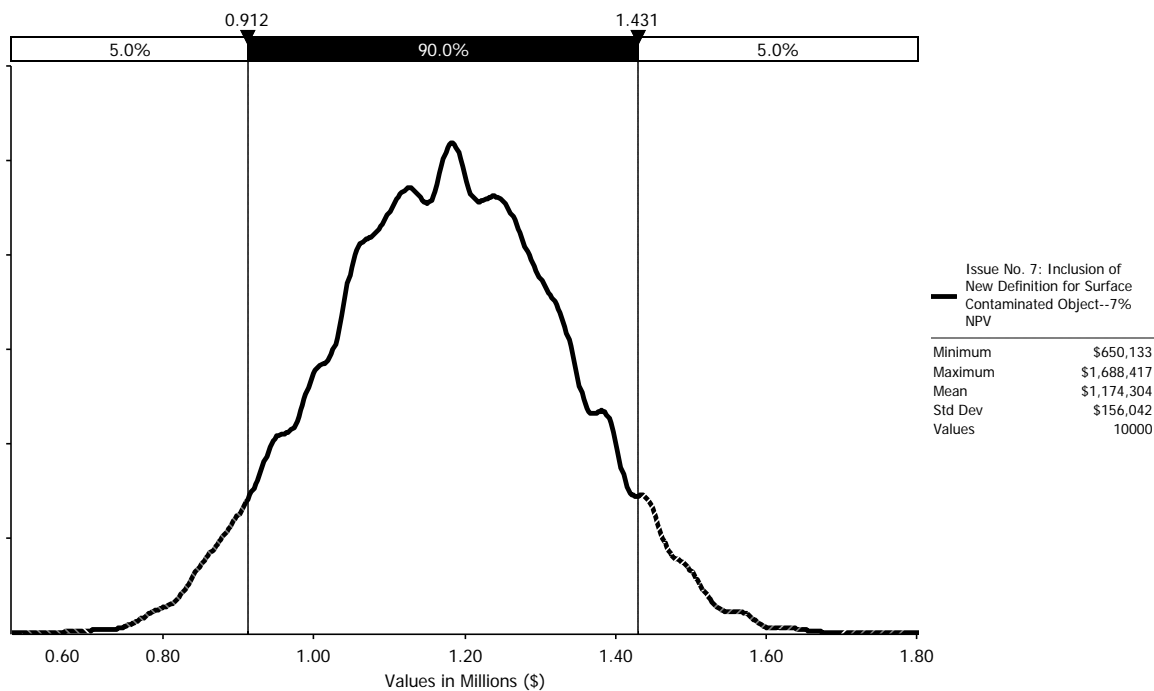


Figure A-4 Issue 7—Inclusion of New Definition for Surface Contaminated Object (SCO-III)—7-Percent NPV

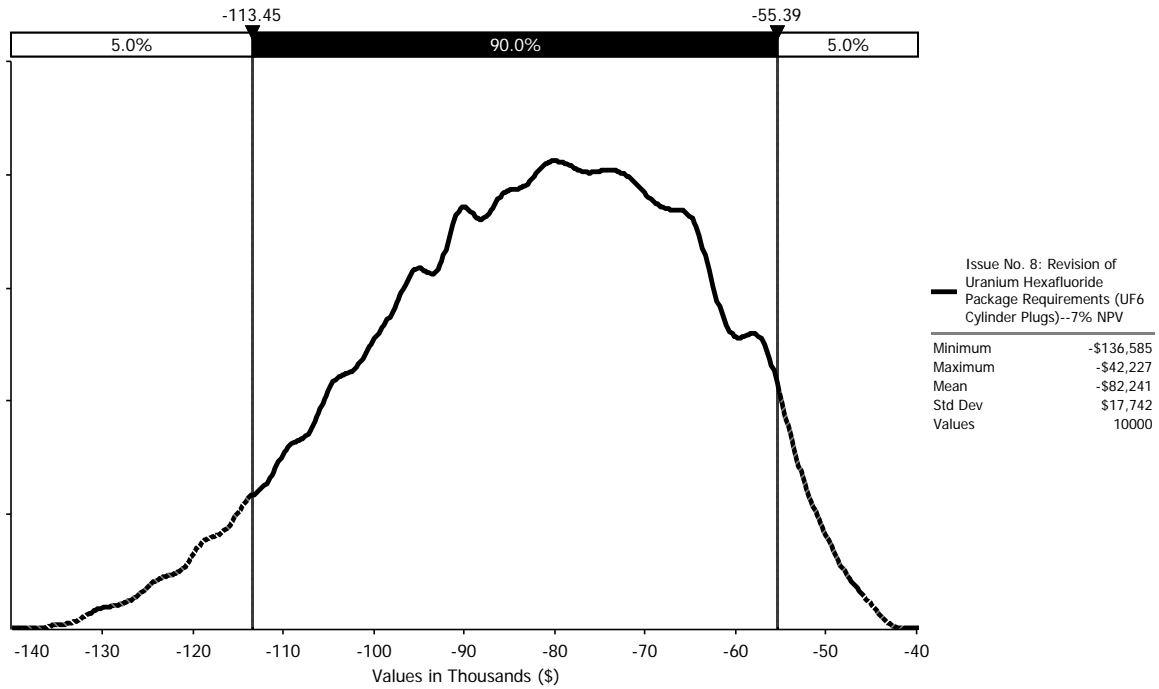


Figure A-5 Issue 8—Revision of Uranium Hexafluoride Package Requirements (UF₆ Cylinder Plugs)—7-Percent NPV

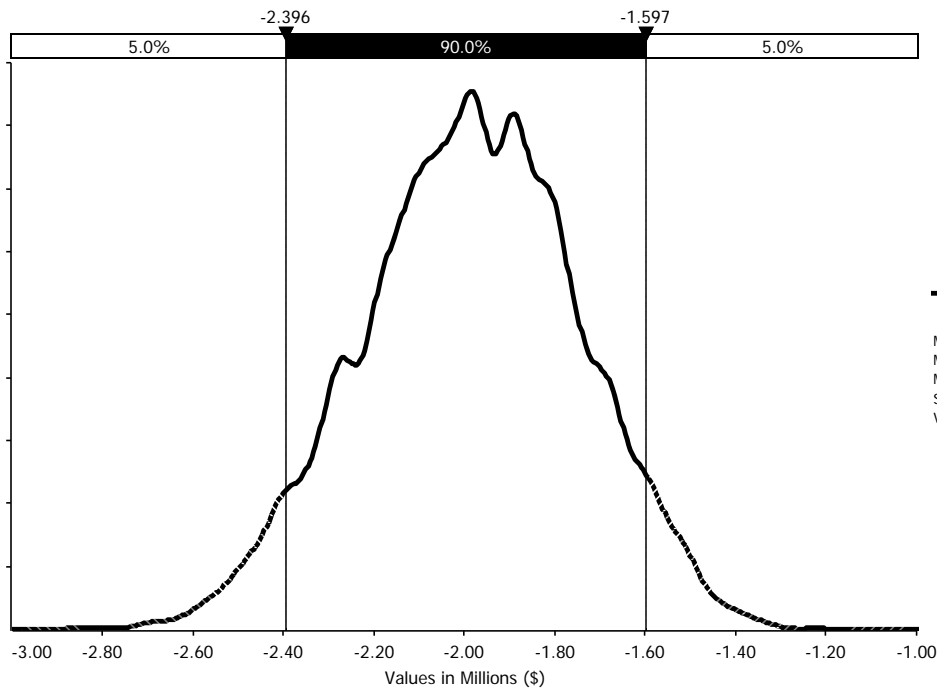


Figure A-6 Issue 10—Revision of Transitional Arrangements—7-Percent NPV

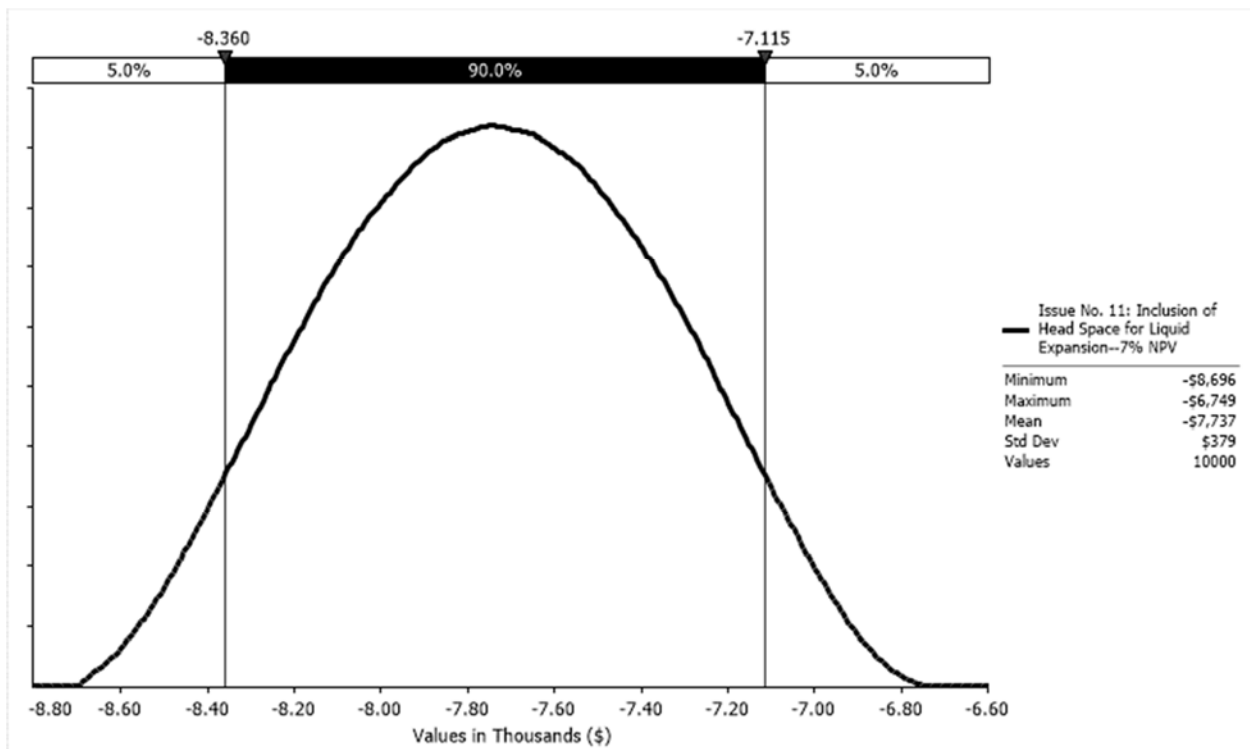


Figure A-7 Issue 11—Inclusion of Head Space for Liquid Expansion—7-Percent NPV

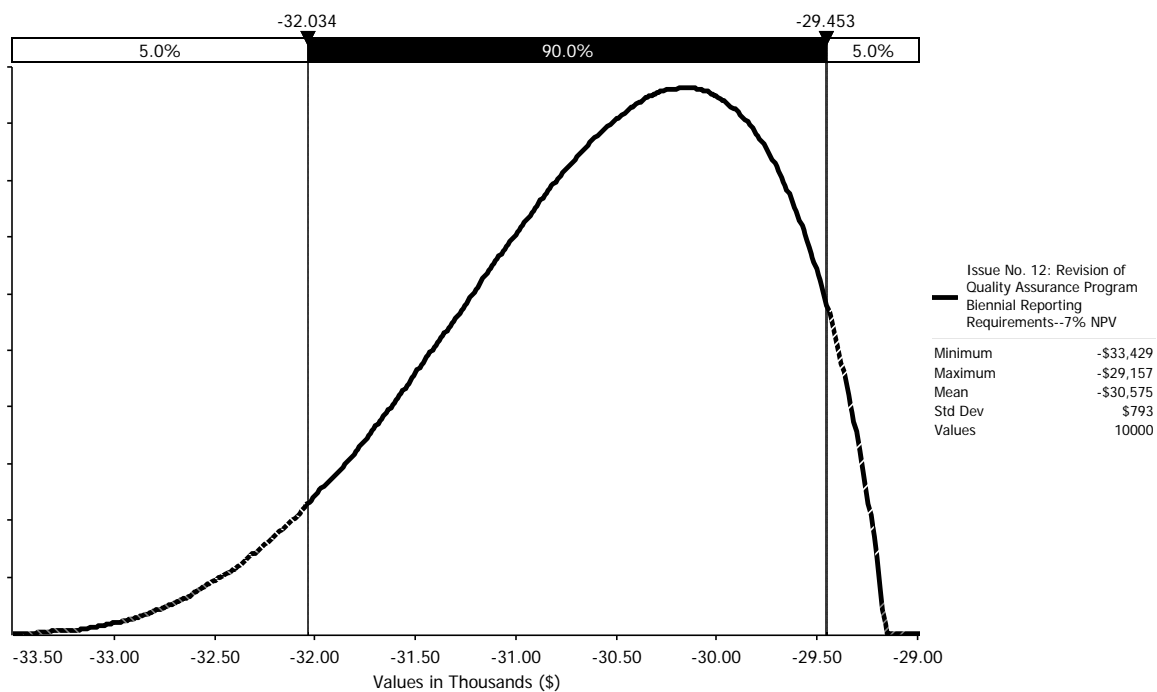


Figure A-8 Issue 12—Revision of Quality Assurance Program Biennial Reporting Requirements—7-Percent NPV

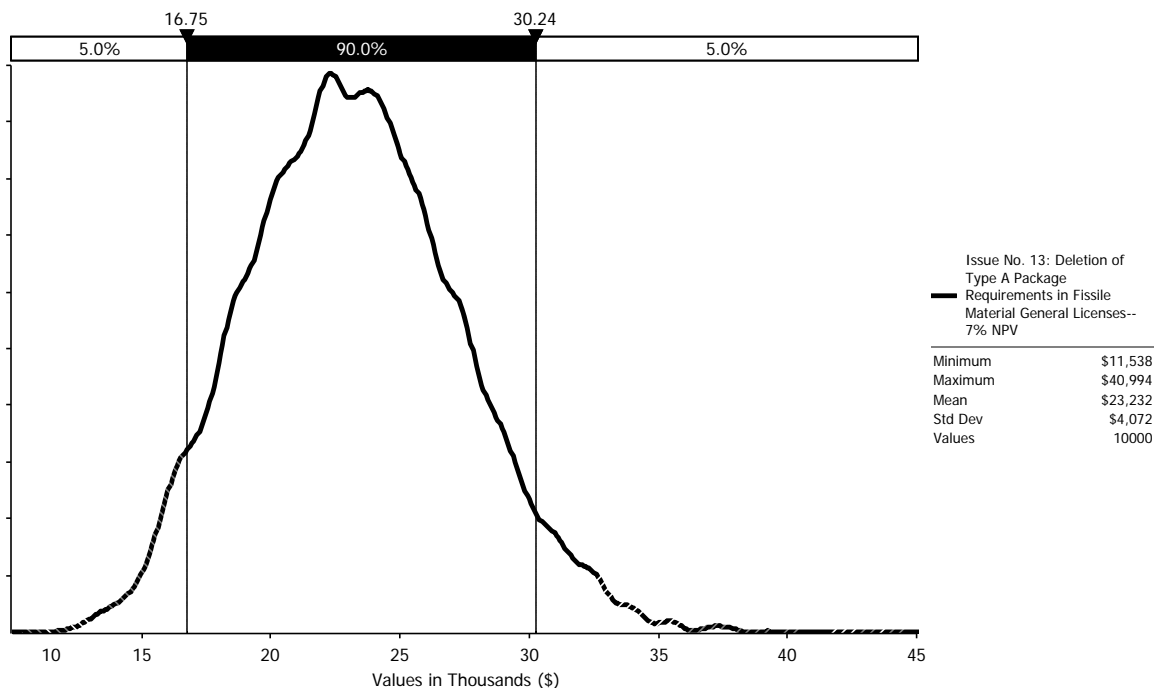


Figure A-9 Issue 13—Deletion of Type A Package Limitations in Fissile Material General Licenses—7-Percent NPV

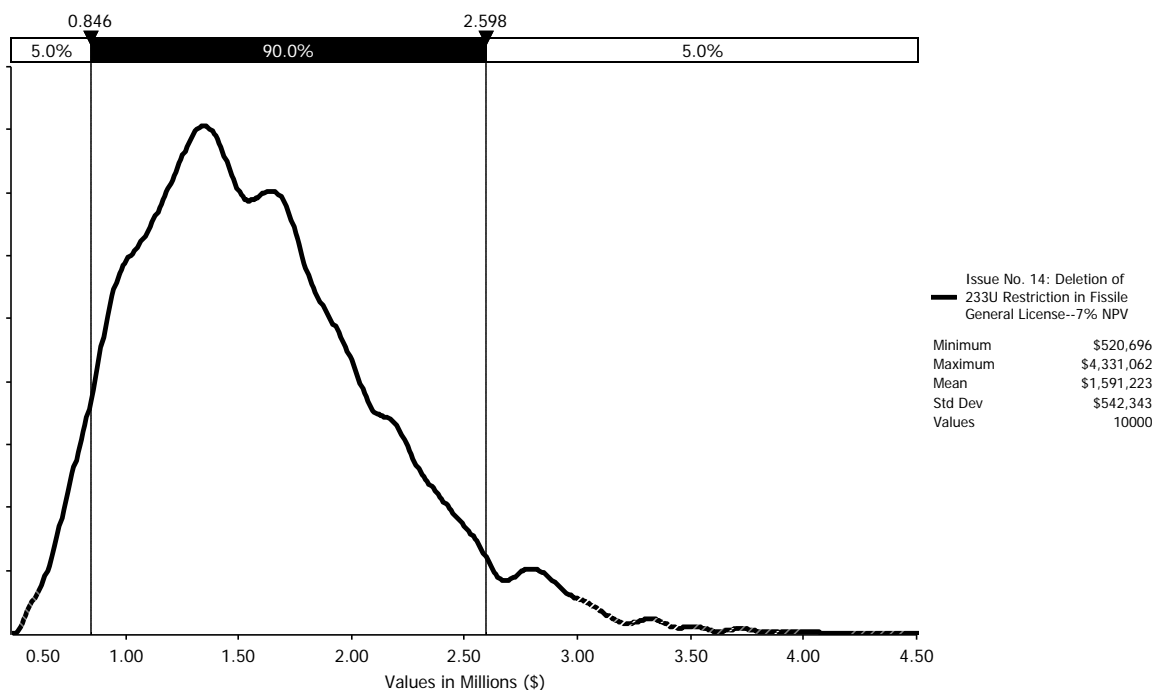


Figure A-10 Issue 14—Deletion of ²³³U Restriction in Fissile General License—7-Percent NPV

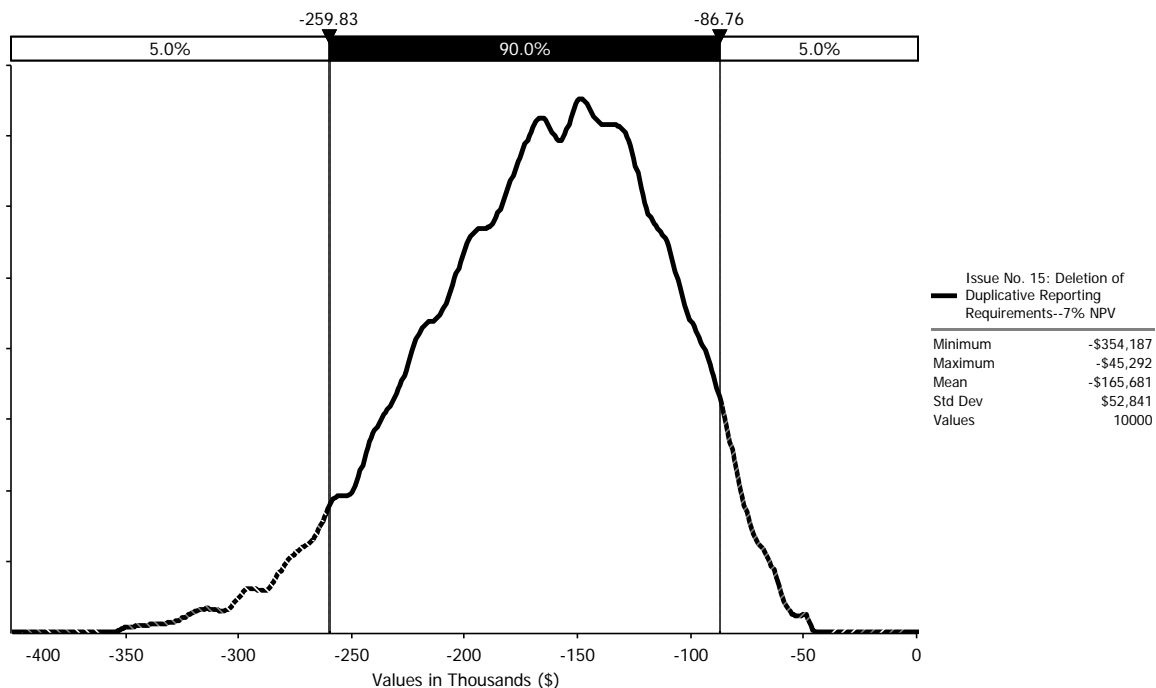


Figure A-11 Issue 15—Deletion of Duplicative Reporting Requirements—7-Percent NPV

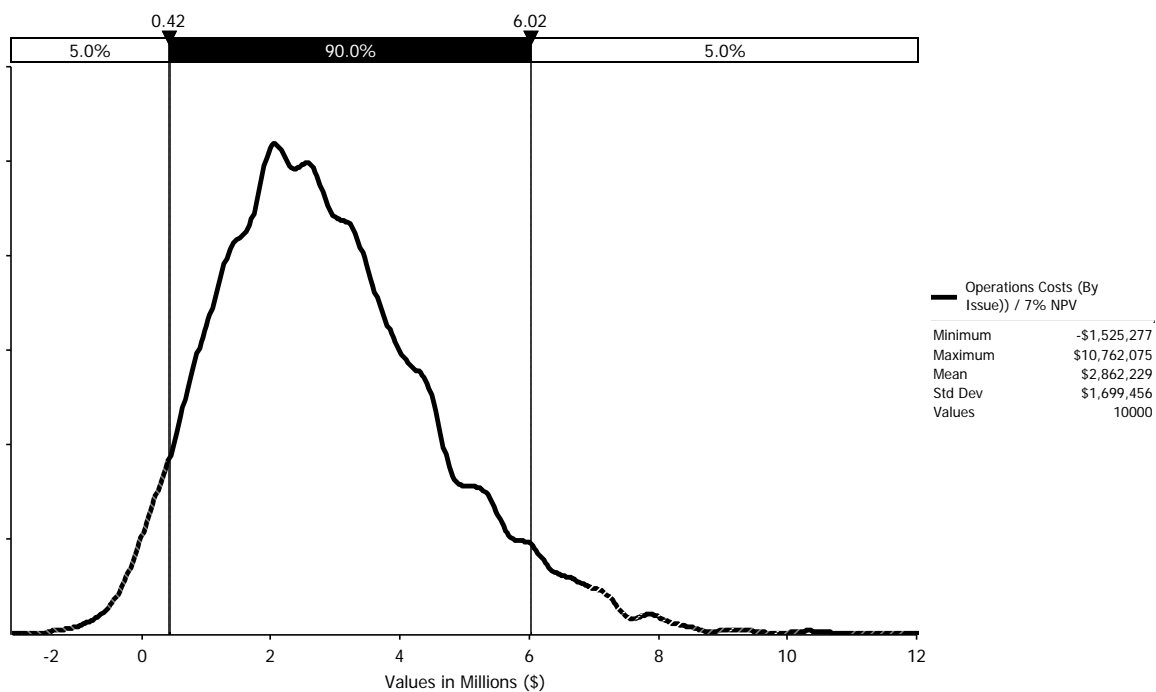


Figure A-12 Net Benefit—7-Percent NPV

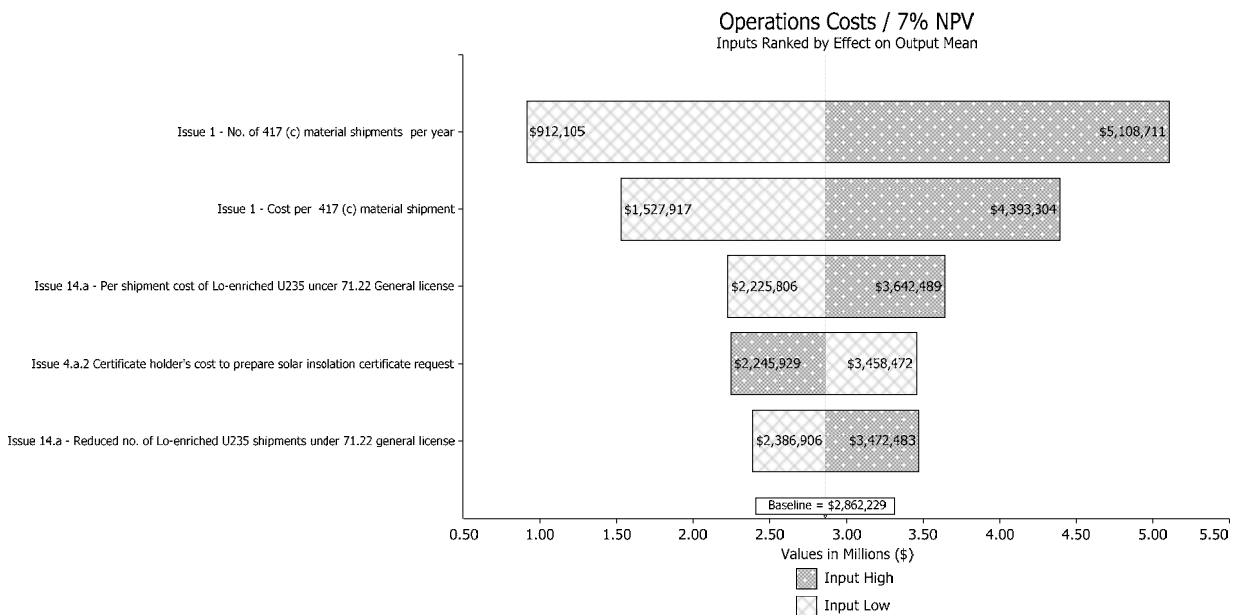


Figure A-13 Tornado Diagram of Rulemaking–7-Percent NPV

Figure A-13 shows a tornado diagram that identifies the key variables whose uncertainty drives the largest impact on net benefits for this recommended alternative. Figure A-13 ranks the variables based on their contribution to cost uncertainty.

As shown in Figure A-13, the estimate for Issue 1 has two variables that contribute to the greatest variation in the overall results. The two variables are the number of material shipments per year and the costs for these shipments. The uncertainty in the number of shipments results in a change in Issue 1 that would result in a change to the mean of \$4.2 million, the difference in averted costs that ranges between \$0.91 million to \$5.11 million with a 90-percent confidence level. The uncertainty in material shipment cost ranges could result in a change in Issue 1 that would result in a change to the mean of \$2.86 million (the difference in averted costs that ranges between \$1.53 million to \$4.39 million with a 90-percent confidence level. However, Table A-1 shows that even with these two large variable uncertainties, the minimum Issue 1 averted costs is \$712,000.

Issue 14 also has two variables that contribute to the greatest variation in the overall results. The two variables are the cost per shipment of low-enriched ²³⁵U under 10 CFR 71.22, General license: fissile material, and the number of shipments. The uncertainty in shipment costs would result in a change to the mean of \$1.41 million, the difference between \$2.23 million and \$3.64 million with a 90-percent confidence level. The uncertainty in the number of low-enriched ²³⁵U shipments would result in a change to the mean of \$1.08 million (the difference between \$2.39 million and \$3.47 million). However, Figure A-10 shows that even with these two variable uncertainties, the minimum Issue 14 averted costs is \$521,000.

The next variable that causes the greatest variation in the incremental costs is the Issue 4 variable for the certificate holders' cost to prepare and submit insolation certification requests. As shown in Figure A-13, this level of variation could change the mean by up to \$1.21 million (the difference between \$2.25 million and \$3.46 million) with a 90-percent confidence level. As shown in Figure A-2, the mean cost to implement Issue 4 is (\$1.4 million) with a minimum cost of (\$2.69 million) and a maximum cost of (\$383 thousand).

Figures A-1 through A-12 present descriptive statistics on the uncertainty analysis. The 5-percent and 95-percent values (i.e., the bands marked 5.0 percent on either side of the 90-percent confidence interval) that appear as numerical values on the top of the vertical lines are shown in the figures in this appendix and provided in Figures A-1 through A-12.

Table A-1 Uncertainty Analysis Input Variables

Description	Mean Estimate	Distribution	Low Estimate	Best Estimate	High Estimate
Alternative 2 - Proposed Rulemaking option					
Issue No. 1: Revision of Fissile Exemptions					
<i>Issue No. 1a: New Fissile Exceptions in IAEA SSR-6, Paragraph 417</i>					
1.a.1.: 417(c) – Uranium with enrichment up to 5.0 weight percent ²³⁵ U, up to 3.5 grams ²³⁵ U per package					
Number of affected fissile material licensees shipping under this exemption	20			20	
# of shipments of 417(c) material per year	23	PERT	5	20	50
Cost per shipment of 417(c) material	\$1,083	PERT	\$500	\$1,000	\$2,000
# of years	11			11	
NRC review and respond to certificate revisions					
NRC review of number of affected fissile material licensees to be revised to current (2018) IAEA regs	0			0	
NRC review (# Hours) for affected fissile material licensees	0	PERT	0	0	0
1.a.2.: 417(d) – up to 2.0 grams fissile nuclides (²³³ U, ²³⁵ U, ²³⁹ Pu, or ²⁴¹ Pu) per package, with up to 15 grams fissile nuclides per consignment	0			0	
1.a.3.a.: <i>For Certificate Holders - Para 417(e) – up to 140 grams fissile nuclides, shipped exclusive use</i>					
Average # of exemptions per year	0.09			0.0909	
Certificate Holder's Averted (Hours) to perform criticality safety evaluation	86.67	PERT	40	80	160
Certificate Holder's Hourly Cost	\$203	PERT	\$180	\$200	\$240
# of years	11			11	
NRC review and respond to certificate revisions					
NRC review of submitted CoC exemptions per year	0.09			0.0909	
NRC review Hours to review affected fissile material submittals	43	PERT	16	40	80
1.a.3.b.: 417(e) – Up to 140 grams fissile nuclides, shipped exclusive use					
Number of affected fissile material licensees shipping under this exemption	30			30	
# of shipments of 417(e) material	11	PERT	5	10	20
Cost savings per shipment of 417(e) material	108	PERT	\$50	\$100	\$200
# of years	11			11	
NRC review and respond to number of affected fissile material licensees to be revised to current (2018) IAEA regs					
NRC review of Number of affected fissile material licensees to be revised to current (2018) IAEA regs	0			0	
NRC review (# Hours) for affected fissile material licensees to be revised	0			0	
<i>Issue No. 1b: Competent Authority-Approved Fissile Exception, SSR-6 Paragraph 417(f)</i>	0			0	
<i>Issue No. 1c: CSI-Controlled Fissile Material Packages, SSR-6 Paragraph 674</i>	0			0	
<i>Issue No. 1d: Plutonium Shipments in Type A Packages, SSR-6 Paragraph 675</i>	0			0	
Issue No. 2: Revision of Reduced External Pressure Test for Normal Conditions of Transport					
2.a. Licensee preparation of certificate revisions					

Description	Mean Estimate	Distribution	Low Estimate	Best Estimate	High Estimate
No. of affected certificates of compliance to be revised	0			0	
Certificate holder's cost to prepare and submit certification request	(\$20,000)			(\$20,000)	
2.a. NRC review and respond to certificate revisions					
NRC review of number of affected fissile material licensees to be revised to current (2018) IAEA regs	0.00			0.00	
NRC review applications for revising certificates (Hours)	63.67	PERT	40.00	60.00	102.00
2.b. Licensee preparation of certificate revisions					
# Change actions to adopt reduced external pressure requirements	0			0	
Licensee's cost to assess the impact of the proposed change	(\$20,000)			(\$20,000)	
2.b. NRC review and respond to certificate revisions					
NRC review of # Change Actions to Adopt Reduced External Pressure Requirements	0			0	
NRC Review (Hours) Change Actions to Adopt Reduced External Pressure Requirements	63.7	PERT	40.00	60.00	102.00
Issue No. 3: Type C Package Standards NOT ANALYZED					
3. Licensee preparation of revised certificates					
3. Licensee preparation of certificate revisions					
Number of certificates to be revised to current (2018) IAEA regs	0			0	
Certificate holder's cost to prepare and submit certification request	\$20,000			\$20,000	
3. NRC review and respond to certificate revisions					
NRC review of # of certificates to be revised to current (2018) IAEA regs	0.00			0.00	
NRC review applications for revising certificates (Hours)	63.33	PERT	40.00	60.00	100.00
Issue No. 4: Revision of Insolation Requirements for Package Evaluations					
Issue No. 4a – Insolation for Normal Conditions of Transport					
4.a.1. Revise Solar Insolation for Normal Conditions of Transport for revised Certificates					
Number of certificates to be revised to current (2018) IAEA regs per year (years 2022 to 2025)	7.5			7.5	
Number of certificates to be revised to current (2018) IAEA regs per year (years 2026 to 2032)	4.0			4	
Certificate holder's cost to prepare and submit certification request	\$8,667	PERT	\$2,000	\$7,500	\$20,000
# of years	11			11	
4.a.1. NRC review and respond to certificate revisions					
NRC review of # of certificates to be revised to current (2018) IAEA regs per year (years 2022 to 2025)	7.5			7.5	
NRC review of # of certificates to be revised to current (2018) IAEA regs per year (years 2026 to 2032)	4.0			4	
NRC review applications for revising certificates (Hours)	14.83	PERT	5.00	15.00	24.00
4.a.2. Licensee preparation of new certificates					
Number of new certificates to be approved to current (2018) IAEA regs	1			1	
Certificate holder's cost to prepare and submit certification request	\$1,083	PERT	\$500	\$1,000	\$2,000
Number of years to next rule change to adopt next version of IAEA regs	11			11	
4.a.2. NRC review and respond to new certificate					
NRC review of # of certificates to be revised to current (2018) IAEA regs per year	1			1	
NRC review applications for revising certificates (Hours)	5.5	PERT	3	5	10

Description	Mean Estimate	Distribution	Low Estimate	Best Estimate	High Estimate
Issue No. 4b – Insolation for Hypothetical Accident Conditions					
4.b.1. Revise Hypothetical Accident Conditions input to include insolation					
Number of certificates to be revised to current (2018) IAEA regs (years 2022 to 2025)	7.5			7.5	
Number of certificates to be revised to current (2018) IAEA regs (years 2026 to 2032)	4.0			4	
Certificate holder's cost to prepare and submit certification request	\$21,833	PERT	\$1,000	\$20,000	\$50,000
4.b.1. NRC review and respond to certificate revisions					
NRC review of # of certificates to be revised to current (2018) IAEA regs (years 2022 to 2025)	7.5			7.5	
NRC review of # of certificates to be revised to current (2018) IAEA regs (years 2026 to 2032)	4.0			4	
NRC review applications for revising certificates (Hours)	15	PERT	5	15	24
4.b.2. Licensee preparation of revised certificates					
Number of new certificates to be approved to current (2018) IAEA regs	1			1	
Certificate holder's cost to prepare and submit certification request	\$6,500	PERT	\$1,000	\$2,000	\$30,000
Number of years to next rule change to adopt next version of IAEA regs	10			10	
4.b.2. NRC review and respond to certificate revisions					
NRC review of # of certificates to be revised to current (2018) IAEA regs per year	1			1	
NRC review applications for revising certificates (Hours)	12	PERT	3	10	30
Issue No. 5: Inclusion of Definition for Radiation Level					
5.a. Licensee costs					
Number of certificates revised to 2018 IAEA regs	0			0	
Licensee cost of preparation of revised applications	\$2,750	PERT	\$1,000	\$2,000	\$7,500
5.a. NRC review and respond to certificate revisions					
Number of revised certificates	5.3			5.25	
NRC review applications for revising certificates (Hours)	0			0	
5.b. Licensee costs					
Number of nuclear power facilities	0			0	
NPP licensee cost to revise facility documentation	(\$15,000)			(\$15,000)	
5.b. NRC review and respond to certificate revisions					
Number of NPP licensees' revised facility documentation	60.0			60	
NRC review NPP licensees' revised facility documentation (Hours)	0			0	
Issue No. 6: Deletion of the Low Specific Activity-III Leaching Test					
6.a. Licensee preparation to assess impact of Deletion of the Low Specific Activity-III Leaching Test					
Number of Low Specific Activity-III Leaching Test	0.45			0.45	
Licensee's cost for deletion of the Low Specific Activity-III Leaching Test	\$21,667	PERT	\$10,000	\$20,000	\$40,000
6.a. NRC Reserved					
6.b. Licensee Reserved					
6.b. NRC staff needs to consider this issue with respect to the review/revision of NUREG-1608 (Hours)	271	PERT	125.00	250.00	500.00
Issue No. 7: Inclusion of New Definition for Surface Contaminated Object					
7.a Licensee assessment of material to qualify as SCO-III					
Number of decommissioned power plants that may apply this new definition	1.6			1.64	

Description	Mean Estimate	Distribution	Low Estimate	Best Estimate	High Estimate
Number of hours for the SCO-III assessment	0			0.00	
Licensee cost to prepare application for consideration of 10CFR 71.41(d)	\$50,000	PERT	\$25,000	\$50,000	\$75,000
7.a NRC harmonizes with DOT regulation changes					
Number of decommissioned power plants that may apply this new definition if DOT	1.6			1.64	
NRC staff hours to review and issue each licensee exemption request 10 CFR 71.41 (based on DOT's decision)	400	PERT	200	400	600
Issue No. 8: Revision of Uranium Hexafluoride Package Requirements (UF ₆ Cylinder Plugs)					
8.a. Licensee preparation of revised certificates					
Number of certificates to be revised to current (2018) IAEA regs	0.09			0.0909	
Certificate holder's cost to drop UF ₆ package, prepare and submit certification request for revised CoC	\$108,333	PERT	\$50,000	\$100,000	\$200,000
8.a. NRC review and respond to certificate revisions					
NRC review of # of certificates to be revised to current (2018) IAEA regs	0.0909			0.0909	
NRC review application for revising certificate (hours)	158.42	PERT	100.00	150.00	250.50
8.b. Licensee preparation of new certificates					
Number of new or amended certificates	0			0	
Certificate holder's cost for additional drop for UF ₆ package plug, prepare and submit certification request for new CoC	\$11,999	PERT	\$6,993	\$10,000	\$25,000
8.b. NRC review and respond to new certificates					
NRC review of # of new or amended certificates	0			0	
NRC review application for revising certificate (Hours)	81.67	PERT	40	50	250
Issue No. 9: Inclusion of Evaluation of Aging Mechanisms and a Maintenance Program					
9.a. Licensee preparation of revised certificates					
Number of certificates to be revised to current (2018) IAEA regs (years 2022 to 2025)	7.5			7.5	
Number of certificates to be revised to current (2018) IAEA regs (years 2026 to 2032)	4.0			4	
Certificate holder's cost to prepare and submit certification request	\$0			\$0	
9.a. NRC review and respond to certificate revisions					
NRC review of applications for revising certificates to current (2018) IAEA regs (years 2022 to 2025)	7.5			7.5	
NRC review of applications for revising certificates to current (2018) IAEA regs (years 2026 to 2032)	4.0			4	
NRC review applications for revising certificates (hours)	0			0	
Issue No. 10: Revision of Transitional Arrangements					
10.a. Licensee preparation of revised certificates					
Number of certificates to be revised to current (2018) IAEA regs (years 2022 to 2025)	7.5			7.5	
Number of certificates to be revised to current (2018) IAEA regs (years 2026 to 2032)	4			4	
Certificate holder's cost to prepare and submit certification request	\$20,000	PERT	\$10,000	\$20,000	\$30,000
10.a. NRC review and respond to certificate revisions					
NRC review of # of certificates to be revised to current (2018) IAEA regs (years 2022 to 2025)	7.5			7.5	
NRC review of # of certificates to be revised to current (2018) IAEA regs (years 2026 to 2032)	4.0			4	
NRC review of licensee reports requesting certificate revisions (hours)	130.00	PERT	60.00	120.00	240.00

Description	Mean Estimate	Distribution	Low Estimate	Best Estimate	High Estimate
10.b. Licensee design, testing/analysis, and preparation of application for new package design					
Number of certificates to be revised to current (2018) IAEA regs (years 2022 to 2026)	0.20			0.20	
Certificate holder's cost to prepare and submit certification request	\$597,500	PERT	\$385,000	\$575,000	\$900,000
10.b. NRC cost to review new package design					
NRC review of # of certificates to be revised to current (2018) IAEA regs (years 2027 to 2029)	0.33			0.33	
NRC review of licensee reports requesting certificate revisions (Hours)	1,056	PERT	229	573	3,817
Issue No. 11: Inclusion of Head Space for Liquid Expansion					
11.a. Licensee preparation of revised certificates					
Number of certificates to be revised to current (2018) IAEA regs	0.55			0.55	
Certificate holder's cost to prepare and submit certification request	(\$1,500)			(\$1,500)	
11.a. NRC Implementation Cost					
NRC review of # of certificates to be revised to current (2018) IAEA regs	0.55			0.55	
NRC time to perform the review of licensee application (hours)	4	PERT	2	4	6
Issue No. 12: Revision of Quality Assurance Program Biennial Reporting Requirements					
12.a. Licensee biennial (every 2 years) change report implementation evaluation.					
Number of licensees to evaluate QA program clarification (one-time occurrence)	(41)			(41)	
Licensee/certificate holders (hours) to reconcile change to current QAP	10			10	
Licensee/certificate holders (cost/hour) to reconcile change to current QAP	\$80			\$80	
12.a. NRC implementation review of biennial QAP report					
NRC review of # of licensee's implementation for QA program clarification (one-time cost)	0.00			0.00	
NRC review of licensee's implementation for QA program clarification (hours)	0.00	PERT		0	
12.b. Licensee biennial (every 2 years) change report submittal					
Number of licensees to submit QA program biennial report (every two-years)	4		1	3	10
Licensee/certificate holders (hours) to develop and submit biennial report	(1)			(1)	
Licensee/certificate holders (cost per hour) to develop and submit biennial report	\$80			\$80	
12.b. NRC review of biennial QAP report					
NRC review of # of licensee's biennial report submittals (every 2 years)	4		1	3	10
NRC review of biennial QAP report (hours)	(1)			(1)	
Issue No. 13: Deletion of Type A Package Limitations in Fissile Material General Licenses					
13.a. Licensee averted costs of criticality evaluation in preparation of new or amended certificates					
Number of affected certificate holders to adopt 10 CFR 71.22 limit for Pu	0.18			0.18	
Certificate holder hourly cost	\$203	PERT	\$180	\$200	\$240
# of hours to prepare criticality safety evaluation for up to 37g Pu	43	PERT	20	40	80
13.a. NRC averted costs of review of criticality evaluation in new or amended certificates					
NRC review of # of affected certificate holders to adopt 10 CFR 71.22 limit for Pu	0.18			0.18	
NRC review of criticality evaluation for new or amended certificates (hours)	43	PERT	15	40	80

Description	Mean Estimate	Distribution	Low Estimate	Best Estimate	High Estimate
13.b. Licensee averted costs of shipping in Type B versus Type BF					
Affected shipments of fissile material under 10 CFR 71.22 General License	3	PERT	1	3	5.0
Cost of shipping B versus BF	\$233	PERT	\$100	\$200	\$500
# of licensees	1			1	
# of years	10			10	
13.b. NRC review and respond to certificate revisions					
NRC cost to review # of Affected shipments of fissile material under 10 CFR 71.22 General License	\$87	PERT	\$40	\$80	\$160
NRC review applications for changing rule (hours)	0.00			0.00	
Issue No. 14: Deletion of ²³³ U Restriction in Fissile General License					
14.a. Licensee averted shipments to be able to ship more ²³⁵ U under 10 CFR 71.22 – General License: Fissile Material					
# of affected fissile material licensees	11			11	
# of shipments of Lo-enriched ²³⁵ U under 10 CFR 71.22 General License	11	PERT	7	10	20
Cost per shipments of Lo-enriched ²³⁵ U under 10 CFR 71.22 General License	\$1,850	PERT	\$800	\$1,700	\$3,500
# of years	11.00			11.00	
14.a. NRC review and respond to rule change					
NRC review of # of exemptions	0.1			0.1	
NRC review licensee exemption requests (hours)	0.0			0	
Issue No. 15: Other Recommended Changes to 10 CFR 71.95					
15.a. Licensee Other Proposed Changes to 10 CFR Part 71					
# of affected fissile material licensees	0			0	
15.a. NRC Other Proposed Changes to 10 CFR Part 71					
NRC review of # of exemptions	0.0			0.0	
15.d. Agreement State Other Proposed Changes to 10 CFR Part 71 [10 CFR 71.95]					
# of Agreement States	(39)			(39)	
# of Agreement States 10 CFR 71.95 reports per year	2		1	2	3
# of Hours per Agreement State to review reports	3	PERT	1	3	5
Rate (hours/\$) of Agreement State to support rulemaking activities	\$101			\$101	
15.d. NRC Other Proposed Changes to 10 CFR Part 71 [10 CFR 71.95]					
NRC review of # of Agreement States reports	0			0	
NRC review of licensee reports (hours)	0	PERT	0	0	0

Table A-2 Descriptive Statistics on the Uncertainty Results (7-Percent NPV)

Issue No.	Issue Title	Incremental Costs and Benefits (2020\$) ^{a b}					
		Min	Mean	St. Dev.	Max	0.05	0.95
1	Revision of Fissile Exemptions	\$711,670	\$3,677,984	\$1,549,090	\$11,460,869	\$1,580,000	\$6,570,000
2	Revision of Reduced External Pressure Test for Normal Conditions of Transport	\$0	\$0	\$0	\$0	\$0	\$0
3	Type C Package Standards NOT ANALYZED	Not Analyzed	Not Analyzed	Not Analyzed	Not Analyzed	Not Analyzed	Not Analyzed
4	Revision of Insolation Requirements for Package Evaluations	(\$2,688,325)	(\$1,399,102)	\$382,175	(\$382,524)	(\$2,046,000)	(\$785,000)
5	Inclusion of Definition for Radiation Level	\$0	\$0	\$0	\$0	\$0	\$0
6	Deletion of the Low Specific Activity-III Leaching Test	\$34,022	\$73,106	\$18,652	\$130,204	\$44,823	\$105,937
7	Inclusion of New Definition for Surface Contaminated Object	\$650,133	\$1,174,304	\$156,042	\$1,688,417	\$912,000	\$1,431,000
8	Revision of Uranium Hexafluoride Package Requirements (UF ₆ Cylinder Plugs)	(\$136,585)	(\$82,241)	\$17,742	(\$42,227)	(\$113,449)	(\$55,394)
9	Inclusion of Evaluation of Aging Mechanisms and a Maintenance Program	\$0	\$0	\$0	\$0	\$0	\$0
10	Revision of Transitional Arrangements	(\$2,892,161)	(\$1,986,874)	\$239,309	(\$1,190,409)	(\$2,396,000)	(\$1,597,000)
11	Inclusion of Head Space for Liquid Expansion	(\$8,696)	(\$7,737)	\$379	(\$6,749)	(\$8,360)	(\$7,115,000)
12	Revision of Quality Assurance Program Biennial Reporting Requirements	(\$33,429)	(\$30,575)	\$793	(\$29,157)	(\$32,034)	(\$29,453)
13	Deletion of Type A Package Limitations in Fissile Material General Licenses	\$11,538	\$23,231	\$4,072	\$40,944	\$16,736	\$30,237
14	Deletion of ²³³ U Restriction in Fissile General License	\$520,696	\$1,592,368	\$542,343	\$4,331,062	\$846,000	\$2,597,992
15	Other Recommended Changes to 10 CFR Part 71.95	(\$1,525,277)	(\$165,654)	\$1,699,456	\$10,762,075	(\$259,832)	(\$86,764)
All Issues		(\$1,191,978)	\$3,198,158	\$1,699,456	\$10,762,075	\$420,000	\$6,020,000

^a The staff did not analyze Issue 3 because licensees did not express a need to include Type C standards in NRC regulations for domestic transport.

^b There may be differences between tables due to rounding.

SUBJECT: HARMONIZATION OF TRANSPORTATION SAFETY REQUIREMENTS WITH
 INTERNATIONAL ATOMIC ENERGY AGENCY, PROPOSED RULE—REGULATORY
 ANALYSIS (RIN NUMBER: 3150-AJ85, NRC DOCKET ID: NRC-2016-0179) DATED: AUGUST
 15, 2022

ADAMS Accession No. ML22209A039

*Concurrence via email

OFFICE	NMSS/REFS/ RASB	NMSS/REFS/ MRPB	NMSS/REFS/ MRPB/BC	NMSS/DRM/ RASB/BC	NMSS/DFM/ STLB/BC
NAME	AGomez	GTartal	JCai*	CBladey*	JMcKirgan*
DATE	4/2/2020	4/3/2020	4/15/2020	4/22/2020	4/20/2020
OFFICE	NMSS/DFM/D	NMSS/REFS/D	OGC	NMSS/D	EDO
NAME	AKock*	JTappert*	ABell, JAzeizat*	RLewis*	MDoane*
DATE	4/22/2020	4/21/2020	8/13/2020, 8/15/2022	10/2/2020	10/30/2020

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