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5 **DRAFT Regulatory Analysis for NUREG-2212,**
6 **“Standard Review Plan for Applications for 10 CFR**
7 **Part 70 Licenses for Possession and Use of Special**
8 **Nuclear Materials of Critical Mass But Not Subject to**
9 **the Requirements in 10 CFR Part 70, Subpart H”**

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15 **U.S. Nuclear Regulatory Commission**
16 Office of Nuclear Material Safety and Safeguards
17 Division of Rulemaking, Environmental, and Financial Support
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19 **December 2022**
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TABLE OF CONTENTS

	Page
LIST OF FIGURES	iv
LIST OF TABLES.....	iv
ABBREVIATIONS AND ACRONYMS	v
1 INTRODUCTION.....	1
1.1 Background.....	1
1.2 Statement of the Problem and Objective.....	3
2 IDENTIFICATION AND ANALYSIS OF ALTERNATIVE APPROACHES.....	4
2.1 Alternative 1: Take No Action.....	4
2.2 Alternative 2: Issue NUREG-2212.....	5
3 ESTIMATION AND EVALUATION OF BENEFITS AND COSTS.....	5
3.1 Affected Entities.....	5
3.2 Analytical Methodology	6
3.3 Evaluation of Alternative 1: Take No Action	10
3.4 Evaluation of Alternative 2: Issue NUREG-2212	10
3.5 Uncertainty Analysis	17
3.6 Disaggregation.....	20
4 PRESENTATION OF RESULTS	20
5 DECISION RATIONALE.....	21
5.1 Recommendation.....	21
6 REFERENCES.....	22
Appendix A	25
List of Applicable Regulations	25

LIST OF FIGURES

Figure 1	Uncertainty analysis of NRC cost savings—Alternative 2	18
Figure 2	Uncertainty analysis of industry cost savings—Alternative 2	18
Figure 3	Uncertainty analysis of total net benefit—Alternative 2	19
Figure 4	Effect of key variable uncertainty on output mean (7 percent discount factor)	20

LIST OF TABLES

Table 1	Radioactive Materials Considered SNM	3
Table 2	Licensees and Applicants Under the Scope of NUREG-2212	6
Table 3	Industry Labor Categories	7
Table 4	CPI-U Inflator	9
Table 5	Net Benefits to the NRC with Implementation of NUREG-2212	11
Table 6	NRC Operation	11
Table 7	NRC Total Averted Costs	13
Table 8	Industry Implementation	14
Table 9	Industry Operation: Averted Cost to GTCM Applicants/Licensees	14
Table 10	Net Industry Benefits (Costs)	16
Table 11	Net Benefits	16
Table 12	Uncertainty Results Descriptive Statistics (7 Percent Discount Factor)	19
Table 13	Summary of Net Benefit (or Cost)	21

ABBREVIATIONS AND ACRONYMS

92		
93		
94	ADAMS	Agencywide Documents Access and Management System
95	BLS	U.S. Department of Labor, Bureau of Labor Statistics
96	CFR	<i>Code of Federal Regulations</i>
97	CPI-U	consumer price index for all urban consumers
98	GTCM	greater than critical mass
99	N/A	not applicable
100	NMSS	Office of Nuclear Material Safety and Safeguards
101	NPV	net present value
102	NRC	U.S. Nuclear Regulatory Commission
103	OMB	Office of Management and Budget
104	PERT	program evaluation and review technique
105	Pu/Be	plutonium/beryllium
106	RAI	request for additional information
107	SNM	special nuclear material
108	U	uranium
109		
110		

1 INTRODUCTION

This document presents the regulatory analysis for NUREG-2212, “Standard Review Plan for Applications for 10 CFR Part 70 Licenses for Possession and Use of Special Nuclear Materials of Critical Mass But Not Subject to the Requirements in 10 CFR Part 70, Subpart H.” NUREG-2212 describes the information required under 10 CFR 70.22, “Contents of applications,” to be included in an application for a new license or for a renewal or amendment of an existing materials license for possession and use of special nuclear material (SNM).¹ Specifically, the guidance concerns applications and licenses for possession and use of quantities of SNM exceeding the critical mass thresholds described in Title 10 of the *Code of Federal Regulations* (10 CFR) 150.11, “Critical mass”; however, this limited class of licenses (currently referred to as greater than critical mass (GTCM)² applicants, licensees, or facilities) conducts activities other than those described in 10 CFR 70.60, “Applicability,” and does not create any of the significant hazards associated with the use of SNM (such as criticality events) covered under the regulations of 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material.” Therefore, applicants and licensees covered under this subset of 10 CFR Part 70 are not subject to the requirements in 10 CFR Part 70, Subpart H, “Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material.”

The standard review plan (SRP) provides the Nuclear Regulatory Commission (NRC) staff reviewers with guidance that describes methods or approaches that the staff has found acceptable for meeting applicable NRC requirements in 10 CFR Part 70 (see [Appendix A](#) to this document). Implementation of the criteria and guidelines in the SRP by staff members in their review of applications provides assurance that a given design ensures adequate protection of the public health and safety and the environment. This NUREG is intended to improve industry and public stakeholder understanding of the staff’s review process. It should be noted that the SRP is not a substitute for NRC regulations, and compliance with the SRP is not required. It also contains related information that applicants and licensees may find useful regarding NRC policy, such as the policy on safety culture (Appendix G), the use of discretion on issuing notices of violations (section 2.2.7, “Audit program”), and the NRC Enforcement Policy (section 2.2.7).

1.1 Background

Requirements for protecting public health and safety and the environment that are relevant to all applicants and licensees that possess and use SNM are set forth in 10 CFR Part 70. The regulations in 10 CFR Part 70, Subpart H, impose additional requirements on applicants planning to, and licensees authorized to, possess SNM for the following activities described in 10 CFR 70.60:

¹ The regulations in 10 CFR 70.4, “Definitions,” define special nuclear material as: “(1) plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Commission, pursuant to the provisions of section 51 of the act, determines to be special nuclear material, but does not include source material; or (2) any material artificially enriched by any of the foregoing but does not include source material.”

² The safety and risks of SNM activities at these facilities are more akin to those inherent with byproduct materials, which result from nuclear fission and are non-fissile. These cannot be used for atomic weapons, so the material is not at risk for proliferation. Byproduct materials are non-fissile and are not subject to self-sustaining criticality or the risks that are associated with criticality. The group of SNM licenses this guidance is developed for are overseen by the NRC because of their use of a quantity of SNM, although they pose little risk of accidental criticality, diversion or proliferation.

- enriched uranium processing
- fabrication of uranium fuel or fuel assemblies
- uranium enrichment
- enriched uranium hexafluoride conversion
- plutonium processing
- fabrication of mixed-oxide fuel or fuel assemblies
- scrap recovery of SNM
- any other activity that the Commission determines could significantly affect public health and safety³

NUREG-2212 provides information on how the NRC staff reviews applications for 10 CFR Part 70 licenses to engage in activities that are not subject to the requirements in 10 CFR Part 70, Subpart H. These GTCM applicants, licensees, and facilities are not engaged in any of the activities described in 10 CFR 70.60. They have become a large enough group to consider their own characteristics differently from other users of SNM who rely on other guidance, such as NUREG-1556, "Consolidated Guidance About Materials Licenses," Volume 17, Revision 1, "Program-Specific Guidance About Special Nuclear Material of Less than Critical Mass Licenses," issued July 2018 (NRC, 2018c), or NUREG-1520, Revision 2 "Standard Review Plan for Fuel Cycle Facilities License Applications," issued June 2015 (NRC, 2015), to complete applications for the possession and use of SNM. Because specific guidance at a level appropriate to GTCM applicants and licensees does not currently exist, the staff has prepared the guidance in NUREG-2212 to assist these applicants, licensees, and facilities in preparing new license or renewal applications for the following activities that are not subject to the requirements in 10 CFR Part 70, Subpart H:

- experiments using subcritical assemblies
- instrument calibration
- instruction in radiation detection and measurement
- experiments with uranium (U)-235 target foils
- low enriched uranium sources for radiation detection testing
- research and development in homeland security applications

This subset of 10 CFR Part 70 applicants and licensees is further delineated pursuant to the SNM thresholds described in 10 CFR 150.11.⁴ In accordance with this regulation, SNM in quantities insufficient to form a critical mass is defined as follows:

³ NUREG-1520 provides guidance for an NRC license to engage in any of these activities in 10 CFR 70.60.

⁴ SNM in any quantity exceeding these thresholds is considered a critical mass quantity of SNM.

- uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235
- U-233 in quantities not exceeding 200 grams
- plutonium in quantities not exceeding 200 grams
- any combination of the above radioactive materials in accordance with the following formula:⁵

$$\frac{\text{grams } ^{235}\text{U}}{350} + \frac{\text{grams } ^{233}\text{U}}{200} + \frac{\text{grams Pu}}{200} \leq 1$$

Therefore, for the purpose of this regulatory analysis and the associated guidance in NUREG-2212, a critical mass quantity of SNM is defined as any SNM exceeding the thresholds described in 10 CFR 150.11. A GTCM licensee or facility is therefore (1) authorized to possess SNM in quantities exceeding the thresholds—the unity rule—in 10 CFR 150.11 (i.e., a critical mass of SNM), (2) engaged in activities not subject to the requirements in 10 CFR Part 70, Subpart H, and (3) exclusively subject to NRC regulatory oversight (i.e., not an Agreement State licensee).

Table 1 shows which radioactive materials are SNM and the threshold quantities of SNM needed for an entity to be considered a GTCM applicant or licensee for the purpose of this guidance. In addition to the limits listed in Table 1, the NRC staff has developed a limit for plutonium/beryllium (Pu/Be) sources for licensees that request authorization for possession and use of Pu/Be sources only. In these cases, a quantity of greater than 2,000 grams of plutonium will be considered a critical mass if the Pu:Be ratio is greater than 1,000.⁶

Table 1 Radioactive Materials Considered SNM

Special Nuclear Material	Covered by This Report	Threshold Quantities GTCM (g)	Regulatory Authority
Plutonium	Yes	>200	NRC/NMSS
U-235	Yes	≥350	NRC/NMSS
U-233	Yes	≥200	NRC/NMSS

1.2 Statement of the Problem and Objective

1.2.1 Problem Statement

NUREG-2212 provides guidance to the NRC staff for the review of a subset of applications for 10 CFR Part 70 licenses to possess and use SNM in critical mass quantities and that do not fall

⁵ Also known as the “Unity Rule,” this formula has been adapted from the one given in 10 CFR 150.11 to state a simple general formula that every applicant can use to determine whether it has met the threshold for a critical mass quantity of SNM.

⁶ The NRC provides the technical basis for considering 2,000 grams of plutonium-239 in the form of Pu/Be sealed sources as less than a critical mass in the “Technical Basis for 2000 Grams of Plutonium Limit in PuBe Neutron Source Mass Limit,” dated June 16, 2020 (NRC, 2020c). The Pu/Be limit will not apply if the request includes possession and use of Pu/Be neutron sources in combination with other types of SNM. If so, then the limits described in 10 CFR 150.11(a) apply.

under the additional requirements in 10 CFR Part 70, Subpart H. The NRC has issued guidance for applications for 10 CFR Part 70 licenses that fall under Subpart H in NUREG-1520, Revision 2. The NRC has also issued guidance for 10 CFR Part 70 applications for quantities of SNM of less than critical mass in NUREG-1556, Volume 17, Revision 1. However, the NRC has not issued guidance that focuses specifically on the review of applications for SNM in critical mass quantities but that are not subject to 10 CFR Part 70, Subpart H. The absence of specific guidance for the licensing of this subset of 10 CFR Part 70 applications could lead to inconsistencies and inefficiencies in applications and staff review documents.

The guidance in NUREG-2212 identifies and describes the information that 10 CFR 70.22 requires to be provided in a new application to possess and use critical mass quantities of SNM under a 10 CFR Part 70 license that is not subject to the requirements in 10 CFR Part 70, Subpart H. NUREG-2212 identifies the information applicants for a new license or for renewal of a license to possess critical mass quantities of SNM must submit to be granted a new, renewed, or amended license. It also provides general information on transfers and terminations of licenses, as well as notifications of matters such as bankruptcy.⁷ The guidance describes the methods the NRC staff accepts for implementing the NRC regulations relevant to GTCM applicants, licensees, and facilities. Importantly, NUREG-2212 provides guidance to the NRC staff on evaluating all applications to possess critical mass quantities of SNM and determining whether the proposed activities are acceptable for the issuance of a license.

1.2.2 Objective

The objective of this regulatory analysis is to assess the benefits and costs of alternatives to issuing NUREG-2212 to ensure that the NRC has selected the most cost-beneficial (i.e., cost-effective) alternative. This NUREG identifies and describes the information that is required by the regulations in 10 CFR Part 70 to be provided in an application for a new license, license renewal, or license amendment for the receipt, possession, use, and storage of critical mass quantities of SNM.

2 IDENTIFICATION AND ANALYSIS OF ALTERNATIVE APPROACHES

The NRC has identified two alternatives for consideration.

2.1 Alternative 1: Take No Action

Under Alternative 1, the NRC would not issue new guidance to provide the staff with a clear framework to assess whether an application provides the information required by 10 CFR 70.22. Alternative 1 would not standardize and streamline the application review process. Alternative 1 serves as the baseline against which the impacts of Alternative 2 will be measured.

Alternative 1 would pose no incremental costs on licensees or applicants for 10 CFR Part 70 GTCM applicants and licenses. The NRC would continue to review new licensee applications, license amendments, and license renewals on a case-by-case basis. Applicants would continue rely on staff interaction to identify the relevant guidance to address in an application. Alternative 1 would not standardize and streamline the application review process and would not increase the efficiency of the staff's review process for new applications, license

⁷ The NRC provides detailed guidance on license transfers and bankruptcy in NUREG-1556, Volume 15, Revision 1, "Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," issued June 2026 (NRC, 2016a).

amendments, or license renewals. The NRC would continue to commit agency and staff resources to assist applicants in developing their application through meetings and teleconferences.

2.2 Alternative 2: Issue NUREG-2212

Under Alternative 2, the NRC would issue NUREG-2212. This draft staff guidance document would consolidate and establish clear, standardized guidance for the NRC staff review of 10 CFR Part 70 license applications for SNM in critical mass quantities that are not subject to the requirements in 10 CFR Part 70, Subpart H.

NUREG-2212 would describe the type of information that should be part of an application for a specific license for the possession and use of critical mass quantities of SNM. The guidance in NUREG-2212 is not intended for the review of license applications for the following:

- possession of quantities of SNM of less than critical mass⁸
- possession of quantities of SNM in excess of formula quantities of SNM⁹
- authorizing the manufacture and distribution of SNM, which includes small entities

In addition to describing the requirements of 10 CFR 70.22 that are relevant to GTCM applicants and licensees, NUREG-2212 identifies additional general information on the requirements for possession and use of sealed and unsealed SNM (e.g., for leak tests of sealed sources and measurements of concentrations in air for areas where radioactive materials are handled or processed in unsealed form).

3 ESTIMATION AND EVALUATION OF BENEFITS AND COSTS

3.1 Affected Entities

The NRC staff expects its issuance of NUREG-2212 will increase the consistency and efficiency of the NRC's licensing process and benefit applicants for, and licensees of, SNM in critical mass quantities under 10 CFR Part 70, that are not subject to the requirements in 10 CFR Part 70, Subpart H. Table 2 lists the relevant GTCM facilities currently regulated by the NRC.

⁸ Applicants seeking guidance for a license for less than critical mass as defined in 10 CFR 150.11 should refer to their corresponding Agreement State program or to NUREG-1556, Volume 17.

⁹ The NRC provides guidance on license applications for possession of quantities of SNM in excess of formula quantities of SNM in NUREG-1520. NUREG-1556, "Consolidated Guidance About Materials Licenses," Volume 12, Revision 1, "Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution," issued May 2018 (NRC, 2018b), contains guidance on license applications for manufacturing and distribution of SNM.

Table 2 Licensees and Applicants Under the Scope of NUREG-2212

Facility	Docket	Current License	Date of Last Renewal	Expiration Date
U.S. Department of Commerce (National Institute of Standards and Technology) (Gaithersburg, MD)	70-0398	SNM-362 (NRC, 2021a)	9/9/2013 (through Amendment 4)	9/9/2023
General Electric Vallecitos (Sunol, CA)	70-0754	SNM-960 (NRC, 2019d)	8/9/2017	8/9/2027
Idaho State University (Pocatello, ID)	70-1374	SNM-1373 (NRC, 2019b, 2019c)	8/11/2011	8/11/2021*
Massachusetts Institute of Technology (Cambridge, MA)	70-0938	SNM-986 (NRC, 2018a)	12/14/2017	12/13/2027
Oregon State University (Corvallis, OR)	70-7019	SNM-2013 (NRC, 2011)	N/A (New)	8/29/2021*
Penn State University (University Park, PA)	70-0113	SNM-95 (NRC, 2020a)	4/24/2018	4/24/2028
Purdue University (West Lafayette, IN)	70-0152	SNM-142 (NRC, 2016b)	9/25/2013	9/25/2023
Sensor Concepts & Applications (Glen Arm, MD) (U.S. Department of Homeland Security contractor)	70-7020	SNM-2017 (NRC, 2018d)	N/A (New)	12/27/2021*
Johns Hopkins University Applied Physics Laboratory (Columbia, MD)	70-7028	SNM-7004 (NRC, 2019a)	N/A (New)	2/22/2029
Defense Threat Reduction Agency	70-7029	SNM-7005 (NRC 2021b)	N/A (New)	5/19/2031
University of Tennessee (Knoxville, TN)	70-7030	Preapplication (Notice of Intent)	N/A	N/A
Permafrix**		Preapplication (Notice of Intent)	N/A	N/A

* Currently on timely renewal

** Permafrix recently provided a notice of intent to apply for a license to the NRC. This applicant is included as one of the two applicant submittals that the NRC expects to receive over the next 10 years.

3.2 Analytical Methodology

This regulatory analysis follows the guidance in NUREG/BR-0058, draft Revision 5, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," dated April 2017 (NRC, 2020b). In addition, the methodology follows the guidance from Office of Management and Budget (OMB) Circular A-4, "Regulatory Analysis," dated September 17, 2003 (OMB, 2003).

In this regulatory analysis, the staff identifies each attribute related to the regulatory action and analyzes it either quantitatively or qualitatively. The benefits include any desirable changes in affected attributes (e.g., monetary savings, improved safety, or improved security), while the costs include any undesirable changes in affected attributes (e.g., monetary costs, increased exposures to radiation, or physical hazards). This regulatory analysis estimates the incremental costs resulting from issuing NUREG-2212 compared to a baseline that assumes the NRC does not undertake any action (Alternative 1). The staff assumes full compliance with existing NRC regulations in establishing the regulatory baseline used in this analysis.

The staff developed expected values for each affected benefit and cost in its quantified regulatory analysis. The staff estimated the level of effort required for each activity under

Alternative 2 and labor rates for the personnel performing those activities. After calculating the benefits and costs, the staff discounted benefits and costs incurred in future years to the current year of the regulatory action. Finally, the staff summed the benefits and costs for Alternative 2 and compared them to the Alternative 1 baseline. After performing the quantitative regulatory analysis, the staff addressed qualitative attributes that are difficult to quantify but important to consider.

The staff gathered data from several sources to estimate levels of effort and unit costs. It applied several cost estimation methods in this analysis and used professional knowledge and judgment to estimate some of the costs and benefits, using an analogy method or extrapolation techniques.

The NRC staff used labor rates from the U.S. Department of Labor, Bureau of Labor Statistics (BLS) (BLS, 2022), to calculate industry labor costs. These labor rates were weighted and summed to create a weighted industry labor rate that represents the different personnel who would participate in these activities. Table 3 shows these estimates. The industry labor categories and the consumer price index for all urban consumers inflator (CPI-U) shown in Table 4 were used to calculate the base year labor rate for the industry's implementation costs presented in Table 8 and the industry's operation costs presented in Table 9.

Table 3 Industry Labor Categories

Labor Category	Percent of Total Time to Complete the Task	Mean Labor Rate	Weighted Labor Rate (2022 Dollars)
Technician	60%	\$123.11	\$73.87
Administrative Staff	15%	\$92.05	\$13.81
Managers	20%	\$168.66	\$33.73
Executives	5%	\$229.34	\$11.47
Weighted Industry Labor Rate			\$132.87

To evaluate the effect of uncertainty on the analysis, the staff employed a Monte Carlo simulation, which is an approach to uncertainty analysis in which input variables are expressed as distributions. The result is a distribution of values for the output variable of interest. With a Monte Carlo simulation, it is also possible to determine the input variables that have the greatest effect on the value of the output variable. Section 3.5 gives a detailed description of the Monte Carlo method and presents the results for this analysis.

3.2.1 Identification of Affected Attributes

Attributes within the public and private sectors that could be affected by the two alternatives are presented below. Descriptions of the potential attributes selected for analysis appear in NUREG/BR-0058.

Potentially affected attributes include the following:

- NRC Implementation: This attribute accounts for the projected one-time net costs and benefits of issuing NUREG-2212 and other related initial activities.
- NRC Operations: This attribute accounts for the projected net economic effect on the NRC after the NUREG is published. If the NRC issues fewer requests for additional

information (RAIs) and performs fewer inspection activities as a result of NUREG-2212, which would reduce the NRC's operation costs.

- Industry Implementation: This attribute measures the projected one-time net economic effect for applicants under NUREG-2212 upon its issuance. These costs would include procedural changes and other one-time actions directly related to the publication of new guidance.
- Industry Operation: This attribute accounts for the projected net economic effect caused by routine and recurring activities required by the alternative on new applications and applicants, such as license applications, amendments, renewals, and responding to RAIs from the NRC.
- Regulatory Efficiency: This qualitative attribute considers potential nonquantifiable benefits in regulatory and compliance improvements beyond those efficiencies estimated in other attributes. The NRC anticipates the issuance of the guidance will improve applicants' knowledge of the acceptable approaches for new specific license applications, amendments, and renewals for the receipt, possession, use, and storage of critical mass quantities of SNM. The NRC staff also expects the issuance of this specialized, consolidated guidance on the NRC's rules and regulations for GTCM applicants and licensees will provide efficiencies. The staff did not identify additional nonquantifiable efficiency gains.

3.2.2 Base Year of Analysis

The NRC assumes it will issue NUREG-2212 in 2022, so all quantified benefits and costs are escalated or discounted to 2022 dollars.

3.2.3 Time Horizon

The staff estimates that the benefits of NUREG-2212 will accrue to the regulated entities for a period of 20 years. Generally, licensees and applicants that would be covered by NUREG-2212 are currently authorized for the receipt, possession, use, and storage of critical mass quantities of SNM under 10-year licenses. Therefore, most current licenses subject to the guidance are expected to expire during the time horizon considered in this analysis. The NRC staff estimates that each specific licensee will submit three license amendments over a period of 10 years, and that each specific licensee will seek renewal of its license. This 20-year time horizon addresses all anticipated new specific license applications, amendments, and renewals.

3.2.4 Cost/Benefit Inflation

The NRC estimated the analysis inputs using the CPI-U and labor rates reported by the BLS. To evaluate the costs and benefits consistently, the staff converted these inputs into base-year (2022) dollars using the CPI-U, where appropriate. Using the CPI-U, the NRC staff converted prior-year dollars to 2021 dollars using the following formula:

$$\frac{CPI - U_{2022}}{CPI - U_{Prior Year}} \times Value_{Prior Year} = Value_{2022}$$

Table 4 summarizes the values of CPI-U used in this regulatory analysis.

Table 4 CPI-U Inflator

Base Year	CPI-U Annual Average*
2018	251.10
2019	255.65
2020	258.84
2021	264.71
2022	271.06

* Statistica, 2022

3.2.5 Net Present Value Calculations

The net present value (NPV) calculations estimate the investment to be made today to ensure that the designated dollar amount is available in a given year in the future. The use of discount factors to calculate costs and benefits allows future incremental costs and benefits to be valued equally when comparing alternatives. Based on Circular A-4, the present-value calculations are shown using both 3 and 7 percent real discount rates, and the decision rationale is based on the 7 percent real discount rate.

3.2.6 Sign Conventions

This analysis uses the convention that all favorable consequences for the alternative are positive and all adverse consequences for the alternative are negative. Negative values are shown using parentheses (e.g., negative \$500 is displayed as (\$500)).

3.2.7 Assumptions

The analysis uses the assumptions and considerations described below to determine the costs associated with the implementation of the alternatives.

The analysis makes the following assumptions for new 10 CFR Part 70 applicants covered by the guidance:

- The NRC receives two new applicant submittals every 10 years; one every 5 years.
- Based on an historical analysis of previous new applicant data and projections of efficiencies gained through implementation of the guidance in NUREG-2212, new applicants would save an estimated 230 hours in the submission of each new license or license renewal application. This 230-hour estimate includes the anticipated time saved due to fewer RAIs. The staff anticipates a 50 percent reduction in RAIs as a result of the new standardized guidance in NUREG-2212.
- In 2018, the NRC staff received one notice of intent to file an application for the possession and use of critical mass quantities of SNM. If the completed application is submitted in early 2023, the staff anticipates completing the licensing process by the end of 2023.

The analysis makes the following assumptions for license amendments:

- Based on historical data, each licensee submits an average of three license amendments over a 10-year time frame.
- Assuming the number of amendment requests remains constant, the staff anticipates the issuance of the standardized application review process discussed in NUREG-2212 will result in a 50 percent reduction in the number of RAIs, with a commensurate saving in NRC staff resources. A reduction in the number of RAIs issued to applicants for license amendments would reduce the time applicants expend on RAI responses by an estimated 58 hours for each amendment.
- As of 2021, the NRC has 10 active licenses covered by the guidance and is processing one preapplication. The staff assumes that the current preapplicant will obtain its license in 2023. The staff assumes that this preapplicant will submit one license amendment every 3 years, consistent with the license amendment assumptions noted in this section.

The analysis makes the following assumptions for license renewals:

- All licensees with current licenses (and the preapplicant) will renew their licenses at the expiration of a 10-year license.
- All licensees are expected to renew their licenses in accordance with the guidance in NUREG-2212, which instructs NRC staff reviewers on how to review an application to assess whether the proposed activities comply with applicable regulations in 10 CFR Part 70. The NRC anticipates these license renewal applications will include the type of information needed to develop an application for a specific license for the possession and use of critical mass quantities of SNM.
- The NRC anticipates that the use of the standardized application review process in NUREG-2212 will result in a 50 percent reduction in the issuance of RAIs, with a commensurate saving in staff resources. The reduction in the number of RAIs submitted to license renewal applicants is expected to reduce the time applicants expend on RAI responses by an estimated 230 hours for each of license renewal.

3.3 Evaluation of Alternative 1: Take No Action

Alternative 1, which is the baseline for the regulatory analysis, does not result in incremental changes to benefits or costs nor creates savings to either the NRC or to applicants/licensees, as current review practices would not change.

3.4 Evaluation of Alternative 2: Issue NUREG-2212

This regulatory analysis compares the incremental impacts of issuing NUREG-2212 (Alternative 2) to a baseline where the staff does not issue NUREG-2212. Attributes which have the potential to be affected by Alternative 2 are evaluated below.

3.4.1 NRC Implementation

The NRC staff would use the consolidated and standardized guidance in NUREG-2212 to streamline its review applications. The guidance presents a common understanding of the technical issues for use by the NRC staff and applicants. The NRC expects that implementing NUREG-2212 would increase the efficiency of the staff's review of applications and reduce the need for resource-intensive, case-by-case reviews of the technical topics generically addressed in the NUREG.

The NRC anticipates that the 10 licensees and the preapplicant will use the description of the staff's licensing review process in NUREG-2212 to prepare better organized and more complete licensing submittals in the future. The staff estimated the costs to the NRC of training staff to use the consolidated and standardized guidance on the licensing review process to review license applications for possession and use of SNM in critical mass quantities not subject to the requirements in 10 CFR Part 70, Subpart H. Table 5 lists these training costs.

Table 5 Net Benefits to the NRC with Implementation of NUREG-2212

Year	Activity	Number of Impacted People	Labor Hours	Hourly Rate	Net Benefits (Costs)*		
					Undiscounted	7% NPV	3% NPV
2022	NRC Training	20	7	\$134	(\$18,500)	(\$17,300)	(\$18,000)
NRC Net Implementation Benefits (Costs)					(\$18,500)	(\$17,300)	(\$18,000)

* There may be small differences among tables due to rounding.

3.4.2 NRC Operation

The NRC staff anticipates that the NRC would realize operational or long-term savings in the costs associated with its licensing reviews. The NRC staff evaluated the information in Table 2 and estimated the long-term savings it would incur in operational costs for reviewing new applications, license amendments, and license renewals based on the assumptions noted in section 3.2.7.

Table 6 presents the net benefits to the NRC expected from the use of the new guidance.

Table 6 NRC Operation

Year	Activity	Number of Reviews	Hours	Hourly Rate	Net Benefits (Costs)*		
					Undiscounted	7% NPV	3% NPV
2023	NRC License Amendment Review	2	58	\$134	\$15,400	\$13,500	\$14,500
2023	NRC License Renewal Review and Approval	2	230	\$134	\$61,600	\$53,800	\$58,100
2024	NRC License Amendment Review	5	58	\$134	\$38,500	\$31,400	\$35,300
2025	NRC License Amendment Review	2	58	\$134	\$15,400	\$11,800	\$13,700
2026	NRC License Amendment Review	4	58	\$134	\$30,800	\$22,000	\$26,600
2027	NRC New Applicant Licensee Review	1	230	\$134	\$30,800	\$20,500	\$25,800

Year	Activity	Number of Reviews	Hours	Hourly Rate	Net Benefits (Costs)*		
					Undiscounted	7% NPV	3% NPV
2027	NRC License Renewal Review and Approval	2	230	\$134	\$61,600	\$41,100	\$51,600
2027	NRC License Amendment Review	5	58	\$134	\$38,500	\$25,700	\$32,300
2028	NRC License Renewal Review and Approval	1	230	\$134	\$30,800	\$19,200	\$25,100
2028	NRC License Amendment Review	2	58	\$134	\$15,400	\$9,600	\$12,500
2029	NRC License Renewal Review and Approval	1	230	\$134	\$30,800	\$17,900	\$24,300
2029	NRC License Amendment Review	2	58	\$134	\$15,400	\$9,000	\$12,200
2030	NRC License Amendment Review	7	58	\$134	\$53,900	\$29,300	\$41,300
2031	NRC License Renewal Review and Approval	4	230	\$134	\$123,300	\$62,700	\$91,700
2031	NRC License Amendment Review	2	58	\$134	\$15,400	\$7,800	\$11,500
2032	NRC New Applicant Licensee Review	1	230	\$134	\$30,800	\$14,600	\$22,300
2032	NRC License Renewal Review and Approval	1	230	\$134	\$30,800	\$14,600	\$22,300
2032	NRC License Amendment Review	3	58	\$134	\$23,100	\$11,000	\$16,700
2033	NRC License Renewal Review and Approval	2	230	\$134	\$61,600	\$27,400	\$43,200
2033	NRC License Amendment Review	3	58	\$134	\$23,100	\$10,300	\$16,200
2034	NRC License Amendment Review	5	58	\$134	\$38,500	\$16,000	\$26,200
2035	NRC License Amendment Review	3	58	\$134	\$23,100	\$9,000	\$15,300
2036	NRC License Amendment Review	5	58	\$134	\$38,500	\$14,000	\$24,700
2037	NRC New Applicant Licensee Review	1	230	\$134	\$30,800	\$10,400	\$19,200
2037	NRC License Renewal Review and Approval	3	230	\$134	\$92,500	\$31,300	\$57,600
2037	NRC License Amendment Review	5	58	\$134	\$38,500	\$13,000	\$24,000
2038	NRC License Renewal Review and Approval	1	230	\$134	\$30,800	\$9,800	\$18,600
2038	NRC License Amendment Review	3	58	\$134	\$23,100	\$7,300	\$14,000
2039	NRC License Renewal Review and Approval	1	230	\$134	\$30,800	\$9,100	\$18,100
2039	NRC License Amendment Review	2	58	\$134	\$15,400	\$4,600	\$9,100
2040	NRC License Amendment Review	8	58	\$134	\$61,600	\$17,000	\$35,200
2041	NRC License Renewal Review and Approval	1	230	\$134	\$30,800	\$8,000	\$17,100
2041	NRC License Amendment Review	3	58	\$134	\$23,100	\$6,000	\$12,800

Year	Activity	Number of Reviews	Hours	Hourly Rate	Net Benefits (Costs)*		
					Undiscounted	7% NPV	3% NPV
2042	NRC License Amendment Review	1	230	\$134	\$30,800	\$7,400	\$16,600
2042	NRC New Applicant Licensee Review	2	230	\$134	\$61,600	\$14,900	\$33,100
2042	NRC License Amendment Review	3	58	\$134	\$23,100	\$5,600	\$12,400
NRC New Applicant Licensee Review Benefit (Cost) Subtotal					\$154,100	\$60,500	\$100,400
NRC Review and Approval of License Renewal Amendments Benefit (Cost) Subtotal					\$585,600	\$294,900	\$427,800
NRC License Amendment Review Benefit (Cost) Subtotal					\$601,000	\$281,200	\$423,000
NRC Operation Benefit (Cost)					\$1,340,700	\$636,600	\$951,200

* There may be small differences among tables due to rounding.

3.4.3 Total NRC Averted Costs

The estimated averted costs (benefits) for the NRC with using NUREG-2212 range between \$619,300 using a 7 percent NPV and \$933,200 using a 3 percent NPV. Table 7 presents the staff's estimates of averted costs to the agency.

Table 7 NRC Total Averted Costs

Attribute	NRC Net Benefits (Costs)*		
	Undiscounted	7% NPV	3% NPV
NRC Implementation Benefits (Costs)	(\$18,500)	(\$17,300)	(\$18,000)
NRC Operation Benefits (Costs)	\$1,340,700	\$636,600	\$951,200
Net NRC Benefits (Cost)	\$1,322,200	\$619,300	\$933,200

* There may be small differences among tables due to rounding.

3.4.4 Industry Implementation

Following the issuance of NUREG-2212, the NRC expects that the industry would use the guidance to prepare new applications, license amendments, and license renewals. The guidance presents a common understanding of the technical issues associated with relevant applications. The NRC staff expects that publication of NUREG-2212 would increase its efficiency in reviewing applications by reducing the need for resource-intensive, case-by-case licensing reviews.

The NRC anticipates that industry would review the NUREG, train staff, and implement the guidance for the one preapplication. The NRC estimates that the use of NUREG-2212 guidance by the 10 licensees and the preapplicant would result in the cost savings shown in Table 8.

Table 8 Industry Implementation

Year	Activity	Number of Entities	Labor Hours	Weighted Hourly Rate	Industry Implementation Benefits (Costs)*		
					Undiscounted	7% NPV	3% NPV
2022	Industry NUREG Review	11	23	\$132	(\$33,300)	(\$31,200)	(\$32,400)
2022	Industry Training	11	6	\$132	(\$8,300)	(\$7,800)	(\$8,100)
Total					(\$41,700)	(\$38,900)	(\$40,500)

* There may be small differences among tables due to rounding.

3.4.5 Industry Operation

NUREG-2212 is expected to bring long-term operational savings to all licensees because it will be used by the regulated community to prepare high-quality, thorough licensing applications. The NRC staff evaluated the information in Table 2 and estimated the long-term savings in operational costs to licensees based on the assumptions in section 3.2.7: (1) one new application would be submitted to the NRC every 5 years, (2) three license amendments would be submitted for each license, and (3) all licensees requesting renewal of their licenses would use the new guidance to prepare their applications.

Table 9 presents the net benefits (i.e., averted costs) expected from the use of the new guidance by NRC-licensed entities.

Table 9 Industry Operation: Averted Cost to GTCM Applicants/Licensees

Year	Activity	Number of Licensees	Hours	Weighted Hourly Rate	Net Benefits (Costs)*		
					Undiscounted	7% NPV	3% NPV
2023	License Amendment	2	58	132	15,200	13,200	14,300
2023	License Renewal	2	230	132	60,600	52,900	57,100
2024	License Amendment	5	58	132	37,900	30,900	34,700
2025	License Amendment	2	58	132	15,200	11,600	13,500
2026	License Amendment	4	58	132	30,300	21,600	26,100
2027	Preapplicant Review of NUREG and Development of Internal Procedures	1	23	132	(3,000)	(2,000)	(2,500)
2027	Preapplicant Implementation of Training	1	6	132	(800)	(500)	(600)
2027	New License Submittal	1	230	132	30,300	20,200	25,400
2027	License Renewal	2	230	132	60,600	40,400	50,800
2027	License Amendment	5	58	132	37,900	25,200	31,700
2028	License Renewal	1	230	132	30,300	18,900	24,600
2028	License Amendment	2	58	132	15,200	9,400	12,300
2029	License Renewal	1	230	132	30,300	17,600	23,900
2029	License Amendment	2	58	132	15,200	8,800	12,000
2030	License Amendment	7	58	132	53,000	28,800	40,700
2031	License Renewal	4	230	132	121,200	61,600	90,200
2031	License Amendment	2	58	132	15,200	7,700	11,300

Year	Activity	Number of Licensees	Hours	Weighted Hourly Rate	Net Benefits (Costs)*		
					Undiscounted	7% NPV	3% NPV
2032	Preapplicant Review of NUREG and Development of Internal Procedures	1	23	132	(3,000)	(1,400)	(2,200)
2032	Preapplicant Implementation of Training	1	6	132	(800)	(400)	(500)
2032	New License Submittal	1	230	132	30,300	14,400	21,900
2032	License Renewal	1	230	132	30,300	14,400	21,900
2032	License Amendment	3	58	132	22,700	10,800	16,400
2033	License Renewal	2	230	132	60,600	26,900	42,500
2033	License Amendment	3	58	132	22,700	10,100	15,900
2034	License Amendment	5	58	132	37,900	15,700	25,800
2035	License Amendment	3	58	132	22,700	8,800	15,000
2036	License Amendment	5	58	132	37,900	13,700	24,300
2037	Preapplicant Review of NUREG and Development of Internal Procedures	1	23	132	(3,000)	(1,000)	(1,900)
2037	Preapplicant Implementation of Training	1	6	132	(800)	(300)	(500)
2037	New License Submittal	1	230	132	30,300	10,300	18,900
2037	License Renewal	3	230	132	90,900	30,800	56,700
2037	License Amendment	5	58	132	37,900	12,800	23,600
2038	License Renewal	1	230	132	30,300	9,600	18,300
2038	License Amendment	3	58	132	22,700	7,200	13,800
2039	License Renewal	1	230	132	30,300	9,000	17,800
2039	License Amendment	2	58	132	15,200	4,500	8,900
2040	License Amendment	8	58	132	60,600	16,800	34,600
2041	License Renewal	1	230	132	30,300	7,800	16,800
2041	License Amendment	3	58	132	22,700	5,900	12,600
2042	Preapplicant Review of NUREG and Development of Internal Procedures	1	23	132	(3,000)	(700)	(1,600)
2042	Preapplicant Review of NUREG and Development of Internal Procedures	1	6	132	(800)	(200)	(400)
2042	New License Submittal	1	230	132	30,300	7,300	16,300
2042	License Renewal	2	230	132	60,600	14,600	32,600
2042	License Amendment	3	58	132	22,700	5,500	12,200
New Licensee Submittal Relief Subtotal					\$121,200	\$52,200	\$82,500
License Renewal Relief Subtotal					\$636,300	\$304,500	\$453,200
License Amendment Relief Subtotal					\$560,800	\$269,000	\$399,700
Industry Operation Net Benefits (Costs)					\$1,318,300	\$625,700	\$935,400

* There may be small differences among tables due to rounding.

3.4.6 Total Industry Averted Costs

The NRC staff estimates the cost savings that would occur if the regulated community included the information described in the consolidated guidance in NUREG-2212 in its licensing applications. Table 10 presents the staff's estimated net benefits (i.e., averted costs) to the industry, which range between \$587,100 using a 7 percent NPV and \$894,900 using a 3 percent NPV.

Table 10 Net Industry Benefits (Costs)

Attribute	Net Benefits (Costs)*		
	Undiscounted	7% NPV	3% NPV
Industry Implementation Benefits (Costs)	(\$41,700)	(\$38,900)	(\$40,500)
Industry Operation Benefits (Costs)	\$1,318,400	\$626,000	\$935,400
Net Industry Benefits (Costs)^b	\$1,276,700	\$587,100	\$894,900

* There may be small differences among tables due to rounding.

3.4.7 Regulatory Efficiency

The NRC anticipates that issuing the guidance would provide for standardization of the staff's licensing reviews. The NRC expects the issuance of NUREG-2212, which consolidates guidance for applicants and licensees for possession and use of SNM in critical mass quantities not subject to the requirements in 10 CFR Part 70, Subpart H, will be useful to the entities covered by the guidance. The submission of more consistent and complete applications is expected to expedite the NRC staff's review process and reduce the issuance of RAIs, with commensurate savings in staff resources. The staff did not identify additional nonquantifiable efficiency gains.

3.4.8 Cost Justification

The NRC staff concludes that publication of NUREG-2212 provides moderate averted costs (benefits) to the NRC and to industry, as shown in Table 11.

Table 11 Net Benefits

Attribute	Net Benefits (Costs)*		
	Undiscounted	7% NPV	3% NPV
Industry Implementation Benefits (Costs)	(\$41,700)	(\$38,900)	(\$40,500)
Industry Operation Benefits (Costs)	\$1,318,400	\$626,000	\$935,400
<i>Net Industry Benefits (Costs)</i>	<i>\$1,276,700</i>	<i>\$587,000</i>	<i>\$894,900</i>
NRC Implementation Benefits (Costs)	(\$18,500)	(\$17,300)	(\$18,000)
NRC Operation Benefits (Costs)	\$1,340,700	\$636,600	\$951,200
<i>Net NRC Benefits (Costs)</i>	<i>\$1,322,200</i>	<i>\$619,300</i>	<i>\$933,200</i>
Net Benefits (Costs)	\$2,598,900	\$1,206,300	\$1,828,100

* There may be small differences among tables due to rounding.

The net averted costs estimated from the use of this NUREG (Alternative 2) range between \$1.206 million (7 percent NPV) and \$1.828 million (3 percent NPV).

3.5 Uncertainty Analysis

To determine the robustness of the estimated costs and benefits, the NRC staff examined how costs change in relation to uncertainties in the analytical assumptions and input data of this regulatory analysis. The staff used a Monte Carlo simulation to examine the impact of uncertainty on the estimated net benefits.

3.5.1 Uncertainty Analysis Results

The NRC staff completed a Monte Carlo sensitivity analysis for this regulatory analysis using the specialty software @Risk®.¹⁰ The Monte Carlo approach answers the question, “What distribution of net benefits results from multiple iterations of the probability distribution assigned to key variables?”

Because the regulatory analysis estimates values that are sensitive to licensee-specific cost drivers and differences among facilities, the NRC staff analyzed those variables with the greatest uncertainty.

Monte Carlo simulations involve introducing uncertainty into an analysis by replacing the point estimates of the variables used to estimate costs and benefits with probability distributions. Defining input variables as probability distributions, instead of as point estimates, enables an effective model of the influence of uncertainty on the results of the analysis (in other words, the net benefits).

The probability distributions that represent the variables in this Monte Carlo analysis are bounded by the ranges of the input variables and reflect the NRC staff’s professional judgment. When defining the probability distributions for use in a Monte Carlo simulation, summary statistics are needed to characterize the distributions. These summary statistics include the minimum, most likely, and maximum values of a program evaluation and review technique (PERT) distribution,¹¹ the minimum and maximum values of a uniform distribution, and the specified integer values of a discrete population. The staff used the PERT distribution to reflect the relative spread and skewness of the distribution defined by the three estimates.

The NRC performed the Monte Carlo simulation by recalculating the results 10,000 times. For each iteration, values were chosen randomly from the probability distributions that define the input variables. The values of the output variables were recorded for each iteration and the values for the output variables were used to define the resultant probability distribution. In developing the distributions in figures 1, 2, and 3, the staff ran 10,000 simulations and changed the values of the key input variables to assess the effects on costs and benefits. Figure 1 shows the incremental averted costs (benefits) to the NRC of adopting NUREG-2212 (Alternative 2). Figure 2 shows the incremental averted costs (benefits) that would accrue to industry under Alternative 2. Figure 3 graphs the total net benefit that would accrue to the NRC and industry

¹⁰ Information about this software is available at <https://www.palisade.com>.

¹¹ A PERT distribution is a special form of 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 the 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.

under Alternative 2. The data plotted in figures 1–3 use a 7 percent NPV discount rate. The staff's uncertainty analyses demonstrate that both the NRC and industry would realize cost savings if the NRC issues NUREG-2212.

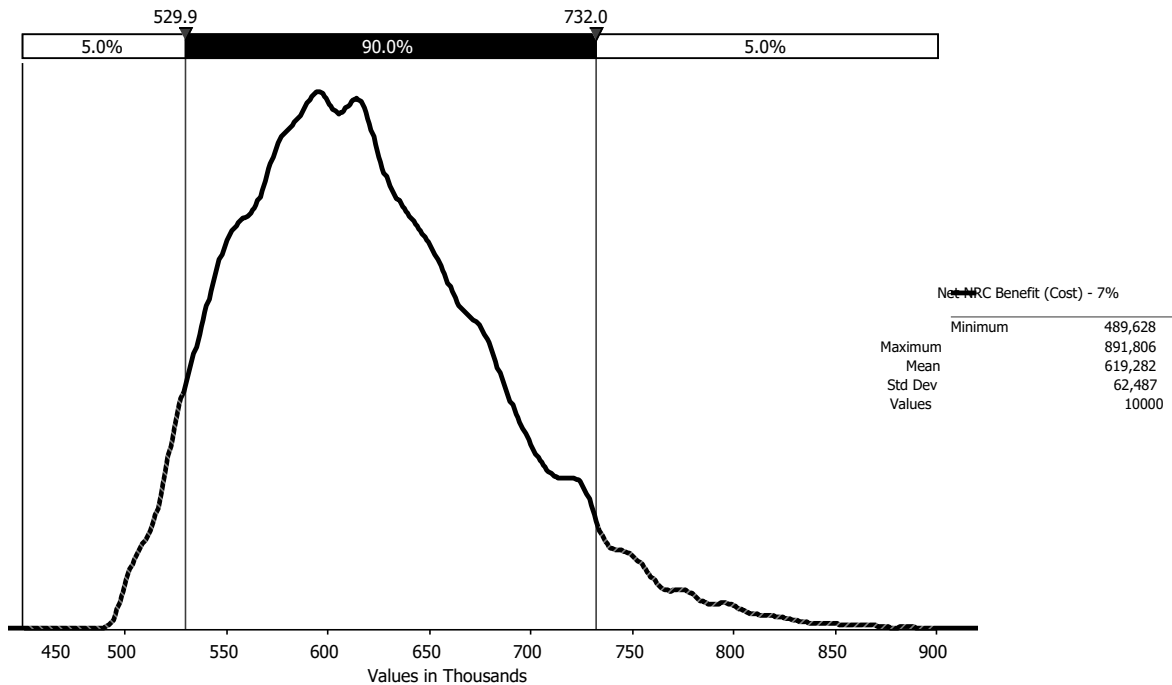


Figure 1 Uncertainty analysis of NRC cost savings—Alternative 2

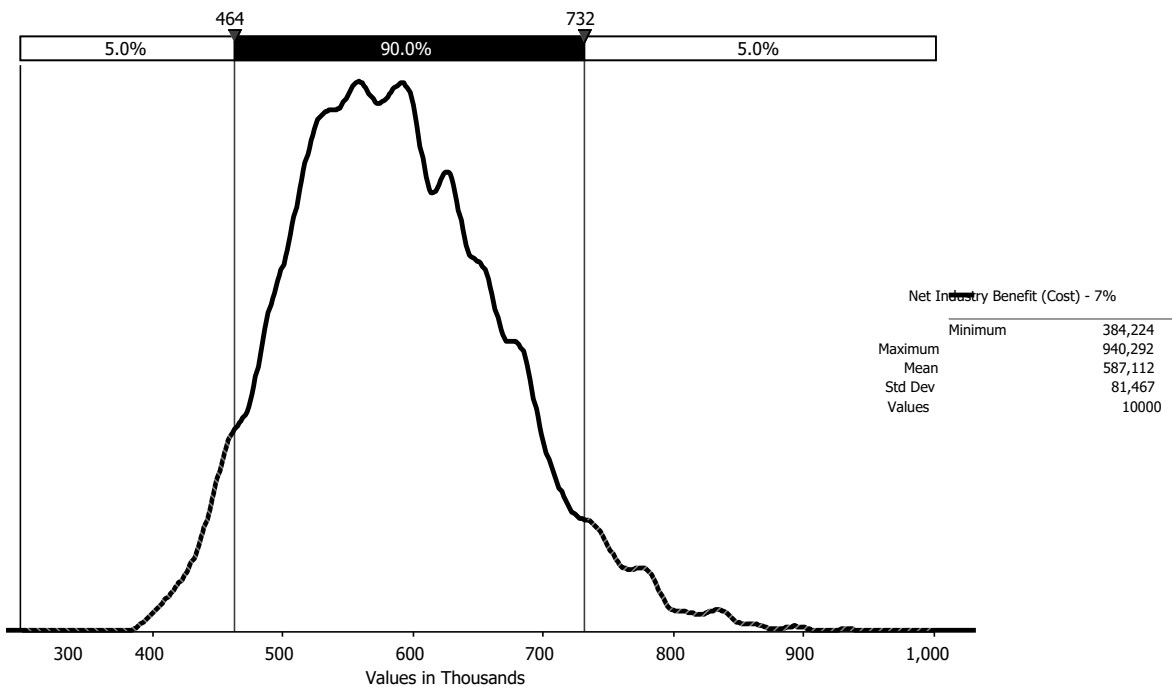


Figure 2 Uncertainty analysis of industry cost savings—Alternative 2

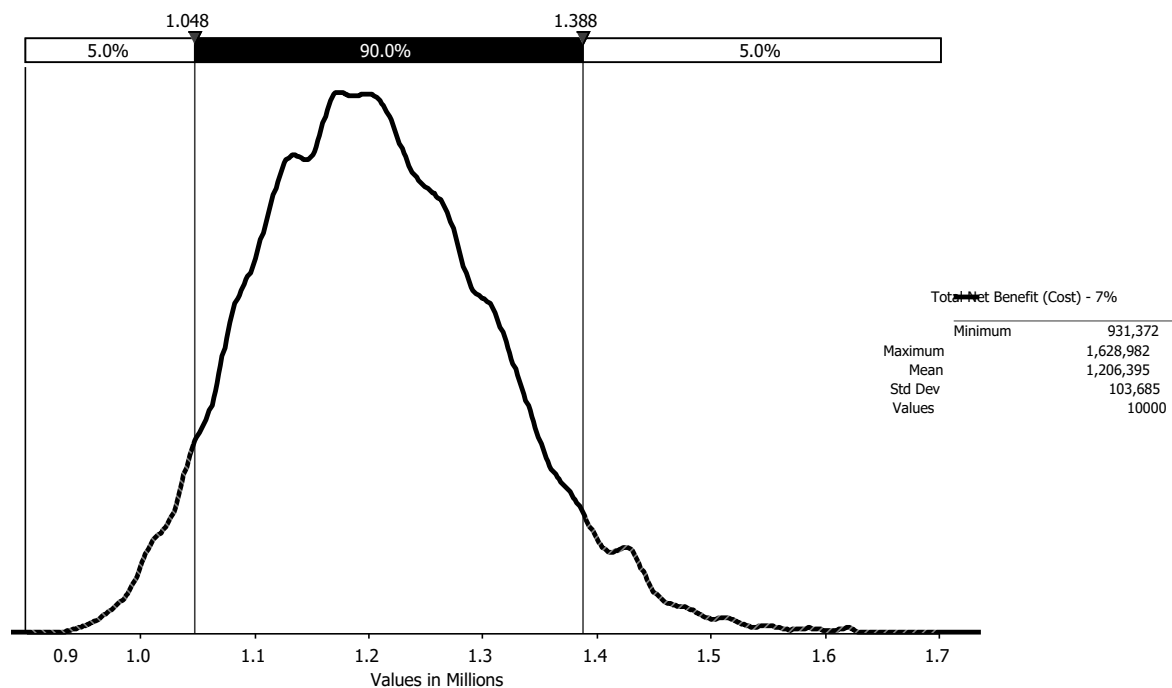


Figure 3 Uncertainty analysis of total net benefit—Alternative 2

Table 12 displays the key statistical results plotted in the distributions in figures 1–3, including the 90 percent confidence interval in which the net benefits would fall between the 5th and 95th percentile values. The output distribution provided in Table 12 allows the staff to conclude with confidence that issuing NUREG-2212 has the potential to result in substantial incremental benefits.

Table 12 Uncertainty Results Descriptive Statistics (7 Percent Discount Factor)

Uncertainty Result	Cost Savings (2021 Million Dollars)				
	Minimum	Mean	Maximum	5th Percentile	95th Percentile
Net Industry Benefits (Costs)	\$0.38	\$0.59	\$0.94	\$0.46	\$0.73
Net NRC Benefits (Costs)	\$0.49	\$0.62	\$0.89	\$0.53	\$0.73
Net Benefits (Costs)*	\$0.93	\$1.21	\$1.63	\$1.05	\$1.39

* The net benefits (costs) is not the sum of the above values because these are not normal distributions.

Figure 4 identifies the variables in the staff's analysis with the largest impact on benefits and costs. The variables are ranked by contribution to cost uncertainty, using a 7 percent discount factor. Five variables contribute the greatest uncertainty in costs: (1) industry labor rate, (2) the NRC staff's resources expended on the review of and determination on license renewal applications, (3) the NRC staff's resources expended on the review of and determination on license amendment requests, (4) the NRC's averted costs in reviewing license renewal applications, and (5) the NRC's averted costs in reviewing license amendment applications.

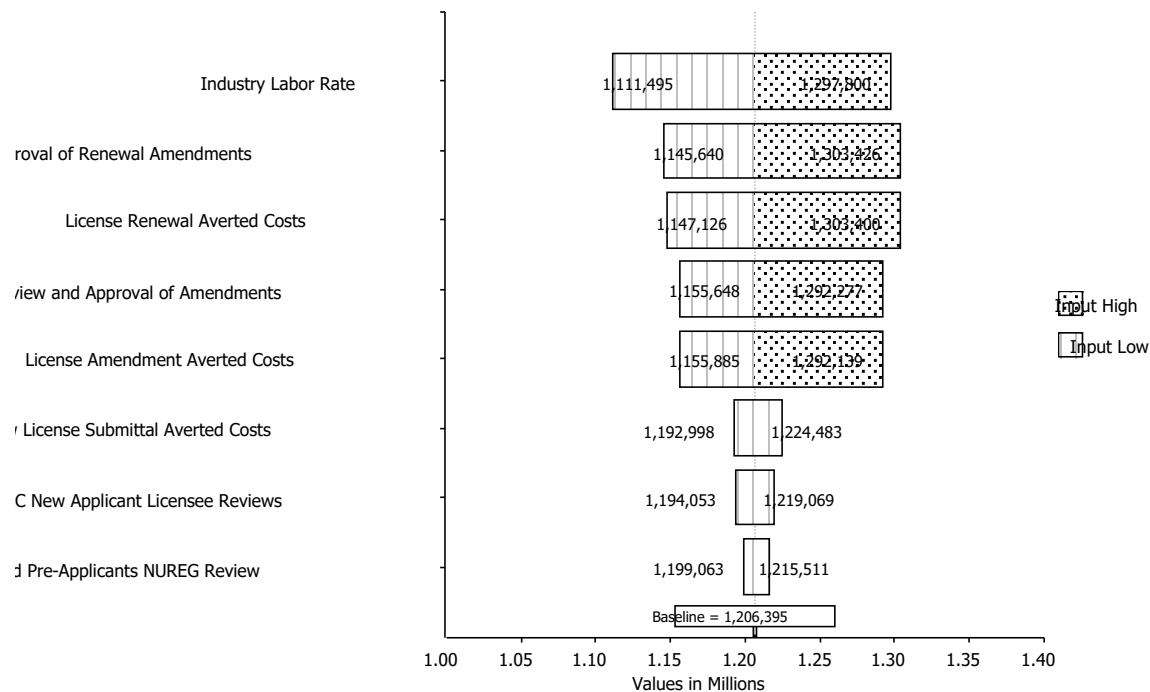


Figure 4 Effect of key variable uncertainty on output mean (7 percent discount factor)

3.5.2 Summary of Uncertainty Analysis

The staff concludes the benefits of issuing NUREG-2212 are a mean net savings to the NRC and to the regulated industry of \$1.206 million, at a 7 percent discount rate. The uncertainty analysis predicts that issuing NUREG-2212 has a greater than 99 percent chance of being cost-effective because the minimum calculated result for all 10,000 simulations is a positive value.

3.6 Disaggregation

The purpose of this section is to discuss the objectives of the proposed action to see whether there are actions recommended that do not support any of the objectives. Because the entire purpose of this action is to publish the NUREG, the staff did not identify any unnecessary or unrelated provisions; therefore, it did not perform a disaggregation for this regulatory analysis.

4 PRESENTATION OF RESULTS

Table 13 summarizes the quantifiable and nonquantifiable costs and benefits that would result from issuing NUREG-2212. Although quantifiable costs and benefits appear to be more tangible, the NRC urges decisionmakers not to discount costs and benefits that are nonquantifiable. The NRC recognizes nonquantifiable benefits or costs can be as (or even more) important than benefits or costs that can be quantified and monetized.

Table 13 Summary of Net Benefit (or Cost)

Monetary Benefit (or Cost)	Nonmonetary Benefit (or Cost)
Alternative 1—No Action \$0	Alternative 1—No Action None
Alternative 2—Issue NUREG-2212 Quantitative Benefits (Costs): NRC Net Benefit: \$0.62 million* using a 7 percent discount rate \$0.93 million using a 3 percent discount rate Industry Net Benefit: \$0.59 million using a 7 percent discount rate \$0.89 million using a 3 percent discount rate Net Quantitative Benefit: \$1.21 million using a 7 percent discount rate \$1.83 million using a 3 percent discount rate	Alternative 2—Issue NUREG-2212 Qualitative Benefits: <ul style="list-style-type: none"> • Addresses the problem of lengthy application reviews and multiple rounds of RAIs due to the lack of submittal standardization. • Provides specific guidance for applicants and licensees to address all the applicable requirements. • Makes available the most current technical information, which helps achieve the NRC's objective of increasing the efficiency of the license review process. • Provides cost savings associated with the NRC's licensing review process. • Enables greater regulatory efficiency and transparency, as applicants will be able to prepare more effectively, and the staff more efficiently review, license applications because of clarity in the staff's technical position and the need for fewer NRC RAIs. • Results in no significant change in public or occupational radiation exposure. Qualitative Costs: <ul style="list-style-type: none"> • None identified. Net Qualitative Benefit: <ul style="list-style-type: none"> • Issuing NUREG-2212 results in a positive qualitative benefit.

* There may be differences among tables due to rounding.

5 DECISION RATIONALE

5.1 Recommendation

NUREG-2212 provides consolidated guidance identifying and describing the information necessary for the NRC's staff review of 10 CFR Part 70 applications for the possession and use of critical mass quantities of SNM not subject to the requirements in 10 CFR Part 70, Subpart H. The NRC staff's cost-benefit analysis of NUREG-2212 demonstrates that the development of clear, standardized guidance for the review of these applications provides substantial benefits to

the NRC by reducing the staff resources needed to complete reviews of applications. Additionally, the issuance of NUREG-2212 should provide substantial benefits to applicants for NRC licenses as well as the industry in general because of the limited availability of NRC guidance specific to this subset of licenses.

The NRC anticipates savings to NRC and the industry over the 20-year regulatory analysis period because reducing the need for RAIs from the NRC staff and reducing redundant case-by-case reviews of the same technical topics would decrease the time required to review and approve new license applications, license amendments, or license renewals. It is anticipated that NUREG-2212 will provide guidance to applicants on the information required in a thorough, high-quality application, thus reducing the need to prepare time-consuming and costly RAI responses for the NRC. The savings to applicants and licensees in the preparation of new license applications, license amendments, and license renewals over the 20-year regulatory analysis period is estimated to be over \$1 million.

Table 11 presents the quantified costs and benefits (averted costs) to both the NRC and industry. The NRC's mean benefit ranges between \$0.61 million (7 percent discount rate) and \$0.90 million (3 percent discount rate). This regulatory analysis shows that the issuance of NUREG-2212 would result in a mean benefit to the industry ranging between \$0.52 million (7 percent discount rate) and \$0.79 million (3 percent discount rate). Therefore, the total quantitative mean net benefit of issuing the guidance would range between \$1.13 million (7 percent discount rate) and \$1.68 million (3 percent discount rate). The non-quantified costs and benefits listed in Table 12 show that issuing the guidance document could result in net benefits to improvements in understanding the NRC's regulations and in streamlining the NRC's licensing reviews, leading to greater regulatory efficiency. The issuance of NUREG-2212 will create clear, standardized, and consolidated guidance for the NRC staff and for the industry.

This regulatory analysis considered quantified and non-quantified costs and benefits and the staff finds that the issuance of NUREG-2212 will result in a beneficial impact. For this reason, the staff concludes that Alternative 2 is the preferred alternative and recommends Alternative 2, the issuance of NUREG-2212.

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Appendix A

List of Applicable Regulations

The following list includes the main requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70, "Domestic Licensing of Special Nuclear Material," that are applicable to licensees authorized (and applicants seeking authorization) to possess special nuclear materials in critical mass quantities not subject to the requirements in 10 CFR Part 70, Subpart H. (**Note:** Other 10 CFR Part 70 requirements may apply as determined by the Commission.)

- 70.9 Completeness and accuracy of information
- 70.21 Filing, (f)
- 70.22 Contents of applications, (a)(1), (2), (3), (4), (6), (7), and (8)
- 70.23 Requirements for the approval of applications, (a)(1), (2), (3), (4), (5), (6), (9) and (10)
- 70.24 Criticality accident requirements
- 70.25 Financial assurance and recordkeeping for decommissioning
- 70.41 Authorized use of special nuclear material, (a)
- 70.42 Transfer of special nuclear material.
- 70.50 Reporting requirements
- 70.51 Records requirements
- 70.52 Reports of accidental criticality
- 70.55 Inspections
- 70.56 Tests
- 70.81 Modification and revocation of licenses
- 70.91 Violations
- 70.92 Criminal penalties

SUBJECT: DRAFT Regulatory Analysis for NUREG-2212, "Standard Review Plan for Applications for Title 10 of the *Code of Federal Regulations* Part 70 Licenses for Possession and Use of Special Nuclear Materials of Critical Mass But Not Subject to the Part 70 Subpart H Requirements", December 2022

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ADAMS Accession No.: ML16278A367 (Package) ML20233A221 (Regulatory Analysis)

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