Regulatory Analysis for the Exempt Distribution of Products Containing Byproduct Material Incidental to Their Production Proposed Rule

RIN No.: 3150-AJ54; NRC Docket ID: NRC-2015-0017

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Division of Rulemaking, Environmental, and Financial Support

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ABSTRACT

Items containing byproduct material incidental to production are irradiated products that serve a useful purpose and contain a minor amount of residual radiation incidental to the production process. The residual byproduct material is not part of the intended end use of the products. Current U.S. Nuclear Regulatory Commission regulations do not address these items, examples of which include polycarbonate track etched membranes, irradiated gemstones, and certain silicon materials used in the electronics industry.

The NRC is conducting this rulemaking to allow for the licensing of this class of irradiated products under Title 10 of the Code of Federal Regulations (10 CFR) Part 30, "Rules of general applicability to domestic licensing of byproduct material," and 10 CFR Part 32, "Specific domestic licenses to manufacture or transfer certain items containing byproduct material." These changes address issues raised in petition for rulemaking PRM-30-65, "Petition for Rulemaking Pursuant to 10 CFR § 2.802 On Behalf of GE Osmonics Inc.," dated April 18, 2011 (Agencywide Documents Access and Management System Accession No. ML120250133), from GE Osmonics, Inc. (the petitioner). Furthermore, the proposed rule is expected to have both quantitative as well as qualitative benefits, i.e., (1) reduction in the regulatory burden on the licensees by requiring only dose-criteria rather than both dose and concentration criteria; (2) assurance that the NRC's regulations continue to be consistent with new emerging materials, avoiding product-specific rulemakings for future technologies; and (3) consistency with the NRC's current approach to licensing classes of exempt materials and products.

Table ES-1 below lists the areas analyzed by the NRC, including the staff-recommended action and estimates of cost and potential benefits by issue. All costs are in 2021 dollars and are calculated using a 7-percent discount rate.

Table ES-1 Recommended Action and Estimated Costs and Savings

Description	Net Benefit (Cost) by Affected Entity (7% NPV) [a,b,c]			
	Industry	NRC	Agreement States	Total (2021$)
Alternative 1 Status Quo - Do Nothing Different				
Averted NRC Rulemaking Discontinuation Costs (SECY, Letter, and FRN)	$0	$0	$0	$0
License Distributors and End Users	$0	$0	$0	$0
Alternative 1 Net Benefits (Costs)	$0	$0	$0	$0
Alternative 2 Proceed with a Rulemaking Inclusive of Items Containing Byproduct Material Incidental to Production (staff's recommendation)				
Item A: Rulemaking Implementation Costs Excluding Rulemaking Termination Costs	$0	($337,000)	($1,460,000)	($1,797,000)
Item B: PCTE Only	($7,239,000)	($184,000)	$0	($7,423,000)
Item C: Silica Chip Only	($61,000)	($84,000)	$0	($145,000)
Item D: Gemstone Only regulated §32.11(c) exemption	$29,000	$40,000	$0	$69,000
Averted Alternative 1 Costs (SECY, Letter, and FRN)	$10,489,000	$12,213,000	$0	$22,702,000
Alternative 2 Net Benefits (Costs)	$3,219,000	$11,648,000	($1,460,000)	$13,407,000

[a] The total net benefit results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

[b] Benefits and averted costs are positive. Costs are (negative).

[c] There may be differences between tables due to rounding.

The total cost in Table ES-1 includes estimates of the NRC implementation costs for 2 years, and the operational costs, where applicable, during the first 15 years after the effective date of the rule. The staff chose this time frame because this is the term of the license. The cost estimates in Table ES-1 represent the net present value of costs (real expense) and averted costs (potential savings). The proposed rulemaking (Alternative 2) recommended by the staff would result in a total net overall savings of $13,407,000 using a 7-percent discount rate.

The proposed rulemaking cost estimate represents the following estimated costs and benefits for the NRC, Industry, and the Agreement States:

- The NRC is expected to result in a net savings of $11,648,000. This includes the rulemaking development and implementation cost of ($337,000).
- Agreement States are expected to incur a cost of ($1,460,000). This estimate represents the implementation cost of the proposed rulemaking by the Agreement States; the rulemaking action will not result in any operation costs to the Agreement States. The Agreement States do not experience savings in licensing their distributors and end users that the NRC benefits from because the exempt distribution regulations are “Compatibility Category NRC,” which the Agreement States do not adopt.
- The proposed rule would result in a net savings to the industry of $3,219,000. This net savings represents operational savings resulting from applying the new rule and implementation activities. Industry implementation costs include procedural and administrative activities including reviewing and commenting on the proposed rule, reading the final rule, and revising procedures and processes to comply.

The proposed rulemaking is cost-justified in that net benefits that would be realized compared to the status quo are estimated to exceed the rulemaking costs and industry implementation costs. The proposed rule addresses nearly all of the issues and would result in net savings to the industry. It is estimated that the proposed rule, if implemented, would result in a net savings of $3,219,000 in averted costs to the licensees. This net savings value is based on 7-percent discounting over a 15-year horizon.

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Abbreviations and Acronyms

ADAMS	Agencywide Documents Access and Management System
A/S	Agreement State
CFR	Code of Federal Regulation
CoC	Certificate of Compliance
ES	Executive Summary Table
FR	Federal Register
FRN	Federal Register Notice
GE	General Electric
IAEA	International Atomic Energy Agency
µSv	microsieverts
NPV	Net Present Value
NRC	U.S. Nuclear Regulatory Commission
NUREG	Nuclear Regulatory Publication
PCTE	Polycarbonate Track Etched Membranes
PERT	Program Evaluation and Review Technique
PRM	Petition for Rulemaking
Rem	Roentgen Equivalent Man
SDA	Standard Design Approval
SRM	Staff Requirements Memorandum

Executive Summary

Items containing byproduct material incidental to production are irradiated products that serve a useful purpose and contain a minor amount of residual radiation incidental to the production process. The residual byproduct material is not part of the intended end use of the products. Current U.S. Nuclear Regulatory Commission regulations do not address these items, examples of which include polycarbonate track etched membranes, irradiated gemstones, and certain silicon materials used in the electronics industry.

The NRC is conducting this rulemaking to allow for the licensing of this class of irradiated products under Title 10 of the Code of Federal Regulations (10 CFR) Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," and 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material." These changes address issues raised in petition for rulemaking PRM-30-65, "Petition for Rulemaking Pursuant to 10 CFR 2.802 On Behalf of GE Osmonics Inc.," dated April 18, 2011 (Agencywide Documents Access and Management System Accession No. ML120250133), from GE Osmonics, Inc. (the petitioner).

Under the staff recommended alternative, the proposed rule would (1) establish standards for the exempt distribution of products that contain byproduct material that is incidental to production, and (2) establish ongoing requirements for the exempt distribution of products approved fordistribution under the new provision.

The alternative considered is shown in Table ES-1: Executive Summary Table Recommended Action and Estimated Costs and Savings. Table ES-1 below lists the items analyzed by the NRC, including the staff-recommended alternative and estimates of cost and potential benefits by issue. All costs are in 2021 dollars and are calculated using a 7-percent discount rate. Alternative 2 results in an averted cost of $13,407,000 at 7 percent.

Table ES-1 Recommended Action and Estimated Costs and Savings

Description	Net Benefit (Cost) by Affected Entity (7% NPV)			
	Industry	NRC	Agreement States	Total (2021$)
Alternative 1 Status Quo - Do Nothing Different				
Averted NRC Rulemaking Discontinuation Costs (SECY, Letter, and FRN)	$0	$0	$0	$0
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[a] The total net benefit results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.

[b] Benefits and averted costs are positive. Costs are (negative).

[c] There may be differences between tables due to rounding.

The total cost in Table ES-1 includes estimates of the NRC implementation costs for 2 years, and the operational costs, where applicable, during the first 15 years after the effective date of the rule. The staff chose this time frame because, on average, the NRC rulemaking to has followed a 15-year cycle. This requires applicants for subsequent license renewals to submit a renewal application no later than 15 years. The proposed rulemaking (Alternative 2) recommended by the staff would result in a net overall savings of $13,407,000.

The proposed rulemaking cost estimate represents the following estimated costs for the Agreement States (A/S), combined with an estimated net savings to the NRC and Industry:

- The NRC is expected to result in a net savings of $11,648,000. This includes the rulemaking development and implementation cost of ($337,000).
- Agreement States are expected to incur a cost of ($1,460,000). This estimate represents the implementation cost of the proposed rulemaking by the Agreement States; the rulemaking action will not result in any operation costs to the Agreement States. The Agreement States do not benefit from the averted costs that the NRC benefits from because the exempt distribution regulations are “Compatibility Category NRC,” which the Agreement States do not adopt.
- The proposed rule would result in a net savings to the industry of $3,219,000. This net savings represents operational savings resulting from applying the new rule and implementation activities. Industry implementation activities include procedural and administrative activities including reviewing and commenting on the proposed rule, reading the final rule, and revising procedures and processes to comply.

The proposed rulemaking is cost-justified in that net benefits that would be realized compared to the status quo are estimated to exceed the rulemaking costs and industry implementation costs. The proposed rule addresses nearly all the issues, and would result in net savings to the industry. It is estimated that the proposed rule, if implemented, would result in a net savings of $3,219,000 in averted costs to the licensees. This net savings value is based on 7% discounting over a 15-year horizon. Furthermore, the proposed rule is expected to have both quantitative and qualitative benefits, i.e., (1) reduction in regulatory burden on the licensees by requiring only dose-criteria rather than both dose and concentration criteria; (2) assurance that the NRC’s regulations continue to be consistent with new emerging materials, avoiding product-specific rulemakings for future technologies; and (3) consistency with the NRC’s current approach to licensing classes of exempt materials and products.

1. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is conducting this rulemaking to allow for the licensing of this class of irradiated products under Title 10 of the Code of Federal Regulations (10 CFR) Part 30, “Rules of general applicability to domestic licensing of byproduct material,” and 10 CFR Part 32, “Specific domestic licenses to manufacture or transfer certain items containing byproduct material.” These changes address issues raised in petition for rulemaking PRM-30-65, “Petition for Rulemaking Pursuant to 10 CFR § 2.802 On Behalf of GE Osmonics Inc.,” dated April 18, 2011 (Agencywide Documents Access and Management System Accession No. ML120250133), from GE Osmonics, Inc. (the petitioner). This rulemaking would add a new class exemption from licensing and associated distribution requirements. This new class exemption would create a path for licensing current and future products that contain byproduct material incidental to production.

2. Statement of the Problem and Objective

2.1 Background

PCTE membranes are used in a variety of research, medical, pharmaceutical, academic, scientific, and industrial applications. The membranes are irradiated to create uniform pore size and distribution, but themanufacturing process leaves behind small amounts of mixed fission products in the membranes. Based on the NRC’s review of the product safety analyses submitted by the petitioner (ADAMS Accession No. ML120800277), the incidental radioactivity of these products presents de minimus risk to public health and safety.

The NRC docketed the petition in November 2011. On September 14, 2012, the NRC published a notice in the *Federal Register* (FR) (77 FR 56793), stating that the petitioner raised a valid regulatory issue about the commercial distribution of PCTE membranes and that the NRC would consider the issue in the rulemaking process.

Under 10 CFR Part 30, the NRC regulates the manufacturing, production, transfer, receipt, acquisition, ownership, possession, and use of byproduct material. NRC Agreement States maintain compatible regulatory requirements regarding their jurisdiction. Typically, the NRC and Agreement States regulate these processes through a specific or general license. Additionally, the regulations in 10 CFR 30.11, “Specific exemptions,” through 10 CFR 30.22, “Certain industrial devices,” provide exemptions from certain licensing requirements. One of these exemptions appears in 10 CFR 30.14, “Exempt concentrations.”

Under 10 CFR 30.14, the NRC exempts any person from licensing requirements if the productor material contains byproduct material in concentrations not in excess of those listed in 10 CFR 30.70, “Schedule A—Exempt concentrations.” The regulations in 10 CFR 30.14 do not permit the transfer of byproduct material contained in a product that is designed to be ingested,inhaled, or applied to a human being. Additionally, 10 CFR Part 30 does not permit the introduction of byproduct material into a product, even in exempt concentrations, unless the person introducing the byproduct material has a specific license issued under 10 CFR 32.11, “Introduction of byproduct material in exempt concentrations into products or materials, and transfer of ownership or possession: Requirements for license.”

The regulations in 10 CFR 32.11 provide the requirements for obtaining a specific license authorizing the introduction of byproduct material into a product or material that will eventually be transferred to a person exempt, in accordance with 10 CFR Part 30, from the licensing requirements.

These current regulations do not cover items that contain byproduct material incidental to production; therefore, these items cannot be licensed for exempt transfers. This class of products includes irradiated gemstones; however, in the staff requirements memorandum (SRM) for SECY-87-186A (ADAMS Accession No. ML092400170), the NRC allowed the interim licensingof irradiated gemstones pursuant to exemptions applied to 10 CFR 32.11 and 10 CFR 30.14. The NRC determined that this practice would not be appropriate for regulating all irradiated items of this type, for the reasons outlined below in Section 3.

2.2 Need of the Proposed Action

The current regulations in 10 CFR Part 30 and 10 CFR Part 32 do not support the exempt distribution for the class of products containing byproduct material incidental to production.

Specifically, both 10 CFR 30.14 and 10 CFR 32.11 provide that the concentrations of byproduct material in a product do not exceed the values listed in Schedule A in 10 CFR 30.70. However, Schedule A would not be appropriate for this class of products for the following reasons.

First, the concentrations in Schedule A pertain to volumetric concentrations in an item containing byproduct material. While volumetric concentrations are useful and appropriate for some products, the NRC is aware of certain products (e.g., polycarbonate membranes, which are thin films) for which volumetric concentrations would not be appropriate due to the products'shape. Consequently, the basis for volumetric concentrations in Schedule A would not be applicable to several items that are in this class of products.

Second, the maximum concentration limits of Schedule A are based on the potential internal dose from the product from continuous occupational exposure. Potential exposures from the irradiated products under consideration involve mainly external exposures, and concentration values, based on continuous internal occupational exposure, are not representative in these situations. Therefore, the Schedule A concentration limits would not beappropriate for this class of products.

Third, the list of radionuclides in Schedule A is not comprehensive for all potential radionuclides in this class of products. While some of the potential radionuclides in these products would fall within the catch-all provision of Schedule A (i.e., beta- or gamma-emitting byproduct material with a half-life less than 3 years), Schedule A will not capture other radionuclides that are in this class of products. For example, PCTE membranes are exposed to nuclear fission fragments, including strontium-90, which remain embedded in the membranes. Schedule A has never specifically included strontium-90 in the table, and strontium-90 would not fall under the catch-all provision of Schedule A because its half-life is more than 27 years. As a result, Schedule A would not include several items that would be in this class of products, such as PCTE membranes, because it does not capture, either specifically or in the catch-all provision, all radionuclides that may be in these products.

Fourth, under the exemption provided by 10 CFR Part 30 and the requirements for a license under 10 CFR 32.11, these irradiated products must not be designed to be ingested, inhaled, or applied, to a human being. However, some items in this class of products could be ingested, inhaled, or applied to a human being. As a result, this prohibition makes the current regulatory structure inappropriate for this class of products.

For the reasons noted above the existing regulatory structure does not support the licensing and distribution of this class of products, under the exempt products category. Nevertheless, these irradiated products are widely used in a variety of beneficial applications, and a regulatory structure provides certainty in a pathway to licensing for this class of products. As a result, revising the regulations is appropriate to allow the potential use of these products under the exemption and distribution provisions in 10 CFR Part 30 and 10 CFR Part 32.

2.3 Objectives

The NRC is conducting this rulemaking to allow for the licensing of this class of irradiated products under Title 10 of the Code of Federal Regulations (10 CFR) Part 30, "Rules of general applicability to domestic licensing of byproduct material," and 10 CFR Part 32, "Specific domestic licenses to manufacture or transfer certain items containing byproduct material." The current regulations in 10 CFR Parts 30 and 32 do not support the exempt distribution for the class of products containing byproduct material incidental to production.

Specifically, the provisions of both §§ 30.14 and 32.11 provide that the concentrations of byproduct material in a product not be in excess of the values listed in Schedule A in § 30.70. However, Schedule A is not inclusive of all isotopes in this class of irradiated products.

3. Identification and Preliminary Analysis of Alternatives

The NRC analyzed the Status Quo and Rulemaking alternatives to the proposed rule as described in this section.

3.1 Alternative 1: Status Quo Take No Action

The NRC's Consumer Product Policy Statement, published in the *Federal Register* on January 16, 2014 (79 FR 2907), states that the NRC should evaluate the overall safety impact of products allowed to be distributed for use by the general public. Products are normally used under an exemption from licensing and from all associated regulatory requirements. The policy statement notes that the general criterion for approval of products containing radioactive material depends on the resulting radiation exposures to the public and the apparent usefulness of the product. Under this alternative, the NRC would continue to rely on existing regulations, orders, and guidance, and no resources would be necessary to perform rulemaking activities. These products are widely used, and this alternative would require each manufacturer, distributor, and user of an irradiated item in this class, except gemstones (see Section 2), to possess a specific license. The resources associated with this approach are outlined in Appendix A. Preparing and evaluating each specific license request would also require NRC resources, as outlined in Appendix A. Without this rulemaking, potential applicants would need to apply for a

specific license to distribute these products, and the end user would need to obtain a possession license to use the products, resulting in additional cost. These costs make the distribution of items such as PCTE membranes and future irradiated products financially challenging, using the current regulatory structure. Further, recognizing the National Materials Program, each Agreement State would need to issue a specific license for these materials, which may cause transboundary issues. Gemstone licensees would continue to be licensed under the current framework and would continue to provide concentration and dose-based criteria in their applications. Additionally, this alternative would require the NRC to prepare a Commission paper, a letter to the petitioner, and a *Federal Register* notice (FRN) to deny the petition and close out PRM-30-65.

For these reasons, continuing with Alternative 1 results in costs to the Licensee Distributors and End Users, as well as the NRC. The costs incurred as described in the preceding two paragraphs are shown as averted costs or benefits in Alternative 2 if Alternative 2 is selected. This is done to show Alternative 1 as the no-cost baseline.

3.2 Alternative 2: Rulemaking

The rulemaking will amend 10 CFR Part 30 and 10 CFR Part 32 to (1) add to 10 CFR Part 30 a new class exemption from licensing requirements and (2) add associated distribution requirements to 10 CFR Part 32. These changes would apply dose criteria, rather than concentration, as the primary means of protecting health and safety. These proposed changes would fully address PRM-30-65, provide a regulatory framework for current (e.g., gemstones) and future irradiated products, and allow this class of products to be licensed without product-specific exemptions that require additional rulemaking in the future. This new regulatory structure would require a licensee to meet only dose-based criteria, which would reduce the burden on current gemstone licensees, who are currently required to provide both concentration and dose-based criteria, as well as limit the NRC's review to only dose-based criteria in the license applications.

In addition to providing dose measurements, the current distributors of irradiated gemstones use a variety of measurements and statistical analysis methods to demonstrate that the concentration of byproduct material at the time of sale to consumers is unlikely to exceed the concentration limits in 10 CFR Part 30 (and derived concentrations for those not specifically included). Under the new provisions, current licensees and applicants (initial distributor or transferrer) would demonstrate that their products are unlikely to result in doses exceeding the dose criteria in the new provisions.

The NRC will amend 10 CFR Part 30 to add a new section specific to products containing byproduct material that is not part of the intended end use of the product but instead is present as a result of production. This new section would only apply to processes that unavoidably result in the incidental addition of byproduct material to the final product. The NRC would add companion paragraphs to 10 CFR 32.11 with the applicable licensing requirements for distribution. The new section in 10 CFR Part 30 would only apply to those products or materials that have an exempt distribution license under 10 CFR 32.11. In the past, the NRC has established class exemptions for categories of products or devices with similar characteristics, rather than establishing individual exemptions for each product. These exemptions appear in 10 CFR Part 30,

"Self-luminous products containing tritium, krypton-85, or promethium-147";
10 CFR 30.20, "Gas and aerosol detectors containing byproduct material"; and
10 CFR 30.22, "Certain industrial devices." The planned rulemaking approach is similar to that for 10 CFR 30.19, 10 CFR 30.20, and 10 CFR 30.22 in that the regulatory structure would allow new products to be licensed without product-specific exemptions, each of which would otherwise require additional rulemaking. Public health and safety are ensured by evaluating each specific product against safety criteria contained in the regulations that apply to all products in a class.

The new provision would be similar in some respects to the class exemptions in the current regulations in that it would require applicants requesting authorization to distribute a product or material to demonstrate that the product or material would meet certain safety criteria. The NRC specifies these safety criteria in 10 CFR 32.23, "Same [specific domestic licenses to manufacture or transfer certain items containing byproduct material]: Safety criteria"; 10 CFR 32.27, "Same [specific domestic licenses to manufacture or transfer certain items containing byproduct material]: Safety criteria"; and 10 CFR 32.31, "Certain industrial devices containing byproduct material: Safety criteria." These safety criteria would form the primary means of ensuring adequate protection of public health and safety. Applicants requesting authorization to manufacture, possess, or distribute items containing byproduct material incidental to production would be required to demonstrate compliance with the safety criteria. These criteria would cover normal use, handling, storage, marketing, distribution, installation, servicing, and disposal as well as potential accidents and misuse.

Under this alternative, the NRC would issue a proposed rule in the *Federal Register* that would:

(1) Establish standards for the exempt distribution of products that contain byproduct material that is incidental to production. These standards would include requiring applicants to provide information relating to the design, manufacture, prototype testing (if applicable), quality control procedures, labeling and marking, and conditions of handling,storage, use, and disposal of the products to demonstrate that the product would meet the following specific safety criteria:

   (a) dose limits to the general public and those occupationally exposed[1] to theproduct, including through transportation, distribution, use, and disposal

   (b) prototype testing (if applicable) to demonstrate the degree of binding or containment under the most severe conditions likely to be encountered in normaluse of the product

(2) Establish ongoing requirements for the exempt distribution of products approved fordistribution under the new provision:

   (a) labeling requirements for final product packaging
   (b) quality control/quality assurance
   (c) recordkeeping and annual transfer reporting

Individuals occupationally exposed include users of PCTE membranes, truck drivers, warehouse workers, and waste disposal workers. For the class exemptions, the existing criteria for such groups are 5–20 millirem (mrem)/year (50–200 microsieverts (μSv)/year) except for disposal scenarios, for which the criterion is 1 mrem/year (10 μSv/year), because the same individuals could be impacted by all of the products allowed to be disposed in landfills and municipal incinerators.

This generic provision would present a more appropriate regulatory framework for irradiated products of this class. It would allow for new products and materials to be developed, evaluated, and licensed under a framework that would adequately protect health and safety without the need for additional rulemaking. The safety criteria would be robust enough to cover any potential future irradiated products. In the long term, these comprehensive proposed changes would be the most cost-effective solution to the NRC and the industry because other irradiated products are expected to be brought to market in the future.

The NRC is issuing draft guidance in conjunction with this proposed rule. Current guidance on 10 CFR parts 30 and 32 for exempt distribution licenses is provided in NUREG-1556, Volume 8, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses." The draft guidance is intended for use by applicants, licensees, Agreement States, and the NRC staff when preparing and evaluating an exempt distribution licensing action for items containing byproduct material incidental to production. These exempt distribution licenses will authorize the initial distribution of byproduct material incidental to production to persons exempt from the regulatory requirements (exempt distribution) for an NRC license under 10 CFR part 30 and exempt from licensing requirements under the equivalent provisions in Agreement State regulations.

3.3 Issue Guidance to Address Without Rulemaking

Regulatory guides and NUREGs provide guidance to licensees and applicants for carrying out specific parts of the NRC's regulations, for techniques used by the NRC staff in evaluating specific problems or postulated accidents, and for data needed by the NRC staff in its review of applications for permits or licenses.

Under this alternative, the NRC would revise, during its regular revision schedule, NUREG-1556, "Consolidated Guidance about Materials Licenses," Volume 8, Revision 1, "Program-Specific Guidance About Exempt Distribution Licenses," issued June 2018 (ADAMS Accession No. ML18158A165), which contains guidance for the issuance of licenses authorizing distribution to exempt persons. The NRC would revise NUREG-1556 to include licensing guidance specific to items containing byproduct material incidental to production.

However, guidance cannot impose new requirements on licensees and, therefore, guidance alone is not a viable approach to provide for the use of a product under exemption from licensing. Therefore, reliance on guidance alone to resolve this regulatory issue is not possible.

4. Estimation and Evaluation of Costs and Benefits

This section describes the process for evaluating the costs and benefits expected to result from Alternative 2 relative to the regulatory baseline (Alternative 1).

4.1 Basis for Cost and Savings Estimates

The following is a summary of the implementation and operational costs to industry (licensees), the NRC, and the Agreement States. Each attribute describes how Alternatives 1 and 2 impacts each attribute. Included in the description are what additional activities would be required and what specific costs would be avoided.

4.2 Identification of Affected Attributes

This section identifies the components of the public and private sectors, commonly referred to as "attributes," that are expected to be affected by the Alternative 1 Status Quo or Alternative 2 Rulemaking. The inventory of the attributes listed in NUREG/BR-0058 Revision 5 were used to determine impacts. The alternatives would apply to licensees and applicants for licensing of this class of irradiated products under Title 10 of the Code of Federal Regulations (10 CFR) Part 30, "Rules of general applicability to domestic licensing of byproduct material," and 10 CFR Part 32.

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. Normal costs (actual expenses) are considered negative, and cost savings and averted costs are considered positive. There are no Industry implementation costs.

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. For Alternative 2, Industry would incur a cost for PCTE and Silica Chip licensing activities of ($7,239,000) and ($61,000) respectively. Gemstones have an averted cost of $29,000.

NRC Implementation. This attribute accounts for the projected net economic effect on the NRC if the rule is implemented. It includes NRC implementation costs for rulemaking including developing regulatory guides, developing the proposed rule, comment resolution for the final rule, and potential savings relative to those expected under the regulatory baseline as described in section 4.4.1. This is estimated to result in a cost of ($337,000).

NRC Operation. This attribute accounts for the projected net economic effect on the NRC after the rule is developed and implemented. For Alternative 2, the NRC would incur a cost for reviewing PCTE and Silica Chip licensing activities of ($184,000) and ($84,000) respectively. Gemstones have an averted cost of $40,000.

Agreement States Implementation. This attribute accounts for the projected net economic effect on the Agreement States to implement all the mandated changes in Parts 30 and 32. Costs include procedural and administrative activities related to harmonizing State regulations with NRC policy and other guidance documents.

NMSS procedure SA-200 describes the categories related to harmonizing State regulations with NRC policy. The Agreement States must have compatible regulations for those regulations that are Compatibility Categories A, B, C, and Health and Safety. Regulations that are a D compatibility category are not required for compatibility purposes, but Agreement States can adopt those as well if they want. Compatibility Category NRC regulations are those which the Agreement States cannot adopt because these are strictly for NRC use.

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 States implementation costs were estimated based on the following considerations:

- The number of Agreement States is 39 based on NRC data located at "https://scp.nrc.gov/rulemaking.html". However, the number of affected Agreement States is 38. The State of Wyoming is not included in this count at this time because Wyoming has a limited Agreement that does not include materials subject to the regulations in this rulemaking.
- The average hourly rate range for a State employee is $95/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.

The NRC determined that there are implementation costs incurred by the Agreement States because of the proposed rule. Agreement States are expected to incur a cost of ($1,460,000). The Agreement States do not benefit from the averted costs that the NRC benefits from because the exempt distribution regulations are "Compatibility Category NRC," which the Agreement States do not adopt.

Agreement States Operation. The rulemaking action will not result in any operation costs to the Agreement States.

4.3 Evaluation of Cost and Benefits for Alternative 2

This section discusses the cost and potential impacts of the proposed changes presented in Section 4 on licensees, the NRC, and Agreement States. The analyses presented in this section are based on the NRC's initial assessment. The NRC considered two alternatives: the status quo (Alternative 1) and rulemaking (Alternative 2). Appendix A provides the assumptions and assessment supporting the cost analysis.

4.4 Analytical Methodology

This section describes the process used to evaluate costs and benefits associated with Alternative 2. The benefits of Alternative 2 include any desirable changes in affected attributes (e.g., monetary savings, improved safety, and improved security). The costs include any undesirable changes in affected attributes (e.g., monetary costs, increased exposures). All costs and benefits are monetized, when possible. The total costs and benefits are then summed to determine whether the difference between the costs and benefits results in a positive benefit. In some cases, costs and benefits are not monetized because meaningful quantification is not possible.

Of the 10 affected attributes, the analysis evaluates four on a quantitative basis, "industry implementation, industry operation, NRC implementation, and NRC operation." Quantitative analysis requires a baseline characterization of the affected society, including factors such as the number of affected entities, the nature of the activities currently performed, and the types of systems and procedures that licensees or applicants would implement, or would no longer implement, because of the alternatives. Where possible, the staff calculated costs for these five attributes using three-point estimates to quantify the uncertainty in these estimates. The detailed cost tables used in this regulatory analysis are included in the individual sections for each of the provisions.

The NRC evaluated the remaining attributes on a qualitative basis because some benefits relating to consistent policy application and improvements in ISI and IST techniques are not quantifiable or because the data necessary to quantify and monetize the impacts on these attributes are not available.

- Improvements in Knowledge: This attribute accounts for improvements in knowledge acquired as the industry and the staff gain experience with new technology before its incorporation into Part 30 and Part 32 and by permitting licensees to avoid costs in asking for incorporating new technologies.

- Regulatory Efficiency: This attribute accounts for regulatory and compliance improvements resulting from the implementation of Alternative 2 relative to the regulatory baseline. Alternative 2 would continue the best practice of aligning NRC regulations with ICBMIP licensing standards, reducing the effort the industry expends generating these requests and considering alternative means to accomplish the goals of these provisions.

- Other Considerations: This attribute accounts for considerations not captured in the preceding attributes. Specifically, this attribute accounts for how Alternative 2 meets specific requirements of the Commission, helps achieve NRC policy, and provides other advantages.

- Attributes with No Effects: Attributes not expected to be affected under any of the alternatives include considerations of public health (routine), offsite property, onsite property, the public, and safeguards and security.

The staff documents its assumptions throughout this regulatory analysis. For reader convenience, Appendix A summarizes the major assumptions and input data.

4.4.1 Regulatory Baseline

This regulatory analysis identifies the incremental impacts of Alternative 2 relative to a baseline (Alternative 1, the Status Quo alternative). The final rule is compared to a baseline that reflects anticipated behavior if the NRC does not undertake regulatory or nonregulatory action (Alternative 1, the Status Quo alternative). The regulatory baseline assumes full compliance with existing NRC requirements, including current regulations and relevant orders. This is consistent with NUREG/BR-0058, Revision 5 "U.S. Nuclear Regulatory Commission Guidance on Performing Cost-Benefit Analyses", ADAMS Accession No. ML17221A000 which states that in evaluating a new requirement, the staff should assume that all existing NRC and Agreement States requirements have been implemented." Section 6 of this regulatory analysis presents the estimated incremental costs and benefits of the alternatives compared to this baseline.

4.4.2 Affected Entities

The proposed changes would provide a regulatory framework for the distribution of irradiated products (e.g., gemstones and PCTE membranes) for current and future NRC licensees. The proposed rule would affect approximately 27 licensees that are subject to the rulemaking and manufacture and/or distribute items containing byproduct material incidental to production, some of which may qualify as small business entities as defined by 10 CFR 2.810. Based upon historical data, the staff estimates that approximately 2 out of the 27 estimated licensees subject to this rulemaking, may qualify as small business entities as defined by 10 CFR 2.810. These 2 small business entities are anticipated to be gemstone licensees. It is expected that all businesses will incur the same savings resulting from the licensing process. These savings are a small percentage of the gross sales; therefore, we conclude that there will be no significant economic impact to small business entities. On the basis of the draft regulatory analysis conducted for this action the estimated averted cost of the proposed rule for affected licensees is $40,000 at 7 percent. The NRC believes that the selected alternative reflected in the proposed rule is the least burdensome, most flexible alternative that would accomplish the NRC's regulatory objective.

Licensees currently distributing irradiated gemstones under 10 CFR 32.11, for use under 10 CFR Part 30, can amend their licenses to comply with the new provisions at the time of the next license renewal. These new provisions will be substantially less burdensome because the licensee would not need exemptions under the new provision and would not be required to submit the concentration data for review.

4.4.3 Base Year

All monetized costs are expressed in 2021 dollars. Ongoing costs of operation related to the alternative being analyzed are assumed to begin no earlier than 30 days after publication of the final rule in the *Federal Register* unless otherwise stated, and they are modeled on an annual cost basis. The NRC assumes that the rule will be effective in 2024.

One-time NRC implementation costs related to rulemaking are considered sunk costs at the final rule stage.

Recurring annual operating expenses are estimated. The values for annual operating expenses are modeled as a constant expense for each year of the analysis horizon where

appropriate. The NRC performed a discounted cash flow calculation to discount these annual expenses to 2021 dollar values.

4.4.4 Discount Rates

In accordance with guidance from U.S. Office of Management and Budget (OMB) Circular A-4, "Regulatory Analysis," issued October 2003 (OMB, 2003), and NUREG/BR-0058, draft Revision 5, net present value (NPV) calculations are used to determine how much society would need to invest today to ensure that the designated dollar amount is available in a given year in the future. By using NPVs, costs and benefits, regardless of when the cost or benefit is incurred, are valued to a reference year for comparison. The choice of a discount rate and its associated conceptual basis is a topic of ongoing discussion within the Federal Government. Based on OMB Circular A-4 and consistent with NRC past practice and guidance, present-worth calculations in this analysis use 3-percent and 7-percent real discount rates. A 3-percent discount rate approximates the real rate of return on long-term Government debt, which serves as a proxy for the real rate of return on savings to reflect reliance on the discounting concept of social rate of time preference.[1] A 7-percent discount rate approximates the marginal pretax real rate of return on an average investment in the private sector, and it is the appropriate discount rate whenever the main effect of a regulation is to displace or alter the use of capital in the private sector. A 7-percent rate is consistent with an opportunity cost[2] of capital concept to reflect the time value of resources directed to meet regulatory requirements.

4.4.5 Cost/Benefit Inflators

The NRC estimated the analysis inputs for some attributes based on the values published in the sources referenced, which are provided in prior year dollars. To evaluate the costs and benefits consistently, these inputs are put into base year dollars. The most common inflator is the Consumer Price Index for All Urban Consumers (CPI-U), developed by the U.S. Department of Labor, Bureau of Labor Statistics (BLS). Using the CPI-U, the prior year dollars are converted to 2021 dollars. The following formula is used to determine the amount in 2021 dollars:

$$\frac{CPI - U_{2021}}{CPI - U_{Base\ Year}}\ x\ Value_{Base\ Year} = Value_{2021}$$

Table 1 summarizes the values of CPI-U used in this regulatory analysis.

[1] The "social rate of time preference" discounting concept refers to the rate at which society is willing to postpone a marginal unit of current consumption in exchange for more future consumption.

[2] "Opportunity cost" represents what is foregone by undertaking a given action. If the licensee personnel were not engaged in revising procedures, they would be occupied by other work activities. Throughout the analysis, the NRC estimates the opportunity cost of performing these incremental tasks as the industry personnel's pay for the designated unit of time.

Table 1 CPI-U Inflator

Base Year	CPI-U Annual Average	Percent Change from Previous Year
2021	264.71 [a]	
2022	271.06 [a]	2.40%
2023	277.84 [b]	2.50%
2024	284.74 [b]	2.45%

Sources:
[a] BLS, "Databases, Tables & Calculators by Subject: CPI Inflation Calculator," issued May 2020 (BLS, 2020).
[b] Congressional Budget Office, "The Budget and Economic Outlook: 2019 to 2029," issued January 2020 (Congressional Budget Office, 2020).

4.4.6 Labor Rates

For the purposes of this regulatory analysis, the NRC developed labor rates that include only labor and material costs that are directly related to the implementation, operation, and maintenance of the final rule requirements. This approach is consistent with the guidance in NUREG-BR-0058, Revision 5, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," April 2017, (ADAMS Accession No. ML17100A480) and general cost-benefit methodology. The NRC incremental labor rate is $137 per hour in 2021 dollars.[3]

The NRC used the 2020 BLS Occupational Employment and Wages data (http://www.bls.gov) for the Pharmaceutical Preparation Manufacturing: [Manufacturing Sector: 31-33]–Nuclear Medicine (Radioactive Isotopes) Preparations Manufacturing (NAICS) Code 325412 which provide and the mean hourly wage rate for this NAICS code, and used the inflator discussed above to inflate these labor rate data to 2021 dollars. The labor rates used in the analysis reflect total hourly compensation, which includes wages and nonwage benefits (using a burden factor of 2.4, applicable for contract labor and conservative for Pharmaceutical Preparation Manufacturing). The NRC used the BLS data tables to select hourly labor rates for performing the estimated procedural, licensing, and Nuclear Medicine (Radioactive Isotopes) Preparations Manufacturing necessary during and following implementation of the alternative. In establishing this labor rate, wages paid to the individuals performing the work plus the associated fringe benefit component of labor cost (i.e., the time for management over and above those directly expensed) are considered incremental expenses and are included. Table 2**Error! Reference source not found.** summarizes the BLS labor categories that were used to estimate industry labor costs to implement this proposed rule, and Appendix A lists the industry labor rates used in the analysis. The NRC also performed an uncertainty analysis, which is discussed in this Regulatory Analysis.

[3] The NRC labor rates presented here differ from those developed under the NRC's license fee recovery program (10 CFR Part 170, "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services under the Atomic Energy Act of 1954, as Amended"). NRC labor rates for fee recovery purposes are appropriately designed for full-cost recovery of the services rendered and thus include nonincremental costs (e.g., overhead, administrative, and logistical support costs).

Table 2 Position Titles and Occupations

Position Title	Occupation (SOC code)	Year	Hourly mean wage	Hourly 25th percentile wage	Hourly 75th percentile wage	Source
Technical Staff	Pharmaceutical Preparation Manufacturing: [Manufacturing Sector: 31-33] - Nuclear Medicine (Radioactive Isotopes) Preparations Manufacturing (325412)	2021	***$35.46***	***$25.89***	***$52.13***	https://www.bls.gov/iag/tgs/iag325.htm#iag325cesehallemp.f.p
Administrative Staff	Office and Administrative Support Occupations (430000)	2020	$20.38	$14.69	$24.40	https://www.bls.gov/oes/current/oes430000.htm
	First-Line Supervisors of Office and Administrative Support Workers (431011)	2020	$29.81	$21.59	$35.90	https://www.bls.gov/oes/current/oes431011.htm
	Office Clerks General (439061)	2020	$18.16	$13.26	$21.87	http://www.bls.gov/oes/current/oes439061.htm
	Average		***$22.78***	***$16.51***	***$27.39***	
Licensing Staff	Paralegals and Legal Assistants (232011)	2020	$27.22	$19.54	$32.25	https://www.bls.gov/oes/current/oes232011.htm
	Lawyers (231011)	2020	$71.59	$40.60	$91.11	https://www.bls.gov/oes/current/oes231011.htm
	Average		***$49.41***	***$30.07***	***$61.68***	

(1) SOC code: Standard Occupational Classification code -- see http://www.bls.gov/soc/home.htm
(2) NAICS code: North American Industry Classification System code -- see http://www.bls.gov/bls/naics.htm

4.4.7 Sign Conventions

The sign conventions used in this analysis are that all favorable consequences for the alternative are positive i.e., averted costs; and all adverse consequences for the alternative are negative. Negative values are shown using parentheses (e.g., negative $500 is displayed as ($500)). Averted costs are costs of activities and actions performed under the existing regulations that would no longer be required if a revision to the regulations is implemented, and they are assigned positive values. Normal costs are implementation and operational costs of new or additional actions associated with the proposed rule, if approved, and they are assigned negative values.

4.4.8 Analysis Horizon

The average expiration date of the operating licenses is 2038, which results in approximately 15 years of operation. The proposed changes would provide a regulatory framework for the distribution of irradiated products (e.g., gemstones and PCTE membranes) for current and future NRC licensees. Licensees currently distributing these products under § 32.11, for use under § 30.14, can amend their license to comply with the new provisions at the time of the next license renewal.

4.4.9 Cost & Impact Considerations

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, as discussed in Section 4.4.1, are considered negative, and cost savings and averted costs are considered positive. There were no Industry implementation costs.

Industry Operations

This attribute accounts for the projected net economic effect of routine and recurring activities required by the alternative for all affected licensees.

There are 9 estimated PCTE Manufacturers and/or Distributors (# Licensees Submittals) who would provide submittals. Each PCTE Licensee submittal requires 60 hours of preparation time at a labor rate of $100. These costs are estimated to occur in 2024, which is the estimated effective date of the rule, and 15-years later in 2038 during license renewal resulting in a cost of ($61,000) at 7-percent. (See Table A-9.)

There are 2,000 estimated PCTE End User Entities (not Manufacturers and/or Distributors) who would provide submittals. Each PCTE End User Entities Licensee submittal requires 50 hours of preparation time at a labor rate of $100. These costs are estimated to occur in a 5-year timeframe beginning in 2024 through 2028 resulting in a cost of ($7,177,000) at 7-percent. See Table A-11.

There are 9 estimated Silica Chip Entity Initial License Applicants who would provide submittals. Each Silica Chip Entity Initial License Applicant submittal requires 60 hours of preparation time at a labor rate of $100. These costs are estimated to occur in 2024 and 15-years later in 2038 during license renewal resulting in a cost of ($61,000) at 7-percent. (See Table A-13.)

There are 9 estimated Gemstone Entity Licensees who would provide submittals. Each Gemstone Entity Licensee submittal will save 40 hours of preparation time at a labor rate of $100. These averted costs are estimated to occur in 2024 resulting in an averted cost of $29,000 at 7-percent. (See Table A-15.)

NRC Implementation

Table 3 NRC Rulemaking Implementation Cost

Year	Activity	Hours	NRC hourly rate	Total Cost		
				Undiscounted	7% NPV	3% NPV
2022	Develop/issue RG for final rule	388	$137	($53,197)	($49,716)	($51,647)

2022	**Develop/issue final rule**	**971**	**$137**	**($132,991)**	**($124,291)**	**($129,118)**
2023	**Develop/issue Comment Resolution for final rule**	**388**	**$137**	**($53,197)**	**($46,464)**	**($50,143)**
2023	**Complete final rule**	**971**	**$137**	**($132,991)**	**($116,160)**	**($125,357)**
	Net (Cost) Benefit:	**2,718**		**($372,376)**	**($336,631)**	**($356,265)**

NRC Operations

There are 9 estimated NRC reviews of PCTE Licensing Entities. Each NRC review of PCTE Entity Licensee applicant submittal requires 60 hours at a labor rate of $137. These costs are estimated to occur in 2024 and 15-years later in 2038 during license renewal resulting in a cost of ($84,000) at 7-percent. (See Table A-10.)

The NRC is estimated to review 9 PCTE End User Entities who would provide submittals. Each NRC review of PCTE End User Entities Licensee submittal requires 100 hours at a labor rate of $137. This results in a cost of ($101,000) at 7-percent. (See Table A-12.)

The NRC is estimated to review 9 Silica Chip Entity Initial License Applicants who would provide submittals. Each NRC review of Silica Chip Entity Initial License Applicant submittal requires 60 hours at a labor rate of $137. These costs are estimated to occur in 2024 and 15-years later in 2038 during license renewal resulting in a cost of ($84,000) at 7-percent. (See Table A-14.)

The NRC is estimated to avert the review of 9 Gemstone Entity Licensees who would provide submittals. Each NRC review of Gemstone Entity Licensee applicant submittal requires 40 hours at a labor rate of $137. These averted costs are estimated to occur in 2024 resulting in an averted cost of $40,000 at 7-percent. (See Table A-16.)

Agreement States Implementation

This attribute accounts for the projected net economic effect on the Agreement States to implement all the mandated changes in Parts 30 and 32. Costs include procedural and administrative activities related to harmonizing State regulations with NRC policy and other guidance documents. Agreement States are expected to incur a cost of ($1,460,000). This estimate represents the implementation cost of the proposed rulemaking by the Agreement States. The Agreement States do not benefit from the averted costs that the NRC benefits from because the exempt distribution regulations are “Compatibility Category NRC,” which the Agreement States do not adopt. (See Table A-7.)

Agreement States Operation

The rulemaking action will not result in any operation costs to the Agreement States.

5. Other Considerations

This section discusses the alternatives to rulemaking that the staff considered, as well as why the alternatives would not be effective approaches to resolve the regulatory problem identified above in Section 3.

5.1 Guidance

Regulatory guides and NUREGs provide guidance to licensees and applicants for carrying out specific parts of the NRC's regulations, for techniques used by the NRC staff in evaluating specific problems or postulated accidents, and for data needed by the NRC staff in its review of applications for permits or licenses. However, guidance cannot impose new requirements on licensees and, therefore, is not viable to provide for the use of a product under exemption from licensing. Therefore, reliance on guidance alone to resolve this regulatory issue is not feasible to resolve the issue.

5.2 Exemption

Under an exemption, the NRC would issue various exemptions under 10 CFR 30.11, “Specific exemptions,” to various regulatory provisions. To ensure public health and safety, the NRC would evaluate the application against applicable standards and regulations. The use of exemptions would not be desirable for the specific licensing of items in this class of products because over time it would take more resources from an applicant, licensee, and the NRC. Therefore, similar to guidance, reliance on exemptions alone to resolve this regulatory issue is not feasible to resolve the issue.

5.3 Stakeholder Interactions

Currently, the only stakeholder input on this topic has been in response to the notice of docketing and request for public comment on the petition (76 FR 36386; June 22, 2011). The NRC received one comment letter (ADAMS Accession No. ML11178A021) from a member of the public opposing the petition. The commenter stated that the current regulations do not place an unfair burden on the petitioner and have been in place for some time. The NRC is making this regulatory analysis available to the public and requesting comments. The agency will consider those comments in developing the proposed rule.

In accordance with Management Directive 5.3, “Agreement State Participation in NRC Working Groups,” (ML18073A142) the staff has provided early opportunity for Agreement State engagement on this rulemaking effort. Specifically, the petition review board included an Agreement State representative. During the process of developing this regulatory analysis, the staff gave Agreement States an early opportunity to participate in the proposed rule and this regulatory analysis and addressed their comments, where appropriate, in finalizing the document. The staff has provided updates during Organization of Agreement States/Conference of Radiation Control Program Directors teleconferences as needed. For this rule, the staff added an Agreement State representative who participated in the development of the proposed rule.

5.4 Cumulative Effects of Regulation

The cumulative effects of regulation are an organizational effectiveness challenge that results from a licensee or other affected entity implementing several complex positions, programs, or requirements within a prescribed implementation period and with limited available resources, including the ability to access technical expertise to address a specific issue.

The proposed rulemaking activity for items containing byproduct material incidental to production would reduce burden on current gemstone licensees, as well as on the NRC staff reviewing any related license applications, by providing a more streamlined regulatory structure for licensing. For all other irradiated products in this class, this rule removes a barrier to product commercialization by providing a viable means to license the product. This is a burden reduction to the licensee and NRC staff.

The proposed rulemaking activity for items containing byproduct material incidental to production would increase burden on current PCTE and Silica Chip licensees, as well as on the NRC staff reviewing any related license applications.

The staff provided early opportunity for Agreement State engagement on this rulemaking effort in accordance with Management Directive 5.3, “Agreement State Participation in NRC Working Groups,” (ML18073A142). Specifically, the petition review board included an Agreement State representative. The proposed rulemaking activity for items containing byproduct material incidental to production would increase burden on Agreement States. There is no Tribal Nation involvement currently.

5.5 Environmental Analysis

This rulemaking would add new provisions to 10 CFR Part 30 and 10 CFR Part 32. Pursuant to 10 CFR 51.21, “Criteria for and identification of licensing and regulatory actions requiring environmental assessments,” the NRC will develop an environmental assessment along with this rulemaking to determine whether issuing this rule will result in any significant impacts. Backfitting is addressed in a separate document and is not part of this regulatory analysis.

The Commission has preliminarily determined under NEPA and the Commission’s regulations in Subpart A of 10 CFR Part 51, that the proposed amendments would not be a major Federal action significantly affecting the quality of the human environment, and therefore, an environmental impact statement is not required. The amendments would amend 10 CFR Part 30 to add a new class exemption from licensing requirements for items containing byproduct material incidental to their production and to amend 10 CFR Part 32 to add new sections for distribution requirements. The environmental impacts arising from the changes have been evaluated and would not involve any significant environmental impact. As such, the rule would not result in impacts to federally-listed threatened or endangered species or their critical habitat; the NRC has determined that Section 7 consultation under the Endangered Species Act is not necessary. Likewise, the NRC determined that the proposed rulemaking would not have the potential to cause effects on or to historic properties. Therefore, the NRC has determined that no further consultation is required under Section 106 of the National Historic Preservation Act.

5.6 Support of Strategic Plan

The planned rulemaking supports the NRC's 2018–2022 Strategic Plan (ADAMS Accession No. ML18032A561) in relation to the strategic goal of ensuring the safe use of radioactive materials. In the area of safety, the proposed rulemaking would support NRC Safety Strategy 2, "Further risk-inform the current regulatory framework in response to advances in science and technology, policy decisions, and other factors, including prioritizing efforts to focus on the most safety-significant issues," by providing a regulatory path for potential licensees to obtain a distribution license for current and future products that contain byproduct material incidental to production. In addition, the planned rulemaking would support NRC Safety Strategy 3, "Enhance the effectiveness and efficiency of licensing and certification activities to maintain both quality and timeliness of licensing and certification reviews," by developing a regulatory framework that facilitates the ability of industry to manufacture and market useful, economical products to support various applications while maintaining adequate protection of health and safety.

5.7 Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.), as amended by the Small Business Regulatory Enforcement Fairness Act, requires the NRC to consider the impact of its rulemakings on small entities and evaluate alternatives that would accomplish regulatory objectives without unduly burdening small entities or erecting barriers to competition. In developing the proposed rule, the staff evaluated how many small entities it anticipates this rulemaking would affect and what steps the NRC can take to mitigate the economic impacts on small entities.

The proposed rule would affect approximately 27 licensees that are subject to the rulemaking and manufacture and/or distribute items containing byproduct material incidental to production, some of which may qualify as small business entities as defined by 10 CFR 2.810. Based upon historical data, the staff estimates that approximately 2 out of the 27 estimated licensees subject to this rulemaking, may qualify as small business entities as defined by 10 CFR 2.810. These 2 small business entities are anticipated to be gemstone licensees. It is expected that all businesses will incur the same savings resulting from the licensing process. These savings are a small percentage of the gross sales; therefore, we conclude that there will be no significant economic impact to small business entities. On the basis of the draft regulatory analysis conducted for this action the estimated averted cost of the proposed rule for affected licensees is $40,000 at 7 percent. The NRC believes that the selected alternative reflected in the proposed rule is the least burdensome, most flexible alternative that would accomplish the NRC's regulatory objective.

6. Summary of the Results

6.1 Summary of Quantified Net Benefits

The NRC estimates that the status quo will incur a cost of ($25,618,000) at a 7-percent discount rate due to the cost of discontinuing rulemaking. These costs stem from the need to prepare a SECY paper, a letter to the petitioner denying the petition, and an FRN. Additionally, this option includes the costs to review initial license applications and subsequent renewals, including costs to end users that are required to have a license. These

costs will become an averted cost if Alternative 2 is selected. This averted cost is shown in Table 3.

6.2 Staff-Recommended Rulemaking

Table 3 shows the staff-recommended rulemaking actions. The Alternative 2 net averted cost is $13,071,000, which comprises industry averted costs of $3,219,000, NRC averted costs of $11,313,000, and Agreement State costs of ($1,460,000) to update their regulations to be compatible with the NRC's. Table 4 shows the net costs to licensees, the NRC,and Agreement States.

Table 4 Alternative 2 Total Net Costs by Affected Entity

Description	Net Benefit (Cost) by Affected Entity (7% NPV in 2021 Dollars)			
	Industry	NRC	Agreement States	Total (2021$)
Alternative 1 Status Quo - Do Nothing Different				
Alternative 1 Net Benefits (Costs)	*$0*	*$0*	*$0*	*$0*
Alternative 2 Proceed with a Rulemaking Inclusive of Items Containing Byproduct Material Incidental to Production (staff's recommendation)				
Item A: Rulemaking Implementation Costs Excluding Rulemaking Termination Costs	$0	($337,000)	($1,460,000)	($1,797,000)
Item B: PCTE Only	($7,239,000)	($184,000)	$0	($7,423,000)
Item C: Silica Chip Only	($61,000)	($84,000)	$0	($145,000)
Item D: Gemstone Only regulated §32.11(c) exemption	$29,000	$40,000	$0	$69,000
Averted Alternative 1 Costs (SECY, Letter, and FRN)	$10,489,000	$12,213,000	$0	$22,702,000
Alternative 2 Net Benefits (Costs)	*$3,219,000*	*$11,648,000*	*($1,460,000)*	*$13,407,000*

[a] The total net benefit results are sensitive to the timing of when costs and benefits occur and to the discount rate applied.
[b] Benefits and averted costs are positive. Costs are (negative).
[c] There may be differences between table summations due to rounding.

Based on the cost estimates shown in Table 3, the NRC concludes that the rulemaking alternative inclusive of all items containing byproduct material incidental to production is the best course of action that addresses the majority of concerns, because the quantitative and qualitative benefits discussed in Section 6.2 and 6.4 exceed the cost of implementing this rulemaking.

The new provisions would become applicable to current licensees at the time of their next license renewal. These new provisions will be substantially less burdensome because the licensee would not need a special exemption under the new provision. regulations that affect small entities.

6.3 Benefits

The staff expects the proposed action to provide the following benefits:

- Establish a regulatory framework and allow new or current products under this category to be licensed without product-specific exemptions, each of which would require additional rulemaking or need to be reviewed on a case-by-case basis.

- Provide an appropriate pathway for licensing these beneficial irradiated products that

are used in a wide variety of applications. Items like PCTE membranes can be made without creating byproduct material incidental to production; however, the industry prefers to use this method to create membranes with uniform pore size and distribution.

- Ensure consistency for regulating different products in this class.

- As described in Table 1, avert an estimated cost at 7 percent of $3.2 million to Industry, $11.6 million averted cost to the NRC and a cost of ($1.5 million) to the Agreement States, for a total net averted cost of $13.4 million by pursuing rulemaking, which includes the cost of updating guidance and developing a compliance guide for regulations that affect small entities.

6.4 Non-quantified Benefits

The rule would affect the following attributes. These inventory of attributes are listed in NUREG/BR-0058 Revision 5.

Improvements in Knowledge. This attribute accounts for improvements in knowledge acquired as the industry and the staff gain experience with new technology before its incorporation into Part 30 and Part 32 and by permitting licensees to avoid costs in asking for incorporating new technologies.

Regulatory Efficiency. This attribute accounts for regulatory and compliance improvements resulting from the implementation of Alternative 2 relative to the regulatory baseline. Alternative 2 would continue the best practice of aligning NRC regulations with ICBMIP licensing standards, thereby providing the industry with the regulatory provisions for which it has sought permission via relief and alternative requests. This rulemaking would reduce the effort the industry expends generating these requests and considering alternative means to accomplish the goals of these provisions.

Other Considerations. This attribute accounts for considerations not captured in the preceding attributes. Specifically, this attribute accounts for how Alternative 2 meets specific requirements of the Commission, helps achieve NRC policy, and provides other advantages or detriments.

Attributes with No Effects. Attributes not expected to be affected under any of the alternatives include considerations of public health (routine), offsite property, onsite property, other governments, the public, safeguards and security, and the environment.

6.5 Uncertainty Analysis

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

6.5.1 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. This was done to determine the robustness of the costs and net benefits of the proposed rule. The NRC examined how anticipated savings change due to uncertainties associated with the NRC's analytical assumptions and input data. As mentioned in Section 3.1, the NRC used Monte Carlo simulation to examine the impact of uncertainty on the estimated net benefits of the proposed rule.

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 tocharacterize the distributions. These summary statistics include the minimum, most likely, andmaximum values of a program evaluation and review technique (PERT) distribution. The staffused the PERT distribution to reflect the relative spread and skewness of the distribution defined by the three estimates, the minimum, most likely, and maximum. Figure A-1 of this document provides the probability distribution function and the descriptivestatistics of the inputs used in the uncertainty analysis.

6.5.2 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 probabilitydistributions 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.

The results of the uncertainty analysis of Alternative 2 net costs using a 7-percent discount rate are provided graphically in Figure A-1. This figure displays the histogram of the incremental netcost for rulemaking to resolve the identified issues. The uncertainty analysis graph showing thenet result is reported in 2021 dollars. The analysis shows that Alternative 2 is cost beneficial for 96 percent of the 10,000 simulations with a 90-percent confidence interval that the net costs are between ($5.5 million) and $47.4 million using a 7-percent discount rate.

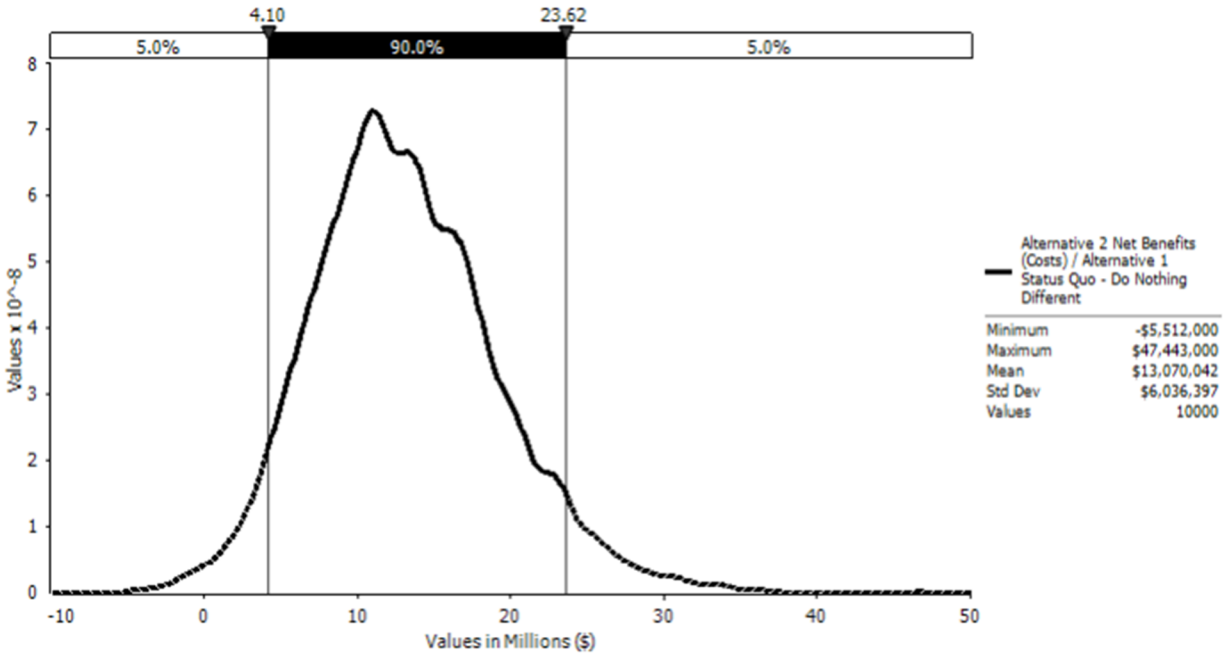

Figure 1 Incremental Net Costs for Alternative 2 (7-Percent Discount Rate)

Figure 2 shows a tornado diagram that identifies the key variables whose uncertainty drives the largest impact on net benefits for this recommended alternative. Figure 2 ranks the variables based on their contribution to cost uncertainty.

The estimate that has the greatest variation in the overall results is the Alternative 2 Averted Costs Derived from Alternative 1 Status Quo PCTE End Users Initial License applications relating to the complexity of the expected applications developed by industry applicants. The uncertainty in this variable would result in a change to the mean of $11.8 million, the difference in averted costs that ranges between $8.2 million to $20.0 million with a 90 percent confidence level.

The estimate that has the second greatest variation in the overall results is the Alternative 2 Averted Costs Derived from Alternative 1 Status Quo NRC Review of PCTE End Users Initial License applications. The uncertainty in this variable would result in a change to the mean of $11.3 million, the difference in averted costs that ranges between $8.2 million to $19.5 million with a 90 percent confidence level.

The estimate that has the third greatest variation in the overall results is the NRC Review of PCTE End Users License Applications. The uncertainty in this variable would result in a change to the mean of $7.8 million, the difference in costs that ranges $8.5 million to $16.3 million with a 90 percent confidence level.

6.6 Summary of Uncertainty Analysis

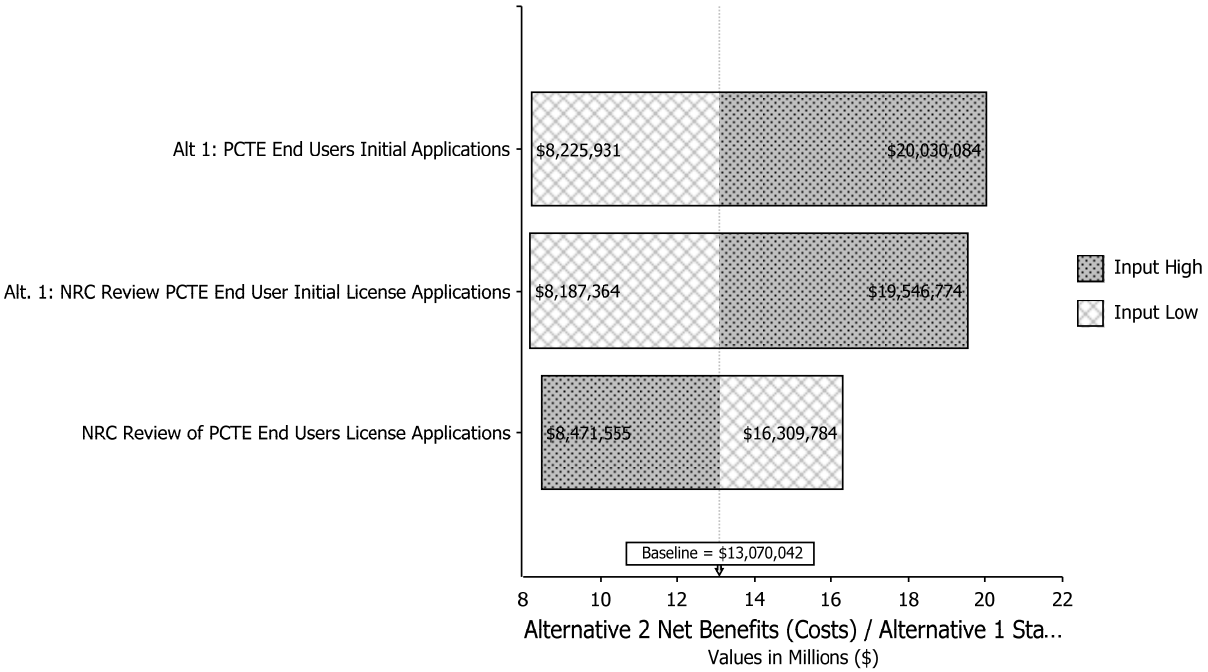

Figure 2 Alternative 2 Cost Drivers (7-Percent Discount Rate)

6.7 Decision Rationale

Relative to Alternative 1 the Status Quo alternative, Alternative 2 results in a net benefit of approximately $13.4 million (total present value), assuming a 7-percent discount rate, or $20.0 million assuming a 3-percent discount rate.

The NRC estimates that the rulemaking would take approximately 2 years to complete from the proposed rule to the final rule and require the time of 4.2 full-time equivalent staff. The rulemaking implementation would result in a cost of ($337,000) to the NRC using a 7-percent discount rate. The rulemaking implementation would result in a cost of ($1,460,000) to the Agreement States using a 7-percent discount rate. This results in a total *implementation* cost of ($1,797,000) to the NRC and the Agreement States using a 7-percent discount rate, which is shown as a separate line item in Table 1, Alternative 2, Item A. Adding the costs for Item A Implementation ($1,797,000), Item B PCTE ($7,423,000), Item C Silica Chip ($145,000); Item D Gemstones averted costs $69,000; and the Averted Alternative 1 costs of $22,702,000, yield the final net averted cost for Alternative 2 is $13,407,000.

Table 5 Summary of Totals

Net Monetary Savings or (Costs)—Total Present Value	Nonquantified Benefits or (Costs)
Alternative 1: Status Quo $0	None
Alternative 2: 'Alternative 2 Proceed with a Rulemaking Inclusive of Items Containing Byproduct Material Incidental to Production (staff's recommendation) I**ndustry**: (all provisions) $3.2 million using a 7% discount rate $6.1 million using a 3% discount rate **NRC**: (all provisions) $11.6 million using a 7% discount rate $15.6 million using a 3% discount rate **Agreement States**: (all provisions) ($1.5 million) using a 7% discount rate ($1.7 million) using a 3% discount rate **Net Benefit (Cost): (all provisions)** $13.4 million using a 7% discount rate $20.0 million using a 3% discount rate	**Benefits:** • Improvements in Knowledge: This attribute accounts for improvements in knowledge acquired as the industry and the staff gain experience with new technology before its incorporation into Part 30 and Part 32 and by permitting licensees to avoid costs in asking for incorporating new technologies. • Regulatory Efficiency: This attribute accounts for regulatory and compliance improvements resulting from the implementation of Alternative 2 relative to the regulatory baseline. Alternative 2 would continue the best practice of aligning NRC regulations with ICBMIP licensing standards, reducing the effort the industry expends generating these requests and considering alternative means to accomplish the goals of these provisions. • Other Considerations: This attribute accounts for considerations not captured in the preceding attributes. Specifically, this attribute accounts for how Alternative 2 meets specific requirements of the Commission, helps achieve NRC policy, and provides other advantages. • Attributes with No Effects: Attributes not expected to be affected under any of the alternatives include considerations of public health (routine), offsite property, onsite property, the public, and safeguards and security. **Costs:** Nonquantified Costs: If the staff has underestimated the number or the complexity of these eliminated submittals, then the averted costs would increase proportionally, causing the quantified net costs of Alternative 2 to decrease.

6.9 Implementation

The rule is expected to become effective in 2024. All monetized costs are expressed in 2021 dollars. Ongoing costs of operation related to the alternative being analyzed are assumed to begin no earlier than 30 days after publication of the final rule in the *Federal Register* unless otherwise stated, and they are modeled on an annual cost basis.

Agreement States have up to 3 years from the effective date of the rule to implement but are expected to implement the rule sooner.

The NRC assumes that the proposed rule would become effective 30 days after its publication in the *Federal Register* in 2024.

7. References

1. Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material."

2. Title 10 of the *Code of Federal Regulations* (10 CFR) Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material."

3. PRM-30-65, "Petition for Rulemaking Pursuant to 10 C.F.R. § 2.802 on Behalf of GE Osmonics Inc.," April 18, 2011 (ADAMS Accession No. ML120250133).

4. GE Osmonics, Inc., "Polymer Track Etch Membrane 10 C.F.R. § 32.14—Manufacture and Distribution Product Safety Information," received March 20, 2012 (ADAMS Accession No. ML120800277).

5. GE Osmonics, Inc., "Environmental Report—Polymer Track Etch Membrane—10 CFR 30.15," received March 20, 2012 (ADAMS Accession No. ML120800264).

6. SECY-87-186A, "Distribution of Radioactive Gems Irradiated in Reactors to Unlicensed Persons (Follow-Up to SECY-87-186)," October 5, 1987 (ADAMS Accession No. ML092400170), and associated staff direction (ADAMS Accession No. ML12289B143).

7. Petition for Rulemaking Submitted by Annette User on Behalf of GE Osmonics, Inc.," on September 14, 2012, 10 CFR Part 30, *Federal Register* (FR) (77 FR 56793).

8. "Consumer Product Policy Statement," 79 FR 2907, January 16, 2014 (ADAMS Accession No. ML13191A732).

9. NUREG-1556, Volume 8, Revision 1, "Consolidated Guidance about Materials Licenses:Program-Specific Guidance About Exempt Distribution Licenses," June 2018 (ADAMS Accession No. ML18158A165).

10. International Atomic Energy Agency, OECD Nuclear Energy Agency, "Radiation Safety for Consumer Products," IAEA Safety Standards Series No. SSG-36, January 2016.

11. International Atomic Energy Agency, IAEA Safety Standards Series, "Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards—General Safety Requirements Part 3 No. GSR Part 3," July 2014.

12. Management Directive 5.3, “Agreement State Participation in NRC Working Groups,”June 22, 2016 (ADAMS Accession No. ML18073A142). “Agreement State Program Policy Statement; Correction,” 82 FR 48535,October 18, 2017.

13. NUREG/BR-0058, Revision 5, “U.S. Nuclear Regulatory Commission Guidance on Performing Cost-Benefit Analyses, April 2017 (ADAMS Accession No. ML 17100A480).

14. NUREG-1614, Vol. 7, “Strategic Plan: Fiscal Years 2018–2022,” February 2018 (ADAMS Accession No. ML18032A561).

Appendix A: Assumptions and Assessment Supporting the Cost Analysis

Table A-1 Data Table

Description	Mean Estimate	Distribution	Low Estimate	Best Estimate	High Estimate
Alternative 1 Status Quo - Do Nothing Different					
Alternative 2 Proceed with a Rulemaking Inclusive of Items Containing Byproduct Material Incidental to Production (staff's recommendation)					
Alternative 2- Averted Cost Derived from Alt 1 Status Quo					
Averted NRC Rulemaking Discontinuation Costs (SECY, Letter, and FRN)					
Rulemaking Discontinuation (NRC)	1			1	
NRC Hours	820	Pert	738	820	902
NRC Labor Rate	$137			$137	
RESERVED					
Averted NRC Review of PCTE End User Initial License Applications					
Number of PCTE End User Licensees	2,000	Pert	1,600	2,000	2,400
Time (Hours)/ NRC review of Licensee End Users Initial Applications	50	Pert	20	40	120
Time (Hours)/ NRC review of Licensee End Users Renewal Applications	25	Pert	10	20	60
NRC Labor Rate	$137			$137	
RESERVED					
Averted NRC Review of PCTE Manufacturers and/or Distributors Initial License Applications					
Number of PCTE Manufacturers and/or Distributors	9	Pert	8	9	10
Time (Hours)/ NRC review of Manufacturers and/or Distributors Initial Applications	100	Pert	90	100	110
Time (Hours)/ NRC review of Manufacturers and/or Distributors Renewal Applications	50	Pert	45	50	55
NRC Labor Rate	$137			$137	
RESERVED					
Averted PCTE End User Licensees Initial License Submittal					
Number of PCTE End User Licensees	2,000	Pert	1,600	2,000	2,400
Time (Hours)/ Licensee End Users Initial Applications	50	Pert	20	40	120
Time (Hours)/ Licensee End Users Renewal Applications	25	Pert	10	20	60
Licensee Average Labor Rate	$100	Trigen	$59	$86	$146
RESERVED					
Averted PCTE Manufacturers and/or Distributors Initial License Submittal					
Number of PCTE Manufacturers and/or Distributors	9	Pert	8	9	10
Time (Hours)/ Manufacturers and/or Distributors Initial Applications	100	Pert	90	100	110
Time (Hours)/ Manufacturers and/or Distributors Renewal Applications	50	Pert	45	50	55
Licensee Average Labor Rate	$100	Trigen	$59	$86	$146
RESERVED					
Agreement States Rulemaking Implementation Costs					

Affected Agreement States (#)	38			38	
Number of Reports per A/S processed	1			1	
Time (Hours)/ Agreement State Report	527	Pert	316	527	738
Agreement States Labor Rate	$95	Pert	86	$95	105
RESERVED					
NRC Rulemaking Implementation					
RESERVED					
Alternative 2- Licensee & NRC Rulemaking Costs					
Item A: Rulemaking Implementation					
Item A (Licensee) Rulemaking and use existing guidance					
Rulemaking and use existing guidance (# Licensees)	0	Pert	0	0	0
Time (Hours)/Licensee	60	Pert	54	60	66
Licensee Average Labor Rate	$100	Trigen	$59	$86	$146
RESERVED					
Item A NRC Rulemaking					
Rulemaking and use existing guidance (NRC)	1	Pert	0.9	1	1.1
Time (Hours)/NRC	2,718			2,718	
NRC Labor Rate	$137			$137	
RESERVED					
Item B: PCTE Only					
PCTE Licensing					
PCTE Manufacturers and/or Distributors (# Licensees Submittals)	9	Pert	8	9	10
PCTE Licensee Hours (Licensee Application Development)	60	Pert	54	60	66
PCTE Licensee Labor Rate	$100	Trigen	$59	$86	$146
RESERVED					
NRC Licensing PCTE Entities					
PCTE (NRC)	9	Pert	8	9	10
NRC Review and Processing Time per Submittal (Hours)	60	Pert	54	60	66
NRC Labor Rate	$137			$137	
RESERVED					
Licensee PCTE End User Entities (not Manufacturers and/or Distributors)					
Number of PCTE End User Licensees	2,000		1,600	2,000	2,400
Time (Hours)/ NRC review of PCTE Licensee End Users Applications	50	Pert	20	40	120
PCTE Licensee Labor Rate	$100	Trigen	$59	$86	$146
RESERVED					
NRC Licensing PCTE End User Entities					
Number of PCTE End User Entities	9	Pert	8	9	10
Time (Hours)/ NRC review of PCTE End User Entities	100	Pert	90	100	110
NRC Labor Rate	$137			$137	
RESERVED					
Item C: Silica Chip Only					
Item C (Licensee) Silica Chip Entity Initial License Application Submittal					

Licensef Number of Silica Chip Licensee Submittals	9	Pert	8	9	10
Review and Processing Time per Submittal (Hours) of Silica Chip Licensees	60	Pert	54	60	66
Silica Chip Licensee Labor Rate	$100	Pert		$100	
RESERVED					
Item C NRC Licensing Silica Chip Entities					
NRC Review of Licensing Silica Chip Entities	9	Pert	8	9	10
Silica Chip Time (Hours)/NRC	60	Pert	54	60	66
NRC Labor Rate	$137			$137	
RESERVED					
Item D: Gemstone Only regulated §32.11(c) exemption					
Item D Licensee Gemstone Exemptions Averted					
Number of Gemstone Exemptions (# Licensees)	9	Pert	8	9	10
Gemstone Entity Licensee Hours/Report	40	Pert	36	40	44
Gemstone Entity Licensee Labor Rate	$100	Trigen	$59	$86	$146
RESERVED					
Item D NRC Gemstone Exemption Processing Averted					
NRC Review of Gemstone Submittals Only	9	Pert	8	9	10
NRC Gemstone Review and Processing Time (Hours)	40	Pert	36	40	44
NRC Labor Rate	$137			$137	
RESERVED					

For cost analysis considerations, the staff estimates for Alternative 2 Averted Cost Derived from Alternative 1 NRC Rulemaking Discontinuation an averted cost of $92 thousand using a 7 percent discount rate to discontinue rulemaking. This cost includes preparing a SECY, a letter to the petitioner to inform them of thedenial of the petition, and an FRN. This cost is shown in Table A-2.

Table A-2 Alternative 2 Averted Cost Derived from Alternative 1 Status Quo - Do Nothing Different -- NRC Rulemaking Discontinuation Cost

Year	Description	NRC Hours	NRC Labor Rate	Undiscounted	7% NPV	3% NPV
2024	Averted NRC Rulemaking Discontinuation Costs SECY, Letter, and FRN)	820	$137	$112,340	$91,703	$102,807
	Net Benefits (Costs)			$112,340	$91,703	$102,807

For cost analysis considerations, the staff estimates an averted cost for Alternative 2 Averted Cost Derived from Alternative 1 NRC review of PCTE End User License Applications a cost of $12.0 million using a 7 percent discount rate. The estimated number of PCTE end user licensees is 4,000. This averted cost is shown in Table A-3.

Table A-3 Alternative 2 Averted Cost Derived from Alternative 1 Status Quo - Do Nothing Different -- NRC Review of PCTE End User License Applications

Year	Description	Number of PCTE End User Initial License Applications	NRC Review Hours	NRC Labor Rate	Undiscounted	7% NPV	3% NPV
2024	Averted NRC Review of PCTE End User Initial License Applications	400	50	$137	$2,740,000	$2,236,656	$2,507,488
2025	Averted NRC Review of PCTE End User Initial License Applications	400	50	$137	$2,740,000	$2,090,333	$2,434,455

2026	Averted NRC Review of PCTE End User Initial License Applications	400	50	$137	$2,740,000	$1,953,582	$2,363,548
2027	Averted NRC Review of PCTE End User Initial License Applications	400	50	$137	$2,740,000	$1,825,778	$2,294,707
2028	Averted NRC Review of PCTE End User Initial License Applications	400	50	$137	$2,740,000	$1,706,334	$2,227,871
2038	Averted NRC Review of PCTE End User Initial License Applications	2,000	25	$137	$6,850,000	$2,168,535	$4,144,363
	Net Benefits (Costs)	4,000			$20,550,000	$11,981,218	$15,972,431

For cost analysis considerations, the staff estimates for Alternative 2 Averted Cost Derived from Alternative 1 NRC review of PCTE manufacturers and distributors license applications an averted cost of $140 thousand using a 7 percent discount rate. The NRC estimated that there are nine PCTE Manufacturers and/or distributor licensees. This averted cost is shown in Table A-4.

Table A-4 Alternative 2 Averted Cost for NRC Review of PCTE Manufacturers and/or Distributors Initial License Applications

Year	Description	Number of PCTE Manufacturers and/or Distributors	NRC Review Hours	NRC Labor Rate	Undiscounted	7% NPV	3% NPV
2024	Averted NRC Review of PCTE Manufacturers and/or Distributors Initial License Applications	9	100	$137	$123,300	$100,650	$112,837
2038	Averted NRC Review of PCTE Manufacturers and/or Distributors Initial License Applications	9	100	$137	$123,300	$39,034	$74,599
	Net Benefits (Costs)				$246,600	$139,683	$187,435

The staff estimates an averted cost of $10.3 million at a 7-percent discount rate for Alternative 2 Averted Cost Derived from Alternative 1. The NRC estimates that there would be 2,000 PCTE end user licensees with one licensee renewal. This averted cost is shown in Table A-5.

Table A-5 Alternative 2 Averted Cost Derived from Alternative 1 Status Quo - Do Nothing Different -- PCTE End User Licensees StatusQuo Expenses

Year	Description	Number of PCTE End User Licensees	Licensee End Users Initial Applications Hours	Licensee Average Labor Rate	Undiscounted	7% NPV	3% NPV
2024	Averted PCTE End User Licensees Initial License Submittal	400	50	$100	$2,004,155	$1,635,988	$1,834,086
2025	Averted PCTE End User Licensees Initial License Submittal	400	50	$100	$2,004,155	$1,528,960	$1,780,666
2026	Averted PCTE End User Licensees Initial License Submittal	400	50	$100	$2,004,155	$1,428,935	$1,728,802
2027	Averted PCTE End User Licensees Initial License Submittal	400	50	$100	$2,004,155	$1,335,453	$1,678,448
2028	Averted PCTE End User Licensees Initial License Submittal	400	50	$100	$2,004,155	$1,248,087	$1,629,562
2038	Averted PCTE End User Licensees Renewal License Submittal	2,000	50	$100	$10,020,776	$3,172,321	$6,062,734

Net Benefits (Costs)	4,000			$20,041,552	$10,349,744	$14,714,298

The staff estimates an averted cost of $140 thousand at a 7-percent discount rate for Alternative 2 Averted Cost Derived from Alternative 1. The analysis estimates nine PCTE manufacturers and distributors would undergo initial licensing in 2024 and license renewal in 2038. This averted cost is shown in Table A-6.

Table A-6 Alternative 2 Averted Cost Derived from Alternative 1 Status Quo - Do Nothing Different -- PCTE Manufacturers andDistributors Status Quo Expenses

Year	Description	Number of PCTE Manufacturers and/or Distributors	Manufacturers and/or Distributors Initial Applications Hours	Licensee Average Labor Rate	Undiscounted	7% NPV	3% NPV
2024	Averted PCTE Manufacturers and/or Distributors Initial License Submittal	9	100	$137	$123,300	$100,650	$112,837
2038	Averted PCTE Manufacturers and/or Distributors Initial License Submittal	9	100	$137	$123,300	$39,034	$74,599
Net Benefits (Costs)					$246,600	$139,683	$187,435

For cost analysis considerations, the staff estimates Agreement States rulemaking implementation costs of ($1.5 million) at a 7-percent discount rate as shown in Table A-7.

Table A-7 Alternative 2 - Agreement States Rulemaking Implementation Costs

Year	Description	Number of Agreement States	Rulemaking Hours	Agreement States Labor Rate	Undiscounted	7% NPV	3% NPV
2024	Agreement States Rulemaking	13	527	$95	($652,662)	($532,767)	($597,278)
2025	Agreement States Rulemaking	13	527	$95	($652,662)	($497,913)	($579,882)
2026	Agreement States Rulemaking	12	527	$95	($602,457)	($429,544)	($519,685)
Net Benefits (Costs)		38			($1,907,782)	($1,460,223)	($1,696,845)

For cost analysis considerations, the staff estimates for NRC rulemaking implementation costs of ($672 thousand) at a 7-percent discount rate as shown in Table A-8.

Table A-8 NRC Rulemaking Implementation Cost

Year	Activity	Hours	NRC hourly rate	Total Cost		
				Undiscounted	7% NPV	3% NPV
2022	Develop/issue RG for final rule	388	$137	($53,197)	($49,716)	($51,647)
2022	Develop/issue final rule	971	$137	($132,991)	($124,291)	($129,118)
2023	Develop/issue Comment Resolution for final rule	388	$137	($53,197)	($46,464)	($50,143)

2023	Complete final rule	971	$137	($132,991)	($116,160)	($125,357)
	Net (Cost) Benefit:	2,718		($372,376)	($336,631)	($356,265)

The staff estimates an average of 9 PCTE entities will apply for licenses under the new regulations. To comply with the new regulations, PCTE licensees will need to submit aninitial application and a renewal application at 15 years. The estimated number of hours per application ranges from a low of 54 hours to a high estimate of 66 hours with a mean value of 60 hours as shown in Table A-9. This results in a cost of ($61 thousand) at a 7-percent discount rate as shown in Table A-9.

Table A-9 PCTE Licensee Implementation Costs

Year	Description	Number of PCTE Licenses	PCTE Licensee Hours	Labor Rate	Undiscounted	7% NPV	3% NPV
2024	PCTE Licensing	9	60	$100	($54,112)	($44,172)	($49,520)
2038	PCTE Licensing	9	60	$100	($54,112)	($17,131)	($32,739)
	Net Benefits (Costs)				($108,224)	($61,302)	($82,259)

The staff estimates that PCTE entities will submit an initial application and a renewal application at 15 years. The estimated number of hours to review the initial and renewal application and issue the licenses ranges from a low of 54 hours to a high estimate of 66 hours with a mean value of 60 hours. This results in a cost of ($84 thousand) at a 7-percent discount rate as shown in Table A-10.

Table A-10 NRC Costs to Issue PCTE Licenses

Year	Description	Number of PCTE Licenses	PCTE License eHours	Labor Rate	Undiscounted	7% NPV	3% NPV
2024	NRC PCTE Licensing	9	60	$137	($73,980)	($60,390)	($67,702)
2038	NRC PCTE Licensing	9	60	$137	($73,980)	($23,420)	($44,759)
	Net Benefits (Costs)				($147,960)	($83,810)	($112,461)

The staff estimates an average of 2,000 licensee PCTE manufacturers and/or distributor end user entities will apply for licenses under the new regulations. The number of hours per application ranges from a low of 20 hours to a high estimate of 140 hours with a mean value of 50 hours. This results in a cost of ($7.2 million) at a 7-percent discount rate as shown in Table A-11.

Table A-11 Licensee PCTE End User Entities (not Manufacturers and/or Distributors)

Year	Description	Number of PCTE End User Licensees	NRC Review Hours	NRC Labor Rate	Undiscounted	7% NPV	3% NPV
2024	Licensee PCTE End User Entities (not Manufacturers and/or Distributors)	400	50	$100	($2,004,155)	($1,635,988)	($1,834,086)
2025	Licensee PCTE End User Entities (not Manufacturers and/or Distributors)	400	50	$100	($2,004,155)	($1,528,960)	($1,780,666)
2026	Licensee PCTE End User Entities (not Manufacturers and/or Distributors)	400	50	$100	($2,004,155)	($1,428,935)	($1,728,802)

2027	Licensee PCTE End User Entities (not Manufacturers and/or Distributors)	400	50	$100	($2,004,155)	($1,335,453)	($1,678,448)
2028	Licensee PCTE End User Entities (not Manufacturers and/or Distributors)	400	50	$100	($2,004,155)	($1,248,087)	($1,629,562)
Net Benefits (Costs)		2,000			($10,020,776)	($7,177,423)	($8,651,564)

The staff estimates an average of 9 NRC reviews of NRC Costs for PCTE Manufacturers and/or Distributor End User Entities that will apply for licenses under the new regulations. The number of hours per application ranges from a low of 90 hours to a high estimate of 110 hours with a mean value of 100 hours. This results in a cost of ($101 thousand) a 7-percent discount rate as shown in Table A-12.

Table A-12 NRC Costs for Licensing PCTE End User Entities

Year	Description	End User Entities (not Manufacturers and/or Distributors)	NRC Hours	NRC Labor Rate	Undiscounted	7% NPV	3% NPV
2024	NRC Licensing PCTE End User Entities	9	100	$137	($123,300)	($100,650)	($112,837)
Net Benefits (Costs)					($123,300)	($100,650)	($112,837)

The staff estimates an average of 9 Silica Chip entities will apply for licenses under the new regulations. To comply with the new regulations, Silica Chip licensees will need to submit an initial application and a renewal application at 15 years. The estimated number of hours per application ranges from a low of 54 hours to a high estimate of 66 hours with a mean value of 60 hours as shown in Table A-13. This results in a cost of ($61 thousand) at a 7-percent discount rate as shown in Table A-13.

Table A-13 Silica Chip Entity Implementation Costs

Year	Description	Number of Silica Chip License Applications	Licensee Hours	Labor Rate	Undiscounted	7% NPV	3% NPV
2024	Silica Chip Entity Initial License Application Submittal	9	60	$100	($54,112)	($44,172)	($49,520)
2038	Silica Chip Entity Licensing	9	60	$100	($54,112)	($17,131)	($32,739)
Net Benefits (Costs)					($108,224)	($61,302)	($82,259)

The staff estimates that nine silica chip entities will submit an initial application and a renewal application at 15 years. The estimated number of hours to review the initial and renewal application and issue the licenses ranges from a low of 54 hours to a high estimate of 66 hours with a mean value of 60 hours This results in a cost of ($84 thousand) at a 7-percent discount rate as shown in Table A-14.

Table A-14 NRC Costs to Issue Silica Chip Licenses

Year	**Description**	**Number of Silica Chip Applications**	**Silica Chip Time (Hours)/NRC**	**NRC Labor Rate**	**Undiscounted**	**7% NPV**	**3% NPV**
2024	Item C NRC Licensing Silica Chip Entities	9	60	$137	($73,980)	($60,390)	($67,702)
2038	Item C NRC Licensing Silica Chip Entities	9	60	$137	($73,980)	($23,420)	($44,759)

Net Benefits (Costs)				($147,960)	($83,810)	($112,461)

The staff estimates an average of 9 gemstone licensees complying with the new regulations. The number of hours saved, when complying with the new regulations, ranges from a low of 36 hours to a high estimate of 44 hours with a mean value of 40 hours. This results in an averted cost of $29 thousand a 7-percent discount rate as shown in Table A-15.

Table A-15 Averted Gemstone Entity Implementation

Year	Description	Number of Gemstone Exemptions Averted	Hours	Labor Rate	Undiscounted	7% NPV	3% NPV
2024	Licensee Gemstone Exemptions Averted	9	40	$100	$36,075	$29,448	$33,014
Net Benefits (Costs)					$36,075	$29,448	$33,014

The staff estimates an average of 9 gemstone licensees complying with the new regulations. The number of hours saved to issue exemptions covering gemstone entities ranges from a low of 36 hours to a high estimate of 44 hours with a mean value of 40 hours. This results in an averted cost of $40 thousand a 7-percent discount rate as shown in Table A-16.

Table A-16 Averted NRC Gemstone Exemption Costs

Year	Description	Number of Gemstone Exemptions Averted	Hours	NRC Labor Rate	Undiscounted	7% NPV	3% NPV
2024	NRC Exemption Processing Averted	9	40	$137	$49,320	$40,260	$45,135
Net Benefits (Costs)					$49,320	$40,260	$45,135