Regulatory Analysis for the Final Rule to Limit The Amount of Activity of Byproduct Material Allowed In a Generally Licensed Device

U.S. Nuclear Regulatory Commission
Office of Federal and State Materials and Environmental Management Programs

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EXECUTIVE SUMMARY

The U.S. Nuclear Regulatory Commission (NRC) is publishing a final rule (RIN: 3150-AI33) to amend its regulations to limit the amount of radioactive material in generally licensed devices containing certain radionuclides that are regulated under Title 10 of the *Code of Federal Regulations* (CFR) 31.5, and to change the Compatibility Category of 10 CFR 31.5(a), 31.5(c)(13)(i) and 31.6 from Category B to C.

The final rule will require licensees who possess generally licensed devices that meet or exceed 1/10 of the International Atomic Energy Agency Category 3 threshold values for certain radionuclides to apply for and receive a specific license (SL) for the device. This regulatory change will enhance the protection of public health and safety by increasing the accountability and security of radioactive material currently possessed under a general license (GL).

The NRC staff estimates that this final rule will affect about 1,400 licensees. Of that total, 280 licensees are regulated by the NRC and 1,120 licensees are regulated by the Agreement States. In the first several years of implementing the final rule, these licensees will incur additional regulatory compliance costs compared to past years, and some licensees will incur higher costs than others due to the differences in regulations among the Agreement States. For example, some Agreement States already require an SL for a portable gauge that meets the NRC criteria for a generally licensed device. In these States the cost impact to a licensee will be less than in States where those same devices are held under a GL.

The new requirement to apply for and maintain an SL will cost each affected licensee about $2,811 as a one-time implementation cost followed by an increase in annual operating costs of about $6,794. Most licensees affected by this final rule have had fewer compliance requirements under a GL than they will have under an SL, but the concerns for source accountability and security require this rule change to enhance the protection of public health and safety by enhancing the accountability and security of radioactive materials. The estimated one-time implementation cost for the NRC is $347,200, with an increase in annual operating costs of $221,693. Total cost of the final rule over 10 years, at 3 percent discount rate, is $19,252,662 for the NRC and its licensees. The total cost over 10 years at 3 percent discount rate for all affected licensees and regulators (i.e., NRC, the Agreement States, and all licensees affected by this rule) is $96,263,310.

The final rule will change the Compatibility Category of 10 CFR 31.5(a), 31.5(c)(13)(i) and 31.6 from Category B to C. Comments from stakeholders received during the proposed rule public comment period were mixed on this topic. The NRC staff concludes that the impact of this change will not be significant over many of the regulatory jurisdictions and thus has included no costs in this Regulatory Analysis due to this change.

This Regulatory Analysis provides an evaluation of two alternatives. The preferred alternative is Alternative 2A, which amends regulations as specified in the final rule. This alternative is less costly than the other alternative and supports a risk-informed regulatory framework to enhance the protection of public health and safety by increasing the accountability and security of radioactive materials.

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1. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is amending 10 CFR 31.5 to limit the quantity of byproduct material contained in a generally licensed device to below one-tenth (1/10) of the International Atomic Energy Agency (IAEA) Category 3 thresholds. Because the general license (GL) authorization no longer exists at or above these threshold values, individuals possessing devices with byproduct material meeting or exceeding the 1/10 of Category 3 threshold values are required to apply for a specific license (SL). In this document, the final rule is referred to as the GL Restrictions rule.

This regulatory analysis evaluates the consequences associated with the GL Restrictions rule, which amends 10 CFR Part 31, "General Domestic Licenses for Byproduct Material." This document presents background material, rulemaking objectives, alternatives, input assumptions, and analysis of the consequences of the final rule language and alternative approaches to accomplish the regulatory objectives.

1.1 Background

After the September 11, 2001, terrorist attacks, the NRC conducted a comprehensive review of radioactive material safety and security requirements, and implemented several measures to increase the safety and security of radioactive sources, with particular focus on radioactive sources of concern. These measures included the issuance of increased control orders to specific licensees who possess IAEA Category 1 and 2 radioactive sources requiring them to exercise added control over such sources. The NRC also created a National Source Tracking System (NSTS) to provide better accountability of Category 1 and 2 sources. The staff has included no costs in this regulatory analysis associated with additional reporting to the NSTS following implementation of the GL Restrictions final rule, because none of the devices subject to this rule require reporting to the NSTS.

The U.S. Congress and the U.S. Government Accountability Office (GAO) raised concerns regarding the safety and security of radioactive sources in generally licensed devices. In a July 12, 2007, report by the U.S. Senate Permanent Subcommittee on Investigations (PSI), the subcommittee expressed concerns about certain U.S. government practices and procedures for issuing licenses to possess radioactive materials and presented certain recommendations to remedy these concerns. The GAO completed two audits of the security aspects of NRC's licensing process, including one in 2007 (GAO-07-1038T; July 12, 2007) that raised concerns about the relative ease with which lower activity sources can be purchased and potentially aggregated to higher activity levels. In addition, the Organization of Agreement States (OAS) filed a petition for rulemaking on June 27, 2005 (PRM-31-5), requesting that NRC "strengthen the regulation of radioactive materials by requiring an SL for higher-activity devices that are currently available under the general license in 10 CFR 31.5." PRM-31-5 requested that the NRC amend its regulations to require specific licensing for devices exceeding the registration quantity limits in 10 CFR 31.5(c)(13)(i). Additionally, the OAS requested that NRC revise the compatibility designation of 10 CFR 31.6 from B to C, which would allow States to better track service providers and distributors of generally licensed devices. In addition, the State of Florida requested a compatibility category change for 10 CFR 31.5(c)(13)(i) from B to C to allow it to continue to require registration of other generally licensed devices in addition to those required to be registered by the NRC.

The current GL regulatory program does not provide the NRC or the Agreement States with an opportunity to review the general licensees' purpose for using licensed material, facilities,

equipment, training, experience, and ability to meet other applicable regulatory requirements. To remedy this, the NRC staff evaluated amendments to 10 CFR Part 31 to require specific licensing for some materials that are currently regulated under the GL regulatory system. On April 24, 2006, the NRC staff submitted SECY-06-0094, "Tracking or Providing Enhanced Controls for Category 3 Sources," to the Commission for review. In that paper, the NRC staff proposed initiating a rulemaking that would set an activity limit for generally licensed devices at one-half (1/2) of the IAEA Category 2 threshold and reserve authorization to possess higher activity sources to those licensees with SLs. As indicated in SECY-06-0094, the bases for the proposed activity limit was that the activity levels in such devices would be close to the Category 2 levels and such a limit would not affect a significant number of licensees. In response to SECY-06-0094, the Commission, in a Staff Requirements Memorandum (SRM), dated June 9, 2006, approved the staff's plan to amend the GL requirements in 10 CFR Part 31.5, but disapproved the staff's recommendation to set the limit at 1/2 of IAEA Category 2. Instead, the Commission instructed the staff to evaluate the specific licensing of general licensees possessing devices greater than or equal to 1/10 of the IAEA Category 3 threshold[1].

The GL Restrictions proposed rule was published on August 3, 2009 (74 FR 38372) to gather public comments on a proposal to amend the NRC's regulations to limit the quantity of byproduct material allowed in a generally licensed device to below 1/10 of the IAEA's Category 3 thresholds, and to change the compatibility category from B to C for 10 CFR 31.5(a), 31.5(c)(13)(i) and 31.6. This proposed rule was directed toward improving the accountability and security of generally licensed devices containing byproduct material greater than or equal to 1/10 of Category 3 threshold values by requiring these devices to be held under an SL, while allowing the remainder of the devices containing material below 1/10 of Category 3 to be regulated under the GL.

2. Objectives of Final Rule

The primary objective of this rulemaking is to limit the quantity of radioactive material that a licensee may possess in a single device under a GL, by amending Part 31 of the Commission's regulations. This amendment requires general licensees to obtain an SL to possess radioactive material meeting or exceeding certain threshold values. A second change modifies the Compatibility Categories of some of the current regulations, from category B to C.

These changes are being promulgated to enhance the protection of public health and safety by increasing the accountability and security of radioactive materials.

3. Identification of Alternative Approaches

NRC staff identified and considered two alternatives for limiting the quantity of byproduct material in generally licensed devices. The following subsections describe these alternatives. Other alternatives were submitted in comment letters on the proposed rule, and these are discussed in section 4.2.3.

[1] Sources referred to as "1/10 of Category 3" were formerly referred to as "Category 3.5" sources in the June 9, 2006, SRM. To be consistent with IAEA terminology, the term "Category 3.5" has been changed to "1/10 of Category 3."

3.1 Alternative 1: No Action

Under the "no action" alternative, the staff would continue its current activities. No limit on the quantity of byproduct material allowed in generally licensed devices would be established. The current GL regulatory program would continue as it currently exists, including maintaining Compatibility Category B in 10 CFR 31.5 (a), 31.5(c)(13)(i) and 31.6.

3.2 Alternative 2: Limiting the Quantity of Byproduct Material Allowed Under the GL

Limiting the quantity of byproduct material allowed in a generally licensed device would require general licensees to obtain an SL to possess radioactive material meeting or exceeding certain thresholds. NRC staff considered the alternatives indicated in Sections 3.2.1 and 3.2.2, below, with regard to instituting activity limits for 10 CFR 31.5.

3.2.1 Alternative 2A: 1/10 of Category 3 Threshold Values

Under this alternative, a limit on devices that can be generally licensed is set at 1/10 of the IAEA's Category 3 threshold values. As a result, general licensees possessing devices containing byproduct material meeting or exceeding these values are required to be specifically licensed, while those below these values may continue to be generally licensed. This alternative allows the NRC and Agreement States to have greater oversight over the activities performed by licensees who possess greater than or equal to 1/10 of Category 3 sources and improves accountability and control over the devices that contain such sources.

In particular, with regard to devices containing byproduct material with an activity level at 1/10 of Category 3, this alternative reduces the likelihood that a sufficient number of these devices (which are actually higher-activity Category 4 sources) can be obtained and aggregated to create the equivalent of a Category 2 source. These "high-end" Category 4 sources can be at levels just below the threshold of a Category 3 source, which is about 1/10 of a Category 2 source, meaning that it would require about 10-12 of these devices to aggregate to a Category 2 quantity. These devices are mostly industrial gauges and thus are in relatively widespread use and broadly used in industry, thus allowing for the potential for aggregation of sufficient numbers of them to Category 2 levels. Alternative 2A does not address concerns regarding aggregation of devices below 1/10 of Category 3 and down to current registration levels (approximately 1/1000 of the Category 3 threshold); but, in general, sources in these devices are of such low activity that hundreds or thousands of these devices would have to be aggregated to constitute a radioactive source in quantities of concern. Therefore, there is a lower likelihood that devices with sources in this range can be aggregated to a quantity of concern.

Under this alternative, a number of current general licensees would need to apply for an SL, which would make them subject to applicable NRC regulations as specific licensees, including appropriate sections of 10 CFR Part 20, "Standards for Protection Against Radiation, " and Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material." These requirements, and their associated costs, are discussed in Section 4 of this Regulatory Analysis.

3.2.2 Alternative 2B: Registration Threshold Values

Under this alternative, a limit on devices that can be generally licensed would be set at the current registration levels listed in 10 CFR 31.5(c)(13)(i). As a result, general licensees with devices containing byproduct material meeting or exceeding the registration levels would be required to be specifically licensed, while those below the registration levels would continue to be generally licensed. This would allow the NRC and Agreement States to have increased oversight over a greater number of licensees than Alternative 2A and would provide a higher level of accountability and control over current generally licensed devices than Alternative 2A.

This alternative would address the concern that devices containing Category 4 and 5 sources could be aggregated to a quantity of concern. In general, the threshold values of Category 4 and 5 sources are so low that hundreds or thousands of devices with such sources would need to be aggregated to constitute a radioactive source in a quantity of concern. Therefore, there is a lower likelihood that a sufficient number of these sources could be aggregated. Alternative 2B would address concerns from stakeholders such as Congress, the GAO, and the Agreement States regarding the potential for aggregation of these lower activity sources, and would provide a higher level of security against the aggregation of these Category 4 and 5 sources to higher category levels in quantities of concern.

Under this alternative, a greater number of current general licensees than under Alternative 2A would need to apply for an SL, which would make them subject to applicable NRC regulations as specific licensees, including appropriate sections of 10 CFR Part 20 and Part 30. These requirements, and their associated costs, are discussed in Section 4 of this Regulatory Analysis.

4. Analysis of Values and Impacts

The following subsections describe the analysis conducted to identify and evaluate the values and impacts expected to result from the final rule. Subsection 4.1 identifies the attributes that the final rule is expected to affect. Subsection 4.2 describes the methodology used to analyze the consequences of the final rule.

4.1 Identification of Affected Attributes

This subsection identifies the attributes, within the public and private sectors, that the final rule is expected to affect, using the list of potential attributes provided in Chapter 5 of NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook," dated January 1997, and in Chapter 4 of NUREG/BR-0058, Rev. 5, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," dated September 2004. The evaluation considered each attribute listed in Chapter 5. The basis for selecting those attributes is presented below.

Limiting the amount of byproduct material that could be allowed in a generally licensed device is expected to affect the following attributes:

- ***Public Health (Accident)***. The final rule allows the NRC to review the applicant's proposed use of the material, the applicant's facilities and equipment, training and experience, and the applicant's ability to meet other regulatory requirements that may be applicable. The final rule is expected to improve the safety, security, and control of a greater number of radioactive sources, which will result in better handling and use of previously generally

licensed devices. The final rule will reduce the possibility of accidents and events, and will therefore have a positive effect on public health.

- ***Offsite Property***. Improvement in the accountability and controls over previously generally licensed devices may avert, to a small degree, potential offsite property damage and resulting costs for response efforts.

- ***Industry Implementation***. Certain licensees who currently use the GL to possess byproduct material will need to submit an application for an SL and will also need to change their internal procedures to comply with SL regulatory requirements. These licensees will incur one-time implementation costs under the final rule.

- ***Industry Operation***. The same licensees who undergo one-time implementation costs will need to manage new administrative and procedural activities, training and other measures to comply with the new requirements. These licensees will incur annual operating costs under the final rule.

- ***NRC Implementation***. The final rule requires the NRC to revise its guidance in NUREG-1556. Specifically, NRC must revise guidance to ensure that licensees apply for an SL and meet other applicable regulatory requirements when in possession of devices containing byproduct material meeting or exceeding the final rule threshold values. For this activity, NRC will incur one-time implementation costs. This work was not completed during the proposed rule phase.

- ***NRC Operation***. On an on-going basis, the NRC staff must review license applications, perform pre-licensing visits, inspections and other regulatory activities to ensure licensee compliance with the new GL Restrictions requirements. The NRC will incur increased annual operating costs to support this work.

- ***Other Government***. The final rule benefits other Federal agencies and State and local governments (e.g., Department of Homeland Security, Agreement States) by imposing more stringent regulatory controls on general licensees by limiting the amount of byproduct material in generally licensed devices. This rulemaking allows better tracking and accountability of materials in the United States and will reduce the possibility for malevolent use of radioactive materials and the potential for aggregation of devices to quantities of concern. The final rule allows Agreement States to better monitor the location of radioactive material of concern and to focus their resources on licensees with higher quantities of radioactive material.

- ***Improvements in Knowledge***. The final rule allows the NRC to assess and enhance the safety of licensed activities, gather updated information, assess accident probabilities or consequences and reduce uncertainties. This additional oversight allows the NRC to increase the protection of public health and safety.

- ***Regulatory Efficiency***. The current GL regulatory system is inherently efficient because it requires very few regulatory resources, with little to no regulatory oversight during use of the generally licensed devices. The final rule creates an overall improvement in regulatory efficiency by facilitating, over the long-term, NRC and Agreement States accountability and oversight of generally licensed devices with a reduction in potential safety issues that can arise from the misuse or improper disposal of generally licensed devices.

- ***Safeguards and Security Considerations***. The final rule allows NRC to better monitor the location and use of radioactive materials of higher activity, and enhances the accountability and control of these devices. The more stringent requirements associated with an SL provide reasonable assurance that persons seeking to obtain such devices are viable, trustworthy and reliable, and minimizes the potential for aggregation of sources to quantities of concern. Consequently, the final rule enhances NRC's ability to protect public health and safety.

- ***Other Considerations***. The final rule increases public confidence in the NRC and Agreement States with respect to the ability to adapt regulations in response to potential threat scenarios affecting public health and safety.

The final rule does not affect the following attributes:

- Public Health (Routine)
- Occupational Health (Accident)
- Occupational Health (Routine)
- Onsite Property
- General Public
- Antitrust Considerations
- Environmental Considerations

4.2 Analytical Methodology and Assumptions

This section describes the methodology used to analyze the consequences associated with the final rule. The values (benefits) include any desirable changes in the affected attributes. The impacts (costs) include any undesirable changes in affected attributes.

The NRC collected input assumptions using data and information from the following sources: NRC workgroups and staff experience; NRC databases; Agreement States; reports and documents (e.g., Office of Management and Budget (OMB) burden statements; and independent research.)

The following sections discuss the specific assumptions for each of the alternatives.

4.2.1 Alternative 1

Under the No-Action alternative, Alternative 1, the current GL regulatory system would remain as is. However, this alternative does not address concerns identified by various stakeholders such as the U.S. Senate PSI and the GAO, both of which expressed concerns with the relative ease with which devices containing byproduct material can be obtained and potentially aggregated to quantities of concern. Agreement States have also raised concerns about the security and accountability of generally licensed materials. The NRC staff believes that, under the current domestic and international threat environment, there is a potential for aggregation of devices containing lower activity sources to quantities of concern and that certain generally licensed devices should be under increased regulatory oversight. This alternative does not adequately increase the protection of public health and safety because it does not address these concerns and issues.

4.2.2 Alternative 2

Alternative 2 limits the quantity of byproduct material allowed in generally licensed devices. The NRC analyzed two threshold values that would serve as limits for the quantity of byproduct material allowed in a generally licensed device. These are described in Sections 4.2.2.1 and 4.2.2.2, and are identified as Alternatives 2A and 2B.

Costs are evaluated in this Regulatory Analysis for NRC licensees and the NRC, and for Agreement State licensees and the Agreement States.

The following cost categories that affect both NRC and Agreement State licensees are evaluated for both alternatives: costs of complying with existing requirements for specific licensees; costs of fees associated with the license (either specific or general); and the costs of any revisions that must be made to a sealed source and device (SS&D) registration certificate. Costs considered include one-time implementation costs and annual operating costs for complying with the new requirements on a continuing basis. No costs were included in this analysis to represent the disposition of devices, currently held under a general license, by licensees who may decide to terminate their business operations instead of applying for a specific license to continue business operations. No comments were received during the proposed rule public comment period that this rule would cause operations to cease. However, the NRC recognizes the cost to properly disposition devices no longer needed may be significant for some businesses, especially those operating in states with no local disposal option.

The following cost categories that affect both the NRC and the Agreement States are evaluated for both alternatives: cost to review license applications, amendments, and renewals made by licensees to comply with existing requirements for specific licensees; costs to review and approve amended SS&D certificates; and costs to revise NUREG-1556 guidance or other State guidance documents. The costs associated with reviewing SL applications and increased inspections are not evaluated for both alternatives because the increased costs are assumed to be covered by the license fees paid by the applicants and licensees.

Tables 1, 2, and 3 contain costs for NRC licensees and the NRC. Since NRC currently regulates about 20 percent of the general licensee population and the Agreement States regulate about 80 percent (i.e., there are about 4 times the number of Agreement State licensees), it is estimated that costs for all Agreement State licensees and all Agreement States would be approximately 4 times the costs for NRC licensees and the NRC, respectively. This is based on the assumption that the unit costs on a per licensee basis are the same for both NRC and Agreement State licensees. This is noted in the footnotes to Tables 1, 2, and 3.

The NRC staff did not estimate the costs associated with changes from B to C in the Agreement State compatibility designations for 10 CFR 31.5(a), 31.5(c)(13)(i) and 31.6 because of the uncertainty in the specific requirements among the States who will have some flexibility in the rule language that they place in their State regulations. The staff is aware that changing to compatibility designation C will be more burdensome for some licensees who conduct business in multiple States, and will be beneficial to some States in their ability to apply the regulatory requirements based on their specific needs.

4.2.2.1 Alternative 2A: 1/10 of Category 3 Threshold Values

This section identifies the cost assumptions for Alternative 2A. For licensees, the costs are included in one of three cost categories: costs that will be incurred by the licensees in changing to an SL, their extra fees in maintaining an SL, and costs to submit an amendment to their SS&D registries. The cost to NRC and Agreement State regulators to implement the final rule are also discussed, with an extra category representing costs to revise NUREG-1556 guidance documents. The cost assumptions per licensee are listed below and are shown as totals for all affected licensees in Table 1 of this document.

In summary, the cost of Alternative 2A to each affected licensee is about $2,811 as a one-time implementation cost and $6,794 as an increase in annual operating costs. The one-time cost to NRC is about $347,200 and to the Agreement States is about $1,388,800. The increase in annual costs to NRC is about $221,693 and the increase in annual costs to the Agreement States is about $886,772.

One consequence of the GL Restrictions final rule that is not modeled in this Regulatory Analysis is the potential response by affected licensees who possess a large number of devices at one site that could be aggregated to a quantity of concern. The NRC issued Increased Control Orders (EA-05-090; November 14, 2005) (70 FR 72128; December 1, 2005) to approximately 2,200 licensees authorized to possess certain risk-significant quantities of radioactive material (category 1 and category 2 quantities). Under these Orders, licensees are required to determine that each person who requires access to radioactive material in quantities of concern to perform their job duties is sufficiently trustworthy and reliable, On December 5, 2007, the NRC issued orders to all other NRC licensees that possessed category 1 or category 2 quantities of radioactive material (EA-07-305) (72 FR 70901; December 13, 2007) to require fingerprinting and FBI criminal history records checks for unescorted access to category 1 or category 2 quantities of radioactive material. To effect nationwide implementation, each Agreement State issued legally binding requirements to licensees under their regulatory jurisdiction. About 10 percent of the 280 NRC licensees affected by the GL Restrictions final rule (i.e., about 30 licensees), who will need to apply for an SL pursuant to this final rule, possess aggregate quantities of certain radionuclides that exceed the threshold for IAEA Category 2. Some of the licensees in Agreement States who are affected by the GL Restrictions final rule may possess similar quantities of those radionuclides. All of the NRC and Agreement State regulated licensees affected by the GL Restrictions final rule who possess quantities of certain radionuclides that exceed IAEA Category 2 will need to decide whether to make changes to physical structures and procedures at their sites to remove concerns of co-located sources, or make no changes and comply with the Increased Controls orders. For purposes of supporting this Regulatory Analysis for the final rule, it was assumed that licensees with this decision will prefer to make changes to physical structures and procedures and that this will be done at a small one-time expense. No costs were modeled for this action by licensees.

a) Cost of complying with existing labor requirements for specific licensees

Under Alternative 2A, a limit on general licenses is set at 1/10 of the IAEA's Category 3 thresholds, and general licensees possessing devices with byproduct material meeting or exceeding these thresholds must obtain an SL. General licensees possessing devices containing byproduct material below these thresholds may continue to be generally licensed.

Based on information in NRC's General License Tracking System (GLTS), about 280 NRC general licensees possess devices with byproduct material meeting or exceeding 1/10 of Category 3 thresholds. Although the GLTS has a dynamic data base and is subject to change and variation, the current estimate of licensees potentially affected is considered adequate for use in this Regulatory Analysis. Since NRC currently regulates about 20 percent of the general licensee population, it is estimated that a total of about 1,400 NRC and Agreement State general licensees possess devices with byproduct material meeting or exceeding the stated limits (i.e., 1,120 Agreement State licensees).

Although the final rule only involves rule text changes to Part 31, the existing general licensees who must become specific licensees would be required to comply with other existing requirements in the NRC's regulations that specific licensees must comply with, such as those in Parts 19, 20, and 30. Licensees might incur additional labor costs to comply with other NRC regulations, such as those in 10 CFR Part 21, but these costs are small compared to those considered here.

All costs in this Regulatory Analysis are in units of 2007 dollars, consistent with the Regulatory Analysis supporting the proposed rule.

The NRC staff used the following estimates to represent one-time implementation and annual operating costs for NRC licensees, with respect to their added labor hours to comply with 10 CFR regulations under Alternative 2A of this final rule:

10 CFR Part 19	One-time labor for Instruction to Workers, per licensee	$800
	Annual operating cost, per licensee	$103
10 CFR Part 20	One-time added labor cost, per licensee	$0
	Annual operating cost, per licensee	$1,893
10 CFR Part 30	One-time cost for an SL application ($1400) and the labor effort (4.4 hours) to complete the application, per licensee	$1,840
	Annual operating cost, per licensee	$2,420

In the Regulatory Analysis supporting the proposed rule, the NRC staff estimated that each of the 1400 licensees affected by Alternative 2A would perform 3 hours of labor per year to perform work in compliance with 10 CFR 30.32(g) to complete Form 313 for the initial license application, any amendments, and any renewal applications. For the final rule Regulatory Analysis, this was increased to 20 hours of labor per year for each licensee. The estimate was increased because NRC realized that most licensees will not be familiar with the SL application process and the time requirement for submitting the initial application, amendments, and renewals is likely to be more than 3 hours per year. The new assumed value of 20 hours per year is for each of the licensees affected by the final rule over the 10-year analysis period (i.e., 200 hours each over 10 years).

Appendix 1 shows the basis of these estimates that are the NRC's assumptions of the licensee labor effort necessary to comply with different sections of regulations in Parts 19, 20, and 30.

Appendix 1 also shows the costs assumed for the NRC's labor effort to perform regulatory oversight for Parts 19, 20, and 30.

Several comments were received during the proposed rule public comment period stating that the cost of the rule would cause dramatic cost increases to licensees due to the additional training and other requirements to comply with 10 CFR Parts 19, 20 and 30, including costs for hiring a radiation safety officer, hiring and training radiation safety personnel including authorized users, and providing additional routine training. The cost assumptions in this Regulatory Analysis assume that a capable and responsible employee at the company currently operating under a general licensee is able to assume the responsibilities of the radiation safety officer and that this person performs the necessary training of other personnel. The NRC staff does not believe it is reasonable or necessary for the company currently operating under a GL to hire a full time radiation safety officer to support the activities performed under the specific license.

b) Costs of fees for maintenance of a license, either specific or general

The NRC maintains a licensing fee system in 10 CFR 170, "Fees for Facilities, Materials, Import and Export Licensees, and other Regulatory Services under the Atomic Energy Act of 1954," and in 10 CFR 171, "Annual Fees for Reactor Licensees and Fuel Cycle Licensees, and Materials Licensees, including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC." The purpose of the regulations in 10 CFR 170 is to set out fees charged for licensing services rendered by the NRC in reviewing applications; the purpose of the regulations in 10 CFR Part 171 is to set out the annual fees charged to persons who hold licenses and other NRC documents for routine licensing review activities, such as review of amendments and renewals, and conducting inspections. For the purpose of this analysis supporting the final rule, the fees are assumed to remain unchanged over the analysis period and are the same as those analyzed for the proposed rule. In the context of the overall, societal regulatory evaluation, NRC's fees are neither a cost nor a benefit, but are considered a distributional effect. To a licensee, however, fees may have a significant impact and therefore they are discussed in detail below and are included in the costs of this Regulatory Analysis.

Section 170.31, Item 3P, indicates that the cost of applying for a specific byproduct materials license is $1,400. This cost is included in Section 4.2.2.1(a) above, and in Appendix 1, Table 3, as part of the cost to general licensees to comply with 10 CFR Part 30.

Section 171.16, Item 3P, indicates that the cost of the annual fee for a specific byproduct materials license is $2,700; this fee covers the costs of amendment review, inspections, etc. It is also noted in Section 170.16 that licensees who demonstrate that they are small entities may pay a reduced annual fee. Section 171.16, Item 3Q indicates that the annual cost for registration of general licensees, as part of the GLTS, is covered through Part 170 fees. Section 170.31, Item 3Q, indicates that the annual GLTS fee is $320.

In estimating the net cost of this final rule, the NRC used the difference between the annual SL fee and the annual GLTS registration fee. The net cost of fees for NRC general licensees is included in Table 1; estimates of the costs for Agreement State licensees are also indicated in Table 1. It is assumed for the purposes of this calculation that there is no reduction in SL fees based on certain licensees being small entities, although it is likely that the actual cost would be lower for small entities.

In summary, since the fee for applying for an SL has been included in the Part 30 costs itemized above, the only fee considered in this section is the increase in annual fee due to maintaining an SL instead of holding the device under a general license.

Extra fees	One-time submittal of an SL application, per licensee	$0
	Increase in annual fees, per licensee	$2,380

c) Costs of any revisions to the sealed source and device registry system

NRC and the Agreement States perform engineering and radiation safety evaluations of the ability of devices containing sealed sources to safely contain radioactivity under the conditions of their possession and use. These evaluations are summarized in registrations that NRC maintains in the National SS&D Registry. The registration certificates contain detailed information on the devices, such as how they are permitted to be distributed and possessed (i.e., SL, GL, or exempt), design and function, radiation safety, and limitations on use. NRC and Agreement States with SS&D authority issue SS&D registration certificates for distributors and manufacturers within their jurisdiction.

As a result of this amendment, certain SS&D certificates will need to be amended on a one-time basis to account for the change in the licensing of the device. In the Regulatory Analysis for the proposed rule, the NRC staff estimated that a total of 30 SS&D certificates will need to be amended for NRC licensees at a labor effort to the licensees of 1 hour per SS&D registry. This was increased by a factor of 4 to represent amended SS&D registries in the Agreement States, at the same 1 hour per registry. Thus, the proposed rule considered a total of 150 SS&D registries in need of amendment at a labor effort of 1 hour per registry.

For the final rule, the NRC staff retained the estimate of 150 total SS&D registries that need to be amended, but increased the labor effort to 16 hours each for licensees and 40 hours each for regulators. The regulatory effort is greater than the licensee effort because the regulators need to include the updated information in the National Sealed Source and Device Registry (NSSDR) and other databases. In addition, the NRC staff and Agreement State staffs will review and amend as necessary the information on inactive SS&D registry sheets. This is estimated to occur on 150 inactive SS&D registries at a labor effort of 8 hours for each inactive registry. This cost is above funds received through fees.

In summary, the NRC staff used the following estimates to represent licensee one-time labor effort to amend 30 active SS&D registries and 30 inactive registries. Increasing these by a factor of 4 to represent SS&D registries administered by Agreement States raises the total to 150 active registries and 150 inactive registries.

Active registry	One-time labor by licensee, per amended SS&D registry	$1,600
Active registry	One-time labor by NRC, per amended SS&D registry	$4,000
Inactive registry	One-time labor by NRC, per inactive registry	$800

d) Costs to revise guidance documents

The NRC will incur costs to revise NUREG-1556 guidance, and the Agreement States will need to incur similar costs to publish the revised regulations and inform their licensees of the changes

in the final rule. The estimate for NRC is shown below; the estimate for all Agreement States is assumed to be 4 times the cost to the NRC (i.e., $320,000).

Rule and guidance	One-time cost to the NRC	$80,000
	Increase in annual costs, NRC	$0

4.2.2.2 Alternative 2B: Registration Threshold Values

This section identifies the cost assumptions for Alternative 2B. The unit cost assumptions are the same in Alternative 2B as those used for Alternative 2A, but the number of affected licensees is higher and the resulting costs are higher in Alternative 2B compared to 2A.

In summary, the cost of Alternative 2B to each affected licensee is about $2,723 as a one-time implementation cost and $6,794 as an increase in annual operating costs. The one-time cost to NRC is about $874,000 and to the Agreement States is about $3,496,000. The increase in annual costs to NRC is about $910,638 and the increase in annual costs to the Agreement States is about $3,642,552 .

a) Cost of complying with existing requirements for specific licensees

Under this alternative, a limit on general licensing would be set at the current registration levels listed in 10 CFR 31.5(c)(13)(i). General licensees possessing devices containing byproduct material meeting or exceeding these levels would be required to be specifically licensed. General licensees possessing devices containing byproduct material below these thresholds would continue to be generally licensed.

Based on information in NRC's GLTS, it is estimated that about 1,150 NRC general licensees possess devices with byproduct material meeting or exceeding the registration levels. Although, as noted above, the GLTS has a dynamic database and is subject to change and variation, the current estimate of licensees potentially affected is considered adequate for use in this Regulatory Analysis. Since NRC currently regulates about 20 percent of the general licensee population, it is estimated that a total of about 5,750 NRC and Agreement State general licensees currently posses devices with byproduct material meeting or exceeding the stated limits that would be set at the registration levels.

Under Alternative 2B, these 5,750 existing general licensees would need to become specific licensees and would be required to comply with existing requirements in Parts 19, 20 and 30.

The unit cost assumptions for one-time implementation and annual operating costs to comply with 10 CFR regulations under Alternative 2B are the same on a per licensee basis as those shown for Alternative 2A. The only difference is the larger number of licensees affected by the final rule. Appendix 1 shows the basis of these estimates which are NRC assumptions of the licensee labor effort to comply with different sections of regulations in Parts 19, 20 and 30. Appendix 1 also shows the costs assumed for NRC labor effort to perform regulatory oversight for Parts 19, 20, and 30.

b) Costs of fees for maintenance of a license, either specific or general

As discussed in Section 4.2.2.1(b), NRC maintains a licensee fee system under requirements for licensees in 10 CFR 170 and 10 CFR 171. The purpose of the regulations in 10 CFR 170 is to set out fees charged for licensing services rendered by the NRC in reviewing applications; the

purpose of the regulations in 10 CFR Part 171 is to set out the annual fees charged to persons who hold licenses and other NRC documents for routine licensing review activities such as review of amendments and renewals, and conducting inspections.

Section 170.31, Item 3P, indicates that the cost of applying for a specific byproduct materials license is $1,400. This cost is included in Section 4.2.2.2(a) above, and in Appendix 1, Table 9, as part of the cost to general licensees for complying with 10 CFR Part 30.

Section 171.16, Item 3P, indicates that the cost of the annual fee for a specific byproduct materials license is $2,700; this fee covers the costs of amendment review, inspections, etc. It is also noted in Section 170.16 that licensees who demonstrate that they are small entities may pay a reduced annual fee. Section 171.16, Item 3Q indicates that the annual cost for registration of general licensees, as part of the GLTS, is covered through Part 170 fees. Section 170.31, Item 3Q, indicates that the annual GLTS fee is $320. In estimating the net cost of this rule amendment, the NRC used the differential between the annual SL fee and the annual GLTS registration fee. The net cost of fees for NRC general licensees is included in Table 2; estimates of the costs for Agreement State licensees are also indicated in Table 2. It is assumed for the purposes of this calculation that there is not a reduction in SL fees based on certain licensees being small entities, although it is likely that the actual cost would be lower.

c) Costs of any revisions to the sealed source and device registry system

As noted in Section 4.2.1.2(c), as a result of this rule amendment, certain SS&D certificates would need to be amended to account for the different nature of the licensing of the device. Because of the larger number of licensees that would be affected by Alternative 2B, it is anticipated that a larger number of manufacturers and distributors would need to amend their SS&D certificates to account for the differing nature of the licensing of the devices.

In the Regulatory Analysis for the proposed rule, the NRC staff estimated that a total of 60 SS&D certificates would need to be amended for NRC licensees at a labor effort to the licensees of 1 hour per SS&D registry. This was increased by a factor of 4 to represent amended SS&D registries in the Agreement States for Alternative 2B, at the same 1 hour per registry. Thus, a total of 300 SS&D registries would need to be amended at a labor effort of 1 hour per registry.

For the final rule, the NRC staff has retained the estimate of 300 total SS&D registries that need to be amended, but has increased the labor effort to 16 hours each for licensees and 40 hours each for regulators, as done for Alternative 2A. In addition, the NRC staff and Agreement State staff will review and amend as necessary the information on inactive SS&D registry sheets. This is estimated to occur on 300 inactive SS&D registries at a labor effort of 8 hours for each inactive registry.

1) Costs to revise guidance documents

The same costs as those assumed in Alternative 2A were used to represent efforts in Alternative 2B to revise guidance documents.

4.2.3 Alternatives Submitted as Public Comments on the Proposed Rule

During the public comment period for the GL Restrictions proposed rule, the NRC received comments suggesting six different alternatives to accomplish the regulatory objectives. These

comments included; (1) amend the regulations to enhance the current registration process under 10 CFR 31.5(c)(13) to include radionuclides and threshold values in the final rule, and to require periodic audits by licensees of their byproduct material held under a GL with inspections by regulators. It was suggested that a corollary activity would be to modernize the quarterly reporting system of registered generally licensed devices to include location of devices; (2) amend the registration requirements in 10 CFR 31.5(c)(13) to include radionuclides and threshold values in the final rule, and require the licensee to perform device leak tests and shutter checks at 3 month or 6 month intervals to improve source accountability; (3) amend the regulations in 10 CFR Part 31 to require manufacturers to provide additional hardening and design features in the generally licensed devices, using specialized tools or welding equipment so that only the manufacturer could remove the sources from the device. Also, the regulations would be amended to: (a) include new security requirements for possession of devices that would also be written on the sealed source device registries, and (b) require periodic inspections by State or NRC regulators of the generally licensed devices that exceed 1/10 of Category 3 threshold value; (4) amend 10 CFR 31.5(a) to exclude all portable devices thereby requiring an SL for portable devices and for devices used in mobile equipment. This change would be accompanied by a Compatibility Category B for 10 CFR 31.5(a) so that Agreement States would not be allowed to deviate from the regulation, thereby making the regulation easier to conform to for those companies doing work in multiple States; (5) provide the manufacturers and distributors of generally licensed devices the option to hold a Master Materials License, or a single licensing mechanism, that would be valid for work in different regulatory jurisdictions. This would alleviate much of the burden associated with changing the Compatibility Category from B to C; (6) amend the regulations to add an annual inventory requirement for all licensees (specific and general) who possess a generally licensed device under 10 CFR 31.5, including the date of inventory and information specified in 10 CFR 31.5(c)(13)(iii)(A)-(F). The licensee would need to maintain the inventory information for inspection by NRC or Agreement State regulators.

In reviewing those six alternatives, the NRC determined that none of those alternatives would provide the necessary level of source accountability and security that is provided through application and maintenance of an SL. The SL requires pre-licensing reviews and inspections by NRC or the State regulatory agency, including safety and security assessments. Specific licensing provides the NRC and Agreement States with an opportunity to know the licensee, create a dialogue with the licensee, and conduct detailed reviews of the licensee's radioactive materials program. In particular, the pre-licensing visits and post-license inspections and record reviews provide the NRC and Agreement States with the ability to ensure that licensees are legitimate companies and that safety, security, and stewardship procedures are being followed. This level of assurance for source security and accountability is not provided by any of the six alternatives submitted in the proposed rule public comments, discussed briefly above. Thus, none of these alternatives were considered as effective as the assurances provided by converting the generally licensed devices to the terms and conditions of an SL.

5. Results

Results are shown for Alternatives 2A and 2B. Alternative 2A is the preferred approach to limit the quantity of byproduct material allowed in a generally licensed device. Existing general licensees affected by the final rule will be required to apply for an SL and follow regulatory requirements that apply to specific licensees.

The cost assumptions in Sections 4.2.2.1 and 4.2.2.2 are presented in constant 2007 dollars for both one-time implementation costs and annual operating costs, and are summarized in Tables 1 and 2. Table 3 shows the net impact of the one-time and annual costs of the final rule over a 10-year analysis period using 3 percent and 7 percent real discount rates, in 2007 dollars.

NRC staff believes that expected qualitative values resulting from the final rule amendments will contribute substantially to the benefits of NRC's licensing system, in particular with regard to accountability and control of devices and the sources that they contain. These qualitative values include:

- *Improved Control of Devices and the Sources they contain.* Placing a limit on the amount of byproduct material in generally licensed devices will result in improved accountability of certain devices that are currently generally licensed and provide additional protection against aggregation of lower activity sources to quantities of concern. This will improve public health (accident/event) and avert potential offsite property damage and costs.

- *Enhanced NRC Ability to Protect Public Health and Safety.* Requiring certain general licensees to obtain SLs will allow regulators to better monitor the adequacy of their operations and material possession, thus improving accountability of devices containing sources meeting or exceeding the threshold. Consequently, the final rule will enhance NRC and State regulators ability to protect public health and safety.

- *Improved Regulatory Efficiency.* The final rule creates an overall improvement in regulatory efficiency by facilitating, over the long-term, NRC and Agreement States accountability and oversight of generally licensed devices with a reduction in potential safety issues that can arise from the misuse or improper disposal of generally licensed devices.

- *Increased Public Confidence.* Information obtained by requiring current general licensees to obtain SLs will allow the NRC and Agreement States to better monitor these licensees and the devices and sources that they possess. This will result in increased public confidence in the regulation of tracking of radioactive materials.

As noted in Table 1, based on the preferred Alternative 2A, the one-time implementation costs are $1,134,400 and the increase in annual operating costs is $2,124,013. NRC licensees incur most of this at $787,200 and $1,902,320, respectively, with the remainder incurred by the NRC. For each of the assumed 280 NRC licensees, the amendments in Alternative 2A will contribute about $2,811 in one-time implementation costs and $6,794 in annual operating costs. Similar cost increases are assumed for each of the 1,120 Agreement State licensees.

As noted in Table 3, the total cost of Alternative 2A for NRC licensees and the NRC over a 10-year analysis period, at 3 percent discount rate, is $19,252,662. The total cost for industry, NRC, and Agreement States is estimated to be $96,263,310 over a 10-year period.

Table 1: Costs of Final Rule for NRC licensees and NRC[1] – Alternative 2A

	One-time Implementation costs	Annual Operating Costs
Industry Costs:		
• Compliance w/existing requirements for SLs [2]	739,200	1,235,920
• Fee	0	666,400
• SS&D amendments	48,000	0
Sub-total	787,200	1,902,320
NRC Costs:		
• Compliance w/existing requirements[3]	123,200	221,693
• Fee	0	0
• SS&D amendments	144,000	0
• Revise NUREG-1556	80,000	0
Sub-total	347,200	221,693
Total	1,134,400	2,124,013

Notes:

1) Costs are for all NRC licensees and NRC. Costs for all Agreement State licensees and the Agreement States would be approximately 4 times the costs in Table 1 (i.e., one-time implementation costs of 4,537,600 and annual operating costs of 8,496,052). Total costs of the final rule for industry, NRC, and the Agreement States would be approximately 5 times the costs in Table 1 (i.e., one-time implementation costs of 5,672,000 and annual operating costs of 10,620,065).
2) Industry cost for compliance with existing requirements is sum of Appendix1, Tables 1-3.
3) NRC cost for compliance with existing requirements is sum of Appendix 1, Tables 4-6.

As noted in Table 2, based on the Alternative 2B, the one-time implementation costs are $4,006,000 and the increase in annual operating costs is $8,723,738. NRC licensees incur most of this at $3,132,000 and $7,813,100, respectively, with the remainder incurred by the NRC. For each of the assumed 1,150 NRC licensees, the cost of the amendments in Alternative 2B would be the same as the cost per licensee for Alternative 2A. costs. Similar cost increases are assumed for each of the 4,600 Agreement State licensees.

As noted in Table 3, the total cost of Alternative 2B for NRC licensees and the NRC over a 10-year analysis period, at 3 percent discount rate, is $78,421,255. The total cost for industry, NRC, and the Agreement States is estimated to be $392,106,275 over a 10-year period.

Table 2: Costs of Final Rule for NRC licensees and NRC [(1)] – Alternative 2B

	One-time Implementation costs	Annual Operating Costs
Industry Costs:		
• Compliance w/existing requirements for SLs [(2)]	3,036,000	5,076,100
• Fee	0	2,737,000
• SS&D amendments	96,000	0
Sub-total	3,132,000	7,813,100
NRC Costs:		
• Compliance w/existing requirements[(3)]	506,000	910,638
• Fee	0	0
• SS&D amendments	288,000	0
• Revise NUREG-1556	80,000	0
Sub-total	874,000	910,638
Total	4,006,000	8,723,738

Notes:

1) Costs are for all NRC licensees and NRC. Costs for all Agreement State licensees and the Agreement States would be approximately 4 times the costs in Table 2 (i.e., one-time implementation costs of 16,024,000 and annual operating costs of 34,894,952). Total costs of the final rule for industry, NRC, and the Agreement States would be approximately 5 times the costs in Table 2 (i.e., one-time implementation costs of 20,030,000 and annual operating costs of 43,618,690).
2) Industry cost for compliance with existing requirements is sum of Appendix1, Tables 7-9.
3) NRC cost for compliance with existing requirements is sum of Appendix 1, Tables 10-12.

Table 3: Estimated Net Impact of Alternatives 2A and 2B for NRC licensees and NRC[(1)]

Regulatory Alternative	10-year total cost at 3% discount rate	10-year total cost at 7% discount rate
Alternative 2A	$19,252,662	$16,052,578
Alternative 2B	$78,421,255	$65,277,885

Note:

1) Costs are for all NRC licensees and NRC. Total costs of the final rule (i.e., Alternative 2A) for all Agreement State licensees and the Agreement States would be approximately 4 times the costs in Table 3 (i.e., 10-year total cost at 3% discount rate is 77,010,648; 10-year total cost at 7% discount rate is 64,210,312). Total costs of the final rule (i.e., Alternative 2A) for industry, NRC, and the Agreement States would be approximately 5 times the costs in Table 3 (i.e., 10-year total cost at 3% discount rate is 96,263,310; 10-year total cost at 7% discount rate is 80,262,890).

6. Backfit Analysis

The NRC has determined that this final rule is not subject to any of the backfitting provisions in 10 CFR 50.109, 70.76, 72.62, or 76.76, or the finality provisions in 10 CFR part 52. The amendments in this rule require certain generally-licensed devices to be licensed under a specific license. The regulatory determination that a device should be licensed under a specific license, as opposed to a general license, represents a matter of regulatory process and is not within the scope of NRC regulatory activities for which the NRC intended to provide backfitting protection. Moreover, a change in the NRC's requirements governing the need for a specific, as opposed to a general license, is not an NRC regulatory action meeting any of the definitions of backfitting. Nor does the change violate any of the issue finality requirements in part 52. Therefore, the NRC has not prepared a backfit analysis or any other documentation for this final rule.

7. Decision Rationale

The consequences have been considered for Alternatives 2A and 2B. Alternative 2A, Limiting Generally Licensed Devices to 1/10 of Category 3 threshold values, will accomplish the following regulatory objectives that are considered benefits of this final rule:

- improve the accountability and control of certain existing generally licensed devices and thereby enhance NRC's ability to protect public health and safety by placing these devices under more stringent regulatory oversight;

- reduce the potential for aggregation of devices for deliberate misuse;

- address potential security vulnerabilities; and

- increase public confidence in the protection of public health and safety.

Although Alternative 2B would also provide these benefits, the low threshold values are evaluated as a significantly lower likelihood that devices with sources in this range would be aggregated to quantities of concern, compared to Alternative 2A, and the increased benefits in limiting generally licensed devices to this lower threshold value are not offset by the higher costs in Alternative 2B compared to Alternative 2A.

Thus, the preferred option is Alternative 2A and the NRC staff considers the costs of implementing this regulatory approach justified compared to the benefits noted above.

8. Implementation

Any general licensee that currently possesses generally licensed devices meeting or exceeding 1/10 of the IAEA's Category 3 thresholds is being given an additional 12 months beyond the effective date of the final rule to submit an application for an SL (i.e., a year and 60 days after the final rule is published in the Federal Register). Additional information regarding implementation of these requirements will be provided as part of guidance for complying with these amended regulations.

The Agreement States are allowed 3-years to adopt the final rule in State regulations. During this time, the Agreement States will amend the SS&D registries to identify the devices that require an SL. A license condition on radioactive materials licenses issued by Agreement States will limit distribution of the devices.

APPENDIX 1:

DETAILED COSTS
ALTERNATIVES 2A AND 2B

Table 1
Option 2-a: Part 19 Estimated Burden for NRC Licensees[1]

Number of Licensees = 280 Cost/hr = $100

		Annual Operating Burden per Licensee			Total Annual Operating Burden	
10 CFR Part	**Requirement**	**Hours/ Action**	**Fraction of Licensees Affected**	**Hours/ Licensee**	**Total Hours**	**Total Annual Operating Cost**
19.12[2]	Instruction to workers	1.0	0.25	0.25	70.0	7,000
19.13(b)	Annual reports to current employees	0.6	1.0	0.6	168.0	16,800
19.13(e)	Reports to terminating employees	0.18	1.0	0.18	50.4	5,040
Totals				1.03	288.4	28,840

Notes:
(1) Total Annual Operating Burden (Hours and Costs) for Agreement State Licensees is about 4 times the values in Table 1
(2) In addition, Initial Implementation Cost for Section 19.12 for Instructions = $224,000 (8 hr per licensee; 280 licensees)

Table 2
Option 2-a: Part 20 Estimated Burden For NRC Licensees[(1)]

Number of Licensees = 280 Cost/hr = $100

		Annual Operating Burden per Licensee			Total Annual Operating Burden	
10 CFR Part	**Requirement**	**Hours/ Action**	**Fraction of Licensees Affected**	**Hours/ Licensee**	**Total Hours**	**Total Annual Operating Cost**
20.1302(b)(2)(ii)	Dose limits to public	0.1	1	0.10	28	2,800
20.1302(c)	Compliance with limit	10	0.0004	0.004	1.12	112
20.1801	Security of material	0.1	1	0.1	28	2,800
20.1802	Security of material	0.1	1	0.1	28	2,800
20.1904	Containers	0.1	1	0.1	28	2,800
20.1906(b)	Containers	0.5	1	0.5	140	14,000
20.1906(d)	Containers	0.25	0.1	0.025	7	700
20.1906(e)	Containers	1	0.5	0.5	140	14,000
20.2006	Manifests-Form 540-541	4	0.5	2	560	56,000
20.2102(a)	Rad Protection Program	4	1	4	1,120	112,000
20.2103(a)	Surveys	8	1	8	2,240	224,000
20.2106	Form 4/5-Occup Monitor	1	1	1	280	28,000
20.2107	Public exposures	0.5	1	0.5	140	14,000
20.2108(a)	Waste disposal	8	0.05	0.4	112	11,200
20.2201(a)	Theft	3	0.006	0.018	5.04	504
20.2201(b)	Theft	3	0.006	0.018	5.04	504
20.2201(d)	Theft	3	0.001	0.003	0.84	84
20.2202(a)	Incidents	1	0.002	0.002	0.56	56
20.2202(b)	Incidents	40	0.008	0.32	89.6	8,960
20.2203(a)	Excessive exposures	6	0.015	0.09	25.2	2,520
20.2204	Excessive exposures	5	0.022	0.11	30.8	3,080
20.2206	Form 4/5-Occup Monitor	40	0.026	1.04	291.2	29,120
Totals				18.93	5,300.4	530,040

Notes: (1) Total Annual Operating Burden (Hours and Costs) for Agreement State Licensees is about 4 times the values in Table 2

Table 3
Option 2-a: Part 30 Estimated Burden for NRC Licensees[1]

Number of Licensees = 280 Cost/hr = $100

		Annual Operating Burden per Licensee			Total Annual Operating Burden	
10 CFR Part	**Requirement**	**Hours/ Action**	**Fraction of Licensees Affected**	**Hours/ Licensee**	**Total Hours**	**Total Annual Operating Cost**
30.32(g)	Application – Form 313[2][3]	29	0.69	20.0	5,600	560,000
30.34(b)	Transfers	2	0.06	0.12	33.6	3,360
30.34(h)	Bankruptcy Filing	0.5	0.002	0.001	0.3	30
30.36(d)	Notify NRC of termination	1	0.066	0.066	18.5	1,850
30.36(j)	Survey/File Form 314	0.5	0.069	0.035	9.8	980
30.37(a)	Renewal/Form 313[2]					
30.38	Amendments/Form 313[2]					
30.41(c)&(d)	Transfer of Material	4	0.04	0.16	44.8	4,480
30.50(a),(b)&(c	Event Notification	4	0.015	0.06	16.8	1,680
30.51(a),(b)&(c	Receipt/transfer	3.5	1	3.5	980	98,000
30.51(d)	Disposal	0.5	0.06	0.03	8.4	840
30.51(f)	Transfer of records	0.5	0.12	0.06	16.8	1,680
Condition 26	Material use circumstances	0.5	0.096	0.048	13.4	1,340
Condition 164	Physical inventory	0.08	0.6	0.048	13.4	1,340
Condition 165(i)	Records of leak test results	0.08	0.6	0.048	13.4	1,340
Totals				24.2	6,770	677,000

Notes:

1) Total Annual Operating Burden (Hours and Costs) for Agreement State Licensees is about 4 times the values in Table 3 and in Footnote 3
2) Renewals and amendments included under 30.32(g). Hours/action increased in final rule compared to proposed rule from 4.4 to 29 based on extra time required to submit the initial application using guidance in NUREG-1556 and increased number of renewal applications over the 10-year analysis period.
3) In addition, Initial Implementation Cost of $515,200 = application fees + labor-time costs for completing applications (280 x $1,400 + 280 x 4.4 x $100)

Table 4
Option 2-a: Part 19 Estimated Burden for NRC(1)

Number of Licensees = 280 Cost/hr = $100

		Annual Operations Burden			Total Annual Operations Burden	
10 CFR Part	**Requirement**	**Hours/ Action**	**Fraction of Licensees Affected**	**Hours/ Licensee**	**Total Hours**	**Total Annual Operations Cost**
19.12	Instruction to workers	0.1	1	0.1	28	2,800
19.13(b)	Annual reports to current employees	0.06	1	0.06	16.8	1,680
19.13(e)	Reports to terminating employees	0.018	1	0.018	5	500
Totals				0.178	49.8	4,980

Notes:
(1) Total Annual Operating Burden (Hours and Costs) for Agreement State Licensees is about 4 times the values in Table 4

Table 5
Option 2-a: Part 20 Estimated Burden for NRC(1)

Number of Licensees = 280 Cost/hr = $100

		Total Annual Operating Burden		
10 CFR Part	**Requirement**	**Licensee Hours**	**NRC Hours**	**Total NRC Annual Operating Cost**
20.1302(b)(2)(ii)	Dose limits to public	28	5.6	560
20.1302(c)	Compliance with limit	1.12	0.22	22
20.1801	Security of material	28	1.4	140
20.1802	Security of material	28	1.4	140
20.1904	Containers	28	2.8	280
20.1906(b)	Containers	140	14	1,400
20.1906(d)	Containers	7	0.33	33
20.1906(e)	Containers	140	0.36	36
20.2006	Manifests-Form 540-541	560	2.52	252
20.2102(a)	Rad Protection Program	1,120	156.8	15,680
20.2103(a)	Surveys	2,240	210.56	21,056
20.2106	Form 4/5-Occup Monitor	280	140	14,000
20.2107	Public exposures	140	0.04	4
20.2108(a)	Waste disposal	112	1.57	157
20.2201(a)	Theft	5.04	5.04	504
20.2201(b)	Theft	5.04	5.04	504
20.2201(d)	Theft	0.84	0.28	28
20.2202(a)	Incidents	0.56	3.36	336
20.2202(b)	Incidents	89.6	6.9	690
20.2203(a)	Excessive exposures	25.2	19.15	1,915
20.2204	Excessive exposures	30.8	6.16	616
20.2206	Form 4/5-Occup Monitor	291.2	145.6	14,560
Totals			729.13	72,913

Notes:
(1) Total Annual Operating Burden (Hours and Costs) for Agreement State Licensees is about 4 times the values in Table 5

Table 6

Option 2-a: Part 30 Estimated Burden for NRC(1)

Number of Licensees = 280 Cost/hr = $100

	Implementation Cost	Total Annual Operating Burden		
Action	**One-time Cost**	**Hours/licensee by NRC for review**	**Total Annual NRC Hours**	**Total Annual Operating Cost**
Review of licensee initial applications	123,200			
Review of reports and records		2.1	588	58,800
Review of amendments(2)		4.4	850	85,000
Totals	123,200		1,438	143,800

Notes:
(1) Total Burden (Hours and Costs) for Agreement State Licensees is about 4 times the values in Table 6
(2) Based on an estimated 0.69 licensing actions per licensee

Table 7

Option 2-b: Part 19 Estimated Burden For NRC Licensees[1]

Number of Licensees = 1,150 Cost/hr = $100

		Annual Operating Burden per Licensee			Total Annual Operating Burden	
10 CFR Part	**Requirement**	**Hours/ Action**	**Fraction of Licensees Affected**	**Hours/ Licensee**	**Total Hours**	**Total Annual Operating Cost**
19.12[2]	Instruction to workers	1	0.25	0.25	287.5	28,750
19.13(b)	Annual reports to current employees	0.6	1	0.6	690	69,000
19.13(e)	Reports to terminating employees	0.18	1	0.18	207	20,700
Totals				1.03	1,184.5	118,450

Notes:
(1) Total Annual Operating Burden (Hours and Costs) for Agreement State Licensees is about 4 times the values in Table 7
(2) In addition, Initial Implementation Cost for Section 19.12 for Instructions = $920,000 (8 hr per licensee; 1150 licensees)

Table 8
Option 2-b: Part 20 Estimated Burden For NRC Licensees[1]

Number of Licensees = 1,150 Cost/hr = $100

		Annual Operating Burden per Licensee			Total Annual Operating Burden	
10 CFR Part	**Requirement**	**Hours/ Action**	**Fraction of Licensees Affected**	**Hours/ Licensee**	**Total Hours**	**Total Annual Operating Cost**
20.1302(b)(2)(i)	Dose limits to public	0.1	1	0.10	115	11,500
20.1302(c)	Compliance with limit	10	0.0004	0.004	4.6	460
20.1801	Security of material	0.1	1	0.1	115	11,500
20.1802	Security of material	0.1	1	0.1	115	11,500
20.1904	Containers	0.1	1	0.1	115	11,500
20.1906(b)	Containers	0.5	1	0.5	575	57,500
20.1906(d)	Containers	0.25	0.1	0.025	28.8	2,880
20.1906(e)	Containers	1	0.5	0.5	575	57,500
20.2006	Manifests-Form 540-541	4	0.5	2	2,300	230,000
20.2102(a)	Rad Protection Program	4	1	4	4,600	460,000
20.2103(a)	Surveys	8	1	8	9,200	920,000
20.2106	Form 4/5-Occup Monitor	1	1	1	1,150	115,000
20.2107	Public exposures	0.5	1	0.5	575	57,500
20.2108(a)	Waste disposal	8	0.05	0.4	460	46,000
20.2201(a)	Theft	3	0.006	0.018	20.7	2,070
20.2201(b)	Theft	3	0.006	0.018	20.7	2,070
20.2201(d)	Theft	3	0.001	0.003	3.5	345
20.2202(a)	Incidents	1	0.002	0.002	2.3	230
20.2202(b)	Incidents	40	0.008	0.32	368	36,800
20.2203(a)	Excessive exposures	6	0.015	0.09	103.5	10,350
20.2204	Excessive exposures	5	0.022	0.11	126.5	12,650
20.2206	Form 4/5-Occup Monitor	40	0.026	1.04	1,196	119,600
Totals				18.93	21,769.5	2,176,950

Notes:
1) Total Annual Operating Burden (Hours and Costs) for Agreement State Licensees is about 4 times the values in Table 8

Table 9

Option 2-b: Part 30 Estimated Burden For NRC Licensees[1]

Number of Licensees = 1,150 Cost/hr = $100

		Annual Operating Burden per Licensee			Total Annual Operating Burden	
10 CFR Part	**Requirement**	**Hours/ Action**	**Fraction of Licensees Affected**	**Hours/ Licensee**	**Total Hours**	**Total Annual Operating Cost**
30.32(g)	Application – Form 313[2][3]	29	0.69	20	23,000	2,300,00
30.34(b)	Transfers	2	0.06	0.12	138	13,800
30.34(h)	Bankruptcy Filing	0.5	0.002	0.001	1.15	115
30.36(d)	Notify NRC of termination	1	0.066	0.066	75.9	7,590
30.36(j)	Survey/File Form 314	0.5	0.069	0.035	40.25	4,025
30.37(a)	Renewal/Form 313[2]				0	0
30.38	Amendments/Form 313[2]				0	0
30.41(c)&(d)	Transfer of Material	4	0.04	0.16	184	18,400
30.50(a),(b)&(c	Event Notification	4	0.015	0.06	69	6,900
30.51(a),(b)&(c	Receipt/transfer	3.5	1	3.5	4,025	402,500
30.51(d)	Disposal	0.5	0.06	0.03	35	3,500
30.51(f)	Transfer of records	0.5	0.12	0.06	69	6,900
Condition 26	Material use circumstances	0.5	0.096	0.048	55.2	5,520
Condition 164	Physical inventory	0.08	0.6	0.048	55.2	5,520
Condition 165(i)	Records of leak test results	0.08	0.6	0.048	55.2	5,520
Totals				24.2	27,807	2,780,700

Notes:

1) Total Annual Operating Burden (Hours and Costs) for Agreement State Licensees is about 4 times the values in Table 9 and in Footnote 3
2) Renewals and amendments included under 30.32(g). Hours/action increased in final rule compared to proposed rule from 4.4 to 29 based on extra time required to submit the initial application using guidance in NUREG-1556 and increased number of renewal applications over the 10-year analysis period.
3) In addition, Initial Implementation Cost of $2,116,000 = application fees + labor-time costs for completing applications (1,150 x $1,400 + 1,150 x 4.4 x $100)

Table 10

Option 2-b: Part 19 Estimated Burden For NRC[(1)]

Number of Licensees = 1,150 Cost/hr = $100

		Annual Operations Burden			Total Annual Operations Burden	
10 CFR Part	**Requirement**	**Hours/ Action**	**Fraction of Licensees Affected**	**Hours/ Licensee**	**Total Hours**	**Total Annual Operations Cost**
19.12	Instruction to workers	0.1	1	0.1	115	11,500
19.13(b)	Annual reports to current employees	0.06	1	0.06	69	6,900
19.13(e)	Reports to terminating employees	0.018	1	0.018	20.7	2,066
Totals				0.178	204.6	20,466

Notes:
1) Total Annual Operating Burden (Hours and Costs) for Agreement State Licensees is about 4 times the values in Table 10

Table 11

Option 2-b: Part 20 Estimated Burden For NRC[(1)]

Number of Licensees = 1,150 Cost/hr = $100

		Total Annual Operating Burden		
10 CFR Part	**Requirement**	**Total Licensee Hours/action**	**NRC Hours**	**Total NRC Annual Operating Cost**
20.1302(b)(2)(ii)	Dose limits to public	115	23	2,300
20.1302(c)	Compliance with limit	4.6	0.92	92
20.1801	Security of material	115	5.76	576
20.1802	Security of material	115	5.76	576
20.1904	Containers	115	11.5	1,150
20.1906(b)	Containers	575	57.5	5,750
20.1906(d)	Containers	28.8	1.38	138
20.1906(e)	Containers	575	1.5	150
20.2006	Manifests-Form 540-541	2,300	10.35	1,035
20.2102(a)	Rad Protection Program	4,600	644	64,400
20.2103(a)	Surveys	9,200	864.8	86,480
20.2106	Form 4/5-Occup Monitor	1,150	575	57,500
20.2107	Public exposures	575	0.17	17
20.2108(a)	Waste disposal	460	6.44	644
20.2201(a)	Theft	20.7	20.7	2,070
20.2201(b)	Theft	20.7	20.7	2,070
20.2201(d)	Theft	3.5	1.14	114
20.2202(a)	Incidents	2.3	13.8	1,380
20.2202(b)	Incidents	368	28.34	2,834
20.2203(a)	Excessive exposures	103.5	78.66	7,866
20.2204	Excessive exposures	126.5	25.3	2,530
20.2206	Form 4/5-Occup Monitor	1,196	599	59,900
Totals			2,995.72	299,572

Notes:

1) Total Annual Operating Burden (Hours and Costs) for Agreement State Licensees is about 4 times the values in Table 11

Table 12

Option 2-b: Part 30 Estimated Burden for NRC(1)

Number of Licensees = 1,150 Cost/hr = $100

	Implementation Cost	Total Annual Operating Burden		
Action	**One-time Cost**	**Hours/licensee by NRC for review**	**Total Annual NRC Hours**	**Total Annual Operating Cost**
Review of licensee initial applications	506,000			
Review of records and reports		2.1	2,415	241,500
Review of license amendments		4.4	3,491	349,100
Totals	506,000		5,906	590,600

Notes:

(1) Total Annual Operating Burden (Hours and Costs) for Agreement State Licensees is about 4 times the values in Table 12

(2) Based on an estimated 0.69 licensing actions per licensee