



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

Draft Report

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

July 2008

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1. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to limit the quantity of byproduct material allowed in a generally licensed device. The amendments to NRC rules would limit the quantity of byproduct material in generally licensed devices to not exceed 1/10 of the International Atomic Energy Agency (IAEA) Category 3 threshold values. Because the general license authorization will no longer exist at or above these threshold values, individuals possessing devices with byproduct material meeting or exceeding these threshold values would be required to apply for a specific license (SL). These amendments, in conjunction with other regulatory program enhancements that the NRC has underway, are intended to enhance the safety and security of radioactive sources.

This regulatory analysis evaluates the costs and benefits associated with this proposed rule, which would amend 10 CFR Part 31, "General Domestic Licenses for Byproduct Material." This document presents background material, rulemaking objectives, alternatives, and analysis results for each of the alternatives considered.

1.1 Background

After the September 11, 2001, terrorist attacks, the NRC conducted a comprehensive review of nuclear material safety and security requirements. As a result of this review, the NRC has implemented several measures to increase the safety and security of radioactive sources, with particular focus on radioactive sources of concern. These measures have 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, as well as initiating, in November 2006, a National Source Tracking System (NSTS) to provide better accountability and control over Category 1 and 2 sources. The NRC has also increased the frequency of inspections to further ensure that there is adequate control of these materials and plans to develop a web-based licensing (WBL) system. In addition, NRC recently proposed, in a separate rulemaking, to expand the NSTS to include sources equal to, or greater than, 1/10 of the IAEA Category 3 threshold to address control of these sources and concerns over potential malevolent aggregation of these lower activity sources to IAEA Category 2 levels. NRC is currently evaluating the comments received on the proposed rule; eighteen of nineteen public comment letters received were opposed to expansion of the NSTS citing concerns that the rule may be premature and not necessary.

The U.S. Congress and the U.S. Government Accountability Office (GAO) have raised concerns regarding the safety and security of radioactive material covered by the general license (GL) regulatory system. In a July 12, 2007, report by the Permanent Subcommittee on Investigations (PSI), the U.S. Senate 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) on the security of the NRC licensing process. In its report, GAO 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 a SL for higher-activity devices that are currently available under the general license in 10 CFR 31.5." Specifically, the petition 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 the State to continue to require registration of other generally licensed devices in addition to those currently registered by the NRC.

The NRC staff has also been considering similar concerns, noting that, under the current general licensing regulatory scheme, there are situations where the NRC and Agreement States do not have an opportunity to review the purpose of use, applicant facilities and equipment, training and experience, and ability to meet any other applicable requirements. Thus, NRC has been considering whether it is more appropriate to amend 10 CFR Part 31 to require specific licensing for some materials 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 licenses. 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 approved moving forward to evaluate requiring specific licensing of general licensees possessing devices greater than or equal to 1/10 of the IAEA’s Category 3 threshold¹.

In this rulemaking, the NRC is proposing to amend its regulations to limit the quantity of byproduct material allowed in a generally licensed device. The proposed amendment to NRC regulations would limit the quantity of byproduct material allowed in a generally licensed device to below 1/10 of the IAEA’s Category 3 thresholds; devices with byproduct material at or above this limit would be required to obtain a specific license. This rulemaking is directed toward improving the security of generally licensed devices with byproduct material falling within IAEA Categories 3 through 5 by requiring a portion of them to have SLs and allowing the remaining portion to continue to have GLs.

2. Objectives of Proposed Regulatory Action

The objective of this rulemaking is to limit the quantity of radioactive material that a licensee may possess under a general license, by amending Part 31 of the Commission’s regulations. These amendments would require general licensees to obtain a SL to possess radioactive material meeting or exceeding certain thresholds. This change would better ensure protection of public health and safety and the common defense and security by enhancing the accountability and security of radioactive materials.

3. Identification and Preliminary Analysis of Alternative Approaches

NRC staff identified and considered three alternatives for limiting the quantity of byproduct material in generally licensed devices. The following subsections describe these alternatives.

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 to the quantity of byproduct material allowed in generally licensed devices would be established. The current regulatory framework would continue as it currently exists. Under this alternative, general licensees would continue to be covered by NRC's GL regulatory system.

3.2 Alternative 2: Limiting the Quantity of Byproduct Material Allowed Under a General License

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 general licenses.

3.2.1 Alternative 2a: Limiting the Quantity of Byproduct Material Allowed in Generally Licensed Devices to 1/10 of the IAEA's Category 3 Thresholds

Under this alternative, a limit on devices that can be generally licensed would be set at 1/10 of the IAEA's Category 3 thresholds. As a result, general licensees possessing devices containing byproduct material meeting or exceeding these thresholds would be required to be specifically licensed, while those below these thresholds would continue to be generally licensed. This alternative would allow the NRC and Agreement States to have greater oversight over these licensees which would improve accountability and control over these devices and also address some of the concerns expressed by stakeholders.

In particular, with regard to devices containing byproduct material that is 1/10 of IAEA Category 3, this alternative would reduce the likelihood that a sufficient number of these devices with sources above 1/10 of IAEA Category 3 (which are actually higher-activity Category 4 sources) could be obtained and aggregated to create the equivalent of Category 2 sources. 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 the threshold of a Category 2 source, meaning that it would require about 10-12 of these devices to aggregate to Category 2 quantity. These devices are to a large degree possessed by those with 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 IAEA Category 2 levels. Alternative 2a would not address concerns regarding aggregation of devices below 1/10 of IAEA's Category 3 thresholds and down to current registration levels (approximately 1/1000 of the IAEA Category 3 threshold); however, in general, the magnitude of the thresholds of these categories is so low that hundreds or thousands of devices with such sources would need to be aggregated to constitute a radioactive source in quantities of concern and, thus, there is a lower likelihood that devices with sources in this range would be aggregated to the higher category levels in quantities 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: Limiting the Quantity of Byproduct Material Allowed in Generally Licensed Devices to Registration Thresholds in 10 CFR 31.5(c)(13)(i)

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 additional accountability and control over currently generally licensed devices.

In particular, with regard to devices containing byproduct material above registration levels, including all of the IAEA Category 4 radioactivity range (i.e., both the “high-end” and “low-end” of the range) and Category 5, this alternative would address the potential that a sufficient number of these devices could be obtained and aggregated to quantities of concern. This alternative would include devices, such as industrial gauges, which are in relatively widespread use and broadly used in industry, thus allowing for a potential for their aggregation. In general, the magnitude of the thresholds of Category 4 and 5 is so low that hundreds or thousands of devices with such sources would need to be aggregated to constitute a radioactive source in quantities of concern, and thus there is a lower likelihood that such aggregation could occur. 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 proposed regulatory action to limit the quantity of byproduct material allowed in a generally licensed device. The analysis of the proposed regulatory action considers the rule requirements as a whole; because the requirements are few and there are not concerns regarding hidden costs of any individual requirements, there are not any issues with bundling of different requirements in this analysis. Subsection 4.1 identifies the attributes that the proposed regulatory action is expected to affect. Subsection 4.2 describes the methodology used to analyze the values and impacts of the proposed regulatory action.

4.1 Identification of Affected Attributes

This subsection identifies the attributes, within the public and private sectors, that the limitations to the quantity of byproduct material in a generally licensed device 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 expected to be affected by limiting the amount of material in a generally licensed device 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 proposed regulatory action would limit the quantity of byproduct material allowed in a generally licensed device, which would require current general licensees possessing devices with byproduct material at or above certain limits to apply for an SL. This requirement would provide the NRC with an opportunity 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. As a result, the proposed regulatory action is expected to improve the safety, security, and control over higher quantities of material, which would result in better handling and use of generally licensed devices and, would reduce the possibility of accidents and events, and therefore have a positive effect on public health.
- **Offsite Property.** As stated above, licensees possessing devices with byproduct material at or above certain limits would be required to apply for an SL. Improvement in the accountability and controls over these devices is expected to avert potential offsite property damage and costs (e.g., long-term relocation, emergency response).
- **Industry Implementation.** The proposed regulatory action would require general licensees with devices containing byproduct material at or above certain limits to submit an application for an SL. As a result, licensees would incur one-time implementation costs under the proposed regulatory action.
- **Industry Operation.** The proposed regulatory action would require licensees to implement new administrative and procedural activities, equipment, labor, training and other measures to comply with the new requirements. As a result, licensees would incur annual operating costs under the proposed regulatory action.
- **NRC Implementation.** The proposed regulatory action would require NRC to perform rulemaking and develop new guidance. Specifically, NRC would develop a proposed and final rule to limit the quantity of byproduct material allowed in a generally licensed device. In addition, the NRC would develop 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 certain thresholds. As a result, NRC would incur one-time implementation costs under the proposed regulatory action.
- **NRC Operation.** The proposed regulatory action would require the NRC staff to review license applications, perform pre-licensing visits, inspections and other regulatory activities to ensure licensee compliance with the new requirements. As a result, NRC would incur increased annual operating costs under the proposed regulatory action.
- **Other Government.** The proposed regulatory action would benefit 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 proposed action would allow better tracking and accountability of materials in the United States and should reduce the possibility for malevolent use of radioactive materials and the potential for aggregation of devices to quantities of concern. The proposed regulatory action would also allow other government agencies to better monitor the location of radioactive material of concern and focus resources on licensees with higher quantities of this material. In addition, the increased tracking and accountability of devices would improve coordination among the various agencies.

- **Improvements in Knowledge.** The proposed regulatory action would require general licensees with devices containing byproduct material meeting or exceeding certain limits to apply for an SL. This proposed action would provide the NRC the opportunity to assess and enhance the safety of licensed activities, gather updated information, assess accident probabilities or consequences and reduce uncertainties. This additional oversight would allow the NRC to better ensure public health and safety.
- **Regulatory Efficiency.** The current GL regulatory system is inherently efficient because it requires very few regulatory resources. Hence, the proposed regulatory action may not create a specific improvement in regulatory efficiency; however it can create an overall improvement in regulatory efficiency by facilitating NRC's regulation of licensees possessing these devices and the potential issues that can arise from their misuse. The proposed amendments would require general licensees with devices containing byproduct material meeting or exceeding certain limits to submit an application for an SL. As a result, the NRC would have the opportunity to review the applicant's purpose of use; the applicant's facilities and equipment, training and experience; and the applicant's ability to meet other requirements that may be applicable.
- **Safeguards and Security Considerations.** The proposed regulatory action would require general licensees with devices containing byproduct material meeting or exceeding certain limits to submit an application for an SL. This requirement would allow NRC to better monitor the location and use of radioactive materials of higher activity, and enhance the accountability and control of these devices. The more stringent requirements of the specific licensing process would provide reasonable assurance that persons seeking to obtain the devices are viable, trustworthy and reliable, and would minimize the potential for aggregation of sources to quantities of concern. Consequently, the proposed regulatory action would enhance NRC's ability to protect public health and safety.
- **Other Considerations.** The proposed regulatory action would require general licensees with devices containing byproduct material meeting or exceeding certain limits to acquire an SL. As a result, the proposed regulatory action could increase public confidence in NRC's regulation of byproduct materials.

Limiting the quantity of byproduct material that could be allowed in a generally licensed device is not expected to 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

This section describes the methodology used to analyze the values and impacts associated with the affected attributes discussed above by the proposed action. 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 used in this analysis for each of the alternatives.

4.2.1 Alternative 1: No Action

Under the No-Action alternative the current GL regulatory system would remain as is. However, this alternative does not address concerns identified by various stakeholders. As noted in Section 1.1, the U.S. Senate and the GAO have expressed concerns on the relative ease with which devices with 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 is not considered appropriate because it does not address these concerns and issues.

4.2.2 Alternative 2: Limiting the Quantity of Byproduct Material Allowed in Generally Licensed Devices

Alternative 2 would limit the quantity of byproduct material allowed in generally licensed devices. The NRC has analyzed two principal alternatives under Alternative 2 based on the value of the limit on the quantity of byproduct material allowed; these are described in Sections 4.2.2.1 and 4.2.2.2.

There are several costs involved in each of the alternatives analyzed, including: costs of complying with existing requirements for specific licensees; costs for complying with an expanded NSTS, if this rule is adopted; costs of fees associated with the license (either specific or general); and the costs of any revisions needing to 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 proposed requirements on a continuing basis. These are discussed in Sections 4.2.2.1 and 4.2.2.2 for Alternatives 2a and 2b, respectively. There are no costs estimated in these sections for changes to the compatibility designations being proposed in this rulemaking because the NRC is not imposing any additional requirements; such requirements may or may not be imposed by the States in their rulemakings.

4.2.2.1 Alternative 2a: Limiting the Quantity of Byproduct Material Allowed in Generally Licensed Devices at 1/10 of the IAEA's Category 3 Thresholds

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

Under Alternative 2a, a limit on general licensing would be set at 1/10 of the IAEA's Category 3 thresholds. General licensees possessing devices containing byproduct material meeting or exceeding these thresholds 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 General License Tracking System (GLTS), it is estimated that about 280 NRC general licensees possess devices with byproduct material meeting or exceeding 1/10 of the IAEA's 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 currently possess devices with byproduct material meeting or exceeding the proposed limits.

Although the proposed amendment only involves changes to Part 31, the existing general licensees who would 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 costs to comply with other NRC regulations, but these costs are small compared to those indicated here). Detailed one-time implementation and annual operating costs for NRC licensee compliance with 10 CFR regulations under this alternative are contained in Appendix 1 and summarized in Table 1; estimates of the costs for Agreement State licensees are also indicated in Table 1.

(b) Costs for Inclusion in an Expanded National Source Tracking System (NSTS)

As discussed above in Section 1.1, NRC currently requires specific licensees who possess IAEA Category 1 and 2 radioactive sources to provide accountability and control over these sources by tracking through the NSTS. Recently, NRC has proposed, in a separate rulemaking (73 FR 19749; April 11, 2008), to expand the NSTS, by amending 10 CFR 20.2207, to also include sources equal to, or greater than, 1/10 of the IAEA Category 3 threshold so as to address concerns over potential malevolent aggregation of these lower activity sources to IAEA Category 2 quantities of concern. Under the NSTS, licensees are required to conduct an initial inventory of sources and an annual reconciliation of their inventory with the NSTS; to report on source transactions, including manufacture, transfer, receipt, disassembly, and disposal; and to assign serial numbers to sources. In addition to costs associated with these activities, the Regulatory Analysis for the proposed rule to expand the NSTS (see ADAMS Accession Number ML080910314) estimated costs to industry to also include costs of setting up an account in the NSTS, training and computer programming, and also estimated costs to NRC to include information technology (IT) development and maintenance activities and inspection costs.

General licensees, who would become specific licensees under the requirements in this proposed rulemaking, would be required to follow the requirements of the proposed amendment to 10 CFR 20.2207, if the proposed rule is adopted, if they possess devices containing sources equal to, or greater than, the proposed threshold in the expanded NSTS.

The costs to the new specific licensees were estimated using the methodology used in the Regulatory Analysis for the proposed rule to expand the NSTS. General licensees who possess devices with sources greater than or equal to 1/10 of Category 3 principally include those with industrial gauges. As noted in Section 4.2, above, there are approximately 280 NRC general licensees (approximately 1,400 NRC and Agreement State licensees) who possess devices with sources greater than or equal to 1/10 of Category 3 and who would be covered by the requirements of an expanded NSTS. The costs of conducting and reconciling the NSTS inventory are based on the number of licensees conducting the inventory. It is estimated that the additional general licensees would increase the total existing population of NRC and Agreement State specific licensees who would be covered by the expanded NSTS by approximately 30 percent.

It is estimated from information in the GLTS that about 355 NRC generally licensed devices containing sources greater than or equal to 1/10 of Category 3 (for a total of approximately 1,800 NRC and Agreement State licensed devices, principally containing relatively long-lived radionuclides such as Am-241, Cs-137, Co-60, Sr-90) would be added to the existing population of sources tracked in the NSTS. As discussed in the Regulatory Analysis for the expanded NSTS, this information is used in estimating the number of transaction reports necessary under the NSTS; the frequency of replacement of sources, which determines the number of transaction reports, depends on the half-lives of the principal radionuclides and the otherwise relatively infrequent changes of industrial gauge devices based on their general location in a facility. Therefore, it is assumed that industrial gauge devices are replaced every 10 years and that licensees would annually perform approximately 200 source replacements.

Using the methodology in the Regulatory Analysis for the rulemaking for the proposed expansion of the NSTS, the costs to NRC general licensees are indicated in Table 1 based on one-time implementation costs to industry for conducting an initial inventory and for account set-up, training, and programming; and annual operating costs to industry for transaction reports, assigning of serial numbers, and annual reconciliation of inventory. The costs in Table 1 also include the one-time implementation cost to NRC for credentialing of the additional existing NRC general licensees added to the NSTS, and the annual operating costs to NRC for inspection of these additional licensees in the NSTS for monitoring of the NSTS. Estimates of the costs for Agreement State licensees are also indicated in Table 1.

(c) 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.

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 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 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 not a reduction in SL fees based on certain licensees being small entities, although it is likely that the actual cost would be lower.

(d) 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 Sealed Source and Devices Registry (NSSDR). The registration certificates contain detailed information on the devices, such as how they are permitted to be distributed and possessed (i.e., specific license, general license, or exempt), design and function, radiation safety, and limitations on use. NRC and certain Agreement States issue SS&D registration certificates for distributors and manufacturers within their jurisdiction.

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. It is estimated that approximately 10 manufacturers and distributors having on average three SS&D certificates would need to amend their certificates to account for the differing nature of the licensing of the devices. It is anticipated that the amendments would consist of primarily administrative changes to the SS&D certificate, totaling approximately 1 hour per licensee, rather than a re-evaluation of the safety of the device. As such, no fees will be charged to licensees. The estimated one-time implementation cost as a result of this rule amendment is indicated in Table 1. It is estimated that the one-time NRC implementation burden to review and process the amendment requests and to amend and re-issue these certificates would be approximately 1 hour per amendment request.

4.2.2.2 Alternative 2b: Limiting the Quantity of Byproduct Material Allowed in Generally Licensed Devices at Registration Thresholds in 10 CFR 31.5(c)(13)(i)

(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 possess devices with byproduct material meeting or exceeding the proposed limits that would be set at the registration levels.

Although the proposed amendment only involves changes to Part 31, the existing general licensees who would 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 20 and 30 (licensees might incur additional costs to comply with other NRC regulations, but these costs are small compared to those indicated here). Detailed one-time implementation and annual operating costs for NRC licensee compliance with 10 CFR regulations under this alternative are in Appendix 1 and are summarized in Table 2; estimates of the costs for Agreement State licensees are also indicated in Table 2.

(b) Costs for Inclusion in an Expanded National Source Tracking System

As discussed above in Section 4.2.2.1(b), there would be costs to certain general licensees who would become specific licensees because they would be required to track sources, under a separate proposed rulemaking to expand the NSTS, if it is adopted, if they possess devices containing sources equal to, or greater than, the proposed threshold in the expanded NSTS. For Alternative 2b, licensees possessing devices with sources below 1/10 of Category 3, but above the registration levels, would not have to comply with the requirements of the proposed expanded NSTS. Thus, there would be no additional costs, beyond those incurred under Alternative 2a for complying with an expanded NSTS. This is indicated in Table 2.

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

As discussed in Section 4.2.2.1(c), 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.

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

As noted in Section 4.2.1.2(d), 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. It is estimated that approximately 20 manufacturers and distributors having on average three SS&D certificates would need to amend their certificates to account for the differing nature of the licensing of the devices. It is anticipated that the amendments would consist of primarily administrative changes to the SS&D certificate, totaling approximately 1 hour, rather than a re-evaluation of the safety of the device. As such, no fees will be charged to licensees. The estimated one-time implementation cost as a result of this rule amendment is indicated in Table 2. It is estimated that the NRC burden hours and costs to review and process the amendment requests and to amend and re-issue these certificates would be approximately 1 hour per license amendment.

5. RESULTS

For the two alternatives evaluated in detail in this regulatory analysis, NRC would require certain existing general licensees to obtain specific licenses as follows:

Alternative 2a: Those with devices containing sources greater than or equal to 1/10 of IAEA Category 3 thresholds.

Alternative 2b: Those with devices containing sources greater than GL registration levels.

In estimating the costs for the two alternatives, it is assumed that existing general licensees affected by the proposed amendment would be required to:

- Apply for an SL and follow requirements in existing sections of the 10 CFR that apply to specific licensees;
- Follow the anticipated tracking requirements of the proposed expanded NSTS for devices with sources greater than or equal to 1/10 of IAEA Category 3 sources; and
- Comply with changes to fee requirements, as appropriate.

Using the cost assumptions discussed in Sections 3.2 and 4.2.2 of this document, the NRC staff estimated incremental costs to industry and the NRC and the Agreement States under Alternative 2a and Alternative 2b.

The costs are presented in constant 2007 dollars, for both one-time implementation costs and annual operating costs in Tables 1 and 2 (summarized from Tables 1-12 in Appendix 1). The impact of the one-time and annual costs of the proposed rule in Tables 1 and 2 is estimated over a 10-year period in Table 3 using 3 percent and 7 percent real discount rates to show an overall effect during this period in terms of 2007 dollars. Alternative 1, the No-Action Alternative, provides a baseline against which the other two alternatives are assessed. It is estimated that the time burden for NRC licensees' compliance under any of these alternatives is about 30 hours per year.

NRC staff believes that expected qualitative values resulting from the proposed rule amendments would 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 is expected to 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 is expected to 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 specific licenses would allow the NRC to better monitor the adequacy of their operations and material possession of licensees with devices containing sources above the limit, and, thus, improve accountability of them. Consequently, the proposed amendment should enhance NRC's ability to protect public health and safety.
- *Improved Regulatory Efficiency.* Although placing a limit on generally licensed devices will not, in and of itself, improve regulatory efficiency, as it will increase the licensing load on the industry, NRC, and the Agreement States, it can improve overall regulatory efficiency by increasing accountability among all parties associated with sources that could aggregate to quantities of concern.
- *Increased Public Confidence.* Information obtained by requiring current general licensees to obtain specific licenses would allow the NRC to better monitor these licensees and the devices and sources that they possess. This is expected to result in increased public confidence in NRC's regulation of inventories and tracking of radioactive materials.

Table 1: Costs to Comply with Proposed Amendment: NRC licensees⁽¹⁾ – Alternative 2a

| | One-time Implementation costs | Annual Operating Costs |
|--|--|-----------------------------------|
| Industry Cost | | |
| - Compliance with existing requirements for specific licenses ⁽²⁾ | 739,200 | 760,920 |
| - Proposed expanded NSTS | 236,200 | 26,000 |
| - Fee | - | 666,400 |
| - SS&D amendments | 3,000 | - |
| Total | 978,400 | 1,453,320 |
| NRC Cost | | |
| - Compliance w/existing requirements ⁽³⁾ | 123,200 | 221,700 |
| - Proposed expanded NSTS | 168,000 | 272,000 |
| - Fee | - | - |
| - SS&D amendments | 3,000 | - |
| - Final rule, guidance, etc | 80,000 | - |
| Total | 374,200 | 493,700 |
| Total | 1,352,600 | 1,947,020 |

Notes:

(1) Costs are for NRC licensees; costs for Agreement State licensees would be approximately 4 times, and total costs for NRC and Agreement State licensees would be approximately 5 times, these costs.

(2) Industry cost for compliance with existing requirements is sum of Appendix 1, Tables 1-3.

(3) NRC cost for compliance with existing requirements is sum of Appendix 1, Tables 4-6.

Table 2: Costs to Comply with Proposed Amendment: NRC licensees⁽¹⁾ – Alternative 2b

| | One-time Implementation costs | Annual Operating Costs |
|--|--|-----------------------------------|
| Industry Costs | | |
| - Compliance with existing requirements for specific licenses ⁽²⁾ | 3,036,000 | 3,125,000 |
| - Proposed expanded NSTS ⁽⁴⁾ | 236,200 | 26,000 |
| - Fee | - | 2,737,000 |
| - SS&D amendments | 6,000 | - |
| Total | 3,278,200 | 5,888,000 |
| NRC Costs | | |
| - Compliance w/existing requirements ⁽³⁾ | 506,000 | 910,700 |
| - Proposed expanded NSTS ⁽⁴⁾ | 168,000 | 272,000 |
| - Fee | - | - |
| - SS&D amendments | 6,000 | - |
| - Final rule, guidance, etc | 80,000 | - |
| Total | 760,000 | 1,182,700 |
| Total | 4,038,200 | 7,071,000 |

Notes:

(1) Costs are for NRC licensees; costs for Agreement State licensees would be approximately 4 times, and total costs for NRC and Agreement State licensees would be approximately 5 times, these costs.

(2) Industry cost for compliance with existing requirements is sum of Appendix 1, Tables 7-9.

(3) NRC cost for compliance with existing requirements is sum of Appendix 1, Tables 10-12.

(4) Includes same NSTS costs as Alternative 2a (see Section 4.2.2.2(b)).

Table 3: Estimated Net Impact of Alternatives 2a and 2b for NRC licensees⁽¹⁾

| Regulatory Alternative | One Time Cost | 10-year total cost at 3% discount rate | 10-year total cost at 7% discount rate |
|----------------------------------|----------------------|---|---|
| Alternative 2a (280 licensees) | \$1,352,600 | \$17,961,080 | \$15,027,650 |
| Alternative 2b (1,150 licensees) | \$4,038,200 | \$64,361,240 | \$53,706,860 |

Notes:

(1) Costs are for NRC licensees; costs for Agreement State licensees would be approximately 4 times, and total costs for NRC and Agreement State licensees would be approximately 5 times, these costs.

6. Backfit Analysis

NRC backfit requirements are set forth in 10 CFR 50.109, 70.76, 72.62, and 76.76. A backfit is the modification of equipment or procedures required to operate a facility resulting from new or amended regulations, the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previous applicable staff position.

The NRC has determined that limiting the amount of byproduct material allowed in a generally licensed device does not impose any backfits on systems, structures or components of a facility. Therefore, a backfit analysis is not required.

7. Decision Rationale

The values and impacts have been considered for the two proposed regulatory alternatives (i.e., 2a and 2b). Alternative 2a, Limiting Generally Licensed Devices to 1/10 of the IAEA's Category 3 Thresholds, is the preferred option because it is expected to: (1) 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; (2) reduce the potential for aggregation of devices for deliberate misuse; (3) address potential security vulnerabilities; and (4) increase public confidence. Although Alternative 2b could also accomplish these ends, the magnitude of the thresholds of the IAEA Categories included under Alternative 2b are so low that there is a lower likelihood that devices with sources in this range would be aggregated to quantities of concern. Thus, NRC believes that the incremental costs to licensees and the NRC under Alternative 2a, compared to Alternative 2b, are justified based on these considerations.

8. Implementation

This proposed action will involve preparation of a Proposed Rule, issuing it for public comment, and preparation of a Final Rule which includes a consideration of the public comments. A final Rule is expected to be promulgated by November 2009.

No impediments to implementation of the recommended alternative have been identified. The proposed regulatory action would require current general licensees possessing devices containing byproduct material in quantities meeting or exceeding 1/10 of the IAEA's Category 3 thresholds to apply for a specific license. Devices containing byproduct material below these thresholds would continue to be subject to general licensing.

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

| 10 CFR Part | Requirement | Annual Operating Burden per Licensee | | | Total Annual Operating Burden | |
|----------------------|-------------------------------------|--------------------------------------|--------------------------------|----------------|-------------------------------|-----------------------------|
| | | 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 | 70 | 7,000 |
| 19.13(b) | Annual reports to current employees | 0.6 | 1 | 0.6 | 168 | 16,800 |
| 19.13(e) | Reports to terminating employees | 0.18 | 1 | 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

| 10 CFR Part | Requirement | Annual Operating Burden per Licensee | | | Total Annual Operating Burden | |
|-------------------|------------------------|--------------------------------------|--------------------------------|----------------|-------------------------------|-----------------------------|
| | | 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

| 10 CFR Part | Requirement | Annual Operating Burden per Licensee | | | Total Annual Operating Burden | |
|------------------|--|--------------------------------------|--------------------------------|----------------|-------------------------------|-----------------------------|
| | | Hours/action | Fraction of Licensees Affected | Hours/Licensee | Total Hours | Total Annual Operating Cost |
| 30.32(g) | Application – Form 313 ⁽²⁾⁽³⁾ | 4.4 | 0.69 | 3.04 | 851.2 | 85,120 |
| 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 | | | | 7.22 | 2,020.4 | 202,040 |

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)

(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

| 10 CFR Part | Requirement | Annual Operations Burden | | | Total Annual Operations Burden | |
|-------------|-------------------------------------|--------------------------|--------------------------------|----------------|--------------------------------|------------------------------|
| | | 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

| 10 CFR Part | Requirement | Total Annual Operating Burden | | |
|-------------------|------------------------|-------------------------------|-----------|---------------------------------|
| | | 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

| 10 CFR Part | Requirement | Annual Operating Burden per Licensee | | | Total Annual Operating Burden | |
|----------------------|-------------------------------------|--------------------------------------|--------------------------------|----------------|-------------------------------|-----------------------------|
| | | 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

| 10 CFR Part | Requirement | Annual Operating Burden per Licensee | | | Total Annual Operating Burden | |
|------------------|------------------------|--------------------------------------|--------------------------------|----------------|-------------------------------|-----------------------------|
| | | 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 | 21,769.6 | 2,176,955 |

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

| 10 CFR Part | Requirement | Annual Operating Burden per Licensee | | | Total Annual Operating Burden | |
|------------------|--|--------------------------------------|--------------------------------|----------------|-------------------------------|-----------------------------|
| | | Hours/action | Fraction of Licensees Affected | Hours/Licensee | Total Hours | Total Annual Operating Cost |
| 30.32(g) | Application – Form 313 ⁽²⁾⁽³⁾ | 4.4 | 0.69 | 3.04 | 3,496 | 349,600 |
| 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 | | | | 7.22 | 8,298.9 | 829,890 |

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)

(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

| 10 CFR Part | Requirement | Annual Operations Burden | | | Total Annual Operations Burden | |
|-------------|-------------------------------------|--------------------------|--------------------------------|----------------|--------------------------------|------------------------------|
| | | 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 | 2,070 |
| Totals | | | | 0.178 | 204.7 | 20,470 |

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

| 10 CFR Part | Requirement | Total Annual Operating Burden | | |
|-------------------|------------------------|-------------------------------|-----------|---------------------------------|
| | | 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