

RULEMAKING ISSUE NOTATION VOTE

September 15, 2008

SECY-08-0137

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: PROPOSED RULE: LIMITING THE QUANTITY OF
BYPRODUCT MATERIAL IN A GENERALLY LICENSED DEVICE
(RIN 3150-AI33)

PURPOSE:

The purpose of this paper is to request Commission approval to publish a proposed rule in the *Federal Register* that would amend 10 CFR Part 31. The proposed amendment would limit the quantity of byproduct material allowed in a generally licensed device to below one-tenth (1/10) of the International Atomic Energy Agency (IAEA) Category 3¹ threshold levels. The proposed rule would also modify the Compatibility Categories contained in the current regulations (10 CFR 31.5 and 31.6). This paper does not address any new commitments.

SUMMARY:

There has been increased concern and focus on devices that are currently possessed under the U. S. Nuclear Regulatory Commission's (NRC) general license (GL) regulatory system, including issues raised by the U.S. Senate and the U.S. Government Accountability Office, by petitions from the Agreement States, and through NRC review of the GL regulatory system.

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

In preparing this proposed rule, the staff has determined that there is a need to enhance the security of generally licensed devices with certain lower activity sources to improve the accountability and control of these sources and to provide additional protection against aggregation of these sources to higher activity levels in quantities of concern. To provide these improvements, the staff proposes to modify the existing GL regulatory system by placing a limit on the quantity of byproduct material allowed in generally licensed devices.

Additionally, the staff provided the States a copy of the draft proposed rule *Federal Register Notice (FRN)* so they could have an early opportunity. Three states commented. Two States commented that the quantity of the byproduct material in generally licensed devices should be limited to Category 4 levels (1/100 Category 3); while the third State commented that they are not in favor of this method of providing additional oversight for generally licensed devices.

The staff also discussed the GL program with the Organization of Agreement States (OAS) at their annual meeting where the Agreement States restated their preference for extending the limit on the quantity of the byproduct material in generally licensed devices to registration levels. The Agreement State concerns and comments were considered and have been reflected in the enclosed draft FRN.

BACKGROUND:

Prior to the terrorist attacks of September 11, 2001 (9/11), several national and international efforts were underway to address the potentially significant health and safety hazards posed by uncontrolled sources. These efforts recognized the need for increased control of high-risk radioactive materials to prevent inadvertent and intentional unauthorized access, primarily due to the potential health and safety hazards posed by the uncontrolled material. Following 9/11 it was recognized that these efforts should also include a heightened awareness and focus on the need to prevent intentional unauthorized access due to potential malicious acts. Proper security and control measures reduce the likelihood that this radioactive material could be used in radiological dispersal devices (RDD) or in radiological exposure devices (RED). These efforts, such as the IAEA Code of Conduct on the Safety and Security of Radioactive Sources (Code of Conduct) concerning Category 1 and 2 sources, seek to increase the control over sources to prevent unintended radiation exposure and to prevent malicious acts.

During this period, additional security and control measures have been imposed by NRC on specific licensees that possess byproduct materials in quantities of concern, and improvements have been made in NRC's regulatory program to ensure that public health and safety and security are adequately protected. These measures have included the issuance of orders to specific licensees who possess IAEA Category 1 and 2 byproduct sources requiring them to exercise added control over such sources, as well as publishing a final rule, in November 2006, establishing 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. Recently, NRC proposed, in a separate rulemaking (73 FR 2476, April 11, 2008), to expand the NSTS 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 levels. The NRC staff is currently evaluating the comments received on the proposed rule; eighteen of the nineteen public comment letters received were opposed to expansion of the NSTS citing concerns that the rule may be premature and not necessary.

During this time period, there has also been increased concern and focus on devices that are currently possessed under NRC's GL regulatory system. The U.S. Senate and the U.S. Government Accountability Office have raised concerns regarding the safety and security of byproduct material covered by the GL regulatory system and, in addition, the Organization of Agreement States (OAS) filed a petition for rulemaking on June 27, 2005 (PRM-31-5), requesting that NRC strengthen its GL regulatory system.

The NRC staff has also been considering similar concerns related to the current GL regulatory system of 10 CFR Part 31 and the GL registration program in § 31.5 for generally licensed devices with byproduct material above the registration levels in § 31.5(c)(13)(i). In its review, the NRC staff has noted there are situations where the NRC or Agreement States do not have an opportunity to review the purpose of use, adequacy of applicant facilities and equipment, training and experience, and ability to meet other applicable requirements. The rulemakings which instituted the GL registration program on August 4, 1999 (64 FR 42269) and on December 18, 2000 (65 FR 79162) indicated that the primary intent of the GL registration program is to ensure that general licensees are aware of and understand the requirements for possession of devices containing byproduct material and that such devices are maintained and transferred properly and not inadvertently discarded. The rulemakings also noted that if general licensees are aware of their responsibilities they would comply with the requirements for proper handling and disposal. Thus, the staff has been considering whether to amend 10 CFR Part 31 to require specific licensing for certain devices currently regulated under the GL regulatory system. Limiting the source activity allowed under a GL would result in expanding the specific licensing regulations to cover more licensees. Because specific license (SL) activities provide for more comprehensive licensing, inspection and security reviews than GL activities, placing a limit on the source activity that can be allowed under a GL (and thus requiring that certain generally licensed devices with higher activity sources be regulated under SLs) can enhance both the safety and security of radioactive sources.

As part of this effort, the NRC staff submitted, for Commission review, SECY-06-0094 (April 24, 2006) entitled "Tracking or Providing Enhanced Controls for Category 3 Sources." In that paper, the staff proposed initiating a rulemaking that would set activity limits for generally licensed devices at one-half (1/2) of the IAEA Category 2 threshold and reserve authorization to possess higher activity sources to SLs. The staff noted that a benefit of setting such a limit would be greater oversight of these licensees, allowing regulatory bodies the opportunity to perform an assessment of a licensee's legitimacy or any other regulatory activities the Commission determined as being necessary. In response to SECY-06-0094, the Commission, in a Staff Requirements Memorandum dated June 9, 2006, approved the staff's plan to amend the GL requirements in Section 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 threshold. The Commission also approved the staff's plan to amend certain associated manufacturer requirements in Part 32 and indicated the staff should consider standardizing the annual registration thresholds at 0.001 of the IAEA Code of Conduct D values (i.e., at about 0.001 of the IAEA Category 3 threshold levels).

The primary elements of the existing GL regulatory framework are contained in 10 CFR Part 31. A generally licensed device is designed with inherent radiation safety features so that it can be used by persons with no radiation training or experience. Thus, the GL regulatory program

simplifies the licensing process because a case-by-case determination of the adequacy of the radiation training or experience of each user is not necessary. As part of the GL regulatory system, NRC evaluates the adequacy of generally licensed products by ensuring that manufacturers and distributors of the products meet the various specific requirements in 10 CFR Part 32. Section 31.5 contains requirements that generally licensed devices containing byproduct material in quantities above “registration” levels listed in §31.5(c)(13)(i) must be registered with the NRC or the Agreement State. The GL registration program is primarily intended to ensure that general licensees are aware of and understand the requirements for the possession of devices containing byproduct materials and that such devices are maintained and transferred properly and not inadvertently discarded.

DISCUSSION:

The IAEA source categorization scheme² includes five categories that are based on the potential for sources to cause deterministic health effects to persons exposed to them. Sources in Category 1 and 2 are considered to be the most “dangerous” because they can pose a high risk to human health if not managed safely and securely. Category 3 sources are less than the Category 2 threshold and the Category 3 threshold is equal to or greater than 1/10 of Category 2; the Category 4 threshold quantities are 1/100 of the Category 3 quantities. At the lower end of the categorization system, sources in Category 5 are the least dangerous; however, even these sources could give rise to doses in excess of the dose limits if not properly controlled. A joint analysis by the U.S. Department of Energy and NRC of potential health effects from misuse of sources for malevolent purposes identified radionuclide “quantities of concern” to be in a range similar to the IAEA Category 2 threshold values.

In preparing this proposed rule, the staff has determined that there is a need to enhance the security of generally licensed devices with certain lower activity sources to improve the accountability and control of these sources and to provide additional protection against aggregation of these sources to higher activity levels in quantities of concern. To provide these improvements, the staff proposes to modify the existing GL regulatory system by placing a limit on the quantity of byproduct material allowed in generally licensed devices. At issue is the appropriate value for the limit, i.e., should the limit be set at 1/10 of the IAEA Category 3 threshold (as suggested in the June 9, 2006 SRM) or should it be set lower to include devices that are above the current GL registration levels which are at a level approximately 1/1000 of the IAEA Category 3 threshold (as suggested in the June 27, 2005 OAS petition). In making a decision on what level to set the limit, consideration has been given to the potential for aggregation of sources to higher activity quantities of concern and also on the additional resource burden placed on licensees and regulatory bodies which would result from such an amendment. These are discussed in Items 1 and 2, below.

1. Potential for aggregation to higher IAEA Category quantities of concern

Requiring certain general licensees to obtain SLs, if their generally licensed devices contain sources greater than or equal to 1/10 of IAEA Category 3, would involve sources in Category 3 as well as sources in the “high end” of the IAEA Category 4 radioactivity range (i.e., those that are greater than or equal to 1/10 of the Category 3 threshold). Category 3 sources are defined by IAEA as “dangerous sources”, i.e., a source that could, if not under control, give rise to

² IAEA Safety Standards Series No. RS-G-1.9 “Categorization of Radioactive Sources”

exposure sufficient to cause severe deterministic effects, and thus even without any aggregation there is rationale for specifically licensing devices with Category 3 sources. In addition, Category 3 sources could be readily aggregated to Category 2 levels, as part of a concerted effort to do so, as they represent sources with activity levels that range from just below the Category 2 threshold down to 1/10 of the Category 2 threshold. Thus, sources at the high end of the range of activities in Category 3 can be at levels just below the threshold of a Category 2 source, meaning that it could take only a few devices with such sources to aggregate to Category 2. The principal type of licensees who possess devices with Category 3 sources are those with industrial gauges and, because these devices are relatively widespread in use and relatively broadly used in industry, there would be potential for aggregation of sufficient numbers of the devices and their sources to Category 2 levels.

With regard to sources that are in the high end of the IAEA Category 4 radioactivity range (i.e., 1/10 of Category 3), a principal rationale for including these sources is the potential that a sufficient number of these 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 devices with such sources to aggregate to Category 2 quantities. These devices with high-end Category 4 sources are possessed by similar licensees noted to have Category 3 sources, namely those with industrial gauges and as previously noted, are in relatively widespread use and broadly used in industry, thus allowing for the potential for aggregation of sufficient numbers of them and their sources to Category 2 levels.

As noted above, the OAS in their June 27, 2005, petition requested that the limit on generally licensed devices be set at a level that would include devices with sources that are at or above the current GL registration levels which are approximately 1/1000 of the IAEA Category 3 threshold. The staff has considered this level, which would include devices with sources in all of the IAEA Category 4 radioactivity range (i.e., including those in the "low-end" of the Category 4 radioactivity range) and also devices with sources in IAEA Category 5, and notes that, 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 byproduct quantity of concern. Thus, there would be a lower likelihood that devices with sources at the lower range of Category 4 or in Category 5 would be aggregated to the higher category levels in quantities of concern.

2. Additional burden on licensees and regulators to comply with proposed amendments

Requiring certain general licensees to obtain SLs would result in additional resource burden to the licensed industry and on NRC and the Agreement States. In the Regulatory Analysis (Enclosure 2) for this rulemaking, the staff analyzed the additional costs and benefits of placing a limit on the quantity of radioactivity allowed in a generally licensed device. A summary of the analysis follows.

Limiting the quantity of byproduct material allowed in generally licensed devices to below 1/10 of the IAEA's Category 3 thresholds would result in about 280 NRC general licensees, and about 1,100 Agreement State licensees, applying for SLs. There would be added costs to these licensees as a result of this proposed amendment including the cost of complying with existing requirements for specific licensees, including those in Parts 19, 20, and 30; increase in cost of

fees associated with the license (i.e., either a GL or a SL); and the costs of any revisions needing to be made to a sealed source and device (SS&D) registration certificate. In addition, these licenses could bear the costs of complying with the expanded NSTS if it goes forward as proposed in the April 11, 2008, *Federal Register* notice. The added number of specific licensees would also result in an increase in NRC and Agreement State resources devoted to reviewing the new SL applications and inspecting licensees. However, these resources are not considered significant because the number of additional general licensees that would obtain SLs represent an increase of only about 6 percent of the existing specific licensee population.

Requiring general licensees above the registration levels to obtain a SL would affect about 1,150 NRC general licensees. These new specific licensees, possessing devices with not only Category 3 and higher-end Category 4 sources but also lower-end Category 4 and Category 5 sources, would incur additional costs in having to follow the same existing requirements in the 10 CFR as other licensees with significantly higher quantities of byproduct material. The added number of specific licensees would also result in a significant increase in NRC and Agreement State resources that would be devoted to reviewing the new SL applications and inspecting the licensees after the license is issued. It is estimated that the number of additional general licensees that would obtain SLs would represent an increase of about 25 percent of existing population of specific licensees. In view of the lower likelihood that devices with sources in the lower range of Category 4 or in Category 5 would be aggregated to quantities of concern, the staff believes that the relatively low security risk does not justify the significant regulatory resources and impacts on licensees that would result from specifically licensing devices with sources in the lower Category 4 and Category 5 ranges.

3. Staff conclusion regarding placing a limit on radioactivity in a generally licensed device

Based on the considerations of Items 1 and 2, the staff has concluded that it is appropriate to propose placing a limit on the quantity of byproduct material that can be in a generally licensed device and to set that limit at 1/10 of the IAEA Category 3 threshold.

The rationale for placing such a limit is the need for additional security and safety provided by the specific licensing process, including as it relates to potential aggregation of devices with Category 3 and high-end Category 4 sources to IAEA Category 2 quantities of concern, and their potential use for malevolent purposes. The NRC believes that the additional burden to licensees and regulatory bodies as a result of the proposed amendment would be reasonable to incur because of the benefits derived from placing these higher activity generally licensed devices under a greater range of regulatory controls, thus enhancing public health and safety and security.

The need for this proposed amendment to the GL regulatory system was not foreseen in detail in 1999 and 2000 when NRC issued the rule amendments instituting the GL registration system. As noted above, the principal rationale for the GL registration program was to make general licensees more aware of applicable requirements, hence reducing the potential for improper handling or disposal of devices due to lack of knowledge or inadvertent misuse, and the belief that if general licensees are aware of their responsibilities they will comply with requirements for proper handling and disposal of generally licensed devices. The current rulemaking proposed to the Commission seeks to reflect the changed domestic and international threat environments, and related U.S. Government-supported international initiatives in the nuclear security area, by setting an upper limit for licensing of generally licensed devices.

The staff has opted not to propose extending this new limit on GL licensing down to the GL registration system 10 CFR 31.5(c)(13)(i) levels, as requested by the OAS in their petition, because it does not believe it is necessary nor appropriate from a source aggregation and cost-benefit basis. Instead, the staff proposes leaving the GL registration program essentially as it currently exists for general licensees below the new GL limit because the rationale and approach in instituting the GL registration program in the 1999 and 2000 rule amendments continue to remain valid today.

Nevertheless, the staff recognizes the desire on the part of the States supporting the OAS petition to exercise greater control over the actions of their licensees and therefore is proposing to revise the Compatibility Category of 10 CFR 31.5(a) from 'B' to 'C' and the Compatibility Category for 10 CFR 31.6 from 'B' to 'C.' The OAS stated that these actions were needed to establish a higher national standard of regulation for higher risk generally licensed devices, and to allow retention of a tool used by Agreement States to track the location and movement of device manufacturers and service providers within the State limits. By revising these compatibility categories, Agreement States will have flexibility to adopt additional requirements, based on their circumstances and needs, if necessary. In addition, the staff is proposing to revise the Compatibility Category of 10 CFR 31.5(c)(13)(i) from 'B' to 'C.' The State of Florida stated that this action was necessary to avoid having to relax its existing health, safety, and security controls, which provide benefit to the safety and security of Florida citizens, in order to be compatible with the less stringent national standards in NRC's regulations. Florida also noted that the registering of additional generally licensed devices in Florida does not have direct and significant effect on the transportation of the devices or on their movement in and out of Florida.

As noted above, a separate rulemaking has been proposed to expand the NSTS to include sources greater than or equal to 1/10 of the Category 3 thresholds. If the NSTS rule is adopted, the general licensees required to obtain SLs under this proposed amendment would also have to follow the requirements of the expanded NSTS. The regulatory analysis for this rulemaking considered this additional cost and it is not expected to result in additional implementation issues related to the expanded NSTS.

The proposed rule is consistent with NRC strategic objectives and performance goals. The proposed rule would continue to ensure the protection of public health and safety and the environment, as well as continue to ensure the secure use and management of radioactive materials. While the proposed rule would not change the physical protection requirements for sources, the proposed changes are part of a comprehensive radioactive source control program. The proposed limit on radioactivity in generally licensed devices would provide greater source accountability and will enable NRC to better risk-inform its inspection and licensing review programs for byproduct material licensees by helping NRC focus on those licensees that possess sources that can be aggregated to quantities of concern, thus making NRC actions more efficient and effective.

The rulemaking will be conducted in an open process. The proposed rule will be published in the *Federal Register* for a 75-day public comment period. The draft proposed rule was prepared with participation by Agreement State representatives and the draft proposed rule was provided to the Agreement States for preliminary review. The rule was also provided to the Standing Committee for Compatibility, which was established as a Management Directive 5.3

working group including State representatives to enhance the existing compatibility determination process and which provides an independent review and assessment of NRC staff designations for the compatibility designation for each new or revised program element. It is anticipated that to assist licensees in implementing the requirements of this rule amendment that NRC would provide licensees with licensing guidance related to specific licensing application and possession process at or around the effective date of the final rule.

Other Considerations

As discussed above, in response to SECY-06-0094, the Commission provided direction to the NRC staff in a June 9, 2006, SRM which, in addition to approving the staff's plan for rulemaking to amend certain general licenses, also approved the staff's approach to amend certain associated manufacturer requirements in Part 32 and also indicated the staff should consider standardizing the annual registration thresholds at 0.001 of the IAEA Code of Conduct D values (about 1/1000 of the Category 3 thresholds). With regard to manufacturers and distributors (M&Ds), SECY-06-0094 discussed potential regulatory improvements for devices that remain under general license including those related to M&D requirements in 10 CFR Part 32. Currently, specific licensees who manufacture and distribute generally licensed devices, above the registration levels, are required by §32.51 to conduct quarterly reporting to NRC of transfer of generally licensed devices, recordkeeping, labeling, and providing of information to users. SECY-06-0094 noted that the staff was not making any specific recommendations for changes to the M&D requirements in §32.51. Thus, for generally licensed devices below 1/10 of Category 3 and thus remaining in the registration program, it is not considered necessary at this time to conduct rulemaking to change the specific license distribution requirements. With regard to standardizing the annual registration thresholds, the staff, in further considering this issue, has determined that the IAEA Category D values are derived from a methodology which is based on severe deterministic health effects (short-term permanent injury or death). The current registration quantities in 10 CFR 31.5(c)(13)(i), on the other hand, consider stochastic effects (e.g., cancer induction) in addition to deterministic impacts. Based on these considerations, the staff believes that the health and safety basis for the existing GL registration quantities is more comprehensive than the health and safety basis for the IAEA Category D values, and, therefore, the registration quantities should not be changed. Therefore, no action is being taken on standardizing the registration criteria in this rulemaking.

Agreement State Issues

A copy of the draft proposed rule FRN was provided to the States on May 2, 2008, so they could have an early opportunity for review. Three States, Washington, New Jersey, and Illinois provided comments on the draft FRN. Two of the States commented that the quantity of byproduct material in generally licensed devices should be limited to Category 4 levels (1/100 Category 3), while one State commented that they are not in favor of this method of providing additional oversight for generally licensed devices.

The GL program was discussed during the August 2008 OAS annual meeting and comments were received from the Agreement States restating their preference for extending the limit on the quantity of byproduct material in generally licensed devices to registration levels. The Agreement State concerns and comments have been considered and reflected in the enclosed draft FRN.

NRC staff has analyzed the proposed rule in accordance with the procedures established within Part III of the Handbook to Management Directive 5.9, "Categorization Process for NRC Program Elements." Staff has determined that the proposed rule is designated as Compatibility Category "C". Compatibility Category C are those program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a national basis. An Agreement State should adopt these essential objectives.

The Standing Committee on Compatibility reviewed the proposed rule and agreed that these amendments to the NRC regulations are a matter of compatibility between the NRC and the Agreement States and that the compatibility designations for these amended sections should be Compatibility Category C.

RECOMMENDATIONS:

The staff recommends that the Commission:

1. Approve for publication, in the *Federal Register*, the proposed amendment to Part 31 of 10 CFR (Enclosure 1).
2. Note:
 - a. That the proposed amendment will be published in the *Federal Register*, allowing 75 days for public comment.
 - b. That the Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b).
 - c. That a Regulatory Analysis has been prepared for this rulemaking (Enclosure 2).
 - d. That appropriate Congressional committees will be informed of this action.
 - e. That a press release will be issued by the Office of Public Affairs when the proposed rulemaking is filed with the Office of the Federal Register.
 - f. Office of Management and Budget (OMB) review is required and a clearance package will be forwarded to OMB no later than the date the proposed rule is submitted to the Office of the Federal Register for publication.

RESOURCES:

To complete and implement the rulemaking, 1.5 full-time equivalent positions will be required. These resources are included in the current budget.

COORDINATION:

The Office of the General Counsel has no legal objection to the proposed rulemaking. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource

implications and has no objections. The rule suggests changes in information collection requirements that must be submitted to OMB no later than the date the proposed rule is forwarded to the *Federal Register* for publication.

/RA Martin Virgilio for/

R. W. Borchardt
Executive Director
for Operations

Enclosures:

1. *Federal Register* Notice
2. Regulatory Analysis

NUCLEAR REGULATORY COMMISSION

10 CFR Part 31

RIN: 3150-AI33

[NRC-2008-0272]

Limiting the Quantity of Byproduct Material in a Generally Licensed Device

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations 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. As a result of this amendment, individuals possessing devices with byproduct material meeting or exceeding these thresholds would be required to apply for a specific license. The proposed amendment would also modify the Compatibility Categories contained in the current regulations (10 CFR 31.5 and 31.6).

DATES: Submit comments on the rule by (**insert 75 days after publication in the *Federal Register***). Submit comments specific to the information collection aspects of this rule by (**insert date 30 days after publication in the *Federal Register***). Comments received after

the above date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments on the rule by any one of the following methods.

Please include the number RIN 3150-AI33 in the subject line of your comments. Comments on rulemakings submitted in writing or in electronic form will be made available to the public in their entirety on the Federal government's rulemaking website: <http://www.regulations.gov>.

Personal information, such as your name, address, telephone number, e-mail address, etc., will not be removed from your submission.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: Rulemaking.Comments@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at 301-415-1677. Comments can also be submitted via the Federal eRulemaking Portal <http://www.regulations.gov>.

Hand-deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. on Federal workdays. (Telephone 301-415-1677)

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission. The fax number is 301-415-1101.

You may submit comments on the information collections by the methods indicated in the Paperwork Reduction Act Statement.

Publicly available documents related to this rulemaking may be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), O-1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. The PDR reproduction contractor will copy documents for a fee.

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at:

<http://www.nrc.gov/reading-rm/adams.html>. From this site, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail:

PDR.Resource@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Frank Cardile, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 telephone (301) 415-6185, e-mail: frank.cardile@nrc.gov, or Solomon Sahle, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-3781 e-mail: solomon.sahle@nrc.gov.

SUPPLEMENTARY INFORMATION:

- I. Background.
- II. Discussion.
 - A. Rationale for limiting the quantity of byproduct material in a generally licensed device.
 - B. Decision on proposed amendment to place a limit on quantity of byproduct material in generally licensed devices.
 - C. Other considerations.
- III. Discussion of Proposed Amendments by Section.
- IV. Criminal Penalties.

- V. Agreement State Compatibility.
- VI. Plain Language.
- VII. Voluntary Consensus Standards.
- VIII. Environmental Impact: Categorical Exclusion.
- IX. Paperwork Reduction Act Statement.
- X. Regulatory Analysis.
- XI. Regulatory Flexibility Certification.
- XII. Backfit Analysis.

I. Background

Prior to the terrorist attacks of September 11, 2001 (9/11), several national and international efforts were underway to address the potentially significant health and safety hazards posed by uncontrolled sources. These efforts recognized the need for increased control of high-risk radioactive materials to prevent inadvertent and intentional unauthorized access, primarily due to the potential health and safety hazards posed by the uncontrolled material. Following 9/11, it was recognized that these efforts should also include a heightened awareness and focus on the need to prevent intentional unauthorized access due to potential malicious acts. Proper security and control measures reduce the likelihood that this radioactive material could be used in radiological dispersal devices (RDD) or in radiological exposure devices (RED). These efforts, such as the IAEA Code of Conduct on the Safety and Security of Radioactive Sources (Code of Conduct) concerning Category 1 and 2 sources, seek to increase the control over sources to prevent unintended radiation exposure and to prevent malicious acts.

In June 2002, the Secretary of Energy and the NRC Chairman met to discuss the adequate protection of inventories of nuclear materials that could be used in a RDD. At the June meeting, the Secretary of Energy and the NRC Chairman agreed to convene an Interagency Working Group on Radiological Dispersal Devices to address security concerns. In May 2003, the joint U.S. Department of Energy (DOE)/NRC report was issued. The report was entitled, "Radiological Dispersal Devices: An Initial Study to Identify Radioactive Materials of Greatest Concern and Approaches to Their Tracking, Tagging, and Disposition."

The NRC has also supported U.S. Government efforts to establish international guidance for the safety and security of radioactive materials of concern. This effort has resulted in a major revision of the IAEA Code of Conduct. The revised Code of Conduct was approved by the IAEA Board of Governors in September 2003, and is available on the IAEA Web site at: http://www-pub.iaea.org/MTCD/publications/PDF/Code-2004_web.pdf. In particular, the Code of Conduct contains a recommendation that each IAEA Member State develop a national source registry of radioactive sources that includes at a minimum Category 1 and Category 2 radioactive sources as described in Annex 1 of the Code of Conduct. The source registry recommendation addressed 16 radionuclides.

The work on the DOE/NRC joint report paralleled the work on the Code of Conduct and the development of IAEA TECDOC-1344, "Categorization of Radioactive Sources."¹ The IAEA updated this categorization system for radioactive sources in August 2005, in the IAEA Safety Standards Series No. RS-G-1.9, "Categorization of Radioactive Sources." The Safety Guide, which is also available on the IAEA's Web site at: http://www-pub.iaea.org/MTCD/publications/PDF/Pub1227_web.pdf, provides the underlying methodology for the development

¹ See Section A.4.1 of this notice for a description of the IAEA source categorization system.

of the Code of Conduct thresholds. The categorization system is based on the potential for sources to cause deterministic effects and uses the D values as normalizing factors. The D values are radionuclide-specific activity levels for the purposes of emergency planning and response. The quantities of concern identified in the May 2003 DOE/NRC report are similar to the IAEA Code of Conduct Category 2 threshold values, and therefore, to allow alignment between domestic and international efforts to increase the safety and security of radioactive sources, NRC has adopted the Category 2 definitions contained in the IAEA's Code of Conduct. The NRC considers IAEA Category 2 (and higher) to be risk-significant radioactive material that has a potential to result in significant adverse impacts that could reasonably constitute a threat to the public health and safety, the environment, or the common defense and security of the United States.

While the various efforts and reviews previously noted in this notice have been ongoing, 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 controls 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 publishing a final rule, in November 2006, on 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. Recently, NRC proposed, in a separate rulemaking, to expand the NSTS 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 levels. NRC is currently evaluating the comments received on the proposed rule; eighteen of the nineteen public comments received were opposed to expansion of the NSTS citing concerns that the rule may be premature and not necessary.

During this time period, there has also been increased concern and focus on devices that are currently possessed under NRC's general license (GL) regulatory program. The requirements for GLs are described in 10 CFR Part 31, "General Domestic Licenses for Byproduct Material." 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 GL regulatory system and, in addition, the Organization of Agreement States (OAS) filed a petition for rulemaking on June 27, 2005 (PRM-31-5), requesting that NRC strengthen its GL regulatory system. The NRC staff has also been considering similar concerns, noting that, under the current GL regulatory system, NRC and the Agreement States do not have an opportunity to review the purpose of use, adequacy of applicant facilities and equipment, training and experience, and ability to meet any other applicable requirements. Further, a licensee's loss of control of radioactive sources, whether it be inadvertent or through a deliberate act, has a potential to result in significant adverse health impacts and could reasonably constitute a threat to the public health and safety. Thus, NRC has been considering whether it is appropriate to amend 10 CFR Part 31 to require specific licensing for some materials currently regulated under the GL regulatory system. Limiting the source activity allowed under a GL would result in expanding the specific licensing regulations to cover more licensees. The specific license (SL) regulatory system and requirements are described in 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Radioactive Material."

II. Discussion

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; licensees with devices containing byproduct material at or above this limit would be required to obtain a SL. This rulemaking is directed toward improving the safety and security of devices now held under a GL having radioactive sources falling within IAEA Categories 3 through 5 by causing a portion of them to be SLs and allowing the remaining portion to continue to be GLs.

In determining whether to place a limit on the quantity of byproduct material allowed in a generally licensed device, the NRC has considered the need to balance the secure handling and use of the materials without discouraging their beneficial use in academic, medical, and industrial applications. Radioactive materials provide critical capabilities in the oil and gas, electrical power, construction, and food industries; are used to treat millions of patients each year in diagnostic and therapeutic procedures; and are used in technology research and development involving academic, government, and private institutions. These materials are as diverse in geographical location as they are in functional use.

Placing a limit on the quantity of byproduct material allowed in a generally licensed device is part of a comprehensive control program for radioactive materials of greatest concern, as discussed in SECY-07-0147, "Response to U.S. Government Accountability Office Recommendations and other Recommendations to Address Security Issues in the U.S. NRC Materials Program," dated August 25, 2007. Although this proposed amendment cannot, by itself, ensure the physical protection of sources, converting certain GLs to SLs can provide greater device accountability and, as part of an overall effort in conjunction with other related activities (e.g., implementation of the NSTS, web-based licensing, pre-licensing site visits, and increased controls orders), can improve the control of radioactive sources and protect public health and safety, as well as common defense and security.

This rulemaking also considers the issues raised by the OAS in its June 27, 2005, petition for rulemaking, in which the OAS requested that NRC revise 10 CFR 31.5 and change

the Compatibility Category of 10 CFR 31.6 from 'B' to 'C'; and the issues raised by the State of Florida in its June 3, 2005, request to change the Compatibility Category of 10 CFR 31.5(c)(13)(i) from 'B' to 'C.' These issues were docketed by the NRC as PRM-31-5.

The following sections of this statement of considerations discuss the rationale for placing a limit on the quantity of byproduct material in a generally licensed device (Section A) and NRC's decision on the approach in this proposed amendment (Section B).

A. Rationale for limiting the quantity of byproduct material in a generally licensed device

A.1 Congressional Concerns/GAO Investigations

The U.S. Senate and the GAO have expressed concerns regarding the safety and security of radioactive sources. In a report by the Permanent Subcommittee on Investigations (PSI), July 12, 2007, 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 their concerns. The GAO completed two investigations of the security aspects of NRC's materials licensing process, including one in 2007 (GAO-07-1038T, July 12, 2007), on the security of the NRC licensing process. In their report, GAO raised concerns about the relative ease with which lower activity sources can be purchased and potentially aggregated to higher activity levels.

A.2 Agreement State Issues

Agreement States have also raised concerns about the security and accountability of byproduct materials in generally licensed devices. In its June 27, 2005, petition for rulemaking,

the OAS requested that NRC “strengthen the regulation of radioactive materials by requiring a specific license 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 also 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. These petitions were docketed by NRC as PRM-31-5. The NRC requested public comment on the PRM-31-5 petition on December 20, 2005 (70 FR 75423). Four comment letters were received on the petition; the commenters disagreed with using the registration levels to require GLs to become SLs but had differing views on changing the compatibility categories. In considering the petition and the public comments on them, the NRC determined it appropriate to consider the concerns and issues raised by OAS and the State of Florida in this rulemaking. By letter dated August 17, 2007, the petitioners were informed of the decision.

A.3 Recent NRC Actions

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 activity limits for GLs at one-half (1/2) of the IAEA Category 2 threshold and reserve authorization to possess higher activity sources to SLs. The staff noted that a benefit of setting such a limit would be greater oversight of these

licensees, allowing regulatory bodies the opportunity to perform an assessment of a licensee's legitimacy or any other regulatory activities the Commission determined as being necessary. The NRC staff, in SECY-06-0094, recommended setting the GL limit at 1/2 of Category 2 because 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 Section 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 threshold².

A.4 Considerations Regarding the Need for Placing a Limit on the Quantity of Byproduct Material Allowed in a Generally Licensed Device, and Determining What the "Limit" Should Be

This section briefly describes the IAEA source characterization system (Section A.4.1); the existing GL regulatory system (Section A.4.2); and the specific rationale for revising the existing GL regulatory system to place a limit on the quantity of byproduct material in a generally licensed device (Section A.4.3).

A.4.1 The five IAEA Categories and the Relative Health and Safety Risk Posed by Sources in those Categories

The IAEA source categorization scheme includes five categories. These categories are based on the potential for sources to cause health effects to persons exposed to them.

² Sources referred to as "1/10 of Category 3" were formerly referred to as "Category 3.5" sources. To be consistent with IAEA terminology, the term "Category 3.5" has been changed to "1/10 of Category 3."

Sources in Category 1 are considered to be the most 'dangerous' because they can pose a very high risk to human health if not managed safely and securely. At the lower end of the categorization system, sources in Category 5 are the least dangerous; however, even these sources could give rise to doses in excess of the dose limits if not properly controlled. Based on analysis of potential health effects, each of the IAEA Categories contain radioactive material in sealed sources in quantities that can be characterized as follows: Category 1: greater than or equal to the Category 1 threshold (e.g., for Co-60: 810 Curies (Ci)); these sources are typically used in practices such as irradiators, radiation therapy, and radiothermal generators. Category 2: less than the Category 1 threshold but equal to or greater than the Category 2 threshold (which is 1/100 of Category 1); (e.g., for Co-60: 8.1 Ci); these sources are typically used in practices such as industrial gamma radiography and high and medium dose rate brachytherapy. Category 3: less than the Category 2 threshold but equal to or greater than the Category 3 threshold (1/10 of Category 2); (e.g., for Co-60: 0.81 Ci); these sources are typically used in practices such as fixed industrial gauges involving high activity sources. Category 4: less than the Category 3 threshold but equal to or greater than the Category 4 threshold (1/100 of Category 3); (e.g., for Co-60: 0.0081 Ci); Category 5: less than the Category 4 threshold down to IAEA exempt quantities.

A.4.2 The existing GL regulatory system in 10 CFR Part 31 and its rationale

The primary elements of the existing GL regulatory framework are contained in 10 CFR Part 31. A generally licensed device usually consists of byproduct material contained in a sealed source within a shielded housing. The device is designed with inherent radiation safety features so that it can be used by persons with no radiation training or experience. Thus, the GL regulatory program simplifies the licensing process because a case-by-case determination

of the adequacy of the radiation training or experience of each user is not necessary. As part of the GL regulatory system, NRC evaluates the adequacy of generally licensed products by ensuring that manufacturers and distributors (who hold specific licenses) of the products meet the various specific requirements in 10 CFR Part 32, Subpart B. Although there is no limit specified in the existing GL regulatory system regarding the quantity of byproduct material that can be allowed in a device and still continue to be generally licensed, at this time all of the generally licensed devices are in IAEA Categories 3 through 5 (i.e., there are no Category 1 or 2 generally licensed devices currently in existence).

As part of the current GL regulatory system, Section 31.5 contains requirements that generally licensed devices containing byproduct material in quantities above “registration” levels listed in §31.5(c)(13)(i) must be registered with the NRC or the Agreement State. There are about 1,200 general licensees possessing such devices who are currently registered with the NRC. The radionuclides listed in §31.5(c)(13)(i) are Co-60, Cs-137, Sr-90, and Am-241 and any other transuranics. As an example, the registration level for Co-60 is 0.001 Ci; for context, this falls in the IAEA Category 5 range and is approximately 1/1000 of the IAEA Category 3 threshold for Co-60 (and approximately 1/10 of the Category 4 threshold). The GL registration program was initiated in rule amendments finalized on August 4, 1999 (64 FR 42269), and December 18, 2000 (65 FR 79162). As noted in the *Federal Register* Notice (FRN) for the August 4, 1999, rulemaking, the GL registration program is primarily intended to ensure that general licensees are aware of and understand the requirements for the possession of devices containing byproduct materials and that such devices are maintained and transferred properly and not inadvertently discarded. In initiating the GL registration program, NRC noted that it was most concerned about occurrences where generally licensed devices had not been handled or disposed of properly and believed that if general licensees are aware of their responsibilities they would comply with the requirements for proper handling and disposal of generally licensed

devices which would help reduce the potential for incidents, including those related to sources not being disposed of properly and being accidentally melted in steel mills, which can cause unnecessary radiation exposure and property contamination.

A.4.3. Rationale for revising the existing GL regulatory system and placing a limit on the quantity of radioactivity allowed in a generally licensed device

In preparing this proposed rule, NRC has determined that there is a need to enhance the security of devices with certain lower activity sources to improve their accountability. At issue are: (1) the basic question of whether to modify the existing GL regulatory system by placing a limit on the quantity of byproduct material allowed in generally licensed devices; and (2) the appropriate value for the limit, i.e., should the limit be set at 1/10 of the IAEA Category 3 threshold (as suggested in the June 9, 2006 SRM) or should it be set lower to include devices that are above the current registration levels which are at a level approximately 1/1000 of the IAEA Category 3 threshold (as suggested in the June 27, 2005 OAS petition for rulemaking). The rationale for modifying the existing GL regulatory system and for the appropriate value of the limit itself are provided in Sections A.4.3.1 and A.4.3.2, respectively.

A.4.3.1 Rationale for Revising the GL Regulatory System to Require GLs Above a Certain Limit to SLs

As part of its overall process, the NRC evaluated its current GL regulatory system, as described in Section A.4.2 of this notice, and noted that it included little in the way of security measures, resulting in unintended potential vulnerabilities for these devices. Because generally licensed devices are subject to relatively few administrative or operational regulatory constraints

(mainly as a result of the safety features incorporated into their design), security vulnerabilities can be a concern. Under the current GL regulatory system, a general licensee would not be subject to the same regulatory controls (i.e., pre-licensing reviews, inspection, safety and security requirements) as specific licensees possessing similar quantities of radioactive material. Placing certain generally licensed devices under the SL process would subject them to elements of oversight that are not part of the GL process, including the license application and review process, and more routine inspections and elements of security requirements. This process would improve not only the ability to prevent any theft or diversion of these materials, but would also help prevent or detect any inadvertent loss of such devices that could potentially impact public health and safety.

With regard to the license application process, limiting the quantity of byproduct material allowed in a generally licensed device and thus requiring certain of them to apply for SLs, would provide an opportunity for a detailed review of the radioactive materials program proposed by an applicant, an opportunity for oral and written dialogue with the applicant, and a regulatory decision as to whether to grant the license as requested, or if certain modifications are necessary. Specifically, this amendment would allow for a more rigorous screening of applicants through pre-licensing visits to the proposed location of licensed activities (currently under consideration); a more efficient licensing process to facilitate the rapid communication between regulators regarding the legitimacy of a given entity; and other potential enhancements to the specific licensing process including the proposed expansion of the NSTS being considered in a separate rulemaking.

With regard to the inspection process, currently, NRC does not normally perform inspections of general licensees. Inspections are only performed in certain circumstances which may come to NRC's attention, such as when there are indications of unsafe practices by the general licensees. By converting certain GLs to SLs, the effectiveness of any applicable

safety and security measures could be accurately determined in a more timely manner if needed. The SL inspection program is implemented by the NRC and Agreement States in a risk-informed manner (e.g., inspection frequency is commensurate with the scope and complexity of the licensed activity and the quantity and type/form of radioactive material authorized by the license) and by use of performance-based inspections which focus on the program outcomes achieved by the licensee and then probe (through interview, observation, and reviews of selected records) where needed and appropriate to understand the basis for a given outcome(s).

A.4.3.2 Specific rationale for determining the limit on the quantity of radioactivity allowed in a generally licensed device

As noted in Section A.4.3 of this notice, NRC considered the appropriate value to limit the quantity of byproduct material allowed in a generally licensed device. The Commission's June 9, 2006, SRM directed the staff to evaluate specific licensing at 1/10 of the IAEA Category 3 thresholds, whereas the OAS in its June 27, 2005, petition requested that the limit be set at a lower level to include devices that are at or above the current registration levels which are approximately 1/1000 of the IAEA Category 3 threshold. Considerations as to at what level to set the limit are based on the potential for aggregation to higher activity quantities of concern and also on the additional resource burden placed on licensees and on the regulatory bodies which would result from such an amendment.

A.4.3.2.1 Potential for aggregation to higher IAEA categories of concern

For devices with sources at or above 1/10 of the IAEA Category 3 thresholds

Converting certain devices with sources that are equal to or greater than 1/10 of Category 3 to SLs would involve sources in Category 3 itself, as well as a subset of IAEA Category 4 sources (i.e., sources at the “high end” of the Category 4 radioactivity range which are equal to, or greater than, 1/10 of the Category 3 threshold). These two groups are discussed below.

Category 3 sources are defined by IAEA as “dangerous sources,” i.e., a source that could, if not under control, give rise to exposure sufficient to cause severe deterministic effects, and thus even without any aggregation there is rationale for specifically licensing devices with Category 3 sources. In addition, devices with Category 3 sources could be easily aggregated to Category 2 levels, as part of a concerted effort to do so, as they contain sources with activity levels that range from just below the Category 2 threshold down to 1/10 of the Category 2 threshold. Thus, sources at the high end of the range of activities in Category 3 can be at levels just below the threshold of a Category 2 source, meaning that it would take only a few devices with such sources to aggregate to Category 2. The major category of licensees who possess devices with Category 3 sources include those with industrial gauges and, because these devices are relatively widespread in use and relatively broadly used in industry, there is potential for aggregation of sufficient numbers of them to Category 2 levels.

With regard to devices with sources that are 1/10 of IAEA Category 3, these are actually a subset of IAEA Category 4 sources that are in the high end of the Category 4 radioactivity range. A principal rationale for including sources at the high-end of the Category 4 range of activities (at 1/10 of Category 3) is the potential that a sufficient number of devices with these

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 devices with such sources to aggregate to Category 2 quantities. Devices with these high-end Category 4 (1/10 Category 3) sources are possessed by similar licensees noted to have Category 3 sources, namely those with industrial gauges, and, as previously noted, 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.

For devices with sources that are at or above registration levels

As noted above, the OAS in its June 27, 2005, petition requested that the GL limit be set at a level that would include devices with sources that are at or above the current registration levels which are approximately 1/1000 of the IAEA Category 3 threshold. The Commission has considered this level, which would include devices with sources in all of the IAEA Category 4 radioactivity range (i.e., including those in the “low-end” of the Category 4 radioactivity range) and also devices with sources in IAEA Category 5, and notes that, 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. In view of the lower likelihood that devices with sources in the lower range of Category 4 or in Category 5 would be aggregated to quantities of concern, the staff believes that the relatively low security risk does not justify the significant regulatory resources and impacts on licensees that would result from specifically licensing devices with sources in the lower Category 4 and Category 5 ranges.

A.4.3.2.2 Consideration of the Additional Resource Burden on Licensees and Regulatory Bodies to Comply with these Proposed Amendments

Requiring certain GLs to convert to SLs would result in increased burden to the licensed industry, and to the NRC and Agreement States, for preparation and review of specific license applications and amendments and for conduct of inspections. In the Regulatory Analysis for this rulemaking (see Section XI of this notice), the Commission analyzed the additional costs and benefits of placing a limit on the quantity of radioactivity allowed in a generally licensed device. A summary of the analysis follows.

For Devices with Sources At or Above 1/10 of the IAEA Category 3 Threshold

Limiting the quantity of byproduct material allowed in generally licensed devices to below 1/10 of the IAEA's Category 3 thresholds would result in approximately 280 NRC general licensees being converted to SLs (approximately 1400 NRC and Agreement State general licensees). These licensees would now have to follow existing requirements of the 10 CFR, including Parts 19, 20, and 30, as do other licensees with similar quantities of radioactive material. The added number of SLs would also result in an increase in the regulatory resources that would be devoted to reviewing the new SL applications and inspecting the licensees after the license is issued. However, the NRC and Agreement State resources incurred are not considered significant because the number of additional GLs that would be converted to SLs represent only about 6 percent of the NRC and Agreement States existing population of SLs and, hence, would not result in significant additional NRC and/or Agreement States resource commitment.

For Devices with Sources At or Above Registration Levels

Limiting the quantity of byproduct material allowed in generally licensed devices to registration levels would result in approximately 1,200 NRC general licensees being converted to SLs (approximately 6,000 NRC and Agreement State general licensees), these licensees, possessing Category 4 and upper-end Category 5 sources, would now have to follow the same requirements in 10 CFR Parts 19, 20, and 30 as other licensees with higher quantities of radioactive material. The added number of SLs would also result in an increase in the regulatory resources that would be devoted to reviewing the new SL applications and inspecting the licensees after the license is issued. It is estimated that the number of additional GLs that would be converted into SLs represent about 25 percent of the NRC and Agreement States existing population of SLs and, hence, would represent a relatively significant additional NRC and/or Agreement States resource commitment. In view of the lower likelihood that devices with sources in the lower range of Category 4 or in Category 5 would be aggregated to quantities of concern, the staff believes that the relatively low security risk does not justify the significant regulatory resources and impacts on licensees that would result from specifically licensing devices with sources in the lower Category 4 and Category 5 ranges.

B. Decision on Proposed Amendment to Place a Limit on the Quantity of Byproduct Material Allowed in Generally Licensed Devices

Based on the considerations of Section II.A, the NRC has decided to propose amending its regulations by placing a limit on the quantity of byproduct material that can be in a generally licensed device and to set that limit at 1/10 of the IAEA Category 3 threshold.

The rationale for placing such a limit is the need for additional security and safety provided by the specific licensing process, including as it relates to potential aggregation of Category 3 and high-end Category 4 radioactive sources to IAEA Category 2 quantities of concern. The NRC believes that the additional burden to licensees and regulatory bodies as a result of the proposed amendments would be reasonable to incur because of the benefits derived from placing these higher activity generally licensed devices under a greater range of regulatory controls, thus enhancing public health and safety and security.

The need for this proposed amendment to the GL regulatory system was not foreseen in detail in 1999 and 2000 when NRC issued the rule amendments instituting the GL registration system. As noted in Section A.4.2 of this notice, and in the Statements of Consideration for those rule amendments, the principal rationale for the GL registration program was to make general licensees more aware of applicable requirements, hence reducing the potential for improper handling or disposal of devices due to lack of knowledge or inadvertent misuse, and the belief that if general licenses are aware of their responsibilities they will comply with requirements for proper handling and disposal of generally licensed devices. The current rulemaking seeks to reflect the changed domestic and international threat environments, and related U.S. Government-supported international initiatives in the nuclear security area, by setting an upper limit for licensing of generally licensed devices at 1/10 of IAEA Category 3.

NRC has chosen not to extend this new limit on GL licensing down to the 10 CFR 31.5(c)(13)(i) registration levels, as requested by the OAS in its rulemaking petition, because it is not believed that it is necessary nor appropriate from a source aggregation and cost-benefit basis and in view of the lower likelihood that devices with sources in the lower range of Category 4 or in Category 5 would be aggregated to quantities of concern; the NRC believes that the relatively low security risk does not justify the significant regulatory resources and impacts on licensees that would result from specifically licensing devices with sources in the

lower Category 4 and Category 5 ranges. Instead, NRC has left the GL registration program essentially as it currently exists for general licensees below the new GL limit because the rationale and approach in instituting the GL registration program in the 1999 and 2000 rule amendments continue to remain valid today. The NRC has been successful in implementing the GL registration program with 80 – 90 percent of general licensees responding with completed registration forms. This rate of registration can be attributed in part to general licensees enhanced awareness of regulatory reporting, transfer, disposal, and recordkeeping requirements.

Nevertheless, the NRC recognizes the desire on the part of the States supporting the OAS petition to exercise greater control over the actions of their licensees. Therefore, the NRC is revising the Compatibility Category of 10 CFR 31.5(a) from 'B' to 'C' and also is revising the Compatibility Category for 10 CFR 31.6 from 'B' to 'C.' The OAS stated that these actions were needed to establish a higher national standard of regulation for higher risk generally licensed devices, and to allow retention of a tool used by Agreement States to track the location and movement of device manufacturers and service providers within the State limits. By revising these compatibility categories, Agreement States will have flexibility to adopt additional requirements, based on their circumstances and needs, if necessary. In addition, the NRC is revising the Compatibility Category of 10 CFR 31.5(c)(13)(i) from 'B' to 'C.' Florida stated that this action was necessary to avoid having to relax its existing health, safety, and security controls, which provide benefit to the safety and security of Florida citizens, in order to be compatible with less stringent national standards in NRC's regulations; Florida also noted that the registering of additional generally licensed devices in Florida does not have direct and significant effect on the transportation of the devices or on their movement in and out of Florida.

The NRC invites comment on its decision to propose placing a limit on the quantity of byproduct material allowed in generally licensed devices, specifically:

1) Whether the 1/10 of IAEA Category 3 limit is the appropriate threshold level of byproduct material below which each generally licensed device can remain under a GL; or

2) Whether there should be additional protection against aggregation of sources by either requiring that if the aggregated amount of byproduct material that a general licensee possesses in devices exceeds 1/10 of IAEA Category 3 that the general licensee be required to obtain a SL, or more simply, by using the IAEA Category 4 threshold level as the limit for a GL;

or

3) Whether an even lower threshold limit for requiring licensees to obtain a SL should be used such as the registration levels in 10 CFR 31.5(c)(13)(i). In providing support for this approach, the NRC is interested in whether there is specific information (i.e., lack of accountability due to GL sources being lost and/or abandoned) that would indicate that the GL registration program as instituted in the 1999 and 2000 rulemakings (see Section II.A.4.2 of this notice) is no longer working satisfactorily from the standpoint of protecting the public health and safety from routine use of these devices by general licensees;

4) Whether the approach regarding Compatibility Categories laid out in Section II.B of this notice, i.e., in which States have flexibility to adopt more rigorous requirements for GLs, based on their circumstances and needs, can work satisfactorily. In particular, will there be any significant transboundary issues related to this approach or, will such an approach not have direct and significant effect on the transportation of the devices or on their movement in and out of States.

C. Implementation of the proposed rule amendments

Under the requirements of the amended regulations, a specific license would have to be obtained for each device or source containing byproduct material meeting or exceeding 1/10 of the IAEA Category 3 thresholds. Additional specific information regarding implementation of these requirements will be provided as part of guidance for complying with these amended regulations. Examples of information that may be included in guidance are: the types of information needed in a license application; how GLs would be notified that they need to obtain an SL (e.g., by NRC, by OAS, or by manufacturer); how general licensees and/or NRC would identify quantity of byproduct material in devices; how decay of the source radioactivity levels within GL devices should be identified and considered; and the relationship of the requirements to the sealed sources and device (SS&D) registry.

The rule would become effective 60 days after the final rule is published in the *Federal Register*. By this date, any licensee that possesses generally licensed devices meeting or exceeding 1/10 of the IAEA's Category 3 thresholds must have submitted an application for an SL, and be subject to the NSTS reporting and inventory requirements.

III. Discussion of Proposed Amendments by Section

Section 31.5(a) General Domestic Licenses for Byproduct Material.

The proposed rule would amend § 31.5(a) to limit the quantity of byproduct material in generally licensed devices to below 1/10 of the IAEA's Category 3 threshold.³ Licensees who possess devices containing byproduct material meeting or exceeding these thresholds be required to become specifically licensed and, therefore, subject to all applicable Title 10 regulations. Devices containing byproduct material below these thresholds would continue to be generally licensed.

³ Appendix E of 10 CFR Part 20 is being amended as part of a separate rulemaking to include Category 3 and 1/10 of Category 3 radioactive materials of concern. These values are provided here as background information.

Radioactive Material	1/10 Category 3 (TBq)	1/10 Category 3 (Ci)
Actinium-227	0.002	0.054
Americium-241	0.006	0.16
Americium-241/Be	0.006	0.16
Californium-252	0.002	0.054
Cobalt-60	0.003	0.081
Curium-244	0.005	0.14
Cesium-137	0.01	0.27
Gadolinium-153	0.1	2.7
Iridium-192	0.008	0.22
Plutonium-238	0.006	0.16
Plutonium-239/Be	0.006	0.16
Polonium-210	0.006	0.16
Promethium-147	4	110
Radium-226	0.004	0.11
Selenium-75	0.02	0.54
Strontium-90	0.10	2.7
Thorium-228	0.002	0.054
Thorium-229	0.002	0.054
Thulium-170	2	54
Ytterbium-169	0.03	0.81

IV. Criminal Penalties

For the purpose of Section 223 of the Atomic Energy Act (AEA) of 1954, as amended, the Commission is proposing to amend 10 CFR Part 31 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

V. Agreement State Compatibility

Under the “Policy Statement on Adequacy and Compatibility of Agreement State Programs” approved by the Commission on June 30, 1997, and published in the *Federal Register* on September 3, 1997 (62 FR 46517), the proposed rule would be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among the Agreement States and NRC’s requirements. NRC staff analyzed the proposed rule in accordance with the procedure established in Part III, “Categorization Process for NRC Program Elements,” of Handbook 5.9 to Management Directive 5.9, “Adequacy and Compatibility of Agreement State Programs.”

As a result of the amendments to § 31.5(a), this section is now designated as Compatibility Category C. Compatibility Category C are those program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a national basis. An Agreement State should adopt these essential objectives. After considering the issues associated with the compatibility requirements for § 31.5(c)(13)(i), this section is now designated as Compatibility Category C. Compatibility Category C are those program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to

avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a national basis. After considering the issues associated with the compatibility requirements for § 31.6, this section is now designated as Compatibility Category C. Compatibility Category C are those program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a national basis.

For the reasons provided in Section B of this notice, NRC has designated § 31.5(a), § 31.5(c)(13)(i), and §31.6 as Compatibility Category C and, by so doing, Agreement States will have flexibility to adopt additional requirements, based on their circumstances and needs, if necessary. This will also allow Agreement States the flexibility to adopt additional requirements for tracking the movement of service providers and the location of generally licensed devices. By designating §31.5(a) and §31.6 as Compatibility Category C the NRC addresses the issues and concerns raised by the OAS in their June 2005, petition for rulemaking and, thus, closes the OAS part of the petition. By designating §31.5(c)(13)(i) as Compatibility Category C the NRC addresses the issues and concerns raised by the State of Florida in their June 2005 request as part of the petition, and, thus, closes the entire petition.

VI. Plain Language

The Presidential Memorandum “Plain Language in Government Writing” published June 10, 1998 (63 FR 31883), directed that the Government’s documents be in clear and accessible language. The NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the **ADDRESSES** heading.

VII. Voluntary Consensus Standards

The National Technology Transfer Act of 1995 (Pub. L. 104-113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC would require licensees that possess generally licensed devices with any of the radioactive sources and thresholds specified in the proposed rule to submit an application for a specific license. This action does not constitute the establishment of a standard that contains generally applicable requirements.

VIII. Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed rule is the type of action described as a categorical exclusion in 10 CFR 51.22(c)(3)(iii). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed rule.

IX. Paperwork Reduction Act Statement

This proposed rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*). This rule has been submitted to the Office of Management and Budget (OMB) for review and approval of the information collection requirements.

Type of submission, new or revision: Revisions

The title of the information collection: 10 CFR Part 31, Limiting the Quantity of Byproduct material in a Generally Licensed Device.

How often the collection is required: Initially during license applications and at license renewals and amendments and other reporting for specific licenses.

Who would be required or asked to report: Licensees in possession of devices containing quantities of byproduct material meeting or exceeding 1/10 of the IAEA Code of Conduct's Category 3 thresholds.

An estimate of the number of annual responses: 7,371 (5,971 responses; 1,400 recordkeepers).

The estimated number of annual respondents: 1,400 (280 NRC; 1,120 Agreement State).

An estimate of the total number of hours needed annually to complete the requirement or request: 49,577.

Abstract: The NRC is proposing to amend its regulations to limit the amount of byproduct material in a generally licensed device to below 1/10 of the IAEA Category 3 thresholds. The proposed amendment would require licensees possessing devices meeting or exceeding these thresholds to submit an application for a specific license, and be subject to the NSTS reporting and inventory requirements. The NRC and/or the Agreement States would review such applications and issue licenses as appropriate.

The NRC is seeking public comment on the potential impact of the information collections contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information would have practical utility?
2. Is the estimate of burden accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

A copy of the OMB clearance package may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O-1 F21, Rockville, Maryland 20852. The OMB clearance package and rule are available at the NRC Worldwide Web site: <http://www.nrc.gov/public-involve/doc-comment/omb/index.html> for 60 days after the signature date of this notice.

Send comments on any aspect of these proposed information collections, including suggestions for reducing the burden and on the above issues, by **(INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER)** to the Records and FOIA/Privacy Services Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS.RESOURCE@NRC.GOV and to the

Desk Officer, Nathan J. Fray, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0010), Office of Management and Budget, Washington, DC 20503. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date. You may also email comments to Nathan J. Frey@omb.eop.gov or comment by telephone at (202) 395-7345.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

X. Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission.

The Commission requests public comment on the draft regulatory analysis. Comments may be submitted to the NRC as indicated under the **ADDRESSES** heading. The analysis is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852, or online at www.regulations.gov. Single copies of the draft regulatory analysis are available from Frank Cardile, telephone (301) 415-6185, e-mail: frank.cardile@nrc.gov, of the Office of Federal and State Materials and Environmental Management Programs, or Solomon Sahle, telephone (301) 415-3781, e-mail: solomon.sahle@nrc.gov, of the Office of Federal and State Materials and Environmental Management Programs,

XI. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule would not, if promulgated, have a significant economic impact on a substantial number of small entities. The proposed rule would affect about 280 NRC licensees and approximately an additional 1,120 Agreement State licensees possessing generally licensed devices with byproduct materials meeting or exceeding the 1/10 of IAEA's Category 3 thresholds. Affected licensees include licensees using fixed gauges, x-ray fluorescence density/moisture/level interface gauges, fixed thickness gauges, and any other licensees possessing devices with sources meeting or exceeding these thresholds, some of which may qualify as small business entities as defined by 10 CFR 2.810. However, the proposed rule is not expected to have a significant economic impact on these licensees.

Because of the widely differing conditions under which impacted licensees operate, the NRC is specifically requesting public comment from licensees concerning the impact of the proposed regulation. The NRC particularly desires comment from licensees who qualify as small businesses, specifically as to how the proposed regulation would affect them and how the regulation may be tiered or otherwise modified to impose less stringent requirements on small entities while still adequately protecting the public health and safety. Comments on how the regulation could be modified to take into account the differing needs of small entities should specifically discuss:

(1) The size of the business and how the proposed regulation would result in a significant economic burden upon it as compared to a larger organization in the same business community;

(2) How the proposed regulation could be further modified to take into account the business's differing needs or capabilities;

(3) The benefits that would accrue, or the detriments that would be avoided, if the proposed regulation was modified as suggested by the commenter;

(4) How the proposed regulation, as modified, would more closely equalize the impact of NRC regulations as opposed to providing special advantages to any individuals or groups; and

(5) How the proposed regulation, as modified, would still adequately protect the public health and safety.

Comments should be submitted as indicated under the **ADDRESSES** heading.

XII. Backfit Analysis

The NRC has determined that the backfit rule (§§ 50.109, 70.76, 72.62, or 76.76) does not apply to this proposed rule because this amendment would not involve any provisions that would impose backfits as defined in the backfit rule. Therefore, a backfit analysis is not required.

List of Subjects in 10 CFR Part 31

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment.

For the reasons set out in the notice and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553; the NRC is proposing to adopt the following amendment to 10 CFR Part 31.

PART 31 – GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

1. The authority citation for Part 31 continues to read as follows:

AUTHORITY: Secs. 81, 161, 183, 68 Stat. 935, 948, 954, as amended (42 U.S.C. 2111, 2201, 2233); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109-58, 119 stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

2. In § 31.5, paragraph (a) is revised to read as follows:

§ 31.5 Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere

(a) (1) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local government agencies to acquire, receive, possess, use or transfer, in accordance with the provisions of paragraphs (b), (c) and (d) of this section, byproduct material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized

atmosphere, provided that each device contains byproduct material in quantities below the thresholds listed in Appendix E of 10 CFR Part 20 for 1/10 of IAEA Category 3.

* * * * *

Dated at Rockville, Maryland, this day of , 2008.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,
Secretary for the Commission.



**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