

**RULEMAKING ISSUE
(Affirmation)**

August 10, 2010

SECY-10-0105

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: FINAL 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 final rule that will amend Title 10 of the *Code of Federal Regulations* (CFR) Part 31, in the *Federal Register*. The amendment will 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. Individuals possessing devices with byproduct material at or above 1/10 of Category 3 threshold values will be required to apply for and obtain a specific license (SL). In this document, the final rule is referred to as the General License (GL) Restrictions rule.

SUMMARY:

There has been increased concern regarding the safety and security of devices that are currently possessed under the U. S. Nuclear Regulatory Commission's (NRC's) GL regulatory program, including issues raised in reports from a U.S. Senate subcommittee and from the U.S. Government Accountability Office, in petitions from the Agreement States, and through NRC review of the GL regulatory program. In response to these concerns, the staff considered whether a limit should be placed on the quantity of byproduct material allowed in generally

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licensed devices, to improve accountability and control over these sources and reduce the potential for the aggregation of lower activity sources to higher activity levels. Based on technical and policy considerations, and on a regulatory analysis of the costs and benefits, the staff is requesting Commission approval of a final rule that will amend 10 CFR Part 31 to limit the quantity of byproduct material allowed in a generally licensed device to below 1/10 of the IAEA Category 3 threshold values.

This rulemaking will also change the compatibility categories of 10 CFR 31.5(a), 10 CFR 31.5(c)(13)(i), and 10 CFR 31.6 from B to C. Compatibility categories are established based on the Commission's Policy Statement on Adequacy and Compatibility of Agreement State Programs (62 FR 46517, September 3, 1997). This Policy Statement sets forth the approach that the Commission uses to classify program elements that should be adopted by an Agreement State to maintain an adequate and compatible program.

BACKGROUND:

On August 3, 2009, the NRC published a proposed rule, "Limiting the Quantity of Byproduct Material in a Generally Licensed Device" (74 FR 38372). The rule proposed to amend the NRC regulations to limit the quantity of certain 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 an SL. This proposed rulemaking was intended to improve the safety and security of devices currently authorized under a GL by requiring a subset of these devices to be specifically licensed.

Reports from a U.S. Senate subcommittee and from the U.S. Government Accountability Office have raised concerns regarding the safety and security of byproduct material covered by the NRC's GL regulatory program. 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 program by revising 10 CFR 31.5. The OAS and the State of Florida also requested changing the compatibility category of 10 CFR 31.6 from B to C so individual States would have flexibility to implement additional regulatory requirements to track and control generally licensed devices in their States.

NRC staff has analyzed the final rule in accordance with the procedures established within Part III of the Handbook to Management Directive 5.9 (MD 5.9), "Categorization Process for NRC Program Elements." MD 5.9 provides guidance on implementation of the Commission's Policy Statement on Adequacy and Compatibility of Agreement State Programs in assigning compatibility categories. Consistent with the policy statement, the NRC program elements are evaluated and placed into compatibility categories which determine the flexibility a State has in adopting a specific program element. Program elements are any component or function of a radiation control regulatory program, including regulations and other legally binding requirements that are imposed on regulated persons or entities.

Compatibility Category B requires the States to adopt essentially identical provisions to those in the NRC program element. Category B covers program elements that have direct and significant transboundary implications. Examples of Category B program elements include transportation packaging requirements, requirements for approval of products that are distributed nationwide and content and format of sealed source and device registration

certificates. Essentially identical NRC and Agreement State programs ensure consistency among multiple jurisdictions implementing these provisions.

In comparison, Compatibility Category C contains program elements whose essential objectives should be adopted by an Agreement State to avoid conflicts, duplications or gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. Agreement States implementing Category C program elements do not need to adopt program elements that are essentially identical to NRC's, as long as the State program elements achieve the intended objective of the NRC program elements. An Agreement State can have more stringent regulatory requirements for Category C program elements. Examples of Category C program elements include reports of lost or stolen material.

Based upon its review of the comments received on the proposed rule, the staff is proposing to adopt changes to 10 CFR 31.5 and change the compatibility category of 10 CFR 31.5(a), 10 CFR 31.5(c)(13)(i), and 31.6 from B to C. The staff proposes not to adopt the amendment to 10 CFR 31.5(b)(5) in the proposed rule that would have required specific licensees that possess generally licensed devices to add those devices to their SL.

DISCUSSION:

The comment period for the proposed rule ended on October 19, 2009, and 55 comment letters were received. Commenters on the proposed rule included Federal agencies, States, licensees, industry organizations, environmental advocacy groups, and individuals.

Comments addressed the following areas: (1) support for and opposition to the general provisions of the proposed rule; (2) alternatives to the proposed rule that would modify the existing GL regulatory program to achieve the regulatory objective of the proposed rule; (3) alternative threshold values; (4) proposed changes in compatibility categories from B to C, and discussion of any transboundary issues related to this approach; and (5) the proposed requirement to prohibit specific licensees from possessing a generally licensed device.

A discussion of each major comment area and the staff's responses are included in the draft *Federal Register* Notice (FRN) (Enclosure 1) and summarized here.

1) Support for and opposition to the general provisions of the proposed rule:

There were 20 commenters who supported establishing a threshold value of 1/10 of Category 3 for material in generally licensed devices. These 20 commenters included the OAS and also 9 individual Agreement States. About the same number of commenters did not support any threshold value for generally licensed devices; some of these commenters believe that the GL regulatory approach should remain as is, while others offered suggestions for modifying the GL regulatory program to achieve the objectives of the proposed rule.

The principal rationale provided by the commenters who supported the proposed rule was the increase in safety and security provided by the proposed rule, particularly the protection against aggregation of sources to quantities of concern. These commenters noted that regulatory change to limit the quantity of byproduct material in a generally licensed device is long overdue from a safety and security perspective and also that the rule would not impose a significant

burden to implement. Thus, these commenters stated that the 1/10 of Category 3 threshold is likely a reasonable compromise between the need for increased safety and security and the burden imposed by these requirements on affected licensees.

The principal rationale provided by the commenters who opposed this provision of the proposed rule was related to safety and security (including aggregation of sources) and also to the cost of complying with the amendments. Some of the commenters questioned whether the NRC has a technical basis or other facts to support the threshold value as necessary to safety and security. In particular, they argued that there is no credible risk of aggregating devices currently held under a GL that are used by industry for manufacturing process control applications, and that it is unrealistic to believe that these devices and their sources will be removed from their assemblies. They noted, for example, that these sources are important and vital to the operation of a manufacturing facility, are firmly mounted in process equipment, are surrounded by mechanical components moving at a high rate of speed with restricted access, and are within a security perimeter, which includes safeguards against entry by unauthorized people. These commenters are also concerned that implementation of the proposed rule would cause a significant cost increase because of the additional requirements associated with an SL, which include training, administration and annual fees, and hiring of a radiation safety officer. An industry trade group commented that small companies with a few customers spread across a large number of States will find it prohibitively expensive to conduct business in those States.

Staff's conclusion regarding comments on the general provisions of the proposed rule:

With respect to comments made regarding safety and security, staff believes that a principal rationale for setting a threshold at 1/10 of Category 3 is the need for increased security for these devices and the potential for aggregation of these sources to quantities of concern. As discussed in the Statement of Considerations for the proposed rule, the relatively few administrative or operational regulatory constraints on generally licensed devices raise a number of concerns about security vulnerabilities. Under the current GL regulatory program, a general licensee possessing a greater than 1/10 of Category 3 quantity of radioactive material is not subject to the same regulatory controls as specific licensees possessing similar quantities of radioactive material. Requiring an SL for higher activity generally licensed devices will provide an opportunity for a detailed review of the radioactive materials program proposed by an applicant, an opportunity for dialogue with the applicant, a regulatory decision as to whether to grant the license as requested or with modifications, and for more routine inspections and enhanced security requirements. Existing general licensees who become specific licensees would be tracked under NRC's Licensing Tracking System, and would no longer be under the General Licensing Tracking System.

The threshold value of 1/10 of Category 3 is based on the potential for aggregation to higher activity quantities of concern. Devices with Category 3 sources could be easily aggregated to Category 2 levels because they contain sources with activity levels that range from just below the Category 2 threshold to 1/10 of the Category 2 threshold (i.e., it would take only a few devices in the Category 3 range to aggregate to Category 2). Similarly, "high-end" Category 4 sources can be at levels just below the threshold of a Category 3 source (i.e., about 10–12 of these devices could be aggregated to create a Category 2 source). Many of the devices containing these Category 3 and high-end Category 4 sources are industrial gauges, which are widely used throughout the United States.

The staff agrees with the commenters that there are configurations at facilities in which the devices are mounted in such a manner that makes it hard for them to be removed or stolen. However, there are other facilities where it would be relatively easy for someone to remove or steal generally licensed devices. It is these other situations that need to be taken into consideration when thinking of aggregation by theft. These other scenarios could allow ample time for an individual to remove the device without detection. The staff believes that a 1/10 of Category 3 threshold is low enough to avoid aggregation by theft to a Category 2 level.

The costs incurred by some licensees who would need to obtain an SL have been estimated in the Regulatory Analysis (Enclosure 2). The staff continues to believe that the need for increased security for these devices and the potential for aggregation of these sources to quantities of concern justifies the regulatory resources and impacts on licensees that would result from implementing this rule.

2) Alternatives to the proposed rule that would modify the existing GL regulatory program to achieve the regulatory objective of the proposed rule:

As noted above, many of the comment letters stated that it is unnecessary to regulate current generally licensed devices under an SL if they are at or above the threshold level in the proposed rule. These commenters suggested alternatives to enhance the current GL regulatory program, including: (a) a combination of features, such as maintaining the existing GL framework while requiring additional hardening and design features in the devices to make it difficult to remove the sources from the devices; imposing new security requirements in the regulations and in the device registries that would apply to users of the devices; requiring inspections on a periodic basis by regulators of the generally licensed devices that meet or exceed 1/10 of Category 3 threshold values; and requiring device leak tests and shutter checks at 3 or 6 month intervals to improve source accountability; (b) strengthening the current GL regulations by adding an annual physical inventory requirement for all licensees who possess a generally licensed device under 10 CFR 31.5; a requirement for generation and retention of written records of the physical inventories for review during regulator inspections; and a requirement for general licensees to report their physical inventory results to the regulator; (c) amending 10 CFR 31.5(a) to exclude all portable devices, thereby requiring an SL for portable devices regardless of their activity level; and (d) offering manufacturers and distributors a Master Materials License or a single licensing mechanism that would be valid for work in different regulatory jurisdictions.

Staff's conclusion regarding alternatives:

This rule is intended to enhance the security of generally licensed devices with activity levels at or above the 1/10 of Category 3 threshold to improve the accountability and control of the sources and provide additional protection against aggregation of these sources to higher activity levels in quantities of concern. The staff considered alternatives that would not require generally licensed devices to be licensed under an SL.

One option would have revised 10 CFR 31.5 to add new requirements to improve the accountability and control of sources and to provide additional protection for generally licensed devices with sources at or above the threshold (e.g., by requiring additional hardening and design features). This alternative was not acceptable because, unlike the specific licensing

process, it would not include a pre-licensing process and opportunity to solicit additional information whereby the legitimacy of licensee operations could be verified, nor would it include periodic inspections by the regulatory authority, and physical inventory requirements. Although the staff agrees that such features may make it somewhat harder to remove a source from a device, there are scenarios, as discussed in Enclosure 1, whereby persons with malicious intent would have the ability to remove a source from a device without detection. In addition, it can be just as easy to remove and steal an entire device rather than to try to remove the source from the device, which would effectively negate any benefit of device hardening.

Another option would have amended 10 CFR 31.5 to exclude all portable devices, thereby requiring an SL for portable devices regardless of their radioactivity level. The staff determined that most generally licensed portable devices contain sources with activity levels below the 1/10 of Category 3 threshold. Therefore, the potential for aggregating enough generally licensed portable devices to a quantity of concern is very low. The staff also determined that this alternative would require general licensees who have portable devices that contain less than the threshold amount to incur costs associated with obtaining an SL and maintaining a specifically licensed radiation safety program with questionable reduction in preventing aggregation of sources to quantities of concern. The staff determined that the current proposed rule change that would require an SL for generally licensed devices that meet or exceed the 1/10 of Category 3 threshold is the preferred option.

In summary, the staff concluded that the GL framework, even with the suggested modifications, does not provide the level of safety and security needed to accomplish the objectives of the rule. In addition, the staff believes that if regulatory requirements similar to an SL are going to be applied then they should be implemented and enforced under the existing SL regulatory program and that a revised or more restrictive GL program would just create more confusion.

3) Alternative threshold values:

Commenters who supported the proposed rule suggested alternative threshold values for material in a generally licensed device. These alternatives included setting a threshold at IAEA Category 3, considering the aggregate level of byproduct material at a site, applying the threshold to the current activity level of the source instead of the licensed activity, and setting a threshold below 1/10 of Category 3, such as the registration levels in 10 CFR 31.5(c)(13)(i).

Staff's conclusion regarding alternative threshold values:

In general, the staff disagrees with the approaches suggested by these commenters. Based on the discussion above, the staff continues to believe that the 1/10 of Category 3 for a single device is the appropriate regulatory threshold below which GL requirements (with registration per 10 CFR 31.5(c)(13)(i)) would still apply. Using the aggregate activity of the sources over the whole site to determine whether the licensee exceeds the threshold would be more burdensome than necessary and thus is not included in the final rule. Also, the actual or current activity level in a device is not used to determine whether a device exceeds the threshold because the activity level is constantly changing due to radioactive decay. Using the current activity level to measure against the threshold would make it unnecessarily difficult to determine whether a device is subject to an SL or a GL. Thus, the threshold is more appropriately measured against the licensed authorized activity in a device. The NRC, in the

proposed rule, considered setting the threshold at a level that would include all devices with Category 4 and Category 5 sources. The NRC has concluded that these sources are so small that hundreds or thousands of devices would be required to aggregate sources to a quantity of concern and that this relatively low security concern 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.

4) Proposed changes in compatibility categories from B to C, and discussion of any transboundary issues related to this approach:

The NRC received 20 comments on the proposal to change the compatibility of 10 CFR 31.5(c)(13)(i) and 31.6 from B to C. The OAS and 13 individual Agreement States supported the proposal; 5 commenters (2 Agreement States and 3 companies that manufacture, distribute, and service generally licensed devices) opposed the proposal; and 1 Agreement State supported the change to 10 CFR 31.5(c)(13)(i) and opposed the change to 10 CFR 31.6.

The commenters who supported the change noted that the changes in the compatibility categories would allow States to continue to impose more rigorous requirements on their licensees. Many of these States commented that they would not support the proposed rule without an accompanying change in compatibility. Some of these States cited the petition for rulemaking from the OAS, dated June 27, 2005, to change the compatibility of 10 CFR 31.6 from Category B to Category C and the request from the State of Florida for a compatibility change for 10 CFR 31.5(c)(13)(i) from Category B to Category C, (70 FR 75423, December 20, 2005).

The commenters who opposed the proposed compatibility change noted that current regulations are very clear and that maintaining compatibility at Category B upholds a single national standard for generally licensed devices. These commenters noted that the change in compatibility would be an administrative nightmare that could result in different sets of rules and guidelines in every State, and would allow Agreement States to arbitrarily set limits on the activity allowed in generally licensed devices that are not based on the risk to public health and safety. Some commenters stated that a change in compatibility would have a significant adverse impact on companies that service generally licensed devices.

Some commenters suggested that the NRC amend 10 CFR 31.5 to remove portable gauges from the GL category and leave the compatibility category as B, which they believe would address the concerns of many States because a number of these States do not allow portable gauges to be held under a GL.

With regard to transboundary issues, several Agreement States indicated that there will be no significant transboundary issues in changing the compatibility category from B to C. Some of these commenters said that for many years, under the current GL regulatory framework, there have been no transboundary issues resulting from their State having more rigorous requirements than neighboring States for devices held under a GL. One State indicated that it has never authorized out-of-State generally licensed devices under reciprocal recognition, in accordance with their State regulations.

One commenter stated that transboundary issues will only occur if some States choose to specifically license portable devices at a threshold lower than that imposed by this rule. The commenter stated that there will be a significant effect on the transportation or movement of these devices into and out of States for devices that need to be converted from a GL to an SL because licensees will need to pay fees and could be subject to reciprocity inspections. Other commenters, primarily manufacturers and service providers, believe that there will be significant transboundary issues in changing compatibility from B to C and support the retention of Compatibility Category B.

Staff's conclusions regarding compatibility and transboundary issues:

The staff recognizes the desire on the part of the States to exercise greater control over the actions of their licensees and enhance regulation for higher activity generally licensed devices. The current compatibility designation for these sections is Category B and was set in the 2000 rulemaking; this designation was primarily based on transboundary implications. Despite this designation, many Agreement States have implemented enhanced regulation of generally licensed devices for many years. This enhanced regulation has included registration with annual reporting requirements and periodic inspection, expanded registration of more types of generally licensed devices, specific licensing of certain generally licensed devices, and specific licensing of all generally licensed devices currently registered by the NRC. Since the 2000 rulemaking, the NRC and Agreement States have increased their focus on security of radioactive materials and improved accountability of radioactive sources.

At this time, the staff has concluded that this proposed rule, combined with a Compatibility Category C designation for 10 CFR 31.5(a), 10 CFR 31.5(c)(13)(i), and 10 CFR 31.6, strikes an appropriate balance between transboundary issues, enhanced security for the higher activity devices currently available under a GL, and Agreement State flexibility under the 1997 Policy Statement to enhance accountability programs in their jurisdictions. The change in compatibility will allow States to retain use of tools to track the location and movement of device manufacturers and service providers within the State limits. Additionally, revising these compatibility categories provides Agreement States the flexibility to adopt additional requirements, based on their specific circumstances and needs.

With regard to whether there are significant transboundary issues associated with the change in compatibility, the staff believes that these issues are addressed by the use of reciprocity inherent with the SL. Reciprocity has worked well for decades and has allowed the transfer, distribution, and servicing of radioactive material devices without significant transboundary issues. As noted above, under the current system there is variability between NRC and Agreement State jurisdictions. Agreement State commenters indicated that the current regulatory system that applies to the distribution and servicing of generally licensed devices works well now and that there is little to no confusion when it comes to reciprocity. The staff is unaware of any significant transboundary issues with the current system. Although the proposed changes to 10 CFR 31.5(a), and the change in compatibility, may require a change in licensing process for some companies, such actions are not considered a significant transboundary issue since the system is already used effectively nationwide for existing specific licensees. Because there are no significant transboundary issues under the current system with Agreement States having varied requirements, the staff expects there will be no significant transboundary issues under the final rule.

Opposition to the proposed requirement to prohibit specific licensees from possessing a generally licensed device:

In the proposed rule FRN dated August 3, 2009 (74 FR 38372), NRC stated that it was considering an additional revision to 10 CFR 31.5 to clarify the applicable requirements when a device that is authorized to be used under the GL provisions in 10 CFR 31.5 is instead held by a specific licensee. All of the comments that addressed this issue opposed this proposal.

Staff's conclusion regarding the proposal to prohibit specific licensees from possessing a generally licensed device:

The staff agrees that the proposal to amend 10 CFR 31.5(b)(3) could cause confusion. The staff intended to preserve the flexibility that licensees currently have to decide whether to transfer generally licensed devices under the authority of an SL for a site, but to specify that if generally licensed devices were transferred to an SL then the terms and conditions of the SL would apply to the generally licensed devices. The staff does not recommend adopting proposed 31.5(b)(3). The staff agrees with the commenters that this change in the regulations would be too burdensome on numerous licensees with little or no improvement in the accountability of the sources in those generally licensed devices.

Non-Concurrence Process:

On April 21, 2010, during the office concurrence process for this final rule, a non-concurrence was provided by a member of the NRC staff. In response, in accordance with MD 10.158, a Non-Concurrence Process Form 757 has been completed and included with this Commission Paper (Enclosure 3). In Section C of Form 757, the staff has prepared responses to address the five reasons raised for the non-concurrence.

Based on Section C of Form 757, the staff continues to believe that the final rule should be provided to the Commission for review at this time and issued as a final rule.

Implementation Date of Final Rule:

The final rule contains an implementation date of 12 months after the effective date of the final rule. The staff concluded that this implementation date is appropriate because it provides time for an existing general licensee to decide to keep its current generally licensed device at or exceeding the threshold limit by obtaining an SL or to properly disposition the device through currently available options; it allows current users of sealed source manufacturing and distribution (M&D) licenses time to modify their processes to distribute certain current generally licensed devices only to specific licensees and to have their M&D SL amended accordingly; and it allows time for changes to sealed source and device (SS&D) registry certificates. New licensees will also be subject to these rules after the effective date.

Outcome of this Final Rule: Advancing NRC's Strategic Goals:

This final rule is consistent with NRC's strategic objectives and performance goals. The final rule would continue to ensure the protection of public health and safety and the environment, as well as ensuring the secure use and management of radioactive materials. While the final rule

would not change the physical protection requirements for sources, the changes are part of a comprehensive radioactive source control program. The proposed limit on radioactivity in generally licensed devices will provide greater source accountability and will enable NRC, through its inspection and licensing review programs for byproduct material licensees, to increase focus on those licensees that possess sources that can be aggregated to quantities of concern, thus making NRC actions more efficient and effective.

AGREEMENT STATE ISSUES:

A review copy of the draft final rule FRN was provided to the Agreement States on February 25, 2010.

Six Agreement States and the OAS provided comments on the draft FRN. Four of the Agreement States and the OAS restated comments they made during the public comment period regarding their support for the rule, specifically the threshold limits for a GL and the compatibility designation of the rule. One State restated its earlier comments opposing the content of the rule, and indicated that it was pleased that the NRC was deleting the proposal to prohibit specific licensees from possessing a generally licensed device. One State restated its earlier comments in support of the threshold and in opposition to the change in compatibility.

The Standing Committee on Compatibility is a joint NRC/Agreement State Working Group that independently evaluates and documents staff compatibility designations for new or revised regulations or other binding requirements to ensure consistency with MD 5.9. 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. Based on rulemaking procedures, the Standing Committee for Compatibility does not need to review the final rule since there are no changes in compatibility designations from the proposed rule.

COMMITMENT:

One volume of the NUREG-1556 series should be updated if this rule is made final. NUREG 1556, Vol. 16, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licenses," would require revisions or supplementation. The staff would update this guidance during the next overall revision of the document after the rule is made final. This action includes no other new commitments other than routine rule-related actions.

RECOMMENDATIONS:

The staff recommends that the Commission:

1. Approve for publication in the *Federal Register* the enclosed notice of final rulemaking (Enclosure 1).

2. Certify that this rule will not have significant impact on a substantial number of small entities, as required by the Regulatory Flexibility Act, 5 U.S.C. 605 (b). This certification is included in the enclosed FRN.
3. Note:
 - a) That the final amendment will be published in the *Federal Register*.
 - 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) A draft Final Regulatory Analysis has been prepared for this rulemaking (Enclosure 2).
 - d) The appropriate Congressional committees will be informed of this action.
 - e) A press release will be issued by the Office of Public Affairs when the final rulemaking is filed with the Office of the Federal Register; and
 - f) The final rule contains amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.) that must be submitted to the Office of Management and Budget (OMB) for its review and approval before publication of the final rule in the *Federal Register*.

RESOURCES:

To complete the rulemaking, 0.1 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 this 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 final rule is forwarded to the *Federal Register* for publication.

/RA by Michael F. Weber for/

R. W. Borchardt
Executive Director
for Operations

Enclosures:

1. *Federal Register* Notice
2. Regulatory Analysis
3. Form 757

NUCLEAR REGULATORY COMMISSION

10 CFR Part 31

RIN 3150-A133

[NRC-2008-0272]

Limiting the Quantity of Byproduct Material in a Generally Licensed Device

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending 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. This amendment will require individuals that possess devices containing quantities of byproduct material at or above these thresholds to apply for and obtain a specific license (SL). This amendment also modifies the compatibility category of the current regulations.

DATES: *Effective Date:* This final rule is effective on (**INSERT DATE THAT IS 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER**). *Implementation Date:* Compliance with the license application provisions in 10 CFR 31.5(a) is required by (**INSERT DATE THAT IS ONE YEAR AFTER THE EFFECTIVE DATE IN THE FEDERAL REGISTER**).

ADDRESSES: You can access publicly available documents related to this document using the following methods:

Federal Rulemaking Website: Go to <http://www.regulations.gov> and search for documents filed under Docket ID **NRC-2008-0272**. Address questions about NRC dockets to Carol Gallagher at 301-492-3668, e-mail: Carol.Gallagher@nrc.gov.

NRC's Public Document Room (PDR): The public may examine and have copied for a fee, publicly available documents at the NRC's PDR, Room O-1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852

NRC's Agencywide Document Access and Management System (ADAMS): Publicly available documents created or received at the NRC are available electronically at the NRC's Electronic Reading Room at: <http://www.nrc.gov/reading-rm/adams.html>. From this page, 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 NRC's PDR Reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to PDR.Resource@nrc.gov.

FOR FURTHER INFORMATION CONTACT: 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. Summary and Analysis of Public Comments on the Proposed Rule.
- III. Discussion of Final Amendments by Section.
- IV. Criminal Penalties.
- V. Agreement State Compatibility.
- VI. Voluntary Consensus Standards.
- VII. Environmental Impact: Categorical Exclusion.
- VIII. Paperwork Reduction Act Statement.
- IX. Regulatory Analysis.
- X. Regulatory Flexibility Certification.
- XI. Backfit Analysis.
- XII. Congressional Review Act.

I. Background

On August 3, 2009, the NRC published a proposed rule, "Limiting the Quantity of Byproduct Material in a Generally Licensed Device" (74 FR 38372). The rule proposed to amend the NRC regulations to limit the quantity of certain 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 an SL. This proposed rulemaking was intended to improve the safety and security of devices currently authorized under a general license (GL) by requiring a subset of these devices to be specifically licensed.

Reports from a U.S. Senate subcommittee and from the U.S. Government Accountability Office have raised concerns regarding the safety and security of byproduct material covered by the NRC's GL regulatory program. In addition, the Organization of Agreement States (OAS), on June 27, 2005, filed a petition for rulemaking (ADAMS Accession No. ML051940187) in which it requested that the NRC revise 10 CFR 31.5 and change the compatibility category of 10 CFR 31.6 from B to C. Also, in a June 3, 2005, petition for rulemaking (ADAMS Accession No. ML052700236), the State of Florida requested that the NRC change the compatibility category of 10 CFR 31.5(c)(13)(i) from B to C. These issues were docketed together by the NRC as PRM-31-5 (70 FR 75423; December 20, 2005).

The NRC has a process, consistent with the 1997 Policy Statement on Adequacy and Compatibility of Agreement State Programs (62 FR 46517, September 3, 1997), to assign compatibility categories to legally binding requirements. This process ensures orderly and consistent regulation of agreement material exists nationwide.

The comment period for the proposed rule ended October 19, 2009, and 55 comment letters were received. Those comments, the NRC responses, and the final revisions to the provisions contained in 10 CFR Part 31 are discussed in the Summary and Analysis of Public Comments on Proposed Rule section of this document.

Based upon its review of the comments received on the proposed rule, the NRC has decided to adopt the proposed changes to 10 CFR 31.5 and the proposed change to the compatibility category of 10 CFR 31.5(a), 10 CFR 31.5(c)(13)(i), and 10 CFR 31.6. The NRC has decided not to adopt the proposed amendment to 10 CFR 31.5(b)(5) that would have required specific licensees that possess generally licensed devices to add those devices to their SL.

II. Summary and Analysis of Public Comments on the Proposed Rule

The proposed rule, "Limiting the Quantity of Byproduct Material in a Generally Licensed Device," was published on August 3, 2009, for a 75-day public comment period (74 FR 38372). The NRC received 55 comment letters on the proposed rule. Commenters included States, licensees, industry organizations, environmental advocacy groups, and individuals. Comments and responses are grouped into the following subjects:

- A. Support for and opposition to general provisions of the proposed rule, specifically whether 1/10 of Category 3 is an appropriate regulatory threshold for material contained in a generally licensed device.
- B. Alternatives for modifying the existing GL regulatory program to achieve the regulatory objective of the proposed rule.
- C. Alternative threshold values.
- D. Proposed changes in compatibility categories from B to C, and discussion of any transboundary issues related to this approach.
- E. Proposed requirement to prohibit specific licensees from possessing a generally licensed device.
- F. Miscellaneous.

To the extent possible, the comments on a particular subject are grouped together. A discussion of the comments and the NRC staff's responses follow.

A. Support for and opposition to general provisions of the proposed rule, specifically whether 1/10 of Category 3 is an appropriate regulatory threshold for material that could be contained in a generally licensed device.

Comment A.1: Some commenters supported the proposed threshold value, 1/10 of IAEA Category 3, for material in generally licensed devices, whereas other commenters opposed the use of any threshold values.

Of the comment letters received on the proposed rule, 20 commenters supported establishing a threshold value of 1/10 of Category 3 for material in generally licensed devices. About the same number did not support any threshold value for generally licensed devices, indicating that the existing GL regulatory program should remain as is, or offering suggestions for modifying the existing GL regulatory program to achieve the objectives of the proposed rule (comments regarding modifying the existing GL regulatory program are discussed in Comment B.1). Other commenters who supported the proposed rule suggested an alternative threshold other than the 1/10 of Category 3 (comments regarding alternative threshold values are discussed in Comment C).

A discussion of the comment letters providing support for, and opposition to, the proposed threshold value are contained in the following subsections.

Support for establishing a threshold for generally licensed devices at 1/10 of Category 3:
Twenty commenters supported the 1/10 of Category 3 threshold values as an upper level for generally licensed devices. These 20 commenters included the OAS and 9 Agreement States. In addition, these 20 commenters included certain industry commenters expressing support for the rule. The principal rationale provided by commenters supporting the rule was the increase in safety and security provided by the 1/10 of Category 3 threshold, in particular the protection against aggregation of sources to quantities of concern. In addition, some of these

commenters, including the industry commenters, indicated that they did not believe that the additional regulatory burden associated with this final rule would be significant.

One commenter indicated that the regulatory change to limit the quantity of byproduct material in a generally licensed device is long overdue from a safety and security perspective. Another commenter indicated that it appreciates NRC's concern that terrorists might illegally acquire a number of low-activity sources and aggregate them to create a radiological dispersal device (RDD) or radiological exposure device (RED) and believes that 1/10 of Category 3 is the lowest value that NRC should consider as the threshold value below which GL requirements would still apply, and that this threshold value is likely a reasonable accommodation between the need to satisfy an increase in safety and security and the additional burden on affected licensees.

Other commenters indicated that they believed the NRC had articulated rational reasons in the proposed rule for requiring that certain industrial sources, which can pose a credible security risk, be licensed under an SL rather than a GL. One commenter also noted that certain existing general licensees already go beyond basic requirements of the GL provisions (e.g., by having a written sealed source device management program) and, hence, requiring those facilities to obtain an SL for certain devices will not be a burden.

One commenter strongly supported the rulemaking and noted that the rule would allow regulatory review prior to material purchase, improve facility/user awareness of regulatory requirements, and improve accountability of these devices. An Agreement State commented that they had the experience of having to retrieve generally licensed devices from the public domain and that promulgation of the proposed SL requirements would enhance accountability of these types of devices.

Most Agreement State commenters, including the OAS, stated that the rule would not impose significant undue burden or hardships to implement.

Opposition to establishing threshold values for generally licensed devices at 1/10

Category 3: About one-half of the commenters opposed the 1/10 of Category 3 threshold value. The commenters' principal rationale for opposing a threshold was related to safety and security and the cost of complying with the amendments. These commenters generally suggested alternative approaches to achieving the regulatory objectives of the proposed rule, in particular modifying the current GL regulatory program (see Comment B for comments on alternative approaches for modifying the current GL regulatory program and Comment C for comments on alternative threshold values).

- Safety and security, including aggregation of sources.

Some of the commenters questioned whether the NRC has a technical basis to support the need for a threshold value to reduce the risk to safety and security. The commenters questioned whether there was increased potential risk associated with the aggregation of sources in generally licensed devices.

One commenter disagreed with the principle of setting activity limits for generally licensed devices and stated that a limitation based on activity levels has no basis related to the safe operation of devices. Several commenters, including two Agreement States, opposed a threshold value because they believe the current GL regulatory program, including actions that can be taken by manufacturing and distribution specific licensees, has been effective in approving the use of safe devices and could be further improved by adding more inspection and audit activities to accomplish the security objectives of this rule. One commenter sees no benefit in the increased safety or reduction in the threat of a terrorist attack that this rule would produce. One commenter did not agree that obtaining an SL will provide additional protection against theft of devices because under a GL inspections and physical inventories and accounting can be undertaken. One commenter indicated that placing these generally licensed

devices under an SL would result in a net decrease in oversight. One commenter indicated that the rule should limit specific licensing to security matters.

With regard to the potential for aggregating sources to quantities of concern, several commenters argued that there is no credible risk of aggregating devices currently held under a GL that are used by industry for manufacturing process control applications, and that it is unrealistic to believe that these devices and their sources could be removed from their assembly and carted off from the plant. One commenter stated that these sources are important and vital to the operation of a manufacturing facility, are firmly mounted in process equipment, and are surrounded by conveyor belts or other mechanical components moving at a high rate of speed with restricted access. The commenter stated that the sources used for manufacturing are often in large, heavy devices that have built-in tamper resistant features that restrict access to the source. The commenter believes there is no practical way an individual or group could aggregate typical process instruments such as web/thickness gauges due to their cost and size. Another commenter stated that it uses sealed sources under a GL within facilities that have a security perimeter and safeguards against entry by unauthorized persons. Further, these sealed sources are often geographically dispersed in a manner that would defy the theft of multiple devices, and are also contained in heavy or bulky equipment which would make it very difficult to remove the device from the equipment. Another commenter said that a group could not aggregate typical process instruments because they would be collected as waste and hauled away by a licensed radioactive waste broker. An Agreement State raised a similar concern and argued that additional protection against aggregation appears to be unnecessary due to the low probability of occurrence and the high number of sources needed to equal a Category 2 quantity. This commenter stated that the loss or theft of this number of devices at one facility or in any given area would certainly result in numerous investigations

under current regulatory oversight. The commenter does not believe that an IAEA analysis exists that would support a feasible aggregation scenario at the 1/10 of Category 3 quantity.

One commenter argued that the NRC provided no technical basis for its risk assessment supporting the need to consider aggregation of low activity sources to a level of activity that is considered dangerous. This commenter questioned whether the NRC has any facts suggesting that there are security issues with the aggregation of generally licensed devices. The commenter says that an RDD has never been set off in the United States and there is no empirical data available for the effects of such an attack. The commenter believes that the NRC should publish a radiation dose risk threshold associated with the likely consequences of aggregating sources in devices currently licensed under a GL and used in an RDD. Another Agreement State commenter argued that the NRC needs to identify a threat basis upon which to make this kind of policy decision, and believes that work performed by the IAEA does not support such a threat basis for the aggregation of sources at the high end of 1/10 Category 3.

- Cost of compliance.

Many of the commenters opposing the proposed threshold value stated that implementation of the proposed rule would cause a significant cost increase in their operations, as they currently perform work under the GL program. These commenters stated that the new requirements would cause dramatic increases in their companies' operating costs to comply with the requirements of an SL which include training, administration, and annual fees. These commenters stated that the increased costs cannot be passed on to their customer base and would adversely affect their ability to compete in an already tight market. Two commenters stated that they use a single gauge in their company operations, and with the source in the gauge exceeding 1/10 of Category 3 they would be required, under the proposed rule, to obtain

an SL. Both of these companies said that the added costs to comply with the new requirements would eliminate any future profit margin, so these companies would be forced to remove the use of the gauge from their operations.

One company cited an example where they had lost an order to another company providing an alternative technology at a lower cost and claimed that this could become commonplace if the rule becomes effective. A comment from an Agreement State echoed the concern about the financial impact on companies currently using generally licensed devices. The commenter noted that market incentive will be lost to purchase products and services currently provided under a GL, and some companies may no longer be able or willing to compete if the companies must obtain and comply with the requirements of an SL. The commenter stated that the advantage of less bureaucracy in the use of a device held under a GL will be lost. This commenter suggested other “less obtrusive” ways to accomplish the objectives of this rulemaking (discussed more fully in Comment B). In addition, the commenter stated that the impact of the new requirements will go far beyond the simple issuance of an SL. The commenter also noted that there would be impacts on the Agreement States. The commenter believes that additional administrative and information technology requirements resulting from the rule may require reprioritization of existing functions, with increased staffing at the State level unlikely due to State budgetary shortfalls.

One commenter, representing an industry trade group for sealed source device distributors and manufacturers, commented that small companies with a few customers spread across a large number of States will find it prohibitively expensive to conduct business in those States. The commenter provided an example of a firm currently operating under a GL, visiting a customer site to perform a leak test twice a year. The proposed rule would cause a major administrative burden on this firm to secure licenses, pay State fees, and give adequate

notification to allow a State inspector to be present for the onsite inspection. The commenter stated that this increased regulation will lessen sales from sealed source manufacturers (and the users of sealed source devices will be less apt to purchase those devices) if they require a full-fledged radiation safety program, a radiation safety officer, and the higher fees associated with an SL compared to other devices that do not require an SL.

One commenter specifically objected to the NRC's calculation of the resource burden of implementing the proposed rule, arguing that the NRC's assumption that an increase in the number of SLs by approximately 6 percent is neither objectively justified as an assumption nor thoroughly considered regarding its impact. The commenter also stated that the NRC presented no basis for its conclusion or for the estimated benefit of implementing the proposed rule, which the commenter believes to be very small. Another commenter noted that converting to an SL would impose serious financial burdens on some generally licensed device users. The costs imposed by this rule would include hiring of a radiation safety officer, hiring and training radiation safety personnel (including authorized users), and providing additional routine training.

Another commenter took strong exception to the 1/10 of Category 3 threshold value and noted that using this threshold value would eliminate the GL program.

Acceptance of establishing a threshold, but only for new licensees. Some commenters indicated that, if a threshold is required, current holders of generally licensed devices with sources in excess of the threshold should not be required to obtain an SL (i.e., grandfathered from the requirement). In this manner, the rule would only apply to new applicants for obtaining material under a GL and not to persons holding existing GLs, because concerns about aggregation of sources by persons with malicious intent would not apply to existing legitimate licensees.

Response: With regard to comments about safety and security, a principal rationale provided in the proposed rule for setting a threshold for material at 1/10 of IAEA Category 3 is the need for increased security for these devices and the potential for aggregation of these sources to quantities of concern. The NRC continues to believe that increased regulation for security enhancements that will result from this rulemaking are warranted and provide sufficient justification for requiring an SL for devices that contain sources greater than 1/10 of Category 3.

The relatively few administrative or operational regulatory constraints imposed on generally licensed devices raise a number of concerns about security vulnerabilities and accountability. Under the current GL regulatory program, a general licensee possessing a greater than 1/10 of Category 3 quantity of radioactive material is not subject to the same regulatory controls as specific licensees possessing similar quantities of radioactive material. Requiring these higher-activity generally licensed devices to be specifically licensed will 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. Further, requiring an SL for some generally licensed devices will 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, a pre-licensing site visit and a regulatory decision as to whether to grant the license as requested, or if certain modifications are necessary. In particular, with regard to inspections, the rule would require regular inspections under an SL as a means of assessing measures to reduce the likelihood of intentional unauthorized access that could result in malevolent use of radioactive material. Generally licensed activities are not typically inspected unless the regulator becomes aware of an event involving generally licensed material or the general licensee is also a specific licensee, in which case generally licensed activities may be inspected in addition to specifically licensed

activities. With regard to physical inventories, 10 CFR 30.34(e) allows the Commission to incorporate, in any SL, additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of byproduct material as it deems appropriate or necessary in order to promote the common defense and security and protect health or to minimize danger to life or property. As standard practice for obtaining an SL, applicants are requested to provide a statement that they will conduct physical inventories of licensed material at a specified frequency or describe procedures to ensure that no licensed material has been lost, stolen, or misplaced. The NRC and Agreement States impose license conditions on all specific licensees whose licenses require an annual inventory of specifically licensed devices. For GLs, 10 CFR 31.5 does not require physical inventories of generally licensed devices, although 10 CFR 31.5(c)(15) requires, in part, that devices that are not in use are held for no longer than 2 years unless they are kept in standby for future use and the general licensee performs quarterly physical inventories of the devices while they are in standby. With regard to security, specific licensees are required to implement such provisions under 10 CFR 20.1801 and 20.1802; the new SLs that would be issued as a result of this rule would be subject to these security requirements. There is no requirement for general licensees to secure materials that are stored in controlled or unrestricted areas. In addition, there is no requirement for general licensees to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. Existing general licensees who become specific licensees would be tracked under NRC's Licensing Tracking System, although they would no longer be under the General Licensing Tracking System. The NRC believes that the existing SL regulatory program works well and that if regulatory requirements similar to an SL are going to be applied then they should be implemented and enforced under the SL regulatory program.

The NRC has no basis to assume that specific licensees who manufacture and distribute generally licensed devices can or would be likely to assume responsibility for the security provisions envisioned by this rule, i.e., that they will take those steps necessary to ensure that there will not be aggregation of devices by persons with malicious intent. Thus, it is not apparent how the current manufacturing and distribution (M&D) requirements in Part 32 can provide assurance that generally licensed devices will not be aggregated by persons with malicious intent.

The 1/10 Category 3 threshold value is based on the potential for aggregation to quantities of concern. Devices with Category 3 sources could be easily aggregated to Category 2 levels because they contain sources with activity levels that range from just below the Category 2 threshold to 1/10 of the Category 2 threshold (i.e., it would take only a few devices in the Category 3 range to aggregate to Category 2). Similarly, “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 (i.e., about 10-12 of these devices could be aggregated to create a Category 2 source). Many of the devices containing these Category 3 and high-end Category 4 sources are industrial gauges, which are widely used throughout the United States, and could be aggregated to Category 2 levels.

The adoption of 1/10 of Category 3 as the limit for generally licensed devices would make it more difficult to aggregate radioactive material to higher consequence Category 2 levels and NRC believes that this new limit will adequately address the concern that 1/10 of Category 3 sources could be aggregated to Category 2 levels. For devices above the proposed limit, licensees will be required to go through the specific licensing process, which will require the regulatory authority to use the appropriate tools (pre-licensing visits, increased controls,

interaction with the licensee prior to receiving the material) to determine if the licensee plans on using the licensed material as intended.

Aggregation of sources can occur when there is not a physical barrier that separates the sources. Barriers can be locked doors, robust chains and cables, securing mechanisms like welding the bolts in place, etc. The NRC agrees with the commenters that there are configurations at facilities in which the devices are mounted in a manner that make it difficult to steal or remove sources. Although this may be true for the commenters' facilities, it may not hold true for other facilities using the various types of generally licensed devices. These other situations which may be located in rural and secluded settings or have few workers in or around the devices, need to be taken into consideration when thinking of aggregation due to theft. These other scenarios could allow ample time for an individual to remove the device from the facility and the site without detection. In considering the issue of aggregation, this rule is intended to proactively require increased security and control measures to reduce the likelihood of intentional unauthorized access that could result in the theft of radioactive material that could be used in an RDD or RED.

Aggregation of sources can also occur through the purchase of the devices from one or multiple distributors. This rule change requires the licensee to apply for an SL in order to purchase sources that are greater than or equal to the 1/10 of Category 3 threshold. Applicants for an SL are subject to NRC's and Agreement States' pre-licensing process. The pre-licensing process provides assurance that the applicant will use the material as authorized on the SL.

With regard to comments made about the costs of the proposed rule, the cost incurred by some licensees who will need to obtain an SL has been calculated in the Regulatory Analysis. In response to some of the comments about the resources necessary to implement this rule, the NRC has updated the estimated costs used in the Regulatory Analysis. The NRC

agrees with the comment that the estimation of burden to the NRC and Agreement States is independent of the burden associated with providing regulatory oversight of other specific licensees. The estimated benefit of implementing the final rule has been discussed qualitatively in the Regulatory Analysis with respect to increased accountability of sources and improved security in using byproduct material. Costs are based on an assumption that a capable and responsible employee at the company currently operating under a GL would assume the responsibilities of the radiation safety officer and that this person would perform the necessary training of other personnel. The NRC does not believe it is reasonable for the company currently operating under a GL to hire a full time radiation safety officer to support the activities performed under the SL.

These new requirements will impose resource burdens on licensees and on the NRC and Agreement States. Licensees will be required to prepare license applications and amendments. The NRC and Agreement States will be required to review SL applications and amendments and to conduct inspections. As a result of this amendment, certain sealed source and device (SS&D) certificates will need to be amended on a one-time basis to accommodate the conversion of generally licensed devices to specifically licensed devices. In addition, about 10 percent of the 280 NRC licensees (i.e., about 30 licensees), who will need to apply for an SL under this final rule, currently possess aggregate quantities of certain isotopes that equal or exceed IAEA Category 2. Licensees in Agreement States who are affected by the final rule may possess similar quantities of these isotopes. Accordingly, some licensees may be affected by the Increased Controls and Increased Controls Fingerprinting orders. In 2005, the NRC issued Increased Control Orders (EA-05-090; November 14, 2005), (70 FR 72128; December 1, 2005), to about 2,200 licensees authorized to possess certain risk-significant quantities of radioactive material (Category 1 and Category 2 quantities). Under these Orders,

licensees are required to determine that each person who requires access to radioactive material quantities of concern to perform their job duties is sufficiently trustworthy and reliable. On December 5, 2007, the NRC issued orders to all other NRC licensees that possessed Category 1 or Category 2 quantities of radioactive material (EA-07-305) (72 FR 70901; December 13, 2007), to require fingerprinting and Federal Bureau of Investigation (FBI) criminal history records checks for unescorted access to Category 1 or Category 2 quantities of radioactive material. To effect nationwide implementation, each Agreement State issued legally binding requirements to licensees under their regulatory jurisdiction

To assist in offsetting the costs of obtaining the SL, the rule contains a delayed implementation of 1 year for obtaining the license. This provides existing licensees time to research and obtain alternative non-radioactive technologies and disposition their existing devices using currently available options if they do not wish to obtain an SL.

In the Regulatory Analysis for this rulemaking, NRC provides an analysis of 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 is contained in Section IX of this document.

As noted in Section I, the OAS submitted a petition requesting that NRC impose a threshold for generally licensed devices significantly below the threshold value adopted in this final rule. Those States who indicated that they agree with the OAS petition have already considered their internal resource needs and found the workload associated with lowering the GL limit to the registration level to be acceptable, so that setting the threshold at 1/10 of Category 3 would result in a lower burden. One Agreement State did not support the petition, because the State currently registers and tracks generally licensed devices to a very high standard.

In response to the commenters who suggested that the threshold in this rule only apply to applicants for new licenses (i.e., grandfathering), the NRC has prepared this rule to require increased security, accountability, and control measures to reduce the likelihood of intentional unauthorized access that could result in the theft of radioactive material that could be used in an RDD or RED. Since individuals within licensees' organizations change and new devices may be obtained, existing general licensees face the threat of malevolent use of licensed material by individuals new to their organizations (i.e., the insider) as well as individuals external to their organizations. Therefore, the NRC believes that the additional oversight and accountability provided by an SL should apply to both existing general licensees and new general licensees.

The NRC continues to believe that the need for increased security for these devices, and the potential for aggregation of these sources to quantities of concern, justifies the use of regulatory resources and impacts on licensees that would result from specifically licensing devices with sources at or above 1/10 of Category 3. Thus, the NRC continues to believe that sources in Category 3 and the upper range of Category 4 should not be contained in generally licensed devices and should be required to be specifically licensed.

B. Alternatives for modifying the existing GL regulatory program to achieve the regulatory objective of the proposed rule.

Comment B.1: Some commenters provided alternative approaches to setting a threshold value, in particular modifying the current GL regulatory program.

Many of the comment letters stated that it is unnecessary to regulate current generally licensed devices under an SL if they are above the threshold level in the proposed rule. These

commenters principally suggested enhancements to the current GL regulatory program.

Alternatives suggested by commenters included the following:

(1) Certain modifications including: (a) maintaining the existing GL regulatory program while requiring additional hardening and design features in the devices to make it difficult to remove the sources from the device; (b) writing new security requirements in the regulations and in the device registries that would apply to users of the device; (c) requiring regulators to conduct periodic inspections of the generally licensed devices that exceed 1/10 of Category 3 values; and (d) requiring device leak tests and shutter checks at 3 or 6 month intervals to improve source accountability.

(2) Strengthen the current GL regulations by adding: (a) an annual physical inventory requirement for all licensees who possess a generally licensed device under 10 CFR 31.5; (b) a requirement for generation and retention of written records of the physical inventories for review during regulator inspections; and (c) a requirement for general licensees to report their physical inventory results to the regulator.

(3) An alternative approach that would amend 10 CFR 31.5(a) to exclude all portable devices, thereby requiring an SL for portable devices regardless of their activity level. This position was supported by four Agreement States.

(4) A large company that manufactures, distributes, and services sealed source devices with customers in all 50 States suggested that the NRC should offer manufacturers and distributors an alternative in the form of a Master Materials License or a single licensing mechanism that would be valid for work in different regulatory jurisdictions.

(5) A company using more than 700 sealed source devices to monitor manufacturing processes at 30 of its facilities suggested that if the regulations are revised to require an SL for

some generally licensed devices, then all devices that contain sources using that same isotope should be required to be placed in the SL.

Response: The intent of this rule is 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 protection against aggregation of these sources by persons with malicious intent to higher activity levels in quantities of concern. The NRC considered alternatives that would not require general licensees possessing devices that exceed the threshold to obtain an SL.

One option was revising 10 CFR 31.5 to add new requirements for general licensees possessing devices with activity levels above the threshold to improve the accountability and control of sources and to provide protection against aggregation of sources to higher activity levels in quantities of concern. This was not considered to be acceptable because, unlike the specific licensing process, it would not include: (1) a pre-licensing process whereby the legitimacy of licensee operations would be verified; (2) the opportunity to solicit additional programmatic information to supplement the initial application; (3) rudimentary source security requirements; and (4) more comprehensive radiation safety training for employees.

Another option was maintaining the existing GL program while requiring additional hardening and design features in the devices to make it difficult to remove the sources from the devices. Although NRC agrees that such features may make it somewhat harder to remove a source from a device, there are many scenarios, as discussed in the response to Comment A.1, including remote site locations and secluded device locations, whereby people with malicious intent would have the ability and/or ample time to be able to remove a source from a device without detection. In addition, someone could simply steal an entire device instead of

removing the source from the device, which would negate any benefits provided by device hardening or other more robust design changes. Thus, NRC has determined that the rule, as proposed to require general licensees possessing devices with activity levels at or above the threshold to obtain an SL, is preferred over this alternative in that it provides increased accountability for devices with sources at or above the threshold values through such measures as pre-licensing visits and periodic inspections by the regulatory authority; trained individuals with an approved radiation safety program; better knowledge of authorized users (including personnel turnover) with access to devices; and physical inventory requirements. Also, such design changes or hardening of a generally licensed device would require a SS&D registry safety reevaluation on these devices, thus increasing the costs to the M&D and to the NRC and Agreement States.

Another option was amending 10 CFR 31.5 to exclude all portable devices, thereby requiring an SL for portable devices regardless of their radioactivity level. The NRC determined that most generally licensed portable devices contain less than the threshold amount. Therefore, the potential for aggregating enough generally licensed portable devices that contain less than the threshold amount to quantities of concern is very low. NRC also determined that this alternative approach would require general licensees who have portable devices that contain less than the threshold amount to incur costs associated with obtaining an SL and maintaining a specifically licensed radiation safety program. This proposal would impose high costs and provide only a limited security benefit because of the large number of devices that would have to be collected to aggregate to a quantity of concern.

Based on the discussion above, the NRC has concluded that these proposed alternatives do not address the security concerns that prompted this rulemaking. The adoption of this final rule does address these concerns because it will allow the NRC to: (1) implement a

pre-licensing process whereby the legitimacy of licensee operations would be verified; (2) solicit additional programmatic information, which supplements the initial application; (3) impose rudimentary source security requirements; and (4) require comprehensive radiation safety training for employees. In addition, as noted in the response to Comment A.1, the NRC believes that if regulatory requirements similar to an SL are going to be applied then they should be implemented and enforced under the existing SL regulatory program and that a revised or more restrictive GL program would just create more confusion.

C. Alternative threshold values.

Comment C.1: Commenters who supported the proposed rule suggested alternative threshold values for material in a generally licensed device. These alternatives included the following:

- a) Set a threshold at or above IAEA Category 3: One commenter stated that the threshold value should be set at one-half of IAEA Category 2. Another commenter argued that the proposed threshold values should be set at Category 3 instead of 1/10 of Category 3 because the IAEA defines Category 3 sources as those "...that, if not under control, could give rise to exposure sufficient to cause several deterministic effects." This commenter stated that the threshold value should apply to individual sealed source devices and to an aggregate of sealed source devices that in total exceed the Category 3 threshold value. An Agreement State supported the use of Category 3 as the threshold value to maintain consistency with the IAEA. Another Agreement State prefers that the threshold values not be set below Category 3 and that certain of the modifications to the existing GL regulatory program discussed in Comment B.1 be implemented.

- b) Set threshold at the aggregate level of byproduct material at a site: One commenter supported a Category 3 threshold value requiring an SL and stated that the Category 3 threshold is the radiation safety threshold of concern and that this threshold value should apply for the single radioactive sealed source as well as for the aggregate of sealed sources possessed by the licensee. The commenter believes that this approach is independent of the number or activity of individual sources and would implement accountability controls before aggregated sources reach the radiation safety threshold of concern. A similar comment was supplied by another commenter who indicated that if one source is higher than the threshold and would require an SL, then all sources using the same isotope be placed in the SL. One commenter believes that using the aggregate amount is effective because the aggregate is a known quantity that is independent of the number or activity level of individual sources.
- c) Set threshold at current activity level of source in a device: One commenter recommended that if a threshold value is used, the current activity level of the sources should be compared to the threshold value, instead of the activity level on the label of the device. Thus, determinations of the need for specific licensing of a device would be done based on a calculation of the current activity level of sources in the device, with the licensee responsible for the calculations of source radioactive decay. The commenter stated that the true measure of concern of a radioactive source is the current activity level.
- d) Set threshold value below 1/10 of Category 3, such as registration levels of 10 CFR 31.5(c)(13)(i): One commenter, from the Metals Industry Recycling Coalition (MIRC), supports a lower threshold value that would include Category 5 sources. This

commenter believes that sources at even these low activity levels pose a significant risk to the metals recycling industry. The commenter discussed incidents where scrap metal and the recycling facility were contaminated with radioactive material from an abandoned sealed source device, typically Cs-137 or Co-60, after the source was inadvertently melted and recycled in a batch of scrap metal. The commenter maintains that metals recycling companies are using sophisticated radiological detection devices to screen scrap shipments before they enter a facility, but even these advanced detection systems cannot be 100 percent effective in locating a single shielded source within a truckload or rail car of scrap. Two Agreement States believe that SLs should be required for some or all licensees with sources below the proposed 1/10 of Category 3 threshold. One State does not support a GL program at all and believes that all of the current generally licensed devices should be specifically licensed. The other State would prefer to see the activity limit for SLs set at the current registration limit established in 10 CFR 31.5(c)(13)(i) because the State believes that this would enhance source accountability, strengthen the protection of the public health and safety and the environment, and alleviate the confusion that currently exists with licensees. On the other hand, three commenters argued against consideration of a threshold value below 1/10 of Category 3, stating that this lower level would be an extraordinary burden on industry and is not supported by the IAEA. An Agreement State commenter stated that even as a worst case scenario, the NRC should not impose a threshold below 1/10 of Category 3.

Response: In general, the NRC disagrees with the approaches suggested by these commenters. Based on the response to Comment A.1, the NRC continues to believe that 1/10 of Category 3 is the appropriate regulatory threshold below which GL requirements (with registration per 10 CFR 31.5(c)(13)) would still apply. This threshold would apply to a single

source or a single device (with multiple sources) that exceeds the 1/10 of Category 3 threshold and would also apply to the activity on the date of manufacture for a single source or the total activity in a device with multiple sources. With regard to setting a threshold at one-half of Category 2, the Commission, in a Staff Requirements Memorandum (SRM-SECY-06-0094), dated June 9, 2006, approved plans by the NRC staff to amend GL requirements in 10 CFR 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. Nothing in the NRC's analysis since that time supports reconsideration of the decision not to set the limit at 1/2 of Category 2.

The rule does not apply to the aggregate of sources across the whole site. This is because by setting the threshold at 1/10 of Category 3 (rather than at Category 3 as suggested by this commenter), the NRC has provided sufficient margin regarding aggregation of sources across the whole site. Thus, having the rule apply to the aggregate of sources across the whole site would be more burdensome than necessary. Also, the actual or current source activity in a device is not used to determine whether it exceeds the threshold because the activity is constantly changing due to radioactive decay. Comparing the current activity to the threshold would make it unnecessarily difficult to determine whether a device is subject to an SL or a GL. Thus, the threshold is more appropriately measured against the licensed authorized activity in a device. NRC considered setting the threshold at the GL registration levels (about 1/1000 of Category 3), which would include all devices with Category 4 and Category 5 sources. In general, the sources in these devices are so small that hundreds or thousands of devices would be required to constitute a radioactive source in a quantity of concern. Because of the additional difficulty in acquiring enough of these devices to aggregate to quantities of concern,

the NRC concluded that the relatively low security concern 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.

D. Proposed changes in compatibility categories from B to C, and discussion of any transboundary issues related to this approach.

Adequacy and compatibility of Agreement State programs are addressed in multiple documents, including the “Statement of Principles and Policy for the Agreement State Program; Policy Statement on Adequacy and Compatibility of Agreement State Programs” (62 FR 46517, September 3, 1997) (Policy Statement); and NRC Management Directive 5.9, “Adequacy and Compatibility of Agreement State Programs” (February 27, 1998). The 1997 Policy Statement indicates that the overall level of protection of public health and safety provided by a State program should be equivalent to, or greater than, the level provided by the NRC program. The NRC designed a process to assign compatibility categories to legally binding requirements to ensure that an orderly pattern for the regulation of agreement material exists nationwide. The NRC believes this approach achieves a proper balance between the need for Agreement State flexibility and the need for coordinated and compatible regulation of agreement material across the country.

The NRC evaluates program elements and uses a range of compatibility categories to ensure that the NRC and Agreement State regulations and programs are compatible. Program elements are any components or functions of a radiation control regulatory program, including regulations and other legally binding requirements, that are imposed on regulated persons or entities.

NRC program elements in Compatibility Category A are those that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Category A program elements that are essentially identical to those of NRC to provide uniformity in the regulation of agreement material on a nationwide basis. NRC program elements in Compatibility Category B are program elements with significant direct transboundary implications, which include transportation packaging requirements, requirements for products that are distributed nationwide, and content and format of sealed source and device registration certificates. The Category B program elements adopted by an Agreement State should be essentially identical to those of NRC. NRC program elements in Compatibility Category C are program elements, the essential objectives of which should be adopted by an Agreement State to avoid conflicts, duplications or gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. Agreement states implementing Category C program elements do not need to adopt program elements that are identical to those adopted by the NRC, provided that the State program meets the essential objectives of the Compatibility Category C program elements. NRC program elements in Compatibility Category D are program elements that do not meet any of the criteria of Category A, B, or C; Agreement States do not need to adopt these program elements for purposes of compatibility. NRC program elements in Compatibility Category Health and Safety are program elements that are not required for compatibility but have been identified as having a particular health and safety role (adequacy) in the regulation of agreement material within the State. An Agreement State should adopt program elements that embody the essential objectives of the NRC program elements because of particular health and safety considerations. NRC program elements that are classified as Areas of Exclusive NRC Regulatory Authority are elements that cannot be

relinquished to Agreement States pursuant to Section 274 of the Atomic Energy Act. For example, NRC regulatory requirements for nuclear power reactors are classified as Compatibility Category NRC. These program elements should not be adopted by Agreement States.

Comment D.1: Support for and opposition to changing compatibility from B to C, including discussion of transboundary issues

The NRC received 20 comments on the proposal to change the compatibility of 10 CFR 31.5(c)(13)(i) and 10 CFR 31.6 from B to C. The OAS and 13 individual Agreement States supported the proposal; 5 commenters (2 Agreement States and 3 companies that manufacture, distribute, and service generally licensed devices) opposed the proposal; and one Agreement State supported the change to 10 CFR 31.5(c)(13)(i) and opposed the change to 10 CFR 31.6.

Support for changing compatibility from B to C: Some Agreement States noted that they have more rigorous requirements than those in 10 CFR Part 31 and argued that the change in the compatibility category of these regulations would allow them to continue to impose more rigorous requirements on their licensees, which many of them have been doing for years. Many of these States commented that they would not support the changes in the proposed rule without the change in compatibility. Some of these States also cited the petition from the OAS, dated June 27, 2005, to change the compatibility of 10 CFR 31.6 from Category B to Category C and the petition from the State of Florida for a compatibility change for 10 CFR 31.5(c)(13)(i) (70 FR 75423; December 20, 2005). Several States argued that the change in compatibility is necessary to provide the flexibility needed to manage their GL program to address health and safety issues and to track the movement of service providers in their State. Other States

argued that the change is necessary to ensure that their existing programs will not be weakened and to allow those programs to continue under their established regulatory program, which includes registration requirements with the flexibility to adapt to new circumstances and any new devices. Several States said that the change in compatibility would allow them to require an SL for all portable devices, or for devices that are part of a mobile system, which they believe would improve security and accountability of sources with isotopes other than those listed in this rule.

Some of these commenters argued that there will be no significant transboundary issues in changing the compatibility category from B to C. Some of these commenters noted that there are currently regulations that are below the threshold limits and that there have been no transboundary issues resulting from States having more rigorous requirements than neighboring States for generally licensed devices. Some commenters noted that there is currently little or no confusion regarding reciprocity.

Opposition to changing compatibility from B to C: A few Agreement States and several companies that manufacture, distribute, and/or service generally licensed devices submitted comments opposing the proposed compatibility change. One company argued that the change in compatibility category for 10 CFR 31.6 from B to C is an administrative nightmare that could result in different sets of rules and guidelines in every State.

Another large company opposes the change because maintaining compatibility at Category B upholds a single national standard for generally licensed devices, and if the NRC identifies problems with this "national standard" then the specific requirements in 10 CFR 31.5(a) and 31.6 should be amended. This commenter believes changing these regulations to Category C would be a step backward and would allow Agreement States to arbitrarily set limits on the activity of generally licensed devices that are not based on the risk to public health and

safety. The commenter is concerned that this would contradict the trend towards a more risk-informed regulatory structure. The commenter also stated that the current regulations are very clear and easy for device manufacturers and distributors to understand, and that a change in compatibility would create confusion because the rules would be different from State to State. The commenter quoted a final rule published by the NRC on December 18, 2000, to support its objection to the change in compatibility: "The Commission's decision not to exercise its authority to license the transfer of products containing atomic energy materials (other than products designed for distribution to the general public) is based on the assumption that Agreement States will maintain continuing compatibility between their programs and Commission programs; and that procedures will be devised assuring reasonable, reciprocal recognition of licenses and licensing requirements among such States and the Commission," (65 FR 79180, December 18, 2000); and "The Commission agrees that there are significant transboundary implications of these regulations. The compatibility requirements for §§ 31.5 and 31.6 are being made a Category B. After the Agreement States make the required changes to their regulations (in about 3 years), the distributors' and other servicers' problems with reciprocity for servicing will be eliminated," (65 FR 79179, December 18, 2000).

Several commenters stated that a change in compatibility would have a significant adverse impact on companies that service generally licensed devices. These commenters said that under current regulations an authorized service provider can immediately perform service on generally licensed devices, without filing a request for reciprocity and providing a 3 business-day advance notice prior to performing work. The commenters stated that a delay in obtaining reciprocal recognition can often delay service by as many as 5 days, which could cost a firm millions of dollars in lost production. The commenters said that most States immediately grant reciprocity in emergencies, but that not all States consider a

reduction in plant output an emergency.

Another large company opposes the change in compatibility in 10 CFR 31.6 because the commenter believes that the change will be overly burdensome and financially detrimental to both manufacturers and licensees, and will not increase security, safety, or accountability. This commenter stated that the current Compatibility Category B is needed to ensure that manufacturers and service providers can operate under one set of regulations that are concise and easy to understand. The commenter further argued that a change to Category C would result in a significantly more confusing situation, more difficult compliance, and a continuous flow of amendments that could have significant transboundary implications. The commenter stated that with the additional amendments, fees can be significant and the cost in labor hours to track regulatory changes, maintain authorization, and document the varied regulatory requirements will be very large, with the costs passed on to other customers.

An Agreement State objected to the change in compatibility, and suggested a change to 10 CFR 31.5. The commenter suggested that the NRC amend 10 CFR 31.5 to remove portable gauges from the generally licensed device category and leave the compatibility category as B. The commenter believes that this would address the concerns of many States because a number of these States do not allow portable gauges to be held under a GL. The commenter contends that making this change and leaving the compatibility category as B would ensure the existence of a nationwide standard and would also address most of the States' concerns. The commenter believes a change to Compatibility Category C would result in inconsistent standards from State to State, which would make it very difficult for licensees operating in multiple jurisdictions to comply with a specific State's regulations. Further, the commenter opposes changing the compatibility designation for 10 CFR 31.6 because if the manufacturer passes the additional cost for reciprocity or licensing to the general licensee,

there could be a financial incentive for noncompliance (including a greater temptation to improperly dispose of the unwanted devices).

Many of these commenters, primarily manufacturers and service providers, believe that there will be significant transboundary issues if the compatibility of these regulations is changed from B to C. One commenter stated that transboundary issues will only occur if some States chose to specifically license portable devices at a threshold lower than that imposed by this rule. The commenter believes that there will be a significant effect on the transportation or movement of these devices into and out of States for devices that need to be converted from a GL to an SL because licensees will need to pay fees and could be subject to reciprocity inspections.

Response: In determining the appropriate compatibility designation of 10 CFR 31.5(c)(13)(i) and 31.6, the NRC has considered the desire of generally licensed device manufacturers and service providers for consistent regulatory requirements across jurisdictional boundaries, as well as the desire on the part of the Agreement States to exercise greater control over the actions of their licensees and enhance regulation for higher activity generally licensed devices.

The current compatibility designation for these sections is B and was set in the 2000 rulemaking; this designation was primarily based on transboundary implications. Despite this designation, many Agreement States have implemented enhanced regulation of generally licensed devices for many years. This enhanced regulation has included registration with annual reporting requirements and periodic inspection, expanded registration of more types of generally licensed devices, specific licensing of certain generally licensed devices, and specific licensing of all generally licensed devices currently registered by the NRC. Since the 2000 rulemaking, the NRC and Agreement States have increased their focus on security of

radioactive materials and improved accountability of radioactive sources. This rulemaking seeks to balance transboundary issues, enhanced security for the higher activity devices currently available under a GL, improved accountability, and Agreement State flexibility to enhance accountability programs in their jurisdictions.

At this time, the NRC has concluded that this rule, combined with a Compatibility Category C designation for 10 CFR 31.5(a), (c)(13)(i), and 31.6, strikes the proper balance. Security will be enhanced by requiring regulatory review prior to purchase of the devices and conducting initial and periodic inspections. Accountability will be improved due to the staff training, designation of a radiation safety officer, and source inventory inherent with an SL.

Consistent with the 1997 Policy Statement, a Compatibility Category C designation will allow Agreement States the flexibility to further enhance accountability, address issues specific to their jurisdictions, continue programs that have proven beneficial, and to adopt additional requirements, based on their specific circumstances and needs. The Policy Statement indicates that “The Commission will minimize the number of NRC regulatory requirements that the Agreement States will be requested to adopt in an identical manner to maintain compatibility,” (62 FR 46525, September 3, 1997). The Policy Statement further states that Agreement States should be provided with flexibility in program implementation to accommodate individual State preferences, State legislative direction, and local needs and conditions. In particular, the Policy Statement comments that an Agreement State would have flexibility “to design its own program, including incorporating more stringent, or similar, requirements provided that the requirements for adequacy are still met and compatibility is maintained, and the more stringent requirements do not preclude or effectively preclude a practice in the national interest without an adequate public health and safety or environmental basis related to radiation protection,” (62 FR 46520, September 3, 1997). The change in

compatibility will also allow States to retain use of tools to track the location and movement of device manufacturers and service providers within the State limits.

With regard to whether there are significant transboundary issues associated with the change in compatibility, the NRC believes that these issues are addressed by the use of reciprocity, inherent with the SL. Reciprocity (i.e., reciprocal recognition of a radioactive materials license issued by another regulatory jurisdiction) has worked well for decades and has allowed the transfer, distribution, and servicing of radioactive material devices with no significant transboundary issues. As noted earlier in this response, under the current system there is variability between NRC and some Agreement State jurisdictions. NRC currently registers a limited subset of generally licensed devices, whereas some Agreement States are more stringent in their regulation of generally licensed devices. One Agreement State commenter indicated that the current regulatory system that applies to the distribution and servicing of generally licensed devices works well now and the OAS noted that there is little to no confusion when it comes to reciprocity. NRC is unaware of any significant transboundary issues with the current system. Although the proposed changes to 10 CFR 31.5(a), and the change in compatibility, may require a change in licensing process for some companies (including any reciprocity changes and fee payments), such actions are not considered a significant transboundary issue since the system is already used effectively nationwide for existing specific licensees. Since there are no significant transboundary issues under the current system of States having varied requirements, the NRC expects there will be no significant transboundary issues under the final rule.

Comment D.2: Another commenter stated that the NRC should be moving toward greater compatibility in the regulations between States and the Federal government, not toward

reduced compatibility. This commenter suggested that the compatibility for 10 CFR 31.6 should be revised from Category B to Category A instead of from B to C.

Response: As detailed in NRC Management Directive 5.9, “Adequacy and Compatibility of Agreement State Programs” (February 27, 1998), NRC program elements in Category A are those that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. Because this rule does not involve such program elements, Compatibility Category A is not appropriate for 10 CFR 31.6. The NRC has concluded that the proposed rule action to require specific licensing for certain higher activity devices currently available under a GL, combined with a Compatibility Category C designation for 10 CFR 31.5(a) and 31.6, results in an appropriate balance of security, accountability, and State flexibility. Security will be enhanced by requiring regulatory review prior to purchase of the devices and conducting initial and periodic inspections. Accountability will be improved through enhanced licensee staff training, designation of a radiation safety officer, and source inventory requirements inherent with an SL. The Compatibility Category C designation will allow Agreement States the flexibility to further enhance accountability, address issues specific to their jurisdictions, and continue their existing programs.

Comment D.3: Potential for abuse in the fee structure among States

A sealed source and device manufacturer asked that the NRC implement a policy to limit the specific licensing fees charged by the States for the possession of a previously generally licensed device, stating that there is a very strong potential for abuse by States in their establishment of State-specific licensing fees.

Response: Agreement States establish their own fees in accordance with their State laws. The NRC has no authority over Agreement State fees just as the Agreement States have no authority over NRC fees. It is worth noting that Agreement State radioactive material licensing fees are generally lower, some times significantly lower, than equivalent fees imposed by the NRC.

E. Proposed requirement to prohibit specific licensees from possessing a generally licensed device.

Comment E.1: General opposition to the proposal to prohibit specific licensees from possessing a generally licensed device

The NRC received no comments in support of the proposal to prohibit specific licensees from possessing a generally licensed device. Numerous comments opposed this proposal.

One commenter opposed this proposal because current regulations already include incentives for licensees to transfer their generally licensed devices to an SL. The transfer process takes significant time and effort by both the licensee and the regulator and can make the SL cumbersome to maintain and enforce due to the large number of low-activity sealed sources.

Several commenters believe the proposal would be unfair to specific licensees because it is likely that companies that possess generally licensed devices and do not have an SL would continue operations under the GL, while companies with both generally licensed devices and an SL would be required to move their generally licensed devices to their SL. This would impose more stringent regulations on specific licensees solely because of the requirements inherent with an SL.

Comments from universities and research and development (R&D) specific licensees argued that the proposal would place a substantial burden on them, requiring the revision of device authorizations by the responsible Radiation Safety Committee for a very large number of generally licensed devices subject to 10 CFR 31.5 (including electron capture detectors containing small quantities of Ni-63 or H-3, calibration standards using Cs-137, Eu-152 or Ba133 in liquid scintillation counters, static eliminators containing Po-210, aerosol neutralizers containing Kr-85, XRF analyzers containing Am-241, Fe-55 or Cd-109, gas chromatographs containing Ni-63, blot analyzers containing Fe-55, and exit signs containing H-3). The commenters noted that placing these generally licensed devices under the authority of an SL would require the users of those devices to have a minimum amount of documented training and experience, and could require personnel radiation monitoring because some specific licensees require dosimetry for all users. The commenters also argued that the users of these generally licensed devices are students and researchers who continuously change; these new requirements would require additional training and documentation that is not necessary under the current GL program. The commenters believe there would be no reduction in the hazard to workers or students due to the transfer of these devices to the broad-scope SL.

Several Agreement States, research organizations, and large corporations supported the existing regulations, which allow licensees the flexibility to decide whether they want to add generally licensed devices to their SLs. One commenter noted the value of maintaining sealed source devices under a GL; the commenter has manufacturing sites across the country and keeps generally licensed devices at one site to serve as back-up instrumentation for the on-line monitoring equipment at its smaller basic manufacturing sites. When on-line monitoring is unavailable at one of the smaller sites, a back-up device is transferred through the device manufacturer to the manufacturing site for temporary use until the on-line monitors are

repaired. This temporary switch-out is rare, and the commenter argues that it would not be feasible to amend an SL fast enough to keep the plant open. A number of universities stated that they would prefer to keep the numerous generally licensed devices used in health care and research environments under the requirements of a GL.

Other comments misinterpreted the proposal. These commenters read the proposed rule as prohibiting a specific licensee from possessing any generally licensed devices at a site for which an SL is authorized. One commenter provided clarifying language for 31.5(b)(3) if the NRC decided to proceed with including this requirement in the final rule.

Response: The NRC had intended to preserve the flexibility that licensees currently have to decide whether to transfer generally licensed devices under the authority of an SL for a site, and to specify that if generally licensed devices were transferred for use under an SL, or if devices approved for use under the GL were obtained as specifically licensed devices, then the terms and conditions of the SL apply to the generally licensed devices. After reviewing the comments, the NRC does not believe that the proposed rule would have accomplished this objective. Accordingly, the NRC is not adopting the proposal to amend 10 CFR 31.5(b)(3). The NRC agrees that the language published in 10 CFR 31.5(b)(3) of the proposed rule may cause confusion. The NRC also agrees with commenters that this change in the regulations would be too burdensome, with little or no improvement in the accountability of the generally licensed sources.

F. Miscellaneous.

Comment F.1: Changes in the sealed source and device registry process

Several commenters identified duplicative designations on the sealed source and device registry that cause problems with tracking generally licensed devices that have been transferred from one licensee to another. One Agreement State indicated that, in their State, multiple sealed source devices are listed as B for both GL and SL on the certificate, which allows the regulatory authority to choose how to license the device. The commenter said that the sealed source device certificate should only be allowed to indicate GL or SL, not both, and the regulatory authorities should abide by that single designation. A second Agreement State also favored allowing only a single designation on the sealed source and device registry. Another Agreement State took a different approach, and argued that the registration certificates should be required to address transfers to both general and specific licensees. One Agreement State indicated that the rule would have the effect of eliminating SS&Ds.

Several Agreement States said that the conversion of currently generally licensed devices to an SL will require all of the product registrations (falling into 1/10 IAEA Category 3 and above) to be amended to change the GL designation and to include security provisions before the licensing process begins. In several Agreement States, the product registries are legally binding documents because they are included in the license. Complete and up-to-date sealed source and device registration certificates are invaluable to the State regulators. Reference to the general requirements for transfer by device category is desirable information on the registry.

Response: Based on the comments received, the NRC agrees that the Sealed Source and Device Registry (SSDR) will need to be changed to reflect those devices that are not authorized to be distributed under 10 CFR 31.5(a). The process and details of how this occurs will be determined by each SSDR issuing agency (Agreement State or NRC) and a consistent format will be used on Page 1 of the SSDR certificate. Since a safety evaluation has already been performed and a determination made that the device may be distributed under the GL dose constraints, any subsequent review will be administrative in nature and will not affect the existing safety evaluation. The NRC recognizes that there may be costs incurred by the SSDR holder, Agreement States, and NRC for these changes. The majority of these costs will be incurred by the issuing agency in making the changes to the SSDR. The NRC believes changes in the SSDR are needed to properly identify the device distribution authorizations under 10 CFR 31.5(a) and recommends that the issuing agency take an active role in identifying the SSDRs that will need to be changed. Since the current rules (10 CFR 32.51) require existing generally licensed devices to be transferred to an SL, the NRC does not recommend that existing devices be re-labeled. This recommendation also applies to devices in existence under an inactive SSDR. The NRC will require new devices to contain new labels and suggests that existing devices that are transferred through an M&D be re-labeled accordingly. Consistent with GL holders having 1 year to obtain an SL, M&Ds also have 1 year to amend the applicable SSDRs to comply with 31.5(a). The affected licensees will be notified through a letter or information notice. The NRC encourages all existing GL registrants that possess devices that exceed the limits in 31.5(a) start the process to obtain an SL as soon as possible to ensure that the process is completed by the compliance date.

Comment F.2: Possible vulnerability of not including isotopes of interest in a revised section for registration under 10 CFR 31.5(c)(13)(i)

One Agreement State comment noted that the proposed rule lists numerous nuclides, including Ac-227, Gd-153, Ir-192, Po-210, Pm-147, Se-75, Tm-170, and Yb-169, that are not listed in 10 CFR 31.5(c)(13)(i). The commenter believes that if these nuclides are on a list of nuclides that present safety concerns, then they should have GL registration limits. The commenter questioned whether there is a possible vulnerability in omitting those nuclides from the registration requirement.

Response: The NRC did review the registration criteria for possible additions and did not identify any radionuclides for which a registration criterion needs to be added. Th-229 and Th-228 are source materials, which are regulated under 10 CFR Part 40 and thus not covered by the GL in 10 CFR 31.5. Some of the radionuclides listed in Appendix E of Part 20 are not used in any current device authorized for use under 10 CFR 31.5 or are used only in small quantities. For practical reasons, relatively long lived radionuclides are used in devices covered by 10 CFR 31.5. Shorter lived radionuclides are not appropriate for use in the registration process, which involves annually accounting for devices. Also, one of the purposes of the registration process is to reduce the probability of devices getting melted in smelters and causing major decontamination costs, which is less likely to occur with short-lived materials.

The NRC believes that it would be misleading to add registration criteria for quantities significantly higher than what actually exists in any generally licensed device, as it would imply that there is such material covered by the provision.

The NRC believes that it would be misleading to add registration criteria for quantities significantly higher than what actually exists in any generally licensed device, as it would imply that there is such material covered by the provision.

Comment F.3: Licensing thresholds for sources not included in the IAEA categorization scheme, but allowed in generally licensed devices

One Agreement State suggested that the NRC identify SL thresholds for devices that contain sources that are not included in the IAEA source categorization scheme, but that are currently approved for distribution under a GL.

Response: The NRC considered whether there are radionuclides used in quantities that would meet the 1/10 Category 3 threshold value but are not listed in Appendix E to Part 20. No generally licensed devices at such levels have been authorized. Therefore, the NRC does not believe it appropriate to include threshold levels for these additional radionuclides.

Comment F.4: Establish provisions other than by rulemaking

One commenter suggested setting site-specific requirements, for example through use of Orders instead of conducting a rulemaking to set requirements.

Response: Based on the response to Comment A.1, the NRC believes that the requirements established by this action are applicable to licensees as a class and therefore is conducting this rulemaking to establish these requirements. Furthermore, it is NRC's preferred policy to establish general requirements through notice-and-comment rulemaking, rather than by continuing use of Orders.

Comment F.5: Hold public meetings to discuss issues and provisions of the proposed rule

One commenter suggested that NRC hold a series of public meetings to discuss the need for the changes and to fully evaluate the impact of the proposed changes.

Response: The NRC determines if there is a need for public involvement, including public meeting, beyond the normal public comment period on a technical basis or proposed rule. The objective of such a meeting would be to obtain additional stakeholder input to ensure that an adequate range of stakeholder input is received and available to staff to evaluate rule options and potential impacts. On this particular rulemaking the NRC issued the proposed rule and regulatory analysis for public comment, which included seeking public comment on specific topics. NRC received over 50 comment letters on the proposed rule expressing a range of well articulated views on both sides of various issues, including whether a threshold value should be implemented for general licensees, alternative approaches for modifying the current GL regulatory system for addressing the issue raised by this rulemaking, alternative threshold values, compatibility issues and transboundary issues, as well as other matters. As a result, the NRC believes it has successfully identified issues associated with the rule and has adequate information from the various stakeholders and the public to proceed with issuance of the final rule without holding a public meeting.

Comment F.6: Rule does not improve the GL registration program

One commenter indicated that the rule only addresses a limited number of generally licensed devices, requiring them to become specifically licensed, and does not improve the GL registration program which it was intended to do.

Response: The scope of this rulemaking has been, from the outset, to address security and accountability concerns associated with certain generally licensed devices and not as a general amendment to the GL registration system.

Comment F.7: Other actions that should be taken

One commenter stated that licenses should not be renewed for licensees that have violated substantive parts of regulations or with more than two violations. Another commenter stated that there should be no more nuclear weapons or nuclear power plants.

Response: Both of these comments are outside the scope of this rulemaking, which is to establish specific requirements for certain generally licensed devices to improve their security and accountability.

III. Discussion of Final Amendments by Section

A. Changes to the Regulations

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

This rulemaking amends 10 CFR 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 for the isotopes listed in Appendix E to 10 CFR Part 20. Licensees who possess devices containing byproduct material meeting or exceeding these thresholds are required to become specifically licensed,

and are subject to all applicable regulations. Devices containing byproduct material below these thresholds continue to be generally licensed.

The values corresponding to Category 3 and 1/10 of Category 3 (or 1/100 of Category 2) are found in Appendix E to 10 CFR Part 20 for byproduct material radionuclides, which is included below.

The Terabecquerel (TBq) values listed in Appendix E are the regulatory standard. The Curie (Ci) values are provided for reference only and rounded after conversion. The Curie values are not intended to be the regulatory standard.

Radioactive Material	Category 3 (TBq)	Category 3 (Ci)	1/10 Category 3 (TBq)	1/10 Category 3 (Ci)
Actinium-227	0.02	0.54	0.002	0.054
Americium-241	0.06	1.6	0.006	0.16
Americium-241/Be	0.06	1.6	0.006	0.16
Californium-252	0.02	0.54	0.002	0.054
Cobalt-60	0.03	0.81	0.003	0.081
Curium-244	0.05	1.4	0.005	0.14
Cesium-137	0.1	2.7	0.01	0.27
Gadolinium-153	1	27	0.1	2.7
Iridium-192	0.08	2.2	0.008	0.22
Plutonium-238	N/A	N/A	N/A	N/A
Plutonium-239/Be	N/A	N/A	N/A	N/A
Polonium-210	0.06	1.6	0.006	0.16
Promethium-147	40	1100	4	110
Radium-226	0.04	1.1	0.004	0.11
Selenium-75	0.2	5.4	0.02	0.54
Strontium-90	1.0	27	0.1	2.7
Thorium-228	N/A	N/A	N/A	N/A
Thorium-229	N/A	N/A	N/A	N/A
Thulium-170	20	540	2	54
Ytterbium-169	0.3	8.1	0.03	0.81

Note: N/A means “not applicable” because Plutonium-238 and Plutonium-239/Be are not byproduct material but are special nuclear material. Thorium-228 and Thorium-229 are source material.

B. The Effective Date and Implementation of the Final Rule

The effective date of this final rule is 60 days after publication of the final rule in the *Federal Register*. This final rule requires an SL for each device containing byproduct material meeting or exceeding 1/10 of the IAEA Category 3 thresholds as listed in Appendix E to 10 CFR Part 20.

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

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

C. Authority for This Rule

With respect to whether the following regulations are being issued under “public health and safety” or “common defense and security,” it should be recognized that almost all

regulations relating to the security of byproduct materials serve both purposes to some degree. For example, the pre-licensing process ensures that a licensee has an appropriate health and safety program to prevent the unintentional exposure of workers and members of the public to the material. The pre-licensing process also protects the common defense and security by ensuring that the radioactive material will be used as intended and not by potential terrorists or others targeting the specific material intending to use it to affect the common defense and security by exposing members of the public to the material. However, the designation of the authority being used for these regulations does have significance in determining whether Agreement States or the NRC will be responsible for overseeing the implementation of these requirements for Agreement State licensees.

Although the NRC relinquishes its regulatory authority to Agreement States for certain materials, under Section 274(m) of the Atomic Energy Act of 1954, no such agreement will affect the authority of the Commission to take regulatory action to protect the common defense and security. Thus, as evidenced by NRC orders issued to Agreement State licensees after 9/11, the NRC always has the ability to take necessary steps to address particular common defense and security needs. If these regulations were to be issued under the NRC's common defense and security authority, only the NRC would have the authority to impose these requirements on Agreement State licensees and the NRC would be responsible for inspection and enforcement of these requirements for Agreement State licensees.

When regulations such as these complement both the NRC's public health and safety and common defense and security missions, the operative question is whether NRC oversight is necessary to fulfill the common defense and security aspects of the regulations. The NRC believes that the Agreement States can consistently and adequately implement the physical protection requirements on a nationwide basis, and as such, there will be no need for

independent NRC action to protect the common defense and security. The NRC has regular oversight of individual Agreement State programs through its Integrated Materials Performance Evaluation Program (IMPEP). As always, the NRC retains the authority under Section 274(m) to take any necessary actions for protection of the common defense and security should individual licensees or State programs develop issues requiring immediate action. The Commission also has the authority under Section 274(j) to terminate or suspend all or part of its agreement with a State and reassert the Commission's licensing and regulatory authority when the Commission determines that doing so is necessary to protect the public health and safety. The failure of an individual Agreement State to implement compatible and adequate legally binding requirements to protect radioactive materials within its jurisdiction disrupts the entire national scheme to protect radioactive materials such that it might raise serious public health and safety or common defense and security concerns that the NRC would have to address. As long as all Agreement States continue to implement compatible and adequate security requirements, there appears to be no benefit to the public health and safety or common defense and security that would justify removing oversight of these requirements from an established regulatory program overseeing Agreement State licensees. Implementing these regulations under the NRC's public health and safety authority would avoid potential complications with licensees being subject to dual regulation for a single activity. Thus, the NRC is proposing to issue these regulations under its public health and safety authority, and these requirements will be applicable to Agreement State licensees through the Agreement State Program.

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), this final rule is a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among the Agreement States and the NRC’s requirements. The NRC staff analyzed the final 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,” (see Compatibility Table for Final Rule).

As a result of the amendments to 10 CFR 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 10 CFR 31.5(c)(13)(i), this section is now designated as

Compatibility Category C. After considering the issues associated with the compatibility requirements for 10 CFR 31.6, this section is designated as Compatibility Category C.

The designations of 10 CFR 31.5(a), (c)(13)(i), and 31.6 as Compatibility Category C will provide Agreement States flexibility to adopt additional requirements, based on their circumstances and needs, and to adopt additional requirements for tracking the movement of service providers and the location of generally licensed devices, if necessary. Designating 10 CFR 31.5(a) and 31.6 as Compatibility Category C addresses the issues and concerns raised by the OAS in their June 2005, petition for rulemaking. Designating 10 CFR 31.5(c)(13)(i) as Compatibility Category C also addresses the issues and concerns raised by the State of Florida in its June 2005 request as part of the petition.

Compatibility Table for Final Rule

Section	Change	Subject	Compatibility	
			Existing	New
Part 31				
31.5(a)	Amend		B	C
31.5(13)(c)(i)	Amend		B	C
31.6	Amend		B	C

VI. 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 final rule, the NRC will require licensees that possess generally licensed devices with any of the radioactive sources and thresholds specified in the final rule to

submit an application for an SL. This action does not constitute the establishment of a standard that contains generally applicable requirements.

VII. Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described as a categorical exclusion in 10 CFR 51.22(c)(3)(i). This section provides a categorical exclusion for amendments to Parts 30 and 31 that relate to “[p]rocedures for filing and reviewing applications for licenses.” This amendment to Part 31 relates to the procedures that are applied to the licensing of devices that are now generally licensed; some of these devices will now be licensed under the specific licensing procedures in 10 CFR Part 30. The amendments do not change what activities are permitted to be conducted by licensees, but only change the process for receiving a license to conduct those activities. Because this amendment relates to the procedures for filing an application for a license for certain types of devices, which are addressed by the categorical exclusion in 10 CFR 21.22(c)(3)(i), neither an environmental impact statement nor an environmental assessment has been prepared for this rule.

VIII. Paperwork Reduction Act Statement

This final rule amends information collection requirements contained in 10 CFR Part(s) 19, 20, 30 and 31, and NRC Form 664, that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, approval number 3150-0016, 3150-0044, 3150-0014, 3150-0017, 3150-0198, and 3150-0120.

The burden to the public for the information collections in 10 CFR Parts 19, 20, 30, and 31, and NRC Form 664, is estimated to average 10.83 hours per response. This includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of these information collections, including suggestions for reducing the burden, to the Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS.Resource@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0016; -0044; -00014; -0017; -0198; and -0120), Office of Management and Budget (OMB), Washington, DC 20503.

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.

IX. Regulatory Analysis

As part of this final rulemaking, the Commission has prepared a regulatory analysis examining the costs and benefits of the rulemaking and alternatives considered by the Commission. A summary of the regulatory analysis follows. Limiting the quantity of byproduct material allowed in generally licensed devices to below 1/10 of the IAEA's Category 3 thresholds will require about 280 NRC general licensees to convert to specific licensees (approximately 1400 NRC and Agreement State general licensees will be affected). These

licensees will have to follow existing NRC requirements including 10 CFR Parts 19, 20, 21, and 30. These new applicants will also increase the regulatory resources that will be needed to review SL applications and to inspect the licensees after the license is issued. However, the additional NRC and Agreement State resources are not considered significant because the number of general licensees that would be converted to specific licensees represent only about 6 percent of the NRC and Agreement State population of specific licensees, which would not result in a significant additional commitment of resources from the NRC or Agreement States.

The regulatory analysis covered a 10-year analysis period using 2007 dollars. The implementation of the final rule by industry, NRC, and Agreement States is estimated to cost about \$96 million, over the 10-year analysis period at a 3 percent discount rate. NRC licensee costs are about \$17 million, and NRC costs are about \$2 million. Agreement State licensee costs are about \$68 million, and Agreement State costs are about \$9 million.

The regulatory analysis is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD, and may be downloaded from the Federal rulemaking Web site at www.regulations.gov by searching on Docket ID NRC-2008-0272. Single copies of the regulatory analysis are available from Solomon Sahle of the Office of Federal and State Materials and Environmental Management Programs, telephone: (301) 415-3781, e-mail: solomon.sahle@nrc.gov.

X. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities. The NRC staff estimates that about 280 NRC materials licensees and

about 1,120 Agreement State licensees will be affected by this final rule and a significant number of these licensees would meet the definition of "small entities" set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121. However, based on the regulatory analysis, the NRC believes that the amendments in this final rule are the least burdensome and most flexible alternative that would accomplish the NRC's regulatory objective, and would not result in a significant economic impact on the affected entities.

XI. Backfit Analysis

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

XII. Congressional Review Act

In accordance with the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

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. 552 and 553; the NRC is adopting the following amendments 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 the thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere, provided that, for devices that contain isotopes listed in Appendix E of 10 CFR Part 20, each device contains less than 1/100th of the thresholds listed in Appendix E of 10 CFR Part 20 for Category 2.

(2) Persons holding a device containing byproduct material greater than 1/100th of the thresholds listed in Appendix E of 10 CFR Part 20 for Category 2 on [INSERT EFFECTIVE DATE] may continue to hold the devices under this general license until [INSERT DATE 1 YEAR AFTER EFFECTIVE DATE] and until the date of the NRC's

final licensing determination, provided that the licensee submits an application for a specific license on or before [INSERT DATE 1 YEAR AFTER EFFECTIVE DATE].

* * * * *

Dated at Rockville, Maryland, this ____ day of _____ 2010.

For the Nuclear Regulatory Commission,

Annette Vietti-Cook,
Secretary of the Commission



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

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

July 2010

EXECUTIVE SUMMARY

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

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

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

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

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

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

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1. Introduction

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

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

1.1 Background

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

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

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

equipment, training, experience, and ability to meet other applicable regulatory requirements. To remedy this, the NRC staff evaluated amendments to 10 CFR Part 31 to require specific licensing for some materials that are currently regulated under the GL regulatory system. On April 24, 2006, the NRC staff submitted SECY-06-0094, "Tracking or Providing Enhanced Controls for Category 3 Sources," to the Commission for review. In that paper, the NRC staff proposed initiating a rulemaking that would set an activity limit for generally licensed devices at one-half (1/2) of the IAEA Category 2 threshold and reserve authorization to possess higher activity sources to those licensees with SLs. As indicated in SECY-06-0094, the bases for the proposed activity limit was that the activity levels in such devices would be close to the Category 2 levels and such a limit would not affect a significant number of licensees. In response to SECY-06-0094, the Commission, in a Staff Requirements Memorandum (SRM), dated June 9, 2006, approved the staff's plan to amend the GL requirements in 10 CFR Part 31.5, but disapproved the staff's recommendation to set the limit at 1/2 of IAEA Category 2. Instead, the Commission instructed the staff to evaluate the specific licensing of general licensees possessing devices greater than or equal to 1/10 of the IAEA Category 3 threshold¹.

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

2. Objectives of Final Rule

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

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

3. Identification of Alternative Approaches

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

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

3.1 Alternative 1: No Action

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

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

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

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

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

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

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

3.2.2 Alternative 2B: Registration Threshold Values

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

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

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

4. Analysis of Values and Impacts

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

4.1 Identification of Affected Attributes

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

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

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

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

- **Offsite Property.** Improvement in the accountability and controls over previously generally licensed devices may avert, to a small degree, potential offsite property damage and resulting costs for response efforts.
- **Industry Implementation.** Certain licensees who currently use the GL to possess byproduct material will need to submit an application for an SL and will also need to change their internal procedures to comply with SL regulatory requirements. These licensees will incur one-time implementation costs under the final rule.
- **Industry Operation.** The same licensees who undergo one-time implementation costs will need to manage new administrative and procedural activities, training and other measures to comply with the new requirements. These licensees will incur annual operating costs under the final rule.
- **NRC Implementation.** The final rule requires the NRC to revise its guidance in NUREG-1556. Specifically, NRC must revise guidance to ensure that licensees apply for an SL and meet other applicable regulatory requirements when in possession of devices containing byproduct material meeting or exceeding the final rule threshold values. For this activity, NRC will incur one-time implementation costs. This work was not completed during the proposed rule phase.
- **NRC Operation.** On an on-going basis, the NRC staff must review license applications, perform pre-licensing visits, inspections and other regulatory activities to ensure licensee compliance with the new GL Restrictions requirements. The NRC will incur increased annual operating costs to support this work.
- **Other Government.** The final rule benefits other Federal agencies and State and local governments (e.g., Department of Homeland Security, Agreement States) by imposing more stringent regulatory controls on general licensees by limiting the amount of byproduct material in generally licensed devices. This rulemaking allows better tracking and accountability of materials in the United States and will reduce the possibility for malevolent use of radioactive materials and the potential for aggregation of devices to quantities of concern. The final rule allows Agreement States to better monitor the location of radioactive material of concern and to focus their resources on licensees with higher quantities of radioactive material.
- **Improvements in Knowledge.** The final rule allows the NRC to assess and enhance the safety of licensed activities, gather updated information, assess accident probabilities or consequences and reduce uncertainties. This additional oversight allows the NRC to increase the protection of public health and safety.
- **Regulatory Efficiency.** The current GL regulatory system is inherently efficient because it requires very few regulatory resources, with little to no regulatory oversight during use of the generally licensed devices. The final rule creates an overall improvement in regulatory efficiency by facilitating, over the long-term, NRC and Agreement States accountability and oversight of generally licensed devices with a reduction in potential safety issues that can arise from the misuse or improper disposal of generally licensed devices.

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

The final rule does not affect the following attributes:

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

4.2 Analytical Methodology and Assumptions

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

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

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

4.2.1 Alternative 1

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

4.2.2 Alternative 2

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

d) Costs to revise guidance documents

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

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

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

4.2.2.2 Alternative 2B: Registration Threshold Values

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

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

a) Cost of complying with existing requirements for specific licensees

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

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

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

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

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

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

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

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

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

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

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

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

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

1) Costs to revise guidance documents

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

4.2.3 Alternatives Submitted as Public Comments on the Proposed Rule

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

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

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

5. Results

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

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

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

- *Improved Control of Devices and the Sources they contain.* Placing a limit on the amount of byproduct material in generally licensed devices will result in improved accountability of certain devices that are currently generally licensed and provide additional protection against aggregation of lower activity sources to quantities of concern. This will improve public health (accident/event) and avert potential offsite property damage and costs.
- *Enhanced NRC Ability to Protect Public Health and Safety.* Requiring certain general licensees to obtain SLs will allow regulators to better monitor the adequacy of their operations and material possession, thus improving accountability of devices containing sources meeting or exceeding the threshold. Consequently, the final rule will enhance NRC and State regulators ability to protect public health and safety.
- *Improved Regulatory Efficiency.* The final rule creates an overall improvement in regulatory efficiency by facilitating, over the long-term, NRC and Agreement States accountability and oversight of generally licensed devices with a reduction in potential safety issues that can arise from the misuse or improper disposal of generally licensed devices.
- *Increased Public Confidence.* Information obtained by requiring current general licensees to obtain SLs will allow the NRC and Agreement States to better monitor these licensees and the devices and sources that they possess. This will result in increased public confidence in the regulation of tracking of radioactive materials.

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

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

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

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

Notes:

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

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

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

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

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

Notes:

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

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

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

Note:

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

6. Backfit Analysis

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

7. Decision Rationale

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

- improve the accountability and control of certain existing generally licensed devices and thereby enhance NRC's ability to protect public health and safety by placing these devices under more stringent regulatory oversight;
- reduce the potential for aggregation of devices for deliberate misuse;
- address potential security vulnerabilities; and
- increase public confidence in the protection of public health and safety.

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

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

8. Implementation

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

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

APPENDIX 1:
 DETAILED COSTS
 ALTERNATIVES 2A AND 2B

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

Number of Licensees = 280 Cost/hr = \$100

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	0.25	0.25	70.0	7,000
19.13(b)	Annual reports to current employees	0.6	1.0	0.6	168.0	16,800
19.13(e)	Reports to terminating employees	0.18	1.0	0.18	50.4	5,040
Totals				1.03	288.4	28,840

Notes:

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

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

Number of Licensees = 280 Cost/hr = \$100

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

Notes:

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

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

Number of Licensees = 280 Cost/hr = \$100

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

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

Notes:

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

Table 6

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

Number of Licensees = 280 Cost/hr = \$100

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

Notes:

(1) Total Burden (Hours and Costs) for Agreement State Licensees is about 4 times the values in Table 6

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

Table 7

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

Number of Licensees = 1,150

Cost/hr = \$100

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	21,769.5	2,176,950

Notes:

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

Table 9

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

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

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

Notes:

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

Table 10

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

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

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	2,066
Totals				0.178	204.6	20,466

Notes:

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

Table 11

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

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

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