

NUCLEAR REGULATORY COMMISSION

10 CFR Part 31

RIN: 3150-AI33

[NRC-2008-0272]

Limiting the Quantity of Byproduct Material in a Generally Licensed Device

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Proposed rule.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to limit the quantity of byproduct material contained in a generally licensed device to below one-tenth (1/10) of the International Atomic Energy Agency (IAEA) Category 3 thresholds. As a result of this amendment, individuals possessing devices with byproduct material meeting or exceeding these thresholds would be required to apply for a specific license. The proposed amendment would also modify the Compatibility Categories contained in the current regulations (10 CFR 31.5 and 31.6).

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

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

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

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

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

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

E-mail comments to: [Rulemaking.Comments@nrc.gov](mailto:Rulemaking.Comments@nrc.gov). If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at 301-415-1677.

Comments can also be submitted via the Federal eRulemaking Portal <http://www.regulations.gov>.

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

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

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

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

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

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

[PDR.Resource@nrc.gov](mailto:PDR.Resource@nrc.gov).

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

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## **I. Background**

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

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

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

The work on the DOE/NRC joint report paralleled the work on the Code of Conduct and the development of IAEA TECDOC-1344, "Categorization of Radioactive Sources."<sup>1</sup> The IAEA updated this categorization system for radioactive sources in August 2005, in the IAEA Safety Standards Series No. RS-G-1.9, "Categorization of Radioactive Sources." The Safety Guide, which is also available on the IAEA's Web site at: [http://www-pub.iaea.org/MTCD/publications/PDF/Pub1227\\_web.pdf](http://www-pub.iaea.org/MTCD/publications/PDF/Pub1227_web.pdf), provides the underlying methodology for the development

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

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

While the various efforts and reviews previously noted in this notice have been ongoing, the NRC has implemented several measures to increase the safety and security of radioactive sources, with particular focus on radioactive sources of concern. These measures have included the issuance of increased controls orders to specific licensees who possess IAEA Category 1 and 2 radioactive sources requiring them to exercise added control over such sources, as well as publishing a final rule, in November 2006, on a National Source Tracking System (NSTS) to provide better accountability and control over Category 1 and 2 sources. The NRC has also increased the frequency of inspections to further ensure that there is adequate control of these materials. Recently, NRC proposed, in a separate rulemaking, to expand the NSTS to also include sources equal to, or greater than, 1/10 of the IAEA Category 3 threshold so as to address concerns over potential malevolent aggregation of these lower activity sources to IAEA Category 2 levels. NRC is currently evaluating the comments received on the proposed rule; eighteen of the nineteen public comments received were opposed to expansion of the NSTS citing concerns that the rule may be premature and not necessary.

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

## **II. Discussion**

In this rulemaking, the NRC is proposing to amend its regulations to limit the quantity of byproduct material allowed in a generally licensed device. The proposed amendment to NRC regulations would limit the quantity of byproduct material allowed in a generally licensed device

to below 1/10 of the IAEA's Category 3 thresholds; licensees with devices containing byproduct material at or above this limit would be required to obtain a SL. This rulemaking is directed toward improving the safety and security of devices now held under a GL having radioactive sources falling within IAEA Categories 3 through 5 by causing a portion of them to be SLs and allowing the remaining portion to continue to be GLs.

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

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

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



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

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

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

### A.1 Congressional Concerns/GAO Investigations

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

### A.2 Agreement State Issues

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

the OAS requested that NRC “strengthen the regulation of radioactive materials by requiring a specific license for higher-activity devices that are currently available under the general license in 10 CFR 31.5.” Specifically, the petition requested that the NRC amend its regulations to require specific licensing for devices exceeding the registration quantity limits in 10 CFR 31.5(c)(13)(i). Additionally, the OAS requested that NRC revise the compatibility designation of 10 CFR 31.6 from “B” to “C,” which would allow States to better track service providers and distributors of generally licensed devices. In addition, the State of Florida also requested a compatibility category change for 10 CFR 31.5(c)(13)(i) from ‘B’ to ‘C’ to allow the State to continue to require registration of other generally licensed devices in addition to those currently registered by the NRC. These petitions were docketed by NRC as PRM-31-5. The NRC requested public comment on the PRM-31-5 petition on December 20, 2005 (70 FR 75423). Four comment letters were received on the petition; the commenters disagreed with using the registration levels to require GLs to become SLs but had differing views on changing the compatibility categories. In considering the petition and the public comments on them, the NRC determined it appropriate to consider the concerns and issues raised by OAS and the State of Florida in this rulemaking. By letter dated August 17, 2007, the petitioners were informed of the decision.

### A.3 Recent NRC Actions

On April 24, 2006, the NRC staff submitted SECY-06-0094, “Tracking or Providing Enhanced Controls for Category 3 Sources,” to the Commission for review. In that paper, the NRC staff proposed initiating a rulemaking that would set activity limits for GLs at one-half (1/2) of the IAEA Category 2 threshold and reserve authorization to possess higher activity sources to SLs. The staff noted that a benefit of setting such a limit would be greater oversight of these

licensees, allowing regulatory bodies the opportunity to perform an assessment of a licensee's legitimacy or any other regulatory activities the Commission determined as being necessary. The NRC staff, in SECY-06-0094, recommended setting the GL limit at 1/2 of Category 2 because the activity levels in such devices would be close to the Category 2 levels and such a limit would not affect a significant number of licenses.

In response to SECY-06-0094, the Commission, in a Staff Requirements Memorandum (SRM), dated June 9, 2006, approved the staff's plan to amend the GL requirements in Section 31.5, but disapproved the staff's recommendation to set the limit at 1/2 of IAEA Category 2. Instead, the Commission approved moving forward to evaluate requiring specific licensing of general licensees possessing devices greater than or equal to 1/10 of the IAEA's Category 3 threshold<sup>2</sup>.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

higher-activity Category 4 sources could be obtained and aggregated to create the equivalent of Category 2 sources. These “high-end” Category 4 sources can be at levels just below the threshold of a Category 3 source, which is about 1/10 of the threshold of a Category 2 source, meaning that it would require about 10-12 devices with such sources to aggregate to Category 2 quantities. Devices with these high-end Category 4 (1/10 Category 3) sources are possessed by similar licensees noted to have Category 3 sources, namely those with industrial gauges, and, as previously noted, are in relatively widespread use and broadly used in industry, thus allowing for the potential for aggregation of sufficient numbers of them to IAEA Category 2 levels.

For devices with sources that are at or above registration levels

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

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

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

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

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

### For Devices with Sources At or Above Registration Levels

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

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

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

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

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

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

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

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

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

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

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

or

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

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

### C. Implementation of the proposed rule amendments

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

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



### III. Discussion of Proposed Amendments by Section

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

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

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

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

#### **IV. Criminal Penalties**

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

#### **V. Agreement State Compatibility**

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

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

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

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

## **VI. Plain Language**

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

## **VII. Voluntary Consensus Standards**

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

## **VIII. Environmental Impact: Categorical Exclusion**

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

## **IX. Paperwork Reduction Act Statement**

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

*Type of submission, new or revision:* Revisions

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

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

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

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

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

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

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

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

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

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

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

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

### **Public Protection Notification**

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

### **X. Regulatory Analysis**

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

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

## **XI. Regulatory Flexibility Certification**

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

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

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



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

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

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

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

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

## **XII. Backfit Analysis**

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

### **List of Subjects in 10 CFR Part 31**

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

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

## PART 31 – GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

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

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

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

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

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

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

\* \* \* \* \*

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

For the Nuclear Regulatory Commission.

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