



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

(FSME-09-066, August, Program, Generally Licensed Device)

August 4, 2009

ALL AGREEMENT STATES, MICHIGAN, NEW JERSEY

OPPORTUNITY TO COMMENT ON PROPOSED RULE ON "LIMITING THE QUANTITY OF BYPRODUCT MATERIAL IN A GENERALLY LICENSED DEVICE," (FSME-09-066)

Purpose: To provide an opportunity to comment on the subject proposed rule. You may submit comments on the rule by one of the several methods, identified in the *Federal Register* notice on August 3, 2009. To inform Agreement States of the U.S. Nuclear Regulatory Commission's (NRC's) efforts in sending copies of *Federal Register* notice to certain NRC general licensees and specific licensees and encourage Agreement States to do so.

Background: In a Staff Requirements Memorandum (SRM) dated May 1, 2009, the Commission approved the staff's draft proposed rule on Limiting the Quantity of Byproduct Material in a Generally Licensed Device. The draft proposed rule was contained in SECY-08-0137; a prior draft of the proposed rule was provided to the States for review and comment on April 30, 2008. Based on the Commission's direction in the SRM, the proposed rule was published in the *Federal Register* on August 3, 2009 (74 FR 38372). A copy of the *Federal Register* notice has been enclosed for your convenience. It can also be accessed at the following internet address:

<http://edocket.access.gpo.gov/2009/pdf/E9-18438.pdf>

Discussion: The proposed rule would require individuals possessing generally licensed devices with byproduct material equal to or exceeding 1/10 of IAEA Category 3 threshold values to apply for and obtain a specific license for those devices. The proposed rule also would add a new paragraph 10 CFR 31 .5(b)(3) to clarify the requirements that apply when a device authorized to be used under the general license is instead held under a specific license. Finally, the proposed rule would modify the Compatibility Categories contained in the current regulations from Category "B" to Category "C."

Two letters are also enclosed for your information: (1) a copy of a letter that the NRC is sending to general licensees who would be affected by the amendment, and (2) a copy of a letter that NRC is sending to NRC specific licenses who are authorized to manufacture and/or distribute these generally licensed devices. The purpose of sending these letters is for NRC to inform those licensees of the proposed rule and the opportunity to provide public comments on the rule. Agreement States are encouraged to do so for their respective licensees who could be impacted by this rule. Note that since Agreement States could impose more restrictive requirements for amendments under Compatibility Category C, you may consider informing a broader group of general licensees than those under NRC jurisdiction.*

. This information request has been approved by OMB 3150-0029, expiration 08/31/2010. The estimated burden per response to comply with this voluntary collection is approximately 8 hours. Send comments regarding the burden estimate to the Records and FOIA/Privacy Services Branch (T-5F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0029), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

If you have any questions regarding this correspondence, please contact me at 301-415-7278 or the individual named below. **Please note the comment period on the proposed rule ends on October 19, 2009.**

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/RA/

Mark R. Shaffer, Director
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and Rulemaking
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and Environmental Management Programs

Enclosures:

1. *Federal Register* Notice
2. Letter to NRC General Licensees
3. Letter to GL Device Manufacturers and/or Distributors

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: 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 and obtain a specific license. The NRC is also proposing to further clarify the requirements that apply when a device authorized to be used under the general license is instead held under a specific license. The proposed amendments would also modify the Compatibility Categories contained in the current regulations.

DATES: Submit comments on the rule by October 19, 2009. Submit comments specific to the information collection aspects of this rule by September 2, 2009. Comments received after the above date will be considered if it is practical to do so, but the NRC is able to ensure 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 Docket ID NRC-2008-0272 in the subject line of your comments. Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site *Regulations.gov*. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they

should not include any information in their comments that they do not want publicly disclosed.

Federal Rulemaking Web site: 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.

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

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

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 at 301-415-1101. You may submit comments on the information collections by the methods indicated in the Paperwork Reduction Act Statement.

You can access publicly available documents related to this proposed rule using the following methods:

NRC's Public Document Room (PDR): The public may examine and have copied for a fee publicly available documents at the NRC's PDR, Public File Area 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*.

Federal Rulemaking Web site: Public comments and supporting materials related to this proposed rule can be found at <http://www.regulations.gov> by searching on Docket ID NRC-2008-0272.

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:

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- II. Discussion
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 - B. Decision on Proposed Amendment To Place a Limit on Quantity of Byproduct Material in Generally Licensed Devices
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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, these efforts were expanded to include a heightened awareness and increased focus on the need to prevent intentional unauthorized access due to potential malicious acts. These efforts, such as the IAEA Code of Conduct on the Safety and Security of Radioactive Sources (Code of Conduct) concerning Category 1 and Category 2 sources, seek to increase the control over sources to prevent unintended radiation exposure and to prevent malicious acts. Proper security and control measures reduce the likelihood of intentional unauthorized access that could result in this radioactive material being used in radiological dispersal devices (RDD) or in radiological exposure devices (RED).

In June 2002, the Secretary of Energy and the NRC Chairman met to discuss the adequate protection 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 working group issued its

report "Radiological Dispersal Devices: An Initial Study To Identify Radioactive Materials of Greatest Concern and Approaches to Their Tracking, Tagging, and Disposition."

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

The DOE/NRC joint report paralleled the work on the Code of Conduct and the development of IAEA TECDOC-1344, "Categorization of Radioactive Sources." (Section A.4.1 of this document contains a description of the IAEA source categorization system.) 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 is available on the IAEA's Web site at http://www-pub.iaea.org/MTCD/publications/PDF/Pub1227_web.pdf and provides the underlying methodology for the development of the Code of Conduct thresholds. The categorization system is based on the potential for sources to cause deterministic effects and uses radionuclide-specific activity levels (D values) as normalizing factors; the D values are used for 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, the NRC has adopted the Category 2 definitions contained in the IAEA's Code of Conduct. The NRC considers IAEA Category 2 quantities (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 (U.S.).

While the various efforts and reviews previously noted in this notice have been ongoing, the NRC also 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 controls orders to specific licensees who possess IAEA Category 1 and Category 2 radioactive sources (70 FR 72128; December 1, 2005). The orders required these licensees to exercise added control over these sources. In addition, the NRC increased the frequency of inspections to further ensure that there is adequate control of these materials. The NRC also published a final rule in November 2006 that established a National Source Tracking System (NSTS) to provide better accountability and control over Category 1 and Category 2 sources. The NRC proposed, in a separate rulemaking (73 FR 19749; April 11, 2008), to expand the NSTS to include sources equal to, or greater than, 1/10 of the IAEA Category 3 threshold values to address accountability of these sources and concerns over potential malevolent aggregation of these lower activity sources to IAEA Category 2 levels. (Note: Sources referred to as "1/10 of Category 3" were formerly referred to as "Category 3.5" sources in these documents. To be consistent with IAEA terminology, the term "Category 3.5" has been changed to "1/10 of Category 3.") The NRC staff evaluated the comments received on this proposed rule and, in SECY-09-0086 dated June 10, 2009, requested approval from the Commission to publish the final rule in the **Federal Register**. Staff's recommendation in SECY-09-0086 was to expand the NSTS to Category 3 sources instead of 1/10 of Category 3. In a Staff Requirements Memorandum (SRM) dated June 30, 2009, the Commission stated that it was unable to reach a decision on the staff's recommendation and therefore did not approve publication of the NSTS Expansion final rule.

During this time, there has been increased concern regarding devices that are currently possessed under NRC's general license (GL) regulatory program. The requirements for general licensees 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) raised concerns regarding the safety and security of radioactive material covered by the GL regulatory system and the

Organization of Agreement States (OAS) filed a petition for rulemaking on June 27, 2005 (PRM-31-5), requesting that the NRC strengthen its GL regulatory system. The NRC staff has been considering similar issues, including that under the current GL regulatory system, the 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 the ability to meet any other applicable requirements for those that possess GL devices. Further, a licensee's loss of control of radioactive sources, whether it be inadvertent or through a deliberate act, could result in significant adverse health impacts, which could constitute a threat to the public health and safety. Thus, the 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 more specifically licensed devices, which would be regulated under 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 the NRC's regulations would 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 a specific license (SL). This rulemaking is directed toward improving the safety and security of devices now held under GL containing radioactive sources falling within IAEA Categories 3 through 5 by causing a portion of them to be specifically licensed allowing the remaining portion to continue to be used under general license.

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 the beneficial use of GL devices 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. Nuclear Regulatory Commission Materials Program," dated August 25, 2007. Although this proposed amendment cannot by itself ensure the physical protection of sources, converting certain devices from use under a GL to use under an SL can provide greater device accountability and, as part of an overall effort in conjunction with other related activities (e.g., potential applicability 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 it requested that the NRC revise 10 CFR 31.5 and change the Compatibility Category of 10 CFR 31.6 from "B" to "C." The rulemaking also considers 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 the 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 subcommittee expressed concerns about certain U.S. Government practices and procedures for issuing licenses to possess radioactive materials and

presented recommendations that would 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 its report, the 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 PRM-31-5 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 general licensees to become specific licensees but had differing views on changing the compatibility categories. In considering the petition and the public comments, the NRC decided 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 this 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 general licensees at one-half ($\frac{1}{2}$) of the IAEA

Category 2 threshold and reserve authorization to possess higher activity sources to specific licensees. 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 to be necessary. The NRC staff, in SECY-06-0094, recommended setting the GL limit at $\frac{1}{2}$ 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 10 CFR 31.5, but disapproved the staff's recommendation to set the limit at $\frac{1}{2}$ 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 $\frac{1}{10}$ of the IAEA's Category 3 threshold.

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. 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, but 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 Cobalt-60 (Co-60): 810 Curies (Ci)); these sources are typically used in 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 $\frac{1}{100}$ of Category 1; e.g., for Co-60: 8.1 Ci); these sources are typically used in 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 ($\frac{1}{10}$ of Category 2; e.g., for Co-60: 0.81 Ci); these sources are typically used in 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 ($\frac{1}{100}$ of Category 3; e.g., for Co-60: 0.0081 Ci); and

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, the NRC evaluates the adequacy of generally licensed products by ensuring that manufacturers and distributors of the products (all of whom hold specific licenses) meet the various specific requirements in Subpart B to 10 CFR Part 32. 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 Category 2 generally licensed devices currently in existence).

As part of the current GL regulatory system, 10 CFR 31.5 contains requirements that certain generally licensed devices containing byproduct material in quantities above "registration" levels listed in 10 CFR

31.5(c)(13)(i) must be registered annually with the NRC. There are about 1,200 general licensees possessing such devices who are currently registered with the NRC. The radionuclides listed in 10 CFR 31.5(c)(13)(i) are Co-60, Cesium-137, Strontium-90, Radium-226, Americium-241, and any other transuranics. As an example, the registration level for Co-60 is 0.001 Ci; which falls in the IAEA Category 5 range and is approximately $\frac{1}{1000}$ of the IAEA Category 3 threshold for Co-60 (and approximately $\frac{1}{10}$ 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, the NRC noted that it was most concerned about generally licensed devices that had not been handled or disposed of properly and believed that if general licensees were made aware of their responsibilities, they would be more likely to comply with the requirements for proper handling and disposal of generally licensed devices. Additional compliance with these requirements would help reduce the potential for incidents, including those related to sources not disposed of properly and 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, the NRC has determined that there is a need to enhance the security and accountability for devices with certain lower activity sources. The issues the NRC considered in this rulemaking include:

(1) 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 $\frac{1}{10}$ 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 $\frac{1}{1000}$ 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 a discussion of the selection of the $\frac{1}{10}$ of Category 3 threshold are provided in Sections A.4.3.1 and A.4.3.2, respectively, of this document.

A.4.3.1 Rationale for Revising the GL Regulatory System To Require Generally Licensed Devices Above a Certain Limit To Become Specific Licenses

As part of its overall process, the NRC evaluated its current GL regulatory system, as described in Section A.4.2 of this document, and found that the relatively few administrative or operational regulatory constraints (mainly as a result of the safety features incorporated into their design), imposed on GL devices raise a number of concerns about security vulnerabilities. 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. The SL regulatory controls 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.

Further, requiring a specific license for some generally licensed devices 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.

The NRC does not routinely perform inspections of general licensees. Inspections of general licensees are only performed in certain circumstances, such as when there are indications of unsafe practices by the general licensees. By converting certain general licensees to specific licensees, 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 each outcome.

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 document, the 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 $\frac{1}{10}$ 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 (approximately $\frac{1}{1000}$ of the IAEA Category 3 threshold). Considerations as to 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 $\frac{1}{10}$ of the IAEA Category 3 Thresholds

Converting certain devices with sources that are equal to or greater than $\frac{1}{10}$ of Category 3 to specific licenses 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 that are equal to, or greater than, $\frac{1}{10}$ of the Category 3

threshold). These two groups are discussed below.

Category 3 sources are defined by IAEA as "dangerous sources"—i.e., sources 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. Further, 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 down to $\frac{1}{10}$ 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 of these 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 $\frac{1}{10}$ 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 $\frac{1}{10}$ 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 $\frac{1}{10}$ of the threshold of a Category 2 source, meaning that it would require about 10–12 of these devices with such sources to aggregate to Category 2 quantities. Devices with these high-end Category 4 ($\frac{1}{10}$ 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 $\frac{1}{1000}$ 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 all devices with sources in IAEA Category 5. In general, these categories 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. 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 general licensees to obtain specific licenses would result in increased burden on licensees, and on the NRC and Agreement States, for preparation and review of specific license applications and amendments and for conducting inspections. In the Regulatory Analysis for this rulemaking (see Section X of this document), the Commission 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 follows.

For Devices With Sources at or Above $\frac{1}{10}$ of the IAEA Category 3 Thresholds:

Limiting the quantity of byproduct material allowed in generally licensed devices to below $\frac{1}{10}$ of the IAEA's Category 3 thresholds would result in approximately 280 NRC general licensees being converted to specific licensees (approximately 1400 NRC and Agreement State general licensees). These licensees would now have to follow existing NRC requirements including 10 CFR Parts 19, 20, and 30. The added number of specific licensees 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 general licensees that would be converted to specific licensees represent only about 6 percent of the NRC and Agreement States existing population of specific licensees 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 specific licensees (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 existing NRC requirements including 10 CFR Parts 19, 20, and 30. The added number of specific licensees would result in an increase in the regulatory resources that would need to be devoted to reviewing the new SL applications and inspecting the licensees after the license is issued. It is estimated that the number of additional general licensees that would be converted into specific licensees represent about 25 percent of the NRC and Agreement States existing population of specific licensees 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 of this document, the NRC has decided to propose amending its regulations by limiting the quantity of byproduct material that can be in a generally licensed device to $\frac{1}{10}$ of the IAEA Category 3 threshold. The regulatory text is based on the existing text of Appendix E to 10 CFR Part 20, *i.e.*, with the limit "less than $\frac{1}{100}$ of the thresholds listed in Appendix E to 10 CFR Part 20 for Category 2."

The basis for this limit is discussed in Section A of this document. In sum, the NRC believes that the additional security and safety provided by the specific licensing process is necessary to limit the potential for aggregating 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 that would result from the proposed amendments is reasonable because of the enhanced public health and safety and security derived from placing these higher activity generally licensed devices under a greater range of regulatory controls.

The need for this proposed amendment to the GL regulatory system was not foreseen in 1999 and 2000 when NRC issued the rule amendments instituting the GL registration system. As noted in Section A.4.2 of this document, and in the Statements of Considerations 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 licensees 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 $\frac{1}{10}$ of IAEA Category 3 for certain isotopes listed in Appendix E to 10 CFR Part 20.

The NRC has chosen not to extend this new limit on generally licensed devices down to the 10 CFR 31.5(c)(13)(i) registration levels, as requested by the OAS in its rulemaking petition because it is neither necessary nor appropriate from a source aggregation and cost-benefit basis. The NRC believes that the relatively low security risk posed by lower Category 4 and Category 5 sources does not justify the significant regulatory resources and impacts on licensees that would result from specifically licensing devices with lower Category 4 and Category 5 sources. Instead, the NRC has left the GL registration program as it currently exists for general licensees below the new GL limit because the rationale for instituting the GL registration program in the 1999 and 2000 rule amendments continues to remain valid today. The NRC successfully implemented the GL registration program with 80 to 98 percent of general licensees responding annually 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 proposing to revise the Compatibility Category of 10 CFR 31.5(a) from "B" to "C" and the Compatibility Category of 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. Revising these compatibility categories would provide the Agreement States the flexibility to adopt additional requirements, based on their circumstances and needs. The NRC is also 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 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 into and out of Florida.

C. Specific Licensees and Generally Licensed Devices

The Commission is considering an additional revision to 10 CFR 31.5. This amendment would clarify the applicable requirements when a device that is authorized to be used under the general license in 10 CFR 31.5 is instead held by a licensee under an SL. Currently, a specific licensee may obtain a device approved for use under 10 CFR 31.5 as a specifically licensed device rather than use the authority of the GL. If a device is initially obtained as a generally licensed device, it can later be transferred for use under the SL in accordance with the procedures outlined in 10 CFR 31.5(c)(8)(iii). Some licensees have found it easier to comply with the regulations if all of their radioactive material is covered by the same requirements. Others have used these devices under their SL in order to minimize their fees. The proposed rule would add a new paragraph, 10 CFR 31.5(b)(3), to further clarify that when a device is held under an SL, all terms and conditions of the SL apply, and the requirements in 10 CFR 31.5 do not apply.

The Commission is also considering and may include in the final rule an additional change concerning generally

licensed devices held by specific licensees. The proposal would prohibit specific licensees from possessing generally licensed devices under 10 CFR 31.5 at the same site. Any specific licensee possessing a device generally licensed under 10 CFR 31.5 at a site for which an SL is in place would be required to transfer the device to the authority of their SL. As noted, the possession and use of the device would then be subject to the terms and conditions of the user's SL. Any such device obtained by specific licensees in the future would be required to be obtained as a specifically licensed device. Under these requirements, all licensed material at a site where specifically licensed material is used would be governed by the same set of regulations.

This option to require all such devices to be held under the SL would make the requirements for these devices uniform with the other material held under the SL. All licensed material at a site (where specifically licensed material is used) would be governed by the same set of regulations and accounted for uniformly. The Commission believes that this proposal would reduce confusion and improve compliance with the regulations because a licensee would have to follow only one set of requirements at each site. This proposal would also reduce the number of generally licensed devices that the NRC would need to track.

If this approach is included in the final rule, it is anticipated that the restriction would be limited to devices used at sites covered by the SL. There may be specifically licensed entities, such as large corporations, that hold generally licensed devices at other sites where specifically licensed material is not used. Such operations may be quite independent of the specifically licensed activities. It would be too burdensome to apply the requirements connected with an SL to generally licensed devices at separate sites owned by the same licensed entity.

D. Specific Questions for Comment

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

(1) Whether the $\frac{1}{10}$ of IAEA Category 3 limit is the appropriate threshold level of byproduct material below which general licenses would still apply;

(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

$\frac{1}{10}$ of IAEA Category 3, then the general licensee must obtain an SL, or more simply, by using the IAEA Category 4 threshold level as the limit for the GL;

(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 generally licensed devices 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 document) is no longer working satisfactorily from the standpoint of protecting the public health and safety from routine use of these devices by general licensees; or

(4) Whether the approach regarding Compatibility Categories laid out in Section II.B of this document, *i.e.*, in which States have flexibility to adopt more rigorous requirements for general licensees, 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?

Concerning the proposal discussed in Section C of this document which would prohibit specific licensees from using GL devices under 10 CFR 31.5 and would require these devices to be possessed and used under an SL, the Commission requests comments to assist in its evaluation of the impacts of such a change on specific licensees and on how best to implement the change. Specific questions for comment:

(A) How should this change be applied in the case of devices used by a specific licensee at different locations? Would there be difficulties in determining which devices used by a given entity must be under the specific license, if the applicability of 10 CFR 31.5 were to be determined by the location of use, as suggested?

(B) How much time should be allowed for the specific licensees to transfer their currently held generally licensed GL devices to their SLs? Should devices currently held under the GL only be added to the SL only at the time of license renewal or amendment?

(C) Should the details of the voluntary transfer process in 10 CFR 31.5(c)(8)(iii) become mandatory and be maintained in the regulation to assist the process?

(D) Would there be a significant impact from the applicability of reciprocity requirements in 10 CFR

150.20 for portable gauges currently licensed under 10 CFR 31.5 and equivalent Agreement State regulations that are used in more than one jurisdiction? How would this proposal affect servicers of devices currently operating under the reciprocity provision of 10 CFR 31.6 and equivalent provisions of Agreement States?

(E) Would it be preferable to maintain the applicability of 10 CFR 31.5, but to apply some or all of the terms and conditions of the SLs, *e.g.*, by removing the exemptions in 10 CFR 31.5(c)(10) for those holding an SL?

(F) How much impact would there be to 10 CFR 32.51 licensees and Agreement State equivalent licensees to ensure that they are transferring these devices to entities without an SL?

(G) Should the sealed source and device registration certificates authorizing devices for use under 10 CFR 31.5 and equivalent Agreement State regulations be required to address transfers to both general and specific licensees?

E. Implementation of the Proposed Rule Amendments

The amended regulations would require a specific license for each device or source containing byproduct material meeting or exceeding $\frac{1}{10}$ of the IAEA Category 3 thresholds as listed in Appendix E to 10 CFR Part 20. Additional 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 general licensees would be notified that they need to obtain an SL (*e.g.*, by the regulator or by the manufacturer); how general licensees and/or NRC would identify the quantity of byproduct material in devices; how decay of the source radioactivity levels within generally licensed devices would 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**. Any general licensee that currently possesses generally licensed devices meeting or exceeding $\frac{1}{10}$ of the IAEA's Category 3 thresholds would be given an additional 90 days beyond the effective date of the final rule to submit an application for a specific license (*i.e.*, 150 days after the final rule is published in the **Federal Register**).

III. Discussion of Proposed Amendments by Section

10 CFR 31.5(a) General Domestic Licenses for Byproduct Material

The proposed rule would amend 10 CFR 31.5(a) to limit the quantity of byproduct material in generally licensed devices to below $\frac{1}{10}$ 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 would be required to become specifically licensed, and would become subject to all applicable regulations. Devices containing byproduct material below

these thresholds would continue to be generally licensed.

The values corresponding to Category 3 and $\frac{1}{10}$ of Category 3 (or 1/100 of Category 2) in Appendix E to 10 CFR Part 20 for byproduct material radionuclides are provided here as information along with the notes to the table.

Radioactive material	Category 3 (TBq)	Category 3 (Ci)	$\frac{1}{10}$ Category 3 (TBq)	$\frac{1}{10}$ 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.

10 CFR 31.5(b)(3)

A clarification concerning the applicable requirements for devices authorized for use under 10 CFR 31.5 but held under specific license would be added.

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 the NRC's requirements. The 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 10 CFR 31.5(a) and new section (b)(3), these sections would now be 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 would now be designated as Compatibility Category C. After considering the issues associated with the compatibility requirements for 10 CFR 31.6, this section would now be designated as Compatibility Category C.

For the reasons provided in Section B of this document, the NRC is proposing to designate 10 CFR 31.5(a), (b)(3), (c)(13)(i), and 31.6 as Compatibility Category C and, by so doing, Agreement States would have flexibility to adopt additional requirements, based on their circumstances and needs, if necessary. This would also allow Agreement States

the flexibility to adopt additional requirements for tracking the movement of service providers and the location of generally licensed devices. Designating 10 CFR 31.5(a) and 31.6 as Compatibility Category C would address 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 the NRC would address the issues and concerns raised by the State of Florida in their June 2005 request as part of the petition. Considering these issues in this rulemaking action 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: Revision.

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 $\frac{1}{10}$ of the IAEA Code of Conduct's Category 3 thresholds.

An estimate of the number of annual responses: 2,975 (1,575 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: 31,114.

Abstract: The NRC is proposing to amend its regulations to limit the amount of certain byproduct material in a generally licensed device to below $\frac{1}{10}$ 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. 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 September 2, 2009 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 INFCOLLECTS.RESOURCE@NRC.GOV and to the Desk Officer, Christine Kymn, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0016), Office of Management and Budget, Washington, DC 20503. Comments on the proposed information collections may also be submitted via Federal Rulemaking Web site <http://www.regulations.gov>, Docket ID NRC-2008-0272. 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 e-mail comments to Christine_J_Kymn@omb.eop.gov or comment by telephone at (202) 395-4638.

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 <http://www.regulations.gov>. Single copies of the draft regulatory analysis are available from Solomon Sahle, telephone (301) 415-3781, e-mail: solomon.sahle@nrc.gov, of the Office of Federal and State Materials and Environmental Management Programs.

XI. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule would not, if promulgated, have a significant economic impact on a substantial number of small entities. The proposed rule would affect about 280 NRC licensees and approximately an additional 1,120 Agreement State licensees possessing generally licensed devices with certain byproduct materials meeting or exceeding the $\frac{1}{10}$ 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 does not apply to this proposed rule because the amendments in this rule modify conditions of a general license for byproduct material, and do not involve any provisions that would impose backfits as defined in 10 CFR 50.109, 70.76, 72.62, and 76.76. Therefore, a backfit analysis has not been prepared for this proposed rule.

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 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), Public Law 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

2. In § 31.5, paragraph (a) is revised and paragraph (b)(3) is added to read as follows:

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

(a) 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 less than 1/100th of the thresholds listed in Appendix E of 10 CFR Part 20 for Category 2.

(b) * * *

(3) For devices meeting the criteria of this general license, but instead held under the authority of a specific license, all of the terms and conditions of the specific license apply in lieu of the provisions in this general license.

* * * * *

Dated at Rockville, Maryland, this 28th day of July 2009.

For the Nuclear Regulatory Commission,
Andrew L. Bates,
Acting Secretary for the Commission.
[FR Doc. E9–18438 Filed 7–31–09; 8:45 am]
BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2009–0663; Directorate Identifier 2007–SW–25–AD]

RIN 2120–AA64

Airworthiness Directives; Eurocopter France Model AS 332 C, L, L1, and L2; AS 350 B3; AS 355 F, F1, F2, and N; SA 365 N and N1; AS 365 N2 and N3; SA 366 G1; EC 130 B4; and EC 155B and B1 Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the specified model helicopters. This proposed AD results from mandatory

continuing airworthiness information (MCAI) originated by the European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community. The MCAI states that the AD is issued following a manufacturing nonconformity found on one batch of the servo-control caps. With a defective servo-control, rotation of the distributor might not be stopped mechanically since only friction of inner seals holds the distributor sleeve in its position. The proposed AD actions are intended to address the unsafe condition created by a manufacturing nonconformity found on one batch of servo-control caps. If not corrected this condition could cause untimely movements of servo-controls, which are used on main and anti-torque rotors, and lead to the loss of control of the helicopter.

DATES: We must receive comments on this proposed AD by September 2, 2009.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* 202–493–2251.

- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

You may get the service information identified in this proposed AD from American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, TX 75053–4005, telephone (972) 641–3460, fax (972) 641–3527, or at <http://www.eurocopter.com>.

Examining the Docket: You may examine the AD docket on the Internet at <http://www.regulations.gov> or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the economic evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Uday Garadi, Aviation Safety Engineer, Regulations and Policy Group, FAA, Rotorcraft Directorate, Fort Worth,

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS
AND ENVIRONMENTAL MANAGEMENT PROGRAMS
WASHINGTON, D.C. 20555

August 5, 2009

SUBJECT: NOTICE OF PUBLICATION OF PROPOSED RULE FOR PUBLIC COMMENT

ADDRESSEES

U.S. Nuclear Regulatory Commission (NRC) general licensees in possession of generally licensed devices containing byproduct materials listed in Appendix E of 10 CFR Part 20, in quantities 1/100 of International Atomic Energy Agency (IAEA) Category 2.

PURPOSE

This is to inform you that the NRC published a proposed rule in the Federal Register, dated August 3, 2009, titled "Limiting the Quantity of Byproduct Material in a Generally Licensed Device." You are receiving this announcement because your company is listed in the NRC's General License Tracking System as possessing one or more generally licensed devices containing byproduct material in excess of 1/100 of IAEA Category 2 (1/10 of IAEA Category 3) threshold values.

A copy of the proposed rule *Federal Register* notice is attached. The NRC is soliciting public comments on the proposed rule.

If you have any questions regarding this correspondence, please contact me at 301-415-7278 or the individual named below. Please note the comment period on the proposed rule ends on October 19, 2009.

POINT OF CONTACT: Solomon Sahle
TELEPHONE: (301) 415-3781

INTERNET: Solomon.Sahle@nrc.gov
FAX: (301) 415-5955

/RA/ K. Hsueh for
Mark R. Shaffer, Director
Division of Intergovernmental Liaison
and Rulemaking
Office of Federal and State Materials
and Environmental Management Programs

Enclosure:
Federal Register Notice

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and Environmental Management Programs

Enclosure:
Federal Register Notice

ML092150226

OFC	DILR	DILR	DILR
NAME	SSahle	KHsueh	MShaffer;KHsueh for
DATE	8/04/09	8/04/09	8/04/09

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS
AND ENVIRONMENTAL MANAGEMENT PROGRAMS
WASHINGTON, D.C. 20555

August 5, 2009

SUBJECT: NOTICE OF PUBLICATION OF PROPOSED RULE FOR PUBLIC COMMENT

ADDRESSEES

U.S. Nuclear Regulatory Commission (NRC) specific licensees who manufacture and/or distribute generally licensed devices containing byproduct materials listed in Appendix E of 10 CFR Part 20, in quantity 1/100 of International Atomic Energy Agency (IAEA) Category 2.

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
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August 5, 2009

SUBJECT: NOTICE OF PUBLICATION OF PROPOSED RULE FOR PUBLIC COMMENT

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Enclosure:
Federal Register Notice

ML092150233

OFC	DILR	DILR	DILR
NAME	SSahle	KHsueh	MShaffer;KHsueh for
DATE	8/04/09	8/04/09	8/05/09

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