RULEMAKING ISSUE
NOTATION VOTE

September 15, 2008 SECY-08-0137

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

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

PURPOSE:

The purpose of this paper is to request Commission approval to publish a proposed rule in the *Federal Register* that would amend 10 CFR Part 31. The proposed amendment would limit the quantity of byproduct material allowed in a generally licensed device to below one-tenth (1/10) of the International Atomic Energy Agency (IAEA) Category 3[1] threshold levels. The proposed rule would also modify the Compatibility Categories contained in the current regulations (10 CFR 31.5 and 31.6). This paper does not address any new commitments.

SUMMARY:

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

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

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

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

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

BACKGROUND:

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

During this period, additional security and control measures have been imposed by NRC on specific licensees that possess byproduct materials in quantities of concern, and improvements have been made in NRC's regulatory program to ensure that public health and safety and security are adequately protected. These measures have included the issuance of orders to specific licensees who possess IAEA Category 1 and 2 byproduct sources requiring them to exercise added control over such sources, as well as publishing a final rule, in November 2006, establishing a National Source Tracking System (NSTS) to provide better accountability and control over Category 1 and 2 sources. The NRC has also increased the frequency of inspections to further ensure that there is adequate control of these materials. Recently, NRC proposed, in a separate rulemaking (73 FR 2476, April 11, 2008), to expand the NSTS to also include sources equal to, or greater than, 1/10 of the IAEA Category 3 threshold so as to address concerns over potential malevolent aggregation of these lower activity sources to IAEA Category 2 levels. The NRC staff is currently evaluating the comments received on the

proposed rule; eighteen of the nineteen public comment letters received were opposed to expansion of the NSTS citing concerns that the rule may be premature and not necessary.

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

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

As part of this effort, the NRC staff submitted, for Commission review, SECY-06-0094 (April 24, 2006) entitled "Tracking or Providing Enhanced Controls for Category 3 Sources." In that paper, the staff proposed initiating a rulemaking that would set activity limits for generally licensed devices at one-half (1/2) of the IAEA Category 2 threshold and reserve authorization to possess higher activity sources to SLs. The staff noted that a benefit of setting such a limit would be greater oversight of these licensees, allowing regulatory bodies the opportunity to perform an assessment of a licensee's legitimacy or any other regulatory activities the Commission determined as being necessary. In response to SECY-06-0094, the Commission, in a Staff Requirements Memorandum dated June 9, 2006, approved the staff's plan to amend the GL requirements in Section 31.5, but disapproved the staff's recommendation to set the limit at 1/2 of IAEA Category 2. Instead, the Commission approved moving forward to evaluate requiring specific licensing of general licensees possessing devices greater than or equal to 1/10 of the IAEA's Category 3 threshold. The Commission also approved the staff's plan to amend certain associated manufacturer requirements in Part 32 and indicated the staff should consider standardizing the annual registration thresholds at 0.001 of the IAEA Code of Conduct D values (i.e., at about 0.001 of the IAEA Category 3 threshold levels).

The primary elements of the existing GL regulatory framework are contained in 10 CFR Part 31. A generally licensed device is designed with inherent radiation safety features so that it can be used by persons with no radiation training or experience. Thus, the GL regulatory program simplifies the licensing process because a case-by-case determination of the adequacy of the radiation training or experience of each user is not necessary. As part of the GL regulatory system, NRC evaluates the adequacy of generally licensed products by ensuring that manufacturers and distributors of the products meet the various specific requirements in 10 CFR Part 32. Section 31.5 contains requirements that generally licensed devices containing byproduct material in quantities above "registration" levels listed in §31.5(c)(13)(i) must be registered with the NRC or the Agreement State. The GL registration program is primarily intended to ensure that general licensees are aware of and understand the requirements for the possession of devices containing byproduct materials and that such devices are maintained and transferred properly and not inadvertently discarded.

DISCUSSION:

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

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

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

Requiring certain general licensees to obtain SLs, if their generally licensed devices contain sources greater than or equal to 1/10 of IAEA Category 3, would involve sources in Category 3

[2] IAEA Safety Standards Series No. RS-G-1.9 "Categorization of Radioactive Sources"

as well as sources in the “high end” of the IAEA Category 4 radioactivity range (i.e., those that are greater than or equal to 1/10 of the Category 3 threshold). Category 3 sources are defined by IAEA as ‘”dangerous sources”, i.e., a source that could, if not under control, give rise to exposure sufficient to cause severe deterministic effects, and thus even without any aggregation there is rationale for specifically licensing devices with Category 3 sources. In addition, Category 3 sources could be readily aggregated to Category 2 levels, as part of a concerted effort to do so, as they represent sources with activity levels that range from just below the Category 2 threshold down to 1/10 of the Category 2 threshold. Thus, sources at the high end of the range of activities in Category 3 can be at levels just below the threshold of a Category 2 source, meaning that it could take only a few devices with such sources to aggregate to Category 2. The principal type of licensees who possess devices with Category 3 sources are those with industrial gauges and, because these devices are relatively widespread in use and relatively broadly used in industry, there would be potential for aggregation of sufficient numbers of the devices and their sources to Category 2 levels.

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

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

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

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

Limiting the quantity of byproduct material allowed in generally licensed devices to below 1/10

of the IAEA's Category 3 thresholds would result in about 280 NRC general licensees, and about 1,100 Agreement State licensees, applying for SLs. There would be added costs to these licensees as a result of this proposed amendment including the cost of complying with existing requirements for specific licensees, including those in Parts 19, 20, and 30; increase in cost of fees associated with the license (i.e., either a GL or a SL); and the costs of any revisions needing to be made to a sealed source and device (SS&D) registration certificate. In addition, these licenses could bear the costs of complying with the expanded NSTS if it goes forward as proposed in the April 11, 2008, *Federal Register* notice. The added number of specific licensees would also result in an increase in NRC and Agreement State resources devoted to reviewing the new SL applications and inspecting licensees. However, these resources are not considered significant because the number of additional general licensees that would obtain SLs represent an increase of only about 6 percent of the existing specific licensee population.

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

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

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

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

The need for this proposed amendment to the GL regulatory system was not foreseen in detail in 1999 and 2000 when NRC issued the rule amendments instituting the GL registration system. As noted above, the principal rationale for the GL registration program was to make general licensees more aware of applicable requirements, hence reducing the potential for improper handling or disposal of devices due to lack of knowledge or inadvertent misuse, and

the belief that if general licenses are aware of their responsibilities they will comply with requirements for proper handling and disposal of generally licensed devices. The current rulemaking proposed to the Commission seeks to reflect the changed domestic and international threat environments, and related U.S. Government-supported international initiatives in the nuclear security area, by setting an upper limit for licensing of generally licensed devices.

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

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

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

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

licensees that possess sources that can be aggregated to quantities of concern, thus making NRC actions more efficient and effective.

The rulemaking will be conducted in an open process. The proposed rule will be published in the *Federal Register* for a 75-day public comment period. The draft proposed rule was prepared with participation by Agreement State representatives and the draft proposed rule was provided to the Agreement States for preliminary review. The rule was also provided to the Standing Committee for Compatibility, which was established as a Management Directive 5.3 working group including State representatives to enhance the existing compatibility determination process and which provides an independent review and assessment of NRC staff designations for the compatibility designation for each new or revised program element. It is anticipated that to assist licensees in implementing the requirements of this rule amendment that NRC would provide licensees with licensing guidance related to specific licensing application and possession process at or around the effective date of the final rule.

Other Considerations

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

Agreement State Issues

A copy of the draft proposed rule FRN was provided to the States on May 2, 2008, so they could have an early opportunity for review. Three States, Washington, New Jersey, and Illinois provided comments on the draft FRN. Two of the States commented that the quantity of byproduct material in generally licensed devices should be limited to Category 4 levels

(1/100 Category 3), while one State commented that they are not in favor of this method of providing additional oversight for generally licensed devices.

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

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

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

RECOMMENDATIONS:

The staff recommends that the Commission:

1. Approve for publication, in the *Federal Register*, the proposed amendment to Part 31 of 10 CFR (Enclosure 1).

2. Note:
   a. That the proposed amendment will be published in the *Federal Register*, allowing 75 days for public comment.

   b. That the Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b).

   c. That a Regulatory Analysis has been prepared for this rulemaking (Enclosure 2).

   d. That appropriate Congressional committees will be informed of this action.

   e. That a press release will be issued by the Office of Public Affairs when the proposed rulemaking is filed with the Office of the Federal Register.

   f. Office of Management and Budget (OMB) review is required and a clearance package will be forwarded to OMB no later than the date the proposed rule is submitted to the Office of the Federal Register for publication.

RESOURCES:

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

COORDINATION:

The Office of the General Counsel has no legal objection to the proposed rulemaking. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections. The rule suggests changes in information collection requirements that must be submitted to OMB no later than the date the proposed rule is forwarded to the *Federal Register* for publication.

/RA Martin Virgilio for/

R. W. Borchardt
Executive Director
for Operations

Enclosures:
1. *Federal Register* Notice
2. Regulatory Analysis

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