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

May 1, 2009

SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-08-0137

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

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of May 1, 2009.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:
1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Klein
Commissioner Jaczko
Commissioner Lyons
Commissioner Svinicki
OGC
EDO
PDR

VOTING SUMMARY - SECY-08-0137

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. KLEIN	X				X	4/24/09
COMR. JACZKO	X				X	11/12/08
COMR. LYONS	X				X	11/3/08
COMR. SVINICKI	X				X	4/8/09

COMMENT RESOLUTION

In their vote sheets, all Commissioners approved the staff's recommendation and provided some additional comments. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on May 1, 2009.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: CHAIRMAN KLEIN

SUBJECT: SECY-08-0137 – PROPOSED RULE: LIMITING THE QUANTITY OF BYPRODUCT MATERIAL IN A GENERALLY LICENSED DEVICE (RIN 3150-AI33)

Approved __X__ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached __x__ None ___

SIGNATURE

4/24/2009

DATE

Entered on "STARS" Yes ✓ No ___

Chairman Klein's Comments on SECY-08-0137
Proposed Rule: Limiting the Quantity of Byproduct Material in a Generally Licensed Device (RIN 3150-AI33)

I approve for publication in the *Federal Register* the proposed amendment to 10 CFR Part 31 to limit the quantity of byproduct material that can be in a generally licensed device.

Along with Commissioner Lyons, I concur with the staff's assessment supporting a change to the compatibility of this rule from B to C to afford implementation flexibility to the Agreement States. I join Commissioners Jaczko and Svinicki in looking forward to the staff's analysis of comments received on this portion of the proposed rule.

I support Commissioner Svinicki's proposal to set the compliance date of this rule at 90 days after the final rule becomes effective in order to provide a realistic amount of time for communications with affected general licensees to occur. During the public comment period on the proposed rule, I would urge the staff and the Agreement States to reach out to general licensees to ensure they are cognizant of the possible impacts on them of the potential regulatory changes resulting from this rulemaking process.

Finally, as it evaluates comments on this proposed rule and information regarding the rule's burdens and safety benefits, the staff should be open to adjusting the threshold above which a specific license should be required or limiting the need for specific licensing to a subset of current generally licensed sources at or above 1/10th of IAEA Category 3.

Dale E. Klein 4/24/2009

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

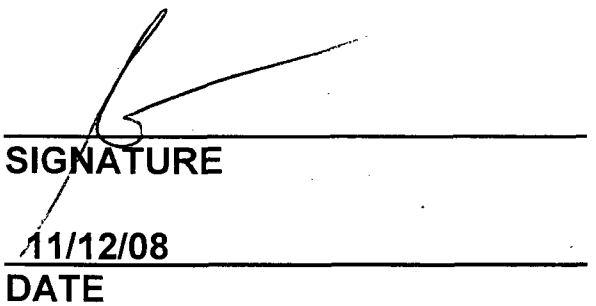
FROM: COMMISSIONER JACZKO

SUBJECT: SECY-08-0137 – PROPOSED RULE: LIMITING THE QUANTITY OF BYPRODUCT MATERIAL IN A GENERALLY LICENSED DEVICE (RIN 3150-AI33)

Approved __X__ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached _X__ None ___



SIGNATURE

11/12/08

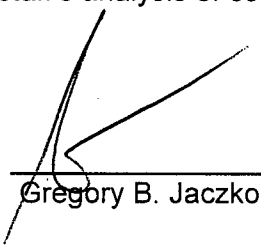
DATE

Entered on "STARS" Yes _X_ No ___

Commissioner Jaczko's Comments on SECY-08-0137

I approve the staff's proposal to publish a proposed rule that would amend 10 CFR Part 31. I support the staff's proposal to limit the quantity of byproduct material allowed in a generally licensed device to below one-tenth of the International Atomic Energy Agency Category 3 threshold levels. I believe that this will help to mitigate security concerns regarding these devices.

The staff has proposed that the Agreement State compatibility be revised from a "B" to a "C," and the Federal Register Notice will specifically ask for comments on this portion of the proposed rulemaking. I look forward to seeing the staff's analysis of comments received on this portion of the proposed rule.



11/12/2008

Gregory B. Jaczko Date

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

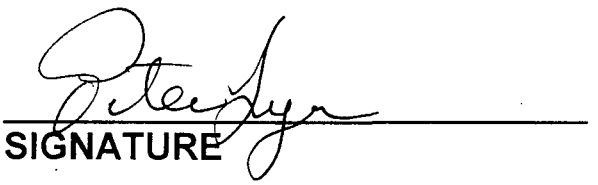
FROM: COMMISSIONER LYONS

SUBJECT: SECY-08-0137 – PROPOSED RULE: LIMITING THE QUANTITY OF BYPRODUCT MATERIAL IN A GENERALLY LICENSED DEVICE (RIN 3150-AI33)

Approved __X__ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached _X_ None ___



SIGNATURE

11/3/08

DATE

Entered on "STARS" Yes X No ___

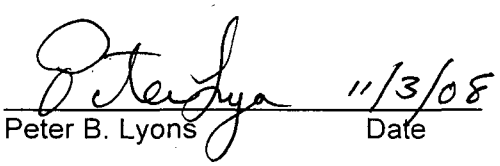
Commissioner Lyons' Comments on SECY-08-00137

I approve the staff's proposal with the following comments. I appreciate the efforts of NRC and the Agreement State staffs in developing this rulemaking package. The proposed action will maintain a focus on health and safety and continue a strong Agreement State role in the nation's materials program. I approve limiting the quantity of byproduct material allowed in devices used under the general license provision of 10 CFR 31.5 to below one-tenth (1/10) of IAEA Category 3 threshold levels.

I view accountability for safety and source tracking for security as two distinct, but related, issues. I don't believe that both the general license and the source tracking must have the same threshold levels. However, once the Commission decides on a threshold for source tracking, tracking should, at that time, be required for sources possessed by both specific and general licensees.

NRC staff analyzed the proposed rule in accordance with Management Directive 5.9. "Adequacy and Compatibility of Agreement State Programs" and determined that a change in compatibility from B to C was warranted. I concur with staff's assessment to change the compatibility as noted in the proposed rule to afford implementation flexibility to the Agreement States.

The general license provision of 10 CFR 31.5 should also be conditioned to indicate that it is not applicable when the user of the product also holds a specific license authorizing possession because, in that case, possession and use of the radioactive material would be subject to the terms and conditions of the user's specific license. This should improve overall compliance with NRC and Agreement State requirements.



Peter B. Lyons 11/3/08

Peter B. Lyons Date

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER SVINICKI

SUBJECT: SECY-08-0137 – PROPOSED RULE: LIMITING THE QUANTITY OF BYPRODUCT MATERIAL IN A GENERALLY LICENSED DEVICE (RIN 3150-AI33)

Approved __XX__ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached _XX_ None ___

SIGNATURE

04/8/09

DATE

Entered on "STARS" Yes √ No ___

Commissioner Svinicki's Comments on SECY-08-0137
Proposed Rule: Limiting the Quantity of Byproduct Material
in a Generally Licensed Device (RIN 3150-AI33)

I approve for publication in the *Federal Register* the proposed amendment to 10 CFR Part 31 as submitted by the staff (Enclosure 1 to SECY-08-0137). I have attached some minor edits to the proposed *Federal Register* notice and make the following, additional comments.

I agree with the comment of Commissioner Lyons in his vote, that the appropriate demarcation between generally and specifically licensed devices – one which will best provide for their safe use, transport, and handling -- is a matter separate and distinct from the establishment of the tracking threshold for such devices, which has been put in place uniquely for the purpose of physical security. Consequently, I have examined issues related to the expansion of the current National Source Tracking System, as a separate matter, in my vote on SECY-09-0011.

I note also that the staff has proposed to establish the Agreement State compatibility for this rule as Category C. As stated by Commissioner Jaczko, I look forward to reviewing the public comments received on this proposal.

Finally, the staff has proposed that the effective date of the final rule would be 60 days after it is published in the *Federal Register* and that, by that same date, any licensee possessing generally licensed devices meeting or exceeding the new rule's thresholds must have submitted an application for a specific license. Based on recent NRC experiences in communicating with holders of general licenses (e.g., owners of tritium exit signs), it may well take the entirety of those 60 days merely to communicate the new rule's requirements to the approximately 300 NRC licensees impacted and to educate them on the steps necessary to submit an application for a specific license. Additionally, as the specific license will subject holders to significantly higher licensing fees, some small entities may need time to evaluate whether they want to apply for a specific license or discontinue holding these devices. I propose, therefore, that the final rule become effective 60 days after publication, but that the compliance date for existing holders of generally licensed devices that would be subject to the new requirements be set at 90 days after the effective date. This schedule would provide a realistic amount of time for communications with affected general licensees to occur and for them to complete the steps necessary to file their applications.

Kristine L. Svinicki 04/8/09

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

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

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

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

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

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

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

A.1 Congressional Concerns/GAO Investigations

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

A.2 Agreement State Issues

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

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

A.3 Recent NRC Actions

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

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

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

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

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

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

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

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

C. Implementation of the proposed rule amendments

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

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

X

OGC to edit consistent with FLS note comment.