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

January 30, 2012

SECRETARY

# COMMISSION VOTING RECORD

DECISION ITEM: SECY-11-0129

TITLE: FINAL RULE: REQUIREMENTS FOR DISTRIBUTION OF BYPRODUCT MATERIAL, 10 CFR PARTS 30, 31, 32, 40, AND 70 (RIN 3150-AH91)

The Commission (with all Commissioners agreeing) approving in part and disapproving in part the subject paper as recorded in the Staff Requirements Memorandum (SRM) of January 30, 2012.

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 Jaczko
Commissioner Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff
OGC
EDO
PDR

# VOTING SUMMARY - SECY-11-0129

## RECORDED VOTES

| | APRVD | DISAPRVD | ABSTAIN | NOT PARTICIP | COMMENTS | DATE |
|---|---|---|---|---|---|---|
| CHRM. JACZKO | X | X | | | X | 12/14/11 |
| COMR. SVINICKI | X | X | | | X | 12/21/11 |
| COMR. APOSTOLAKIS | X | X | | | X | 12/19/11 |
| COMR. MAGWOOD | X | X | | | X | 12/29/11 |
| COMR. OSTENDORFF | X | X | | | X | 12/7/11 |

# AFFIRMATION ITEM

## RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Chairman Gregory B. Jaczko

SUBJECT: SECY-11-0129 – FINAL RULE: REQUIREMENTS FOR DISTRIBUTION OF BYPRODUCT MATERIAL, 10 CFR PARTS 30, 31, 32, 40, AND 70 (RIN 3150-AH91)

Approved _X_ Disapproved _X_ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached _X_ None ___

SIGNATURE

12/14/11

DATE

Entered on "STARS" Yes _x_ No ___

**Chairman Jaczko's Comments on SECY-11-0129,**
**"Final Rule: Requirements for Distribution of Byproduct Material,**
**10 CFR Parts 30, 31, 32, 40, and 70"**

I approve some parts, and disapprove other parts, of this proposed final rule. This rule is intended to revise the regulations to make the requirements for distributors of byproduct material clearer, less prescriptive, and more risk-informed and up-to-date. For the most part, this proposed rule does just that; however, I have some concerns as described below.

As I indicated in my vote on the proposed rule in September 2009, I do not agree that a new class exemption should be added to the rule. The agency is generally moving towards more accountability of radioactive material, not less. Therefore, staff should remove the provision for a new class exemption.

Staff has requested that the Commission reconsider its previous direction given during the proposed rule phase, and now approve development of a proposed rule that would revise the safety criteria for products to be used under the existing class exemptions and the general license in 10 CFR 31.5. In February 2010, the Staff Requirements Memorandum for the proposed rule had directed the staff to instead consider revision of these safety criteria as part of its effort to develop the technical basis for possible revision of the NRC's radiation protection regulations to be consistent with the 2007 recommendations of the ICRP (ICRP-103). In the SECY paper for this final rule, staff has indicated that "[t]he existing criteria for the approval of devices under §31.5 present both safety and security concerns." My staff has discussed this issue with FSME staff and it would appear that although there are currently no devices licensed under these safety criteria that could cause a concern, there is the possibility for an applicant to apply for such a device in the future. Therefore, staff should continue to follow the previous direction regarding the revision of the safety criteria but should notify the Commission if it appears that there is an applicant for a device that could lead to safety or security concerns under the current regulations.

In this rule, staff has proposed imposing a quantity limit in order to, among other things, address concerns about aggregation and misuse of exempt sources. In his vote, Commissioner Ostendorff has disapproved the staff's recommendation of a quantity limit in exempt devices, stating that "there is no clear threat of such an occurrence or indication that this scenario is likely beyond the notion that aggregation is possible." I disagree with Commissioner Ostendorff on this point. As relayed in several media outlets a few years ago, a British national was found guilty and sentence to life in prison after pleading guilty to planning attacks on financial centers, with some plans including the use of radioactive material obtained from purchasing smoke detectors. His plans were meant to cause "injury, fear, terror, and chaos," as specifically discussed in NRC's Fact Sheet on Dirty Bombs. Also, the interagency 2010 Radiation Source Protection and Security Task Force Report discusses the fact that some radionuclides may be of concern when aggregated. In addition, the staff has indicated that there are other benefits to quantity limitations, such as the fact that lower quantities will contribute to the ability to ensure that overall impacts to waste disposal workers are not significant. Therefore, I support staff's approach of using quantity limits to help ensure the safety and security of exempt devices.

12/14/11

Gregory B. Jaczko Date

# AFFIRMATION ITEM

## RESPONSE SHEET

**TO:** Annette Vietti-Cook, Secretary

**FROM:** COMMISSIONER SVINICKI

**SUBJECT:** SECY-11-0129 – FINAL RULE: REQUIREMENTS FOR DISTRIBUTION OF BYPRODUCT MATERIAL, 10 CFR PARTS 30, 31, 32, 40, AND 70 (RIN 3150-AH91)

**Approved** XX In Part **Disapproved** XX In Part **Abstain** _____

**Not Participating** _____

**COMMENTS:** Below ___ Attached XX None ___

SIGNATURE

12/21/11
DATE

**Entered on "STARS"** Yes ✓ No ___

**Commissioner Svinicki's Comments on SECY-11-0129 – Final Rule: Requirements For Distribution of Byproduct Material, 10 CFR PARTS 30, 31, 32, 40, and 70 (RIN 3150-AH91)**

I approve for publication in the *Federal Register* the final amendments to 10 CFR Parts 30, 31, 32, 40, and 70 (Enclosure 1 to SECY-11-0129), subject to the attached edits. I certify that this rule, if promulgated, will not have a significant impact on a substantial number of small entities, as noted in the *Federal Register* notice. I agree with Commissioner Ostendorff that the rule should be revised to remove the quantity limit for the proposed new exemption class and that the statements of consideration should clarify that the basis for the misuse criteria is safety. The safety criteria for the new class exemption will ensure that devices containing material in quantities that may pose a safety concern are subject to appropriate controls.

I disapprove the initiation of the development of an additional proposed rule to revise the safety criteria in 10 CFR Part 32. The staff should continue to follow the existing direction to consider revision of the safety criteria as part of its effort to develop the technical basis for possible revision of the NRC's radiation protection regulations to align more closely to the recommendations of ICRP-103.

Kristine L. Svinicki 12/21/11

No. ML082910862), and NUREG-1717. The applicable requirements in § 32.14(b) require information to be submitted to allow an evaluation of the potential radiation exposure and, in accordance with § 32.14(d), the NRC makes a determination that the byproduct material is "properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling." But the information to support this evaluation of the particular product is not considered necessary to routinely provide to the Agreement States through the SS & D Registry.

No sealed source and device review is conducted for the products used under the general licenses in §§ 31.8 or 31.11. The general license in § 31.8 is specifically for no more than 0.185 MBq (5 μCi)[2] of americium-241 or radium-226 in the form of calibration and reference sources, and applies only to specific licensees. The safety of these sources is also well established, with the individual product being reviewed and approved in the licensing process. The general license in § 31.11 pertains to in-vitro clinical or laboratory testing using prepackaged units containing certain limited quantities of byproduct material, e.g., iodine-125 in units not exceeding 10 μCi (0.37 MBq). These ~~in~~ in-vitro kits are not sealed sources or devices. They can be used only by physicians, clinical laboratories, hospitals, and practitioners of veterinary medicine who preregister with the Commission and by Part 35 licensees. There is also no SS & D registration for the recently added general license in § 31.12, which covers only items produced prior to the NRC gaining jurisdiction over radium-226. Because there is no allowance for future production of items to be used under this general license, there are no associated distributor requirements and thus, no requirement for a product to be registered in

[2] The NRC's policy on units calls for new and amended regulations to use the International System of Units (SI) with the English unit equivalent following in parentheses. In this document, a number of references are made to existing regulations that are currently in English units; in referencing such values, the actual regulatory value is given first with the SI unit equivalent, sometimes a rounded approximation, following in parentheses. Also, when discussing comments, units used by the commenter are used.

sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA). Thus, it is appropriate for licensees to consider new developments in technology and standards as they may impact ALARA in the design of products. However, because § 32.210(f) requires the certificate holder to manufacture and distribute products in accordance with the provisions of the registration certificate and any statements made in the request for registration, and no reevaluation of a source or device, once approved, is normally required, the regulatory structure may limit rather than encourage industry improvement.

There may be reasons to reevaluate a sealed source or device in some circumstances with regard to either the actual design of a source or device, or such other aspects as quality assurance or information provided to the user on safe use. While the current regulations provide adequate authority to do so, recalling a registration certificate for review and reissuance in the absence of a significant safety problem with the product is an activity very rarely conducted by the NRC in the past. This final rule also includes an explicit provision to specifically address such a process in § 32.210(h). The Commission will complete such an evaluation in accordance with the criteria specified in § 32.210. As noted under Section II. A.1, "Updating Regulations to Add Registration Requirements," of this document, this final rule adds specific provisions delineating which sealed sources and devices must be registered in the SS & D Registry, broadening the applicability of § 32.210 to some generally licensed and exempt products. The Commission may use the new provision in § 32.210(h) to update the certificate with respect to applicable ~~industry~~ current regulatory standards ~~or current security concerns~~ or to ensure the quality of the summary of safety information and the information on conditions of use contained in the registration certificate that is available to the various jurisdictions.

the new class exemption include additional criteria to ensure that the radionuclide quantities allowed for use under the exemption are limited, such that the maximum possible dose is controlled, even if the circumstances leading to such a dose are extremely improbable.

The accident criteria currently in § 32.23(d), § 32.24, Column IV, § 32.27(c), § 32.28, Column III, and § 32.51(a)(2)(iii) were expected to limit the total amount of radioactive material likely to be approved for use under the relevant exemption or general license, irrespective of the design to contain or shield the material. However, designs to contain the material even under severe conditions of use or accident have resulted in relatively large quantities of materials being approved in some cases. Although the radiological risk is well controlled by these designs, possible scenarios of misuse or malicious use are not required to be evaluated.

For this new exemption, a criterion is included requiring that specific scenarios of misuse be analyzed and shown to meet certain dose limits. The analysis required to meet this misuse criterion will be relatively simple. Evaluating actual risk from possible misuse ~~or malicious use~~ would be much more difficult, but such risks will be limited by this misuse criterion. The criterion is 100 mSv (10 rem), plus an additional skin dose criterion. This criterion is slightly lower than the accident criterion of 15 rem (150 mSv) applicable to products covered by the existing class exemptions and the general license in § 31.5. This criterion is considered to be a more appropriate value given the high level of uncertainty in estimates of doses under accident conditions.

Limiting the radionuclide quantities allowed for use under the exemption, even if well contained, has the additional benefits of: 1) minimizing risks associated with devices becoming subject to scrap metal recycling, such as property damage due to contamination resulting from smelting; 2) further controlling overall impacts to waste disposal workers; 3) minimizing overall impacts to the environment from uncontrolled disposal of products used under exemptions from licensing; and 4) minimizing the potential problems of products exempted by the NRC being

# AFFIRMATION ITEM

## RESPONSE SHEET

**TO:** Annette Vietti-Cook, Secretary

**FROM:** Commissioner Apostolakis

**SUBJECT:** SECY-11-0129 – FINAL RULE: REQUIREMENTS FOR DISTRIBUTION OF BYPRODUCT MATERIAL, 10 CFR PARTS 30, 31, 32, 40, AND 70 (RIN 3150-AH91)

**Approved** X **Disapproved** X **Abstain** _____

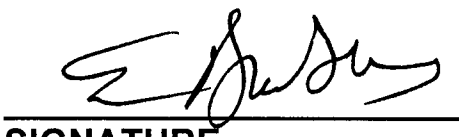
**Not Participating** _____

**COMMENTS:** **Below** X **Attached** ___ **None** ___

I approve staff's recommendation to publish the final amendments to 10 CFR Parts 30, 31, 32, 40 and 70. I concur with staff's assessment that this rule, if promulgated, will not have a significant impact on a substantial number of small entities.

I do not approve staff's recommendation to conduct an additional rulemaking to revise the safety criteria in 10 CFR Part 32. Staff provided no compelling rationale to change a previous Commission decision.

I agree with Commissioner Ostendorff that the statements of consideration should clarify the basis for the misuse criteria.



**SIGNATURE**

12/19/11

**DATE**

**Entered on "STARS"** Yes x No ___

# AFFIRMATION ITEM

## RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MAGWOOD

SUBJECT: SECY-11-0129 – FINAL RULE: REQUIREMENTS FOR DISTRIBUTION OF BYPRODUCT MATERIAL, 10 CFR PARTS 30, 31, 32, 40, AND 70 (RIN 3150-AH91)

Approved X Disapproved X Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached X None ___

SIGNATURE

29 December 2011
DATE

Entered on "STARS" Yes X No ___

**Commissioner Magwood's Comments on SECY-11-0129,**
**"Final Rule: Requirements for Distribution of**
**Byproduct Material, 10 CFR 30, 31, 32, 40, and 70"**

I approve staff's recommendation to proceed with publication of the final rule amending the 10 CFR Parts 30, 31, 32, 40, and 70 requirements for distribution and use of exempt and generally licensed byproduct material. I also approve staff's recommendation to redefine categories of devices to be used under exemptions, add explicit provisions regarding the sealed sources and devices registration process, and add flexibility to the licensing of users of sealed sources and devices. I also agree with Commissioner Ostendorff that the statement of consideration for the rule should clarify the basis for the "misuse" criteria.

I appreciate staff's recommendation to establish a quantity limit as part of the safety criteria for the new exemptions. However, other similar regulatory exemptions do not impose a quantity requirement and staff has not presented clear evidence or analysis that demonstrates either a safety or a security basis for a quantity limit. I cannot, therefore, support such a limit at this time. Nevertheless, I recognize that the security environment continues to evolve; for that reason, I invite staff to propose a path forward to better assess and define the potential safety and, particularly, security risks that might be mitigated by a quantity limit.

Finally, I see no basis to alter the Commission's previous guidance regarding the need for an additional rulemaking to revise the safety criteria in 10 CFR Part 32. Should staff encounter specific new information that warrants Commission reconsideration of its previous direction, I encourage staff to provide the Commission with a new notation voting paper that provides the factual basis for a change in course and options for moving forward.

12/29/11

**William D. Magwood, IV** **Date**

# AFFIRMATION ITEM

## RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER OSTENDORFF

SUBJECT: SECY-11-0129 – FINAL RULE: REQUIREMENTS FOR DISTRIBUTION OF BYPRODUCT MATERIAL, 10 CFR PARTS 30, 31, 32, 40, AND 70 (RIN 3150-AH91)

Approved X Disapproved X Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached X None ___

SIGNATURE

12/7/11
DATE

Entered on "STARS" Yes X No ___

**Commissioner Ostendorff's Comments on SECY-11-0129, "Final Rule: Requirements for Distribution of Byproduct Material, 10 CFR 30, 31, 32, 40, and 70"**

I approve in part and disapprove in part the final rule amending the 10 CFR Parts 30, 31, 32, 40, and 70 requirements for the distribution and use of exempt and generally licensed byproduct material, subject to the attached edits. I believe that, overall, the proposed revisions appropriately update and risk-inform these requirements. However, I do not think that there is a sufficient basis to limit the quantity of material in the devices under the new class exemption or to initiate a proposed rule revising the safety criteria in 10 CFR Part 32. Therefore, I disapprove of the quantity limit for the new class exemption and initiating a rule to revise the safety criteria. The statements of consideration should also clarify that the basis for the misuse criteria is safety, not security.

I continue to believe that there is not a clear safety or security risk reduction that would justify further regulatory actions related to low risk sources such as those in exempt devices. The safety criteria for the new class exemption will ensure that devices containing material in quantities that may pose a safety concern are subject to appropriate controls. The basis for the proposed quantity limit is a concern that exempt devices could be aggregated and used maliciously. Yet, there is no clear threat of such an occurrence or indication that this scenario is likely beyond the notion that aggregation is possible. Therefore, the rule should be revised to remove the quantity limit for the proposed new class exemption. In addition, while I agree with the inclusion of a misuse criteria to clarify the scope of the required safety analyses, the staff should modify the statements of consideration to clarify that the basis for this criteria is safety, not security.

Regarding the proposal to initiate a new rule to revise the 10 CFR Part 32 safety criteria, I agree with the Commission's previous position that there is no new information to support this change. The staff's analysis of this issue in SECY-09-0035 indicated that there was no compelling safety or security issue that requires rulemaking given the quantity and type of material contained in these devices. I therefore disapprove of initiating a separate rulemaking at this time.

protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA). Thus, it is appropriate for licensees to consider new developments in technology and standards as they may impact ALARA in the design of products. However, because § 32.210(f) requires the certificate holder to manufacture and distribute products in accordance with the provisions of the registration certificate and any statements made in the request for registration, and no reevaluation of a source or device, once approved, is normally required, the regulatory structure may limit rather than encourage industry improvement.

There may be reasons to reevaluate a sealed source or device in some circumstances with regard to either the actual design of a source or device, or such other aspects as quality assurance or information provided to the user on safe use. While the current regulations provide adequate authority to do so, recalling a registration certificate for review and reissuance in the absence of a significant safety problem with the product is an activity very rarely conducted by the NRC in the past. This final rule also includes an explicit provision to specifically address such a process in § 32.210(h). The Commission will complete such an evaluation in accordance with the criteria specified in § 32.210. As noted under Section II. A.1, "Updating Regulations to Add Registration Requirements," of this document, this final rule adds specific provisions delineating which sealed sources and devices must be registered in the SS & D Registry, broadening the applicability of § 32.210 to some generally licensed and exempt products. The Commission may use the new provision in § 32.210(h) to update the certificate with respect to ~~applicable industry~~ current regulatory standards, ~~or current security concerns~~ or to ensure the quality of the summary of safety information and the information on conditions of use contained in the registration certificate that is available to the various jurisdictions. Generally, the Commission has not made standards more restrictive with regard to

allowed for use under the exemption are limited, such that the maximum possible dose is controlled, even if the circumstances leading to such a dose are extremely improbable. The accident criteria currently in § 32.23(d), § 32.24, Column IV, § 32.27(c), § 32.28, Column III, and § 32.51(a)(2)(iii) were expected to limit the total amount of radioactive material likely to be approved for use under the relevant exemption or general license, irrespective of the design to contain or shield the material. However, designs to contain the material even under severe conditions of use or accident have resulted in relatively large quantities of materials being approved in some cases. Although the radiological risk is well controlled by these designs, possible scenarios of misuse or malicious use are not required to be evaluated. For this new exemption, a criterion is included requiring that specific scenarios of misuse be analyzed and shown to meet certain dose limits. The analysis required to meet this misuse criterion will be relatively simple. Evaluating actual risk from possible misuse ~~or malicious use~~ would be much more difficult, but such risks will be limited by this misuse criterion. The criterion is 100 mSv (10 rem), plus an additional skin dose criterion. This criterion is slightly lower than the accident criterion of 15 rem (150 mSv) applicable to products covered by the existing class exemptions and the general license in § 31.5. This criterion is considered to be a more appropriate value given the high level of uncertainty in estimates of doses under accident conditions.

Limiting the radionuclide quantities allowed for use under the exemption, even if well contained, has the additional benefits of: 1) minimizing risks associated with devices becoming subject to scrap metal recycling, such as property damage due to contamination resulting from smelting; 2) further controlling overall impacts to waste disposal workers; 3) minimizing overall impacts to the environment from uncontrolled disposal of products used under exemptions from licensing; and 4) minimizing the potential problems of products exempted by the NRC being