

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



May 14, 2007

SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-07-0062

TITLE: FINAL RULE: REQUIREMENTS FOR EXPANDED
DEFINITION OF BYPRODUCT MATERIAL (RIN: 3150-AH84)

The Commission (with all Commissioners agreeing) approved this final rule as noted in an Affirmation Session and recorded in the Staff Requirements Memorandum (SRM) of May 14, 2007.

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

A handwritten signature in black ink, appearing to read "Annette L. Vietti-Cook".

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:

1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Klein
Commissioner McGaffigan
Commissioner Merrifield
Commissioner Jaczko
Commissioner Lyons
OGC
EDO
PDR

VOTING SUMMARY - SECY-07-0062

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. KLEIN	X				X	5/3/07
COMR. McGAFFIGAN	X				X	4/26/07
COMR. MERRIFIELD	X				X	4/26/07
COMR. JACZKO	X				X	4/27/07
COMR. LYONS	X				X	5/1/07

COMMENT RESOLUTION

In their vote sheets, all Commissioners approved the final rule as noted in an Affirmation Session and reflected in the SRM issued on May 14, 2007.

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: CHAIRMAN KLEIN
SUBJECT: SECY-07-0062 - FINAL RULE: REQUIREMENTS FOR
EXPANDED DEFINITION OF BYPRODUCT MATERIAL
(RIN: 3150-AH84)

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below _____ Attached X None _____



SIGNATURE

5/3/07

DATE

Entered on "STARS" Yes No _____

Chairman Klein's Comments on SECY-07-0062

I approve, as revised below, the staff's proposed Final Rule on the Requirements for Expanded Definition of Byproduct Material. This is a complex rulemaking that required interaction with multiple stakeholders, including regulatory programs in both the Agreement and non-Agreement States. I commend the staff for the exceptional effort to conduct such a complex rulemaking, and for employing innovative methods to expedite the process.


Clearly, development of a discrete source definition was a difficult undertaking. This is an area, as Commissioner Merrifield indicated, where a small change could result in large unintended consequences, and it is important that the definition be clear as to what it includes and excludes. I believe both the proposed discrete source definition and the discussion in the Statements of Consideration should be further clarified. The revised definition proposed in Commissioner McGaffigan's vote removes unnecessary ambiguity, and I approve its inclusion in the final rule. To ensure this revised definition has the intended result, during the five years following the effective date of the rule, staff should assess licensee and Agreement State implementation of the definition to determine if significant unintended consequences occur.

I agree with my colleagues that the discussion in the Statements of Considerations on military use of the newly added byproduct material should be clarified. I believe the implementation of the EAct with respect to military uses of radioactive material can and should remain consistent with the Commission's longstanding policy of providing regulatory oversight of material in the possession of the military, except when used in military operations. Therefore, the Statements of Consideration should be revised to indicate that byproduct material in the possession of military operational forces will not be subjected to NRC oversight, but that other military uses will be subject to NRC oversight consistent with current Commission policy. This approach will provide consistent and predictable NRC oversight for all byproduct material, regardless of whether in the possession of the military or when the material is transferred from the military to the civilian sector for commercial use or disposal.

Appropriate communication of the new requirements to affected users of the newly added byproduct material and coordination with the States is imperative for a smooth transition of authority and successful implementation of the final rule. To this end, I agree with the following additional communication and coordination activities proposed by my colleagues:

- The staff should interact with the Department of Defense to obtain a common understanding of the military uses of this material to resolve any specific potential conflicts on a case-by-case basis.
- The staff should take steps to ensure appropriate communication of these requirements to existing users who will become specific and general licensees, such as prominently highlighting the new requirements and upcoming changes on NRC's web site.
- The staff should share the revised definition of discrete source with the Agreement State representatives on the rulemaking working group prior to finalizing the rule, and informally transmit the revisions to the Statements of Consideration to the Commission before the final rule is published.

I also support Commissioner Lyons' recommendation on seeking Agreement State views when the Commission is considering a change to rule language that could impact the States.


Dale E. Klein 5/3/10
Date Date

AFFIRMATION ITEM

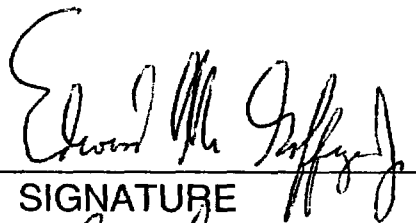
RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER MCGAFFIGAN
SUBJECT: **SECY-07-0062 - FINAL RULE: REQUIREMENTS FOR
EXPANDED DEFINITION OF BYPRODUCT MATERIAL
(RIN: 3150-AH84)**

Approved Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below _____ Attached None _____



SIGNATURE
April 26, 2007

DATE

Entered on "STARS" Yes No _____

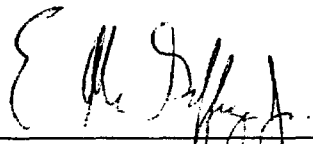
Commissioner McGaffigan's Comments on SECY-07-0062

I approve for publication in the *Federal Register* the final amendments to 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171 to include jurisdiction over discrete sources of radium-226, accelerator-produced radioactive materials, and discrete sources of naturally-occurring radioactive material, as required by the Energy Policy Act of 2005 (EPAc).

I continue to appreciate the good work of the NRC staff on this rulemaking, particularly in light of the complex and difficult nature of some of the issues. There are, however, two areas where I believe the staff should amend the rule and Statements of Consideration (SOC) to more clearly describe the changes that were made since publication of the proposed rule. The first of these areas is the definition of "discrete source." The second is the new determination that discrete sources of radium-226 that are still under the control of the military do not constitute "commercial use" under the EPAc and are, therefore, outside the Commission's jurisdiction.

With respect to the definition of "discrete source," I believe both the proposed definition and the accompanying SOC should be clearer. I propose to maintain just two conditions of the proposed definition, and reorganize them as follows: A discrete source is "a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities." The accompanying SOC text should clearly describe the meaning and purpose of the remaining two conditions in the definition of "discrete source."

On the second matter, with regard to the general license provisions in the new 10 CFR 31.12, the staff has, since the issuance of the proposed rule, construed the phrase "commercial, medical, or research activity," in the new definition of byproduct material to mean that military use of these materials is excluded from NRC jurisdiction. This exclusion is limited to luminous gauges and other items containing radium-226 installed in air, marine, or land vehicles still under control of the military. Nonetheless, the SOC should be absolutely clear that this exclusion is limited to Atomic Energy Act (AEA) 11e.(3)(A) radium-226-bearing materials and that AEA 11e.(3)(B) accelerator-produced material for use in medical or research activities conducted by the Department of Defense falls squarely under NRC jurisdiction. We cannot and should not exempt military medical centers while covering VA medical centers. All of these facilities hold NRC licenses.



Edward McGaffigan, Jr.

4/26/07

(Date)

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER MERRIFIELD
SUBJECT: **SECY-07-0062 - FINAL RULE: REQUIREMENTS FOR
EXPANDED DEFINITION OF BYPRODUCT MATERIAL
(RIN: 3150-AH84)**

Approved Disapproved Abstain

Not Participating

COMMENTS: Below Attached None



SIGNATURE

4/26/07

DATE

Entered on "STARS" Yes No

Comments from Commissioner Merrifield on SECY-07-0062:

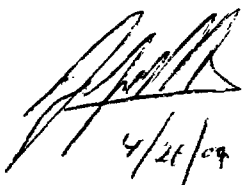
I approve as revised in the following paragraphs the staff's proposed final rule as described in SECY-07-0062, Final Rule: Requirements for Expanded Definition of Byproduct Material. But first I want to compliment the staff on their efforts to complete this rulemaking in a very tight time frame. This is a complex rulemaking where small changes in one section can result in large unintended consequences in another section. In addition, there are many stakeholders directly affected by this final rule and the transition period will require diligence to complete in a safe and timely manner. I have every confidence that the staff will be successful in this endeavor.

There are two areas that require revisions to the rule and/or Statements of Consideration. The specific revision to the Statements of Consideration discussed below should be informally transmitted to the Commission before the final rule is sent to the publisher to give the Commission a final quick review of what is being proposed.

The first area is the definition of a discrete source. After the paper was submitted to the Commission, there were additional discussions on the definition of a discrete source. The compromise reached for the new definition of a discrete source is as follows. "Discrete Source means a radionuclide that has been processed so that so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities." I approve this revised version of the definition.

The second area concerns military uses of this byproduct material. Starting on page 38, the current Statements of Considerations state that the "Commission has determined that discrete sources of radium-226 still under the control of the military do not constitute 'commercial use' under the EAct and are, therefore, outside the Commission's jurisdiction." The short justification provided basically states that because the EAct does not specifically mention that military use falls under our justification then the NRC does not have regulatory authority in this area. This is an interpretation of the wording in the EAct and is basically a Commission policy statement. However, as stated, this is a very broad policy statement which could have a number of unintended consequences.

I will approve this policy statement if the Statements of Consideration are modified to provide a paragraph describing some details of what this determination means. I have no objections to stating that while the material is in possession of the military operational forces it is outside of the EAct. But when it is used by the military in medical or research activities that are not being conducted under DOE authorization or is material that is transferred from the military to the civilian sector for commercial use or disposal, then it is regulated by the NRC. There is an acknowledged potential inconsistency between military applications and controls and civilian requirements for this same material. I do not expect the Statements of Consideration to articulate every potential unintended consequence or resolve all potential conflicts that may arise. But the Statements of Consideration should indicate that the NRC will interact with the Department of Defense to obtain a common understanding of the uses of radium-226 by the military and to resolve any specific potential conflicts on a case by case basis.



4/26/09

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: **COMMISSIONER JACZKO**
SUBJECT: **SECY-07-0062 - FINAL RULE: REQUIREMENTS FOR
EXPANDED DEFINITION OF BYPRODUCT MATERIAL
(RIN: 3150-AH84)**

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below _____ Attached X None _____



SIGNATURE

4/27/07

DATE

Entered on "STARS" Yes X No _____

Commissioner Jaczko's Comments on SECY-07-0062
Final Rule: Requirements for Expanded Definition of Byproduct Material

I approve the staff's recommendation to publish in the *Federal Register* the final amendments to 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171. These amendments establish the criteria for expanding the Nuclear Regulatory Commission's authority for discrete sources of radium-226 and naturally occurring radioactive material, and accelerator produced materials as required by the Energy Policy Act of 2005 (EPAcT). This amendment also establishes the definition for a discrete source as required by the EPAcT.

The EPAcT required the staff to complete this rulemaking on the fast track. Given the breadth and complexity of this rulemaking, I believe the staff has done a laudable job in providing the Commission with very good product. I believe, however, that there are a couple of areas that require modification prior to publication in the *Federal Register*.

Regarding the definition of the "discrete source," I continue to believe that a minimum level of compatibility may be needed. One of the principle reasons for the augmentation of the Commission's authority in this area was to provide uniformity among states in the use of accelerator-produced and naturally occurring radioactive materials. As a matter of policy the Commission has required Agreement States to adopt certain legal and technical definitions, essentially verbatim, into their regulations. I believe that the definition of discrete source meets the threshold for being both a legal and technical definition.

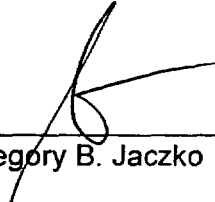
I am not suggesting that the Commission change the adequacy determination for the discrete source definition, at this time. I believe, however, that the staff should monitor the potential impact of the health and safety adequacy determination over a period of two to three years once states have adopted the rule and inform the Commission of any impacts on licensees operating across jurisdictions.

The definition of discrete source developed by the staff upon inspection does not appear to clearly define the radioactive materials it is intended to cover. Including the phrase "that is distinct from the sources present in nature" within the definition seems preferential to radioactive materials converted in an accelerator. The definition should clearly capture all of the materials identified in the statute. I am certain that radium-226 purposely concentrated for any one of the applications identified in the statute is not distinct from radium-226 that exists in nature. Radium-226 is radium-226. Thus, I agree with Commissioner McGaffigan's definition of discrete source. I also believe that the language in the Statements of Consideration should be clarified to communicate the conditions that these radioactive materials are required to meet to be considered a discrete source.

With regard to the general license provisions in the new 10 CFR 31.12, the staff is proposing that radium-226 "produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for commercial, medical, or research activity" still under control of the military be excluded from regulatory control. I believe that military use of these materials are within the Commission's authority. Thus, military licensees utilizing these materials for the purposes defined in the statute should be covered by rule.

Lastly, I agree with the staff's assessment that certain activities in this rule, such as repair of timepieces and possession of non-intact timepieces, be covered by a general license. I am,

however, concerned that these new general licensees may not be aware of requirements of the general license. Thus, I believe the staff should consider developing a regulatory information summary or some other form of communication to inform general licensees of their responsibilities under the rule to prevent the inadvertent handling, transfer, or disposal of these materials.



Gregory B. Jaczko

4/27/07

Date

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: **COMMISSIONER LYONS**

SUBJECT: **SECY-07-0062 - FINAL RULE: REQUIREMENTS FOR EXPANDED DEFINITION OF BYPRODUCT MATERIAL (RIN: 3150-AH84)**

Approved Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached None ___



SIGNATURE

5/1/07

DATE

Entered on "STARS" Yes No _____

Commissioner Lyons' Comments on SECY-07-0062

I approve publication of the final rule in the *Federal Register* to amend 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171, which will establish the regulatory framework for regulating radium sources, accelerator-produced radioactive material, and certain discrete sources of naturally occurring radioactive material with the following edits.

Page 133, line 10	Delete "(such as taking more samples or scaling)"
Page 232, 31.12 (c)(2) and (3)	Replace the term "device" with "products".
Page 232, 31.12 (c)(4)	Delete "by export only as provided by Paragraph (c)(3) of this section".


Further, I support the staff's determination that the rule will not have a significant impact on a substantial number of small entities.

I join Commissioners McGaffigan and Merrifield in commending the staff's efforts and in supporting the staff's proposed revision to the definition of discrete source. As provided by staff the definition would now read as follows: "A radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities."

I further agree with Commissioners McGaffigan and Merrifield that the Statements of Consideration should clearly articulate under which conditions military use of byproduct material is excluded from NRC jurisdiction.

I am surprised that the stakeholders did not provide more comments and information on the proposed regulations involving such a major change in regulation of material in the United States. Given the sparseness of additional information about use of products containing radium, staff is to be commended on using risk-informed decisions to develop the final rule. Staff should conduct a review of the effectiveness of this rulemaking, after it has gained some experience with implementing the new regulations. This review should occur no sooner than 18 months after the effective date of the rule and include recommendations for studies or rule changes that may be needed to more effectively implement the EPAct.

Issuance of the final rule will be a significant milestone in the implementation of the Energy Policy Act of 2005, a milestone of which the NRC and State staff should be very proud.


Peter B Lyons
5/1/07
Date

Supplement to Commissioner Lyons' vote on SECY-07-0062

I am supplementing my vote in response to recent information which I learned that staff's revised discrete source definition was not shared with the Agreement State representatives on the Rulemaking Working Group before being provided to the Commission for deliberation. Agreement States have been actively involved in this rulemaking. I ask my fellow Commissioners to support directing staff to share this definition with the Agreement State representatives on the Rulemaking Working Group prior to finalizing the rule.

Furthermore, for all future rulemakings involving a working group with Agreement State participation, I recommend that staff be directed to involve the working group as the rule is developed and at anytime the Commission is considering a change to the rule language. I believe it is imperative for Commission decisions to be informed with Agreement State views on rulemakings that will directly affect the State and its licensees. Staff should develop for Commission approval a revised set of procedures for sharing more information with the Agreement States.

 5/1/07
Peter B Lyons Date