



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

June 28, 2006

SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-06-0069

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

The Commission (with Chairman Diaz and Commissioners McGaffigan, Jaczko and Lyons agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of June 28, 2006. Commissioner Merrifield approved in part and disapproved in part.

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", written over a horizontal line.

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:

1. Voting Summary
2. Commissioner Vote Sheets

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

VOTING SUMMARY - SECY-06-0069

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. DIAZ	X				X	5/26/06
COMR. McGAFFIGAN	X				X	6/6/06
COMR. MERRIFIELD	X	X			X	6/6/06
COMR. JACZKO	X				X	6/7/06
COMR. LYONS	X				X	5/23/06

COMMENT RESOLUTION

In their vote sheets, Chairman Diaz and Commissioners McGaffigan, Jaczko and Lyons approved the subject paper. Commissioner Merrifield approved in part and disapproved in part. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on June 28, 2006.


NOTATION VOTE
RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: CHAIRMAN DIAZ
SUBJECT: **SECY-06-0069 - PROPOSED RULE:
REQUIREMENTS FOR EXPANDED DEFINITION
OF BYPRODUCT MATERIAL (RIN: 3150-AH84)**

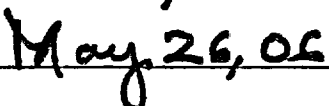
Approved Disapproved _____ Abstain _____
Not Participating _____

COMMENTS:

See attached comments.



SIGNATURE



DATE

Entered on "STARS" Yes No _____

Chairman Diaz's Comments on SECY-06-0069

I approve the staff's recommendations to publish a proposed rule in the *Federal Register* that would amend Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171. I commend the staff for formulating a comprehensive proposed rule that addresses the intent of the requirements of the Energy Policy Act of 2005 to expand the definition of by-product material. This proposed rule would establish an effective regulatory framework for regulating certain discrete sources of radium-226, accelerator-produced radioactive material, and certain discrete sources of naturally occurring radioactive material.

I approve the staff's proposed implementation strategy that would allow NARM users to possess and use material without a license for a limited period of time, i.e., authorization by rule rather than the use of enforcement discretion. It is unnecessary for the staff to solicit comments on using enforcement discretion.

The issue of Agreement State compatibility with this proposed rule is clearly sensitive. The staff has made the proper recommendation in designating this rule as "health and safety" (H&S). The key issue associated with this designation will be how it is implemented within the context of IMPEP reviews. The staff should be flexible when working with States, the Organization of Agreement States, and the Conference of Radiation Control Program Directors to develop evaluation guidelines that meet the NRC's needs for making health and safety judgments, while accommodating existing State programs and needs, consistent with the intent of Section 651(e) of the Energy Policy Act of 2005.

To maintain consistency with the Atomic Energy Act and the NRC's activities related to radioactive source control, the proposed definition of discrete source should be revised to begin as follows: "*Discrete source* means a radioactive source..." (Underline added for emphasis.)

I note that the proposed rule will be noticed in the Federal Register for 45 days for public comment, and that it will also be sent to the Office of Management and Budget for the required review under the Paperwork Reduction Act. I also note that the Chief Counsel for Advocacy of Small Business Administration will be informed of the NRC's certification that this proposed rule will not be overly burdensome to a large number of small entities, as required by the Regulatory Flexibility Act.



NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER MCGAFFIGAN
SUBJECT: **SECY-06-0069 - PROPOSED RULE:
REQUIREMENTS FOR EXPANDED DEFINITION
OF BYPRODUCT MATERIAL (RIN: 3150-AH84)**

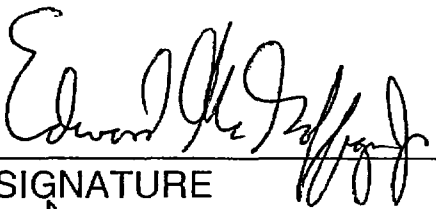
w/comments and edits

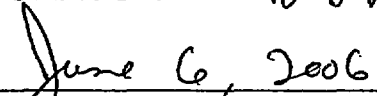
Approved Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

See attached comments and edits.



SIGNATURE


DATE

Entered on "STARS" Yes No _____

Commissioner McGaffigan's Comments and Edits on SECY-06-0069

I wish to commend the staff for its outstanding efforts on the proposed rule for naturally-occurring and accelerator-produced radioactive material (NARM). I both appreciate and agree with the February 2, 2006, observation of the OAS Board that the staff have worked hard to prepare a *Federal Register* notice that is extremely well written, clear and easy to understand, and effectively communicates the new requirements. I also appreciate the participation of the staff and Mr. Thompson of the OAS, Mr. O'Kelley of the CRCPD, Mr. Brown of CORAR, and Ms. Schwartz of ACMUI, during a Commission briefing on May 15, 2006, on the status of the implementation of the Energy Policy Act of 2005.

After consideration of this paper and the additional information provided to the Commission on May 15, I approve, with two substantive changes, the staff's recommendation to approve for publication in the *Federal Register* the proposed amendments to 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171. I also approve the staff's proposed implementation strategy that would allow NARM users to possess and use material, without a license, for a limited period of time (i.e., authorization by rule). With regard to the first change, I propose that we revise the definition of "discrete sources," to more clearly make the distinction between "radiation" and "radioactivity." The definition should read: *Discrete source* means a source with physical boundaries, which is separate and distinct from the radioactivity-radiation present in nature, and in which the radionuclide concentration has been increased by human processes with the intent that the concentrated material will be used for its radiological properties." I also propose to modify the draft *Federal Register* notice so that it is clear that the Commission is inviting public comment on whether it should revise Appendix B to 10 CFR Part 20 to include specific allowable limits on intake (ALIs), derived air concentrations (DACs), and effluent concentrations for oxygen-15 and nitrogen-13.

On a matter related to the proposed implementation strategy, the staff asked the Commission whether the proposed rule should seek comment on an alternative, which would have the Commission not authorizing continued use of newly-added byproduct material after the termination of the EAct Section 651(e)(5) temporary waiver from the new byproduct material requirements. Under this alternative, the NRC would exercise enforcement discretion, provided that NARM users meet other conditions in the regulations and submit either a license amendment or new application within a specified time period. I believe the staff's proposed approach, which involves the termination of waivers in stages, and reasonable transition periods, is clearly the better of the two options, and I see no benefit of including a question in the proposed rule regarding the alternative. I look forward to reading the staff's proposed approach for developing the transition plan this summer.

In my vote on SECY-06-0094, I proposed a lower limit of Category 3.5 for specific licensing of radioactive sources incorporating IAEA Code of Conduct radionuclides of concern. The Category 3.5 threshold is 110 millicuries for radium-226. The staff's proposed exemptions, such as the 1 microcurie quantity limit in §30.15(a)(viii) for intact timepieces and the 5 µCi limit in §31.8 for calibration sources, are certainly well below Category 3.5 levels. The new general license for antiquities, luminous items, and small radium sources at §31.12, which includes, for example, a 100 item limitation on luminous items no longer installed in aircraft, is also likely to ensure that individuals possess no more than Category 3.5 levels under a general license. Therefore, I support the exemptions and the new general license in the proposed rule.

I believe the staff's decisions on matters addressed in the proposed rule are sound, well-reasoned, and risk-informed. For example, the staff recommends a graded regulatory approach for discrete sources of radium-226, which includes exemptions, modified and new general licenses for certain antiquities and luminous items, and specific licensing for the remainder.

I also agree with the proposed approach for the regulation of accelerator-produced materials. The staff's proposal to regulate intentionally and incidentally produced accelerator-produced radioactive materials draws a clear distinction between the accelerator-product radioactive materials which NRC proposes to regulate and those we don't. I commend the staff for taking sensible steps to minimize the regulatory impact of the availability of accelerator-produced radioactive drugs (which includes positron-emission tomography, or PET materials), such as "grandfathering" from the new training and experience requirement those who are currently responsible for the production of PET radionuclides.

Several organizations, including OAS, CRCPD, and CORAR, have provided feedback on whether several new and revised definitions in the proposed rule are program elements that are required in State programs for compatibility with NRC's regulations. OAS and CRCPD support a compatibility category of "D," largely because States already regulate NARM in a manner consistent and compatible with other byproduct material. CORAR, which has a vested interest in uniformity across State lines, supports a compatibility category of "B." The definitions in question are those for byproduct material, discrete source, accelerator-produced radioactive material, particle accelerator, and Positron Emission Tomography (PET) radionuclide production facility. The staff has explained that these definitions are not, in fact, required for compatibility, but are required for adequacy. I believe that the staff has provided a clear, rational basis for why these definitions are not required for compatibility, but are identified as having a particular health and safety role, subject to NRC review, and are thus properly designated "H&S." The "H&S" designation means that the State should adopt program elements that embody the essential objectives of the NRC program elements. Most States already have 11e.(3) byproduct materials covered in their statutes or regulations, using either the term "byproduct material" or another term such as "radioactive materials," and I believe that most States will not have difficulty demonstrating the adequacy of their programs.

EXM Edits to Enclosure

1. Draft *Federal Register* Notice, p. 17, Section titled "Radium-226":

"Radium is a chemically reactive, silvery white, radioactive, metallic element with an atomic number of 88 and symbol of Ra. Radium-226, the most abundant and most stable isotope of radium, is formed by the radioactive disintegration of thorium-230 in the decay series starting with uranium-238. Radium-226 can be found in all uranium ores. ~~Of the isotopes of radium, the most abundant and most stable is the isotope with a mass number of 226.~~ The half-life of radium-226 is 1599 years. Radium-226 emits alpha particles, gamma radiation, and decays to radon gas."

2. Draft *Federal Register* Notice, p. 21, first full paragraph:

"The EPA does not give the NRC ~~any~~ authority to regulate the possession or use of particle accelerators, ~~themselves.~~"

3. Draft *Federal Register* Notice, p. 23, second full paragraph, second sentence:

~~"In recent years, radiopharmaceuticals using~~ The use of fluorine-18, carbon-11, nitrogen-13, and even oxygen-15 in radiopharmaceuticals, also known as the PET drugs, ~~have become popular.~~ has increased in recent years."

4. Draft *Federal Register* Notice, p. 31, second full paragraph, first sentence, and conforming changes to other instances of this definition on pp. 111, 117, 156, and 159.

"The NRC is proposing to define the term *Discrete source*, in defining radium-226 and other naturally occurring radioactive material, other than source material, as byproduct material, as "*a source with physical boundaries, which is separate and distinct from the radioactivity-radiation present in nature, and in which the radionuclide concentration has been increased by human processes with the intent that the concentrated radioactive material will be used for its radiological properties.*"

5. Draft *Federal Register* Notice, p. 35, first full paragraph:

"Timepieces containing radium-226.

The exemption in 10 CFR 30.15(a)(viii) would be revised to include timepieces that were ~~previously~~ manufactured prior to the effective date of the rule and containing no more than 37 kBq (1 μ Ci) of radium-226. This limit is consistent with the SSRs."


- 6.a Draft *Federal Register* Notice, p. 48, ***Consideration of NARM in 10 CFR Part 20, Appendix B.***

"The comparable provisions in Part D of the SSRs do not include any new accelerator-produced radionuclides other than the ones already in 10 CFR Part 20, Appendix B. The NRC considered whether some other radionuclide-specific values should be added to 10 CFR Part 20, Appendix B. Since nitrogen-13 and oxygen-15 are two of the accelerator-produced

radionuclides that are produced for medical uses, the NRC performed a preliminary calculation of values based on dose factors published in Federal Guidance Report 12. ~~Certain dose conversion factors were not readily available. This necessitated using an alternative approach to calculate these values for nitrogen-13 and oxygen-15.~~ Results from these preliminary calculations yielded a derived air concentration (DAC) based on the submersion scenario for both nitrogen-13 and oxygen-15 of about 4×10^{-6} microcurie per milliliter (1.48×10^{-2} becquerels per milliliter) for occupational exposure and a corresponding effluent concentration of 2×10^{-8} microcurie per milliliter (7.4×10^{-4} becquerels per milliliter) for exposure of members of the public. The above calculated values are lower than ~~relatively close to the default values for DAC and effluent concentration and different only by a factor of 40 and 20, respectively, in 10 CFR Part 20, Appendix B.~~ Because the approach used in calculating values for nitrogen-13 and oxygen-15 is different from that used for other radionuclides included in 10 CFR Part 20, Appendix B, ~~and because the NRC's preliminary calculated DAC and effluent concentration values for both nitrogen-13 and oxygen-15 are relatively close to the default values in 10 CFR Part 20, Appendix B,~~ the NRC is not proposing to add specific values for these radionuclides in this rulemaking at this time. However, the Commission understands that CORAR plans to file a petition for rulemaking asking NRC to adopt a specific DAC for these two radionuclides at levels similar to the above calculated values and NRC intends to deal with the petition in this rulemaking. Therefore, the Commission specifically requests public comment on the proposed default values, and whether it should include lower specific values for oxygen-15 and nitrogen-13 in the final rule.

6.b Draft *Federal Register* Notice, p. 65, G. **Summary of Issues for Public Comment**
Add a new item 4, and renumber the subsequent items

- (4) The adequacy of the applicable default ALIs and DACs in Appendix B to 10 CFR 20 for oxygen-15 and nitrogen-13, and whether should staff develop lower specific values for these radionuclides.


Edward McGaffigan, Jr.

6/6/06

(Date)


NOTATION VOTE
RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER MERRIFIELD
SUBJECT: **SECY-06-0069 - PROPOSED RULE:
REQUIREMENTS FOR EXPANDED DEFINITION
OF BYPRODUCT MATERIAL (RIN: 3150-AH84)**

Approved Disapproved Abstain
Not Participating

COMMENTS:

See attach comments



SIGNATURE
6/6/06

DATE

Entered on "STARS" Yes No

Comments from Commissioner Merrifield on SECY-06-0069:

I approve, with revisions discussed in subsequent paragraphs, the staff's recommendations in SECY-06-0069 concerning publishing a proposed rule providing an expanded definition of byproduct material. I commend the staff for their hard work in producing this proposed rule in a relatively short period of time. While I appreciate the effort by the staff, I am also concerned about potential unintended consequences. This is a complicated rulemaking that may have impacts not fully identified. Hopefully, the public comment period will serve to identify unintended consequences so that the final rule can be appropriately modified.

One area of considerable uncertainty with a potentially large number of unintended consequences involves the regulation of Ra-226 (radium-226) and specifically as related to the use of Ra-226 in antique watches and dials. States had chosen not to regulate Ra-226 in antiques and consequently there is little data on which to base decisions. With very little data to determine the risk significance to either antique collectors or antique repair facilities (including watch repair facilities in general), staff has proposed that collectors with less than a specified number (somewhat arbitrarily defined) of dials or watches containing Ra-226 would be authorized to possess the equipment under a general license and if they possessed more than the specified number they would be required to have a specific license. But they can do no repairs. Facilities which repair dials or watch faces containing Ra-226 would be required to have a specific license (with an estimated \$3,500 licensing fee and an estimated annual fee of \$8,200). Without more specific data and justification, I disapprove the staff's proposed actions concerning antiques containing Ra-226.

Antiques containing Ra-226 have been essentially unregulated for years and there is no data to indicate the risk significance of this activity. There is data which indicates past problems with manufacturing and distribution facilities involving Ra-226, and such facilities should be appropriately regulated. However, there is no data about the risk to antique collectors or small repair shops. Arbitrarily implementing such regulations without a firm basis could have significant unintended or at least unrecognized consequences. This relatively arbitrary decision could have a significant impact on small businesses and antique collectors throughout the country. In addition, there would be a significant impact on the regulator determining exactly who should have what type of license and attempting to enforce that decision without regards to the safety significance of the activity.

The proposed rule language should be modified to grant an exemption to antique collector facilities and repair shops which repair less than a specified number of dials and watch faces containing Ra-226 in a given year. The Statement of Consideration should state that this exemption is being granted in recognition of historical practices while staff gathers data to determine if more specific requirements should be placed on the possession and repair of antiques containing Ra-226. The *Federal Register* Notice should contain appropriate specific questions requesting data on provisions which should be considered concerning antiques with Ra-226, the safety significance of these provisions, alternatives to potential regulations, or justification for continuing exemptions in this area. When the final rule is proposed to the Commission, there should be a stronger justification for whatever the staff proposes in this area.

Although I believe the issue has been resolved, staff should continue to work with the Agreement States to address any concerns related to the compatibility issue.

The following additional comments are specific to the proposed *Federal Register* Notice:

1. On page six, under the heading "Current Regulatory Structure", the first paragraph should be revised to reflect the current Minnesota Agreement State status.

2. On page 17, under the heading "B. The New Expanded Definition of Byproduct Material", the last sentence reads "A different definition for the term Byproduct material is used in 10 CFR Part 40, and it remains unchanged by this proposed rule." It may not be obvious to the general public why the Part 40 definition of byproduct material is not also being revised by this regulatory action. A short justification (1 to 3 sentences at most) should be provided in this paragraph.



6/6/6


NOTATION VOTE
RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: **COMMISSIONER JACZKO**
SUBJECT: **SECY-06-0069 - PROPOSED RULE:
REQUIREMENTS FOR EXPANDED DEFINITION
OF BYPRODUCT MATERIAL (RIN: 3150-AH84)**

Approved Disapproved Abstain

Not Participating

COMMENTS: See attached comments.



SIGNATURE

9/7/06

DATE

Entered on "STARS" Yes No

Commissioner Jaczko's Comments on SECY-06-0069
Proposed Rule: Requirements for Expanded Definition of Byproduct Material

I approve of the staff's recommendation to publish in the *Federal Register* the proposed rule to Title 10 Code of Federal Regulations Parts 20, 30, 31, 32, 33, 35, 50, 61, 72, 110, 150, 170, and 171 to implement the provision in the Energy Policy Act of 2005 which expands the definition of byproduct material. The publishing of this proposed rule communicates to all of our stakeholders the regulatory framework the Nuclear Regulatory Commission intends to implement for certain discrete sources of radium-226, naturally occurring and accelerator-produced radioactive material (NARM), and certain discrete sources of NARM.

The staff proposed that the definition of byproduct material be designated health and safety for purposes of adequacy. Although I support the staff's determination that this issue should involve a health and safety adequacy determination, the staff should solicit comment on whether a compatibility finding is necessary as well. The staff should specifically solicit comment on (1) whether the lack of a compatibility finding for the byproduct definition will create difficulties for interstate commerce and (2) whether the addition of a compatibility requirement may provide a more timely and more transparent mechanism to identify potential problems in an Agreement State program. I believe that compatibility in this area can be accomplished with a compatibility "C" finding. States must demonstrate that they have statutory authority to regulate NRC byproduct material, either specifically using a definition of byproduct material identical to the Atomic Energy Act definition or with a broader radioactive material definition.

As part of this proposed rule the staff intends to take comments on whether private collectors of items containing radium-226 will stay within the bounds of the proposed general license or whether they will need a specific license for the quantity of items they possess. I agree with the staff that we should engage interested stakeholders concerning consumer products that contain sources of radium that could pose a potential health and safety risk to the public; however, I believe we need to do more to develop a better understanding of the number of sources that exist, the potential exposure rates from the sources, and who currently possesses these sources. The staff should consider developing a database or some type of inventory through engaging vendors and requesting that they submit information about devices and consumer products they distribute or have distributed to the public in the recent past. The staff should also engage the Agreement States concerning specific licenses that they have issued to entities to develop the database or inventory to assist in developing the technical basis needed to support the proposed general license or any future exemptions.

In addition, as Commissioner McGaffigan has suggested (in another venue), the staff should consider reviewing regulatory actions and thresholds for discrete sources of radium-226 to align them with the Code of Conduct as a basic organizing principle.

Finally, the staff should seek comment specifically on the exemptions to the training requirements in section 35.57. Under the proposed rule a Radiation Safety Officer, medical physicist, or nuclear pharmacist would be exempt from the training requirements of 35.50, 35.51, and 35.55 by simply demonstrating that the individual used only accelerator-produced radioactive materials, discrete sources of radium-226 or both prior to the new byproduct definition becoming effective. While I support this standard, the exemption provisions for past users of non-NARM materials create a much higher standard for exemption. The Commission has maintained throughout that the regulation of radiological sources should be consistent

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary


FROM: COMMISSIONER LYONS

SUBJECT: **SECY-06-0069 - PROPOSED RULE:
REQUIREMENTS FOR EXPANDED DEFINITION
OF BYPRODUCT MATERIAL (RIN: 3150-AH84)**

Approved X Disapproved _____ Abstain _____
w/comments

Not Participating _____

COMMENTS:



SIGNATURE

5/23/06

DATE

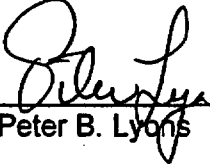
Entered on "STARS" Yes ✓ No _____

Commissioner Lyons comments on SECY-06-0069

I approve publication of the proposed 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 certain radium sources, accelerator-produced radioactive material, and certain discrete sources of naturally occurring radioactive material. I offer the following general comments.

I commend the staff on a high quality rulemaking package. Staff was required under Section 651(e) of the Energy Policy Act to develop a regulatory framework for licensing and regulating this newly added byproduct material within 18 months, to consult with states and other stakeholders in establishing requirements, and, and to the maximum extent practicable, to cooperate with States and to use model State standards in developing the regulations. I believe staff has already or is in the process of accomplishing each major element of Section 651 (e).

Staff should continue to work with the States during the development of the transition plan in order to accomplish a smooth transition as well as to provide adequate implementation time for Agreement States. Also staff should communicate with the States to resolve any misunderstanding that might have occurred regarding the compatibility category of the definition of byproduct material.


Peter B. Lyons 5/23/06
Date