



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

February 3, 2010

SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-09-0035

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

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of February 3, 2010.

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 Jaczko
Commissioner Klein
Commissioner Svinicki
OGC
EDO
PDR

VOTING SUMMARY - SECY-09-0035

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. JACZKO	X				X	9/28/09
COMR. KLEIN	X				X	8/21/09
COMR. SVINICKI	X				X	1/12/10

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 February 3, 2010.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: GREGORY B. JACZKO
SUBJECT: SECY-09-0035 – PROPOSED RULE: REQUIREMENTS
FOR DISTRIBUTION OF BYPRODUCT MATERIAL,
PARTS 30, 31, 32, 40, AND 70 (RIN 3150-AH91)

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached X None ___



SIGNATURE

09/28 /2009

DATE

Entered on "STARS" Yes X No ___

Chairman Jaczko's Comments on SECY-09-0035
Proposed Rule: Requirements for Distribution of Byproduct Material,
Parts 30, 31, 32, 40, and 70

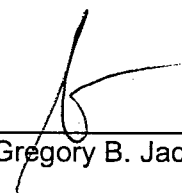
I approve the staff's recommendation to publish the proposed amendments to 10 CFR Parts 30, 31, 32, 40, and 70 in the Federal Register. This is a complicated and wide-ranging proposed rule, and I commend the staff for the effort that they have put into this paper. Given the number of topics addressed in this proposed rule, I suggest that the staff consider whether the clarity of the Federal Register Notice would be enhanced by the addition of a section containing "Questions and Answers," similar to sections that have been included in Federal Register Notices for other rulemakings. Also, summarizing all of the areas for which staff is specifically requesting public comment would be helpful to the reader.

I agree with Commissioner Klein's comment that the justification for the proposed new class exemption for certain types of industrial devices should be based on safety considerations. The discussion should be revised to reflect that the difficulty of maintaining accountability of these types of devices is not the basis for the proposed revision. In addition, since this new exemption is an area that could have the largest impact, it should be highlighted for public comment.

More importantly, I am not convinced that we should be allowing for a new class exemption at this time. As the proposed rule states, "Under the proposed exemption from licensing requirements, there would be no controls on disposal; the devices would be disposed of without regard to their radioactivity." In general, the agency is moving towards more accountability of radioactive material, not less. I look forward to reviewing the public comments on this issue.

The staff proposes to remove unnecessary limitations from the class exemption for gas and aerosol detectors by revising the requirement of "designed to protect life or property from fires and airborne hazards" to instead be "designed to protect health, safety, or property." This would seem to be a requirement that is much harder to define. I recommend that the staff highlight this as an area for public comment.

I also agree that the staff should ensure that it has completed revising the licensing and inspection guidance affected by this rulemaking by the time the draft final rule is provided to the Commission for consideration. Should the Commission direct that the final rule be issued, the staff should publish the revised guidance for public comment as soon thereafter as possible.



Gregory B. Jaczko

9/28/09

Date

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER KLEIN

SUBJECT: SECY-09-0035 – PROPOSED RULE: REQUIREMENTS FOR DISTRIBUTION OF BYPRODUCT MATERIAL, PARTS 30, 31, 32, 40, AND 70 (RIN 3150-AH91)

Approved Disapproved Abstain

Not Participating

COMMENTS: Below Attached None



SIGNATURE

8/21/2009

DATE

Entered on "STARS" Yes No

**Commissioner Klein's Comments on SECY-09-0035, Proposed Rule: Requirements for
Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70**

I approve, as modified below, the staff's recommendation to publish the proposed amendments to 10 CFR Parts 30, 31, 32, 40, and 70 in the *Federal Register*. This proposed rule is a piece of unfinished business dating from the tenure of my former colleague, Peter Lyons. My views on this matter are largely aligned with his, and my comments are based on the vote that Dr. Lyons cast before the end of his term.


Rather than address the safety criteria discussed in this proposal during this rulemaking, the staff should consider them 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 International Commission on Radiological Protection (ICRP-103). The staff and the Advisory Committee on Reactor Safeguards have indicated that the current regulatory framework for radiation protection continues to provide for adequate protection of worker and public health and safety and of the environment, and no new information has been provided to support changing the safety criteria at this time.

Many of the criteria contained in the Commission's 1965 Consumer Product Policy Statement are still valid for approval of products intended for use by the general public. However, some of this information is dated, so the staff should update this policy statement concurrent with this rulemaking.

The *Federal Register* notice should be revised as follows:

- It appears that part of the rationale for a new class exemption is that it is too difficult to maintain accountability for certain types of devices. The justification for a class exemption should be based only on safety considerations, and pages 22 and 23 of the notice should be revised to reflect this emphasis.
- The notice should be revised to include a table that clearly indicates the Agreement State compatibility requirements for each proposed regulation change.
- The notice should include a section that summarizes all the requests for comments contained in the notice to ensure readers can comprehensively understand the issues at hand and can then make informed comments.
- To more clearly explain how new regulatory requirements will be implemented on a case-by-case basis during amendment or renewal of a specific license authorizing distribution, the staff should augment the notice with a discussion that clarifies the specific changes being contemplated to quality control, quality assurance and prototype testing requirements.

The staff should ensure that it has completed revising the licensing and inspection guidance affected by this rulemaking by the time the draft final rule is provided to the Commission for consideration. Should the Commission direct that the final rule be issued, the staff should publish the revised guidance to solicit public comment as soon thereafter as possible.



Dale E. Klein 8/21/2009

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER SVINICKI
SUBJECT: SECY-09-0035 – PROPOSED RULE: REQUIREMENTS
FOR DISTRIBUTION OF BYPRODUCT MATERIAL,
PARTS 30, 31, 32, 40, AND 70 (RIN 3150-AH91)

Approved XX Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below _____ Attached XX None _____



SIGNATURE

01/2/10

DATE

Entered on "STARS" Yes No _____

Commissioner Svinicki's Comments on SECY-09-0035, Proposed Rule: Requirements for Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70

I approve, with modifications, as noted, the staff's recommendation to publish the proposed amendments to 10 CFR Parts 30, 31, 32, 40, and 70 in the *Federal Register*. The development of this proposed rule has a somewhat tortured history tracing most directly to previous Commission decisions on SECY-02-0196 and SECY-05-0151, which themselves have complex voting records. In understanding the staff's proposal, I would have been severely disadvantaged were it not for the existence of the comprehensive written votes of former Commissioners, the individual narratives and rationales of which were invaluable in reviewing this paper. In addition to providing scrutability to the public, access to such written votes, for a Commissioner uninvolved in previous developments, is a core strength of the Commission's notation voting process, and an essential guidepost as the Commission loses and gains new members.

As acknowledged in the Regulatory Flexibility Certification, a significant number of the licensees affected by this action would meet the definition of "small entities" as defined by the Small Business Administration because the proposed amendments affect not only the manufacturers and distributors of sealed sources and devices containing byproduct materials but also future users of such devices. The resources of consumers and small entities to participate in our public comment processes are, in many cases, limited. Therefore, the amendments proposed, the bases for those changes, and our explanation of both must be well-reasoned and well-articulated.

In two cases of note, I believe the regulatory burden of a proposed change is not well known. The rule proposes to raise the NRC's statistical acceptance criteria; i.e., the required confidence that the Tolerance Percent Defective will not be exceeded would increase from the current 90 percent to 95 percent. The proposed rule would also require that distribution of any part, or sub-lot, of a rejected lot must be in accordance with procedures spelled out in the license and that testing after repairs must be performed by an independent reviewer. I am not confident that the staff yet knows the impact of these changes on impacted licensees, especially small entities. Both of these areas should be highlighted by staff as areas for public comment.

I support many of the actions proposed by my colleagues, in their votes, which would increase comprehensibility of the proposed rule, such as including a table to clearly indicate compatibility requirements for each proposed regulatory change; repeating all of the solicitations for public comment on specific questions in a separate section; explaining more clearly how new regulatory requirements would be implemented on a case-by-case basis during amendment or renewal of specific licenses; and, revising the statement of rationale for the new exemption class. Further, the staff should remove the speculative references to prospective Commission action to expand the National Source Tracking System that appear on page 27 and may appear elsewhere.

I also agree with my colleagues that staff should ensure that it has completed revising the licensing and inspection guidance affected by this rulemaking by the time the draft final rule is provided to the Commission for consideration and – if the Commission approves issuance of the final rule – staff should publish the revised guidance for public review and comments as soon thereafter as possible.

Finally, I am approving the publication of these proposed amendments at this time but intend to take the intervening period prior to receiving public comment and the development of any draft final rule to clarify my understanding of two issues identified by former members of the Commission, put forward in their votes on the prior papers. I found these issues compelling and want to quote at some length here, because I think these statements form a useful part of the current deliberation.

The first is from Chairman Diaz's vote on SECY-02-0196 on the topic of the development of safety criteria for certain exemptions. He wrote, "I have consistently emphasized that we should base our regulations, associated documents, and regulatory decisions on the most up-to-date scientific information, methodology, and models and realistic scenarios. Therefore, before the staff proceeds with either developing or revising safety criteria associated with exempt materials, staff should provide the Commission with a comprehensive plan for evaluating the latest scientific information and the recommendations of the international/national radiation protection organizations for possible incorporation into our regulatory activities, policies, and regulations." I think his statement is relevant because this rulemaking may now be outpacing rulemaking activities related to ICRP-103. The Commission needs to keep sight of this larger effort.

Commissioner McGaffigan's vote on SECY-02-0196 was more pointed on the topic of risk-informing these regulations, "Another example is the staff's proposal to revise some of the exempt quantity limits . . . because the doses may be unacceptable. This raises the issue of what the staff considers an 'unacceptable dose'? It is not clear at all in the paper but it appears to me as if the staff is using 1 mrem/yr as a criterion. I am very concerned that the staff is proposing to lower any exempt quantity limits for which the potential dose exceeds 1 mrem/yr. . . I do not think 1 mrem/yr is a reasonable criterion."

The second issue I would note relates to imposing point-of-sale labeling requirements, addressed in SECY-02-0196. On this topic, Commissioner McGaffigan wrote: "The staff recommends increasing the items that require labeling. I do not agree and believe that changing the labeling requirements at this point would be too resource intensive. The Commission has designated these quantities of source and byproduct material as exempt because they pose very little risk. The doses associated with the use of these products are so low that the products can be used and disposed of with no restrictions. Requiring labeling seems to be in direct conflict with the staff's goal of risk-informing all materials regulations and regulatory activities." Chairman Diaz simply stated, "[A] statement that the use and disposal of the product are exempt from regulations would needlessly confuse and/or alarm the public. In general, we need to develop and implement consistent policies and regulations that are commensurate with the risk to public health and safety."

On both of these subjects, I intend to research the basis for the staff's actions more thoroughly before final action.



Kristine L. Svinicki 01/12/10