



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

June 16, 2010

SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-09-0179

TITLE: PROPOSED RULE: DISTRIBUTION OF SOURCE MATERIAL TO EXEMPT PERSONS AND TO GENERAL LICENSEES AND REVISION OF GENERAL LICENSE AND EXEMPTIONS (RIN 3150-AH15)

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of June 16, 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 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 Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff
OGC
EDO
PDR

VOTING SUMMARY - SECY-09-0179

RECORDED VOTES

| | APRVD | DISAPRVD | ABSTAIN | PARTICIP | NOT COMMENTS | DATE |
|-------------------|-------|----------|---------|----------|-----------------|---------|
| CHRM. JACZKO | X | | | | X | 1/31/10 |
| COMR. SVINICKI | X | | | | X | 6/7/10 |
| COMR. APOSTOLAKIS | X | | | | X | 5/25/10 |
| COMR. MAGWOOD | X | | | | X | 5/28/10 |
| COMR. OSTENDORFF | X | | | | X | 5/20/10 |

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 June 16, 2010.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Chairman Jaczko

SUBJECT: SECY-09-0179 – PROPOSED RULE: DISTRIBUTION OF SOURCE MATERIAL TO EXEMPT PERSONS AND TO GENERAL LICENSEES AND REVISION OF GENERAL LICENSE AND EXEMPTIONS (RIN 3150-AH15)

Approved Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below Attached _____ None _____

I approve the publication in the Federal Register of the proposed amendments to 10 CFR 30, 40, 70, 170, and 171. I agree with the staff that the proposed changes will better ensure the protection of public health and safety. The proposed reporting requirements will allow the agency to better understand the use and distribution of these materials. I also believe that the proposed new requirement in 10 CFR 40.22(c) to minimize contamination at the site and to ensure that the site is cleaned up to be protective of future worker and public health and safety, and the proposed clarification of disposal requirements in 10 CFR 40.22(b)(2), are both positive steps. I look forward to the public's comments on this proposed rule.



SIGNATURE

1/31/10

DATE

Entered on "STARS" Yes No _____

NOTATION VOTE

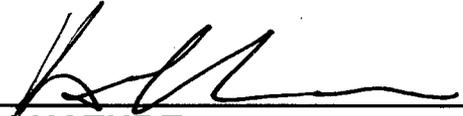
RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER SVINICKI
SUBJECT: SECY-09-0179 – PROPOSED RULE: DISTRIBUTION OF SOURCE MATERIAL TO EXEMPT PERSONS AND TO GENERAL LICENSEES AND REVISION OF GENERAL LICENSE AND EXEMPTIONS (RIN 3150-AH15)

Approved XX Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below _____ Attached XX None _____



SIGNATURE

06/7/10

DATE

Entered on "STARS" Yes No _____

Comments of Commissioner Svinicki on SECY-09-0179
Proposed Rule: Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions (RIN 3150-AH15)

I approve for publication in the *Federal Register* the proposed amendments to 10 CFR Parts 30, 40, 70, 170, and 171, subject to the attached edits and further comments, below.

Given the challenges in creating awareness of these proposed amendments among the organizations that would be most impacted by the proposed amendments – a point noted by three of my colleagues in their votes – I do not believe that the staff's proposed comment period of 75 days is sufficient, especially as the NRC only commits to consider comments received within the first 30 days of the comment period, with comments after that time considered only "if it is practical to do so." I believe a comment period of 120 days is more appropriate, with a commitment to consider comments received within the first 60 days, as a minimum. Further, I join my colleagues in supporting the publication of the draft guidance documents during the public comment period to ensure that all affected or interested parties will have the information they need to understand the proposed amendments to the rule.

In its draft Regulatory Analysis, the staff concludes that the "proposed rule would have a somewhat significant impact on both small and large entities" and further finds that, under the Regulatory Flexibility Act of 1980, a "significant number of the licensees affected by this action would meet the definition of 'small entities.'" In light of this, it is important for the staff to solicit specific comment on the proposed new fee categories and initial fee amounts (up to \$10,100 for an application and \$17,400 for the annual fee). As noted by the staff, it is "expected that a small number of persons currently possessing and using source material under the existing general license may be required to obtain a specific license for continued use of the source material under this proposed rulemaking." Staff should also undertake specific outreach efforts to find this small number of entities and solicit their comments on the rule.

Finally, in accordance with Internal Commission Procedures (Chapter III, "Voting" – section entitled, "Comments on draft Congressional letters and Press Releases associated with SECY papers"):

1. Draft Congressional letters and Press Releases that require Commission approval (policy formulation, rulemaking, and adjudication) are forwarded separately with the associated SECY Paper to SECY.
2. SECY attaches a cover sheet which indicates that the supplemental material is being forwarded in support of SECY-06-XXXX and circulates it with the associated SECY Paper to the Commission for review and comment.

The Supplemental Material in Support of SECY-09-0179 contained only draft Congressional letters and State Liaison letters. The staff should transmit its draft press release in support of SECY-09-0179 to the Commission for its review and comment, in accordance with existing Commission procedures.



Kristine L. Svinicki

06/110

DATES: The comment period expires [INSERT DATE ¹²⁰~~35~~ DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit comments specific to the information collections aspects of this rule by [INSERT DATE ⁶⁰~~30~~ DAYS AFTER PUBLICATION].

Comments received after these dates will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before these dates.

ADDRESSES: You may submit comments by any one of the following methods. Please include Docket ID **NRC-2009-0084** in the subject line of your comments. Comments submitted in writing or in electronic form will be posted on the NRC website and on the Federal rulemaking website Regulations.gov. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want to be publicly disclosed.

Federal Rulemaking Website: Go to <http://www.regulations.gov> and search for documents filed under Docket ID **NRC-2009-0084**. Address questions about NRC dockets to Carol Gallagher at 301-492-3668; e-mail Carol.Gallagher@nrc.gov.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: Rulemaking.Comments@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at 301-415-1677.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays. (Telephone 301-415-1677)

powdered form which allows for a greater chance of inhalation or ingestion of the source material. Although the Commission expects that these doses from manufacturing may be tremendously reduced if ^{the} process is performed in hot cells or if workers generally use respiratory protection (e.g., dust masks) in response to other regulatory requirements, the NRC is concerned about the potential exposures because a § 40.22 licensee is not required to meet the health and safety requirements for protection against radiation in 10 CFR Part 20 nor the training requirements in 10 CFR Part 19. X

The proposed new limits in § 40.22(a)(1) are intended to reduce the likelihood that a person operating under a general license would be able to exceed dose limitations in 10 CFR Parts 19 and 20, which would require additional controls if the person were specifically licensed. Based upon the bounding dose calculations in the PNNL study, the NRC expects this proposed lower quantity to limit the potential for a worker to be exposed at levels exceeding 1 mSv (100 mrem) per year. In addition, by limiting the amount of such source material allowed to be received in a calendar year, the NRC expects that the potential for surface contamination buildup (similar to that identified in PRM-40-27) would be also be reduced. By reducing the amount of source material that is available for inhalation and ingestion, the NRC has concluded the exemptions to 10 CFR Parts 19, 20, and 21 would continue to be acceptable.

It is expected that a small number of persons currently possessing and using source material under the existing general license may be required to obtain a specific license for continued use of the source material under this proposed rulemaking. Persons currently possessing source material in dispersible forms, or processing source material, in quantities greater than 1.5 kg (3.3 lb) of source material at any one time, or receiving more than 7 kg (15.4 lb) of source material in 1 year, would be required to obtain a specific license if they could not reduce their possession and use of the source material to below the proposed new limits.

Under the proposed § 40.22(a)(2), the general licensee would be allowed to possess up to 7 kg (15.4 lb) total source material at any one time as long as any source material possessed in addition to that possessed under the limits in § 40.22(a)(1) is in a solid, non-dispersible form (e.g., a metal or sintered object; contained in protective envelope or in a foil; or plated on an inactive surface) and not chemically or physically altered. The licensee is limited to the receipt of no more than 70 kg (154 lb) of source material per calendar year. If the licensee does physically or chemically alter the solid source material, that altered source material would be required to fall within the 1.5 kg (3.3 lb) at one time limit and no more than 7 kg (15.4 lb) per calendar year limits of the proposed § 40.22(a)(1). Because the greater impact from the possession and use of source material results from inhalation or ingestion, allowing source material, in a solid, non-dispersible form, to continue to be possessed at a limit of 7 kg (15.4 lb) at any one time is not expected to significantly impact health and safety of workers handling or near such material because of the unlikely chance of inhalation or ingestion.

Under the proposed § 40.22(a)(3), persons treating drinking water by removing uranium for the primary purpose of meeting U.S. Environmental Protection Agency regulations, would continue to be allowed to possess up to 7 kg (15.4 lb) of source material at one time and process no more than 70 kg (154 lb) of uranium per calendar year. The NRC has concluded that the types of activities used to remove ^{uranium from} drinking water adequately contain the uranium to protect worker health and safety. The NRC also is concerned that the implementation of reduced possession limits on such persons could significantly impact operating costs, if such facilities are required to obtain specific licenses, and thereby impact their ability to provide safe drinking water. Although persons operating such facilities would not be impacted by changes in possession limits, they would be required to meet the other requirements of the proposed rule. However, these persons continue to have multiple options for operating within the NRC's regulations, including operation under a specific license or applying for enforcement discretion

10 CFR 40.22(b)(5) – Would clarify that export of source material is subject to 10 CFR Part 110.

10 CFR 40.22(c) - Would require that any person who receives, possesses, uses, or transfers source material in accordance with paragraph (a) of § 40.22 must conduct activities so as to minimize contamination of the facility and the environment.

10 CFR 40.22(d) – Would revise and move the requirements currently under paragraph (b) of this section to paragraph (d) of this section.

10 CFR 40.22(e) – Would restrict initial distribution for use under the general license to a specific license issued under § 40.54 or equivalent provisions of an Agreement State.

SPACE
Section 40.52 Certain items containing source material; requirements for license to apply or initially transfer.

10 CFR 40.52 - Would establish requirements for a license authorizing distribution for use under the exemptions from licensing in § 40.13(c) and equivalent provisions of Agreement States.

Section 40.53 Conditions of licenses issued under § 40.52: Quality control, labeling, and records and reports.

10 CFR 40.53 – Would establish requirements for licenses issued under § 40.52, including reporting and recordkeeping requirements for distributions of products for use under § 40.13(c) and equivalent provisions of Agreement States.

Section 40.54 Requirements for license to initially transfer source material for use under § 40.22.

10 CFR 40.54 - Would establish requirements for a license authorizing initial transfer or distribution for use under § 40.22 and equivalent provisions of Agreement States.

Section 40.55 Conditions of licenses issued under § 40.54: Quality control, labeling, safety instructions, records and reports.

10 CFR 40.55 – Would establish requirements for licenses issued under § 40.54, including reporting and recordkeeping requirements for distributions of source material for use under the general license in § 40.22 and equivalent provisions of Agreement States.

Section 40.82 Criminal penalties.

10 CFR 40.82(b) – Would add sections to the list of provisions that are not subject to criminal sanctions.

Section 70.5 Communications.

10 CFR 70.5(b)(1)(iv) - Would add a reference to the proposed § 40.52 as a licensing category not delegated to the NRC Regions.

Section 170.31 Schedule of fees for materials licenses and other regulatory services, including inspections, and import and export licenses.

10 CFR 170.31 – Would add to the schedule of fees, three new categories for distributors of source material.

Section 171.16 Annual fees: Materials licensees, holders of certificates of compliance, holders of sealed source and device registrations, holders of quality assurance program approvals, and government agencies licensed by NRC.

10 CFR 171.16 – Would add three fee categories for distributors of source material to the annual fees.

| Section | Change | Subject | Compatibility | |
|----------|--------|---|---------------|-----|
| | | | Existing | New |
| 40.55(a) | New | Conditions of licenses issued under § 40.54: Quality control, labeling, safety instructions, and records and reports | - | B |
| 40.55(b) | New | Conditions of licenses issued under § 40.54: Quality control, labeling, safety instructions, and records and reports | - | B |
| 40.55(c) | New | Conditions of licenses issued under § 40.54: Quality control, labeling, safety instructions, and records and reports | - | B |
| 40.55(d) | New | Conditions of licenses issued under § 40.54: Quality control, labeling, safety instructions, and records and reports | - | B |
| 40.55(e) | New | Conditions of licenses issued under § 40.54: Quality control, labeling, safety instructions, and records and reports | - | C |
| 40.82 | Amend | Criminal penalties | D | D |
| Part 70 | | | | |
| 70.5 | Amend | Communications | D | D |
| Part 170 | | | | |
| 170.31 | Amend | Schedules of fees for materials licenses and other regulatory services, including inspections, and import and export licenses | D | D |
| Part 171 | | | | |
| 171.16 | Amend | Annual fees for materials licenses and other regulatory services | D | D |

* Denotes an existing provision that is currently designated Compatibility Category B which will be removed from the regulations as a result of these proposed amendments. Agreement States should remove this provision from their regulations when the amendment becomes final.

The NRC invites comment on the compatibility category designations in the proposed rule and suggests that commenters refer to Handbook 5.9 of Management Directive 5.9 for more information. The NRC notes that, like the rule text, the compatibility category designations can change between the proposed rule and final rule, based on comments received and

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: Commissioner Apostolakis
SUBJECT: SECY-09-0179 – PROPOSED RULE: DISTRIBUTION OF SOURCE MATERIAL TO EXEMPT PERSONS AND TO GENERAL LICENSEES AND REVISION OF GENERAL LICENSE AND EXEMPTIONS (RIN 3150-AH15)

Approved X Disapproved Abstain

Not Participating

COMMENTS: Below Attached X None



SIGNATURE

5/25/10

DATE

Entered on "STARS" Yes X No

Commissioner Apostolakis' Vote on SECY-09-0179- Proposed Rule: Distribution of Source Material to Exempt Persons and to General Licensees and Revisions of General License and Exemptions.

I appreciate the staff's efforts to provide the Commission a proposed rulemaking on a difficult and complex issue that will allow NRC to more accurately assess the public health and safety concerns regarding the distribution and use of certain source material. I approve the staff's recommendation to publish in the *Federal Register* the proposed amendments to Parts 30, 40, 70, 170 and 171, subject to the following comments.

I am concerned with the staff's proposed use of safety instructions to reduce the exposures of exempt persons and the reliance on a general licensee to assess the release criteria of 10 CFR 20.1401 if evidence of significant contamination is identified. Given the history of the current regulatory provisions and staff's concerns, it may be necessary to clearly define those activities that should not be under an exemption or a general license. Therefore, in addition to the specific question proposed by Commissioner Ostendorff, staff should also include questions in the *Federal Register* to determine whether these products or activities should or should not be authorized for use by exempt persons or under the general license provision.

Since the persons affected by this proposed rule have limited interaction with the Nuclear Regulatory Commission, staff should plan to publish the draft guidance documents during the public comment period to ensure that all interested parties will have the information they need to understand the proposed new requirements. Additionally, staff should use additional stakeholder outreach beyond the publication of this proposed rule. This outreach might include for example, public meetings, direct mailing to identified general licensees, or stakeholder newsletters, to ensure that the broadest populations of affected users are aware of the rulemaking. I support Commissioner Ostendorff's request that the staff report back on the methods utilized and results from such enhanced interactions.

Include in the *Federal Register* a conforming change to 10 CFR 40.32(f) "General requirements for issuance of specific licenses." that would reference the proposed rule Sections 40.52 and 40.54.



George Apostolakis

Date 5/25/10

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER MAGWOOD
SUBJECT: SECY-09-0179 – PROPOSED RULE: DISTRIBUTION OF SOURCE MATERIAL TO EXEMPT PERSONS AND TO GENERAL LICENSEES AND REVISION OF GENERAL LICENSE AND EXEMPTIONS (RIN 3150-AH15)

Approved Disapproved Abstain

Not Participating

COMMENTS: Below Attached None



SIGNATURE

5-28-10

DATE

Entered on "STARS" Yes No

COMMISSIONER MAGWOOD's Comments on SECY-09-0179

I approve the publication in the Federal Register of the proposed amendments to 10 CFR 30, 40, 70, 170 and 171. I agree with the staff that the proposed rule will ensure that the health and safety impacts in 10 CFR 40.22 are aligned with current standards and the reporting requirements will provide the NRC with a better understanding of how much source material is being distributed.

Currently, many general licensees dispose of source material in RCRA Type C and D landfills. The proposed amendments are welcome in that they take steps toward clarifying the source material disposal responsibilities of holders of general licenses and granting an exemption from 10 CFR Part 20 requirements for quantities of up to 1.1 pounds annually. Nevertheless, I believe the proposed amendments leave general licensees with practical challenges regarding the disposal of source material in excess of the proposed limit. Uncertainty or high hurdles to dispose of lawfully obtained source materials could impact the effectiveness of the provisions of the proposed amendments in protecting the common and health and safety of the public. Therefore, the proposed rulemaking should solicit comments on how licensees should dispose of larger quantities of source material in their possession, including disposal of all source material in RCRA Type C and D landfills.

In addition, it is important that staff establish early dialogue with organizations that would be most impacted by the proposed amendments to determine whether workshops are needed to explain the process for obtaining a specific license.

Patrick M. Butler for 5/28/10
William D. Magwood, IV Date

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER OSTENDORFF
SUBJECT: SECY-09-0179 – PROPOSED RULE: DISTRIBUTION OF SOURCE MATERIAL TO EXEMPT PERSONS AND TO GENERAL LICENSEES AND REVISION OF GENERAL LICENSE AND EXEMPTIONS (RIN 3150-AH15)

Approved Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below _____ Attached None _____

W. Ostendorff
SIGNATURE

5/20/10
DATE

Entered on "STARS" Yes No _____

Commissioner Ostendorff's comments on SECY 09-0179

I approve the publication in the Federal Register of the proposed amendments to 10 CFR 30, 40, 70, 170, and 171. I agree that revision to the current regulations will provide for better public and worker radiological protection from the hazards associated with certain isotopes of source material in dispersible form. Many of the proposed changes, such as requiring a specific license for initial distribution of generally licensed material, annual reporting of initial transfers, and providing instructions for safe use, are consistent with the NRC's general license provisions in other agency regulations.

The staff should revise, however, the requirement that a general licensee report to the NRC if there is evidence of "significant" contamination. Specifically, the staff should clarify how a general licensee might detect that significant contamination exists and what is considered significant. In addition, the proposed rule would not require surveys and it is expected that most general licensees do not retain staff qualified to evaluate whether a dose of 25 mrem may be exceeded if the facility is decommissioned for unrestricted use. Therefore, the staff should specifically solicit comments on the proposed requirements in 10 CFR 40.22 (c) to report to the NRC if significant contamination is identified and to work with the NRC staff to identify appropriate sampling activities to determine if the dose limit in 10 CFR 20.1402 may be exceeded.

Lastly, it is important that the proposed rule be clearly and extensively communicated to general licensees. Most general licensees, as the paper points out, have little if any contact with the NRC. Therefore, it is important that the staff communicates these changes in venues in addition to the Federal Register, such as trade journals and pertinent conferences, that capture the population of general licensees who would be affected by the proposed rule. The staff should communicate to the Commission in the final rule the methods used to communicate these changes and the feedback received from stakeholders on the proposed rule.