RULEMAKING ISSUE
NOTATION VOTE

December 10, 2009 SECY-09-0179

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

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

PURPOSE:

To request Commission approval to publish a proposed rule, in the *Federal Register*, that would amend 10 CFR Parts 30, 40, 70, 170, and 171.

SUMMARY

The proposed amendments would revise 10 CFR Part 40 to require specific licenses for the initial distribution of source material to exempt persons and to § 40.22 general licensees and would introduce new corresponding fee categories in Parts 170 and 171. In addition, the proposed amendments would modify the existing possession and use requirements for the § 40.22 general license to better align the requirements with current health and safety standards and ensure that certain isotopes of concern can no longer be possessed under the general license. Finally, proposed amendments would revise, clarify, or delete certain exemptions in § 40.13(c) to make the exemptions more risk informed. Other proposed revisions include minor conforming amendments in Parts 30 and 70.

BACKGROUND:

In April 2001, the staff submitted a rulemaking plan to the Commission (see Attachment 3 to SECY-01-0072, "Draft Rulemaking Plan: Distribution of Source Material to Exempt Persons and

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to General Licensees and Revision of 10 CFR 40.22 General License"). In the rulemaking plan, the staff recommended that Part 40 be amended to: (1) establish requirements for distribution of source material to exempt persons and to persons generally licensed under § 40.22; (2) revise certain exemptions; (3) address two petitions for rulemaking (PRMs), PRM-40-27 and PRM-40-28; (4) revise § 40.22 to create a two- (or more) tiered general license, applying increasing requirements potentially based on quantity, activity, form, and/or concentration, while retaining the exemption to 10 CFR Parts 19, 20, and 21 for persons involved with smaller quantities; and (5) revise § 40.25 to make it more broadly applicable to the regulatory program.

In the staff requirements memorandum (SRM) to SECY-01-0072, dated June 5, 2003, the Commission disapproved the development of the recommended regulatory changes at that time and directed the staff to compile additional available information about the products and quantities of source material distributed and used by exempt persons and general licensees and to conduct a realistic assessment of the need for regulatory changes. The SRM directed the staff to: (1) provide the Commission with the results of the assessment and any follow-up recommendations for changes in the associated regulatory program; (2) grant PRM-40-28, which raised concerns about the disposition of depleted uranium in aircraft counterweights; and (3) address issues in PRM-40-27, which raised concerns about the use of source material by general licensees resulting in some situations where exposures to workers are above 1 millisievert (mSv) per year (100 millirem (mrem) per year) and forward proposed resolutions for this petition with the aforementioned recommendations requested by the Commission.

Subsequently the staff has taken the following actions based on the Commission direction:

1) The staff resolved PRM-40-28, which requested additional rules for the control of depleted uranium aircraft counterweights, by denying the petition after consultation with the Commission, and instead issuing a regulatory information summary (RIS), RIS-05-003, "10 CFR Part 40 Exemptions for Uranium Contained in Aircraft Counterweights - Storage and Repair," dated February 28, 2007. RIS-05-003 clarified the regulatory requirements of the existing rule consistent with the petitioner's request.

2) The staff provided an evaluation based upon available current data on the distribution and use of source material under the § 40.22 general license in SECY-07-0196, "Information About Products and Quantities of Source Material to and Used by Exempt Persons and 10 CFR 40.22 General Licensees," dated November 6, 2007.

3) The staff closed PRM-40-27, which recommended changes to the existing § 40.22 general license, through a *Federal Register* Notice (FRN) (74 FR 46512, September 10, 2009) announcing that the petitioner's request would be considered as part of the enclosed rulemaking. This petition is further addressed in the discussion section.

On November 1, 2002, the staff provided the Commission with an evaluation of certain product exemptions, including those provided in Part 40 as part of SECY-02-0196, "Recommendations Stemming from the Systematic Assessment of Exemptions from Licensing in 10 CFR Parts 30 and 40; and a Rulemaking Plan for Risk-Informing 10 CFR Parts 30, 31, and 32." In that paper, the staff informed the Commission that revisions to 10 CFR Part 40 would be separately undertaken as part of the proposed revisions to 10 CFR 40.22 as proposed in SECY-01-0072.

In the SRM to SECY-05-0092, "Proposed Rule: National Source Tracking of Sealed Sources," dated June 30, 2005, the Commission directed the staff to "provide a paper to the Commission regarding tracking or providing enhanced controls for sources below the Category 2 thresholds." The staff responded to that direction by providing SECY-06-0094, "Tracking or Providing Enhanced Controls for Category 3 Sources," to the Commission on April 24, 2006. As part of the recommendations in SECY-06-0094, the staff requested approval to initiate a rulemaking to amend the general licenses in §§ 31.5 and 40.22 to limit the activity levels and to make regulatory improvements in §§ 31.5 and 40.22 (and manufacturer and distributor requirements in 10 CFR Parts 32 and 40) to ensure that similarly categorized sources are regulated more consistently. Specifically, in Enclosure 2 of SECY-06-0094, the staff recommended reconsideration of option 5 from the rulemaking plan found in SECY-01-0072. In the SRM to SECY-06-0094, dated June 9, 2006, the Commission approved the staff's recommended approach and directed the staff to amend the general license and to include manufacturer requirements. In SECY-07-0196, "Information About Products and Quantities of Source Material Distributed to and Used by Exempt Persons and 10 CFR 40.22 General Licensees" under "Additional Staff Findings," the staff further outlined the areas expected to be addressed by the proposed rule.

DISCUSSION:

The proposed rule would add new requirements for those persons who initially transfer, for sale or distribution, products and materials containing source material for receipt under an exemption or the general license in § 40.22. This proposed rule would also make a number of additional revisions to the regulations governing the use of source material under exemptions from licensing and under the general license in § 40.22. These changes are intended to better ensure the protection of public health and safety in an efficient and effective manner.

Establish New Requirements for Specific Licenses for Initial Distribution of Source Material

Currently, there are no regulatory mechanisms for the Commission to ensure that products and materials distributed for use under the general license in § 40.22 or use under exemption are maintained within the applicable constraints of the requirements for these uses. Because the staff cannot readily identify who possesses source material under the general license in § 40.22 or how and in what quantities the source material possessed under § 40.22 is being used, the staff cannot fully assess the resultant risks to public health and safety. The staff is proposing to address these concerns by requiring persons (e.g., manufacturers or importers) initially distributing source material to § 40.22 general licensees or to persons receiving products under exemption to obtain a specific license for such distribution. The requirements of such a license would include certain labeling and quality control requirements, as well as new reporting and recordkeeping requirements. These new requirements are expected to better ensure that persons safely possess such source material and that the U.S. Nuclear Regulatory Commission (NRC) will have a better understanding of how much source material is being distributed annually.

It should be noted that the NRC is not requiring registration by general licensees and so there still may be a number of persons possessing source material under the § 40.22 general license that the NRC and the Agreement States remain unaware of. These unidentified general licensees could obtain source material either by initially generating source material themselves (e.g., removal of uranium from drinking water) or through secondary transfers from general

licensee to general licensee. Although the staff may only have limited information about these general licensees, the staff does not believe the burden required to identify such persons is warranted at this time. These unidentified general licensees, though, are still required to meet the conditions in § 40.22.

New fee categories and fee amounts for these proposed new specific licenses are being proposed as revisions to Parts 170 and 171. These fees would be the only fees required by the NRC of distributors whose possession and use of source material is licensed by an Agreement State or who only import finished products for distribution. These fees would be in addition to existing fee requirements already applied to persons possessing or using source material under another NRC specific license. This is similar to the breakdown of fees for distributors of exempt byproduct material.

Revise Regulations for Possession and Use of Source Material under § 40.22

The staff is proposing to make major revisions to the requirements in the § 40.22 general license for small quantities of source material. In 1999, the State of Colorado and the Organization of Agreement States submitted a petition for rulemaking, PRM-40-27. In their petition, they identified concerns regarding the use of source material under the general license granted under § 40.22. In particular, the petitioners were concerned that general licensees are specifically exempted from meeting the requirements of Parts 19 and 20, despite the fact that situations exist where use of the material could result in exposures to workers above 1 mSv per year (100 mrem per year). The staff considered the petitioner's concerns and determined that situations can and do occasionally occur that exceed limitations under which Parts 19 and 20 usually apply, although most source material possessed under § 40.22 is likely handled in quantities, physical forms, or in uses and conditions that would justify the continued use of the exemptions to Parts 19, 20, and 21.

In light of the foregoing, the staff is proposing to revise § 40.22 to limit the opportunity for persons to receive doses exceeding 10 CFR Part 20 public dose limits by reducing the general licensee's possession limit to 1.5 kg (3.3 lb) at one time and limiting receipt to no more than 7 kg (15.4 lb) per calendar year for source material in a dispersible form or being processed. The possession limits for persons possessing source material in a solid, non-dispersible form (e.g., display samples of depleted uranium metal) that will not be processed and for persons treating drinking water to remove uranium would not be changed. In addition, the staff is proposing to implement new requirements for contamination control, decommissioning, and disposal to ensure that contamination and abandonment of source material possessed by general licensees become less of a concern. These new requirements would still be less than the requirements of a specific license, which is warranted because of the reduced risk by lowering the possession limits, and are intended to clarify many ongoing issues resulting from the current rule language in § 40.22.

The staff is also proposing to modify the type of source material allowed to be possessed under § 40.22. The International Atomic Energy Agency (IAEA) has categorized radioactive sealed sources according to the potential for radiological consequences that the sources pose. The IAEA categorization system is based primarily on the potential for radioactive sources to cause deterministic health effects, without any regulatory controls in place. Certain isotopes of uranium (U-232) and thorium (Th-228 and Th-229) could be possessed in quantities exceeding Category 1 limits of the IAEA Categorization under the existing § 40.22 general license.

Although the staff is not aware of the commercial possession or production of such isotopes, the staff is proposing to limit the possession of source material under the § 40.22 general license to only source material in its natural isotopic concentration or in the form of depleted uranium to ensure isotopes of concern cannot be legally possessed under the § 40.22 general license.

Delete or Revise Certain Product Exemptions

The staff is proposing multiple changes to the existing source material product exemptions to update the exemptions to account for current uses and health and safety impacts. The staff is proposing to delete exemptions for products that are no longer being used or manufactured, or to restrict future initial distribution of such products while allowing for the continued possession and use of previously distributed items. Specifically, it is believed that fire detection units containing source material have never been manufactured for commercial use and that ceramic tableware containing source material possessed under exemption could result in significant doses if routinely used. Therefore, the staff is recommending to delete the exemption in § 40.13(d) and to restrict continued possession of ceramic tableware under the exemption in § 40.13(c)(2)(i) to those products that were previously distributed prior to implementation of the proposed rule. The staff is also recommending to reduce the concentration limit for glassware containing source material in § 40.13(c)(2)(iii) from 10 percent to 2 percent by weight. The staff's evaluation indicates that most glassware is currently manufactured below this proposed limit; however, the staff would recommend continuing to exempt glassware previously manufactured under the existing concentration limit.

The staff is similarly proposing to reduce the source material concentration limit for optical lenses in § 40.13(c)(7) from 30 percent to 10 percent by weight to account for currently identified practices. In addition, because it has become more practical to apply the thorium as a thin-film coating instead of entraining the thorium within the lens, the staff is proposing to expand the exemption in § 40.13(c)(7) to include lenses coated with source material. The staff's evaluation indicates that coated lenses use significantly less source material than those containing homogenous source material throughout the lens and will result in exposure significantly below 10 microsieverts (μSv) per year (1 mrem per year). The expanded exemption would also include products with uranium coatings (currently it addresses only thorium) and apply to mirrors containing or coated with source material for its optical properties.

Minor Clarifying or Administrative Revisions

Other proposed revisions include minor conforming amendments in Parts 30 and 70.

Outcome of this Proposed Rule: Advancing the NRC's Strategic Goals and Objectives

The staff recommends this rulemaking because it best resolves the need for action on these issues arising from the current § 40.22 general license. The rulemaking is consistent with the agency's goals of ensuring: adequate protection of public health and safety and the environment, adequate protection in the secure use and management of radioactive material, and effectiveness and openness in the regulatory process. In general, the rulemaking process is intended to establish regulations which are enforceable; afford opportunity for public involvement; and are readily available to regulators, licensees, and the general public.

AGREEMENT STATE ISSUES:

A copy of the draft proposed rule FRN was provided to the Agreement States so they could have an early opportunity for review. Two Agreement States (Washington and Illinois) provided comments on the draft FRN.

The State of Washington identified three concerns in their comments: (1) that NRC was removing jurisdiction from the Agreement States through this rulemaking; (2) that reporting of transfers of source material to general licensees was already required (and that secondary transfers were prohibited); and (3) that NRC should do more to assure that general licensees follow the rules that already exist. The staff directly responded to the State to explain that this rulemaking did not remove any previously relinquished jurisdiction from the Agreement States and that they were likely confusing requirements for byproduct material general licensees with those for source material general licensees.

The State of Illinois generally supported the requirements to specifically license manufacturers and initial distributors. However, the State believes that the reduced possession limits (including for disposal) are harsh and could make it much more expensive for general licensees to dispose of their material or for government agencies to collect the material from schools or labs because of the additional requirements. Also, the State notes that the reporting requirements in 10 CFR 40.53(c) and 40.55(d) appear to parallel the general licensing reporting system currently in place for byproduct material devices and is concerned about the need to develop a tracking system and do inspections. Although the staff acknowledges these comments, no changes were made to the FRN. The staff concluded that the proposed reduction in possession limits would adequately protect public health and safety without the need to further tier the conditions of the general license to address all possible scenarios. Because the current regulations are not clear about the disposal requirements for material possessed under the § 40.22 general license, the staff included language in the proposed rule to clarify the disposal requirements with the specific intent to allow facilities possessing very small quantities of source material under the § 40.22 general license (e.g., educational and small labs) to directly dispose of the source material with minimal cost and impact to public health and safety. In response to the concerns about the reporting system, there is no expectation that States would be required to undertake a tracking and inspection system similar to that for byproduct devices; instead, the collected information would allow a State to better understand what source material is entering its State and who is operating under a general license within the State. Finally, the State provided responses to specific questions outlined in Section C of the “Discussion” section in the FRN itself. The NRC staff will hold those responses for consideration during the public comment period in order to provide equal consideration to all parties.

The NRC staff has analyzed the proposed rule in accordance with the procedures established within Part III of the Handbook to Management Directive 5.9, “Categorization Process for NRC Program Elements.”

The proposed rule would be a matter of compatibility between the NRC and the Agreement States, thereby requiring consistency among NRC and Agreement State requirements. The NRC staff is proposing that because the exemptions in § 40.13 and the general license in § 40.22 are Compatibility Category B, the revisions of these sections would also be Compatibility Category B (with the exception of § 40.22(b)(4) which would be Compatibility D

and § 40.22(c) which would be Compatibility Category C). New requirements in §§ 40.52 and 40.53 are proposed to be Compatibility Category NRC. New requirements in §§ 40.54 and 40.55 are proposed to be Compatibility Category B (with the exception of § 40.55(e) which would be Compatibility Category C). Sections 30.6, 40.5, 40.8, 40.82, 70.5, 170.31, and 171.16 are Compatibility Category D and would remain so.

The Standing Committee on Compatibility reviewed the proposed rule and agreed that these amendments to the NRC regulations are a matter of compatibility between the NRC and the Agreement States. The Committee agrees with the staff's compatibility designations as proposed in the rule.

COMMITMENTS:

Two volumes of the NUREG-1556 series should be updated if this rule is made final. NUREG-1556, Vol. 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses" and NUREG-1556, Vol. 16, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licenses" would require minor revisions or supplementation. The staff would update this guidance during the next overall revision of these documents after the rule is made final. This action includes no other new commitments other than routine rule related actions.

RECOMMENDATIONS:

That the Commission:

1. Approve for publication, in the *Federal Register*, the proposed amendments to 10 CFR Parts 30, 40, 70, 170, and 171 (Enclosure 1).

2. Note:

   a. That the proposed amendments will be published in the *Federal Register*, allowing 75 days for public comment.

   b. That the Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b).

   c. That a draft Regulatory Analysis has been prepared for this rulemaking (Enclosure 2).

   d. That a draft Environmental Assessment has been prepared for this rulemaking (Enclosure 3).

   e. That appropriate Congressional committees will be informed of this action.

   f. That a press release will be issued by the Office of Public Affairs when the proposed rulemaking is filed with the Office of the Federal Register.

g. Office of Management and Budget (OMB) review is required and a clearance package will be submitted electronically to OMB on or immediately after the date the proposed rule is in the *Federal Register*.

RESOURCES:

To complete and implement the rulemaking, the staff estimates that 1 full-time equivalent position will be required to finalize the rulemaking. This rulemaking was originally scheduled to be completed in FY 2010; however, because some staff resources were redirected to other higher priority rulemakings, the rulemaking has been delayed and staff estimates that the rulemaking will not be finalized until FY 2011. The staff estimates this project to require 0.8 FTE in FY 2010 and 0.2 FTE in FY 2011. Because the current FY 2010 budget allocates only 0.6 FTE and there is no allocation of resources for FY 2011, the staff will update budget allocations during the next rulemaking prioritization cycle to be consistent with these estimates. The reallocations from lower priority rulemakings will not impact overall funding for rulemaking efforts in FY 2010 and FY 2011.

COORDINATION:

The Office of the General Counsel has no legal objection to the proposed rulemaking. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections. The rule suggests changes in information collection requirements that must be submitted to OMB on or immediately after the date the proposed rule is published in the *Federal Register*.

/RA/ Martin Virgilio for

R. W. Borchardt
Executive Director
for Operations

Enclosures:
1. *Federal Register* Notice
2. Draft Regulatory Analysis
3. Draft Environmental Assessment

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Enclosures:
1. *Federal Register* Notice
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