

RULEMAKING ISSUE
(Affirmation)

July 19, 2012

SECY-12-0099

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: FINAL 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 final rule, in the *Federal Register*, that amends Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 30, 40, 70, 170, and 171.

SUMMARY:

The final rule revises 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 introduces new corresponding fee categories in 10 CFR Parts 170 and 171. In addition, the rule modifies the existing possession and use requirements in 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, the rule revises, clarifies, or deletes certain exemptions in § 40.13 to make the exemptions more risk informed. Other revisions include clarifying amendments and minor conforming amendments in 10 CFR Parts 30 and 70.

BACKGROUND:

In a Staff Requirements Memorandum (SRM) dated June 16, 2010 (NRC Agencywide Documents Access Management System (ADAMS) Accession No. ML101670483), the Commission approved publication of the proposed rule, "Distribution of Source Material to

CONTACT: Gary Comfort, FSME/DILR
301-415-8106

Exempt Persons and to General Licensees and Revision of General License and Exemptions,” (SECY-09-0179, December 10, 2009). It was published in the *Federal Register* on July 26, 2010 (75 FR 43425). The comment period was originally scheduled to close November 23, 2010, but was extended until February 15, 2011 (75 FR 70618; November 18, 2010). This was to allow the public sufficient time to review and comment on the proposed rule with the benefit of review of the draft implementation guidance, which was posted for public comment. A notice indicating the interim guidance was available for comment was published in the *Federal Register* on January 7, 2011 (76 FR 1100).

Fourteen comment letters from nine parties were received. The commenters on the proposed rule included licensees, industry organizations, a university, and an individual. A comment letter received from a State during the earlier Agreement State review was also addressed with the comments received during the public comment period. The comments are discussed in detail in the *Federal Register* notice (Enclosure 1).

Because of the lack of existing reporting requirements, there is not much data available on the identity of the affected stakeholders; nonetheless, the staff attempted to identify and notify affected stakeholders about the comment period for the proposed rule. First, the staff directly notified the only known distributor of source material for use by general licensees and requested that the distributor inform clients about the proposed rule. Also, the staff asked the distributor to identify journals that would broadly reach persons operating under a general license. This outreach did not prove successful. Second, the staff requested Agreement States to either contact known general licensees in their states or identify them so that the U.S. Nuclear Regulatory Commission (NRC) staff could contact them; several Agreement States were able to do so. Additionally, the staff identified a small contractor who provided support to numerous source material licensees. The contractor voluntarily included multiple notices about the comment period in its monthly newsletter. During the comment period, the staff spoke with representatives of the Zirconium Environmental Committee (ZEC) by telephone to clarify questions that ZEC had about the rule so that the ZEC could better formulate its comments. Finally, during resolution of the comments, the staff spoke with one commenter, by telephone, to clarify some of its more general comments, particularly regarding perceived burden. The staff clarified some misunderstandings during the call - no new comments were requested or contributed.

DISCUSSION:

The final rule adds 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 final rule also makes 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.

New Requirements for Specific Licenses for Initial Distribution of Source Material

Currently, there are no regulatory mechanisms for the NRC to ensure that products and materials distributed for use under the general license in § 40.22 or for 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 rule addresses 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 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 NRC will have a better understanding of how much source material is being distributed annually, who is using that material under a general license, and how that material is being used.

Through public comments received on the proposed rule the staff learned that some analytical laboratories may receive and analyze samples under the § 40.22 general license or may return samples received from a general licensee or exempt person. In order to reduce burden on these potential routine operations, the staff concluded that transfers to or from laboratories for the purpose of analyzing sample concentrations should not be considered initial distributions and thus subject to the requirements for a specific license for distribution. Similarly, the staff is proposing to revise the definition of “unrefined and unprocessed ore” to clarify that ore samples continue to be considered as “unprocessed” in order to alleviate potential violations where a laboratory may unexpectedly identify source material in an ore that would normally require licensing. The definition is also revised to clarify other activities that are not considered to result in “processed” ore.

New fee categories and fee amounts for these new specific licenses are included in draft final revisions to 10 CFR Parts 170 and 171. These fees are the only fees required by the NRC for source material distributors whose possession and use of source material is licensed by an Agreement State, or who only import finished products for distribution. These fees are 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. The staff will update the fees in the final rule to be consistent with any changes made to the current schedules of annual and materials fees prior to publication of the final rule.

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

The final rule would make significant 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 (the petitioners) submitted a petition for rulemaking, PRM-40-27. In the petition, the petitioners 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 10 CFR Parts 19 and 20, despite the fact that situations exist where use of the material could result in exposures to workers above 1 milliSievert (mSv) per year (100 millirem (mrem) per year). The staff considered the petitioners’ concerns and determined that situations can, and do, occasionally occur that exceed limitations under which 10 CFR 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 10 CFR Parts 19 and 20.

The draft final rule would revise § 40.22 to limit the opportunity for persons to receive doses exceeding 10 CFR Part 20 public dose limits, or the dose level at which workers would be required to be trained if working for a specific licensee, 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 that is processed or in a dispersible form (i.e., liquid, gaseous, or powder). The possession limits for persons possessing source material in a solid, non-dispersible form that will not be processed, for persons treating drinking water to remove uranium, and for analytical laboratories are not changed. In addition, the final rule contains 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 are less for a general licensee than those for a specific licensee, which is warranted because of the reduced risk by lowering the possession limits. In addition, the new requirements are intended to clarify the current rule language in § 40.22.

The final rule also would modify the type of source material allowed to be possessed under § 40.22. The International Atomic Energy Agency (IAEA) has categorized radioactive 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 source material, in particular thorium-228, could be possessed in quantities exceeding Category 1 limits of the IAEA Categorization under the existing § 40.22 general license. It should be noted that previously, the staff indicated that other isotopes (e.g., uranium-232 and thorium-229) could also be possessed under the general license; however, based upon further evaluation as a result of a comment received, the staff determined that these isotopes are "byproduct material" as defined in 10 CFR 30.4 because they are only yielded through reactions occurring in nuclear reactors or are produced in an accelerator and are not the "source" of special nuclear material. The staff has made this clarification in the statement of considerations for the final rule. Although the staff is not aware of any large scale commercial production of thorium-228, the final rule limits 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 that isotopes with high specific activities cannot be possessed under the § 40.22 general license or otherwise assumed to be covered by the general license.

Deletion and Revision of Certain Product Exemptions

The final rule would update the exemptions related to products containing source material to account for current uses and health and safety impacts by deleting exemptions for products that are no longer being used or manufactured and by restricting future initial distribution of such products. The final rule allows for the continued possession and use of previously distributed items for the revised exemptions. 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 rule removes the exemption in § 40.13(d) and restricts continued possession of ceramic tableware under the exemption in § 40.13(c)(2)(i) to those products that

were distributed prior to the effective date of the final rule. The rule would also 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 limit; however, the rule continues to exempt glassware previously manufactured under the previous concentration limit.

Similarly the rule would 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 exemption in § 40.13(c)(7) would be expanded to include lenses coated with source material. The staff's evaluation indicates that coated lenses use significantly less source material than those containing homogeneous 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 (previously, it only addressed thorium) and apply to mirrors containing or coated with source material for its optical properties.

Minor Clarifying or Administrative Revisions

Other revisions include minor conforming amendments in 10 CFR Parts 30 and 70.

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

The staff recommends approval of this final rule because it best resolves the need for action on these issues. 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.

It should be noted that the staff did not specifically consider cumulative effects of regulation during this rulemaking, primarily because most of this rulemaking effort was completed before the Commission's recent approach to reducing cumulative effects was established. However, because of the previously stated difficulties in identifying affected parties and because there have been no other significant rulemakings in this area for over 50 years, the staff concluded that the cumulative effects of regulation in this area would be minimal.

AGREEMENT STATE ISSUES:

A copy of the draft final rule *Federal Register* notice (FRN) was provided to the Agreement States so they could have an early opportunity for review. One Agreement State (Illinois) provided comments on the draft FRN. The State's comments primarily focused on its understanding of how the final rule would be implemented. The State did voice a concern that the recently revised final rule amending § 110.27 (77 FR 27113; May 9, 2012) would allow a "blank check" to import source material because no limits were defined and this would make it harder to identify importers. It should be noted that the Part 110 rulemaking only clarified the status quo, that a specific license was not necessary for the import of source material for use

under an exemption; however, once the new Part 40 requirements become effective, a person importing source material for domestic distribution for use under exemption will require a specific license.

Under the "Policy Statement on Adequacy & Compatibility of Agreement State Programs," the final rule is a matter of compatibility between the NRC and the Agreement States, thereby requiring consistency among NRC and Agreement State requirements. Therefore, the staff analyzed the final 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 staff determined that because the exemptions in § 40.13 and the general license in § 40.22 are Compatibility Category B, the revisions of these sections are also Compatibility Category B (with the exception of § 40.22(b)(4) which is Compatibility Category D and § 40.22(c) which is Compatibility Category C, and redesignated § 40.13(c)(5)(iv) which is Compatibility Category NRC). New requirements in §§ 40.52 and 40.53 are determined to be Compatibility Category NRC. New requirements in §§ 40.54 and 40.55 are determined to be Compatibility Category B (with the exception of § 40.55(e) which is Compatibility Category C). Sections 30.6, 40.5, 40.8, 40.82, 70.5, 170.31, and 171.16 are Compatibility Category D and remain so.

The Standing Committee on Compatibility reviewed the final 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.

COMMITMENTS:

Interim guidance will be issued when the final rule is published.

Two volumes of the NUREG-1556 series will also be updated to include guidance related to this rule. 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" both require minor revisions or supplementation as a result of the rulemaking. The staff is updating these guidance documents and will issue them for public comment 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 notice of final rulemaking (Enclosure 1).
2. To satisfy the requirement of the Regulatory Flexibility Act, 5 U.S.C. 605 (b), certify that this rule, if promulgated, will not have significant impact on a substantial number of small entities. This certification is included in the enclosed FRN.

3. Note:

- a. 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);
- b. A final Regulatory Analysis has been prepared for this rulemaking (Enclosure 2);
- c. A final Environmental Assessment has been prepared for this rulemaking (Enclosure 3);
- d. The staff has determined that this action is not a “major rule,” as defined in the Congressional Review Act of 1996 [5 U.S.C 804(2)] and has confirmed this determination with the Office of Management and Budget (OMB). The appropriate congressional and Government Accountability Office contacts will be informed;
- e. The appropriate congressional committees will be informed;
- f. A press release will be issued by the Office of Public Affairs when the final rulemaking is filed with the Office of the Federal Register; and
- g. The final rule contains amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.) that must be submitted to the OMB for its review and approval before publication of the final rule in the *Federal Register*.

RESOURCES:

To complete this final rule, no more than 0.1 full-time equivalent (FTE) positions will be required. To implement the rulemaking, 0.2 FTE positions will be required for reviewing new license applications for distribution to exempt persons and to general licensees, and less than 0.1 FTE per year will be required for inspections and amendments. These resources are within existing budget allocations.

COORDINATION:

The Office of the General Counsel has no legal objection to the final rulemaking. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

/RA by Michael F. Weber for/

R. W. Borchardt
Executive Director
for Operations

Enclosures:

1. *Federal Register* notice
2. Regulatory Analysis
3. Environmental Assessment

COORDINATION:

The Office of the General Counsel has no legal objection to the final rulemaking. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

/RA by Michael F. Weber for/

R. W. Borchardt
Executive Director
for Operations

Enclosures:

1. *Federal Register* notice
2. Regulatory Analysis
3. Environmental Assessment

ML12171A152/WITS200700410/EDATS: SECY-2010-0582

OFC	DILR/FSME	DILR/FSME	DILR/FSME	DMSSA/FSME
NAME	GComfort	JDanna	JPiccone/DJackson for	BMcDermott
DATE	6/22/12	6/27/12	7/5/12	5/16/12
OFC	DWMEP/FSME	OCFO	OIS	OGC
NAME	LCamper	MKidwell	TDonnell	TStokes
DATE	4/18/12	4/24/12	6/20/12	6/8/12
OFC	OE	ADM	Tech Editor	FSME
NAME	JWray for RZimmerman	CBladey	PTressler	MSatorius
DATE	4/23/12	5/2/12	7/10/12	7/13/12
OFC	EDO			
NAME	RWBorchardt (MWeber for)			
DATE	7/ 19/12			

OFFICIAL RECORD COPY