

## **RULEMAKING ISSUE INFORMATION**

November 6, 2007

SECY-07-0196

FOR: The Commissioners

FROM: Luis A. Reyes  
Executive Director for Operations

SUBJECT: INFORMATION ABOUT PRODUCTS AND QUANTITIES OF SOURCE  
MATERIAL DISTRIBUTED TO AND USED BY EXEMPT PERSONS AND  
10 CFR 40.22 GENERAL LICENSEES

PURPOSE:

To provide the Commission with the results of the assessment conducted by the staff on information compiled about the products and quantities of source material distributed and used by exempt persons and general licensees, and to provide the Commission with a schedule for the associated rulemaking. This paper does not address any new commitments.

SUMMARY:

Per direction in the staff requirements memorandum (SRM) to SECY-01-0072, "Draft Rulemaking Plan: Distribution of Source Material to Exempt Persons and to General Licensees and Revision of 10 CFR 40.22 General License," dated June 5, 2003, the staff collected information about the products and quantities of source material distributed and used by exempt persons and general licensees. The staff evaluated the collected information to determine the scope of needed regulatory changes. The staff found that although the use of most source material under § 40.22, "Small quantities of source material," is protective of public health and safety, there are certain situations that may occur where potential doses could exceed limits that would normally require additional regulation. Based upon this information and in consideration of the direction to proceed with rulemaking provided in the SRM to SECY-06-0094, "Tracking or Providing Enhanced Controls for Category 3 Sources," dated April 24, 2006, the staff has prepared a proposed schedule for rulemaking. The rulemaking would: (1) establish

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requirements for initial distribution reporting for exempt products and source material distributed to general licensees; (2) revise § 40.22 to make the health and safety requirements more consistent with the use of other radionuclides; and (3) revise other exemptions to make them more risk-informed. The staff will also clarify decommissioning and disposal requirements for § 40.22 licensees as part of the rulemaking.

#### BACKGROUND:

In April 2001, the staff submitted a rulemaking plan to the Commission (see Attachment 3 to SECY-01-0072). 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 of the 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 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 SRM to SECY-01-0072, dated June 5, 2003, the Commission disapproved the development of a tiered general license. The Commission instead 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 any regulatory changes. The SRM also 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 the issues in PRM 40-27 and forward proposed resolutions for this petition with the aforementioned recommendations requested by the Commission.

PRM-40-27 was submitted by the State of Colorado and the Agreement States in 1999. The petition raised concerns about the possession and use of source material by general licensees, under § 40.22, that could result in situations where exposures to workers could exceed 1 mSv/year (100 mrem/year), while the licensee is currently exempt from the requirements in Parts 19, 20, and 21. The petitioner recommended not allowing the exemption to Parts 19, 20, and 21 apply to persons: (1) whose use of source material could exceed the occupational dose limits in §20.1201 through §20.1208; (2) whose use of source material could require the use of personnel monitoring under §20.1502(a), (b) or (c); or (3) whose operation requires posting under §20.1902.

PRM-40-28 requested additional rules for the control of depleted uranium aircraft counterweights. This petition was subsequently denied, after consultation with the Commission, and instead a regulatory information summary, RIS-05-003, "10 CFR Part 40 Exemptions for Uranium Contained in Aircraft Counterweights - Storage and Repair," dated February 28, 2007, was issued to clarify that the regulatory requirements of the existing rule were already consistent with the petitioner's request.

In a memorandum dated August 3, 2004, "Update on Progress of Information Collection from Distributors of Source Material to Exempt Persons and General Licensees," (ML040760929), the staff provided the Commission a detailed update on its information collection activities. The

staff reported that it had adequate information on the uses of source material exemptions for products in § 40.13(c). Proposed revisions of these exemptions had been previously discussed further in Attachment 6 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," dated November 1, 2002.

Also in 2004, the staff contacted the only known remaining primary distributor of source material to general licensees, CERAC, Inc., and requested that the company voluntarily submit information regarding its distributions over the past 3 years. Subsequently, in January 2005, CERAC submitted the requested proprietary data. A follow-up status report on the information collected from the distributors was provided in a memorandum dated December 5, 2005, "Status of Information from Distributors of Source Material to Exempt Persons and General Licensees," (ML053210026).

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." In the requested paper (SECY-06-0094) the staff asked for 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 Part 32 and Part 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, the Commission approved the staff's recommended approach, to amend certain general licensees (Sections 31.5 and 40.22) and associated manufacturer requirements (Parts 32 and 40). The SRM also directed the staff to use Category 3.5 data in evaluating the general and specific licensing limits. The staff will develop a rulemaking package, as addressed in this paper, for the Part 40 issues, and will provide a separate rulemaking package for proposed changes to § 31.5 and Part 32.

## DISCUSSION

### *Data Collection*

With support from the Office of Nuclear Regulatory Research, a contract was established to assist with the evaluation of the 2005 CERAC data and previously collected distribution records from five distributors from the mid-1980's. The contractor, Pacific Northwest National Laboratory (PNNL), also conducted additional searches of the internet and used other professional resources in attempts to identify common uses of source material under the general license.

The collected information enabled PNNL to identify the primary operations conducted under the § 40.22 general license and equivalent provisions of the Agreement States, and to identify some potential new source material applications. Primarily based on the data submitted by CERAC, Inc. in 2005, the optical lens manufacturing industry was identified as the chief industry currently using source material under the general license in § 40.22. CERAC's proprietary data showed that, between July 2002 and December 2004, general licensees received shipments of source material from CERAC in various chemical forms. Of those shipments to general licensees, approximately half appear to be bulk shipments of thorium-fluoride (ThF<sub>4</sub>) sent to optical lens

manufacturers for lens coating operations. Other groups of general licensees included specialty chemical suppliers and academic institutions receiving various chemical forms of thorium and uranium. Although CERAC was the only current source material distributor identified, there are likely other domestic distributors and importers that the staff is not aware of because of the lack of reporting requirements.

PNNL developed a survey for the optical lens industry to obtain additional manufacturing information to assist in the development of more realistic evaluations. The voluntary questionnaire was sent to nine manufacturers. Only 3 of the 9 manufacturers responded. One of the respondents was a specific licensee and provided information about operations and employee exposures at their facility. The information provided in the two other responses afforded minimal insight into the details of how persons actually operate under the § 40.22 general license. These responses were not sufficiently detailed for the staff to determine if these general licensees use operating procedures as protective as those required of the specific licensee. Additionally, the effort continued to indicate the difficulty in identifying and obtaining information from persons operating under the § 40.22 general license using existing regulations.

#### *Dose Assessment*

To determine the potential impacts on health and safety from the existing § 40.22 general license, PNNL prepared a report, titled "PNNL-16148, Rev. 1 - Dose Assessment for Current and Projected Uses of Source Material Under U.S. NRC General License and Exemption Criteria" (ML070750105). The primary objective of PNNL's report was to identify and evaluate uses of source material permitted under § 40.22, and to assess the potential individual radiation dose to workers and members of the public from potential common and new uses of source material under the § 40.22 general license. This assessment also developed and assessed bounding but realistic scenarios for public exposure to source material using maximum amounts of source material as permitted under § 40.22. A secondary objective of this assessment was to similarly develop and assess bounding but realistic scenarios for public exposure to source material permitted under §§ 40.13(a) and 40.13(b) to support other staff activities.

In summary, the dose assessment indicates that the use of source material in consumer products and building materials is declining, with the number of identified major distributors of source material to general licensees having fallen from approximately five to one since 1986. The results of these radiation dose assessments are summarized in Table 17 on page 6.2 of the assessment report. The results suggest the following:

- Uranium and thorium-coated optical lenses yield minimal dose under routine use and accident conditions. However, the unprotected occupational worker exposed to thorium and uranium powders during the lens manufacturing process can potentially receive an annual internal radiation dose up to 560 mrem, and an annual committed effective dose approaching 800 mrem. Under the evaluated scenario (see section 5.1.2.3 of the PNNL report for greater detail), it is assumed that a small manufacturing facility produces lenses in a vacuum chamber. Worker exposures result from a single worker opening and cleaning the chamber on a daily basis, during which a fraction of the source material is dispersed into the air is respirable. In real world use, the staff believes these manufacturing doses would be tremendously reduced because they are done in hot cells and workers generally use respiratory protection (i.e., dust masks) in response to other regulatory requirements.

- As might be expected, the dose results for each of the bounding scenarios are not inconsequential, with the most extreme case being the bounding scenario used to evaluate source material usage under the general license. According to the PNNL report (see section 5.3.1), the annual committed effective dose to the individual using thorium-based materials could approach about 4.7 rem, for the bounding case of a single worker processing up to 150 lb/yr of thorium with progeny. Under this scenario, an owner or employee operating a small, dusty pottery operation works full-time preparing pottery, mixing pigments, and applying glazes all containing source material. This scenario is different than the one for manufacturing lenses in that it deals with a smaller room, the work is not done in a vacuum chamber, and a lower ventilation rate is assumed. Bounding scenario results need to be considered in light of the fact that the scenarios were developed with the specific intent of being conservatively bounding, but realistic.

As a result of these assessments, the staff believes that most source material possessed under § 40.22 is likely handled in quantities, physical forms, or in uses in conditions that would justify the continued use of the exemptions to Parts 19, 20, and 21. However, as indicated by PRM-40-27, and by the PNNL dose assessment's bounding dose calculations, situations can and do occasionally occur that do exceed limitations under which Parts 19 and 20 usually apply. The draft rulemaking will limit possession and use of source material under § 40.22 such that, under normal operating conditions, the limits that usually apply to Parts 19 and 20 are not exceeded and instead use of such material exceeding those limits will require a specific license. These proposed changes to § 40.22 would address the actions requested in PRM-40-27. Any changes in possession limits in this section will also consider Category 3.5 data in evaluating the general and specific licensing limits.

#### *Additional Staff Findings*

During collection of the data and development of the dose assessments, the staff identified the following additional issues resulting from the use of source material under the § 40.22 general license:

##### a. Lack of Reporting Requirements

The current lack of reporting requirements makes it difficult for the staff to ensure that the minimal restrictions in § 40.22 are being adhered to by the general licensees. Likewise, lack of reporting requirements makes it difficult to adequately understand the general licensees' use of source material. As shown by the problems the staff had in obtaining data, the staff is still basing its evaluation on a minimal data set. Because the usages are based primarily from the data from an individual distributor, it is unclear how much source material is actually possessed or distributed under the general license. This makes enforcement by NRC or the Agreement States dependent upon reports or allegations received. New reporting requirements for distribution to § 40.22 general licensees will therefore be included in the rulemaking to help identify persons operating under the § 40.22 general license and thereby allow NRC to better ensure that the material is being used consistently with the regulations. As also discussed in Option 5 of SECY-01-0072, the staff proposes to add new requirements for licensees distributing source material to exempt persons to better ensure that such distributions continue

to protect public health and safety and to understand how many exempt products are distributed to the general public.

#### b. Disposal and Decommissioning Concerns

Disposal and decommissioning of source material possessed under § 40.22 have also become concerns. The Part 20 decommissioning requirements are not applicable to facilities operating under the § 40.22 general license. Likewise, the Part 20 disposal requirements are not applicable to facilities operating under the § 40.22 general license. However, as indicated by PRM-40-27, residual contamination at an abandoned § 40.22 site could result in the potential for exposures to persons that exceed those normally requiring regulation under Part 20. Additionally, some § 40.22 general licensees may believe that they can release material as effluents or dispose of material in unlimited concentrations and amounts because of the exemption to Part 20.

The staff believes, however, that because a § 40.22 general licensee is not exempt from the transfer requirements in § 40.51, "Transfer of source or byproduct material," the general licensee may not dispose of or release source material as exempt material, unless that source material falls under an existing exemption in § 40.13, "Unimportant Quantities of Source Material." Section 40.51 requires that source material may only be transferred from a licensee to someone authorized to receive the material. The staff believes this section requires that the licensee transferring the material must ensure that the recipient is authorized and willing to receive the source material. If the general licensee does not adhere to these transfer requirements, a general licensee could transfer the source material without notice, resulting in a person unknowingly becoming a general licensee. Furthermore, transfers to an unlicensed disposal site, such as a land fill or waste water treatment facility, where numerous transfers from multiple sites could happen, could result in the recipient unknowingly violating requirements to obtain a specific license, thus putting undue burden upon the recipient. Similarly, § 40.51 could also be interpreted to require decommissioning prior to abandoning (or effectively transferring) the site to someone else's possession to ensure the recipient of the site does not inadvertently become a general licensee. As part of this rulemaking, the staff will clarify that the § 40.51 transfer requirements apply to § 40.22 general licensees and that the general licensee is required to notify the recipient prior to the transfer if it has the potential to make the recipient a general or specific licensee to ensure the recipient is authorized and willing to receive the source material. The staff will also clarify that prior to abandoning a site, the § 40.22 licensee should ensure that the facility is decommissioned to a state that any future person does not unknowingly become a general licensee.

#### c. Changes to Exemptions

As discussed in SECY-02-0196, and the staff's August 2004 memorandum, the staff believes it has adequate information on the uses of some source material exemptions for products listed in § 40.13(c). Accordingly, the staff will revise these exemptions during the development of the proposed rule. In particular, the staff plans to clarify the use of thorium-coated lenses under the product exemption in § 40.13(c)(7).

#### *Rulemaking Schedule*

The staff has developed a schedule intended to provide the Commission with a proposed rule by December 2008. The rulemaking will begin by assembling a working group, which will include a representative of the Organization of Agreement States, Inc. Specific milestones in the schedule are as follows:

<b>Action [Milestone]</b>	<b>Date</b>
Initiate Rulemaking with Working Group	December 2007
Issue Proposed Rule Package to Agreement States for Comment	August 2008
End Agreement State Comment Period	September 2008
Proposed Rule Package to EDO	November 2008
Proposed Rule Package to Commission	December 2008
Final Rule Package to Commission	~December 2009

The schedule is based upon the availability of resources and prioritization of this rule against other projects.

#### RESOURCES:

The staff has budgeted 2.4 FTEs and \$125,000 for technical support over 2.5 fiscal years (FY) to complete the rulemaking. A breakdown of the resource requirements is shown below:

Office/Division	FY08	FY09	FY10
FSME/DILR	0.6	0.9	0.3
FSME/DMSSA	0.1	0.1	0.1
OGC	0.1	0.1	0.1
FSME \$K	70	45	10

FY 2008 resource requirements are included in the FY 2008 budget. FY 2009 resources are being requested through the FY 2009 Planning, Budgeting, and Performance Management (PBPM) process. FY 2010 budget estimates are reasonable based on current schedule.

#### COORDINATION:

OGC has reviewed this paper and has no legal objections. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections. This paper has also been coordinated with the Chair of the Organization of Agreement States, Inc., and no issues were identified.

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