

## RULEMAKING ISSUE (Notation Vote)

April 25, 2001

SECY-01-0072

FOR: The Commissioners

FROM: William D. Travers  
Executive Director for Operations

SUBJECT: DRAFT RULEMAKING PLAN: DISTRIBUTION OF SOURCE MATERIAL  
TO EXEMPT PERSONS AND TO GENERAL LICENSEES AND  
REVISION OF 10 CFR 40.22 GENERAL LICENSE

### PURPOSE:

To provide the Commission with a draft rulemaking plan that includes an analysis of options for revising requirements in Title 10 of the Code of Federal Regulations, Part 40 (Part 40) related to general licenses and exemptions, and to request Commission approval to proceed with such a rulemaking.

### SUMMARY:

The staff recommends 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 Petition for Rulemaking (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.

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BACKGROUND:

Source material is used under specific license, general license, and various exemptions from licensing requirements in Part 40. Currently, however, 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 how these materials are being used and in what quantities, the staff cannot fully assess the resultant risks to public health and safety.

Because the Atomic Energy Act of 1946 focused on source material primarily in terms of common defense and security, the initial regulation of source material did not, apparently, consider public health and safety. In fact, "public health and safety" was not mentioned in relation to source material until the Atomic Energy Act of 1954; however, the emphasis on source material appears to still have been in terms of its significance to the production of special nuclear material. The last major modification of Part 40 occurred in 1961 in an attempt to establish licensing procedures, terms, and conditions for source material to be substantially similar to those set forth in Part 30, "Licensing of Byproduct Material." Since then, although both Parts 20 and 30 have been revised in response to issues involving public health and safety, Part 40 has not been significantly revised.

Concerns regarding the exemptions from licensing, in the Commission's regulation of byproduct and source material, prompted the Commission to consider the impacts of these exemptions. As a result, an assessment of potential and likely doses that might occur because of the exemptions, including those in § 40.13 was conducted in draft NUREG-1717: "Systematic Radiological Assessment of Exemptions for Source and Byproduct Material." Based on this assessment, using Part 20 methodology, it was found that the potential existed, during certain exempt activities (e.g., thorium welding rod users), for doses to exceed 1 mSv/year (100 mrem/year). In addition, PRM 40-28 was filed by Mr. David A. Barbour, Philotechnics, to raise specific concerns about the exemption for uranium in counterweights related to long-term storage and disposal. This followed the submission of PRM 40-27 from the State of Colorado and the Organization of Agreement States. The PRM 40-27 petitioners are concerned that § 40.22 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 (or at sites contaminated by material from activities completed under general license) could result in exposures to workers above 1 mSv/year (100 mrem/year). Attachment 1 includes copies of the PRMs.

In November 1999, the staff submitted SECY-99-259, "Exemption in 10 CFR Part 40 for Materials Less Than 0.05 Percent Source Material - Options and Other Issues Concerning the Control of Source Material," to the Commission. The paper includes a discussion of the issues discussed in the petitions (PRM 40-27 and PRM 40-28). The Commission issued a Staff Requirements Memorandum (SRM) dated March 9, 2000, in response to SECY-99-259. In this SRM, the Commission directed the staff to "... develop a rulemaking plan to improve the control of distribution of source material to exempt persons and to general licensees, and the incorporation of the resolution of PRM 40-27 in order to make Part 40 more risk-informed."

DISCUSSION:

In response to the SRM dated March 9, 2000, the Part 40 Rulemaking Working Group (hereafter referred to as the Working Group) was established. The Working Group includes representatives from both the Organization of Agreement States, the Conference of Radiation Control Program Directors, Inc., and the U.S. Nuclear Regulatory Commission staff. The Working Group held meetings beginning in October 2000, during which the participants identified problems with the existing Part 40 and developed options on how to resolve those problems. The Charter for the Working Group is provided in Attachment 2. Members of the public were allowed to observe the Working Group activities and participate, at appropriate times, during all Working Group meetings.

The Working Group identified numerous problems with the existing Part 40 regulations, most of which are found in §§ 40.13 and 40.22. Of particular concern to the Working Group was the lack of any mechanism that the Commission can use to readily identify the types and quantities of source materials being used under exemption or general license, so as to conduct a realistic assessment of impacts on public health and safety.

REGULATORY OPTIONS:

Based on the Working Group's findings, rulemaking options were developed to address possible solutions to the perceived problems with Part 40. These options and staff recommendations are listed below. A more detailed discussion, including pros and cons for each rulemaking option, is provided in the attached rulemaking plan (Attachment 3).

Option 1 - No Action

This option would leave the provisions of § 40.13 and § 40.22 unchanged, including the exemption noted for Parts 19, 20, and 21. PRM 40-27 and PRM 40-28 would be denied. There would continue to be no regulatory mechanism for the Commission to obtain information to fully assess the resultant risks to public health and safety, and no controls in place to ensure that products and materials distributed are maintained within the applicable constraints of the exemptions. This could impact NRC's ability to maintain safety and protect the environment.

Although this option would not increase regulatory burden on existing users of source materials, the inability of the Commission to be able to effectively communicate to the public the amounts and types of source material in use could impact public confidence. Because no change results under this option, there would be no change in the effectiveness, efficiency, or realism of NRC's activities and decisions.

Option 2 - Address PRM 40-27 and PRM 40-28 only.

Under this option, the staff would modify Part 40 to address the issues raised by the petitioners; all other areas of Part 40 would remain as they are. In response to PRM 40-27, § 40.22(b) would be modified to require general licensees to follow the requirements of Parts 19, 20, and 21 if: (1) their use of source material could exceed the occupational dose limits in § 20.1201 through § 20.1208; (2) their use of source material would require the use of personnel monitoring under § 20.1502; or (3) their operation

would require posting under § 20.1902. In response to PRM 40-28, the staff would provide clarification regarding the exemption for depleted uranium aircraft counterweights in § 40.13(c)(5), to require specific licensing for long-term storage and uses other than those indicated in the exemption, and identify requirements for disposal options in approved facilities.

Because the rulemaking changes proposed by this option would be responsive to the petitions and would allow NRC additional regulatory control, there would likely be some increase in public confidence. If problems are verified to exist, there is a potential for increasing NRC's ability to maintain safety; however, these changes would also result in an increase to regulatory burden. Some increase in the effectiveness, efficiency, and realism of NRC's activities and decisions may result because the petitions are based upon observed experiences.

#### Option 3 - Establish distribution requirements

Under this option, a specific license for distribution would be required to initially transfer products containing source material to exempt persons and to commercially transfer source material to general licensees under § 40.22 and equivalent Agreement State provisions. Any additional changes to Part 40 (including resolutions of PRM 40-27 and PRM 40-28) would be deferred until data could be collected, as provided under this option, on the amounts and uses of these types of source material.

The rulemaking changes proposed by this option would allow the Commission to be better informed about the types and amounts of source material being used under an exemption or a general license and should result in an increase in public confidence; however, it would also increase regulatory burden (primarily from new reporting and record keeping requirements) for both the staff and distributors. In the longer term, the data collected should help identify where additional modifications to Part 40 may be necessary and lead to a more efficient and effective approach for any additional rulemaking. However, if the data support the development of additional rulemaking similar to that proposed in either Option 4 or 5, this option could have the highest cost because of the duplicated rulemaking steps. There could be an impact on NRC's ability to maintain safety and protect the environment because of the deferral in addressing the PRMs.

#### Option 4 - Develop a tiered approach for regulating general licensees.

Under this option, the modifications in Option 3 would be completed. In addition, this option would modify § 40.22(a) by creating tiers of increasing requirements for general licensees, instead of maintaining the current general exemption to Parts 19, 20, and 21. These tiers would be developed using a risk-informed approach and could be based upon quantity, use, form, and/or concentration. Finally, exemptions would be reevaluated and other clarifications would be made throughout Part 40.

The changes presented under this option would increase NRC's ability to maintain safety and protect the environment. Any new regulations would be based on evaluated risk in order to create an efficient and effective regulatory program such that any additional burdens to users of source material were minimized. In addition, these

actions would likely increase public confidence because the regulations in Part 40 would be more consistent with regulations in other existing parts (e.g., Part 32). These changes would also address the concerns of PRM 40-27 and PRM 40-28. Although data would be collected from distributors, similar to Option 3, the results would not be evaluated before revision to other parts of the regulation and therefore, the actual impact of these regulatory changes on persons using source material under exemption or general license would not be fully identified. Without the more accurate data, the additional revisions may not result in the most efficient and effective regulatory program, thus leading to the possibility of a future revision. However, the staff believes that the changes proposed in this option warrant more immediate consideration because they will provide a greater assurance that generally licensed source material is being used safely and will maintain safety and protect the environment.

#### Option 5 - Require certain general licensees to become specific licensees

This option is the same as Option 4, except that instead of a tiered approach for regulating licensees, any current general licensee who would normally be required to take action under Part 20 (e.g. establish monitoring, etc.) if Part 20 applied, would be required to become a specific licensee.

This change would allow the Commission to better identify users and to enforce these requirements. This would lead to a greater assurance that generally licensed source material is being used safely, thus maintaining safety and protecting the environment. Further, because the specific license conditions are already in place, some regulatory development costs would be reduced. This option would also provide an existing method for fee recovery. However, this option would increase regulatory burden for both the new licensees and the staff, compared with the approach in Option 4 because of the increased number of specific licenses. The staff's problem in identifying the general or exempt source material users, that are impacted by the regulatory changes, would still apply, whereas the benefits of creating a more consistent regulatory approach and an expected increase in public confidence would also accrue.

#### AGREEMENT STATE COMMENT ON THE DRAFT RULEMAKING PLAN:

The Working Group includes representatives from both the Organization of Agreement States and the Conference of Radiation Control Program Directors, Inc. The draft rulemaking plan was provided to the Agreement States for their comments for a 30-day comment period beginning on January 31, 2001. Three comments were received regarding the draft rulemaking plan (see Attachment 4) during the comment period. The States of Colorado and Georgia preferred Option 5 over Option 4. Both States believe that a tiered approach for licensing would be overly complicated and would not sufficiently address the safety issues because of the limited amount of inspection or monitoring compared with what could be done under specific licensing. Further, the State of Colorado believes that the exemption from Parts 19 and 20 should be completely eliminated in order to provide equal protections for all persons. Washington State believes that Option 4 encompasses Option 5 well enough that Option 5 should be omitted. Further, although Washington State's preference is Option 4, it believes that there are insufficient data available to develop the tiers and therefore, suggests using a contractor to collect the data suggested under Option 3 in a shorter time period.

RESOURCES:

If the Commission directs the staff to go forward with Option 1, no resources would be required. Options 2 and 3 would cost 2.7 full-time equivalents (FTEs) and \$90,000 for technical support, spread out over 2 fiscal years. For Option 4, the resources would be approximately 5.5 FTEs and \$215,000 spread over 3 fiscal years. Option 5 is estimated to cost 4.75 FTEs and \$190,000 for technical support spread over 3 fiscal years. The FTE for each option include approximately 0.2 FTEs and 0.25 FTEs per year for working group support from the Office of State and Tribal Programs (OSTP) and the Office of the General Counsel (OGC), respectively. The resources for the staff's recommended option, Option 4, are available within the budget for fiscal years 2001, 2002, and 2003. The staff will need to evaluate the priority of the rulemaking, and other rulemaking activities, in accordance with the Planning, Budgeting, Program Management process. Because Option 4 is the most resource intensive, the resources could also be made available for any of the other options.

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. The Office of Enforcement has reviewed this paper for enforcement issues and concurs on it. OSTP has reviewed this paper for Agreement State implementation issues and concurs on it.

RECOMMENDATION:

The staff recommends that the Commission approve implementation of Option 4 in the rulemaking plan. This would result in more risk-informed regulation of general licensees through tiering, without adding as much regulatory burden as is envisioned under Option 5. Further, revisions to Part 40 would be evaluated in terms of current Part 20 requirements to better maintain safety and protection of the environment. Finally, the control of distribution would be improved, which should improve public confidence.

**/RA/**

William D. Travers  
Executive Director  
for Operations

## Attachments:

1. PRM 40-27 and PRM 40-28
2. Working Group Charter
3. Draft Part 40 Rulemaking Plan
4. Agreement State Comments

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1. PRM 40-27 and PRM 40-28 2. Working Group Charter 3. Draft Part 40 Rulemaking Plan  
4. Agreement State Comments DOCUMENT NAME: C:\ORPCheckout\FileNET\ML010860323.wpd  
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