

**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.

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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

State of Colorado

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Colorado Department  
of Public Health  
and Environment

May 10, 1999

The Secretary  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

Attention: Rulemakings and Adjudications Staff

RE: Petition for Rulemaking

The Officers of the Organization of Agreement States and the State of Colorado petition the U.S. Nuclear Regulatory Commission to eliminate the blanket exemption for source material general licensees from the requirements of 10 CFR Parts 19 and 20. This petition requests that the exemption in 10 CFR 40.22(b) be revoked for any source material general licensee that: 1) could exceed public dose limits; 2) could exceed the dose equivalent limits for an embryo/fetus; 3) would require personnel monitoring; or 4) would require posting of a radiation area.

This petition addresses significant safety issues that impact protection of public health and safety, and the environment.

Enclosed is the petition that sets forth the proposed regulation that is to be modified; the petitioner's grounds for and interest in the action requested; and the specific issues and facts that support the petition.

Stanley R. Marshall, Chairman  
Organization of Agreement States

Robert Quillin, Director  
Laboratory and Radiation Services Division,  
Colorado Department of Public Health  
And Environment

Enclosure: as stated

PETITION FOR RULE MAKING  
Modification of Exemptions to Parts 19 and 20 in 10 CFR 40.22(b)  
by the  
Officers of the Organization of Agreement States and  
the State of Colorado

Proposed Regulatory Text

NRC should restrict the exemption from 10 CFR 19 and 20 for general licensees. Any licensee that has the potential to exceed any dose limits or release limits, or which generates a radiation area as defined in Part 20 should be required to meet requirements in both Parts 19 and 20.

10 CFR 40.22 states:

(b) Persons who receive, possess, use, or transfer source material pursuant to the general license issued in paragraph (a) of this section are exempt from the provisions of parts 19, 20, and 21, of this chapter to the extent that such receipt, possession, use or transfer are within the terms of such general license: Provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to this part.

As proposed, this section would read:

(b) Persons who receive, possess, use, or transfer source material pursuant to the general license issued in paragraph (a) of this section are exempt from the provisions of part 19, 20, and 21, of this chapter to the extent that such receipt, possession, use or transfer are within the terms of such general license: Provided, however, that this exemption shall not be deemed to apply to any such person:

(1) who is also in possession of source material under a specific license issued pursuant to this part;

(2) whose use of source material could exceed the occupational dose limits in §20.1201 through §20.1208;

(3) whose use of source material could require tile use of personnel monitoring under §20.1502(a), (b) or (c): or

(4) whose operation requires posting under §20.1902

Statement of Considerations

Background

In 10 CFR Part 20, the NRC established basic radiation standards that apply to specific and most general licensees. These standards are consistent with national and international guidance. They are necessary to provide a frame work in which a licensee can conduct safe operations, prevent radiation workers and the public from exceeding dose limits, and to maintain all radiation exposures As Low As Reasonably Achievable (ALARA).

The NRC has also promulgated provisions in 10 CFR 19 to protect and inform individuals participating in licensed activities. The requirements in Part 19 are not restricted to certain licensees. §19.2 states:

“The regulations in this part apply to *all persons* who receive, possess, use, or transfer material licensed by the Nuclear Regulatory Commission pursuant to the regulations in parts 30 through 36, 39, 40, 60, 61, 70, or part 72 of this chapter...” [emphasis added]

While the NRC has established these basic standards and protections, it has exempted one class of licensee from meeting the requirements of both Parts 19<sup>1</sup> and 20.

Perhaps when this exemption was granted, generally licensed quantities of source material were not thought to be a health and safety hazard. Since this exemption was promulgated, that idea has been shown to be false, and the basic radiation standards have changed. These licensees can:

- expose workers to levels of radiation that require monitoring,
- dispose of radioactive materials in a manner that would not be acceptable for other licensees,
- produce contamination that exceeds release limits, and
- potentially exceed public dose limits to individuals other than those working at their facilities<sup>2</sup>.

It is the petitioners' contention that there is no basis for exempting licensees from complying with basic health and safety standards if the licensee can exceed any of Part 20 dose limits, or can produce “radiation areas”<sup>3</sup> as defined in Part 20.

If a radiation hazard exists that would require most licensees to implement corrective procedures, all licensees who create similar hazards should be required to eliminate the hazard. All individuals using radioactive materials, as well as the general public, should be protected from unsafe and unnecessary exposures to radiation resulting from a licensed operation. The petitioners further contend that individuals participating in licensed activities, and who may receive exposures in excess of the public dose limits in Part 20, should be instructed in both their rights as radiation workers and the procedures necessary to use radioactive materials safely.

The Officers of the Organization of Agreement States and the State of Colorado are impacted by the NRC exemption in two ways. First, because of the exemption, radioactive materials that are potentially hazardous can be transported into our states without the knowledge or control of the Radiation Control Programs. Secondly, experience has already shown that in at least two

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<sup>1</sup> It is noted that the exemption in §40.22(b) is inconsistent with §19.2.

<sup>2</sup> Because Part 20 defines “Radiation Worker”, and source material general licensees are exempt from part 20, these licensees technically do not have “Radiation Workers.”

<sup>3</sup> Because “Radiation area” is defined in Part 20, and these licensees are exempt from Part 20, a source material general licensee could technically have a “radiation area”, regardless of the exposure rate.

cases, state and/or local health departments have had to become involved in remediation efforts.

#### Discussion of problem

On January 28, 1999, Colorado Radiation Control Program received notice that a roll-off Dumpster had set off a radiation alarm at a landfill. The Dumpster had been used for construction debris resulting from a remodeling project after a source material general licensee vacated the structure. Exposure levels exterior to the Dumpster were 4.9 mR/hr. An investigation determined that the generator of the radioactive material was indeed a source material general licensee, who ensured his procurement did not exceed the 150 pounds per year limit in §40.22(a). Further investigation revealed that this licensee vacated the building with levels of contamination that exceeded limits for release for uncontrolled use, and that the licensee had significant levels of exposure at its new facility. Under the exemption in §40.22(b) (and equivalent requirements in Colorado's Regulations), this licensee, and others who use similar quantities of source material, is exempt from the basic health and safety criteria of Part 20.

To demonstrate the significance of this problem, the following is a summary of the measurements, analyses, and calculations of exposure that are associated with the Colorado incident. All exposures resulted from Thorium and its daughters.

- Effective dose equivalent to workers estimated to be up to 1 rem per year based on measurements made at the current facility's workstations.
- Residual contamination at the vacated facility in excess of current standards. Using NRC's computer code DandD version 1, the Maximum Annual Total Effective Dose Equivalent was calculated at 734 mrem, and compared to NRC's standard for unrestricted release - 25 mrem.

The Colorado incident is not the first one involving a source material general licensee. An Internet search identified a 1994 EPA enforcement against Broomer Research, Inc. of Islip, Long Island, New York. The plant manufactured optical lenses and used Thorium Fluoride. EPA identified "appreciable levels of radionuclides, assumed to be thorium, in the sludge discharged"<sup>4</sup> It is unlikely that these facilities are unique. A brief search on the Internet identified multiple suppliers of Thorium Fluoride, and at least one other optical coating company in California. Colorado has contacted manufacturers of Thorium Fluoride and attempted to obtain a list of their Colorado customers. However, to date, only one has supplied the requested information.

The exemption in §40.22(b) permits licensees to exceed the dose limits and ignore the safety issues in Part 20. It has been demonstrated that source material general licensees use materials in quantities that cause hazards and would require a specific licensee to adhere to the following requirements:

- Develop radiation and ALARA programs
- Limit occupational exposures - adults, embryo/fetus and minors

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<sup>4</sup> EPA FY 1994 Enforcement and Compliance Assurance Accomplishments Report - Section 3: Regional and State Enforcement and Compliance Assurance Activities.  
<http://es.epa.gov/comply/oeca/section3.html>

- Limit public dose
- Release limits
- Survey and monitoring requirements
- Storage and control of radioactive materials
- Posting storage areas, containers and radiation areas
- Procedures for receiving and opening packages
- Waste disposal requirements - this may also impact waste brokers and permitted sanitary landfills (see issues below)
- Waste manifests
- Worker training
- Posting of the "Notice to Workers"

There is no logical basis for exempting these licensees from general safety provisions, and allowing them to expose radiation workers and the public at levels greater than is allowed for specific licensees. The exemption should be modified so that it applies to any licensee that might exceed dose limits, release limits or whose operations involve working in a radiation area as defined in 10 CFR Part 20.

In addition to the exposure problems identified above, the "radiation workers" training, protections and rights that apply to all other licensees are exempted by §40.22(b) - even though they work in "a radiation area".

Waste disposal is another item that slips through file cracks because of the exemption. The requirements for the disposal of radioactive waste are also included in 10 CFR Part 20. Disposal is controlled for specific licensees. Unless specifically authorized by regulation or license condition, they must properly dispose of radioactive waste. They are not allowed to dispose of it as common trash. They are not allowed to dilute the waste so it can pass through gate monitors at landfills. If the radioactive waste from source material general licensees is transferred to a broker, that broker may be unaware of the hazard and potentially exposed, and may transfer the hazard to another waste handler for processing, who is likewise unaware of the problem. General licensees who possess source material believe that waste disposal is not an issue because it is only "Generally Licensed"<sup>5</sup>

How the regulatory revisions will solve the problem.

Restricting the exemption in §40.22(b) will ensure that there is a uniform standard of radiation safety for all that need it. All radiation workers will be protected. All licensees will limit public exposures to safe levels. All radioactive waste will be disposed of in accordance with Part 20 requirements.

#### Proposed Regulatory Action & Alternative Approaches

In addition to modifying the exemptions in §40.22(b) as requested, three other regulatory approaches were considered - no action, issuing a license to each general licensee who uses source material and could exceed any of the limits in Part 20, and removing the exemption for all source material general licensees.

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<sup>5</sup> The disposal of Low Level Radioactive Waste (LLRW) is also an issue for LLRW compacts, but this issue is not part of the petition.

The no action alternative is not acceptable because it permits licensees to exceed basic radiation standards and does not provide rights and protections to radiation workers.

Issuing a licensing document to each source material general licensee would be more expensive than changing the regulations, inappropriate, and unworkable. It is less expensive to modify the regulations once, than to issue licensing documents to each source material licensee; especially when companies come into and go out of business. Secondly, it is inappropriate to apply conditions to every such licensee rather than to go through a rule making process. Further, the NRC would not be able to easily determine the scope activity for each source material general licensee.

The third alternative, removing the exemption for all source material general licenses, is not appropriate in relation to the potential risks. There are many licensees that use only small amounts of source material and pose only minimal risks to workers and the public. For example, a laboratory that uses only gram amounts of uranyl nitrates poses little risk, and trace amounts are permitted to be disposed as other than radioactive waste.

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August 30, 1999  
99-0870

U. S. Nuclear Regulatory Commission  
Mr. Joe Decicco, NMSS/IMNS/OB  
Washington, D.C. 20555-0001

Subject: Depleted Uranium Aircraft Counterweights

Dear Mr. Decicco,

We note that the NRC is currently engaged in a rulemaking to establish additional requirements for certain generally licensed devices containing by-product material. We believe that similar concerns are relevant to depleted uranium aircraft counterweights. Although they are not within the scope of the present rulemaking, we believe that these items actually pose a more immediate and larger potential for public exposure. We submitted the comments contained in this letter for consideration in the rulemaking because many of the issues had strong parallels, but we have been informed that an expansion of the current rulemaking scope is unlikely. The following discussion supports the need for additional rules to define and clarify responsibilities for the effective control of depleted uranium counterweights. It also substantiates a pressing need for timely guidance to advise users of the requirements already established for the proper management of these items. Perhaps an IEE notice would be an effective medium for accomplishing this. A summary of key points that should be considered for incorporation in such a notice is also attached.

The problems associated with depleted uranium (DU) aircraft counterweights must be understood in the context of the practices of the aviation industry. Counterweights, made of extremely dense material such as DU, are used to balance the control surfaces of ailerons and elevators to facilitate hydraulic adjustments during flight. When properly marked by a licensed manufacturer, depleted uranium counterweights are currently exempted from all licensing requirements as an "unimportant quantity" while installed on a plane or stored or handled incident to installation or removal. The implication, confirmed verbally by the NRC staff, is that when counterweights are removed from service, they lose their exemption. This means that when a fleet is "set down" or a plane is scrapped out, hundreds to thousands of pounds of DU counterweights suddenly become source material requiring a license. When this happens, they are generally in the possession of an organization that has no license and no knowledge of the hazards of the material or of any regulatory requirements. Over the past nine months, we have conducted extensive informal industry surveys that confirm widespread unawareness of responsibilities and the controls that are applicable to depleted uranium aircraft counterweights.

A general license cannot be invoked to control this material because the amount of DU that can be possessed under a general license is limited to 15 pounds. Very few counterweights weigh less than this, e.g. a 1524834-101 counterweight for the L-1011 weighs about 11 pounds. In

contrast, an AMC-7226 counterweight from a DC-10 weighs approximately 191 pounds. Most DU counterweights for wide-body aircraft weigh between 20 and 50 pounds. Collectively, the quantities at issue almost always exceed the general license limit because a "ship set" of counterweights includes many counterweights and cumulatively weighs over 1,000 pounds for most aircraft models.

Depleted uranium counterweights were once widely used on the L-1011 Tristar, the DC-10 and the Boeing 747 wide-body commercial aircraft. DU was also used on general aviation planes such as the JetStar. Many military and naval aircraft employed DU for their counterweights. The A-7, F-111, C-5A, C-130, C-141, P-3C, S-3B are examples. Some, like the C-141, continue to use DU counterweights. Others, like the S-3B, are having their counterweights converted to tungsten. Some, like the A-7, have passed out of U.S. service to our allies, along with their DU components. So far we have been unable to locate an authoritative and comprehensive listing of all the planes for which DU counterweights were manufactured and distributed. Researching this may be complicated by the facts that some counterweights were manufactured in Canada and that a primary domestic producer, National Lead of Albany, went out of business in the 80's and decommissioned its Colonie, NY plant. As a result, DU counterweights may be in service on additional commercial aircraft types.

The use of depleted uranium for counterweights fell from favor, and today counterweights for new production aircraft are made from tungsten. A legacy of depleted uranium counterweights remains on the older planes. The total amount of these DU counterweights is difficult to determine accurately because the quantity varies for each different model of the wide-body types. We used parts listings and structural drawings to determine the amount of DU in ship sets of counterweights for representative L-1011, DC-10, 747 and JetStar aircraft. Based on the numbers of these planes in existence and a survey of the quantities of some of the counterweights in the inventories of aviation parts suppliers, we estimate that as many as two million pounds may be in service, world-wide, for commercial aircraft. As these planes approach the end of their economical service life, DU counterweights are beginning to enter uncontrolled disposal channels in a rapidly increasing stream.

The average of ages of existing wide-body commercial aircraft are 22.9 years for the L-1011, 23.4 years for the DC-10, and 15.8 years for the 747. Increasing numbers of these planes are now being "set down", "parted-out" and scrapped. Major airlines are knowledgeable enough to insure appropriate disposal of their surplus counterweight spares, although, in the process, they usually store the (now non-exempt) counterweights for prolonged periods without a license. The fate of counterweights entering parts and salvage channels generally consists of abandonment or of transfer to unlicensed operators and disposal in municipal and industrial landfills and other sites. Thousands of pounds are now being so disposed. It is clear that many of these companies are unaware of proper storage and disposal requirements.

Depleted uranium counterweights often remain on aircraft that are retired from service and consigned to long-term storage, parts recovery, or salvage. DU counterweights are corrosion prone but are plated and painted to retard oxidation. When they cease to be maintained in airworthy condition and subjected to systematic inspection, release of radioactive uranium oxides is highly probable. Although military aircraft are not subject to FAA inspection and maintenance directives, recent observations of the C-141 maintenance program confirm that without on-going surveillance, corrosion of DU counterweights can progress to the point where radiological contamination of maintenance facilities and long-term storage areas is threatened.

This potential for environmental release could be minimized by terminating the exemption of counterweights on aircraft that are not in active use.

The findings of the NRC Study of Conformity with General License Conditions apply even more emphatically to the possessors of DU counterweights. Ignorance of the hazards and properties of the material and of regulatory controls on alteration, transfer and disposal are virtually total. During our inquiries, responsible managers have casually explained their company's regular procedures for turning over hundreds and thousands of pounds to unlicensed salvage operators and scrap dealers. They obviously have no idea that they are doing anything wrong or violating regulatory requirements. Although counterweights manufactured after 31 December 1969 were required to be marked "Unauthorized Alterations Prohibited", we have received anecdotal reports of individuals sawing up counterweights and using them for "bucking bars" to set rivets. State and municipal officials have begun to encounter abandoned counterweights at airports and discarded in trash dumpsters.

A recent incident involving a DU counterweight is illuminating. On 28 July 1999, the NRC published, in its Daily Events Report, an incident in which some Air Force mechanics at Robbins Air Force Base removed a DU counterweight from a C-14 aileron with a hammer and chisel, scattering a small quantity of dust and debris. This incident is now the subject of a formal investigation because someone at the scene was aware of the hazard. The irony of this level of response, while hundreds of thousands of pounds of the same material are being released into the public domain, speaks for itself.

Several complimentary regulatory responses to this situation may be appropriate. The existing regulations urgently require clarification of a number of issues including the point, and the circumstances under which, the exemption from licensing ceases, the length of time counterweights for which there is no demand or use can be stored as exempt material, the extent to which DU-bearing aircraft leaving service can be transferred to unlicensed parts dealers and salvage operators, and the need for radiological surveillance of long-term aircraft storage parks and facilities where counterweights have been stored for protracted periods under unmonitored conditions. As an attachment to this letter, some of these points are defined and discussed in more detail. Many of these issues closely parallel the ones that are being addressed in the current rulemaking. This circumstance suggests the alternatives of expanding its scope or of initiating a separate one along similar lines.

In the interim, it is clear that some immediate notification is necessary to advise the organizations currently in possession of depleted uranium aircraft counterweights of their responsibilities to the public. The aviation community is a tightly regulated and law-binding one. There are extremely effective channels of communication with its primary regulator, the Federal Aviation Administration. Perhaps the NRC could take advantage of these existing channels by encouraging the FAA to issue an appropriate advisory bulletin informing the aviation community of its responsibilities for managing depleted uranium counterweights. An effective and practical solution must clearly involve the active participation of the aviation community and must be based on a detailed understanding of the realities that govern its daily activities and operations.

The management of depleted uranium aircraft counterweights is a real problem that merits serious regulatory review. At this stage, it can probably be brought under control, and previous inappropriate disposals and releases can be corrected and remediated. If I can provide any additional information or insights, I will be glad to do so.

Sincerely,

Donald A. Barbour  
Project Manager, Depleted Uranium Programs

Enclosures

c Dr. Thomas T. Holloway, Manager  
Environment, Energy, and Employee Safety Division  
Federal Aviation Administration

## UNRESOLVED ISSUES AND QUESTIONS RE DEPLETED URANIUM AIRCRAFT

1. When an airline or operator "sets down" a fleet of DU-bearing aircraft, how long does it have to effect disposition of spare parts inventories of DU counterweights before it needs to apply for a source material license to maintain possession of them? Based on informal conversations with the NRC staff and with state regulators, one interpretation is that DU counterweights lose their exemption from licensing when they are no longer intended for their original use. Criteria based upon intent (such as intent to sell surplus counterweights to another operator) tend to be difficult to enforce. As aging planes are retired and "parted out", spare parts inventories will predictably swell even as real demand disappears, along with the number of aircraft to be supported. This development would reflect the fact that it may be cheaper to store DU counterweights indefinitely rather than to pay the costs of authorized disposal. Frequency of demand or period of non-use might afford one objective tool for determining the credibility of a representation of intent for future use. The NRC encountered an analogous problem in enforcing its requirement that licensees clean up and decommission their unused facilities. Licensees deferred clean-up costs by claiming possible future uses. The NRC finally promulgated the "Timeliness Rule", which requires that, if a licensed facility has remained idle for two years, the decommissioning process must be initiated. Perhaps, by analogy, DU aircraft counterweights should lose their exemption from licensing if they have not been used in flight (or, for a particular part number, have experienced no demand) for a specified period. Another objective indication of intended use relates to how the part is managed. Modern commercial aircraft incorporate over one million different parts. They are almost always managed by an automated data processing system. All parts are classified in such a system as either "repairable" or "consumable". Another common industry term for parts that may be economically repairable is "rotable". "Consumable" parts, on the other hand, that do not meet criteria for airworthiness are automatically directed to disposal channels. The "system" will not allow the issuance of a repair order for a "consumable" part. Categorization of DU counterweights as "consumable" parts in an organization's ADP system is therefore a clear indication that such a part loses its exemption from licensing as soon as it is removed from an aircraft.
2. Presumably, the exemption from licensing for DU counterweights, stored incident to installation on an aircraft, applies to counterweights in the inventories of aviation parts dealers who are attempting to sell them back to operators and maintenance organizations for their originally intended use. Do such counterweights, that are held in storage for a specified period without being sold, lose their exemption from licensing, requiring the aviation parts dealer to apply for a source material license or to transfer the parts to an appropriate special licensee, e.g. for controlled disposal?
3. Can DU counterweights in the possession of a salvor, scrap dealer, or parts broker be considered as exempt from licensing because of a (theoretical) possibility of future use on an aircraft? Such organizations often acquire parts (such as DU counterweights) that they do not expressly want because they are included in a large-scale consignment, transaction, or inventory transfer along with other high demand parts. An important factor in making such a determination should be the recognition that the Federal Aviation Administration requires a documentation of airworthiness for all parts used on an aircraft. This is effected by means of a completed FAA Form 8130-3 (Airworthiness Approval Tag) (or JAA Form One or equivalent for foreign carriers) that must accompany the part. Counterweights coming out of a tear-down facility would have to be shipped to an FAA

licensed repair station for inspection, repair (if required), and issuance of the FAA Forms 8130-3 before they could be put to their original intended use. This is an expensive procedure and is not economically justified by the current negligible demand for DU counterweights. If a scrap or parts dealer accepted a consignment of material from an aircraft tear-down facility and did not obtain accompanying FAA Forms 8130-3 for the counterweights, it would be a good indication that there was no realistic prospect for their reuse. In fact, transfers of counterweights, without Forms 8130-3, from a tear-down activity to an unlicensed scrap or parts dealer is probably inconsistent with the intent of the regulations. From the time that DU counterweights are removed from an aircraft and enter either parts or salvage channels, the possessor should bear the burden of demonstrating a realistic probability of reuse, either by obtaining Forms 8130-3 immediately upon transfer or by other affirmative means.

4. Do DU counterweights installed on an aircraft lose their exemption from licensing if they remain installed on an aircraft that is placed in long-term storage, "moth-balled", or transferred for "parting out" or salvage? Aircraft that are not maintained in airworthy condition and subjected to periodic inspections and maintenance will eventually experience corrosion of counterweights and release of radioactive oxide onto storage areas and into the adjacent environment. The FAA defines an aircraft as a device intended for flight, so aircraft taken out of service cease to be aircraft in its view. If installation, even on a non-operational aircraft, qualifies the counterweights for exemption from licensing, it means that the parts company performing a tear-down could remove engines, avionics and other high value components for refurbishment and reuse and leave the counterweights attached to the carcass consigned for scrapping. At what point does the stripped aircraft cease to be an aircraft? Can the DU counterweights be left attached to a bare airframe or a subassembly and legally abandoned?
5. Under the proposed rule-making, devices containing by-product material that were stored for two years without being used are going to require disposition. By analogy, should depleted uranium counterweights installed on aircraft parked in long-term storage and not flown for a specified period lose their exemption? Would the owner/operator of the storage facility be required to obtain a source material license, remove the counterweights and place them in controlled storage, or perform periodic radiation monitoring and surveillance to insure against release of corrosion products into the environment?
6. Military aircraft with DU counterweights, e.g. the A-7 Corsair, have been transferred to allied governments through foreign military sales. The gaining organizations are not always aware of the presence of the DU or of the controls that are appropriate. The notifications and information requirements that are appropriate to such transfers should be established.

## SUGGESTED POINTS FOR AN INFORMATION NOTICE

- Depleted uranium (DU) counterweights installed in aircraft are exempt from the requirements for licensing.
- The exemption also applies to counterweights that are being handled or temporarily stored incident to installation or removal.
- When these conditions are not met, DU counterweights are not exempt, and an organization must possess an NRC (or "agreement state") radioactive material license to retain possession of them.
- When DU counterweights lose their exempt status, there are three ways by which they may properly be brought under license control. The possessor may apply for his own radioactive material license. He may, alternatively, contract with a special licensee whose "umbrella" type license authorizes him to provide radiological protection support services to a third party. He may also transfer the counterweights to a special licensee, such as a radioactive waste broker, for authorized management or disposal.
- Depleted uranium aircraft counterweights may not enter unlicensed disposal channels. Transfer of DU counterweights to unlicensed scrap dealers, salvors, or disposal facilities is prohibited.
- The exemption of counterweights from licensing while they are being stored incident to removal or installation is not an exemption for indefinite storage. Factors and circumstances that would indicate counterweights were not exempt from licensing include: low recorded demand for a counterweight part number or prolonged storage period for a particular counterweight, lack of a current accompanying FAA Form 8130-3 (Airworthiness Approval Tag), classification of a removed counterweight as a "consumable" part in the organization's automated data processing system (part not subject to repair orders), existence of a corporate decision or policy to replace DU counterweights with tungsten equivalents, and accumulation and storage of counterweights under conditions similar to those applied to scrap materials or wastes.
- Counterweight users should be aware that the uranium oxide corrosion products from improperly maintained counterweights are radioactive, chemically toxic, and easily spread. Maintenance and storage areas where depleted uranium corrosion products have been released should be radiologically surveyed. Radiological contamination of facilities should be reported to the NRC or appropriate state agency so that required clean-up actions can be verified.

## 10 CFR PART 40 RULEMAKING WORKING GROUP CHARTER

October 17, 2000

**Purpose** Propose options to address problems in 10 CFR Part 40 (excluding regulations specific to uranium recovery activities) identified by the working group in order to improve the control of distribution of source material to exempt persons and to general licensees and make 10 CFR Part 40 more risk-informed.

### Working Group

Gary Comfort, NRC, NMSS, Group Leader  
Catherine Mattsen, NRC, NMSS  
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Jean-Claude Dehmel, NRC, NMSS  
Myron Fliegel, NRC, NMSS  
Betsy Ullrich, NRC, Region I  
Bill Sinclair, State of Utah, Agreement State representative  
Steve Collins, State of Illinois, CRCPD representative

### Background

10 CFR Part 40 defines source material as “(1) Uranium or thorium, or any combination thereof, in any physical or chemical form or (2) ores which contain by weight one-twentieth of one percent (0.05%) of: (i) Uranium, (ii) thorium or (iii) any combination thereof. Source material does not include special nuclear material.”

Apart from a specific license, source material is used under various exemptions from licensing requirements in Part 40 for which there is no regulatory mechanism for the Commission to obtain information from distributors/manufacturers to fully assess the resultant risks to public health and safety. No controls are in place to ensure that products and materials distributed are maintained within the applicable constraints of the exemptions. An assessment of potential and likely doses occurring as a result of these exemptions has been recently conducted (Draft NUREG-1717: “Systematic Radiological Assessment of Exemptions for Source and Byproduct Material”) which raises concerns that some exemptions may need to be reexamined. A recent petition, PRM-40-28, also raises concerns about the exemption for uranium in counterweights.

In addition, the amounts of source material allowed under the general license in § 40.22 could result in exposures to workers at facilities exempt from Parts 19 and 20 that are greater than 10 CFR Part 20 exposure limits. A recent petition from the State of Colorado and the Organization of Agreement States, PRM-40-27, addresses this issue. Like source material exempt from the requirements in Part 40, there currently are no requirements specifically for those distributing source material for use under § 40.22; and thus, no regulatory mechanism exists for the NRC to identify the general licensees or get information on what material types and quantities are distributed or to fully assess the resultant risks to public health and safety. Without knowledge of the identity and location of the general licensees, it would be difficult to enforce restrictions on the general licensees. In Part 40, the Commission has no provisions setting forth requirements for licensing the distribution of source material to exempt persons or to persons using the general license in § 40.22.

The working group will consider recent health and safety data to determine what (if any) problems exist with the current content of 10 CFR Part 40. This would not include regulations dealing specifically with uranium recovery activities that are being addressed separately. This working group will identify problems with 10 CFR Part 40 and propose options to address these problems. This will be done through a risk-informed approach while attempting to minimize the impact to current and potential licensees.

### **Function**

- Bring together NRC and State representatives to identify problems with 10 CFR 40 and suggest options to address these problems in order to better protect the safety of the public and the environment regarding the use of source material. This would not include regulations dealing specifically with uranium recovery activities that are being addressed separately.
- Identify advantages and disadvantages of any proposed options to address the identified problems with 10 CFR Part 40 and their impacts to the public, licensees and potential licensees, and regulators.
- Provide input into the development of a draft rulemaking plan and any subsequent rulemaking package.

### **Desired Products**

- Draft Rulemaking Plan.
- Draft Rulemaking Package.
- Documentation of the activities of the Working Group.

**Rulemaking Plan**  
10 CFR Part 40

DISTRIBUTION OF SOURCE MATERIAL TO EXEMPT PERSONS AND TO  
GENERAL LICENSEES AND REVISION OF 10 CFR PART 40.22 GENERAL LICENSE

REGULATORY ISSUE

Source material is used under specific license, general license, and various exemptions from licensing requirements in Title 10 of the Code of Federal Regulations, Part 40 (Part 40). Currently, however, there are no regulatory mechanisms for the Commission to ensure that products and materials distributed for use under a general license in § 40.22 or use under exemption are maintained within the applicable constraints of the requirements for these uses. Because the NRC staff cannot readily identify how these materials are being used and in what quantities, the NRC staff cannot fully assess the resultant risks to public health and safety.

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 as a result 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, a Petition for Rulemaking (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).

For this rulemaking effort, a working group consisting of staff from the NRC, the Organization of Agreement States, and the Conference of Radiation Control Program Directors, Inc., has been established. The working group held its first meeting in October 2000, and held two teleconference calls in November 2000. Members of the public have observed these meetings and participated, as appropriate.

## EXISTING REGULATORY FRAMEWORK

Section 40.13 exempts persons from licensing requirements for the possession and use of a number of products and types of source material.

Section 40.22 provides a general license authorizing commercial and industrial firms, research, educational and medical institutions, and Federal, State, and local government agencies to use and transfer not more than fifteen (15) pounds of source material at any one time for research, development, educational, commercial or operational purposes. A person authorized to use or transfer source material under this general license, may not receive more than a total of 150 pounds of source material in any one calendar year. Persons using this general license are exempt from Parts 19, 20, and 21, unless such persons are also in possession of source material under a specific license.

Part 32 sets out requirements for distributors of byproduct material to exempt persons and to persons using a general license; however, Part 40 contains no similar requirement except in §§ 40.34 and 40.35 for applicants/licensees to distribute certain products and devices using depleted uranium for use under the general license in § 40.25.

## RULEMAKING OPTIONS

### **OPTION 1: No Action.**

This option would leave the provisions of § 40.13 and § 40.22(a) and (b) unchanged, including the exemption noted for Parts 19, 20, and 21. 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. PRM 40-27 and PRM 40-28 would be denied.

### Advantages

- No resources would be required to perform or implement rulemaking.
- No new burden on licensees.

### Disadvantages

- Part 40 would continue to allow uses which could result in exposures greater than 1 mSv (100 mrem).
- Concerns in PRM 40-27 and PRM 40-28 would not be resolved.
- No improvements to the control of distribution of source material would be made.
- Does not address concerns stemming from draft NUREG-1717 regarding source material exemptions.

**OPTION 2:** Address PRM 40-27 and PRM 40-28 only.

Under this option, the NRC staff would modify Part 40 to address the issues raised by the petitioners, as follows. No changes would be made to other aspects of Part 40.

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. Currently § 40.22 general licensees are exempted from the requirements of Parts 19, 20, and 21.

In response to PRM 40-28, the NRC staff would provide clarification to 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.

Advantages

- The time to develop a proposed rule to address the issues in the PRMs is likely to be less than the time it would take to complete a more comprehensive rulemaking.
- Limits expenditure of resources because of focused goal and decision to accept petitioner's recommended approach.

Disadvantages

- Implementation of the petitioner's proposal in PRM 40-27, by itself, would still not provide NRC staff adequate information to enforce any regulatory changes because general licensees would still not be readily identifiable.
- Increased costs associated with requiring all § 40.22 general licensees, even those using very small quantities, to become more knowledgeable of Part 20 requirements and to make dose assessments to determine if the requirements of Parts 19, 20, and 21 would apply to them.
- Increased burden on persons using uranium aircraft counterweights by potentially requiring general or specific licensing for long-term storage.
- No improvements to the control of distribution of source material would be made.
- Does not address concerns stemming from draft NUREG-1717 regarding source material exemptions.

**OPTION 3:** Revise Part 40 to establish requirements for distribution of source material to exempt persons and to persons operating under the general license provisions of § 40.22.

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. Applicants for authorization to distribute would be required to provide information about the types of products or materials to be distributed, the expected useful life of any products, the methods used to dispose of these products after their useful life, and the type of information (e.g., instructions, safety

notices, etc.) to be included with products or materials. Material transfer reporting would be required of distributors. The reported data would be expected to include identification of products distributed, the amounts or concentrations of source material contained in each product, and the total amount of source material transferred in a reporting period. Reports from distributors to § 40.22 general licensees would also include information such as the identity and address of the general licensees. Details of these and any other additional requirements that may be placed on applicants and licensees for distribution authorization would be decided during the rulemaking process, but are expected to be similar to the requirements for distribution authorized in Parts 30 and 32.

This information would provide the NRC staff with a method of identifying many of the uses of source materials that are currently unknown. Because of the current lack of reporting requirements, the NRC staff has minimal knowledge of the use and amounts of source material currently under exemption or general license. As a result, the NRC staff is concerned that the actual impacts of this material to public and workers is not understood enough to determine the level of additional oversight necessary to make risk-informed regulatory changes. After approximately 2 years of data gathering on these uses, the NRC staff would recommend additional rulemaking based upon any identified impacts from the newly collected data. This would allow sufficient time to gather information characterizing industries that use or distribute products that contain source material, identify additional distributors and general licensees, better characterize the use of source material under exemptions, and review the collected data to evaluate the impacts. Resolution of PRM 40-27 and PRM 40-28 would be deferred until this new data is collected so that the NRC staff can evaluate it to better characterize the need and impact of the changes proposed in the PRMs.

#### Advantages

- NRC would focus specifically on one issue in rulemaking in the near term, allowing more timely resolution of the specific issue.
- Limits expenditure of NRC resources in the near term because of focused goal.
- Rulemaking, in the near term, would only impact a small category of persons (distributors of source material).
- No additional burden on most persons using source material under exemptions or general licenses.
- Additional collected data would allow the NRC staff to make future changes to Part 40 based upon a more complete and accurate data set for evaluating impacts to public and persons using source material resulting in a more effective, efficient, and realistic regulatory program.
- The Commission's ability to inform the public on the products distributed to the public and the resulting doses would be improved, thus improving public confidence.

#### Disadvantages

- PRM 40-27 and PRM 40-28 would not be resolved in a timely manner.
- Resolution of many other issues related to Part 40 (e.g., clarifications, draft NUREG-1717 data, etc.) would be deferred to a much later time.

- Additional regulatory burden is put on distributors of source material (primarily from new record keeping and reporting requirements).
- If only a small set of distributors can be identified, the information collected may not be representative of the actual impacts.
- May delay overall development of additional rulemaking activities associated with source material and result in a greater number of resources to take action on the possible multiple rulemakings.

**OPTION 4:** Revise Part 40 to establish requirements for distribution of source material to exempt persons and to persons generally licensed under § 40.22; revise certain of the exemptions; address PRM 40-27 and PRM 40-28; revise § 40.22 to create a two- (or more) tiered general license, applying increasing requirements potentially based upon quantity, activity, form, and/or concentration, while retaining the exemption to Parts 19, 20, and 21 for persons involved with smaller quantities; and revise § 40.25 to make it more broadly applicable (e.g., include depleted uranium shielding, etc.) to the regulatory program.

This option would modify § 40.22(a) by creating tiers of increasing requirements for general licensees, based upon risk, 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. This risk-informed evaluation could also result in some current general licensees moving into the specific license category or, possibly some specific licensees becoming general licensees. The actual tiers and the resulting requirements (e.g., applicability of portions or all of Parts 19, 20, and 21) would be developed during the rulemaking process and based upon evaluations of impacts to persons and the environment to ensure that resulting annual doses would be unlikely to exceed 1 mSv (100 mrem) under routine conditions, including disposal. One tier would continue to maintain the exemption to Parts 19, 20, and 21 (with possibly limited exceptions) if the amounts or form of source material used or transferred stayed within the redefined limits. One or more additional tiers would be developed to include the requirement to follow most or all of Parts 19, 20, and 21. This would address the concerns raised in PRM 40-27.

Additionally, 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 as presented in Option 3. The additional data gathered under these new reporting requirements for distributors would be evaluated to determine if any additional regulations or other changes to the new regulations would be required.

Consideration will also be given to the revision or removal of exemptions for source material in § 40.13, based on PRM 40-28, the dose estimates in draft NUREG-1717, and other considerations. Section 40.25, and related distributor requirements in §§ 40.34 and 40.35, would be revised to make them more risk-informed and reduce the regulatory burden associated with these parts. As part of these revisions, the application of § 40.25 to all new depleted uranium products (including depleted uranium shielding, which accounted for approximately 20 percent of Part 40 specific licenses in 1992) would be considered.

Additional clarifications would be made throughout Part 40.

## Advantages

- There would be greater assurance that generally licensed source material is being used safely.
- Tiering of general licensees would allow for more risk-informed regulation, without adding additional costs of requiring general licensees to become specific licensees (as suggested in Option 5).
- The control of distribution of source material would be improved.
- The Commission's ability to inform the public on the products distributed to the public and the resulting doses would be improved thus improving public confidence.
- PRM 40-27 and PRM 40-28 would be addressed and resolved.
- For those who may be required to be specifically licensed, NRC would provide more oversight to specific licensees than to general licensees to ensure that Parts 19, 20, and 21 requirements are being met.
- Inconsistencies between Part 40 and Part 20 would be minimized through the review of exemptions and changes to § 40.22.
- Additional collected data would allow the NRC staff to make future changes to Part 40 based upon a more complete and accurate data set for evaluating impacts to public and persons using source material resulting in a more effective, efficient, and realistic regulatory program.
- Improved accountability for the control of depleted uranium products and devices.
- Would allow § 40.25 to be more broadly applicable to the regulatory program by reducing the regulatory burden currently associated with this section and making a general license available to some specific licensees (e.g., users of depleted uranium shielding).

## Disadvantages

- More burden to many of those current general licensees who would have increased regulatory requirements.
- NRC staff workload would be increased in both regulatory development and implementation.
- Additional regulatory burden on distributors of source material (primarily from new record keeping and reporting requirements).
- Regulatory program may not be as efficient, effective, or realistic as one developed after collecting data as proposed under Option 3.
- Could potentially result in negative impacts to some industries because of changes to exemptions.
- Legitimate use of material may be discouraged because of increased costs (for example, users may substitute materials or methods that do not use source materials).

**OPTION 5:** Same as Option 4, except that § 40.22 would be revised to authorize a smaller quantity of source material for use under the general license and require persons using quantities above this revised limit to obtain a specific license.

This option is the same as Option 4, except, instead of creating a tiered approach, this option would modify § 40.22(a) by reducing the quantities of source material currently allotted under the provisions of the general license, i.e., 15 pounds of source material at any one time and

150 pounds of source material in any one calendar year. The reduction in the allowable quantity of source material would be based on radiation protection considerations so that the new limit would ensure that resulting annual doses would be unlikely to exceed 1 mSv (100 mrem) under routine conditions, including disposal. Persons wanting to use or transfer amounts of source material greater than the new limit would be required to obtain a specific license, and would be subject to the full requirements of Parts 19, 20, and 21. This is different from Option 4, which would require the application of portions or all of Parts 19, 20, and 21, dependent upon quantity, form, use, and/or concentration, without the additional burdens (e.g., license applications) of specific licensing. Option 5 would still retain (with possibly limited exceptions) the provisions of § 40.22(b) regarding the exemption to Parts 19, 20, and 21 if the amounts of source material used or transferred are within the quantities specified by the revised limit. This would address the concerns raised in PRM 40-27.

#### Advantages

- There would be greater assurance that generally licensed source material is being used safely.
- NRC would provide more oversight to specific licensees than to general licensees to ensure that Parts 19, 20, and 21 requirements are being met.
- Licensing and annual fees would be applicable to the new specific licensees to offset increased NRC and Agreement State regulatory costs.
- The control of distribution of source material would be improved.
- The Commission's ability to inform the public on the products distributed to the public and the resulting doses would be improved thus improving public confidence.
- PRM 40-27 and PRM 40-28 would be addressed and resolved.
- Inconsistencies between Part 40 and Part 20 would be minimized through the review of exemptions and changes to § 40.22.
- Additional collected data would allow the NRC staff to make future changes to Part 40 based upon a more complete and accurate data set for evaluating impacts to public and persons using source material resulting in a more effective, efficient, and realistic regulatory program.
- Improved accountability for the control of depleted uranium products and devices.
- Would allow § 40.25 to be more broadly applicable to the regulatory program by reducing the regulatory burden currently associated with this section and making a general license available to some specific licensees (e.g., users of depleted uranium shielding).

#### Disadvantages

- Additional regulatory and financial burden on general licensees that are moved to specific licenses.
- NRC staff workload would be increased in both regulatory development and implementation.
- Regulatory program may not be as efficient, effective, or realistic as one developed after collecting data as proposed under Option 3.
- Additional regulatory burden on distributors of source material (primarily from new record keeping and reporting requirements).

- Could potentially result in negative impacts to some industries because of changes to exemptions.
- Legitimate use of material may be discouraged because of increased costs (for example, users may substitute materials or methods that do not use source materials).

#### RECOMMENDED APPROACH

**OPTION 4:** Revise Part 40 to establish requirements for distribution of source material to exempt persons and to persons generally licensed under § 40.22; revise certain of the exemptions; address PRM 40-27 and PRM 40-28; revise § 40.22 to create a two- (or more) tiered general license, applying increasing requirements potentially based upon quantity, activity, form, and/or concentration, while retaining the exemption to Parts 19, 20, and 21 for persons involved with smaller quantities; and revise § 40.25 to make it more broadly applicable to the regulatory program.

Implementation of Option 4 should result in more risk-informed regulation of general licenses through tiering, without adding as much regulatory burden as 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 and would allow the Commission to better inform the public about the products being distributed, which should improve public confidence.

OPTION 5 is recommended as a close second choice, because the use of a specific license for persons required to meet the requirements of Parts 19, 20, and 21 would make it easier to identify those persons for oversight. However, the NRC staff recommends Option 4 over Option 5 primarily because it will likely have less impact on persons currently operating under a general license. As discussed under Option 3, the NRC staff does not have readily available information to specifically identify the impacts of these proposed regulatory changes to persons currently holding general licenses or operating under an exemption. Option 5 allows the NRC staff greater flexibility to limit the impact on these persons until more information can be collected and provides additional protections against potential impacts to the public, workers, and the environment.

#### THE OFFICE OF THE GENERAL COUNSEL (OGC) LEGAL ANALYSIS

The Office of the General Counsel (OGC) has reviewed the NRC staff's plans for a rulemaking to amend Part 40. The NRC staff has developed five options for consideration ranging from Option 1, which maintains the status quo, to Option 5, which addresses the distribution of source material to exempt persons and to general licensees and would also amend the provisions for a general license contained in § 40.22. In addition, Options 2, 4, and 5 of the rulemaking plan also address two pending petitions for rulemaking. The NRC staff recommends the development of Option 4.

Based on direction from the Commission in the March 9, 2000, SRM on SECY-99-259, the purpose of undertaking rulemaking activities to revise Part 40 would be to improve control of the distribution of source material to exempt persons and to general licensees. Option 4 is a comprehensive revision of Part 40 that includes establishing requirements for the distribution of source material to exempt persons and to persons generally licensed under § 40.22. Section

40.22 would be amended to create a two-tiered general license using a risk-informed approach. Those authorized to use a smaller quantity of source material would still be exempt from the requirements of Parts 19, 20, and 21, while those using greater amounts under the general license would, appropriately so, be subject to those parts. The risk-informed evaluation could result in some current general licensees moving to the specific license category. In addition, this approach could also result in the availability of a general license to some specific licensees, e.g., users of depleted uranium shielding. Therefore, this option would address PRM 40-27 which raises concerns about the exposures to workers exempt from Parts 19 and 20 from the amounts of source material allowed under the general license in § 40.22. In addition, it would address PRM 40-28, which raises concerns about the control of exempted depleted uranium counterweights used in aircraft after the aircraft are no longer in service.

The development of a proposed rule would require the preparation of an environmental assessment (EA) to determine if there would be any significant impacts to the public health and safety or the environment, because it appears that there are no categorical exclusions in § 50.51(c) that are applicable. In addition, a proposed rule would require a regulatory analysis to examine the costs and benefits of the options considered by the NRC staff in this rulemaking plan; and, pursuant to the Regulatory Flexibility Act, whether the rule, if adopted, would have a significant impact on a substantial number of small entities.

The rulemaking plan adequately describes implementation issues associated with the Agreement States, i.e., the distribution of materials to persons exempt from licensing is reserved to the NRC and is, therefore, classified as compatibility Category “NRC” and would remain so. The general license in §40.22 and most of the provisions related to distribution of materials to general licensees are and would remain compatibility Category B. Consideration will be given to changing some or all of the provisions in §§ 40.25, 40.34, and 40.35 from Category C to Category B because of their significant transboundary implications.

Because a proposed rule would involve additional information collection requirements that are not provided for in the current Part 40, the NRC staff must prepare an Office of Management and Budget (OMB) package. In addition, as required by the Small Business Regulatory Enforcement Fairness Act, the NRC staff will confirm with OMB before issuing a final rule that this action does not constitute a “major rule.”

We do not believe a proposed rule would require a backfit analysis because this action would not be considered a backfit pursuant to the regulations in Parts 50, 72, and 76.

In conclusion, OGC has determined that there are no known bases for legal objection to proceeding with Option 4 as proposed in this rulemaking plan.

#### BACKFIT CONSIDERATIONS

None of the affected licensees come under requirements subject to the backfit requirements of §§ 50.109, 72.62, or 76.76.

## AGREEMENT STATE IMPLEMENTATION ISSUES

Under the “Policy Statement on Adequacy and Compatibility of Agreement State Programs” approved by the Commission on June 30, 1997, and published in the *Federal Register* on September 3, 1997 (62 FR 46517), distribution of materials to exempt persons is classified as compatibility Category “NRC.” The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act or provisions of Title 10 of the Code of Federal Regulations, Chapter I. The general license in § 40.22 and most of the provisions related to distribution of materials to general licensees are compatibility Category B. Category B means the provisions affect a program element with significant direct transboundary implications. The State program element should be essentially identical to that of NRC. The general license in § 40.25 is compatibility Category C. Category C means that the provisions affect a program element, the essential objectives of which should be adopted by the State to avoid conflicts, duplications, or gaps in the national program. The requirements for distributors to general licensees under § 40.25 contained in §§ 40.34 and 40.35 are a mix of Categories B, C, and D. Category D means that the provision does not have to be adopted as a matter of compatibility.

The proposed requirements for distributors of source material to exempt persons will be Category “NRC.” The changes to § 40.22 and the new requirements for distribution of source material to § 40.22 general licensees will be Category B. Consideration will be given to changing some or all of the provisions in §§ 40.25, 40.34, and 40.35 from Category C to Category B, because of the significant transboundary implications.

## SUPPORTING DOCUMENTS

This rulemaking would require a detailed regulatory analysis that the NRC staff believes would show a benefit to the public by maintaining safety and protecting the environment, while increasing public confidence. The information provided in the Regulatory Analysis for each change concerning the impact on small entities would be sufficient to support a Regulatory Flexibility Analysis or a certification that the proposed rule would not have a significant economic impact on a substantial number of small entities. A backfit analysis is not needed. An Office of Management and Budget (OMB) clearance package will be needed because the rulemaking will impose new record keeping and reporting requirements. An environmental assessment would be necessary to demonstrate that there are no significant impacts to the environment and public health and safety.

Consideration should be given to revising NUREG-1556, Vol. 8, “Consolidated Guidance About Materials Licenses; Program-Specific Guidance About Exempt Distribution Licenses;” NUREG-1556, Vol. 16, “Consolidated Guidance About Materials Licenses; Program-Specific Guidance About Licenses Authorizing Distribution to General Licenses to include guidance for source material distribution licenses;” and Regulatory Guide 10.4, “Guide for the Preparation of Applications for Licenses to Process Source Material, Rev. 2, December 1987.”

## SMALL BUSINESS REGULATORY ENFORCEMENT FAIRNESS ACT

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC believes that this action is not a "major rule" and, before issuing the final rule, will verify this with the Office of Information and Regulatory Affairs, OMB.

### RESOURCES

The resource estimate to complete this rulemaking using Option 4 is:

<u>Fiscal Year</u>	<u>FTEs</u>	<u>Technical Assistance</u>
2001	1.0	\$40,000
2002	3.0	\$100,000
2003	1.5	\$75,000

Resources for Option 5 are estimated to be about 4.75 full-time equivalents (FTEs) and \$190,000 for technical support spread across 3 fiscal years. This is slightly less than the resources estimated for Option 4 because regulations for specific licenses are already in place and would not require additional development. Under Option 4, regulations to each specific tier would require development. In both Options 4 and 5, significant work would be involved in determining where those tiers should be placed. However, the longer-term operating costs after implementation of Option 5 would be greater than Option 4 for both the Agency and the users due to the efforts required to develop and review the additional number of specific license applications.

The resource estimate for Option 3 is 2.7 FTEs and \$90,000 spread over 2 fiscal years. Because Option 3 would not require any development or changes to general licenses or exemptions, except those related to changes for distributors, the resource estimate for Option 3 is less. Because it is expected that the regulatory changes envisioned under Option 3 would be modeled after the Part 30 design, these changes could be implemented in a shorter period of time than either Option 4 or 5. However, depending upon the results of data collected under Option 3, resources for implementing any further changes to Part 40, resulting from the evaluation of the collected data, would likely result in the use of a greater number of resources overall (due to the effort of developing additional rulemakings).

Estimates for Option 2 are 2.7 FTEs and \$90,000 spread over 2 fiscal years. This estimate is similar to Option 3 because the steps to develop the rule would be equivalent.

Finally, Option 1 would result in the expenditure of no resources toward rulemaking.

LEAD OFFICE STAFF AND STAFF FROM SUPPORTING GROUPS

Staff Level Working Group

Concurring Official

Lead Office

NMSS/IMNS - Gary Comfort  
Catherine R. Mattsen  
NMSS/DWM - Jean-Claude Dehmel  
NMSS/FCSS - Mike Fliegel  
NMSS/RGN I - Betsy Ullrich

Martin J. Virgilio

Supporting Offices

OGC - Maria Schwartz  
OSTP - Kevin Hsueh

Stuart Treby  
Paul Lohaus

Agreement States

Bill Sinclair, Utah

CRCPD

Steven Collins, Illinois

STEERING GROUP

NMSS	Don Cool
OGC	Stuart Treby
STP	Paul Lohaus
CRCPD/OAS	Barbara Hamrick

ENHANCED PUBLIC PARTICIPATION

There is no need for enhanced public participation for this rulemaking at this time. This rulemaking plan and any subsequently published proposed rule would be placed in the NRC's rulemaking website. This website allows users to submit comments electronically as well as to review comments submitted by others. If public interest increases in the future regarding this rulemaking, the NRC staff will make arrangements to provide enhanced public participation by holding public meetings in locales determined at that time to provide the greatest efficiency in allowing public participation.

EDO OR COMMISSION ISSUANCE

This rulemaking would be issued by the Commission.

## SCHEDULE

Establish expanded working group  
(Add OCFO, ADM, OCIO, OE)

1 month after approval of rulemaking plan.

Proposed rule to EDO  
Public Comment Period

18 months after approval of rulemaking plan.

120 days because of the difficulty in identifying  
impacted parties

Final rule to EDO

9 months following expiration of public comment  
period.

**State of Georgia (rcvd 2/26/01) :**

In All Agreement States Letter STP 01-007 NRC requested comments on options in the draft proposed rulemaking plan to revise 10 CFR Part 40. In particular, NRC was interested in whether Options 4 and 5 are sufficiently distinct to warrant separation, or whether they should be combined.

Staff reviewed the prm in STP-01-007, and have concluded that Option 4 and Option 5 are distinct enough to choose between them and we think that option 5 is the better of the two. Because of the lack of over sight of general licensees versus specific licensees option 4 would not provide for the required over sight. Since general licensees are not inspected or monitored on as frequent a basis, this option is not a real change from the status quo.

Thomas E. Hill, Manager  
Radioactive Materials Program  
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## **State of Washington (rcvd 2/27/01):**

We have reviewed the draft Part 40 information found on the Technical Conference Forum and have just posted comments at that site. However, given the short time frame left in the comment period we are forwarding our comments to all Agreement States for your information and opportunity to comment as well.

Regulatory Issue -- The use of 100 millirem per year as the general license "limit" is referenced here as well as in Options 4 and 5. Given that public exposures from these devices or materials could easily come from several different items, shouldn't the same argument prevail as that used for site decommissioning and a limit of 25 mrem per year be used thereby assuring that no one receives more than 100 mrem?

Option 1 -- No comment

Option 2 -- The list of "disadvantages" includes "Increased costs associated with requiring ... licensees ... to become more knowledgeable ..." This should be counterbalanced in the list of "Advantages" with "Likely increased worker awareness of potential hazards due to licensee efforts to become more knowledgeable of Part 20 requirements".

Option 3 -- Gathering information on "distributors" includes those distributing to general licensees. This requires Agreement State efforts to implement and enforce rules on reporting the distributions. Since Agreement States generally have three years to implement NRC regulations, the information from Agreement States likely will not be available. This will create a significant gap in the data gathered by NRC if it goes ahead with a review after two years as stated. If knowledge of actual distribution and uses of source material is as deficient as inferred, how can meaningful regulations, even preliminary ones, be established under Options 4 and 5? It would appear Option 3 (data gathering) is a very important point and should be handled nationwide for best results. However, we suggest a contractor be used to do the research in a short time frame followed by an assessment of the risks involved (six months of sampling rather than 2 years of a regulatory power play to get distributors to cough up all their customers!) Then changes in the regulations would be in order based on the data you infer we now lack.

Option 4 -- The "tiered" approach is more in line with "risk informed" regulation. We agree that Option 4 should be the recommended approach. However, some effort at data collection needs to be done prior to rule development. We do not believe a 100% knowledge of every distribution is required to assess the risk of such distributions so long as essentially all avenues are identified.

Option 5 -- Delete. This is a "regulatory ratcheting" approach in that a lower limit is immediately set for specific licenses followed by data collection and possible (probable?) further changes. The lower limit for section 40.22 is the only distinction between this Option 5 and Option 4. It is an insufficient difference to be separated out as an Option 5 and should be removed from consideration.

In both Options 4 and 5, a concern is expressed in the "Disadvantages" that a "Legitimate use of material may be discouraged because of increased costs". While this may be a real concern if SAFETY is compromised, the parenthetical example "users may substitute materials or methods that do not use source materials" is improper. It should not be our concern if an economic

decision results in elimination of a route of radiation exposure to the public or workers. After all, that is what ALARA is all about!

Recommended Approach -- We agree that Option 4 should be the preferred Option. Option 5 should be eliminated from consideration. Data gathering and assessment should be emphasized as a preliminary to formulating draft rules and should be accomplished in a "shorter" time frame than the 2 years stated for Option 3 (the new "second choice").

Agreement State Implementation Issues -- We agree that this rule should be Category B (except for distribution of materials to exempt persons) because of the direct transboundary implications.

Enhanced Public Participation -- Unless some effort is made to "get the word out" (beyond posting on the website), the affected "public" and potential licensees, will not be aware of the new rules in a timely manner and thus have no opportunity for input. This is a surefire method to increase the disdain the public has for bureaucratic regulators. We recommend that a concerted effort be made to reach distributors and recipients of source material. This could include state and regional press releases, announcements in industry and trade journals, and notification to known distributors requesting the information be forwarded to customers.

Summary of Planned Provisions -- While we agree that the steps listed are reasonable, the "data gathering and assessment" of Option 3 (or 4 or 5) needs to be done prior to "locking these in".

Submitted by John Erickson, Division Director; Gary Robertson, Supervisor, Waste Management; Terry Frazee, Supervisor, Radioactive Materials

**State of Colorado (rcvd 3/2/01):**

March 2, 2001

Gary C. Comfort  
Division of Industrial and Medical Nuclear Safety, NMSS  
U. S. Nuclear Regulatory Commission  
Washington, DC 20555

RE: PART 40 DRAFT PROPOSED RULEMAKING PLAN (STP-01-007)

The State of Colorado recommends the Commission adopt Option 5 with one modification - that the exemptions from Parts 19 and 20 be completely eliminated.

There were two fundamental principles that behind the OAS-Colorado petition - all persons should be protected equally, and radiation control programs should be able to ensure no one is overexposed. Options that merely "minimize" the inconsistencies between the current Part 40 and Part 20 are not acceptable. Experience has shown that source material general licensees can have radiation areas, and can contaminate facilities to levels that exceed release limits. When a facility is identified that exposes individuals in excess of Part 20 limits, the regulatory agency must be able to take enforcement action. This can not be done when the regulations exempt the facility.

Colorado agrees a study is needed to improve knowledge of the uses of source material. However, we should provide protections as we gain that knowledge. While evaluation of current practices and distribution practices can determine the level at which to continue a general license, it is unlikely that it will consider all possible uses that could occur, or scenarios where the source material could accumulate, or be used in such a manner as to create a health risk.

If a health risk exists, the NRC should not be prevented from requiring corrective actions. General licensees can create air borne hazards, create radiation areas, and contaminate facilities such that they can not be released for unrestricted use. It would be wrong if this were allowed to continue just because the NRC's evaluation could not foresee all potential uses of source material. Users of generally licensed source materials, and the public around those facilities, deserve the same protection as those using and near general licensees using byproduct material.

We believe Option 5 is superior to Option 4 because the tiered option may be difficult to administer.

Converting existing general licenses into specific licenses need not be overly burdensome on licensees. The proper level of regulatory control can be determined as part of the NRC's Phase II study. Under a specific license, the appropriate level of control by general licensees can be tailored to the level of risk and addressed in guidance. As information is gained, the guidance can be modified, and eventually codified into regulation as appropriate.

When evaluating the increased burden on source material general licensees, one should not just compare it to the existing burden on them, but also compare them to the requirements for byproduct general licensees.

While Option 2 does address the petitions, and would provide the legal basis to address safety issues, it does nothing to identify which facilities have increased risks due to safety issues.

Option 3, as presented is also unacceptable. Health and safety issues resulting from the use of generally licensed source material have been identified, but Option 3 does not provide a regulatory basis to address these issues. Under Option 3, individual using source material will not receive the same protection as those using byproduct material for approximately an additional 2 years. The reason Colorado petitioned the NRC was to provide the protection of Parts 19 and 20 to all persons.

Including safety notices with the distribution of source material is helpful, but experience has shown that the information is too easily ignored. We do not see requiring general licensees to become more knowledgeable as a disadvantage. Providing information gives those at risk the knowledge to make decisions. Those with a very small risk should also be informed; if they are not, Radiation Control Programs will be contacted to provide the missing information, and the NRC does not include in its regulatory analyses the burden to Radiation Control Programs that result from a lack of knowledge on the part of licensees.

Further, the information gathered under Option 3 does not appear to provide sufficient information to make decisions on the potential risk resulting from the use of source material. Determining how the material is used, as a solid, liquid or vaporized, will identify the potential risk better than the report of sales. Reviews have shown that the same commercial operation can pose significantly different risks depending on their respective radiation safety programs.

A concern with Option 4 is that a multi-tiered general license scheme can quickly become cumbersome, with routine disputes as to what uses should be in what tier. A second problem is that it still provides an exemption requirements necessary to protect health and safety. Even if the exemption were allowed only for very small quantities, a new use or procedure could cause that small quantity to become a concern. Source material users, like those using byproduct material, should be subject to basic radiation safety standards. As long as the exemption exists, there exists a potential for overexposures for which the regulatory agency can not take an action.

Like other options, Option 4 assumes future decisions can be made by gathering data on the distribution of source material. Decisions need to be made based on data about the final use.

We do not see the total elimination of the exemption for generally licensed source material licensees as an undue burden. For example, if the licensee does not expose individuals to ten percent of allowable limits, they will not be required to provide personnel monitoring. Why would individual exposed to byproduct material deserve more protection than those exposed to source material that receive the same dose?

We agree that the rule should be Category B because of the transboundary implications.

W. Jacobi  
Program Manager