RULEMAKING ISSUE
NOTATION VOTE

December 10, 2009 SECY-09-0179

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

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

PURPOSE:

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

SUMMARY

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

BACKGROUND:

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

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

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

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

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

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

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

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

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

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

DISCUSSION:

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

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

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

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

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

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

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

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

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

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

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

Delete or Revise Certain Product Exemptions

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

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

Minor Clarifying or Administrative Revisions

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

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

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

AGREEMENT STATE ISSUES:

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

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

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

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

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

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

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

COMMITMENTS:

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

RECOMMENDATIONS:

That the Commission:

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

2. Note:

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

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

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

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

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

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

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

RESOURCES:

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

COORDINATION:

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

/RA/ Martin Virgilio for

R. W. Borchardt
Executive Director
for Operations

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

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 40, 70, 170, and 171

RIN 3150-AH15
[NRC-2009-0084]

Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or "the Commission") is proposing to amend its regulations to require that the initial distribution of source material to exempt persons or general licensees be explicitly authorized by a specific license, which would include new reporting requirements. The proposed rule is intended to provide the Commission with more complete and timely information on the types and quantities of source material distributed for use either under exemption or by general licensees. In addition, the NRC is proposing to modify the existing possession and use requirements of the general license for small quantities of source material to better align the requirements with current health and safety standards. Finally, the NRC is proposing to revise, clarify, or delete certain source material exemptions from licensing to make the exemptions more risk informed. This rule would affect manufacturers and distributors of certain products and materials containing source material and certain persons using source material under general license and under exemptions from licensing.

DATES: The comment period expires **[INSERT DATE 75 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Submit comments specific to the information collections aspects of this rule by **[INSERT DATE 30 DAYS AFTER PUBLICATION]**. Comments received after these dates will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before these dates.

ADDRESSES: You may submit comments by any one of the following methods. Please include Docket ID **NRC-2009-0084** in the subject line of your comments. Comments submitted in writing or in electronic form will be posted on the NRC website and on the Federal rulemaking website Regulations.gov. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want to be publicly disclosed.

Federal Rulemaking Website: Go to http://www.regulations.gov and search for documents filed under Docket ID **NRC-2009-0084**. Address questions about NRC dockets to Carol Gallagher at 301-492-3668; e-mail Carol.Gallagher@nrc.gov.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: Rulemaking.Comments@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at 301-415-1677.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays. (Telephone 301-415-1677)

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101. You may submit comments on the information collections by the methods indicated in the Paperwork Reduction Act Statement.

You can access publicly available documents related to this proposed rule using the following methods:

NRC's Public Document Room (PDR): The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, Public File Area O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

NRC's Agencywide Documents Access and Management System (ADAMS): Publicly available documents created or received at the NRC are available electronically at the NRC's Electronic Reading Room at http://www.nrc.gov/reading-rm/adams.html. From this page, the public can gain entry into ADAMS, which provides text and image files of the NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov.

Federal Rulemaking Website: Public comments and supporting materials related to this proposed rule can be found at http://www.regulations.gov by searching on Docket ID **NRC-2009-0084**.

FOR FURTHER INFORMATION CONTACT: Gary Comfort, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-415-8106, e-mail: Gary.Comfort@nrc.gov or Kimyata Morgan Butler, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-415-0733, e-mail: Kimyata.MorganButler@nrc.gov.

SUPPLEMENTARY INFORMATION:

XI. Regulatory Flexibility Certification

XII. Backfit Analysis

I. Background

A. Introduction

Source material is regulated by the NRC under Title 10 of the Code of Federal Regulations (10 CFR) Part 40, "Domestic Licensing of Source Material." Source material includes uranium and thorium in any physical or chemical form. Naturally occurring uranium and thorium and their decay chains emit alpha, beta, and gamma radiation. Uranium exhibits toxic chemical properties that can impair kidney function when ingested or inhaled in large quantities.[1] Thorium dioxide is classified as a "known carcinogen" by the U.S. Agency for Toxic Substances and Disease Registry and has been linked to lung and liver diseases.[2] Because of the potential for uranium and thorium to produce health effects from both chemical toxicity and radiological effects, it is important for the NRC to understand how and in what quantities uranium and thorium are being used under general license and various exemptions in order to better evaluate potential impacts to public health and safety.

The last major modification of 10 CFR Part 40 occurred in 1961 and established licensing procedures, terms, and conditions for source material that were substantially similar to those set forth, at the time, in 10 CFR Part 30, "Licensing of Byproduct Material." Since then, the health and safety requirements in 10 CFR Part 20, "Standards for Protection against Radiation," have been revised. In particular, radiation dose limits for individual members of the public were significantly reduced in the revision to 10 CFR Part 20. In addition, training and other requirements have been moved and revised from an earlier version of 10 CFR Part 20 into 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations."

[1] U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry. "ToxFAQs™" for Uranium," 1999.
[2] U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry. "ToxFAQs™ for Thorium," 1999.

Although the requirements in 10 CFR Part 30 have been revised to address the changes to the health and safety requirements in 10 CFR Part 20 and the training requirements in 10 CFR Part 19, these changed standards have generally not been addressed with respect to the use of source material in 10 CFR Part 40.

Some products currently covered by the exemptions from licensing in 10 CFR Part 40 were in use before the enactment of the original Atomic Energy Act of 1946. Exemptions for the possession and use of many of these products were included in the original 10 CFR Part 40 issued in 1947. As beneficial uses of radioactive material have developed and experience with the use of such material has grown, new products intended for use by the general public have been invented and the regulations have been amended to accommodate the use of new products. The regulations contained in 10 CFR Part 40 currently include no requirements to report how much source material is being distributed in the form of products for use under the exemptions from licensing.

Section 40.22, “Small quantities of source material,” provides a general license authorizing commercial and industrial firms; research, educational, and medical institutions; and Federal, State, and local governmental agencies to use and transfer not more than 15 pounds (lb) (6.8 kilograms (kg)) of source material in any form at any one time for research, development, educational, commercial, or operational purposes. Not more than a total of 150 lb (68 kg) of source material may be received in any calendar year. Section 40.22 general licensees are exempt from the provisions of 10 CFR Parts 19, 20, and 21, unless the general licensee also possesses source material under a specific license. The general license prohibits the administration of source material or the radiation emanating from the source material, either externally or internally, to human beings except as may be authorized in a specific license issued by the Commission. There are no reporting requirements for persons transferring source material, initially or otherwise, for use under this general license. Thus, the NRC does not have

significant information on whom, how, or in what quantities persons are using source material under this general license.

The current § 40.22 general license (post-1961) is much less restrictive than the previous version (1953-1961), which only permitted receipt of up to 3 lb (1.4 kg) of source material per year by pharmacists and physicians for medicinal purposes and by educational institutions and hospitals for educational and medical purposes only. In the previous version of this general license, resale of source material was prohibited. The current general license not only authorizes larger quantities of source material, but also allows broader types of authorized users and uses of source material. Also, resale is not prohibited.

In the 1990's, the NRC conducted a reevaluation of the exemptions from licensing for byproduct and source material in the NRC's regulations. The assessment of doses associated with most of these exemptions can be found in NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," published June 2001.[3] Doses were estimated for the normal life cycle of a particular product or material, covering distribution and transport, intended or expected routine use, accident and misuse scenarios, and disposal using dose estimation methods consistent with those reflected in the current 10 CFR Part 20. The report identified potential and likely doses to workers and members of the public under the

[3] NUREG-1717 is a historical document developed using the models and methodology available in the 1990s. The NUREG provides estimates of radiological impacts from various exemptions from licensing and is based on what was known about distribution of material under the exemptions in the early 1990s. NUREG-1717 was used as the initial basis for evaluating the regulations for exemptions from licensing requirements and determining whether those regulations adequately ensured that the health and safety of the public were protected consistent with NRC policies related to radiation protection. The agency will not use the results presented in NUREG-1717 as a sole basis for any regulatory decisions or future rulemaking without additional analysis. Copies of NUREGs may be purchased from the Superintendent of Documents, U. S. Government Printing Office, P.O. Box 37082, Washington, DC 20013-7082. Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. A copy is also available for inspection and/or copying for a fee at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Public File Area O1-F21, Rockville, MD.

exemptions contained in 10 CFR Parts 30 and 40. In general, the reevaluation concluded that no major problem exists with the use of products containing source material under the exemptions from licensing. Many of the products containing source material that are used under exemption from licensing present the potential for higher exposures under routine use conditions than the products used under exemption that contain byproduct material because of differences in allowed forms and uses; however, risks from accidents are generally smaller. Although containment is a key to safety for many products containing byproduct material, containment is generally less important for products containing source material because of the low specific activity of the source material contained in such products.

In 1999, the State of Colorado and the Organization of Agreement States submitted a petition for rulemaking, PRM-40-27, which stated their concerns regarding potential exposures to persons using source material under the general license in § 40.22. The petitioners requested that the exemption for these general licensees from 10 CFR Parts 19, 20, and 21 be restricted such that any licensee that has the potential to exceed any dose limits or release limits, or generates a radiation area as defined in 10 CFR Part 20 should be required to meet requirements in both 10 CFR Parts 19 and 20. The petition indicated that the State of Colorado had identified a site operated under the general license in § 40.22 at which there was significant source material contamination. The petitioners calculated that resultant exposures for the source material contamination were significantly above the exposure limits allowed to members of the public in 10 CFR Part 20. The petitioners indicated that public dose limits were considered applicable because workers operating under the general license were exempt from training requirements that would normally be required for radiation workers under 10 CFR Part 19. The petitioners also referenced other situations, which based on their research, appeared to have resulted in § 40.22 (or Agreement State equivalent) general licensees

potentially exceeding public health and safety or disposal limits that would apply to most other licensees.

In response to the petition, the NRC sought to develop more information on the use of the general license in § 40.22. Although the NRC had identified six persons distributing source material to § 40.22 general licensees in the mid-1980's, the NRC was able to identify only one remaining distributor in 2005. In 2006, the NRC contracted Pacific Northwest National Laboratory (PNNL) to examine whether the regulations concerning general licenses and certain exemptions for source material were consistent with current health and safety regulations. In 2007, PNNL completed their evaluation and documented their findings in "PNNL-16148, Rev. 1- Dose Assessment for Current and Projected Uses of Source Material under U.S. NRC General License and Exemption Criteria," (the PNNL study). The study used available information to identify and assess the primary operations conducted under the § 40.22 general license and equivalent provisions of the Agreement States. The available data was collected from information voluntarily submitted by specific licensees known to have distributed source material to general licensees in the past, through surveys to certain identified general licensees, and through use of searches from the Internet, publications, and professional societies. The available information was found to be limited and may not be representative of all present day, or future, uses of source material under the existing general license.

B. Regulatory Framework

The NRC has the authority to issue both general and specific licenses for the use of source material and to exempt source material from regulatory control under Section 62 of the Atomic Energy Act of 1954, as amended ("the Act" or AEA). A general license is provided by regulation, grants authority to a person for particular activities involving source material as described within the general license, and is effective without the filing of an application or the

issuance of a licensing document. Requirements for general licensees appear in the regulations and are designed to be commensurate with the specific circumstances covered by each general license. A specific license is issued to a named person who has filed an application with the Commission. Exemptions are provided in situations where there is minimal risk to public health and safety and allow the end user, who ordinarily requires a license, to possess or use the source material without a license.

The NRC regulations contained in 10 CFR Part 40 set forth the basic requirements for licensing of source material. Section 62 of the AEA authorizes the Commission to determine that certain quantities of source material are "unimportant." Section 40.13, "Unimportant quantities of source material," sets forth several exemptions from the licensing requirements for source material.

The regulations contained in 10 CFR Part 40 authorize a number of different general licenses for source material; one of which is for small quantities of source material (§ 40.22). Because general licenses are effective without the filing of an application with the NRC, there are no prior evaluations of user qualifications, nature of use, or safety controls to be exercised. Some general licenses do include reporting requirements for transfers of source material.

The regulations contained in 10 CFR Part 40 also authorize specific licenses for source material. Basic requirements for submittal of an application for a specific license are found in § 40.31 and general requirements for issuance of a specific license are found in § 40.32. Terms and conditions of licenses are contained in § 40.41. With the exception of requirements found in §§ 40.34 and 40.35, related to the manufacture and initial transfer of products and devices containing depleted uranium to be used under the general license in § 40.25, and the broad transfer authorizations contained in § 40.51, there are no specific requirements applicable to the distribution of products and materials containing source material.

C. Why are Revisions to 10 CFR Part 40 Considered Necessary?

Currently, 10 CFR Part 40 does not include any requirement to report information about source material being distributed for use under the general license in § 40.22 or under any exemption from licensing in § 40.13. Because the NRC does not require the reporting of products and materials distributed for use under the general license or exemptions, the NRC cannot readily determine if the source material is being maintained in accordance with the regulatory requirements for those uses, or how or in what quantities the source material is being used. As a result, the NRC cannot fully assess the resultant risks to public health and safety. Despite the limited availability of information, the NRC has assembled some data regarding the use of source material under both exemptions and the § 40.22 general license. Because of the difficulty of collecting such information and its limited reliability, the NRC has concluded that new reporting requirements on the distribution of source material to § 40.22 general licensees and persons exempt from licensing would significantly increase the NRC's ability to evaluate impacts and more efficiently and effectively protect the public health and safety from the use of source material.

Product Exemptions

NUREG-1717 identified some source material product exemptions as being obsolete or no longer manufactured at the upper limits allowed under § 40.13(c). As a result, the NRC concludes that it is preferable to delete or reduce the concentration limits allowed in future products to reduce the potential for exposures to the general public from these products.

In addition, based upon numerous questions from industry in the past, the NRC has learned that industry has generally moved from the manufacture of optical lenses containing thorium to the manufacture of lenses with thin coatings of thorium. This has led to the question of the applicability of the product exemption in § 40.13(c)(7) to those lenses coated with thorium.

As a result, the NRC is considering expanding the exemption in § 40.13(c)(7) to accommodate current manufacturing practices to make the exemption more useful.

Section 40.22 General License

When the current general license in § 40.22 was established in 1961, provisions were included to exempt the general licensees from 10 CFR Parts 19, 20, and 21. The exemption was based upon the known uses of source material at the time and the health and safety requirements at that time. Because the § 40.22 general license was expanded to include commercial applications in 1961, it is likely that some current practices were not properly evaluated as part of that rulemaking. In addition, since that time, limits for protecting health and safety in 10 CFR Part 20 were significantly lowered and the training requirements in 10 CFR Part 19 were expanded. This combination of events has led to the recognition that some general licensees could expose workers to levels above 1 millisievert (mSv) per year (100 millirem (mrem) per year) which would normally require radiation training under 10 CFR Part 19. In addition, because of the exemption to 10 CFR Part 20, the NRC recognizes that some § 40.22 general licensees may dispose of source material in manners that would not be acceptable for other licensees where 10 CFR Part 20 applies and may abandon sites with contamination at levels exceeding 10 CFR Part 20 release limits. These actions could result in individual members of the public being exposed to dose levels above that permitted by 10 CFR Part 20. The PNNL study indicated that most source material possessed under § 40.22 is likely handled in quantities, physical forms, or in uses and conditions that would justify the continued application of the exemptions to 10 CFR Parts 19, 20, and 21. However, as indicated by PRM-40-27, and by bounding dose calculations in the PNNL study, situations can occur where § 40.22 general licensees exceed limitations under which certain requirements in 10 CFR Parts 19 and 20 would apply to a specific licensee. For example, because of the current exemption to 10 CFR Part 20, a § 40.22 general licensee could abandon a site resulting in a

situation where the next occupant is exposed at levels above public dose limits in § 20.1301 and the unrestricted release limits in § 20.1402. As a result, the NRC determined that consideration should be given to making the § 40.22 general license more consistent with current training requirements and public health and safety standards, as set forth in 10 CFR Parts 19 and 20.

In addition, the current § 40.22 general license allows persons to obtain 15 lb (6.8 kg) of uranium or thorium in any form, including any specific isotopes. Certain isotopes of thorium and uranium have specific activities so high that 15 lb of those isotopes could result in doses far in excess of dose limits normally allowed under NRC's regulations without significant controls; thus, although these separated radioisotopes are not commercially available in such quantities, the NRC has concluded that persons should not be allowed to obtain large quantities of these isotopes without applying for a specific license.

II. Discussion

A. What Actions are Being Proposed by the NRC?

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

A.1 Specific Licensing of Distribution of Source Material

The NRC is proposing two new provisions, §§ 40.13(c)(10) and 40.22(e), which would prohibit the initial transfer for sale or distribution of products or materials containing source

material to persons exempt from licensing under § 40.13(c) or to a § 40.22 general licensee, respectively, by a person without authorization by a specific license. The initial transfer for sale or distribution is considered to be the first transfer of the product or material containing source material to a person who will be receiving the source material for possession under an exemption listed in § 40.13(c) or under the general license in § 40.22. Subsequent transfers of source material from exempt person to exempt person or from general licensee to general licensee would continue to be allowed without the requirement for a specific license.

Under the proposed § 40.13(c)(10), in conjunction with the proposed § 40.52, a person currently operating under a § 40.22 general license that manufactures and initially transfers or distributes a product for possession under an exemption listed in § 40.13(c) would no longer be allowed to operate under the general license and would instead need a specific license under this proposed rule. The NRC is not aware of any widespread production and distribution of exempt products under the general license; however, with the proposed expansion of the exemption in § 40.13(c)(7) (discussed further in Section A.5 of this document), persons currently manufacturing thorium-coated lenses under the general license would be required to obtain a specific license if the lenses are distributed for use under the expanded exemption.

A specific license for the initial distribution of products for use under an exemption listed in § 40.13(c) would be issued only by the NRC, including for those persons located in an Agreement State, under a new provision § 40.52, “Certain items containing source material; requirements for license to apply or initially transfer.” Conditions for the proposed § 40.52 licenses are being proposed in a new provision § 40.53, “Conditions of licenses issued under § 40.52: Quality control, labeling, and records and reports.” In 10 CFR 150.15, the Commission retains the authority to license the transfer of possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or byproduct material whose subsequent possession, use, transfer, and

disposal by all other persons are exempted from licensing and regulatory requirements. The licensing of the export from and import into the United States of byproduct and source material is also wholly reserved to the Commission by this section. Thus, a distributor in an Agreement State involved in the initial transfer of materials or products containing byproduct or source material to exempt persons, whether a manufacturer or an importer, requires authority to distribute such material from the Commission in addition to any Agreement State license.

In the past, the Commission has chosen not to require licensing of the transfer of source material to exempt persons by manufacturers or importers of products in Agreement States (with the exception of the manufacture of counterweights to be used under § 40.13(c)(5)). This proposed rule, in requiring specific authorization for the initial transfer for sale or distribution of materials or products containing source material to exempt persons, in conjunction with 10 CFR 150.15, would clarify that distributors in Agreement States would need specific licenses, issued by the NRC, authorizing initial transfer of products containing source material for sale or distribution for use under the exemptions in § 40.13(c) or equivalent Agreement State regulations. However, the possession and use of materials or products containing source material by Agreement State licensees would continue to be regulated by the Agreement State.

Importers of finished products containing source material would be exempt from 10 CFR Parts 19 and 20 - this is different than the existing regulations governing the initial transfer of byproduct material. The exemption from 10 CFR Parts 19 and 20 for importers of finished products is being proposed because the health and safety concerns for this type of distributor are no different than those for a secondary distributor of source material, who is neither currently, nor in the proposed rule, required to obtain a specific license for distribution. Importers of finished products would not be allowed to process the products and would not be expected to handle the products in any way that would create health and safety impacts beyond what is projected to occur under the exemption.

A specific license for the initial distribution of source material for use under the § 40.22 general license would be issued under a new provision § 40.54, “Requirements for license to initially transfer source material for use under § 40.22.” Conditions for the § 40.54 licenses are being proposed in a new section, § 40.55, “Conditions of licenses issued under § 40.54: Quality control, labeling, safety instructions, and records and reports.”

The process for obtaining a specific license to distribute source material is expected to be relatively straightforward. Applications for these specific licenses for distribution would be made through the provisions of § 40.31, “Application for specific licenses,” and applicants would be required to meet part or all of the provisions of § 40.32, “General requirements for issuance of specific licenses.” Regulatory Guide 10.4, "Guide for the Preparation of Applications for Licenses to Process Source Material," which may be used by non-fuel-cycle source material applicants, already addresses the submittal of information on types and quantities of source material planned to be distributed to exempt persons. Under both proposed paragraphs § 40.13(c)(10) and § 40.22(e), an initial distributor would be allowed to continue distribution of products or materials containing source material for 1 year beyond the effective date of this rule. However, if an application for a specific license (or license amendment, in the case of an existing NRC licensee) has been submitted, the applicant would be allowed to continue their distributions while issuance of the license is pending. Persons legally importing products for possession under an exemption for their own personal use or to be given as a personal gift would not be required to obtain a specific license for those products. Similarly, persons importing source material for use under a general license would not be required to obtain a specific license unless they subsequently transfer the source material to another person for use under a general license or exemption.

The regulations contained in 10 CFR Part 40 currently do not require a person to obtain a specific license to distribute source material to persons exempt from licensing or to

§ 40.22 general licensees (with the exception of counterweights for which this is included as a constraint within the exemption in § 40.13(c)(5)). The regulations in § 40.51 allow such transfers to occur without a distribution license and do not require any reporting of the transfers. This is not true for byproduct material licensees, who are required in 10 CFR Part 32 to obtain a specific license for the initial distribution of byproduct material to persons exempt from licensing or for use under a general license. The import of exempt materials or products is generally licensed by 10 CFR 110.27(a)(2) and 10 CFR 110.27(a)(3) provides a general license for the import to those persons authorized to receive products or materials under a license. However, in the case of source material distribution to exempt persons or to § 40.22 general licensees, no other license is currently required, nor are there any requirements to report the transfer or receipt of the imported material.

Because of the lack of reporting requirements associated with the possession of source material under exemption or the § 40.22 general license, the NRC does not have a clear understanding of the amounts, types, or uses of source material under exemption or under the § 40.22 general license. Most information gathered by the NRC to date comes from a few specific licensees who have voluntarily provided distribution data. Because this information may not fully represent actual usage, it is difficult for the Commission to make risk-informed decisions in updating the related source material regulations. Without the proposed specific licenses for initial distributors, it would be difficult or impossible to enforce reporting requirements on unidentified distributors. Requiring initial distributors of source material to exempt persons or to certain general licensees to obtain a license for distribution would allow the NRC to track the amount and types of source material being distributed to those persons through proposed reporting requirements that would be associated with the new specific licenses.

A.2 Distribution of Products to Persons Exempt From Regulation

A prohibition on distribution without a specific license is proposed in a new § 40.13(c)(10), which directs persons seeking to distribute source material to exempt persons, to the proposed new § 40.52. The proposed § 40.52 provides conditions for approval of a license application for initial distribution of source material to exempt persons. Additionally, the proposed § 40.53 contains a number of conditions for initial distributors including requirements for reporting and recordkeeping, quality control, and labeling.

The new reporting and recordkeeping requirements are proposed in § 40.53(c). An initial distributor of products for use under the exemption in § 40.13(c) would be required to submit a report, by January 31 of each year, regarding transfers made in the previous calendar year. The report would identify the distributor and indicate what products, types of source material and amounts, and number of units distributed.

The regulations contained in 10 CFR Part 40 were initially based on the assumption that the health and safety impacts of source material were low and that considerations of protecting the common defense and security were more significant. When the AEA was initially written, one of the major focuses was to ensure that the United States government would have an adequate supply of uranium and thorium as “source material” for atomic weapons and the nuclear fuel cycle. Exemptions from licensing were made for certain consumer products already in production, such as gas mantles containing thorium, and these exemptions have not been substantially modified since they were included in the original issuance of 10 CFR Part 40 in 1947. These exemptions essentially accommodated existing practice without much emphasis on health and safety. Recent studies have indicated that the manufacture and use of such products has decreased as alternative products, not containing source material, have become more readily available. Consistent with a policy statement on consumer products published on March 16, 1965 (30 FR 3462), the Commission has periodically made various evaluations of

potential doses from exempt products to ensure that exposures from any individual exempt practice do not exceed a small fraction of the overall recommended dose limit for the public and that the combined effect of exposures from various exempt practices does not result in a significant impact to public health and safety. However, because the Commission has little data on distributions of source material to exempt persons, these evaluations for source material have been particularly difficult to conduct, and may not necessarily represent real world conditions.

The data collected by virtue of the proposed rule would provide the NRC with a more accurate and complete representation of material distributed to the public for use under exemptions in § 40.13(c). This would allow the NRC to recognize trends in distribution which could alter earlier estimates of individual or collective doses and affect earlier findings regarding health and safety. These changes would provide a better basis for considering any future regulatory changes in this area and in allocating the NRC's resources. The proposed reporting requirements would also aid in ensuring that exposures to the public from all sources controlled by the NRC are monitored and are unlikely to exceed 1 mSv (100 mrem) per year.

These proposed reporting and recordkeeping requirements are expected to impose a minimal burden on those persons requiring a specific license for initial distribution of source material, particularly given the current state of information technology. The first report may include information on transfers for which records have not been required; however, this information is expected to be available because of basic business recordkeeping practices. If exact numbers cannot be given for this first report, a best estimate for the whole calendar year would be acceptable.

In addition to reporting and recordkeeping, there are a few additional requirements being proposed for initial distribution of products for use under exemption. The new requirements would help to ensure that products being distributed were within the quantity or concentration

limits for those exemptions that include such limits and that the products were properly labeled as currently required by the existing conditions in the exemptions.

In the NUREG-1717 assessment, it was identified that certain products containing source material and used under exemptions from licensing (e.g., welding rods and gas mantles) have the potential for routine exposures that are higher than is generally acceptable for use under exemption. However, the use of thorium in these products has significantly declined, being replaced by rare earth compounds, such as lanthanum and yttrium. As a result, routine use of thorium containing products of these types by individuals to the exclusion of similar products containing rare earths is less likely and typical exposures to users is likely less than previously estimated. At the same time, the likely exposures can be limited by the user who is properly informed concerning the inherent risks of exposures and methods for reducing exposure. Thus, rather than eliminate these exemptions, the Commission is proposing to include in the proposed distributor requirements the requirement to provide safe handling instructions. Some distributors have done so voluntarily in the past. Welding has other inherent risks, thus, welding rod manufacturers and importers are required by OSHA regulations to prepare and distribute Material Safety Data Sheets (MSDSs) on the use of welding rods. While these identify the presence of thorium for thorium-containing welding rods, they typically do not include information specifically about the radiological hazard.

New fee categories and initial fee amounts for this new specific license type are being proposed as revisions to 10 CFR Parts 170 and 171. There would be a category for the distribution aspect and a separate one for manufacturing or processing. The applicants and licensees under the proposed licensing provision § 40.52 would come under a newly established fee category, 2.C. “Licenses to distribute items containing source material to persons exempt from the licensing requirements of 10 CFR Part 40 of this chapter” (the current 2.C. “All other source material licenses” is proposed to be redesignated as 2.F. by this rule).

This new fee category would apply to all initial distributors of products containing source material for use under § 40.13(c). The fee associated with this category would be the only fee required by the NRC of distributors whose possession and use of source material is licensed by an Agreement State or who only import finished products for distribution. There would be an additional fee category for those manufacturing or processing such products. This is similar to the breakdown of fees for manufacturers and distributors of exempt byproduct material. The initial fee associated with the distribution aspect of licensing for source material would be lower than those related to distribution of products containing byproduct material to exempt persons, because this rule would add more limited requirements applicable to the distribution aspect of licensing for source material. Proposed initial fee amounts for the proposed new category 2.C. are as follows: $ 7,000 for an application; $ 10,000 for the annual fee.

The new fee category for manufacturing and processing would be 2.E, “Licenses for possession and use of source material for processing or manufacturing of products or materials containing source material for commercial distribution.” It is proposed that the initial fees associated with manufacturing or processing be the same amount as those that currently apply to a manufacturer of a product containing source material that now comes under the current fee category 2.C, “All other source material licenses.” These fees are currently $ 10,100 for an application and $ 17,400 for the annual fee. It is proposed that the initial fee amounts applicable to the new fee category 2.E. be the same as those for the current category 2.C. at the time this rule is made effective, which amount is subject to change prior to finalization of this rule.

After the implementation of this rule, the fee amounts for these new categories would change annually in accordance with NRC policy and procedures. Biennially, the NRC evaluates historical professional staff hours used to process a new license application for materials users fee categories which often results in changes to the flat application fees. In addition, results from the biennial review impacts the annual fee for the small materials users since the NRC

bases the annual fees for each fee category within this class on the application fees and estimated inspection costs for each fee category. Each year the annual fee for the materials users is calculated using a formula which distributes the NRC allocated budget amount for the small materials users to the various fee categories based on application fees, inspections costs, inspection frequency, and the number of licensees in the fee category.

A.3. Distribution of Source Material to General Licensees

The prohibition on distribution without a specific license in the proposed § 40.22(e) directs persons seeking to distribute source material to § 40.22 general licensees to the proposed new § 40.54. The proposed § 40.54 provides conditions for approval of a license application for initial distribution of source material to § 40.22 general licensees. Additionally, the proposed § 40.55 contains a number of conditions for initial distributors including requirements for reporting and recordkeeping, labeling, and notifications.

The proposed rule would add § 40.55(d) and (e) to establish reporting and recordkeeping requirements for initial distributors of source material to persons generally licensed under § 40.22 or equivalent Agreement State provisions. The rule would require that transfers be reported to the NRC and, if applicable, to the Agreement State where the material is transferred, annually by January 31. The report would cover transfers of source material completed in the previous calendar year. The reports would identify each general licensee receiving quantities of source material greater than 50 grams (g) (0.11 lb) within any calendar quarter by name and address, the responsible agent who may constitute a point of contact between the NRC or the Agreement State agency and the general licensee, and the type, physical form, and quantity of source material transferred. In addition, the distributor would be required to report the total quantity of source material distributed each calendar year, including those transfers of less than 50 g (0.11 lb) in a quarter to any person.

When the small quantity general license was originally granted, it was intended to be used by pharmacists and physicians for medicinal purposes and by educational institutions and hospitals for educational and medical purposes (although the general license was later revised in 1980 to prohibit use for medicinal and medical purposes). When the general license was expanded in 1961, both in terms of how much material and what it could be used for, no consideration was made to include reporting requirements at the time. As a result, the NRC has not been able to readily identify persons using source material under this general license nor verify its proper use.

The proposed reporting requirements, when also applied to distributors in Agreement States by those States, would help the NRC identify § 40.22 general licensees using larger quantities of source material. This would enable the NRC to better communicate with or inspect these general licensees, if necessary, to ensure that public and worker health and safety is adequately protected. The Commission would also use collected data to assess the extent of use of this general license in order to better evaluate alternatives for future revisions to this general license. Because the proposed reporting requirement is intended to apply only to anyone initially distributing source material to § 40.22 general licensees, transfers of source material from general licensee to general licensee would still not be reported.

Records of the initial transfer of source material for use under § 40.22 would be required to be stored for 1 year after inclusion in a report to the Commission or to an Agreement State agency. Maintaining records for this length of time will facilitate the licensee's preparation of the report and allows for verification of the accuracy of the report by the NRC or the Agreement State. This is shorter than the recordkeeping requirements for transfers of generally licensed devices in byproduct material regulations. For generally licensed devices, longer recordkeeping is appropriate because of the possible need for tracing particular devices if generic defects were identified.

These proposed reporting and recordkeeping requirements are expected to impose a minimal burden on those persons requiring a specific license for initial distribution of source material, particularly given the current state of information technology. The first report may include information on transfers for which records have not been required; however, this information is expected to be available because of basic business recordkeeping practices. If exact numbers cannot be given for this first report, a best estimate for the whole calendar year would be acceptable.

In addition to reporting and recordkeeping, there are a few additional requirements being proposed for distribution of material for use under § 40.22 and equivalent Agreement State provisions. The new requirements would primarily require the licensee to ensure the quantity or concentration of material is as labeled. The initial distributors would be required to provide to their customers copies of key relevant regulations and radiation safety precautions and instructions. Requiring initial distributors to provide copies of such regulations would make the recipient aware that the source material is possessed under a general license and what the requirements are under that general license.

New fee categories and fee amounts for this new specific license type are being proposed as revisions to 10 CFR Parts 170 and 171. The applicants and licensees under the proposed licensing provision § 40.54 would come under a newly established fee category, 2.D. "Licenses to distribute source material to persons generally licensed under 10 CFR Part 40 of this chapter." Proposed initial fee amounts are as follows: $ 2,000 for an application; $ 5,000 for the annual fee. These applicants and licensees would also be subject to the proposed new category, 2.E., "Licenses for possession and use of source material for processing or manufacturing of products or materials containing source material for commercial distribution." As discussed in section A.2 of this document, the initial fee amounts for this category would be equal to the fee for current fee category 2.C at the time this rule is made effective. These fee

amounts would subsequently be revised in accordance with applicable NRC policy and procedures.

The Commission currently has no licensees under the existing licensing provision of § 40.34, which also authorizes distribution to a category of general licensees (those licensed under § 40.25 and Agreement State equivalent provisions). The proposed new fee categories 2.D. for persons who initially distribute source material to general licensees and 2.E. for manufacturing or processing of source material for commercial distribution would also cover future NRC applicants and licensees that apply for or possess a license under § 40.34.

A.4. Possession and Use of Source Material under § 40.22

The NRC is proposing to revise § 40.22, "Small quantities of source material," in its entirety.

Under the proposed § 40.22(a), the general license would be limited to thorium and uranium in their natural isotopic concentrations and depleted uranium. This differs from the existing § 40.22(a) which allows possession of any isotopic concentration of source material. Certain radionuclides of uranium and thorium, when isotopically separated, have the potential to present significantly higher doses, in particular, thorium-228, thorium-229, and uranium-232. Thorium-230 when separated from the uranium decay series is also a higher specific activity material. Although the NRC is not aware of these isotopes being separated for commercial use, if the separated isotopes were readily available, the current provisions of § 40.22 would allow a person to receive quantities large enough in terms of activity to present a security concern without obtaining a specific license. The proposed revised general license would limit uranium and thorium to their natural isotopic concentrations or as depleted uranium to ensure that persons could not obtain these much higher specific activity materials in an isotopically separated form without the authorization and safety controls provided by a specific license.

Under the proposed § 40.22(a)(1), the general licensee would be limited to possession of less than 1.5 kg (3.3 lb) of source material at any one time and 7 kg (15.4 lb) per calendar year for all source material that is in a dispersible form or has been processed by the general licensee. Under the current general license, assurance of safety is based primarily on two limiting conditions: (1) the amount of source material that may be used at any one time and (2) the amount that may be obtained in any calendar year. It had been assumed that the activities likely to be conducted under the general license would be unlikely to result in significant intakes of source material. These conditions, however, may not be totally effective in affording a proper level of safety as raised by PRM-40-27 and substantiated by the PNNL study. PRM-40-27 and the PNNL study indicate that situations can occur that exceed limitations under which certain requirements in 10 CFR Parts 19 and 20 usually would apply to specific licensees. These situations primarily result from the use of source material used or possessed in a dispersible form.

In PRM-40-27, the petitioners stated that they had identified a site, where source material was likely possessed under the general license in § 40.22, that had significant amounts of surface contamination from source material. The petitioners indicated that resultant exposures for the source material contamination were significantly above the dose limits (possibly as high as 1 rem (10 mSv) per year) allowed to members of the public in 10 CFR Part 20.

The PNNL study confirmed that such exposures were possible under the existing § 40.22 general license conditions and indicated that unprotected workers exposed to thorium and uranium powders during the lens manufacturing process, as licensed under a § 40.22 general license, can potentially receive an annual internal radiation dose up to 5.6 mSv (560 mrem), and an annual committed effective dose approaching 8 mSv (800 mrem) without regard to excess contamination. This type of manufacturing process uses source material in a

powdered form which allows for a greater chance of inhalation or ingestion of the source material. Although the Commission expects that these doses from manufacturing may be tremendously reduced if process is performed in hot cells or if workers generally use respiratory protection (e.g., dust masks) in response to other regulatory requirements, the NRC is concerned about the potential exposures because a § 40.22 licensee is not required to meet the health and safety requirements for protection against radiation in 10 CFR Part 20 nor the training requirements in 10 CFR Part 19.

The proposed new limits in § 40.22(a)(1) are intended to reduce the likelihood that a person operating under a general license would be able to exceed dose limitations in 10 CFR Parts 19 and 20, which would require additional controls if the person were specifically licensed. Based upon the bounding dose calculations in the PNNL study, the NRC expects this proposed lower quantity to limit the potential for a worker to be exposed at levels exceeding 1 mSv (100 mrem) per year. In addition, by limiting the amount of such source material allowed to be received in a calendar year, the NRC expects that the potential for surface contamination buildup (similar to that identified in PRM-40-27) would be also be reduced. By reducing the amount of source material that is available for inhalation and ingestion, the NRC has concluded the exemptions to 10 CFR Parts 19, 20, and 21 would continue to be acceptable.

It is expected that a small number of persons currently possessing and using source material under the existing general license may be required to obtain a specific license for continued use of the source material under this proposed rulemaking. Persons currently possessing source material in dispersible forms, or processing source material, in quantities greater than 1.5 kg (3.3 lb) of source material at any one time, or receiving more than 7 kg (15.4 lb) of source material in 1 year, would be required to obtain a specific license if they could not reduce their possession and use of the source material to below the proposed new limits.

Under the proposed § 40.22(a)(2), the general licensee would be allowed to possess up to 7 kg (15.4 lb) total source material at any one time as long as any source material possessed in addition to that possessed under the limits in § 40.22(a)(1) is in a solid, non-dispersible form (e.g., a metal or sintered object; contained in protective envelope or in a foil; or plated on an inactive surface) and not chemically or physically altered. The licensee is limited to the receipt of no more than 70 kg (154 lb) of source material per calendar year. If the licensee does physically or chemically alter the solid source material, that altered source material would be required to fall within the 1.5 kg (3.3 lb) at one time limit and no more than 7 kg (15.4 lb) per calendar year limits of the proposed § 40.22(a)(1). Because the greater impact from the possession and use of source material results from inhalation or ingestion, allowing source material, in a solid, non-dispersible form, to continue to be possessed at a limit of 7 kg (15.4 lb) at any one time is not expected to significantly impact health and safety of workers handling or near such material because of the unlikely chance of inhalation or ingestion.

Under the proposed § 40.22(a)(3), persons treating drinking water by removing uranium for the primary purpose of meeting U.S. Environmental Protection Agency regulations, would continue to be allowed to possess up to 7 kg (15.4 lb) of source material at one time and process no more than 70 kg (154 lb) of uranium per calendar year. The NRC has concluded that the types of activities used to remove drinking water adequately contain the uranium to protect worker health and safety. The NRC also is concerned that the implementation of reduced possession limits on such persons could significantly impact operating costs, if such facilities are required to obtain specific licenses, and thereby impact their ability to provide safe drinking water. Although persons operating such facilities would not be impacted by changes in possession limits, they would be required to meet the other requirements of the proposed rule. However, these persons continue to have multiple options for operating within the NRC's regulations, including operation under a specific license or applying for enforcement discretion

as discussed in the 2006 Regulatory Information Summary (RIS-2006-020), ”Guidance for Receiving Enforcement Discretion When Concentrating Uranium at Community Water Systems,” dated September 14, 2006.

The proposed § 40.22(b) primarily provides clarification of how existing regulations apply to § 40.22 general licensees. Paragraph 40.22(b)(1) restates an existing requirement prohibiting the administration of source material to humans, unless authorized by a specific license.

Under the proposed § 40.22(b)(2), the NRC is clarifying disposal requirements for source material possessed under § 40.22. Because § 40.22 currently exempts the general licensee from the requirements in 10 CFR Part 20, one can infer that disposal of source material may be exempt from regulation because 10 CFR Part 20 includes disposal requirements. However, there is no exemption from § 40.51 which includes transfer provisions for licensees (including general licensees) which, depending upon how the general licensee disposes of the material, may be applicable and therefore limit disposal opportunities. The NRC is proposing in § 40.22(b)(2) to specifically prohibit abandonment of source material but allow up to 0.5 kg (1.1 lb) of source material per calendar year to be permanently disposed of without further NRC restrictions as long as the source material is in a solid, non-dispersible form (e.g., a metal brick, encapsulated in cement, etc.). The person receiving the source material to be permanently disposed would still be required to meet the applicable regulations of other agencies regarding such disposals. The NRC concludes that such small quantities would allow small general licensees (e.g., educational institutions) to economically dispose of the source material and would result in minimal impact to public health and safety because its form would limit ingestion and inhalation of the source material. The person receiving source material transferred under the provisions of § 40.22(b)(2)(i) would not be subject to further regulation by the NRC to the extent that the source material received under this provision was promptly and permanently

disposed of by the recipient. Larger quantities of source material would be required to be disposed of as radioactive material through the provisions of § 20.2001 (e.g., at an appropriately licensed disposal facility, or below the effluent release concentrations in 10 CFR Part 20, etc.) or transferred to another person otherwise authorized to receive the source material.

Because § 40.22 does not currently exempt the general licensee from other requirements in 10 CFR Part 40, the NRC is proposing in § 40.22(b)(3) to direct the general licensee's attention to other applicable sections of 10 CFR Part 40. Similarly, § 40.22(b)(5) directs the general licensee's attention to regulations regarding export of source material.

As part of its attempt to evaluate the current use of source material under the general license, the NRC found it difficult to obtain significant information voluntarily from general licensees. The proposed new condition in § 40.22(b)(4) would clearly obligate general licensees to respond to the NRC's written requests within 30 days.

As identified in PRM-40-27, contamination may become problematic for some persons using source material under the general license. The NRC is concerned that not only might a licensee not attribute what could be significant amounts of source material contamination to its possession limits but also, such as in the case identified in PRM-40-27, might abandon significant amounts of source material in place. This abandonment could result in other manufacturers, later inhabiting the facility, to unknowingly expose their workers or others to the source material contamination. As a result, in proposed § 40.22(c), the NRC is proposing to require the general licensee to minimize contamination at the site and ensure that the site is cleaned up to be protective of future worker and public health and safety. If the general licensee identifies evidence that there may be significant contamination, such that the contamination has the potential to result in the 25 mrem (0.25 mSv) limits in § 20.1401 being exceeded, the license would be required to notify the NRC and may consult with the NRC as to the appropriateness of sampling and restoration activities. In the proposed § 40.22(d), the NRC

is proposing to continue to exempt persons generally licensed under § 40.22 from 10 CFR Parts 19, 20, and 21, with the exceptions concerning disposal and decommissioning in proposed § 40.22(b)(2) and (c). In addition, the NRC is proposing that this exemption would not extend to any NRC specific licensee; in the current regulation only 10 CFR Part 40 licensees are excluded. This modification is expected to provide minimal impact to those other specific licensees who possess source material under the general license, because they would already be subject to 10 CFR Parts 19, 20, and 21 for other licensed materials.

A.5 Revision of Exemption for Thorium Lenses

Paragraph 40.13(c)(7) exempts thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium and meets certain use limitations, including that the thorium not be contained in contact lenses, spectacles, or eyepieces in binoculars or other optical instruments. Thorium is used in or on lenses to modify optical properties of the lens. The exemption, when originally established, was intended for uses where the thorium was homogonously spread throughout the lens. However, more recently, manufacturers are more likely to apply a thin coating of thorium to the lens; this has brought up concerns of the applicability of the existing exemption for such coated lenses. Also, NRC has identified that source material may also be used as a coating on mirrors.

To clarify the regulatory status of these coated lenses and to address coatings on mirrors, the rule proposes three changes to the existing exemption: (1) expand the exemption to include source material in or on finished coated lenses and mirrors; (2) reduce the source material limit from 30 percent by weight to 10 percent by weight for products distributed in the future; and (3) expand the exemption to include uranium. The remaining limitations on use would continue to apply.

Although historical information indicates that lenses containing up to 28 percent by weight of thorium oxide were manufactured in the past, most lenses that have been possessed under this exemption have contained concentrations closer to 10 percent by weight of thorium. The NRC has not been able to identify any manufacturers or distributors of lenses containing homogeneous amounts of thorium since 1980, because the industry appears to have moved to using thorium as a thin-film coating on the surface of lenses. The NRC's evaluation found that thin-film coated lenses contain a significantly lower total mass of thorium than that generally found in the same size homogeneous lenses. In addition, the NRC has learned that certain lens manufacturers also use thorium in combination with uranium to achieve desired properties. Although a coated lens does not contain the source material homogeneously within the lens (as is the case with lenses that may currently be possessed under the exemption), the PNNL study indicated that doses from both normal and accident conditions from lenses coated with either or both uranium and thorium were estimated to be well below 10 microsievert (μSv) per year (1 mrem per year). As a result, the NRC is proposing to expand the exemption to include these thin-film coatings and to also apply the exemption to lenses and mirrors containing uranium. The NRC's expectation is that the source material would be fixed onto the lens or mirror and not readily able to be removed from the surface. The exemption prohibits and would continue to prohibit shaping, grinding, polishing, and any other manufacturing process other than assembling the finished lens into an optical system or device.

The NRC is also proposing to revise § 40.13(c)(7) to limit the source material contained on or in the lens to no more than 10 percent by weight of source material across the volume of the lens, although lenses containing up to 30 percent by weight of thorium that were produced prior to the effective date of this rule would continue to be covered by this exemption from licensing. Based on information that the manufacture of lenses containing homogeneous thorium is no longer occurring and that the majority of lenses currently being manufactured,

contain concentrations less than 10 percent by weight of thorium, this reduction in the limit is expected to have minimal impact on industry. The actual percent by weight of source material on a thin-coated lens is expected to be well below this limit as averaged over the entire lens.

A.6 Revision of Exemption for Glassware

Paragraph 40.13(c)(2)(iii) exempts glassware containing up to 10 percent source material by weight. Although the estimated doses associated with this exemption are acceptable, the benefit from this use of source material is limited to achieving a unique color and glow in the glassware. Such glassware has been used in products such as dinnerware and toys. This use of source material might be considered frivolous, which is not in keeping with the policy of the Commission with regard to consumer products. However, this use predates the AEA, has been ongoing for decades, and continues today. Current manufacturing is relatively limited and the concentration in any recently produced items appears to be less than 2 percent source material (uranium). The one NRC-licensed manufacturer maintains concentration in products to within 1 percent by weight uranium. This rule proposes to limit products manufactured in the future to no more than 2 percent by weight source material. This would have minimal impact on the industry, limited to any costs associated with ensuring and documenting that products do not exceed this limit. It would ensure that doses to members of the public exposed to products distributed for use under this exemption in the future would be unlikely to exceed 10 μSv (1 mrem) per year. This is more appropriate for products with minimal societal benefit and is consistent with the concept of ALARA (as low as reasonably achievable).

A.7. Obsolete Exemptions

Some exemptions from licensing are considered obsolete in that no products are being distributed for use under the exemption. In at least one case, no products covered by the exemption remain in use. Generally, this has occurred because new technologies have made the use of radioactive material unnecessary or less cost-effective.

The NRC is proposing to delete exemptions for products that are no longer being used or manufactured, or to restrict further distribution while allowing for the continued possession and use of previously distributed items. NUREG-1717 describes the various products covered by the individual exemptions. Two of the conclusions in that report concerning distribution are:

- For § 40.13(d): It is believed that fire detection units containing source material have not been manufactured for commercial use; and
- For § 40.13(c)(2)(i): The exemption for ceramic tableware containing source material could result in significant doses, which might be of concern, if used as one's everyday dinnerware.

The exemption in § 40.13(d) would be removed; however, in the unlikely event that persons possess products covered by this provision, this action would not change the regulatory status of any products previously manufactured in conformance with the provisions of the regulations applicable at the time. In the case of ceramic tableware, the proposed rule would limit the exemption to previously manufactured products. This action would provide assurance that health and safety are adequately protected from possible future distribution. Preliminary estimates indicated a potential for exposures higher than is appropriate for materials being used under an exemption. However, these were estimated using particularly conservative assumptions for routine use, rather than the more typical use as a collectable.

Deleting the provision in § 40.13(d) would simplify the regulations by eliminating extraneous text. Also, the Commission periodically reevaluates the exposure of the general

public from all products and materials distributed for use under exemption, to ensure that the total contribution of these products to the exposure of the public will not exceed small fractions of the allowable limits. Eliminating obsolete exemptions would add to the assurance that future use of products in these categories would not contribute to exposures of the public and would also eliminate the need to reassess the potential exposure of the public from possible future distributions of these products.

There are other products covered by the exemptions in § 40.13(c) for which distribution is very limited and may have ceased, however, without the types of distributor requirements now being proposed, it is difficult to be certain concerning whether any distribution continues.

This risk-based approach to exemptions is in line with the strategic plan of the NRC.

B. Whom Would This Action Affect?

This proposed rule would affect manufacturers and distributors of certain products and materials containing source material, and persons using source material under the general license in § 40.22. Certain persons initially transferring source material to exempt persons or general licensees would be required to obtain a specific license for such distribution. Certain persons currently possessing a general license under § 40.22 may be required to obtain a specific license for the continued possession and use of source material if they cannot adapt their operations to the newly proposed possession limits or if they initially transfer products containing source material. The proposed rule would exempt persons who possess thorium or uranium coated lenses or mirrors from licensing requirements for those lenses and mirrors through a proposed revision to § 40.13(c)(7).

C. Specific Requests for Comment

The NRC has identified specific questions related to this proposed rulemaking as well as some questions for consideration in potential future rulemakings.

The NRC seeks comments, in particular, on the following specific questions presented in the proposed rulemaking:

(1) In the proposed expansion to § 40.13(c)(7), the exemption is limited by a concentration limit. It is expected that coatings on lenses are always very thin in practice such that it is unlikely that coated lenses would be near the concentration limit. However, a concentration limit may not be the most appropriate control, as it is generally not appropriate for surface contamination or hot spots to be averaged with other material for comparison to a concentration limit. Should other controls (e.g., mass or activity limit) be used and if so, what limits should be considered?

(2) On the proposed revision to the general license for small quantities of source material in § 40.22, is the limitation to natural or depleted uranium and natural thorium the most appropriate way to prevent persons from obtaining source material radionuclides with high specific activities without applying for a specific license? Does this adequately protect public health and safety from, for example, thorium-230 extracted from ore high in uranium content? Should an activity limit(s) be added to the weight limit? If so, what activity limit would adequately protect health and safety without adding significant implementation burden for ensuring the activity limit(s) are not exceeded?

(3) In § 40.22(c), the NRC proposes to require persons to contact the NRC if they identify significant contamination. Should the NRC require general licensees to complete surveys in accordance with the provisions of § 20.1501 to ensure that the limits in § 20.1402 are not exceeded, in particular for those licensees possessing source material under the proposed

§ 40.22(a)(1)? Would this result in unnecessary expenses, particularly for general licensees possessing very small quantities or should such a requirement be limited and, if so, how?

The NRC would also welcome preliminary input on the following issues for potential future rulemaking:

(1) Should the general license in § 40.22 be expanded to cover 11(e)2 byproduct material, i.e., mill tailings and wastes, to allow for small quantities, such as samples, to be more readily transferred for testing, for example? Given that the entire material is 11(e)2 byproduct material, and not just the uranium or thorium contained in the material, would higher weight limits be appropriate? If allowed, should any other conditions be changed (e.g., waste disposal, etc.) or added?

(2) Should explicit provisions be added to 10 CFR Part 40 and 10 CFR Part 70 to cover the inclusion of source material and special nuclear material in items in the sealed source and device registry, similar to 10 CFR 32.210?

(3) There has been little use of the provisions in §§ 40.25 and 40.34 for the use of depleted uranium under a general license. How could these provisions be revised to expand the likely use of these provisions and make the general license more useful to the regulatory program? Is the subjective nature of the findings in § 40.34(a)(3) and (b) concerning the usefulness of a product or device and the benefits from the use of the depleted uranium a deterrent to applicants/potential distributors? Also, should the exposure limits in § 40.34(a)(2) be reduced to 1 mSv (100 mrem) per year?

D. What Should I Consider as I Prepare My Comments to the NRC?

Recommendations for preparing your comments:

i. Identify the rulemaking: Docket ID **NRC-2009-0084**.

ii. Explain why you agree or disagree.

iii. Suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns, and suggest alternatives.

vii. Explain your views as clearly as possible.

viii. Make sure to submit your comments by the comment period deadline identified.

ix. See Section V of the preamble for the request for comment on Agreement State Compatibility, Section VI for the request for comment on the use of plain language, Section VIII for the request for comments on the draft environmental assessment, and Section IX for the request for comments on the information collection, and Section X for the request for comments on the draft regulatory analysis.

III. Summary of Proposed Amendments by Section

Section 30.6 Communications.

10 CFR 30.6(b)(1)(iv) - Would add a reference to new § 40.52 as a licensing category not delegated to the NRC Regions.

Section 40.5 Communications.

10 CFR 40.5(b)(1)(iv) - Would add a reference to new § 40.52 as a licensing category not delegated to the NRC Regions.

Section 40.8 Information collection requirements: OMB approval.

10 CFR 40.8(b) – Would add sections to the list of information collection requirements.

Section 40.13 Unimportant quantities of source material.

10 CFR 40.13(c) – Would clarify that persons exempt from licensing requirements are also exempt from 10 CFR Parts 19, 20, and 21.

10 CFR 40.13(c)(2)(i) – Would restrict the exemption for use of source material in certain ceramic tableware to that previously manufactured.

10 CFR 40.13(c)(2)(iii) – Would revise the exemption for use of source material in glassware to reduce the limit of 10 percent by weight source material to 2 percent by weight source material for glassware manufactured in the future.

10 CFR 40.13(c)(5) – Would remove paragraph (c)(5)(i), as it is redundant with the new paragraph (c)(10), and renumber the subsequent paragraphs within (c)(5).

10 CFR 40.13(c)(7) – Would revise the exemption for use of source material in optical lenses to: (1) reduce the limit of 30 percent by weight thorium to 10 percent by weight thorium for glassware manufactured in the future; (2) accommodate lenses with coatings; (3) add uranium to the material that may be combined with or on the lenses; and (4) add mirrors.

10 CFR 40.13(c)(10) – Would add paragraph (c)(10) to restrict initial distribution under the exemption and direct one to requirements for authorization under an NRC specific license to initially transfer or distribute source material.

10 CFR 40.13(d) – Would remove an obsolete exemption for use of source material in fire detection units.

Section 40.22 Small quantities of source material.

10 CFR 40.22(a)(1) – Would apply a limit of 1.5 kg (3.3 lb) at any one time to certain forms of source material that may be inhaled or ingested during normal working conditions and would restrict receipt to less than 7 kg (15.4 lb) per year.

10 CFR 40.22 (a)(2) - Would allow additional possession of certain forms of source material that are not expected to be normally inhaled or ingested. However, the total amount of source material possessed under the general license would still be limited to 7 kg (15.4 lb) at any one time and the receipt of no more than 70 kg (154 lb) of source material per year.

10 CFR 40.22(a)(3) – Would allow persons removing uranium from drinking water to continue to possess up to 7 kg (15.4 lb) of uranium at any one time and to remove up to 70 kg (154 lb) of uranium from drinking water per calendar year.

10 CFR 40.22(b)(1) – Would continue to prohibit persons from administering source material, or the resulting radiation, either externally or internally, to human beings except as authorized by the NRC in a specific license

10 CFR 40.22(b)(2) - Would clarify that any person who receives, possesses, uses, or transfers source material under § 40.22 may not abandon source material. The source material may be transferred under § 40.51 or permanently disposed. The general licensee would be allowed to dispose of up to a total of 0.5 kg (1.1 lb) per calendar year of source material through transfer to any person for permanent disposal as long as the source material is in a solid, non-dispersible form (e.g., metal brick, encapsulated in cement, etc.). The recipient of the source material would not be required to obtain a license from the NRC as long as it was permanently disposed. Permanent disposal of quantities of source material exceeding 0.5 kg (1.1 lb) of source material per calendar year or in non-solid forms (e.g., is readily ingested or inhaled) would be required to be in accordance with § 20.2001.

10 CFR 40.22(b)(3) – Would clarify which provisions in 10 CFR Part 40 apply under the general license.

10 CFR 40.22(b)(4) - Would add a provision to explicitly require that licensees must respond to written requests by the NRC.

10 CFR 40.22(b)(5) – Would clarify that export of source material is subject to 10 CFR Part 110.

10 CFR 40.22(c) - Would require that any person who receives, possesses, uses, or transfers source material in accordance with paragraph (a) of § 40.22 must conduct activities so as to minimize contamination of the facility and the environment.

10 CFR 40.22(d) – Would revise and move the requirements currently under paragraph (b) of this section to paragraph (d) of this section.

10 CFR 40.22(e) – Would restrict initial distribution for use under the general license to a specific license issued under § 40.54 or equivalent provisions of an Agreement State.

Section 40.52 Certain items containing source material; requirements for license to apply or initially transfer.

10 CFR 40.52 - Would establish requirements for a license authorizing distribution for use under the exemptions from licensing in § 40.13(c) and equivalent provisions of Agreement States.

Section 40.53 Conditions of licenses issued under § 40.52: Quality control, labeling, and records and reports.

10 CFR 40.53 – Would establish requirements for licenses issued under § 40.52, including reporting and recordkeeping requirements for distributions of products for use under § 40.13(c) and equivalent provisions of Agreement States.

Section 40.54 Requirements for license to initially transfer source material for use under § 40.22.

10 CFR 40.54 - Would establish requirements for a license authorizing initial transfer or distribution for use under § 40.22 and equivalent provisions of Agreement States.

Section 40.55 Conditions of licenses issued under § 40.54: Quality control, labeling, safety instructions, records and reports.

10 CFR 40.55 – Would establish requirements for licenses issued under § 40.54, including reporting and recordkeeping requirements for distributions of source material for use under the general license in § 40.22 and equivalent provisions of Agreement States.

Section 40.82 Criminal penalties.

10 CFR 40.82(b) – Would add sections to the list of provisions that are not subject to criminal sanctions.

Section 70.5 Communications.

10 CFR 70.5(b)(1)(iv) - Would add a reference to the proposed § 40.52 as a licensing category not delegated to the NRC Regions.

Section 170.31 Schedule of fees for materials licenses and other regulatory services, including inspections, and import an export licenses.

10 CFR 170.31 – Would add to the schedule of fees, three new categories for distributors of source material.

Section 171.16 Annual fees: Materials licensees, holders of certificates of compliance, holders of sealed source and device registrations, holders of quality assurance program approvals, and government agencies licensed by NRC.

10 CFR 171.16 – Would add three fee categories for distributors of source material to the annual fees.

IV. Criminal Penalties

For the purpose of Section 223 of the Atomic Energy Act (AEA), the Commission is proposing to amend § 40.22 and add §§ 40.53 and 40.55 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

V. Agreement State Compatibility

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* (62 FR 46517; September 3, 1997), this proposed rule would be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among the Agreement States and the NRC requirements. The NRC staff analyzed the proposed rule in accordance with the procedure established within Part III, "Categorization Process for NRC Program Elements," of Handbook 5.9 to Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs" (a copy of which may be viewed at http://www.nrc.gov/reading-rm/doc-collections/management-directives/).

NRC program elements (including regulations) are placed into four compatibility categories (see the Draft Compatibility Table in this section). In addition, the NRC program elements can also be identified as having particular health and safety significance or as being reserved solely to the NRC. Compatibility Category A are those program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Category A program elements in an essentially identical manner to provide uniformity in the regulation of

agreement material on a nationwide basis. Compatibility Category B are those program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. Compatibility Category C are those program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. An Agreement State should adopt the essential objectives of the Category C program elements. Compatibility Category D are those program elements that do not meet any of the criteria of Category A, B, or C, above, and, thus, do not need to be adopted by Agreement States for purposes of compatibility.

Health and Safety (H&S) are program elements that are not required for compatibility but are identified as having a particular health and safety role (i.e., adequacy) in the regulation of agreement material within the State. Although not required for compatibility, the State should adopt program elements in this H&S category based on those of the NRC that embody the essential objectives of the NRC program elements, because of particular health and safety considerations. Compatibility Category NRC are those program elements that address areas of regulation that cannot be relinquished to Agreement States under the Atomic Energy Act, as amended, or provisions of Title 10 of the Code of Federal Regulations. These program elements are not adopted by Agreement States. The following table lists the Parts and Sections that would be revised and their corresponding categorization under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs."

Draft Compatibility Table for Proposed Rule
Distribution of Source Material to Exempt Persons and to General Licensees
And Revision of General License and Exemptions

Section	Change	Subject	Compatibility	
			Existing	New
Part 30				
30.6	Amend	Communications	D	D
Part 40				
40.5	Amend	Communications	D	D
40.8	Amend	Information collection requirements: OMB approval	D	D
40.13(c)	Amend	Unimportant quantities of source material	B	B
40.13(c)(2)(i)	Amend	Unimportant quantities of source material	B	B
40.13(c)(2)(iii)	Amend	Unimportant quantities of source material	B	B
40.13(c)(7)	Amend	Unimportant quantities of source material	B	B
40.13(c)(10)	New	Unimportant quantities of source material	-	B
40.13(d)	Remove	Unimportant quantities of source material	B	*
40.22(a)	Amend	Small quantities of source material	B	B
40.22(a)(1)	New	Small quantities of source material	-	B
40.22(a)(2)	New	Small quantities of source material	-	B
40.22(a)(3)	New	Small quantities of source material	-	B
40.22(b)	Amend	Small quantities of source material (Previously 40.22(c))	B	B
40.22(b)(1)	New	Small quantities of source material	-	B
40.22(b)(2)	New	Small quantities of source material	-	B
40.22(b)(3)	New	Small quantities of source material	-	B
40.22(b)(4)	New	Small quantities of source material	-	D
40.22(b)(5)	New	Small quantities of source material	-	B
40.22(c)	New	Small quantities of source material	-	C
40.22(d)	Amend	Small quantities of source material (Previously 40.22(b))	B	B
40.22(e)	New	Small quantities of source material	-	B
40.52	New	Certain items containing source material; requirements for license to apply or initially transfer	-	NRC
40.53	New	Conditions of licenses issued under § 40.52: Quality control, labeling, and records and reports	-	NRC
40.54	New	Requirements for license to initially transfer source material for use under § 40.22	-	B

Section	Change	Subject	Compatibility	
			Existing	New
40.55(a)	New	Conditions of licenses issued under § 40.54: Quality control, labeling, safety instructions, and records and reports	-	B
40.55(b)	New	Conditions of licenses issued under § 40.54: Quality control, labeling, safety instructions, and records and reports	-	B
40.55(c)	New	Conditions of licenses issued under § 40.54: Quality control, labeling, safety instructions, and records and reports	-	B
40.55(d)	New	Conditions of licenses issued under § 40.54: Quality control, labeling, safety instructions, and records and reports	-	B
40.55(e)	New	Conditions of licenses issued under § 40.54: Quality control, labeling, safety instructions, and records and reports	-	C
40.82	Amend	Criminal penalties	D	D
Part 70				
70.5	Amend	Communications	D	D
Part 170				
170.31	Amend	Schedules of fees for materials licenses and other regulatory services, including inspections, and import and export licenses	D	D
Part 171				
171.16	Amend	Annual fees for materials licenses and other regulatory services	D	D

* Denotes an existing provision that is currently designated Compatibility Category B which will be removed from the regulations as a result of these proposed amendments. Agreement State should remove this provision from their regulations when the amendment becomes final.

The NRC invites comment on the compatibility category designations in the proposed rule and suggests that commenters refer to Handbook 5.9 of Management Directive 5.9 for more information. The NRC notes that, like the rule text, the compatibility category designations can change between the proposed rule and final rule, based on comments received and

Commission decisions regarding the final rule. The NRC encourages anyone interested in commenting on the compatibility category designations in any manner to do so during the comment period.

VI. Plain Language

The Presidential Memorandum "Plain Language in Government Writing" published June 10, 1998 (63 FR 31883), directed that the Government's documents be in clear and accessible language. The NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the "ADDRESSES" heading in this document.

VII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC would establish requirements for distributors of source material to persons exempt from regulation and to general licensees. In addition, the proposed amendments would modify the existing possession and use requirements for the general license for small quantities of source material to better align the requirements with current health and safety standards. The Commission is also proposing to revise, clarify, or delete certain exemptions from licensing to make the requirements for the use of source material under the exemptions more risk informed. The NRC is not aware of any voluntary consensus standards that address the proposed subject matter of

this proposed rule. The NRC will consider using a voluntary consensus standard if an appropriate standard is identified. If a voluntary consensus standard is identified for consideration, the submittal should explain why the standard should be used.

VIII. Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, not to prepare an environmental impact statement for this proposed rule because the Commission has concluded on the basis of an environmental assessment that this proposed rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment.

The majority of the provisions in the proposed rule come within the scope of categorical exclusion in § 51.22, and as such, an environmental review is not necessary. The implementation of the remaining provisions of the proposed rule would not result in any significant negative impact to the environment. Proposed revisions to § 40.22 primarily provide additional limitations on, and clarify the requirements of, the § 40.22 general licensee, thus, potentially reducing the impact on environmental resources from the status quo. Similarly, certain exemptions are being revised or deleted to limit the future use of certain products containing source material. Although the NRC is proposing to expand the exemption from licensing in § 40.13(c)(7) to allow coated lenses, the NRC’s evaluation indicated that these products contain significantly less source material than those currently authorized under the exemption. The Commission has determined that the implementation of this proposed rule would be procedural and administrative in nature.

The determination of this environmental assessment is that there would be no significant impact to the public from this action. However, the general public should note that the NRC

welcomes public participation. Comments on any aspect of the Environmental Assessment may be submitted to the NRC as indicated under the ADDRESSES heading in this document.

The NRC has sent a copy of the Environmental Assessment and this proposed rule to every State Liaison Officer and requested their comments on the Environmental Assessment. The Environmental Assessment may be examined at the NRC Public Document Room, O-1F21, 11555 Rockville Pike, Rockville, MD 20852, or online at http://www.regulations.gov under Docket ID NRC-2009-0084.

IX. Paperwork Reduction Act Statement

This proposed rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). The information collection requirements in this proposed rule have been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

Type of submission, new or revision: Revision.

The title of the information collection: 10 CFR Parts 30, 40, 70, 170, and 171; Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions.

The form number: NRC Form 313.

How often the collection is required: One time for licensing applications and amendments for new initial distribution licenses or for certain general licensees ceasing

activities; annual for reports on initial distribution of source material; occasional for responses to direct NRC requests for information.

Who will be required or asked to report: Applicants and licensees who manufacture or initially distribute products or materials containing source material to persons exempt from the regulations or for use under a general license, and some users of source material possessed under a general license.

An estimate of the number of annual responses: 164.3 (10 CFR Part 19 = 1 response, 10 CFR Part 20 = 7 responses, 10 CFR Part 40 = 95 responses, NRC Form-313 = 12.3 responses, plus 49 recordkeepers).

The estimated number of annual respondents: 75 (10 CFR Part 19 = 1 respondent, 10 CFR Part 20 = 2.33 respondents, 10 CFR Part 40 = 75 respondents, NRC Form-313 = 11.3 respondents). Because some licensees may report under multiple parts, the total number of respondents for the proposed rule is 75 (40 NRC licensees plus 35 Agreement State licensees).

An estimate of the total number of hours needed annually to complete the requirement or request: 753.3 (10 CFR Part 19 = 45.3 hours, 10 CFR Part 20 = 255 hours, 10 CFR Part 40 = 361.4 hours, NRC Form-313 = 91.6 hours).

Abstract: The NRC is proposing to amend its regulations in 10 CFR Part 40 to establish new requirements for distributors of source material to persons exempt from the regulations or for use under a general license in § 40.22. In addition, the Commission is also proposing to

modify the existing possession and use requirements for § 40.22 general licensees to align the requirements with current health and safety standards. Finally, the Commission is proposing to revise, clarify, or delete certain exemptions in § 40.13(c) to make the exemptions more risk informed. Conforming changes would be made to 10 CFR Parts 30, 70, 170 and 171. These changes would affect manufacturers and distributors of products and materials containing source material and future users of some products used under exemptions from licensing and under the § 40.22 general license.

Information collections would result from new requirements for certain persons initially distributing source material to obtain a specific license. These new specific licensees would be required to provide reports regarding their initial distributions of source material to the NRC and the Agreement States on an annual basis and maintain records of such reports, as well as meet existing information collection requirements in 10 CFR Parts 19 and 20. In addition, labeling requirements and notifications to recipients would be required for certain initial distributions of source material. Proposed revisions to the general license provisions in § 40.22 would specifically require the general licensee to respond to NRC requests for information in a timely manner and notify the NRC when ceasing activities if significant contamination is identified.

The NRC is seeking public comment on the potential impact of the information collections contained in the proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?

2. Is the estimate of burden accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

A copy of the OMB clearance package may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O-1 F21, Rockville, MD 20852. The OMB clearance package and rule are available at the NRC worldwide Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/index.html* for 60 days after the signature date of this notice.

Send comments on any aspect of these proposed information collections, including suggestions for reducing the burden and on the above issues, by (**INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER**) to the Records and FOIA/Privacy Services Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to INFOCOLLECTS.RESOURCE@NRC.GOV and to the Desk Officer, Christine Kymn, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0014, 3150-0020, 3150-0044 and 3150-0120), Office of Management and Budget, Washington, DC 20503. Comments on the proposed information collections may also be submitted via the Federal Rulemaking Website *http://www.regulations.gov*, docket ID NRC-2009-0084. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date. You may also e-mail comments to ckymn@omb.eop.gov or comment by telephone at 202-395-4638.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

X. Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission.

The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading in this document. The analysis is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852, or online at www.regulations.gov under Docket Number ID NRC-2009-0084. Single copies of the draft regulatory analysis are available from Gary Comfort, telephone: (301) 415-8106, e-mail: Gary.Comfort@nrc.gov, or Kimyata Morgan Butler, telephone: (301) 415-0733, e-mail: Kimyata.MorganButler@nrc.gov, of the Office of Federal and State Materials and Environmental Management Programs.

XI. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule would not, if promulgated, have a significant economic impact on a substantial number of small entities. A significant number of the licensees affected by this action would meet the definition of "small entities" set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121. However, none of the proposed revisions to the regulatory program would result in a significant economic impact on the affected entities.

XII. Backfit Analysis

The NRC's backfit provisions are found in the regulations at §§ 50.109, 52.39, 52.63, 52.83, 52.98, 52.145, 52.171, 70.76, 72.62, and 76.76. The requirements contained in this proposed rule do not involve any provisions that would impose backfits on nuclear power plant licensees as defined in 10 CFR Parts 50 or 52, or on licensees for gaseous diffusion plants, independent spent fuel storage installations or special nuclear material as defined in 10 CFR Parts 70, 72 and 76, respectively, and as such a backfit analysis is not required. Therefore, a backfit analysis need not be prepared for this proposed rule to address these classes of entities. With respect to Part 40 licensees, the NRC has determined that there are no provisions for backfit in 10 CFR Part 40. Therefore, a backfit analysis need not be prepared for this proposed rule to address part 40 licensees.

List of Subjects

10 CFR Part 30

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 40

Criminal penalties, Government contracts, Hazardous materials transportation, Nuclear materials, Reporting and recordkeeping requirements, Source material, Uranium.

10 CFR Part 70

Criminal penalties, Hazardous materials transportation, Material control and accounting, Nuclear materials, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material.

10 CFR Part 170

Byproduct material, Import and export licenses, Intergovernmental relations, Non-payment penalties, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

10 CFR Part 171

Annual charges, Byproduct material, Holders of certificates, registrations, approvals, Intergovernmental relations, Nonpayment penalties, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553; the NRC is proposing to adopt the following amendments to 10 CFR Parts 30, 40, 70, 170, and 171.

PART 30 - RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

1. The authority citation for Part 30 continues to read as follows:

Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 549 (2005).

Section 30.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102-486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

2. In § 30.6, paragraph (b)(1)(iv) is revised to read as follows:

§ 30.6 Communications.

* * * * *

(b) * * *

(1) * * *

(iv) Distribution of products containing radioactive material to persons exempt under §§ 32.11 through 32.30 and § 40.52 of this chapter.

* * * * *

PART 40-DOMESTIC LICENSING OF SOURCE MATERIAL

3. The authority citation for Part 40 continues to read as follows:

Authority: Secs. 62, 63, 64, 65, 81, 161, 182, 183, 186, 68 Stat. 932, 933, 935, 948, 953, 954, 955, as amended, secs. 11e(2), 83, 84, Pub. L. 95-604, 92 Stat. 3033, as amended, 3039, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2014(e)(2), 2092, 2093, 2094, 2095, 2111, 2113, 2114, 2201, 2232, 2233, 2236, 2282); sec. 274, Pub. L. 86-373, 73 Stat. 688 (42 U.S.C. 2021); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 275, 92 Stat. 3021, as amended by Pub. L. 97-415, 96 Stat. 2067 (42 U.S.C. 2022); sec. 193, 104 Stat. 2835, as amended by Pub. L. 104-134, 110 Stat. 1321, 1321-349 (42 U.S.C. 2243); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. No. 109-59, 119 Stat. 594 (2005).

Section 40.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102-486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851). Section 40.31(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 40.46 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 40.71 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

4. In § 40.5, paragraph (b)(1)(iv) is revised to read as follows:

§ 40.5 Communications.

* * * * *

(b) * * *

(1) * * *

(iv) Distribution of products containing radioactive material to persons exempt under §§ 32.11 through 32.30 and § 40.52 of this chapter.

* * * * *

5. In § 40.8, paragraph (b) is revised to read as follows:

§ 40.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 40.9, 40.22, 40.23, 40.25, 40.26, 40.27, 40.31, 40.34, 40.35, 40.36, 40.41, 40.42, 40.43, 40.44, 40.51, 40.52, 40.53, 40.54, 40.55, 40.60, 40.61, 40.64, 40.65, 40.66, 40.67, and appendix A to this part.

* * * * *

6. In § 40.13, paragraphs (c)(5)(i) and (d) are removed; paragraphs (c)(5)(ii), (c)(5)(iii), and (c)(5)(iv) are redesignated as (c)(5)(i), (c)(5)(ii), and (c)(5)(iii); the introductory language to paragraph (c) and paragraphs (c)(2)(i), (c)(2)(iii), and (c)(7) are revised; and paragraph (c)(10) is added to read as follows:

§ 40.13 Unimportant quantities of source material

* * * * *

(c) Any person is exempt from the requirements for a license set forth in section 62 of the Act and from the regulations in this part and parts 19, 20, and 21 of this chapter to the extent that such person receives, possesses, uses, or transfers:

* * * * *

(2) * * *

(i) Glazed ceramic tableware manufactured before [insert effective date of rule], provided that the glaze contains not more than 20 percent by weight source material;

* * * * *

(iii) Glassware containing not more than 2 percent by weight source material or, for glassware manufactured before [insert effective date of rule], 10 percent by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction;

* * * * *

(7) Thorium or uranium contained in or on finished optical lenses and mirrors, provided that each lens does not contain more than 10 percent by weight thorium or uranium or, for lenses manufactured before [insert effective date of rule], 30 percent by weight of thorium; and that the exemption contained in this paragraph does not authorize either:

(i) The shaping, grinding or polishing of such lens or mirror or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror; or

(ii) The receipt, possession, use, or transfer of uranium or thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.

* * * * *

(10) No person may initially transfer for sale or distribution a product containing source material to persons exempt under this paragraph (c), or equivalent regulations of an Agreement State, unless authorized by a license issued under § 40.52 to initially transfer such products for sale or distribution.

(i) Persons initially distributing source material in products covered by the exemptions in this paragraph (c) before [Insert the effective date of this rule] without specific authorization may continue such distribution for 1 year beyond this date. Initial distribution may also be continued until the Commission takes final action on a pending application for license or license amendment to specifically authorize distribution submitted no later than 1 year beyond this date.

(ii) Persons authorized to manufacture, process, or produce materials or products containing source material by an Agreement State and persons who import finished products or parts for sale or distribution must be authorized by a license issued under § 40.52 for distribution only and are exempt from the requirements of parts 19 and 20 of this chapter, and § 40.32(b) and (c).

7. Section 40.22 is revised to read as follows:

§ 40.22 Small quantities of source material.

(a) A general license is hereby issued authorizing commercial and industrial firms; research, educational, and medical institutions; and Federal, State, and local government agencies to receive, possess, use, and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operational purposes in the following forms and quantities:

(1) Not more than 1.5 kg (3.3 lb) of uranium and thorium in any form at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 7 kg (15.4 lb) of source material in any one calendar year. Source material possessed under paragraph (a)(2) of this section does not apply toward these limits; and

(2) Not more than 7 kg (15.4 lb) of uranium and thorium at any one time so long as the form is solid and non-dispersible. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year and may not alter the chemical or physical form of the source material possessed under this paragraph. The total quantity of source material possessed under this paragraph must include source material possessed under paragraph (a)(1) of this section; or

(3) Not more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under this paragraph.

(b) Any person who receives, possesses, uses, or transfers source material in accordance with the general license in paragraph (a) of this section:

(1) Is prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the NRC in a specific license.

(2) Shall not abandon such source material. Source material may be disposed of as follows:

(i) A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for

permanent disposal. The recipient of source material transferred under the provisions of this paragraph is exempt from the requirements to obtain a license under this part to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued under this chapter; or

(ii) In accordance with § 20.2001 of this chapter.

(3) Is subject to the provisions in §§ 40.1 through 40.10, 40.41(a) through (e), 40.46, 40.51, 40.60 through 40.63, 40.71, and 40.81.

(4) Shall respond to written requests from the NRC to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the person cannot provide the requested information within the allotted time, the person shall, within that same time period, request a longer period to supply the information by providing the Director of the Office of Federal and State Materials and Environmental Management Programs, using an appropriate method listed in § 40.5(a), a written justification for the request;

(5) Shall not export such source material except in accordance with part 110 of this chapter.

(c) Any person who receives, possesses, uses, or transfers source material in accordance with paragraph (a) of this section shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the Director of the Office of Federal and State Materials and Environmental Management Programs by an appropriate method listed in § 40.5(a) about such contamination and may consult with the NRC as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material

remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in § 20.1402 of this chapter.

(d) Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in paragraph (a) of this section is exempt from the provisions of parts 19, 20, and 21 of this chapter to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of §§ 20.1402 and 20.2001 of this chapter to the extent necessary to meet the provisions of paragraphs (b)(2) and (c) of this section. However, this exemption does apply to any person who also holds a specific license issued under this chapter.

(e) No person may initially transfer or distribute source material to persons generally licensed under paragraph (a) of this section, or equivalent regulations of an Agreement State, unless authorized by a specific license issued in accordance with § 40.54 or equivalent provisions of an Agreement State. Initial distribution of source material to persons generally licensed by paragraph (a) of this section before [Insert the effective date of this rule] without specific authorization may continue for 1 year beyond this date. Distribution may also be continued until the Commission takes final action on a pending application for license or license amendment to specifically authorize distribution submitted no later than 1 year beyond this date.

8. Sections 40.52, 40.53, 40.54, and 40.55 are added under the undesignated heading Transfer of Source Material to read as follows:

§ 40.52 Certain items containing source material; requirements for license to apply or initially transfer.

An application for a specific license to apply source material to, incorporate source material into, manufacture, process, or produce the products specified in § 40.13(c) of this part or to initially transfer for sale or distribution any products containing source material for use under § 40.13(c) or equivalent provisions of an Agreement State will be approved if:

(a) The applicant satisfies the general requirements specified in § 40.32. However, the requirements of § 40.32(b) and (c) do not apply to an application for a license to transfer products manufactured, processed, or produced in accordance with a license issued by an Agreement State or to the import of finished products or parts.

(b) The applicant submits sufficient information regarding the product pertinent to the evaluation of the potential radiation exposures, including:

(1) Chemical and physical form and maximum quantity of source material in each product;

(2) Details of construction and design of each product, if applicable. For coated lenses, this must include a description of manufacturing methods that will ensure that the coatings are unlikely to be removed under the conditions expected to be encountered during handling and use;

(3) For products with applicable quantity or concentration limits, quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet;

(4) The proposed method of labeling or marking each unit, and/or its container with the identification of the manufacturer or initial transferor of the product and the source material in the product; and

(5) The means of providing radiation safety precautions and instructions relating to handling, use, and storage of products to be used under § 40.13(c)(1)(i) and (c)(1)(iii).

(c) Each product will contain no more than the quantity or the concentration of source material specified for that product in § 40.13(c).

§ 40.53 Conditions of licenses issued under § 40.52: Quality control, labeling, and records and reports.

(a) Each person licensed under § 40.52 shall ensure that the quantities or concentrations of source material do not exceed any applicable limit in § 40.13(c).

(b) Each person licensed under § 40.52 shall ensure that each product is labeled as provided in the specific exemption under § 40.13(c). Those distributing products to be used under § 40.13(c)(1)(i) and (c)(1)(iii) or equivalent regulations of an Agreement State shall provide radiation safety precautions and instructions relating to handling, use, and storage of these products as specified in the license.

(c)(1) Each person licensed under § 40.52 shall file a report with the Director, Office of Federal and State Materials and Environmental Management Programs by an appropriate method listed in § 40.5(a), including in the address: ATTN: Document Control Desk/Exempt Distribution.

(2) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee and indicate that the products are transferred for use under § 40.13(c), giving the specific paragraph designation, or equivalent regulations of an Agreement State.

(3) The report must include the following information on products transferred to other persons for use under § 40.13(c) or equivalent regulations of an Agreement State:

(i) A description or identification of the type of each product and the model number(s), if applicable;

(ii) For each type of source material in each type of product and each model number, if applicable, the total quantity of the source material; and

(iii) The number of units of each type of product transferred during the reporting period by model number, if applicable.

(4) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. Licensees who permanently discontinue activities authorized by the license issued under § 40.52 shall file a report for the current calendar year within 30 days after ceasing distribution.

(5) If no transfers of source material have been made to persons exempt under § 40.13(c) or the equivalent regulations of an Agreement State, during the reporting period, the report must so indicate.

(6) The licensee shall maintain all information concerning transfers that support the reports required by this section for 1 year after each transfer is included in a report to the Commission.

§ 40.54 Requirements for license to initially transfer source material for use under § 40.22.

An application for a specific license to initially transfer source material for use under § 40.22, or equivalent regulations of an Agreement State, will be approved if:

(a) The applicant satisfies the general requirements specified in § 40.32; and

(b) The applicant submits adequate information on and the Commission approves the methods to be used for quality control, labeling, and providing safety instructions to recipients.

§ 40.55 Conditions of licenses issued under § 40.54: Quality control, labeling, safety instructions, and records and reports.

(a) Each person licensed under § 40.54 shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words, “radioactive material.”

(b) Each person licensed under § 40.54 shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

(c) Each person licensed under § 40.54 shall provide the information specified in this paragraph to each person to whom source material is transferred for use under § 40.22 or equivalent provisions in Agreement State regulations. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

(1) A copy of §§ 40.22 and 40.51, or relevant equivalent regulations of the Agreement State.

(2) Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.

(d) Each person licensed under § 40.54 shall report transfers as follows:

(1) File a report with the Director, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555. The report shall include the following information:

(i) The name, address, and license number of the person who transferred the source material;

(ii) For each general licensee under § 40.22 or equivalent Agreement State regulations to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

(iii) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

(2) File a report with the responsible Agreement State agency for transfers of greater than 50 grams (0.11 lb) of source material transferred to a general licensee in an Agreement State within a calendar quarter. The report shall include the following information specific to those transfers made to the Agreement State being reported to:

(i) The name, address, and license number of the person who transferred the source material; and

(ii) The name and address of the general licensee to whom source material was distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred.

(iii) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the Agreement State.

(3) Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under § 40.22 or equivalent Agreement State provisions during the current period, a report shall be submitted to the Commission indicating so. If no transfers have been made to general licensees in a

particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon request of the agency.

(e) Each person licensed under § 40.54 shall maintain all information that supports the reports required by this section concerning each transfer to a general licensee for a period of 1 year after the event is included in a report to the Commission or to an Agreement State agency.

9. In § 40.82, paragraph (b) is revised to read as follows:

§ 40.82 Criminal penalties

* * * * *

(b) The regulations in part 40 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 40.1, 40.2, 40.2a, 40.4, 40.5, 40.6, 40.8, 40.11, 40.12, 40.13, 40.14, 40.20, 40.21, 40.31, 40.32, 40.34, 40.43, 40.44, 40.45, 40.52, 40.54, 40.71, 40.81, and 40.82.

PART 70 - DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

10. The authority citation for part 70 continues to read as follows:

Authority: Secs. 51, 53, 161, 182, 183, 68 Stat. 929, 930, 948, 953, 954, as amended, sec. 234, 83 Stat. 444, as amended, (42 U.S.C. 2071, 2073, 2201, 2232, 2233, 2282, 2297f); secs. 201, as amended, 202, 204, 206, 88 Stat. 1242, as amended, 1244, 1245, 1246 (42 U.S.C. 5841, 5842, 5845, 5846). Sec. 193, 104 Stat. 2835 as amended by Pub.L. 104-134, 110

Stat. 1321, 1321-349 (42 U.S.C. 2243); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 194 (2005).

Sections 70.1(c) and 70.20a(b) also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

Section 70.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102-486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851). Section 70.21(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 70.31 also issued under sec. 57d, Pub. L. 93-377, 88 Stat. 475 (42 U.S.C. 2077). Sections 70.36 and 70.44 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 70.81 also issued under secs. 186, 187, 68 Stat. 955 (42 U.S.C. 2236, 2237). Section 70.82 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138).

11. In § 70.5, paragraph (b)(1)(iv) is revised to read as follows:

§ 70.5 Communications.

* * * * *

(b) * * *

(1) * * *

(iv) Distribution of products containing radioactive material to persons exempt under §§ 32.11 through 32.30 and 40.52 of this chapter.

* * * * *

PART 170--FEES FOR FACILITIES, MATERIALS, IMPORT AND EXPORT LICENSES AND OTHER REGULATORY SERVICES UNDER THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

12. The authority citation for part 170 continues to read as follows:

Authority: Sec. 9701, Pub. L. 97-258, 96 Stat. 1051 (31 U.S.C. 9701); sec. 301, Pub. L. 92-314, 86 Stat. 227 (42 U.S.C. 2201w); sec. 201, Pub. L. 93-438, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 205a, pub. L. 101-576, 104 Stat. 2842, as amended (31 U.S. C. 901, 902); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 623, Pub. L. 109-58, 119 Stat.783 (42 U.S.C. 2201(w)); sec. 651(e), Pub. L. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

13. Section 170.31 is revised by revising and redesignating materials license category 2.C. as category 2.F. and adding new categories 2.C., 2.D., and 2.E. to read as follows:

§ 170.31 Schedules of fees for materials licenses and other regulatory services, including inspections, and import and export licenses.

* * * * *

SCHEDULES OF MATERIALS FEES

[See footnotes at end of table]

Categories of materials licenses and types of fees[1]	Fee[2,3]
* * * * *	
2. Source material	
* * * * *	
C. Licenses to distribute items containing source material to persons exempt from the licensing requirements of part 40 of this chapter.	
Application [Program Code(s): 11240]	$7,000
D. Licenses to distribute source material to persons generally licensed under part 40 of this chapter.	
Application [Program Code(s): 11230 and 11231]	$2,000
E. Licenses for possession and use of source material for processing or manufacturing of products or materials containing source material for commercial distribution.	
Application [Program Code(s): 11710]	$10,100
F. All other specific source material licenses.	
Application [Program Code(s): 11200, 11220, 11221, 11300, 11800, 11810]	$10,100
* * * * *	

[1] *Types of fees* - Separate charges, as shown in the schedule, will be assessed for pre-application consultations and reviews; applications for new licenses, approvals, or license terminations; possession only licenses; issuance of new licenses and approvals; certain

amendments and renewals to existing licenses and approvals; safety evaluations of sealed sources and devices; generally licensed device registrations; and certain inspections. The following guidelines apply to these charges:

(a) *Application and registration fees.* Applications for new materials licenses and export and import licenses; applications to reinstate expired, terminated, or inactive licenses except those subject to fees assessed at full costs; applications filed by Agreement State licensees to register under the general license provisions of 10 CFR 150.20; and applications for amendments to materials licenses that would place the license in a higher fee category or add a new fee category must be accompanied by the prescribed application fee for each category.

(1) Applications for licenses covering more than one fee category of special nuclear material or source material must be accompanied by the prescribed application fee for the highest fee category.

(2) Applications for new licenses that cover both byproduct material and special nuclear material in sealed sources for use in gauging devices will pay the appropriate application fee for fee Category 1.C. only.

(b) *Licensing fees*. Fees for reviews of applications for new licenses and for renewals and amendments to existing licenses, pre-application consultations and reviews of other documents submitted to NRC for review, and project manager time for fee categories subject to full cost fees, are due upon notification by the Commission in accordance with § 170.12(b).

(c) *Amendment fees.* Applications for amendments to export and import licenses must be accompanied by the prescribed amendment fee for each license affected. An application for an amendment to an export or import license or approval classified in more than one fee category must be accompanied by the prescribed amendment fee for the category affected by the amendment unless the amendment is applicable to two or more fee categories, in which case the amendment fee for the highest fee category would apply.

(d) *Inspection fees*. Inspections resulting from investigations conducted by the Office of Investigations and non-routine inspections that result from third-party allegations are not subject to fees. Inspection fees are due upon notification by the Commission in accordance with § 170.12(c).

(e) *Generally licensed device registrations under 10 CFR 31.5*. Submittals of registration information must be accompanied by the prescribed fee.

[2] Fees will not be charged for orders related to civil penalties or other civil sanctions issued by the Commission under 10 CFR 2.202 or for amendments resulting specifically from the requirements of these orders. For orders unrelated to civil penalties or other civil sanctions, fees will be charged for any resulting licensee-specific activities not otherwise exempted from fees under this chapter. Fees will be charged for approvals issued under a specific exemption provision of the Commission's regulations under Title 10 of the Code of Federal Regulations (e.g., 10 CFR 30.11, 40.14, 70.14, 73.5, and any other sections in effect now or in the future), regardless of whether the approval is in the form of a license amendment, letter of approval, safety evaluation report, or other form. In addition to the fee shown, an applicant may be assessed an additional fee for sealed source and device evaluations as shown in Categories 9.A. through 9.D.

[3] Full cost fees will be determined based on the professional staff time multiplied by the appropriate professional hourly rate established in § 170.20 in effect when the service is provided, and the appropriate contractual support services expended. For applications currently on file for which review costs have reached an applicable fee ceiling established by the June 20, 1984, and July 2, 1990, rules, but are still pending completion of the review, the cost incurred after any applicable ceiling was reached through January 29, 1989, will not be billed to the applicant. Any professional staff-hours expended above those ceilings on or after January 30, 1989, will be assessed at the applicable rates established by § 170.20, as appropriate, except

for topical reports whose costs exceed $50,000. Costs which exceed $50,000 for each topical report, amendment, revision, or supplement to a topical report completed or under review from January 30, 1989, through August 8, 1991, will not be billed to the applicant. Any professional hours expended on or after August 9, 1991, will be assessed at the applicable rate established in § 170.20.

PART 171--ANNUAL FEES FOR REACTOR LICENSES AND FUEL CYCLE LICENSES AND MATERIALS LICENSES, INCLUDING HOLDERS OF CERTIFICATES OF COMPLIANCE, REGISTRATIONS, AND QUALITY ASSURANCE PROGRAM APPROVALS, AND GOVERNMENT AGENCIES LICENSED BY NRC

14. The authority citation for part 171 continues to read as follows:

Authority: Sec. 7601, Pub. L. 99-272, 100 Stat. 146, as amended by sec. 5601, Pub. L. 100-203, 101 Stat. 1330 as amended by sec. 3201, Pub. L. 101-239, 103 Stat. 2132, as amended by sec. 6101, Pub. L. 101-508, 104 Stat. 1388, as amended by sec. 2903a, Pub. L. 102-486, 106 Stat. 3125 (42 U.S.C. 2213, 2214), and as amended by Title IV, Pub. L. 109-103, 119 Stat. 2283 (42 U.S.C. 2214); sec. 301, Pub. L. 92-314, 86 Stat. 227 (42 U.S.C. 2201w); sec. 201, Pub. L. 93-438, 88 Stat. 1242, as amended (42 U.S.C. 5841);sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

15. In § 171.16, the table in paragraph (d) is revised by revising and redesignating materials license category 2.C. as category 2.F. and adding new categories 2.C., 2.D., and 2.E. to read as follows:

§ 171.16 Annual fees: Materials licensees, holders of certificates of compliance, holders of sealed source and device registrations, holders of quality assurance program approvals and government agencies licensed by the NRC.

* * * * *

(d) * * *

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC

[See footnotes at end of table]

Category of Materials Licenses	Annual fees[1,2,3]
* * * * *	
2. Source Material	
* * * * *	
C. Licenses to distribute items containing source material to persons exempt from the licensing requirements of part 40 of this chapter [Program Code(s): 11240]	$10,000
D. Licenses to distribute source material to persons generally licensed under part 40 of this chapter [Program Code(s): 11230 and 11231]	$5,000
E. Licenses for possession and use of source material for processing or manufacturing of products or materials containing source material for commercial distribution. [Program Code(s): 11710]	$17,400
F. All other specific source material licenses. [Program Code(s): 11200, 11220, 11221, 11300, 11800, 11810]	$17,400
* * * * *	

[1] Annual fees will be assessed based on whether a licensee held a valid license with the NRC authorizing possession and use of radioactive material during the current FY. The annual fee is waived for those materials licenses and holders of certificates, registrations, and approvals who either filed for termination of their licenses or approvals or filed for possession only/storage licenses before October 1, 2007, and permanently ceased licensed activities entirely before this date. Annual fees for licensees who filed for termination of a license, downgrade of a license, or for a possession only license during the FY and for new licenses issued during the FY will be prorated in accordance with the provisions of § 171.17. If a person holds more than one license, certificate, registration, or approval, the annual fee(s) will be assessed for each license, certificate, registration, or approval held by that person. For licenses that authorize more than one activity on a single license (e.g., human use and irradiator

activities), annual fees will be assessed for each category applicable to the license. Licensees paying annual fees under Category 1.A.(1) are not subject to the annual fees for Categories 1.C. and 1.D. for sealed sources authorized in the license.

[2] Payment of the prescribed annual fee does not automatically renew the license, certificate, registration, or approval for which the fee is paid. Renewal applications must be filed in accordance with the requirements of parts 30, 40, 70, 71, 72, or 76 of this chapter.

[3] Each FY, fees for these materials licenses will be calculated and assessed in accordance with § 171.13 and will be published in the *Federal Register* for notice and comment.

Dated at Rockville, Maryland, this day of , 2010.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.

Draft Regulatory Analysis for Proposed Rulemaking – Requirements for Distribution of Source Material:
(10 CFR Parts 30, 40, 70, 170, and 171)

U.S. Nuclear Regulatory Commission
Office of Federal and State Materials and Environmental Management Programs

DRAFT REGULATORY ANALYSIS

Table of Contents

1. STATEMENT OF THE PROBLEM

The U.S. Nuclear Regulatory Commission (NRC or "the Commission") conducted a systematic reevaluation of the exemptions from licensing in 10 CFR Parts 30 and 40, which govern the use of byproduct and source material. During this reevaluation, the Commission identified several areas in which the regulations for source material could be improved, or made more risk-informed and up to date. Issues related to the regulation of byproduct materials have been addressed separately.

The NRC is proposing to amend its regulations governing the use of source material to establish requirements for initial distributors of source material and to make the exemptions in 10 CFR 40.13 and the general license in 10 CFR 40.22 more risk-informed. This action is primarily intended to improve the control of distribution and use of source material, so that the NRC may better ensure adequate protection of the health and safety of workers and the public. It would affect manufacturers and initial distributors of products containing source material and future users of source material under general license or exemption from licensing.

2. EXISTING REGULATORY FRAMEWORK

Part 40 sets out the basic requirements for licensing of source material and includes a number of exemptions from licensing requirements. The exemptions from licensing requirements are in § 40.13.

Part 40 also includes a number of general licenses. Of particular interest is § 40.22, which authorizes commercial and industrial firms, research, educational, and medical institutions; and Federal, State, and local governmental agencies to use and transfer not more than 15 pounds (lb) of source material in any form at any one time for research, development, educational, commercial, or operational purposes. Not more than a total of 150 lb of source material may be received in any one calendar year. Such general licensees are exempt from the provisions of Parts 19, 20, and 21, except those licensees who also possess source material under a specific license.

3. ALTERNATIVES CONSIDERED

3.1 No action

One alternative to proposing rule changes would be to take no action. The no-action alternative would allow current practices to continue. If the NRC does not take action, there would not be any change in costs or benefits to the public, licensees, or the NRC. The no-action alternative would not address identified concerns.

3.2 Proposed Rulemaking to Revise 10 CFR Parts 30, 40, 70, 170, and 171

This alternative would amend 10 CFR Parts 30, 40, 70, 170, and 171 to resolve several issues related primarily to the goals of ensuring public health and safety in the use of source material under general license and under exemptions from licensing. The regulatory amendments would create a regulatory framework for the initial distribution of source material which would allow for the Commission to be aware of what types and quantities of products containing source material are distributed for use under the exemptions from licensing and to identify persons using significant quantities of source material under the general license in § 40.22. It would also ensure that general licensees under § 40.22 are informed of applicable regulations before they obtain source material. These changes would affect licensees who distribute source material and future users of some materials currently used under general license or exemption from licensing.

3.3 Other Alternatives

Other alternatives, such as developing or revising guidance or issuing generic communications, are not viable because these alternatives would not provide the necessary regulatory basis to mandate particular licensee actions and cannot adequately address concerns directly related to the regulations themselves. To ensure the adequate protection of public health and safety in the future, changes in the regulations are necessary.

4. ANALYSIS OF ALTERNATIVES

Sections 4.1 through 4.7 describe and discuss each of the proposed amendments in the rule. Quantitative estimates of the costs to the licensees, the NRC, the Agreement States, and the public related to each amendment are provided where sufficient data is available. Benefits and unquantified costs are discussed qualitatively. Section 4.8 estimates the costs to the NRC and Section 4.9 estimates costs to the Agreement States for rulemakings to promulgate the amendments.

Throughout this analysis, various labor rates are used. These rates are used consistently for all of the issues and their derivations are described below.

Licensee labor rates were obtained from National Wage Data available on the Bureau of Labor Statistics web site (www.bls.gov). Depending on the industry and the occupation (e.g., manufacturing, health and safety, etc.), an appropriate mean hourly labor rate is selected. The rate is then increased using a multiplier of 1.4 to account for benefits (insurance premiums, pension, and legally required benefits). Because exact hourly rates would be difficult to obtain and may not be sufficiently recent, nationwide mean hourly rates are used.

In the context of the overall, societal regulatory evaluation, the NRC's fees are neither a cost nor benefit, but are considered a distributional effect. To a licensee, however, fees may have a significant impact and therefore they are mentioned, but not quantified, below in situations where they may be a significant factor.

NRC labor rates are determined per the calculation methodology in Abstract 5.2 of NUREG/CR-4627, Rev.1, "Generic Cost Estimates, Abstracts from Generic Studies for Use in Preparing Regulatory Impact Analyses." This methodology considers only variable costs that are directly related to the implementation, operation, and maintenance of the proposed requirement. Currently, this hourly labor rate for FSME is $100.

Agreement States' labor rates vary in amount and in how each rate is determined. A survey of a particular industry would reveal a labor rate that can be compared to the NRC's labor rate, or the Bureau of Labor Statistics web site can be used to obtain an hourly labor rate. Either of these methods is likely to yield similar results. For the purpose of this analysis, the average Agreement State hourly labor rate was obtained from the Bureau of Labor Statistics Employer Costs for Employee Compensation data set, "Management, professional, and related occupations" limited to State and local government workers[1]. This wage was then increased by the same factor of 1.4 described earlier to obtain an hourly labor rate of $46 and an annual labor rate of $82,000.

The estimation of costs for rulemaking is based on professional staff full-time equivalent (FTE). As described in the Office of Management and Budget (OMB) Circular A-76, "Performance of Commercial Activities," the number of productive hours in one year is 1,776. Therefore, a professional staff FTE is based on 1,776 hours. Costs are determined by multiplying the number of FTEs by 1,776 hours times the hourly labor rate, for the NRC or the Agreement States as appropriate.

For all licensee labor rates, $49 per hour is used. This rate is based on the Bureau of Labor Statistics Employer Costs for Employee Compensation data set, "Health and Safety Engineers, Except Mining Safety Engineers and Inspectors"; however, some of the actions evaluated may be conducted by lower paid employees, such as clerical staff.

This Regulatory Analysis was prepared in accordance with NUREG/BR-0058(4), "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," to support the NRC's regulatory action and examine the costs and benefits of the alternatives considered by the Commission. The NRC staff has evaluated each attribute listed in Chapter Five of NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook." The following attributes would be affected by the proposed rule:

- Occupational Health (Routine and Accident/Event) – The proposed rule would reduce likely doses to workers using some types of products under exemptions from license and generally licensed materials distributed in the future.
- Public Health (Routine and Accident/Event) – The proposed rule would result in some reduction in public doses, and provide greater assurance that exposures received as a result of products being used under exemptions from licensing and materials used under the subject general license do not exceed appropriate levels.

[1]Department of Labor (U.S.), Bureau of Labor Statistics, Employer Costs for Employee Compensation, 4th Quarter 2007. Series IDs CMU3020000100000D and CMU3020000100000P.

- Safeguards and Security Considerations – The proposed rule would improve assurance that radionuclides of concern to security are not made available through the general license.
- Industry Implementation - Costs to industry would result in connection with those manufacturers and distributors who would require new specific licenses for distribution.
- Industry Operation – The proposed rule would improve licensing of distribution of certain source material by making the regulations clearer, more up-to-date, and more risk-informed. Costs to industry would primarily impact those persons who currently operate under general license.
- NRC Implementation and Operation – The NRC would incur costs to develop a rule and to revise existing guidance. The proposed rule would result in effects on operating costs, as an increase in specific licensees would result.
- Other Government – The Agreement States would need to amend their regulations to maintain compatibility with NRC requirements; impacts to the Agreement State regulatory programs would be minimal. The U.S. Environmental Protection Agency could see reduced costs if instances of significantly contaminated general licensee sites are avoided in the future.
- Environmental Considerations – The proposed rule would eliminate or make more restrictive some of the exemptions from licensing. This would result in less source material being disposed of in municipal landfills and incinerators. Changes to the general license in § 40.22 may also impact such disposal.
- Regulatory Efficiency – The proposed rule would increase efficiency by improving the regulatory framework for the distribution of source material, removing obsolete provisions, and clarifying some of the regulations.
- Improvements in Knowledge – The rule would allow the NRC to better track the number and types of products and materials distributed for use under exemptions from license and to better estimate the impacts of these products and materials. The proposed rule would allow the NRC and the Agreement States to more easily identify general licensees using source material and to improve their knowledge about their activities.
- Other Considerations – The proposed rule could increase public confidence in the NRC by making the regulations more protective of public health and safety by allowing the NRC to better evaluate and provide information on exposures of the public and certain workers from source material.

The above attributes are evaluated more fully in Sections 4.1 through 4.7 as they pertain to the individual issues.

The proposed rule would *not* be expected to affect the following attributes:

- Offsite Property
- Onsite Property
- General Public
- Antitrust Considerations

One difficulty is determining to what extent each of these attributes can be quantified. For some attributes, like NRC implementation costs, this is relatively straight forward. For many others, it cannot be done due to lack of information or methodological problems. However, the Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, NUREG/BR-0058, Revision 4, states that "[e]ven inexact quantification with large uncertainties is preferable to no

quantification, provided the uncertainties are appropriately considered." In ideal circumstances, dollar amounts are added up and a "net benefit" is given -- the amount by which values exceed impacts. Often, only costs (impacts) can be quantified. In the absence of dollar estimates for benefits and costs, a regulatory analysis may be able to provide some other quantitative information.

Valuable information on estimating costs and benefits can be found in the Regulatory Analysis Technical Evaluation Handbook, NUREG/BR-0184.

4.0 DESCRIPTION, DISCUSSION, AND ANALYSIS OF VALUES AND IMPACTS OF THE AMENDMENTS

4.1 Create Requirements for the Initial Distribution of Source Material Products to Exempt Persons in § 40.52 and § 40.53

New provisions would be created to establish a regulatory framework for authorizing the initial transfer of products used under exemptions from licensing. Licensing requirements for distribution of products for use under the exemptions from licensing would be contained in § 40.52. A new provision, § 40.53, would be created to set out conditions of license for licenses issued under § 40.52. These requirements would cover: quality control, labeling, and reporting and recordkeeping. Quality control would be required for products to be used under exemptions containing specific quantity or concentration limits. Labeling would be required for those exemptions which currently require a label and as needed to provide instructions for those using gas mantles or welding rods under § 40.13(c)(1)(i) or (c)(1)(iii), and equivalent provisions in Agreement State regulations. A new paragraph (§ 40.13(c)(10)) would be added to prohibit initial distribution without specific authorization to do so; it would direct those wishing to be distributors of products used under the exemptions in § 40.13(c) to apply for a license under § 40.52. This prohibition would include a transition provision to allow current distributors to continue to do so and apply for the required license within 1 year.

Under these proposed provisions, manufacturers and distributors of products to be used under the exemptions from licensing in § 40.13(c) and equivalent provisions in Agreement State regulations would be required to apply for an NRC specific license authorizing distribution to exempt persons.

There are no alternatives to rulemaking that could accomplish the same result. However, there are other approaches in changing the regulations that could be used to improve the control of distribution and use of such products. These include requiring specific authorization for distribution without a specific licensing provision. This would be difficult to implement as the authorization to transfer material for use under exemption from licensing is reserved to the NRC under 10 CFR 150.15(a)(6). In order to adequately control the materials used under exemption, this NRC retained authority should be utilized. It would be significantly more efficient and effective to do so and to use a unique regulatory provision.

Cost Impacts:

Costs to Industry/Licensees (Manufacturers and Distributors)

Costs to distributors will depend on whether they are currently an NRC or an Agreement State specific licensee or are currently operating under § 40.22 or equivalent State provisions, or an importer generally licensed under 10 CFR 110.27(a)(2) with no other license.

One time costs applicable to all distributors of products for use under exemption:

Illustrative estimate of application costs for these assumptions:

25 in Agreement States
2 current NRC specific licensees
3 current NRC general licensees

NRC Exempt-Distribution License Required:

30 applications x 8 hours/application x $49/hour = ~$11,800

For distributors of welding rods and gas mantles only, initial costs associated with providing safety instructions:

Since hazard and safety information exists (e.g. American Welding Society (AWS) Safety and Health Fact Sheet No. 2 and No. 27), the effort to develop a distributor-specific label or instruction is estimated to take an average of 20 hours.
4 applications X 20 hours/application X $ 49/ hour = ~$3,900

Continuing costs applicable to all distributors of products to be used under exemption from licensing:

Quality control (§ 40.53(a)):

Although there would now be an explicit requirement, distributors should be ensuring that products meet applicable limits in any case. New costs are limited to those connected with documentation of the program for the NRC. Those are included in the application costs estimated above.

Reporting (§ 40.53(c)):

0.5 hours/licensee X 30 licensees X $49/hour = $735/year

Recordkeeping (§ 40.53(c)):

1 hour/licensee X 30 licensees X $49/hour = $1,470/year

Labeling and safety instructions (§ 40.53(b)):

The time involved will depend on the number of products transferred per year and will vary for each licensee. As the labeling requirements are associated with existing label requirements in the exemptions, the only new actions required are for distributors of gas mantles and welding rods to provide instructions for safe handling and use. Only a few initial distributors are expected to apply for a specific license. There are no known domestic manufacturers.

Illustrative estimate for 4 importers providing instructions:

A printed piece of paper is likely to cost $0.03 per page. For purposes of this analysis, it is assumed that 1,000,000 thoriated welding electrodes are distributed annually in the United States, and that they are typically sold in quantities of ten. Larger quantities are also sold, primarily to secondary distributors.

After the initial implementation of the change, the time and effort to meet this requirement would be minimal. Automation may eliminate any time spent; however, for purposes of this analysis, it assumed that 0.02 hours/brochure is spent preparing and inserting instructions in packaging.

Therefore, the maximum expected cost associated with required instructions is estimated to be:

100,000 sales/year x $0.03/package insert = $3,000/year

100,000 sales/year x 0.02 hr/sale x $49/hr = $98,000/year

~$100,000 total/year

Costs would likely be less if required information is added to existing packaging and particularly if the information specific to the radiological hazards of thorium are included in Material Safety Data Sheets (MSDS) already required by the Occupational Safety and Health Administration (OSHA).

Similar costs would be incurred if any distributors of thoriated gas mantles are licensed.

Fees

These distribution licensees would be subject to a new fee category, proposed as 2.C (with current category 2.C. redesignated). This fee would be lower than the similar category, 3.I. for distribution of products containing byproduct material to be used under exemption from licensing, because of the more limited requirements to be applied to this category of licensed activity. They would also fall into a new fee category if they are manufacturing or processing the products under an NRC specific license. The new fee category is proposed as category 2.E. and would initially be the same as a manufacturer of products containing source material would pay now. Small entities, however, can pay reduced fees.

Additional costs applicable to those obtaining a specific license who would not otherwise be specifically licensed:

Importers of finished products would be exempt from Parts 19 and 20. In addition importers would be exempt from § 40.32(b) and (c), which concern the adequacy of training, experience, facilities, and equipment to protect health and minimize danger to life and property. For importers, the costs of being a specific licensee would be almost exclusively the costs directly involved with requirements covering distribution estimated above. For others, the requirements of Parts 19 and 20 and the additional requirements in Part 40 (and equivalent Agreement State requirements) related to the possession and use of the source material would add to the costs of being specifically licensed.

The costs of being subject to Parts 19 and 20 (and equivalent Agreement State requirements) would depend on a number of factors. New specific licensees, who are not importers of finished products, would be those currently manufacturing a product covered by an exemption in § 40.13(c), including coated lenses if they are added to the exemption in § 40.13(c)(7) as proposed, who are now operating under the general license in § 40.22 (or equivalent Agreement State provisions).

The costs for complying with Part 19 are primarily those associated with training employees; most of this is only required if workers' exposures are likely to exceed 1 millisiever (mSv) (100 millirem (mrem)) per year. Ongoing costs would routinely result for all licensees from § 19.13, Notifications and reports to individuals.

The primary costs for complying with Part 20 would result from requirements to have and to document a radiation protection program, including having a radiation safety officer, as well as, maintaining cognizance of the requirements in order to maintain compliance. The primary applicable requirements related to this are in: § 20.1101, along with applicable limits in Subparts C and D, Subpart F (surveys and monitoring), § 20.1906 (receipt and opening of packages); and § 20.2102 (records). The complexity of this radiation protection program would depend on the degree of hazard it is intended to control.

One time costs for a general licensee/manufacturer becoming a specific licensee and instituting a radiation protection program, including training, would be on the order of $10,000 in capital costs and 20 hours of labor (@ $49 per hr) for roughly an additional $1000, totaling $11,000 per entity. Ongoing efforts applicable to all specific licensees are likely to involve 22 hours per year for routine requirements, primarily notification of workers of their exposures (§ 19.13), records of radiation protection program (§ 20.2102) and records of surveys (§ 20.2103). Thus, a minimum of:

22 hr x $49/hr = ~$1,100/year

Other requirements in Part 20 that may result in significant costs are those related to waste disposal in Subpart K, Appendix G, and § 20.2108 (Records of waste disposal).

There are a large number of other specific reporting and recordkeeping requirements within Part 20; however, these types of licensees would have limited circumstances for needing to report under many of them. Ones that would clearly be applicable include: requirements for labeling of containers (§ 20.1904) and reports of theft or loss (§ 20.2201).

At some point in the future, these licensees are likely to incur costs when they discontinue use of the source material and terminate their license, as they would be subject to Subpart E of Part 20 on criteria for release of the site.

How much all of this adds to the cost of doing business depends on how responsible the general licensee is in protecting health and safety for other reasons, such as good business practice, control of liability, and compliance with OSHA requirements, and thus, how much change in operations would be required to comply with all of the applicable regulations.

A typical manufacturer likely to be currently operating under a general license would be someone applying a coating to optical lenses. Typically, these operations involve coating the lenses in vacuum chambers. These chambers, and other equipment, need to be cleaned periodically to remove residual material, sometimes with sandblasting. Adequate radiation protection may involve the use of equipment such as glove boxes and some form of respiratory protection. These operations would tend to have significant wastes for disposal.

It is expected that at least some of the appropriate equipment and training for radiation protection would be provided even under the general license. Air sampling and monitoring of the work environment are unlikely to be conducted as they would be if operations were under a specific license. Thus, these requirements would add to operating costs.

Additional provisions in Part 40 that may result in costs being incurred:

General licensees under § 40.22 are not exempt from Part 40; however, certain requirements would become applicable to a specific licensee/applicant which otherwise would not be applicable to the general licensee, in particular § 40.31, Application for specific licenses; § 40.32, General requirements for issuance of specific licenses; § 40.42, Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas; § 40.43, Renewal of licenses; and § 40.44, Amendment of licenses. Also, § 40.36, Financial assurance for decommissioning, applies only to specific licensees; however, these manufacturers would not have enough source material to meet the criteria for this requirement. In the near term, the most significant costs of these additional Part 40 requirements are from the initial application and any changes that would be needed to obtain the initial license.

Very few, if any, NRC general licensees are likely to be manufacturing products used under exemption, and would obtain specific licenses as a result of this rule. The NRC estimates that fewer than 20 entities nationally would be manufacturing such products under a general license and become NRC § 40.52 licensees as a result of these new requirements. For those in Agreement States, the costs discussed above concerning the applicability of Parts 19 and 20 would mostly come about through equivalent Agreement State regulations as applied to the possession and use licenses they would obtain from the Agreement State where each is conducting business. Given the large variability in costs to individual affected parties and the large uncertainty in the number of affected parties, no attempt has been made to fully quantify the total cost.

Other Costs to Industry

In addition to the manufacturers and importers who would obtain distribution licenses under the proposed provisions in § 40.52, there would be additional affected entities currently operating in these industries. It is expected that, particularly for import and to some degree for manufacturing, there would tend to be consolidation of operations into fewer entities within an industry. For example, thoriated welding rods are not being manufactured domestically and may be being imported by a number of parties. Under the proposed rule, only a few distributors are likely to obtain licenses, and other importer/distributors would obtain any imported welding rods containing thorium through those few distributors, with some additional cost. This would not likely be a major impact to their business as there are many types of welding rods, of which those containing thorium are a limited portion. Some general licensees currently manufacturing lenses with thin coatings of source material may choose to stop manufacturing such products to avoid specific licensing, if it is not a significant aspect of their business.

Costs to NRC:

One time:

30 applications x 8 hours/application x $100/staff hour = ~$24,000

3 include consideration of manufacturing safety

3 x 10 additional hours/application x $100/staff hour = ~$3,000

Total: ~$27,000

Annual:

Small additional ongoing costs for inspections:

If average of 6 additional inspections per year
6 inspections x 12 hr/inspection x $100/staff hr = ~$7,200

Small increase in number of amendments/year:

6 amendments/yr x 5 hr/amendment x $100/staff hour = ~$3,000

Total: ~10,000/year

Costs to Agreement States

Agreement State licensing and inspection programs would be impacted to the extent that they require possession and use specific licenses for any distributors currently operating under equivalent provisions to the general license in § 40.22.

In addition, both the NRC and the Agreement States will incur costs associated with a rulemaking. These are discussed in Sections 4.8 and 4.9.

Costs to Public

The costs to distributors may result in increased prices of their products.

Occupational Health/Public Health

Small incremental increases to occupational exposures could occur as a result of additional labeling; it is not expected to be significant.

Benefits:

Benefits to Licensees/Distributors

The distributors may obtain some benefit from the addition of a clear regulatory framework. NRC oversight may act to limit their liability concerns.

Benefits to Workers

General licensees required to become specific licensees may result in reductions in occupational exposures and better radiation safety training.

Benefits to NRC/Benefits to Agreement States

These provisions would allow the Commission to better control the products containing source material used under exemptions from licensing. These controls would make future considerations related to the Commission's consumer product policy and its efforts to evaluate the net effect of products and materials released from regulatory control more efficient and effective.

Benefits to Users/Public

These provisions would help to minimize doses resulting from the use of products containing source material under exemptions from licensing. Given the limited information on types and quantities currently distributed and on how these may be impacted by the addition of distributor requirements, it is not possible to adequately quantify these benefits.

Environmental Considerations

These provisions would allow the Commission to better control the products containing source material used under exemptions from licensing which are ultimately disposed of without regard to their radioactivity. This could improve assurance that disposal of products used under exemptions do not result in significant environmental impacts.

Alternatives Considered

Requiring the labeling of products or point-of-sale containers for all products, even when particular instructions to users are not necessary to enhance safety, was also considered to notify consumers of the presence of radioactive material and clarify that end users are exempt

from all regulation. This would provide for greater knowledge concerning the use of radioactivity in such products and limit questions and concerns about appropriate disposal options, but with no clear benefit to health and safety.

4.2 Revise the Exemption for Glassware in § 40.13(c)(2)(iii)

Paragraph 40.13(c)(2)(iii) exempts glassware containing up to 10 percent source material by weight. It excludes commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction. This rule proposes to limit products manufactured in the future to no more than 2 percent by weight source material. As well as can be determined, this is consistent with current production and most past production.

Cost Impacts:

Costs to Licensees/Distributors

No costs are anticipated. Limited costs could result if ensuring and demonstrating that products do not exceed the lower limit is somewhat more difficult. However, the 1 current NRC specifically licensed manufacturer is limiting its products to no more than 1 percent by weight uranium and a major distributor was previously determined to be using 0.5 percent by weight uranium in its glassware. Although the amount of importation of glassware containing source material has not been determined, if foreign-produced glassware did contain more than 2% uranium by weight, there would be an impact on foreign suppliers (or importers). Due to a lack of information on this particular matter, the result of the impact cannot be quantified.

Costs to NRC

No incremental cost over those associated with the changes discussed under Section 4.1 and a small portion of the development and implementation costs discussed under Section 4.8 are anticipated.

Costs to Agreement States

There are no costs to the Agreement States other than the rulemaking. Both the NRC and the Agreement States will incur costs associated with a rulemaking. These are discussed in Sections 4.8 and 4.9.

Costs to Users

The glassware currently being manufactured contains less than or equal to 2 percent uranium by weight. While the addition of more uranium is likely to cause the price of the product to increase, glassware manufacturers tend to use the minimal amount of uranium necessary to keep their costs down. As a result, the proposed change is not expected to result in a cost to the end user.

Benefits:

Benefits to Licensees/Distributors

While the proposed change is not expected to produce significant additional costs for the licensees, it is not expected to produce additional benefits.

Benefits to NRC/Agreement States

Possible benefits to the NRC and the Agreement States include ensuring that ALARA (as low as reasonably achievable) principles are utilized. If current industry practice is to use less than the regulatory limit, then lowering the concentration limits is an implementation of the ALARA policy. Additionally, the NRC and the Agreement States would have greater assurance that doses to members of the public are not likely to exceed the regulatory dose limit, or the doses estimated in NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials" (NRC, June 2001).

Public Health

There would be better assurance that likely exposures would be unlikely to exceed 10 microsieverts (μSv) (1 mrem) per year.

Environmental Considerations

No significant effect is anticipated, although there would be better assurance that glassware manufactured in the future and ultimately disposed of without regard to its radioactivity has the lower concentration of source material.

Alternatives Considered

The Commission also considered restricting any further distribution, or further limiting the types of products that can be manufactured in the future for use under the exemption, such as possibly banning use in toys or other products intended for use by children. If exposures are unlikely to exceed 10 μSv (1 mrem) per year and typically much lower, negative impacts to industries may not be justified.

4.3 Revise the Exemption for Optical Lenses in § 40.13(c)(7)

Paragraph 40.13(c)(7) exempts thorium contained in optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium and meets certain use limitations. The proposed rule would modify this exemption in a number of ways: It would expand it to cover coated lenses, and also mirrors, expand it to include uranium, and reduce the limit on weight percent of source material from 30 to 10 weight percent. The remaining limitations on uses would continue to apply.

Cost Impacts:

Cost to Licensees (Manufacturers and Distributors)

No costs are anticipated. Limited costs could result if ensuring and demonstrating that products do not exceed the lower limit is more difficult.

Costs to NRC

No incremental cost over those associated with the changes discussed under Section 4.1 and a small portion of the development and implementation costs discussed under Section 4.8 are anticipated.

Costs to Agreement States

There are no costs to the Agreement States other than the rulemaking. These are discussed in Section 4.9.

Benefits:

Benefits to Licensees/Distributors

Manufacturers and distributors of lenses that are not currently covered by the exemption or that are not clearly covered would benefit by opening up the market for their lenses and mirrors.

Benefits to NRC/Agreement States

Clarification of the regulatory status of coated lenses would save the regulatory agencies time dealing with the types of questions that have previously arisen.

Benefits to Users/Potential Users

The reduction of the weight percent limit would provide better assurance that exposures would be ALARA. Expanding the exemption would make more products more readily available, from which various benefits may be obtained. Many products may have previously been used under § 40.22 and equivalent general licenses of the Agreement States; others may be developed as a result of products being clearly covered by the exemption.

Alternatives Considered

The Commission also considered developing and providing limits on lenses with coatings that might be more appropriate than a weight percent limit. Although the approach of averaging content with a lens plus coating has its drawbacks, a practical limit on thickness or total quantity of source material was difficult to determine. If more information is provided in comments on the proposed rule, an alternative approach may be considered in the final rule.

4.4 Remove Obsolete Provisions

The exemptions in § 40.13(c) provide for persons to receive, possess, use, transfer, own, or acquire certain products containing source material. Some of those products are no longer being used or manufactured. The general reason for their obsolescence is because of new technologies that have made the use of radioactive material unnecessary or less cost-effective. Obsolete exemptions are: glazed ceramic tableware (§ 40.13(c)(2)(i)) and fire detection heads (§ 40.13(d)). The Commission would remove the exemption for these products or prohibit further distribution while allowing for the continued possession and use of previously distributed items.

The rule would prohibit further distribution of products that are no longer being manufactured, but may remain in use. This is the case for § 40.13(c)(2)(i). For those products believed to never have been distributed, the rule would remove the provision entirely, i.e., § 40.13(d).

Section 40.13(c)(2)(i) contains a provision for glazed ceramic tableware. Based on dose estimates included in NUREG-1717, this is the only exemption identified for source material that could result in significant doses to individual members of the public. Although these products have not been manufactured in many years, this change would ensure that they are not domestically manufactured or imported in the future.

Cost Impacts:

Costs to Licensees (Manufacturers and Distributors)

There are no manufacturers or distributors for these products.

Costs to NRC and Agreement States

The only costs to the NRC are those discussed in Section 4.8.

Section 40.13 is Compatibility Category B requiring essentially identical wording in Agreement State regulations. Revising § 40.13(c) and removing § 40.13(d) requires comparable changes in Agreement State regulations; however, each State is expected to conduct one rulemaking following this revision of Parts 30, 40, 70, 170, and 171. The cost for the Agreement State rulemaking is discussed in Section 4.9.

Costs to the Public

There are no expected costs to the public from this action.

Benefits:

Deleting these unnecessary regulations would simplify the regulations by eliminating extraneous text. This would eliminate the need to reassess the potential exposure of the public from these exemptions for possible future distributions of the products. Also, these exemptions would no longer need to be considered when assessing the total potential doses to the public from multiple sources. Additionally, there is a potential benefit to the public from the elimination of future exposures. Based on dose estimates performed for the exemption for tableware

(§ 40.13(c)(2)(i)), potential exposures could be higher than is appropriate for exempt materials. As a result of this action, members of the public would be assured that exposures from products manufactured in the future would not occur.

4.5 Create Requirements for the Distribution of Source Material to § 40.22 General Licensees in § 40.54 and § 40.55

New provisions would be created to establish a regulatory framework for authorizing the initial transfer of source material to be used under the general license in § 40.22 and equivalent Agreement State provisions. Licensing requirements for distribution of source material for use under this general license would be in § 40.54. A new provision § 40.55 would be created to set out conditions of license for licenses issued under § 40.54. These requirements would cover: quality control, labeling, and reporting and recordkeeping. Quality control would be required to ensure that the quantities of source material are as identified. Licensees would be required to provide instructions for those using the material under the general license.

Under these proposed provisions, manufacturers and distributors of materials to be used under the § 40.22 general license would be required to apply for a specific license authorizing distribution to general licensees. Manufacturers and distributors in Agreement States would be licensed under equivalent Agreement State regulations.

There are no non-rulemaking alternatives that could accomplish the same result. However, there are other approaches in changing the regulations that could be used to control the distribution and use of source material under this general license. These include establishing similar regulations but requiring that all distribution be authorized by the NRC. This could be more efficient than having the Agreement States establish equivalent provisions, given the small number of distributors nationally.

Cost Impacts:

<u>Costs to Licensees (Distributors)</u>

Only one initial distributor of source material to § 40.22 general licensees has been identified (the distributor is specifically licensed by an Agreement State). It is assumed that there may be a few other Agreement State licensees that would be required to come under the new licensing requirements, when equivalent provisions are added to Agreement State regulations.

One time costs applicable to all distributors of materials for use under § 40.22 or equivalent Agreement State provisions:

Illustrative estimate of application costs for these assumptions:

4 distributors (1 NRC; 3 Agreement State)

General License-Distribution License Required:

4 applications x 8 hours/application x $49/hour = ~$1,600

Continuing costs applicable to all distributors of materials for use under § 40.22 or equivalent Agreement State provisions, following Agreement State implementation of equivalent regulations:

Quality control (§ 40.55(a)):

Although there would now be an explicit requirement, good business practice would require distributors to ensure that materials are in the quantity sold and so labeled. New costs are limited to those connected with documentation of the program for the NRC or the State. Those are included in the application costs estimated above.

Reporting (§ 40.55(d)):

0.6 hr/licensee (reports to NRC) X 4 licensees X $49/hr = ~$120
0.3 hr/report to a State x average 5 States/licensee x 4 licensees x $49/hr = ~$300

Recordkeeping (§ 40.55(e)):

1 hour/licensee X 4 licensees X $49/hour = ~$200

Labeling (§ 40.55(b)):

The time involved would depend on the number of products transferred per year and would vary for each licensee. Distributors would be expected to already be labeling containers with the quantities contained. New costs are primarily those connected with documentation of the program for the NRC. Those are included in the application costs estimated above.

Providing copies of relevant regulations and safety instructions (§ 40.55(c)):

Distributors would be required to provide safety instructions to each recipient prior to the first transfer each year.

Illustrative estimate for 4 distributers providing instructions:

Initial costs associated with providing safety instructions:

The effort to develop an instruction pamphlet is estimated to take an average of 40 hours.

4 applications X 40 hours/application X $ 49/ hour = ~$7,800

Continuing costs of providing safety instructions:

A printed piece of paper is likely to cost $0.03 per page. For purposes of this analysis, it is assumed that a 4-page pamphlet of instructions is typical and that there are 100 recipients annually in the U.S.

After the initial implementation of the change, the time and effort to meet this requirement would be minimal. For purposes of this analysis, it assumed that 0.02 hours per pamphlet is spent preparing and providing instructions to customers.

Therefore, the expected ongoing cost associated with required instructions is estimated to be:

100 total recipients/year x $0.12/package insert = $12/year

100 recipients/year x 0.02 hr/recipient x $49/hr = ~$100/year

~$110 total/year

Fees associated with these licenses would depend on the State they are in. If the licensee is under the NRC's jurisdiction, two new fee categories would be applied: 2.D. for distribution and 2.E. for possession and use for processing. The proposed initial fee amounts for 2.D. are $2,000 for an application and $5,000 annual fee. The initial fees for category 2.E. would be the same as current manufacturers and processors of source material (not uranium recovery) pay.

Costs to NRC and Agreement States

Costs would be incurred by the regulatory agencies for licensing and inspecting a few licensees for the additional requirements concerning distribution.

Illustrative costs for 4 applicants/licensees:

1 application to NRC x 8 hours/application x $100/staff hour = $800
3 applications to States x 8 hours/application x $46/staff hour = ~$1,100

Total: ~$1,900

There would also be small additional ongoing costs for inspections.

As for all the issues, there are costs associated with rulemaking, which are discussed in Sections 4.8 and 4.9.

Benefits:

Benefits to General Licensees

These provisions would ensure that users of source material under the general license provisions obtain copies of relevant regulations and safety instructions. This would help to minimize doses resulting from the use of source material under this general license.

Benefits to NRC/Benefits to Agreement States

These provisions would allow the Commission and the Agreement States to better control the source material used under this general license. It would allow them to identify general

licensees receiving significant amounts of source material, so that they can communicate with them and inspect them as needed.

Benefits to Public

Better control of the materials being distributed for use under general license and better knowledge on the part of the general licensees concerning applicable regulations and safe use of source material should contribute to reductions to exposures of the public from inappropriate use and disposal of materials used under the general license.

4.6 Revise the General License in § 40.22

The proposed rule would revise § 40.22 in a number of ways: (1) to limit the general license to thorium and uranium in their natural isotopic concentrations and depleted uranium; (2) to limit possession to less than 1.5 kilograms (kg) (3.3 lb) of source material at any one time and 7 kg (15.4 lb) per calendar year for dispersible forms, and continue to allow up to 7 kg (15.4 lb) at any one time and 70 kg (154 lb) per calendar year for most solid forms and for removal of uranium from drinking water; (3) to clarify disposal requirements and the applicability of other Part 40 regulations; (4) to require a general licensee to respond to NRC requests for information; and (5) to require the general licensee to minimize contamination at the site and ensure that the site is cleaned up after use of source material is ended.

Cost impacts:

Costs to Industry/Licensees

Costs would depend on how many general licensees choose to become specific licensees and how many continue operating under the more restrictive general license. It is anticipated that few if any current general licensees would become specific licensees, other than those who would be required to do so under the issues discussed in Sections 4.1 and 4.5. Costs to any that do would be similar to those discussed under Costs to Industry/Licensees (Manufacturers and Distributors) in Section 4.1.

Costs to General Licensees

Some of these proposed explicit requirements should apply as a result of the fact that general licensees are not exempt from all of Part 40; for some, these changes are clarifications of general licensee responsibilities. It is expected that most, if not all, general licensees under this provision who are not manufacturing and distributing products to others (who would be required to become a specific licensees to continue those activities) use very small quantities and would not have difficulty continuing their current activities within the additional constraints being proposed. Costs for those remaining under the general license are expected to be small and are difficult to quantify. The most significant may be if activities resulted in a significant contamination of a building or site that ultimately requires a major cleanup effort. However, the reduced limits for dispersible forms would reduce this likelihood for those using materials under the general license in the future.

Costs to Public

Any increased costs to licensees may result in costs passed on to others for a variety of products and services, although this is expected to have minimal effect.

Benefits:

Benefits to Licensees/Distributors

Clarifying the requirements of the general license, including a clear allowance for some materials to be disposed of as non-radioactive waste, may increase some uses of source material, thus leading to additional customers for the distributors.

Benefits to General Licensees

Exposures of general licensees and their employees to radiation, as well as to the toxic effects of source material, would likely be reduced. General licensees may reduce their liabilities for perceived harm from exposures.

Benefits to NRC/Benefits to Agreement States

Regulatory agencies would have better assurance that the health and safety of the public are adequately protected and that security of certain materials of concern is adequate and appropriate. In the long term, there would be fewer difficulties with abandoned contaminated sites to deal with and fewer resources spent answering questions concerning the applicability of various regulatory provisions to this category of general licensees.

Benefits to Public

There would be less probability of general licensees causing unnecessary contamination and leaving it for others to be exposed to. Public confidence may be enhanced.

4.7 Minor Clarifying or Administrative Revisions

Other minor revisions are included to better organize, clarify, or update the regulations in these parts, such as the addition of appropriate sections under lists of information collections and clarification of which requirements are subject to criminal penalties. Minor conforming amendments are included in Parts 30 and 70 because the delineation of the delegation of licensing programs to the Regions is written broadly in these parts.

Cost Impacts:

No costs are anticipated beyond the costs of inclusion in the rulemaking. Overall costs for NRC and Agreement State implementation are discussed in Sections 4.8 and 4.9. Such changes constitute a small portion of the implementation costs.

Benefits:

Improvements of this type in the regulations contribute to increases in efficiency, effectiveness, and public confidence.

4.8 Development and Implementation Costs

NRC development costs are the costs of preparation of a regulation before its promulgation and implementation. Such costs may include expenditures for research in support of this regulatory action, publishing notices of rulemaking, holding public meetings, responding to public comments, and issuing a final rule. NRC implementation costs are those "front-end" costs necessary to effectuate the action; they may arise from the necessity of developing procedures and guidance to assist licensees in complying with the final action. All costs associated with pre-decisional activities are viewed as "sunk" costs and are excluded from NRC implementation costs.

Developmental and implementation costs within the scope of this analysis are the costs of proceeding with a rulemaking, as well as efforts on guidance development associated with this rule. These are mainly costs of the effort of NRC professional staff members in the Office of Federal and State Materials and Environmental Management Programs expended in developing the rule.

Approximately 1 FTE is estimated for the analysis of comments and development of the final rule. One NRC professional staff member costs $177,600 per FTE.

NRC staff would need to update existing guidance in the NUREG-1556 series related to distribution licensing to reflect the revisions to the regulations. NUREG-1556, Vol. 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses" and NUREG-1556, Vol. 16, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licenses" would require minor revisions or supplementation. If the changes for this rule are made within overall revisions of these NUREGs, the additional updating needs should involve relatively limited cost impact as a result of this rulemaking.

4.9 Costs to Agreement States of Compatible Regulations

Costs would be incurred by the Agreement States for development and implementation of compatible regulations. The costs would vary significantly by State because of differences in internal procedures for developing regulations. Some rule changes would be required to meet Compatibility Category B for certain revisions. As these revisions would be required to be essentially word-for-word compatible, the process should be relatively simple. For this proposed rule, the NRC assumes an average of 0.1 FTE at $82,000 per FTE for each state. There are currently 37 Agreement States; therefore, the total cost for all Agreement States would be approximately $303,000.

5. DECISION RATIONALE

The assessment of costs and benefits discussed above, quantitatively when possible and qualitatively otherwise, leads the Commission to the conclusion that the overall impacts of the proposed rulemaking would be assurance of the protection of public health and safety in the future and more effective licensing of distribution to exempt persons and to generally licensed persons. Although there are costs associated with some of the amendments, the Commission believes that these costs will be outweighed by those non-quantifiable benefits associated with regulatory efficiency and protection of the health and safety of the public. In particular, the manufacturers likely to incur the most cost as a result of these changes are those who would need to make the most changes in order to adequately protect the health and safety of their workers and of those potentially exposed to site contamination from inappropriate procedures or incomplete cleanup after operations.

This rule would advance to varying degrees the Commission's goals of ensuring adequate protection of public health and safety and the environment and adequate protection in the secure use and management of radioactive materials, as well as its objectives of effectiveness and openness in the regulatory process.

A significant cost would be implementation of the proposed rulemaking by the NRC and the Agreement States. However, by handling several issues together, the Commission minimizes its costs as well as costs for the Agreement States compared to addressing each of these issues separately.

6. IMPLEMENTATION

The NRC's schedule for implementation of this rulemaking calls for the effective date of the rule to be in 2011 for the NRC's jurisdiction and full implementation by the Agreement States by 2014. The applicable guidance documents are NUREG-1556, Vol. 8, and NUREG-1556, Vol. 16. These have additional updating needs and could be revised as part of a broader update following the issuance of the rule. There are no changes requiring entirely new guidance; i.e., nothing that would necessitate having guidance available in draft for comment along with the proposed rule. Some revision to these two documents would be appropriate as a result of this rule in order to expand the scope to include source material distribution.

For all changes that affect Compatibility Category B, the Agreement States have 3 years to make changes to their affected regulations.

Known affected licensees and other parties would be sent a copy of the proposed and final *Federal Register* Notice. Because the NRC cannot readily identify all general licensees, it may take some time to notify all persons distributing source material and those using source material under the general license in § 40.22.

7. IMPLICATIONS FOR OTHER FEDERAL AGENCIES

Promulgation of this proposed rule would have no adverse effects on other Federal agencies.

8. EFFECT ON SMALL ENTITIES

The proposed rule would have a somewhat significant impact on both small and large entities who are currently manufacturing and distributing products for use under § 40.13 and are not already specifically licensed. It is not known exactly how many such entities exist but is believed to be fewer than 20. Small entities are provided with relief from the impact of fees through reduced fees amounts.

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Environmental Assessment for Proposed Rulemaking – Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions (10 CFR Parts 30, 40, 70, 170, and 171)

U.S. Nuclear Regulatory Commission

Table of Contents

1.0 Introduction

The U.S. Nuclear Regulatory Commission (NRC or "the Commission") is amending its regulations governing the use of source material in 10 CFR Parts 30, 40, 70, 170, and 171. These proposed amendments add new specific licensing requirements, reporting requirements, and fees for the initial distribution of products and materials containing source material for receipt under an exemption or the general license in § 40.22, "Small quantities of source material." In addition, the proposed amendments modify the existing possession and use requirements for the general license in § 40.22 to better align the requirements with current health and safety standards. Finally, the proposed amendments revise, clarify, or delete certain licensing exemptions (also known as "unimportant quantities") in order to make the requirements for those exemptions more risk informed. These actions are intended to better ensure the protection of the public health and safety in the future; provide the NRC and Agreement States with more complete and timely information on the types and quantities of source material distributed for use under exemption or by general licensees; modify the requirements for possession of certain products under exemptions; and remove obsolete exemptions. These changes may affect licensees who initially distribute source material to exempt persons and general licensees or use source material under general license. The NRC has prepared this environmental assessment (EA) to determine whether this rule will have any significant environmental impact.

1.1 Background

The Commission's regulations for source material are in 10 CFR Part 40, which sets out the basic requirements for domestic licensing of source material. Source material is uranium and thorium or ores containing uranium and thorium in concentrations greater than 0.05 percent by weight of the uranium or thorium. The NRC has the authority to issue both general and specific licenses for the use of source material and to exempt source material from regulatory control under Section 62 of the Atomic Energy Act of 1954, as amended. A general license, provided by regulation, grants authority to a person for particular activities involving source material as described within the general license, and is effective without the filing of an application with the Commission or the issuance of a licensing document. Requirements for general licensees appear in the regulations, such as the general license provided in § 40.22, and are designed to be commensurate with the specific circumstances covered by each general license. A specific license is issued to a named person who has filed an application with the Commission. Basic requirements for submittal of an application for a specific license are found in § 40.31 and general requirements for issuance of a specific license are found in § 40.32. Terms and conditions of specific licenses are contained in § 40.41. Exemptions, provided in situations where there is minimal risk to public health and safety, allow the end user to possess or use the source material without a license. The exemptions from the licensing requirements for source material are listed in § 40.13. With the exception of requirements for the manufacture and initial transfer of products and devices to be used under the general license in § 40.25 (contained in §§ 40.34 and 40.35), there are no specific requirements applicable to the distribution of products and materials containing source material.

Other parts are affected by this rulemaking. Part 30 provides the basic requirements for possession and use of byproduct material, while Part 70 provides the basic requirements for possession and use of special nuclear material. Both of these parts would be amended to conform to the changes made to Part 40. Parts 170 and 171 address fees associated with licensing and would be amended to include the proposed Part 40 distribution licenses.

The NRC has conducted a systematic reevaluation of the exemptions from licensing in Parts 30 and 40 of the NRC's regulations, which govern the use of byproduct and source material,

respectively. A major part of the effort was an assessment of the potential and likely doses to workers and the public under these exemptions. The assessment of doses associated with most of these exemptions can be found in NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials" (NRC, June 2001). In the past few years, several issues have been identified where improvements could be made to the regulations governing these products. The amendments to exemptions considered in this document largely stem from this analysis.

In 2006, the NRC directed Pacific Northwest National Laboratory (PNNL) to review and assess regulations related to the use of source material under general license and certain exemptions. PNNL's findings were reported in PNNL-16148, Rev. 1, "Risk Assessment for Current and Projected uses of Source Material Under a U.S. NRC General License and Exemption Criteria" (PNNL, February 2007). Many of the amendments to the general license also stem from this analysis.

1.2 Document Organization

This environmental assessment presents a discussion of the basic subjects specified in 10 CFR 51.30 and fulfills the requirements of the National Environmental Policy Act. This environmental assessment is organized to best accommodate the rule's complexity. This complexity is due to the Commission's decision to aggregate multiple issues into this single rulemaking, with the purpose of minimizing the cost of the activities. The rule is therefore best understood and discussed as a collection of separate small issues. Many of the amendments meet the criteria for categorical exclusion – as detailed below – and do not require an environmental assessment to be prepared. The amendments not meeting these criteria are discussed issue-by-issue, and are the focus of the environmental assessment.

A discussion of the need for the actions is contained in Section 2.0. The applicability of categorical exclusions to certain amendments is discussed in Section 3.0. For those issues where a categorical exclusion does not apply, a discussion of the actions and their alternatives is presented generically in Section 4.0, and specifically on an issue-by-issue basis in Section 5.0 along with their environmental impacts. The conclusion is in Section 6.0. A list of agencies and persons consulted and an identification of sources used are contained in Sections 7.0 and 8.0, respectively.

2.0 Need for the Proposed Action

Currently, there are no regulatory mechanisms for the Commission to ensure that products and materials distributed for use under the general license in § 40.22 or an exemption in § 40.13 are maintained within the applicable constraints of the requirements for these uses. Because the staff cannot readily identify who possesses source material under the general license in § 40.22 or how and in what quantities the source material possessed under § 40.22 is being used, the staff cannot fully assess the resultant risks to public health and safety. In addition, certain radionuclides of uranium and thorium, when isotopically separated, have the potential to present significantly higher potential doses, in particular, thorium-228, thorium-229, and uranium-232. Although the NRC is not aware of these isotopes being separated for commercial use, if the separated isotopes were readily available, the current provisions of § 40.22 could allow a person to receive quantities large enough in terms of activity to present a security concern without obtaining a specific license.

The State of Colorado and the Organization of Agreement States submitted a petition for rulemaking (PRM), PRM-40-27. In PRM-40-27, the petitioners identified concerns regarding the use of source material under the general license granted under § 40.22. In particular, the petitioners were concerned that general licensees are specifically exempted from meeting the requirements of 10 CFR Part 19, "Notices, Instructions, and Reports to Workers: Inspection and Investigations," and 10 CFR Part 20, "Standards for Protection Against Radiation." Both Parts 19 and 20 have certain requirements and limits that apply to specific licensees. The petitioners identified certain situations where they calculated that the use of source material under the § 40.22 general license could result in exposures to workers, not trained in radiation protection, that exceeded exposure limits for protection of members of the public that apply to specific licensees.

In response to PRM-40-27, the NRC has attempted to collect data on general licensees in order to evaluate the impact of the use of source material under this general license. Of the information provided, one of the respondents was a specific licensee and the two other responses afforded minimal insight into the details of how persons actually operate under the § 40.22 general license. In addition, the NRC attempted to gather information from the internet, publications, and professional societies without much insight provided by the collected data. These efforts are indicative of the difficulty in identifying and obtaining information from persons operating under the § 40.22 general license using existing regulations.

The findings in the PNNL study indicated that the use of source material in consumer products is declining. The results of the evaluation indicated that most source material possessed under § 40.22 is likely handled in quantities, physical forms, or in uses and conditions that would justify the continued use of the exemptions to Parts 19 and 20. However, as indicated by PRM-40-27, and by the bounding dose calculations evaluated in the PNNL study, situations can and do occasionally occur that exceed limitations under which Parts 19 and 20 usually apply.

3.0 Applicability of Categorical Exclusion for Certain Amendments

As noted earlier, many of these amendments belong to a category of actions that the Commission has determined to be a categorical exclusion, having found that these types of actions do not individually or cumulatively have a significant effect on the human environment. Therefore, this EA is not required to evaluate these amendments.

In accordance with § 51.22(c)(1), the proposed amendments to Parts 170 and 171 are categorically excluded, and do not require an environmental assessment.

Additionally, under § 51.22(c)(3), amendments to Parts 30, 40, and 70 that relate to procedures for filing and reviewing application for licenses, recordkeeping, and reporting – paragraphs (i), (ii), and (iii), respectively – do not require an environmental assessment. The proposed §§ 40.13(c)(10) and 40.22(e) would require that affected persons comply with §§ 40.52 and 40.54, respectively. Sections 40.52 and 40.54 provide the requirements for approval of a specific license and are covered by this categorical exclusion. The proposed recordkeeping and reporting requirements for initial distributors of source material to general licensees and exempt persons in §§ 40.53 and 40.55 are also covered by this categorical exclusion. Finally, the proposed amendments to §§ 30.6, 40.5, and 70.5 which deal with communications, § 40.8, "Information collection requirements: OMB approval", and § 40.82, "Criminal penalties" are also covered by this categorical exclusion.

4.0 The Proposed Federal Action and Alternatives: Generic Discussion

Under this federal action, the NRC is amending certain Sections of 10 CFR Parts 30, 40, 70, 170, and 171 by rulemaking in accordance with the Administrative Procedure Act of 1946, as amended. The alternatives to rulemaking would be to take no action, or to take various non-rulemaking actions. Non-rulemaking alternatives include: generic letters, guidance documents, and direct one-on-one contact with licensees.

Generic letters request that addressees: (1) perform analyses or submit descriptions of proposed corrective actions regarding matters of safety, safeguards, or the environment and submit in writing that they have completed the requests with or without prior NRC approval of the action; (2) submit technical information that the NRC needs to perform its functions; or (3) submit proposed changes to technical specifications. By a generic letter, the NRC may also provide the addressees: (1) staff technical or policy positions not previously communicated or broadly understood or (2) solicit participation in voluntary pilot programs. A generic notice could be used to clarify the NRC's policy on certain activities by a § 40.22 general license such as disposal requirements based upon the transfer requirements in § 40.51; however, reductions to possession limits, implementation of new decommissioning or cleanup requirements, or changes to the exemptions could not be accomplished under a generic letter because there would be no regulatory basis for requiring such changes.

Guidance documents are used to provide additional direction (usually indicating actions preferred by the NRC) on how specific regulatory requirements can be met. However, guidance documents usually do not include all applicable methods of meeting requirements that may be acceptable under a regulation and cannot, by themselves, implement new requirements. The NRC could issue guidance for operation under the § 40.22 general license that could suggest preferences to limit possession of certain forms of source, for properly dispose of source material, or to maintain one's site that would be consistent with the proposed alternative; however, as long as the general licensee maintains operations within the regulations, they cannot be required to meet those preferences found in the guidance. Similarly, guidance would have no impact on changes to the exemptions.

The NRC could address issues with general licensees through one-on-one contact directly with each licensee of concern. The only practicable method to require the licensee to meet the goals of the preferred action would be through issuance of orders. In such a case, the NRC would have to show there was a significant health and safety or security concern separately for each licensee that required the licensee to meet the new requirements. This process would both be inefficient if a large number of licensees needed to be addressed and does not provide the process provided by the Administrative Procedures Act. In addition, because of the current lack of reporting requirements, the NRC and Agreement States cannot easily identify persons operating under the § 40.22 general license (or the Agreement State equivalent).

The no-action alternative is to maintain the status quo. The no-action alternative would not address the identified concerns. Specific details of the implications of the proposed action and the no-action alternative are discussed below, issue by issue. Because the non-rulemaking alternatives discussed above do not achieve the goals of the proposed action nor result in any differences from the no-action alternative, they are not discussed further.

5.0 The Proposed Federal Actions, Alternatives, and Environmental Impacts: Discussion of Specific Issues

5.1 Revise 10 CFR 40.22 in its Entirety

Section 40.22 provides the requirements for possession and use of small quantities of source material under a general license. The current regulations in § 40.22 allow possession and use of up to 15 pounds (lb) (~7 kilograms (kg)) of source material at one time and receipt of no more than 150 lb of source material within a calendar year. These requirements have no associated reporting or registration requirements and exempt the user from the health and safety requirements in Part 20 and the training requirements in Part 19, thus effectively allowing the general license to operate similar to those exempt from licensing.

The proposed rule would revise § 40.22 to: (1) limit the general license to natural isotopic concentrations of thorium and uranium and to depleted uranium; (2) limit possession to less than 1.5 kg (3.3 lb) of source material at any one time and 7 kg (15.4 lb) per calendar year for dispersible or processed forms, while continuing to allow up to 7 kg (15.4 lb) of total source material at any one time and receipt of no more than 70 kg (154 lb) per calendar year for additional source material in solid, non-dispersible forms or for persons removing uranium from drinking water; (3) clarify disposal requirements and the applicability of other Part 40 regulations; and (4) require the general licensee to minimize contamination at the site and ensure that the site is cleaned up after the use of source material is ended.

The proposed amendments in § 40.22 requiring a general licensee to respond to NRC written requests and prohibition of the initial transfer of source material to a general license without a specific license are considered to respectively be reporting requirements and procedures related to the filing of an application, and therefore the categorical exclusion in § 51.22(c)(3) applies (see Section 3.0, above). The remaining requirements in § 40.22 are restated from the current requirements in § 40.22.

5.1.1 Revision of 10 CFR 40.22 Possession Limits

Although source material, in particular thorium, has an external radiation impact, the primary concern when dealing with source material is limiting internal uptake. The 2006 PNNL report concluded that certain activities, allowed under the current possession limits in § 40.22, could expose workers to almost 5 rem (50 millisieverts (mSv)) per year (both internal and external doses) using conservative assumptions. More realistic scenarios indicated worker exposures could still exceed 800 millirem (mrem) (8 mSv) per year. In both cases, the majority of the exposures were related to inhalation and ingestion which would only result from material that was dispersible in air or processed to create dust. By reducing the possession limit for such material to the proposed levels of 1.5 kg (3.3 lb) of source material and receipt of up to 7 kg (15.4 lb) of source material in dispersible or processed forms, the NRC expects worker exposures to generally be below 100 mrem (1 mSv) per year, which is the limit in § 20.1301 that applies to most NRC licensees for protection of members of the public. Because § 40.22 general licensees are not required to meet the training requirements in Part 19, it is more appropriate to treat the workers similar to members of the general public. Implementation of normal industrial hygiene requirements would significantly further reduce these potential exposures. In addition, by limiting the types of source material to only natural isotopic concentrations of thorium and uranium and depleted uranium, the new possession limits reduces the possibility that a person will accumulate large quantities of isotopes with high specific activities. Possession of large quantities of certain isotopes of source material (in particular thorium-228, thorium-229, and uranium-232) could significantly increase the possibility of high exposures.

The use of quantities of source material above the proposed limits would require specific licensing and thereby entail much greater controls on the use of the source material. Reduction of the possession limits for dispersible or processed source material, as proposed, would better align the general license with the health and safety requirements required for most other radioactive material. This proposed amendment to possession limits will likely reduce the potential impact to environmental resources compared to not changing the possession limits.

The NRC is proposing to retain the possession limits and annual receipt limits for solid, unprocessed source material (e.g., ore or uranium metal samples that are used for display) or for removal of uranium from drinking water. Because solid, unprocessed source materials will likely not contribute significantly to internal uptakes of source material or significantly result in additional contamination, the NRC has determined that the current limit is sufficient. In the case of water treatment, the primary treatment method that is expected to accumulate concentrations of source material that would fall under the general license would be from ion exchange. In this case, the uranium would be expected to be selectively isolated from its progeny. As a result, exposures from the uranium itself, because the uranium would be imbedded on resin and not readily available for internal uptake, are expected to be minimal. Because there is no change being made to the possession limits for non-dispersible source material or for water treatment activities from the current general license, there would be no significant impact to any environmental resources.

5.1.2 Clarification of Disposal Requirements for 10 CFR 40.22

Under the existing § 40.22 requirements, the general licensee is exempt from the requirements in 10 CFR Part 20 unless the person is also in possession of a specific license. Because the NRC's disposal requirements are found in Part 20, this has often led to the conclusion that there are no restrictions on the disposal of source material possessed under the general license. However, restrictions in § 40.51, which allows the general licensee to transfer source material only to a person authorized to receive it, may make transfer for disposal more problematic. If a disposal facility, not specifically licensed for possession of source material, receives the material, they would either be limited to the restrictions in the current § 40.22 general license (15 lb (~7 kg) total at one time) or need to ensure that the source material received could be possessed under the exemption in § 40.13(a). Section 40.13(a) provides an exemption from the licensing requirements for persons possessing or using materials containing source material in concentrations of less than 0.05 percent by weight source material. Absent discussion with the recipient, the general licensee cannot be certain that the recipient is authorized to receive the source material nor is it proper for the general licensee to place the disposal facility in a position that it is unknowingly in violation of the NRC's regulations. Because the lack of clarity in the current regulations associated with the § 40.22 general license with regard to disposal and the difficulty in identifying licensees, this environmental assessment assumes that much of the source material possessed by general licensees is currently disposed of at unlicensed landfills.

The proposed amendment to § 40.22 would clarify the disposal requirements by explicitly authorizing up to 0.5 kg (1.1 lb) of source material to be disposed of per calendar year as long as it was in a solid, non-dispersible form (e.g., in the form of a metal bar or encapsulated in cement, etc.) to limit the possibility of internal uptake. The recipient of the material would not require licensing as long as the source material was permanently disposed. All other permanent disposal of source material would be required to be consistent with the requirements in § 20.2001, "General requirements" for waste disposal.

By clearly delineating the amount and form of source material allowed to be disposed of without further NRC licensing, the proposed action would reduce the potential for much greater quantities of source material (conceivably up to 150 lb (~70 kg) per general licensee per year) to be disposed of at an unlicensed facility. The purpose of allowing smaller quantities of source material to continue to be disposed of without further NRC licensing is to allow an economical disposal route for persons (e.g., educational institutions) possessing very small quantities of source material. Requiring the disposal of larger quantities of source material in a manner consistent with § 20.2001 would reduce the impact to workers, the public, and the environment resulting from larger disposals at unlicensed facilities that could be construed to be acceptable under the current regulations.

Because of the limited availability of licensed disposal sites, the proposed action could result in longer transportation routes than disposal at the local landfill. Longer transportation routes have a potential to increase the opportunity for higher exposures to drivers, accidents, exhaust emissions, and use of non-renewable resources (gasoline or diesel). Because the possession limits in the proposed action would limit disposal of at most 7 kg (15.4 lb) of source material at one time, it is likely that the general licensee would use either a waste consolidator, or, if Department of Transportation regulations allowed, common shippers, in order to limit transportation costs and packaging costs. Waste consolidators and common shippers would likely already be transporting other materials to or near the locales of the licensed disposal site thus limiting these potential adverse effects.

Because the proposed action is generally more restrictive than potential current practices, the proposed amendment to clarify the current disposal requirements would have no significant impact on environmental resources compared to taking no action.

5.1.3 Requirements to Minimize Contamination and Adequately Decommission the Site

Under the existing § 40.22 requirements, general licensees are exempt from the contamination control and decommissioning requirements in 10 CFR Part 20 unless they also possess a specific license. As a result, the NRC and Agreement State regulators have identified situations where sites possessing source material under the § 40.22 general license were operated and abandoned with significant quantities of source material in the form of contamination. It is expected, although not confirmed, that many general licensees do not account for such contamination toward their overall possession limit.

The proposed amendment to § 40.22 would require a licensee to conduct activities so as to minimize contamination of the facility and the environment. This requirement would minimize the potential exposure to workers who are not required to have radiation training. In addition, minimizing contamination would help ensure that the general licensee does not unexpectedly exceed total possession limits. If the NRC identifies substantial contamination from source material, the proposed action would allow the NRC to require the general licensee to restore the site to levels protective of public health and safety.

The proposed amendment to § 40.22 would also require that when activities involving source material are permanently ceased at any site, the general licensee does not abandon the site with quantities of source material that could result in exposures exceeding the limits in § 20.1402. Section 20.1402 requires a licensee to restore a site for unrestricted use such that residual radiation that is distinguishable from background will not result in exposures above 25 mrem (0.25 mSv). Because of the current Part 20 exemption, a § 40.22 general licensee is not required to decommission the site. The proposed action would require the licensee to notify the NRC if significant source material contamination (i.e., there is a potential the residual

contamination would exceed the limits in § 20.1402) is identified upon completion of activities. The NRC could then advise the general licensee about decommissioning and surveying options and, if necessary, inspect the facility upon completion of such activities.

Because these amendments are more restrictive than the current practices, the proposed amendments would have an insignificant impact on environmental resources compared to the current contamination control and decommissioning requirements for § 40.22 general licensees.

5.2 Revise 10 CFR 40.13(c)(7) Exemption for Thorium Lenses

The existing regulation in § 40.13(c)(7) provides an exemption from licensing for the possession of finished optical lenses containing thorium homogenously distributed throughout the lens at a concentration of no greater than 30 percent thorium by weight. Shaping, grinding, or polishing of the lenses is specifically prohibited. In addition, the use of lenses in applications where the lens is in close proximity to the eye (e.g., contact lenses, spectacles, or eyepieces in binoculars or other optical instruments) is also prohibited.

The proposed amendment would revise § 40.13(c)(7) to expand the exemption to clearly cover thorium-coated lenses. In addition, the proposed amendment would be expanded to allow the use of uranium in and on lenses as well as to include mirrors. The concentration of source material allowed on or within the lens would be reduced from 30 percent by weight to 10 percent by weight; however, lenses containing thorium homogenously distributed throughout the lens and manufactured prior to the effective date of the rule would continue to be exempt at concentrations up to 30 percent by weight of the thorium. The restrictions on processing and uses currently in § 40.13(c)(7) would continue to apply.

5.2.1 Addition of Uranium and Thorium Coated Lenses to Exemption

Thorium is used as a thin-film optical coating on the surfaces of a lens or entrained within the lens to reduce reflection and glare in the ultraviolet, visible, and infrared light spectra and to increase reflection in the extreme ultraviolet and soft x-ray spectra. In recent years, it has become more practical to apply the thorium as a thin-film coating instead of entraining the thorium within the lens. As a result, the applicability of the current exemption to such coated lenses has been questioned. In addition, the NRC has also recently become aware that lenses coated with uranium are now being manufactured.

The PNNL report specifically evaluated the use and manufacture of thorium and uranium thin-film optical coatings. Based upon the findings in the report, a lens manufactured with a thin-film of source material contained significantly less source material than those lenses that contained thorium homogeneously distributed throughout the lens. Lenses evaluated in NUREG-1717 incorporated up to 100 grams (g) of thorium, while thin-film coated lenses have approximately 0.02 g of thorium applied to the lens. Routine doses (accounting for external exposures only) from the lenses with thin-film optical coatings of thorium were calculated to be less than 0.004 millirem (mrem) (0.04 microsieverts (μSv)) per year to an individual. Doses from uranium coated lenses were found to be even lower. Doses resulting from accidents while using the thin coated lenses were expected to be similarly small. Thin-film coatings of uranium or thorium applied to mirrors would be expected to have similar impacts.

The Commission has a consumer product policy (30 FR 3462, March 16, 1965) which calls for the Commission to monitor the overall impact of its exemptions from licensing. The Commission evaluated the potential exposure impacts from consumer products in the early ’60’s, again in the

late ‘70’s, and more broadly of all of its exemptions in the ‘90’s. The second of these analyses was published as NUREG/CR-1775, “Environmental Assessment of Consumer Products Containing Radioactive Material,” in 1980. As noted in the Section 1.1, Background, the dose assessments from the latest of these evaluations were published as NUREG-1717. The Commission’s policy is for consumer products to routinely expose users to only a small fraction of the public dose limit. The estimated doses under routine use conditions for lenses having thin-film optical coatings of uranium and thorium results in only a small fraction of the public dose limit (well below 10 μSv (1 mrem) per year). As a result, expanding the exemption for lenses to include lenses or mirrors coated with thorium or uranium would not significantly impact public or occupational health.

5.2.2 Reduction of Allowable Concentration to 10 Percent by Weight

The proposed action would reduce the concentration limit for source material to 10 percent by weight from the current 30 percent by weight. The evaluation in NUREG-1717 assumed that a camera operator used a lens system containing 3 lenses, each containing 100 grams of thorium and concentrations of 10 percent by weight of thorium. The resulting dose was 200 μSv (20 mrem) per year to an operator, and is considered higher than a small fraction of the public dose limit. Although this may be considered an industrial use rather than a consumer product use (thus the higher allowable exposure), the reduction in concentration is warranted due to the availability of alternative materials that can be applied or incorporated to lenses to achieve similar effects. Additionally, the NRC has not been able to identify any persons currently manufacturing lenses using concentrations in excess of 10 percent. This is likely because of the increased prevalence of lenses with thin optical coatings or other materials. Lenses containing thorium homogenously distributed throughout the lens and manufactured prior to the effective date of the rule would continue to be exempt at concentrations up to 30 percent by weight thorium to account for those lenses still possessed that may be in excess of the proposed limit of 10 percent by weight.

If lenses were to be manufactured in the future containing thorium or uranium in concentrations greater than 10 percent by weight, they would require a specific license for possession. The NRC is unaware of any situation where health and safety of the public or protection of the environment would be impacted if such lenses could not be possessed under exemption. Because the NRC is unaware of situations where lenses are currently being manufactured for use under the exemption in excess of 10 percent by weight, the only notable distinction between the no-action alternative and the rulemaking is that the proposed action would prohibit future distribution without an NRC reevaluation. However, future distribution is unlikely in the no-action alternative because the products are no longer being manufactured nor is there an expectation that they would be manufactured in the future. Therefore, it is unlikely that the reduction of the concentration limit would have a significant impact on environmental resources.

5.3 Revise 10 CFR 40.13(c) and (d)

Paragraphs 40.13(c) and (d) establish exemptions from licensing for many products containing source material. The specific provisions of § 40.13(c) evaluated in this document are: § 40.13(c)(2)(i) – glazed ceramic tableware; and (iii) – glassware. Section § 40.13(d) establishes an exemption from licensing for uranium contained in detector heads for use in fire detection units.

The NRC's proposed action is to restrict the exemption for glazed ceramic tableware to include only those previously distributed products and delete the exemption for uranium contained in detector heads for use in fire detection units. The NRC is proposing to reduce allowable concentration levels of source material to levels for glassware; however, previously distributed glassware would still be exempted at the previous concentration level. In addition, the introductory paragraph of § 40.13(c) is being revised to specifically indicate that a person using these products is exempt from 10 CFR Parts 19, 20, and 21.

NUREG-1717 identified that these provisions are for products that have never been used or manufactured (detector heads), are no longer being manufactured (glazed ceramic tableware), or are no longer being manufactured at concentration levels originally established in the exemption (glassware). Because, the proposed action is not intended to change the regulatory status of any products previously distributed in conformance with the provisions of the regulations applicable at the time, the exemptions for tableware and glassware distributed before the effective date of the final rule would continue; all newly manufactured products would be required to meet the amended, lower concentration limits.

Because the NRC is unaware of situations where products are currently being distributed under the exemption being removed or distributed containing concentrations higher than those proposed, the only notable distinction between the no-action alternative and the rulemaking is that the proposed action would prohibit future distribution without the NRC's reevaluation. However, future distribution is unlikely because the products are outmoded or potentially considered frivolous. Therefore, it is unlikely that the amendments to these exemptions would have a significant impact on environmental resources.

The proposed amendment to the introductory paragraph of § 40.13(c) will clearly state that a person possessing a product under an exemption in § 40.13(c) is not only exempt from obtaining a license or meeting the requirements of Part 40, but also is not required to meet the notification and training requirements of Part 19, the health and safety requirements of Part 20, and the reporting requirements in Part 21. Because this is the current practice under the exemption, the addition of this clarifying language will not affect any environmental resources.

5.4 No Action

The no-action alternative is to maintain the status quo.

The no-action alternative would not address identified concerns. General licensees would continue to possess source material in quantities or isotopic concentrations that could significantly exceed public health and safety limits while still being exempt from Parts 19 and 20. Confusion regarding disposal requirements would continue, thus potentially permitting licensees to dispose of source material in unlicensed disposal facilities. In addition, not implementing contamination controls would allow the licensee to potentially abandon source material in place and thus expose other persons to exposure levels normally not allowed for unrestricted use. Although the no-action alternative would not adversely affect any environmental resources, this alternative would not provide the improvements to health and safety that could result from the proposed action.

With respect to the proposed reduction of concentrations allowed by or deletion of certain exemptions, the no-action alternative would have no perceptible difference than the proposed action because it appears that no one is manufacturing those products at levels that they would be impacted. The no-action alternative would not expand the exemption for thin-coated optical lenses and thus would not adversely affect any environmental resources.

6.0 Conclusion

The NRC has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's implementing regulations in Subpart A of 10 CFR Part 51, not to prepare an environmental impact statement for this proposed rule because the Commission has concluded on the basis of this environmental assessment that this proposed rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment. While most of the proposed revisions fall under a categorical exclusion, the proposed revisions to § 40.22 primarily provide additional limitations on, or clarify what a general licensee is allowed under, the general license, thus, potentially reducing the impact on environmental resources from the status quo. Similarly, certain exemptions are being revised or deleted to limit the future use of certain products containing source material. Although the NRC is proposing to expand the exemption from licensing in § 40.13(c)(7) to allow coated lenses, the NRC's evaluation indicated that these products contain significantly less source material than those currently authorized under the exemption.

The determination of this environmental assessment is that there would be no significant impact to the public from this action and therefore the proposed actions do not warrant the preparation of an environmental impact statement. Accordingly, a finding of no significant impact (FONSI) will be published in the *Federal Register* as part of the publication of the proposed rule for public comment.

7.0 List of Agencies and Persons Consulted

The NRC has determined that the proposed action is not a type of activity that has potential to cause effects on historic properties. Therefore, no further consultation is required under Section 106 of the National Historic Preservation Act. Additionally, the NRC has determined that Section 7 consultation with the U.S. Fish and Wildlife Service is not required because the proposed action will not affect listed species or critical habitat.

8.0 Sources Cited

Administrative Procedure Act of 1946, 5 U.S.C Chapter 5 (1946).

Code of Federal Regulations, Title 10, Energy, Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations."

Code of Federal Regulations, Title 10, Energy, Part 20, "Standards of Protection Against Radiation."

Code of Federal Regulations, Title 10, Energy, Part 21, "Reporting of Defects and Noncompliance."

Code of Federal Regulations, Title 10, Energy, Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material."

Code of Federal Regulations, Title 10, Energy, Part 40, "Domestic Licensing of Source Material."

Code of Federal Regulations, Title 10, Energy, Part 51, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,” Subpart A, “National Environmental Policy Act – Regulations Implementing Section 102(2).”

Code of Federal Regulations, Title 10, Energy, Part 70, “Domestic Licensing of Special Nuclear Material.”

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