

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 on the rule by (insert 120 days from date of publication). Submit comments specific to the information collections aspects of this rule by ~~[INSERT DATE (insert date 30 DAYS AFTER PUBLICATION)] days from date of publication~~. Comments received after ~~these~~the above dates will be considered if it is practical to do so, but the NRC is able to ~~en~~assure consideration only for comments received on or before ~~these dates~~.this date.

**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. ~~For instructions on submitting comments and accessing documents related to this action, see Section I, "Submitting Comments and Accessing Information" in the SUPPLEMENTARY INFORMATION section of this document. You may submit comments by any one of the following methods.~~

**Federal Rulemaking Web Site:** 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, telephone 301-492-3668, e-mail [Carol.Gallagher@nrc.gov](mailto: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](mailto: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 a.m. and 4:15 p.m. 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.

**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](mailto:Gary.Comfort@nrc.gov) or Catherine Mattsen, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-415-6264, e-mail: [Catherine.Mattsen@nrc.gov](mailto:Catherine.Mattsen@nrc.gov).

**SUPPLEMENTARY INFORMATION:**

I. Submitting Comments and Accessing Information

II. Background

A. Introduction

B. Regulatory Framework

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

III. Discussion

A. *What Action is the NRC Taking?*

A.1 Specific Licensing of Distribution of Source Material

A.2 Distribution of Products to Persons Exempt From Regulation

A.3 Distribution of Source Material to General Licensees

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

A.5 Revision of Exemption for Thorium Lenses

A.6 Revision of Exemption for Glassware

A.7 Obsolete Exemptions

*B. Whom Would This Action Affect?*

*C. Specific Requests for Comment.*

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

IV. Summary of Proposed Amendments by Section

V. Criminal Penalties

VI. Agreement State Compatibility

VII. Plain Language

VIII. Voluntary Consensus Standards

IX. Finding of No Significant Environmental Impact - Availability

X. Paperwork Reduction Act Statement

XI. Regulatory Analysis

XII. Regulatory Flexibility Certification

XIII. Backfit Analysis

#### I. Submitting Comments and Accessing Information

Comments submitted in writing or in electronic form will be posted on the NRC ~~website~~Web site and on the Federal rulemaking ~~website-Regulations~~Web site <http://www.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.

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You can access publicly available documents related to this ~~proposed rule~~ document 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 Room O-1F21~~, 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~~ ~~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, or 301-415-4737, or by e-mail to [PDR.Resource@nrc.gov](mailto:PDR.Resource@nrc.gov).

**Federal Rulemaking Website Web Site:** 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: 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:~~

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~~— A. Introduction~~

~~— B. Regulatory Framework~~

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

~~II. Discussion~~

~~A. What Actions are Being Proposed by the NRC?~~

~~A.1 Specific Licensing of Distribution of Source Material~~

~~A.2 Distribution of Products to Persons Exempt From Regulation~~

~~A.3 Distribution of Source Material to General Licensees~~

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

~~A.5 Revision of Exemption for Thorium Lenses~~

~~A.6 Revision of Exemption for Glassware~~

~~A.7 Obsolete Exemptions~~

~~B. Whom Would This Action Affect?~~

~~C. Specific Requests for Comment~~

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

~~III. Summary of Proposed Amendments by Section~~

~~IV. Criminal Penalties~~

~~V. Agreement State Compatibility~~

~~VI. Plain Language~~

~~VII. Voluntary Consensus Standards~~

~~VIII. Finding of No Significant Environmental Impact—Availability~~

~~IX. Paperwork Reduction Act Statement~~

~~X. Regulatory Analysis~~

~~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.<sup>1</sup> 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.<sup>2</sup> Because of

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<sup>1</sup> U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry. “ToxFAQs™” for Uranium,” 1999.

<sup>2</sup> U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease

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 ~~a~~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." 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.<sup>3</sup> 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 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

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<sup>3</sup> 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.

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~~6 persons distributing source material to § 40.22 general licensees in the mid-1980's, the NRC was able to identify only ~~one~~1 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). [A copy of the PNNL study can be found in ADAMS by searching for Accession Number ML070750105.](#) 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.

### III. Discussion

#### A. ~~What Actions are Being Proposed by~~ *Action is the NRC Taking?*

The ~~proposed rule would~~NRC is proposing to 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~~ Occupational Safety and Health Administration 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, but will change to \$ 10,200 and \$ 21,100 respectively on August 16, 2010, as a result of the 2010 fee rule published June 16, 2010 (75 FR 34219). 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. These amounts are subject to change prior to the 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~~uranium and thorium at any one time and 7 kg (15.4 lb) per calendar year for all ~~source material~~uranium and thorium 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 the 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~~uranium and thorium at any one time, or receiving more than 7 kg (15.4 lb) of ~~source material~~uranium and thorium 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~~uranium and thorium 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~~ uranium and thorium 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~~ uranium 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 ~~uranium from~~ uranium from 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, persons that~~ later inhabiting the facility, ~~to from~~ unknowingly exposing 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. ~~The goal of this requirement is to reduce the likelihood that any remaining contamination would have the potential to result in the 25 mrem (0.25 mSv) limits in § 20.1401 being exceeded.~~ The NRC would expect a licensee to

identify a concern about significant contamination based on both visual inspection (i.e., particulates remaining from operations) and operational and historical data (e.g., operations often resulted in airborne or dispersed particulates or there were history of spills, etc.). If there is any doubt as to whether remaining contamination may be considered significant, the licensee should consult with the NRC or a health physics consultant.

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 homogeneously 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 ( $\mu\text{Sv}$ ) 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  $\mu$ Sv (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~~ but does not specifically identify what is

considered to be significant contamination. Is this a reasonable approach or are there other approaches the NRC should consider? Should NRC prescribe what is considered significant contamination, and if so, what should be defined as significant contamination? Should the NRC instead specifically 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 requirement for such surveys result in unnecessary expenses, particularly for general licensees possessing very small quantities, or should such a requirement be limited and, if so, how?

(4) In assessing proposed changes to § 40.22, has the NRC properly identified and assessed the range of activities undertaken under the existing general license? Has the NRC overestimated or underestimated the potential for impacts from such operations and if so, how (e.g., is there exposure data available that the NRC did not have available during development of the proposed rule, but should be considering)? Similarly, are the assumptions discussed in the proposed revisions to exemptions in § 40.13 correct (i.e., are some products still being manufactured at concentration levels above the proposed concentration limits)?

(5) In § 170.31, the NRC is proposing to add new categories 2.C., 2.D., and 2.E. and associated fees for applications for those categories. Similarly, in § 171.16, the NRC is proposing to add new categories 2.C., 2.D., and 2.E and associated annual fees to the table in paragraph (d). In both situations, the proposed new fees are based upon similar existing activities, although in future years these fees would be based upon actual NRC effort on these activities as data is accumulated. Are these new fee categories appropriate and are the initial fees reasonable?

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?

(4) Are there product exemptions in § 40.13(c) that should be considered obsolete and revised to allow only those products that were previously distributed? Are there other changes to the exemptions in § 40.13(c) that should be considered?

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

Recommendations for preparing your comments:

- i. Identify the rulemaking: ~~Docket ID-RIN 3150-AH15~~; [NRC-2009-0084].
- ii. Explain why you agree or disagree.
- iii. ~~Suggest~~; suggest alternatives and substitute language for your requested changes.

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

~~v.~~ ~~iv.~~ 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.~~ ~~v.~~ 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 viii.~~ Section ~~V~~ VI of ~~the preamble for the~~ this document contains a request for comment on ~~Agreement State Compatibility~~, the compatibility designations for the proposed rule; Section ~~VI for the request for comment on the use of plain language~~, Section ~~VIII for the VII~~ contains a request for comments on the ~~draft~~ use of plain language; Section IX contains a request for comments on the environmental assessment, ~~and~~; Section ~~IX for the X~~ contains a request for comments on the information collection, ~~and requirements~~; Section ~~X for the XI~~ contains a request for comments on the draft regulatory analysis; and Section XII contains a request for comments on the impact of the proposed rule on small businesses.

#### ~~III.~~IV. 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~~uranium and thorium 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~~uranium and thorium that are not expected to be normally inhaled or ingested. However, the total amount of ~~source-material~~uranium and thorium 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~~uranium and thorium 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 40.32 General Requirements for issuance of a specific license

10 CFR 40.32(f) – Would add §§ 40.52 and 40.54 to the list of sections that have special requirements that need to be satisfied for the issuance of certain specific licenses.

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~~and 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.

#### **IVV. 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.VI. 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

Section	Change	Subject	Compatibility	
			Existing	New
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
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 States 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.

#### VII. 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.

#### VIII. 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.X.** 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.

#### ~~IXX~~. Paperwork Reduction Act Statement

This proposed rule contains new or amended information collection requirements contained in 10 CFR Part 40 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). These 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. ~~The proposed rule changes to 10 CFR Parts 30, 70, 170, and 171 do not contain new or amended 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-Internet electronic mail to and to the Desk Officer, Christine Kymn, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0014, 3150-0020, 3150-0044 and 3150-0120AH15), Office of Management and Budget, Washington, DC 20503.~~ Comments on the proposed information collections may also be submitted via the Federal ~~Rulemaking Website~~ [Rulemaking Portal http://www.regulations.gov](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 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~~.XI. 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](http://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](mailto:Gary.Comfort@nrc.gov), or ~~Kimyata-Morgan-Butler~~Catherine Mattsen, telephone: (301) 415-~~07336264~~, e-mail: [Catherine.Mattsen@nrc.gov](mailto:Catherine.Mattsen@nrc.gov), of the Office of Federal and State Materials and Environmental Management Programs.

## XII. 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.

## XIII. 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.

Annual charges, Byproduct material, Holders of certificates, ~~registrations,~~  
~~approvals~~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 ~~P~~parts 30, 40, and 70,  
and 10 CFR parts 170, and 171, as amended on June 16, 2010 at 75 FR 34219, effective  
August 16, 2010.

## **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~~ uranium and thorium 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~~ uranium and thorium 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. In § 40.32, paragraph (f) is revised to read as follows:

**§ 40.32 General requirements for issuance of a specific license.**

\* \* \* \* \*

(f) The applicant satisfies any applicable special requirements contained in §§ 40.34, 40.52, and 40.54.

\* \* \* \* \*

8-9. 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.

~~9.10.~~ 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**

~~10.11.~~ 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).

44-12. 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~~-13. 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~~-14. 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 <sup>1</sup>	Fee <sup>2,3</sup>
* * * * *	
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, <del>100</del> 200
F. All other specific source material licenses.	
Application [Program Code(s): 11200, 11220, 11221, 11300, 11800, 11810]	\$10, <del>100</del> 200
* * * * *	

<sup>1</sup> *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; issuances 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 the 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.

<sup>2</sup>-Fees<sup>2</sup>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.

<sup>3</sup>-Full<sup>3</sup>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 whosefor which 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**

44.15. 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).

15-16. 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 <sup>1,2,3</sup>
* * * * *	
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]	<del>\$17,400</del> 21,100
F. All other specific source material licenses. [Program Code(s): 11200, 11220, 11221, 11300, 11800, 11810]	<del>\$17,400</del> 21,100
* * * * *	

<sup>4</sup>Annual<sup>1</sup>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<sup>9</sup>, 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.

<sup>2</sup>~~Payment~~<sup>2</sup>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.

<sup>3</sup>~~Each~~<sup>3</sup>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.