

RULEMAKING ISSUE
(Affirmation)

July 19, 2012

SECY-12-0099

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

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

PURPOSE:

To request Commission approval to publish a final rule, in the *Federal Register*, that amends Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 30, 40, 70, 170, and 171.

SUMMARY:

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

BACKGROUND:

In a Staff Requirements Memorandum (SRM) dated June 16, 2010 (NRC Agencywide Documents Access Management System (ADAMS) Accession No. ML101670483), the Commission approved publication of the proposed rule, "Distribution of Source Material to

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Exempt Persons and to General Licensees and Revision of General License and Exemptions,” (SECY-09-0179, December 10, 2009). It was published in the *Federal Register* on July 26, 2010 (75 FR 43425). The comment period was originally scheduled to close November 23, 2010, but was extended until February 15, 2011 (75 FR 70618; November 18, 2010). This was to allow the public sufficient time to review and comment on the proposed rule with the benefit of review of the draft implementation guidance, which was posted for public comment. A notice indicating the interim guidance was available for comment was published in the *Federal Register* on January 7, 2011 (76 FR 1100).

Fourteen comment letters from nine parties were received. The commenters on the proposed rule included licensees, industry organizations, a university, and an individual. A comment letter received from a State during the earlier Agreement State review was also addressed with the comments received during the public comment period. The comments are discussed in detail in the *Federal Register* notice ([Enclosure 1](#)).

Because of the lack of existing reporting requirements, there is not much data available on the identity of the affected stakeholders; nonetheless, the staff attempted to identify and notify affected stakeholders about the comment period for the proposed rule. First, the staff directly notified the only known distributor of source material for use by general licensees and requested that the distributor inform clients about the proposed rule. Also, the staff asked the distributor to identify journals that would broadly reach persons operating under a general license. This outreach did not prove successful. Second, the staff requested Agreement States to either contact known general licensees in their states or identify them so that the U.S. Nuclear Regulatory Commission (NRC) staff could contact them; several Agreement States were able to do so. Additionally, the staff identified a small contractor who provided support to numerous source material licensees. The contractor voluntarily included multiple notices about the comment period in its monthly newsletter. During the comment period, the staff spoke with representatives of the Zirconium Environmental Committee (ZEC) by telephone to clarify questions that ZEC had about the rule so that the ZEC could better formulate its comments. Finally, during resolution of the comments, the staff spoke with one commenter, by telephone, to clarify some of its more general comments, particularly regarding perceived burden. The staff clarified some misunderstandings during the call - no new comments were requested or contributed.

DISCUSSION:

The final rule adds 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 final rule also makes 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.

New Requirements for Specific Licenses for Initial Distribution of Source Material

Currently, there are no regulatory mechanisms for the NRC to ensure that products and materials distributed for use under the general license in § 40.22 or for use under exemption are maintained within the applicable constraints of the requirements for these uses. Because the

staff cannot readily identify who possesses source material under the general license in § 40.22 or how and in what quantities the source material possessed under § 40.22 is being used, the staff cannot fully assess the resultant risks to public health and safety. The rule addresses these concerns by requiring persons (e.g., manufacturers or importers) initially distributing source material to § 40.22 general licensees or to persons receiving products under exemption to obtain a specific license for such distribution. The requirements of such a license include certain labeling and quality control requirements, as well as new reporting and recordkeeping requirements. These new requirements are expected to better ensure that persons safely possess such source material and that the NRC will have a better understanding of how much source material is being distributed annually, who is using that material under a general license, and how that material is being used.

Through public comments received on the proposed rule the staff learned that some analytical laboratories may receive and analyze samples under the § 40.22 general license or may return samples received from a general licensee or exempt person. In order to reduce burden on these potential routine operations, the staff concluded that transfers to or from laboratories for the purpose of analyzing sample concentrations should not be considered initial distributions and thus subject to the requirements for a specific license for distribution. Similarly, the staff is proposing to revise the definition of “unrefined and unprocessed ore” to clarify that ore samples continue to be considered as “unprocessed” in order to alleviate potential violations where a laboratory may unexpectedly identify source material in an ore that would normally require licensing. The definition is also revised to clarify other activities that are not considered to result in “processed” ore.

New fee categories and fee amounts for these new specific licenses are included in draft final revisions to 10 CFR Parts 170 and 171. These fees are the only fees required by the NRC for source material distributors whose possession and use of source material is licensed by an Agreement State, or who only import finished products for distribution. These fees are in addition to existing fee requirements already applied to persons possessing or using source material under another NRC specific license. This is similar to the breakdown of fees for distributors of exempt byproduct material. The staff will update the fees in the final rule to be consistent with any changes made to the current schedules of annual and materials fees prior to publication of the final rule.

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

The final rule would make significant revisions to the requirements in the § 40.22 general license for small quantities of source material. In 1999, the State of Colorado and the Organization of Agreement States (the petitioners) submitted a petition for rulemaking, PRM-40-27. In the petition, the petitioners identified concerns regarding the use of source material under the general license granted under § 40.22. In particular, the petitioners were concerned that general licensees are specifically exempted from meeting the requirements of 10 CFR Parts 19 and 20, despite the fact that situations exist where use of the material could result in exposures to workers above 1 milliSievert (mSv) per year (100 millirem (mrem) per year). The staff considered the petitioners’ concerns and determined that situations can, and do, occasionally occur that exceed limitations under which 10 CFR Parts 19 and 20 usually apply, although most source material possessed under § 40.22 is likely handled in quantities,

physical forms, or in uses and conditions that would justify the continued use of the exemptions to 10 CFR Parts 19 and 20.

The draft final rule would revise § 40.22 to limit the opportunity for persons to receive doses exceeding 10 CFR Part 20 public dose limits, or the dose level at which workers would be required to be trained if working for a specific licensee, by reducing the general licensee's possession limit to 1.5 kg (3.3 lb) at one time and limiting receipt to no more than 7 kg (15.4 lb) per calendar year for source material that is processed or in a dispersible form (i.e., liquid, gaseous, or powder). The possession limits for persons possessing source material in a solid, non-dispersible form that will not be processed, for persons treating drinking water to remove uranium, and for analytical laboratories are not changed. In addition, the final rule contains new requirements for contamination control, decommissioning, and disposal to ensure that contamination and abandonment of source material possessed by general licensees become less of a concern. These new requirements are less for a general licensee than those for a specific licensee, which is warranted because of the reduced risk by lowering the possession limits. In addition, the new requirements are intended to clarify the current rule language in § 40.22.

The final rule also would modify the type of source material allowed to be possessed under § 40.22. The International Atomic Energy Agency (IAEA) has categorized radioactive sources according to the potential for radiological consequences that the sources pose. The IAEA categorization system is based primarily on the potential for radioactive sources to cause deterministic health effects, without any regulatory controls in place. Certain isotopes of source material, in particular thorium-228, could be possessed in quantities exceeding Category 1 limits of the IAEA Categorization under the existing § 40.22 general license. It should be noted that previously, the staff indicated that other isotopes (e.g., uranium-232 and thorium-229) could also be possessed under the general license; however, based upon further evaluation as a result of a comment received, the staff determined that these isotopes are "byproduct material" as defined in 10 CFR 30.4 because they are only yielded through reactions occurring in nuclear reactors or are produced in an accelerator and are not the "source" of special nuclear material. The staff has made this clarification in the statement of considerations for the final rule. Although the staff is not aware of any large scale commercial production of thorium-228, the final rule limits the possession of source material under the § 40.22 general license to only source material in its natural isotopic concentration or in the form of depleted uranium to ensure that isotopes with high specific activities cannot be possessed under the § 40.22 general license or otherwise assumed to be covered by the general license.

Deletion and Revision of Certain Product Exemptions

The final rule would update the exemptions related to products containing source material to account for current uses and health and safety impacts by deleting exemptions for products that are no longer being used or manufactured and by restricting future initial distribution of such products. The final rule allows for the continued possession and use of previously distributed items for the revised exemptions. Specifically, it is believed that fire detection units containing source material have never been manufactured for commercial use and that ceramic tableware containing source material possessed under exemption could result in significant doses if routinely used. Therefore, the rule removes the exemption in § 40.13(d) and restricts continued possession of ceramic tableware under the exemption in § 40.13(c)(2)(i) to those products that

were distributed prior to the effective date of the final rule. The rule would also reduce the concentration limit for glassware containing source material in § 40.13(c)(2)(iii) from 10 percent to 2 percent by weight. The staff's evaluation indicates that most glassware is currently manufactured below this limit; however, the rule continues to exempt glassware previously manufactured under the previous concentration limit.

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

Minor Clarifying or Administrative Revisions

Other revisions include minor conforming amendments in 10 CFR Parts 30 and 70.

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

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

It should be noted that the staff did not specifically consider cumulative effects of regulation during this rulemaking, primarily because most of this rulemaking effort was completed before the Commission's recent approach to reducing cumulative effects was established. However, because of the previously stated difficulties in identifying affected parties and because there have been no other significant rulemakings in this area for over 50 years, the staff concluded that the cumulative effects of regulation in this area would be minimal.

AGREEMENT STATE ISSUES:

A copy of the draft final rule *Federal Register* notice (FRN) was provided to the Agreement States so they could have an early opportunity for review. One Agreement State (Illinois) provided comments on the draft FRN. The State's comments primarily focused on its understanding of how the final rule would be implemented. The State did voice a concern that the recently revised final rule amending § 110.27 (77 FR 27113; May 9, 2012) would allow a "blank check" to import source material because no limits were defined and this would make it harder to identify importers. It should be noted that the Part 110 rulemaking only clarified the status quo, that a specific license was not necessary for the import of source material for use

under an exemption; however, once the new Part 40 requirements become effective, a person importing source material for domestic distribution for use under exemption will require a specific license.

Under the "Policy Statement on Adequacy & Compatibility of Agreement State Programs," the final rule is a matter of compatibility between the NRC and the Agreement States, thereby requiring consistency among NRC and Agreement State requirements. Therefore, the staff analyzed the final rule in accordance with the procedures established within Part III of the Handbook to Management Directive 5.9, "Categorization Process for NRC Program Elements." The staff determined that because the exemptions in § 40.13 and the general license in § 40.22 are Compatibility Category B, the revisions of these sections are also Compatibility Category B (with the exception of § 40.22(b)(4) which is Compatibility Category D and § 40.22(c) which is Compatibility Category C, and redesignated § 40.13(c)(5)(iv) which is Compatibility Category NRC). New requirements in §§ 40.52 and 40.53 are determined to be Compatibility Category NRC. New requirements in §§ 40.54 and 40.55 are determined to be Compatibility Category B (with the exception of § 40.55(e) which is Compatibility Category C). Sections 30.6, 40.5, 40.8, 40.82, 70.5, 170.31, and 171.16 are Compatibility Category D and remain so.

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

COMMITMENTS:

Interim guidance will be issued when the final rule is published.

Two volumes of the NUREG-1556 series will also be updated to include guidance related to this rule. NUREG-1556, Vol. 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses," and NUREG-1556, Vol. 16, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licenses" both require minor revisions or supplementation as a result of the rulemaking. The staff is updating these guidance documents and will issue them for public comment after the rule is made final. This action includes no other new commitments other than routine rule-related actions.

RECOMMENDATIONS:

That the Commission:

1. Approve for publication in the *Federal Register* the notice of final rulemaking ([Enclosure 1](#)).
2. To satisfy the requirement of the Regulatory Flexibility Act, 5 U.S.C. 605 (b), certify that this rule, if promulgated, will not have significant impact on a substantial number of small entities. This certification is included in the enclosed FRN.

3. Note:

- a. That the Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b);
- b. A final Regulatory Analysis has been prepared for this rulemaking ([Enclosure 2](#));
- c. A final Environmental Assessment has been prepared for this rulemaking ([Enclosure 3](#));
- d. The staff has determined that this action is not a “major rule,” as defined in the Congressional Review Act of 1996 [5 U.S.C 804(2)] and has confirmed this determination with the Office of Management and Budget (OMB). The appropriate congressional and Government Accountability Office contacts will be informed;
- e. The appropriate congressional committees will be informed;
- f. A press release will be issued by the Office of Public Affairs when the final rulemaking is filed with the Office of the Federal Register; and
- g. The final rule contains amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.) that must be submitted to the OMB for its review and approval before publication of the final rule in the *Federal Register*.

RESOURCES:

To complete this final rule, no more than 0.1 full-time equivalent (FTE) positions will be required. To implement the rulemaking, 0.2 FTE positions will be required for reviewing new license applications for distribution to exempt persons and to general licensees, and less than 0.1 FTE per year will be required for inspections and amendments. These resources are within existing budget allocations.

COORDINATION:

The Office of the General Counsel has no legal objection to the final rulemaking. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

/RA by Michael F. Weber for/

R. W. Borchardt
Executive Director
for Operations

Enclosures:

1. *Federal Register* notice
2. Regulatory Analysis
3. Environmental Assessment

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: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) is amending its regulations to require that the initial distribution of source material to exempt persons or to general licensees be explicitly authorized by a specific license, which includes new reporting requirements. The rule is intended to provide the NRC with timely information on the types and quantities of source material distributed for use either under exemption or by general licensees. In addition, the rule modifies 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 rule revises, clarifies, or deletes certain source material exemptions from licensing to make the exemptions more risk informed. This rule affects 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: *Effective Date:* This final rule is effective on **[INSERT DATE 90 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Please refer to Docket ID NRC-2009-0084 when contacting the NRC about the availability of information for this final rule. You may access information and comment submittals related to this final rulemaking, which the NRC possesses and is publicly available, by the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2009-0084.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may access publicly-available documents online in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

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.

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I. Background

A. Introduction

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

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

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

² U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry. “ToxFAQs™ for Thorium,” 1999.

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

In the 1990s, the NRC conducted a reevaluation of the exemptions from licensing for byproduct and source material in the NRC's regulations. The assessment of doses associated with most of these exemptions can be found in NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," published June 2001.³ Doses were estimated for the normal life cycle of a particular product or material, covering distribution and transport, intended or expected routine use, accident and misuse scenarios, and disposal using dose estimation methods consistent with those reflected in the current 10 CFR part 20. The report identified potential and likely doses to workers and members of the public under the 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 or byproduct material under the exemptions from licensing. Many products containing source material used under an exemption from licensing present the potential for higher exposures under routine use conditions than products containing byproduct material used under an exemption because of differences in allowed forms and uses; however, risks from accidents are generally smaller for products containing source material. 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.

³ See <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1717/>.

In 1999, the State of Colorado and the Organization of Agreement States (the petitioners) submitted a petition for rulemaking, PRM-40-27 (ADAMS Accession No. ML082261305), which stated their concerns regarding potential exposures to persons using source material under the general license in 10 CFR 40.22, "Small quantities of source material." The petitioners requested that the exemption for these general licensees from 10 CFR parts 19 and 20 be restricted such that any licensee that has the potential to exceed 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 from 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 apply to most other licensees.

In order to evaluate potential impacts of the current limits in § 40.22, the NRC tried to collect additional information on the use of source material under the general license. However, although the NRC had identified six persons distributing source material to § 40.22 general licensees in the mid-1980's, the NRC was able to identify only one remaining distributor in 2005. In 2006, the NRC contracted Pacific Northwest National Laboratory (PNNL) to examine whether the regulations concerning general licenses and certain exemptions for source material were consistent with current health and safety regulations. In 2007, PNNL completed its evaluation

and documented its 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) (ADAMS Accession No. ML070750105). The PNNL 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. In this study, PNNL developed and evaluated bounding scenarios for the use of source material under the general license in § 40.22. The results suggested that reasonable scenarios exist for uses under the general license that could result in potential doses that can exceed 1 millisievert (mSv) per year (100 millirem (mrem) per year) to workers or members of the public. However, the available information was found to be limited and may not be representative of all current, 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 (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 NRC. Exemptions are provided in situations where there is minimal risk to public health and safety

and allow the end user 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 40.13, "Unimportant quantities of source material," sets forth several exemptions from the licensing requirements for source material. Some products containing uranium or thorium, now covered by the exemptions from licensing in 10 CFR part 40, were in use before the originally enacted Atomic Energy Act of 1946. Exemptions for the possession and use of many of these products were included in regulations noticed on March 20, 1947 (12 FR 1855). 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. Unlike the regulations for the distribution of byproduct material, the regulations contained in 10 CFR part 40 currently include no requirements to report how much source material is distributed in the form of products for use under the exemptions from licensing.

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.

Section 40.22 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 by any one general licensee in any calendar year. Section 40.22 general licensees are

exempt from the provisions of 10 CFR parts 19 and 20 and 10 CFR part 21, "Reporting of Defects and Noncompliance," 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 NRC. Unlike the regulations for the distribution of byproduct material, 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 who, how, or in what quantities persons are using source material under this general license.

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, "Application for specific licenses," and general requirements for issuance of a specific license are found in § 40.32, "General requirements for issuance of specific licenses." Terms and conditions of licenses are contained in § 40.41, "Terms and conditions of licenses." With the exception of the requirements found in §§ 40.34, "Special requirements for issuance of specific licenses," and 40.35, "Conditions of specific licenses issued pursuant to § 40.34," related to the manufacture and initial transfer of products and devices containing depleted uranium to be used under the general license in § 40.25, "General license for use of certain industrial products or devices," and the broad transfer authorizations contained in § 40.51, "Transfer of source or byproduct material," 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?

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 for 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 “Schedule I: Exempted Product,” in the original issuance of Title 11 of the *Code of Federal Regulations* part 40, “Control of Source Material,” in 1947.⁴ These exemptions essentially accommodated existing practice at that time without any consideration about 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),⁵ the NRC has periodically evaluated potential doses from exempt products to ensure that the exposure from any individual exempt product does 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 significantly impact public health and safety. However, because the NRC 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.

As previously stated, 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 provided in § 40.13. Because the NRC does not require the reporting of products and materials distributed for use under the general license or

⁴ In 1949, the regulations for atomic energy activities were moved to Title 10.

⁵ On October 14, 2011, the Commission published a proposed revision to this policy (76 FR 63957). It does not present significant changes; rather, it is a general updating of the current policy. This updated version has not yet been finalized.

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 will 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 that some source material product exemptions are obsolete and that certain products are no longer manufactured at the upper limits allowed under § 40.13(c). As a result, the NRC concludes that it is preferable to remove an unused exemption 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 and whether § 40.13(c)(7) should be revised to clarify this issue.

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 and 20. 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 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 mSv (100 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 and 20. 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 the § 40.22

general license should be revised to make it consistent with current training requirements and public health and safety standards, as set forth in 10 CFR parts 19 and 20.

Another issue of concern is that the current § 40.22 general license allows persons to obtain 15 lb (6.8 kg) of uranium or thorium in any form, including separated isotopes of natural uranium or thorium that meet the definition of source material. Specifically, thorium-228 (Th-228) has a high specific activity such that 15 lb of Th-228 could potentially result in a dose in excess of dose limits in 10 CFR part 20, and as a result would normally require controls under other NRC regulations. Thus, although Th-228 is not normally commercially available in such quantities, the NRC has concluded that persons should not be allowed to obtain quantities of Th-228 or other naturally-occurring separated isotopes of uranium and thorium (excluding depleted uranium) under the general license. Instead, persons desiring to possess such isotopes (other than depleted uranium) must obtain a specific license prior to possession.

II. Discussion

A. What Action is the NRC Taking?

The NRC is adding 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 final rule also makes 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 for the Distribution of Source Material

The NRC is adding two new provisions, §§ 40.13(c)(10) and 40.22(e), which 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, without authorization by a specific license. New reporting requirements associated with these specific licenses will allow the NRC to track the amount and types of source material being distributed to those persons. Other new requirements will allow the NRC to better ensure that products for use under exemption are manufactured and distributed within the constraints of the exemptions, and that general licensees have a better understanding of their responsibilities under the regulations.

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 continue to be allowed without the need to obtain a specific license authorizing such transfers.

Because § 40.13(c)(10), in conjunction with § 40.52, requires a specific license authorizing initial transfers, 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) will no longer be allowed to operate under the general license and, instead, needs to obtain a specific license under this final rule.

In response to public comments concerning the possibility of an analytical laboratory operating under a general license and the potential unintended consequences and costs to both the laboratory and clients, the final rule excludes transfers to or from analytical laboratories from being required to be made under a specific license for distribution. The NRC expects such

transfers would normally involve small quantities and would not provide useful information on use or amounts of source material being distributed in general. The process for obtaining a specific license to distribute source material is expected to be relatively straightforward.

Applications for specific licenses for distribution are made through the provisions of § 40.31 and an applicant is required to meet the applicable provisions of § 40.32. Under both §§ 40.13(c)(10) and 40.22(e), an initial distributor is 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 specific licensee) has been submitted within 1 year of the effective date of this rule, the applicant will be allowed to continue their distributions until the NRC takes final action on the application.

A.2 Distribution of Products to Persons Exempt from Regulation

A specific license for the initial distribution of products for use under an exemption listed in § 40.13(c) may only be issued by the NRC, including for those persons located in an Agreement State. This license will be issued under a new provision § 40.52, "Certain items containing source material; requirements for license to apply or initially transfer." Conditions for § 40.52 licenses are added in a new provision in § 40.53, "Conditions of licenses issued under § 40.52: Quality control, labeling, and records and reports."

In 10 CFR 150.15(a)(6), the NRC retains the authority to license the initial transfer of materials containing source 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 source material is also wholly reserved to the NRC by § 150.15(a)(2). Thus, a distributor, whether a manufacturer or an importer, that is located in an Agreement State and involved in the initial transfer of materials or products

containing source material to exempt persons, requires authority to distribute such material from the NRC. This NRC license is in addition to any Agreement State license that may be required for possession or use of the source material in the Agreement State. Because the Agreement State continues to license possession and use and, therefore, the health and safety of such activities, a person initially distributing source material is exempted by the NRC from meeting the requirements of 10 CFR parts 19 and 20.

Importers of products containing source material that meets the requirements for possession under an exemption also need a specific license for initial distribution under this final rule. If the importer does not modify the product in a manner inconsistent with the applicable exemption(s), the importer is exempt from the requirements in 10 CFR parts 19 and 20 -- this is different than the existing regulations governing the initial transfer of byproduct material, which do not provide an exemption from 10 CFR parts 19 and 20 for importers of finished products containing byproduct material. The exemption from 10 CFR parts 19 and 20 for importers of finished products is included 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 by the final rule, required to obtain a specific license for distribution. Importers of finished products are not expected to process or modify the products under the distribution license (except as would be expected under the normal use of the product as allowed by the conditions of the exemption). Persons processing or modifying the products must be authorized by a specific license for possession and use and are not entitled to the exemption from 10 CFR parts 19 and 20 if under the NRC's jurisdiction.

The new § 40.52 provides conditions for approval of a license application for initial distribution of source material to exempt persons. Additionally, § 40.53 contains a number of conditions for initial distributors including requirements for reporting and recordkeeping, quality control, and labeling.

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

The data collected by virtue of the new requirements will provide the NRC with a more accurate and complete representation of source material distributed to the public for use under the exemptions in § 40.13(c). This will allow the NRC to recognize trends in distribution which could alter earlier estimates of doses to workers and to members of the public. This information will also provide a better basis for considering future regulatory changes in this area and in allocating the NRC's resources. The data collected through the final reporting requirements will also aid in confirming that routine exposures to the public from all sources controlled by the NRC remain unlikely to exceed 1 mSv (100 mrem) per year.

These 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 previously been required; however, this information is expected to be available because of basic business recordkeeping practices. If detailed information is not readily available for this first report, a best estimate for the whole calendar year will be acceptable.

In addition to reporting and recordkeeping, there are a few additional requirements being added for initial distribution of products for use under exemption. The new requirements help to ensure that products being distributed are within the quantity or concentration limits for those exemptions that include such limits and that the products are properly labeled as currently required by the existing conditions in the exemptions. In addition, the new § 40.52(b)(4)

requires distributors to propose a method of labeling or marking each unit and/or its container with information that identifies the manufacturer or initial distributor of the product and the type of source material in the product. In accordance with § 40.53(b), the proposed method of labeling must satisfy any exemption-specific labeling requirements.

In NUREG-1717, certain products containing source material and used under an exemption from licensing (e.g., welding rods and gas mantles) were identified as having the potential for routine exposures that are higher than is generally acceptable for use under an exemption. However, the use of source material in many of these products has significantly declined, being replaced by rare earth compounds, such as lanthanum and yttrium. For example, the routine use of thorium contained in welding rods and gas mantles is becoming less likely and typical exposures to users is likely less than previously estimated. At the same time, exposures can be limited by a user who is properly informed concerning the inherent risks of exposures and methods for reducing exposure. Thus, rather than eliminate these exemptions, the NRC is requiring distributors of gas mantles and welding rods containing thorium for use under the exemptions in § 40.13(c)(1)(i) and (iii), respectively, to include safe handling instructions along with the distributed product.

The expected information to be provided in an application, as required by § 40.52, and in reports, as required in § 40.53, is described in general terms because of its applicability to a broad range of industries and, therefore, different industries may be required to provide different details dependent upon their individual businesses. The exact information to be provided may be discussed with the NRC during development of an application with the intent that the information provided will be adequate for the NRC to ensure that products being distributed are within the limits of the exemption and will provide the NRC with reasonable approximations of the types and number of products being distributed and what kinds and amounts of source material are in those products.

New fee categories and initial fee amounts for this new specific license type are added as revisions to §§ 170.31 and 171.16. There is a category for distribution and a separate category for manufacturing or processing. Applicants and licensees under the new licensing provision § 40.52 fall 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” in both sections (the current 2.C. “All other source material licenses” is redesignated as 2.F. by this rule). This new fee category applies to all initial distributors of products containing source material for use under § 40.13(c). The fee associated with this category is 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. However, persons located in Agreement States may be subject to separate fees set forth by the Agreement State for the manufacture and processing of 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 are lower than those related to distribution of products containing byproduct material to exempt persons, because this rule adds more limited requirements applicable to the distribution aspect of licensing for source material. Initial fee amounts for the 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 is 2.E., “Licenses for possession and use of source material for processing or manufacturing of products or materials containing source material for commercial distribution” in §§ 170.31 and 171.16. This fee category is not applicable to persons located in Agreement States, although the Agreement State may impose their own fees for this category. The fees for this new category are \$5,400 for an application and \$12,400 for the annual fee and are the same as those for the current category 2.C., “All other source material licenses.” As stated in the proposed rule, these fees

have been revised from those in the proposed rule to be consistent with the current category 2.C. fees.

After the implementation of this rule, the fee amounts for these new categories will 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. It should be noted that under § 171.16(c), a licensee who is required to pay an annual fee may qualify as a small entity. If a licensee qualifies as a small entity and provides the NRC with the proper certification along with its annual fee payment, the maximum annual fee would be currently limited to \$500 or \$2,300, depending on the size of the entity.

A.3. Conditions for the Distribution of Source Material to General Licensees

Unlike the specific license for the distribution of source material to an exempt person, a specific license for the initial distribution of products or materials for use under the § 40.22 general license may be issued by the NRC or, for persons located in an Agreement State, by the Agreement State. For licenses issued by the NRC, a specific license for the initial distribution of source material for use under the § 40.22 general license will be issued under a new provision in § 40.54, "Requirements for license to initially transfer source material for use under § 40.22." Conditions for the § 40.54 licenses are added in a new section, § 40.55,

“Conditions of licenses issued under § 40.54: Quality control, labeling, safety instructions, and records and reports.” Section 40.54 provides conditions for approval of a license application for the initial distribution of source material to § 40.22 general licensees. Additionally, § 40.55 contains a number of conditions for initial distributors including requirements for reporting and recordkeeping, labeling, and notifications.

The final rule adds § 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 requires that all initial transfers be reported to the NRC annually by January 31. Additionally, the distributor must also provide a separate report, annually by January 31, to each Agreement State to which the distributor initially transfers source material to a general licensee. The reports cover transfers of source material completed in the previous calendar year. The reports will 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 will be required to report the total quantity of source material distributed each calendar year, including any transfers of less than 50 g (0.11 lb) made to any person during the calendar year.

The reporting requirements, when also applied to distributors in Agreement States by those States, will help the NRC and the Agreement States identify § 40.22 general licensees using larger quantities of source material. This will enable the NRC and the Agreement States to better communicate with or inspect these general licensees, if necessary, to ensure that public and worker health and safety is adequately protected. The NRC will 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 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 will still not be reported.

Records of the initial transfer of source material for use under § 40.22 are required to be retained for 1 year after inclusion in a report to the NRC 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 retention 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 tracking particular devices if generic defects were identified.

These 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 will be acceptable.

In addition to reporting and recordkeeping, there are a few requirements being added for distribution of material for use under § 40.22 and equivalent Agreement State provisions. The new requirements primarily require the licensee to ensure the quantity or concentration of material is as labeled. The initial distributors are required to provide to their customers copies of key relevant regulations and radiation safety precautions and instructions to help minimize exposures. Requiring initial distributors to provide copies of such regulations makes 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 added as revisions to §§ 170.31 and 171.16. The applicants and licensees under the new licensing provision § 40.54 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,” in both sections. Initial fee amounts are as follows: \$2,000 for an application; \$5,000 for the annual fee. These applicants and licensees are also subject to the 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,” in §§ 170.31 and 171.16. As discussed in section II.A.2 of this document, the initial fee amounts for this category are equal to the fee for current fee category 2.C. at the time this rule is made effective. These fee amounts will subsequently be revised in accordance with applicable NRC policy and procedures.

The NRC 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 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, 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

Section § 40.22, “Small quantities of source material,” is revised in its entirety. Under revised § 40.22(a), the general license is limited to thorium and uranium in their natural isotopic concentrations and depleted uranium. This differs from the previous § 40.22(a) which allowed possession of any naturally occurring isotopes of uranium and thorium in any isotopic concentration. In particular, Th-228, when isotopically separated, has the potential to present significantly higher doses because of its higher specific activity. The current provisions of

§ 40.22 may allow a person to receive quantities large enough in terms of activity to present a security concern without obtaining a specific license. The revised general license limits uranium and thorium to their natural isotopic concentrations or as depleted uranium to ensure that persons could not obtain significant quantities of high-specific activity source material in an isotopically separated form without the authorization and safety controls provided by a specific license.

Under the revised § 40.22(a)(1), the general licensee is limited to possession of less than 1.5 kg (3.3 lb) of uranium and thorium at any one time and 7 kg (15.4 lb) per calendar year for all uranium and thorium that is in a dispersible form or has been processed by the general licensee. A material is considered to be in a dispersible form if it can be readily ingested or inhaled (e.g., in a gaseous, liquid, or powder form) in normal or accidental situations or if it is processed in a manner such that the material containing source material is physically or chemically changed. Under the previous general license, assurance of safety was based primarily on two limiting conditions: 1) the amount of source material that could be used at any one time; and 2) the amount of source material that could 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. Both PRM-40-27 and the PNNL study suggest that situations could occur where the general licensee exceeded 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 or possession of source material 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. The petitioners indicated that resultant exposures for the source

material contamination were above the dose limits allowed to members of the public in 10 CFR part 20 and were possibly as high as 1 rem (10 mSv) per year.

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 NRC expects that the 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 new limits in § 40.22(a)(1) are intended to reduce the likelihood that a person operating under the general license will exceed dose limitations in 10 CFR part 20, and criteria in 10 CFR parts 19 and 20, that would normally require additional controls if the person were specifically licensed. Based upon the bounding dose calculations in the PNNL study, the NRC expects the reduction in the possession and throughput limits will significantly decrease the potential for a worker to be exposed at levels exceeding 1 mSv (100 mrem) per year. The reduction in possession and throughput limits also reduces the likelihood that a person will exceed the chemical toxicity limits for soluble uranium in § 20.1201(e) that would normally apply to an NRC specific licensee. 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) will be also be reduced. By reducing the amount of source material that is available for inhalation and ingestion, the NRC has concluded that the exemptions to 10 CFR parts 19 and 20 continue to be acceptable. The exemption to 10 CFR part 21 also continues to apply because 10 CFR part 21 addresses concerns that are unlikely to arise under § 40.22.

Under the final rule, persons currently possessing source material in dispersible forms, or processing source material, in quantities greater than 1.5 kg (3.3 lb) of uranium and thorium at any one time, or receiving more than 7 kg (15.4 lb) of uranium and thorium in 1 year, are required to obtain a specific license if they cannot reduce their possession and use of the source material to below the new limits. As a change from the proposed rule, in § 40.22(a)(1), a person requiring a specific license because of the reduction in possession limits has up to 1 year to apply for such license or reduce their possession of source material to below the new limits in § 40.22(a)(1). A person who decides not to apply for a specific license has additional time (up to the end of the calendar year following the effective date of the final rule) to reduce their throughput so that they are not affected by a mid-year change in a calendar year limit. A person applying for a new possession license is allowed to operate at the previous, higher possession limits until such license application is acted on by the NRC. This allows persons that require a specific license for initial distribution if currently operating under the general license to continue to possess and process source material while action on their license application is pending. It is expected that only a small number of persons currently possessing and using source material under the existing general license will be required to obtain a specific license for continued use of the source material as a result of the reduction in possession limits in § 40.22(a)(1). The NRC expects that most persons possessing source material above the limits in § 40.22(a)(1) are likely manufacturing products for use under exemption and, thus, will

already be required to obtain a specific license under the new distribution requirements in § 40.52.

Under the new § 40.22(a)(2), the general licensee is allowed to possess up to a total of 7 kg (15.4 lb) total uranium and thorium at any one time – this limit must include any inventory of source material possessed under § 40.22(a)(1). Any source material possessed in excess of the limits in § 40.22(a)(1) must be 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 by the general licensee. The licensee is limited to the receipt of no more than 70 kg (154 lb) of uranium and thorium per calendar year under § 40.22(a)(2), including the inventory of source material possessed under § 40.22(a)(1). If the licensee does physically or chemically alter the solid source material, that altered source material must 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 new § 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.

The rule language of § 40.22(a)(1) and (2) was revised in response to comments received on the proposed rule and to better clarify the new requirements. The intent and limits of the requirements stated in the proposed rule were not changed by the final rule.

Under § 40.22(a)(3), persons treating drinking water by removing uranium for the primary purpose of meeting U.S. Environmental Protection Agency regulations continue to be allowed to possess up to 7 kg (15.4 lb) of 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 drinking water will adequately contain the uranium and are not

expected to result in unacceptable exposures to workers. 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 are not impacted by changes in possession limits, they are required to meet the other requirements of the final rule. However, these persons continue to have multiple options for operating within the NRC's regulations, including operation under a specific license.

In response to public comments concerning the possible use of the general license by analytical laboratories and the potential unintended impacts of the proposed changes to their activities, a new paragraph (a)(4) has been added to § 40.22 in the final rule. This new paragraph allows laboratories operating under the general license to continue to receive, possess, use, and transfer up to 7 kg (15.4 lb) of source material at one time, and to process no more than 70 kg (154 lb) of source material per calendar year, for the purpose of determining the concentration of the uranium and thorium contained within the material; however, the constraint that this material be in its natural isotopic concentrations or in the form of depleted uranium is included. It is expected that these analytical laboratories deal with a number of hazardous chemicals and likely have procedures which would limit the likelihood of inadvertent exposures from the source material as well as the hazardous chemicals normally used. In addition, under the revised definition of "unrefined and unprocessed ore," a laboratory is allowed to analyze an unlimited amount of source material that meets the conditions of the exemption in § 40.13(b).

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

Under the revised § 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 might infer that disposal of source material by these general licensees may be exempt from regulation because 10 CFR part 20 includes requirements for waste disposal. However, there is no exemption from § 40.51 which includes transfer provisions for licensees (including general licensees) and thus disposal opportunities under the general license are limited to only those persons authorized to receive the source material. In § 40.22(b)(2)(i), the NRC is specifically prohibiting abandonment of source material, but allowing 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 is still required to meet the applicable regulations of other agencies regarding such disposals. The NRC concludes that such small quantities will allow general licensees who normally only possess very small quantities of source material at one time (e.g., uranyl acetate at educational institutions) to more economically dispose of the source material and will result in minimal impact to public health and safety because its form limits the ingestion and inhalation of the source material. The person receiving source material transferred under the provisions of § 40.22(b)(2)(i) is not 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 are 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 adding § 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 exportation of source material.

Additionally, 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 new condition in § 40.22(b)(4) obligates general licensees to respond to the NRC's written requests for information within 30 days or as otherwise specified in the request.

As identified in PRM-40-27, contamination may be 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, that a licensee might abandon significant amounts of source material in place. This abandonment could result in other persons that later inhabit the facility unknowingly exposing their workers or others to the source material contamination. As a result, the new § 40.22(c) requires the general licensee to minimize contamination at the site and ensure that the site is cleaned up so as to be protective of future worker and public health and safety. If the general licensee identifies evidence that there may be significant contamination, the licensee is 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 expects 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 § 40.22(d), the NRC continues to exempt persons generally licensed under § 40.22 from 10 CFR parts 19, 20, and 21, with the exceptions concerning disposal and decommissioning in revised § 40.22(b)(2) and (c). In addition, the NRC revised this exemption such that it no longer applies to any NRC specific licensee; in the current regulation only 10 CFR part 40 specific licensees are excluded. This modification is expected to provide minimal impact to specific licensees who possess source material under the general license, because they are already subject to 10 CFR parts 19, 20, and 21 for other licensed materials.

A.5 Revision of Exemption for Thorium Lenses

Paragraph (c)(7) in § 40.13 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. This position was restated in the statement of considerations (SOC) for a 1977 proposed rule, "General License for Government Agencies' Operational Use of Small Quantities of Source Material," (42 FR 43983; September 1, 1977). In that SOC, the NRC confirmed that the exemption in § 40.13(c)(7) was not intended to be applicable to coated lenses because the thorium was not evenly distributed in the finished lens. The SOC for final rule (42 FR 61853; December 7, 1977), did not change the position that the exemption applied only to thorium that is homogeneously spread throughout the lens.

In the past, the categorization of coated lenses was not a major concern because such lenses could be possessed under the § 40.22 general license which currently works similarly to an exemption. Because of the increased usage of coated lenses along with the planned new requirements introduced for the § 40.22 general license and for initial distribution, the categorization of coated lenses has become more important.

To clarify the regulatory status of these coated lenses and to address coatings on mirrors, the final rule makes three changes to the existing exemption: 1) it expands the exemption to include source material in *or on* finished coated lenses *and mirrors*; 2) it reduces the source material limit from 30 percent by weight to 10 percent by weight for products distributed in the future; and 3) it expands the exemption to include uranium. The remaining limitations on use 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 less than 10 percent by weight of thorium. The NRC has not been able to identify any manufacturers or distributors of lenses containing homogeneous amounts of thorium since 1980, because the industry appears to have moved to using thorium as a thin-film coating on the surface of lenses. The NRC's evaluation found that thin-film coated lenses contain a significantly lower total mass of thorium than that generally found in the same size homogeneous lenses. In addition, the NRC has learned that certain lens manufacturers also use thorium in combination with uranium to achieve desired properties. Although a coated lens does not contain the source material homogeneously within the lens (as is the case with lenses that may currently be possessed under the exemption), the PNNL study indicated that doses from both normal and accident conditions from lenses coated with either or both uranium and thorium were estimated to be well below 10 microsievert (μSv) per year (1 mrem per year). As a result, the NRC is expanding the exemption to include lenses, as well

as mirrors, with thin-film coatings and to also apply the exemption to lenses and mirrors containing uranium. The NRC's expectation is that the source material will be fixed onto the lens or mirror and not readily removed from the surface. The exemption prohibits, and will continue to prohibit, shaping, grinding, polishing, and any other manufacturing process other than assembling the finished lens into an optical system or device.

The final rule also revises § 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 will 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 (c)(2)(iii) in § 40.13 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 remaining NRC-licensed manufacturer for glassware

containing source material maintains concentration in its products to within 1 percent by weight uranium. This rule limits products manufactured in the future to no more than 2 percent by weight source material. This will have minimal impact on the industry, limited to any costs associated with ensuring and documenting that products do not exceed this limit. It will ensure that doses to members of the public exposed to products distributed for use under this exemption in the future would be unlikely to exceed 10 μSv (1 mrem) per year. This is more appropriate for products with minimal societal benefit and is consistent with the concept of as low as reasonably achievable (ALARA).

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 deleting exemptions for products that are no longer being used or manufactured, and is restricting further distribution while allowing for the continued possession and use of previously distributed items. The various products covered by the individual exemptions are described in NUREG-1717. 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 every day dinnerware.

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

Deleting the provision in § 40.13(d) simplifies the regulations by eliminating extraneous text. Also, the NRC 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 adds to the assurance that future use of products in these categories will not contribute to exposures of the public and also eliminates 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 new distributor requirements, it is difficult to confirm whether any distribution continues. This risk-based approach to exemptions is in line with the strategic plan of the NRC.

A.8 Revision of Definition of “Unrefined and unprocessed ore,” as Used in § 40.13(b)

Based upon comments received regarding the transfer of source material samples to laboratories, the NRC has included a clarifying amendment to the definition of “Unrefined and unprocessed ore” in § 40.4, “Definitions,” in the final rule to indicate that activities related to the sample analysis of an unprocessed ore and a few other specified activities are not considered to be processing and that the ore would remain exempt under § 40.13(b). This amendment alleviates potential violations where a laboratory may unexpectedly identify source material in an unprocessed ore that would normally require licensing but the laboratory does not already have a license for the unexpected source material; instead, the laboratory may treat the processed sample as unprocessed ore under the exemption in § 40.13(b). This change is consistent with section 65 of the AEA which states that “reports shall not be required with respect to (a) any source material prior to its removal from its place of deposit in nature, or (b) ...or the reporting of which will discourage independent prospection for new deposits.” The other examples of activities not considered to be processing, i.e., sieving or encapsulation of ore, are intended to provide examples of other activities which NRC has become aware of that were not intended to be considered processing when this definition was initially established. Sieving is considered to be a simple mechanical technique for separating particles of different sizes in an ore where the actual physical particles themselves are not modified (e.g., separating rocks from sand). Encapsulation would be an activity in which the unprocessed ore is coated, for example with glass or polyurethane, but again, the ore itself is not physically or chemically changed.

A.9 Other Revisions

Minor clarifying changes and administrative corrections have been made to rule language text from that found in the published proposed rule language.

B. *Whom Will This Action Affect?*

This final rule will 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 will 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 new possession limits or if they initially transfer products containing source material. The final rule exempts persons who possess thorium or uranium coated lenses or mirrors from licensing requirements for those lenses and mirrors through a revision to § 40.13(c)(7).

C. *When Do These Actions Become Effective?*

The regulations in this final rule become effective **[INSERT DATE THAT IS 90 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. However, persons requiring a new license for initial distribution have up to 1 year from this date to apply for a new specific license or discontinue such distributions. Similarly, persons in possession of source material in excess of the limits in § 40.22(a)(1) have up to 1 year from this date to apply for a specific license for possession with the previous throughput limit applying until action is taken by NRC on their license application. If they choose not to apply for a license, they have through December 31, **[the staff will insert the year that is 15 months after publication prior to sending to the *Federal Register*]**, to reduce the quantity of source material under their possession to below the new limits.

D. In What Situations Do I Now Need a License?

The new requirements in this rule require a person to obtain a specific license in three situations: 1) if the person is an initial distributor of source material to another person for use under an exemption in § 40.13(c); 2) if the person is an initial distributor of source material to another person for use under the general license in § 40.22; or 3) if the person possesses and uses source material in excess of the new limits in § 40.22(a)(1) and the source material is in a dispersible form or the material is processed such that it modifies the material's physical or chemical form. Normally a person requiring a specific license for initial distribution will also be required to obtain a specific license for possession and use of the source material.

E. With Whom Do I Apply for a Specific License?

For any activity requiring a specific license associated with the use of source material, persons located in a State under the NRC's jurisdiction are required to apply for the specific license in accordance with the requirements in § 40.31. Persons located in Agreement States are required to apply for possession and use licenses from the Agreement State in which they are located; however, persons located in an Agreement State who are initially distributing products containing source material for use under the exemptions in § 40.13(c) are also required to apply to the NRC for a specific license, authorizing the initial distribution of those products, in accordance with the requirements in § 40.31 (and specifically § 40.52 in this case).

Interim guidance related to these new requirements can be found in "Guidance for Implementation of the Final Rule, 'Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions,' in 10 CFR Parts 30, 40, 70, 170, and 171" (ADAMS Accession No. ML12172A120). Two volumes of the NUREG-1556 series will also be updated to provide final guidance related to this rule. NUREG-1556, Vol. 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt

Distribution Licenses,” and NUREG-1556, Vol. 16, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licenses,” both require minor revisions or supplementation. The staff is updating these guidance documents and will issue them for public comment.

III. Summary and Analysis of Public Comments on the Proposed Rule

The proposed rule was published on July 26, 2010 (75 FR 43425), for a 75-day public comment period that ended on November 23, 2010. The NRC published an extension notice on November 18, 2010 (75 FR 70618), that extended the public comment period until February 15, 2011, to allow time to review proposed implementation guidance that was announced on January 7, 2011 (76 FR 1100). The NRC received 15 comment submittals from 10 organizations and individuals. The commenters on the proposed rule included an individual, a radiation safety officer from a university, an Agreement State, and representatives of industry organizations and individual companies. Copies of the public comments can be accessed using any of the methods provided in the ADDRESSES section of this document. In general, all commenters opposed one or more aspects of the rulemaking. One commenter requested significant revision or withdrawal of the rule. Two commenters voiced concerns that the impacts of the rule will be widespread and more significant than the NRC envisions. One commenter did state that the process for initial licensing appears the same as that in place for exempt byproduct material, and that that process has worked well. The comments and responses have been grouped into the following areas: a) changes to the small quantities of source material general license (§ 40.22); b) distribution of source material for possession under a product exemption; c) distribution of source material for possession under the general license; d) exemptions; e) fees; f) miscellaneous; and g) future rulemaking considerations. To the extent

possible, all of the comments on a particular subject are grouped together. In the notice of proposed rulemaking, the NRC also specifically requested input on a variety of subjects. These questions are identified within the related response group, along with any comments received on the question. A discussion of the comments and the NRC staff's responses follow.

A. Changes to the Small Quantities of Source Material General License (§ 40.22).

A.1 Definition of "Person"

Comment: One commenter stated that the NRC issues the general license to organizations but places the quantity limitations under 10 CFR 40.22(a)(1) & (2) on "a person." The commenter stated that § 20.1003 defines a person as "[a]ny individual, corporation, partnership, firm, association, trust, estate, public or private institution, group... and any legal successor, representative, agent, or agency of the foregoing." The commenter suggested that if an organization can treat an "individual" as the general licensee rather than the organization itself, it would greatly reduce the potential problem of needing to obtain a specific license.

Response: Although the term "person" is used in these paragraphs of the general license and the definition of "person" identified by the commenter is the same definition as that included in § 40.4, the applicability of the general license is limited to "commercial and industrial firms; research, educational, and medical institutions; and Federal, State, and local government agencies," which is a subset of "person." The 1960 SOC for the proposed rule to revise 10 CFR part 40 (25 FR 8619; September 7, 1960), specifically identified the classes of users under the general license and stated that "[i]ndividual members of the general public therefore would not be generally licensed." Although the identified class of users has changed since that time, the general license authorized specific classes of users which still do not include individual members of the general public. However, a "person" under § 40.22 is not necessarily the

largest entity in a class of user. The SOC for a 1977 final rule (42 FR 61853; December 7, 1977), amending § 40.22 stated “[m]oreover, in order to permit the greatest flexibility in use of small quantities of source material under the general license, the rule does not restrict application of the general license to the largest unit in any class of person specified.” It continues “this general license is applicable to any size unit, other than individuals, which is physically separate from other units. The purpose of the physical separation is to make it unlikely that more than 15 lb of source material could be brought together in a single location.” Therefore, it is not appropriate to consider each individual in an organization as a separate general licensee. However, the NRC has normally considered separate facilities operated by the same entity to be separate general licensees, even if both facilities are in different parts of the same city.

A.2 Restriction to Only Naturally Occurring Isotopic Concentrations and Depleted Uranium

Comment: One commenter stated that by definition, the term “source material” as applied to uranium, already only includes natural uranium and depleted uranium. The commenter stated that the definition of “special nuclear material” effectively removed two isotopes (U-233 and U-235) from being source material. Similarly, the commenter stated that there are only 3 isotopes of uranium found in nature (U-234, U-235, and U-238) and that 11 other isotopes are only manufactured as a product of reactions occurring in nuclear reactors or accelerator produced and should thus be considered byproduct material.

Response: After review, the NRC agrees that uranium (other than that deemed special nuclear material) yielded from reactions in a nuclear reactor or that is accelerator produced should be considered to be “byproduct material” (under Section 11e.(1) and (3) of the AEA); this would also be true for isotopes of thorium yielded in a nuclear reactor or that are accelerator produced. Historically, the few persons that have possessed these separated isotopes of

uranium and thorium have held a specific license for both byproduct and source material that did not segregate the two types of materials and so a distinction was not necessary. Although the definition of “source material” by itself would appear to leave little question that any isotope of uranium or thorium would be considered to be source material, Section 62 of the AEA discusses requirements for licensing source material as beginning “after removal from its place in nature.” As isotopes of uranium and thorium yielded in a reactor or from an accelerator are not obtained from nature, the NRC believes that the intent of the AEA was for these isotopes to be considered byproduct material. However, the text of the final revision of § 40.22(a) remains as proposed because Th-228 is still considered to be source material and could be possessed under the general license, if § 40.22(a) were not revised in this way. In addition, because of the past ambiguity related to this issue, the revision would make it clear that these isotopes cannot be possessed under the general license in § 40.22.

The notice of proposed rulemaking included a specific request for comment on whether the limitation to natural or depleted uranium and natural thorium is the most appropriate way to prevent persons from obtaining source material radionuclides with high specific activities without applying for a specific license. In addition the specific request for comment asked if this approach would adequately protect public health and safety from, for example, thorium-230 (Th-230) extracted from ore high in uranium content.

Comment: One commenter indicated that the proposed description appeared adequate while a second commenter asked that relative to the example case regarding the potential use of Th-230 extracted from “high grade uranium ores” for some nefarious activity, if the NRC had any evidence that the toxicity of this isotope, a secular equilibrium daughter of U-238, is a significant health hazard at any concentration. The second commenter also stated that the benefit from developing uranium ore bodies to support nuclear power generation far outweighs the risk of terrorists utilizing a pure alpha emitter as a weapon of mass destruction. In addition,

the second commenter stated that it should be noted that currently unlimited quantities of one percent solutions of both natural thorium and natural uranium analytical metal standards may be purchased by non licensed facilities.

Response: The restriction of the general license to natural and depleted uranium and natural thorium will have no impact to the development of ore bodies. The question concerned whether this limitation was adequate to control both safety and security concerns with the possible high concentration of Th-230 relative to Th-232 normally dominant in natural thorium. The specific activity of Th-230 is higher than the specific activity of Th-232 or natural thorium, by roughly five orders of magnitude. Because of its low concentrations in ore, the NRC is not particularly concerned about Th-230 when contained within ores or ore wastes. However, as Th-230 could be independently separated from natural uranium and still be considered to be in its natural isotopic concentration, persons could potentially possess enough Th-230 under the general license to cause significant exposures. The NRC is currently not aware of any instances of this practice and believes that there is minimal probability of such occurring.

The statement about one percent solutions being available to non-licensed facilities is incorrect. These materials are likely being obtained and possessed under the § 40.22 general license and the revisions to 10 CFR part 40 will not change this. As there has been little communication with this category of general licensees in the past, and a person does not have to apply for a license, many persons are not aware of their general license status and may, instead, incorrectly infer that the material is possessed under exemption. Under the final rule, persons initially distributing source material for possession and use under the § 40.22 general license will be required to provide copies of the applicable regulations to their customers to inform the recipient about the requirements of the general license.

A.3 New Possession Limits

Comment: One commenter recommended that based on the general license being limited to only naturally occurring isotopes and depleted uranium, that there was no risk basis to lower the possession limits under the general license. The commenter argued that the primary human health issue with natural or depleted uranium is chemical toxicity and not radiological toxicity, making uranium's primary toxicological hazard no different than that of other heavy metals. The commenter supported its arguments with a reference to "Toxicological Profile for Uranium," (U.S. Department of Health and Human Services, Public Health Service Agency for Toxic Substances and Disease Registry; September 1999), with a supporting quote indicating that "uranium is a chemical substance that is also radioactive" and "no human cancer of any type has ever been seen as a result of exposure to natural or depleted uranium." The commenter also supported its argument by indicating that the chemical toxicity limits for uranium in § 20.1201(e) provided a lower limit than the limits established based on radiologic toxicity provided in 10 CFR part 20, appendix B, Table 1 for natural uranium and fully depleted uranium (U-238). The commenter indicated that these additional restrictions on uranium are not necessary and are being driven more by perceived radiological risk than real chemical risks. Similarly, the commenter added that NRC's concerns about thorium should be alleviated by the proposal to only allow natural isotopic concentrations of thorium under the general license without requiring the possession limits to be lowered, because natural thorium is predominantly Th-232 which has a very low specific activity.

Response: The commenter is correct that the NRC's regulations provide multiple limitations for source material in 10 CFR part 20 including toxicity limits in § 20.1201(e) and inhalation and ingestion limits based on radiological impacts in Table B of 10 CFR part 20. However, the current and revised § 40.22 both exempt the licensee from these requirements and instead institute the quantity possession limit. The additional chemical risks add to the

reasons for better controlling quantities of materials in a readily inhalable or ingestible form. If the inhalation and ingestion limits in Table B were implemented for general licensees instead of the current quantity limit, a licensee would be expected to incur additional costs and possibly be required to meet numerous other requirements in 10 CFR parts 19 and 20 that they are currently exempt from because the inhalation and ingestion limits in Table B are based on occupational exposures. For example, a licensee would likely need to meet the requirements in § 19.12, "Instructions to workers," to be consistent with NRC's health and safety protections to better protect workers who may exceed exposures of 100 mrem (1 mSv) per year. Because the regulation continues to exempt the licensee from the requirements in 10 CFR part 19, the NRC concluded that it is best to limit potential exposures to the extent possible below which instruction would normally be required by § 19.12. Additionally, if the limits in Table B were applied, the licensee would need to purchase appropriate monitoring equipment and likely need to obtain the services of a health physicist to ensure that the limits are being met. The reduced possession limits also help to ensure that general licensees will not exceed the chemical toxicity limit in § 20.1201(e). The PNNL report used reasonable assumptions based on 150 lb of uranium being received in a calendar year in their scenarios; using these same assumptions for uranium intake, the NRC has concluded that the weekly average inhalation levels of uranium should be below the limit in § 20.1201(e) for uranium. The reduction in the possession and throughput for dispersible source material further reduce the chance of this limit being exceeded without having to require more elaborate monitoring that may be required if the limit in § 20.1201(e) were used instead as a control. Finally, the lowered limits were also chosen to limit the likelihood of large amounts of contamination being left behind by a general licensee, which could result in a later property owner unknowingly exposing his employees to the radiological contamination.

Comment: Four commenters identified potential impacts on industries from the proposed reduction in possession limits. One of these commenters indicated that chemical suppliers routinely sell uranium and thorium compounds in quantities of 25 to 250 g and, in the past, sales of quantities of 500 g were not unusual, thus it would be easy for universities or large institutions with many laboratories to quickly exceed the new possession limits. Another of these commenters voiced concern that their customers may be modifying exempt products under the provision of the general license, but may no longer be able to do so under the reduced limits in the proposed § 40.22(a)(1) limits. Two of these commenters also indicated that it would be difficult for analytical laboratories and their customers who rely on the current general license to stay within the new limits, thus potentially driving up industry costs. One of these commenters indicated that the restrictions on the end user seemed rather harsh and would be very limiting for research and steel industry users, as well as manufacturers of various ceramic valves and coatings for the steel industry and manufacturers of metal halide lamps.

Response: The records that were voluntarily provided by the largest supplier of generally licensed thorium and uranium identified by the NRC showed that relatively few general licensees were receiving quantities near the existing limits, and that many were receiving much lower amounts. The revised regulations will allow a person to possess up to 1.5 kg (3.3 lb) of uranium and thorium in any form. A monthly transfer of 500 g (1.1 lb) would not reach the throughput limit of 7 kg (15.4 lb). Most general licensees with a significant throughput that exceeds the new limit are very likely manufacturers of products or distributors that would be required to obtain a specific license because of other provisions in the final rule. In practice, some general licensees who use uranium and thorium in the form of ore (considered by definition to be source material in its entirety) will actually see allowable possession limits significantly increase under the final rule because they only need to account for the mass of the uranium and thorium itself rather than the ore mass. In addition, the final rule includes a

provision specifically for analytical laboratories, which essentially maintains the limits, in order to reduce unforeseen impacts on that particular category of user.

Comment: One commenter stated concerns that while the inventory reduction in § 40.22(a)(1) from 15 lb to 3.3 lb was a 78 percent reduction, the reduction in the annual receipt limit from 150 lb to 15.4 lb was a 90 percent reduction. The commenter indicated that the reason for this discrepancy was unclear and that to be consistent the NRC should only reduce the annual usage threshold to 33 lb in the proposed § 40.22(a)(1).

Response: There is no historical record of a specific rationale for the ratio; therefore, maintaining the ratio of quantity limit to throughput limit was not considered to be important in establishing the criteria for the revised rule. For readily inhalable or ingestible materials, intake and contamination likelihoods are typically more related to throughput than the maximum quantity of source material present at any one time. On the other hand, external hazards are more directly related to the quantity present. As a result, the NRC concluded that the greater reduction in the annual throughput level for dispersible source material was merited. The new limits were developed using the bounding doses calculated in the PNNL study by reducing possession limits by a factor that would limit the likelihood that a person could possess source materials in quantities that would result in doses exceeding 100 mrem (1 mSv) per yr. Additionally, activities involving larger throughput are generally going to involve distribution, which will be required to be done under the authorization of a specific license under the final rule; as a result, the NRC expects that only a few persons will be directly impacted by the reduction in possession limits.

A.4 Clarification of Chemical or Physical Form

Comment: One commenter requested clarification of what would constitute chemical, physical, or metallurgical treatment or processing. The commenter provided an example that

some of its customers using thoriated tungsten alloys under § 40.13(c)(4) may very well perform some sort of physical operation on the piece (e.g., machining, heat treatment, welding, etc.), which would appear to invalidate the § 40.13(c)(4) exemption. However, the amount of thorium sold to those end users typically meets the current definition of small quantities in § 40.22, thus they do not require a specific license. The commenter recommended that, in order for users of source material under § 40.13(c)(4) and § 40.22(a)(2) to better understand the limitations on the use of source material under these paragraphs, that the NRC provide a clear definition in § 40.4 of “altering chemical or physical form” and “chemical, physical, or metallurgical treatment or processing.”

Response: Although the rule is not amending § 40.13(c)(4), as the commenter indicated, § 40.13(c)(4) does not authorize the chemical, physical or metallurgical treatment or processing of a product possessed under the exemption, similar to the constraint proposed in § 40.22(a)(2). Under this exemption, an activity such as machining or heat treatment, where the primary purpose of the action is to modify the product, is not allowed; however, welding the final product to another component would be acceptable even though there might be slight modifications of the product while installing it as intended. As also indicated by the commenter, these activities could be accomplished under the general license in § 40.22; however, the resulting products, if distributed for further use under the exemption in § 40.13(c)(4) or another exemption, would require the person modifying the product to obtain a § 40.52 distribution license because it would be considered to be the initial distribution of a new product. If the person physically or chemically modified the material containing source material under § 40.22, but does not plan to distribute the new product for use under an exemption, the person would be subject to the lower possession limits found in § 40.22(a)(1) because they actively processed the source material. The NRC believes these restrictions are necessary because chemically or physically processing material containing source material may increase the likelihood of some

source material entering into forms that could be more easily ingested or inhaled. If the person were allowed to modify the exempt product without restriction, the person could create unanalyzed health and safety issues for his workers or the public (particularly in the form of accumulated contamination that may be more easily ingested or inhaled). Rather than broadly restricting these modifications, the NRC could instead implement limits on inhalation and ingestion to prevent exposures; however, such requirements would likely introduce additional costs in the form of air monitoring equipment and the need for a health physicist. As a result, the NRC concluded that limiting possession limits by use (chemical or physical alteration) would be easier and less costly for the general licensee to identify when the lower limits were necessary. The NRC has also concluded that the terms “altering chemical or physical form” and “chemical, physical, or metallurgical treatment or processing” are sufficiently clear and do not require a specific definition in § 40.4.

A.5 Disposal of Source Material under General License

Comment: One commenter requested clarification as to whether the disposal limit of 0.5 kg (1.1 lb) of source material proposed in § 40.22(b)(2)(i) applies to just the uranium or thorium content or to the material which contains the uranium and thorium.

Response: The limit is intended to account for only the mass of the uranium and thorium and not the material that contains the source material.

Comment: One commenter stated that the proposed disposal limit of 1.1 lb, only in a non-dispersible form, was very restrictive. The commenter indicated that most users would have to resort to expensive disposal options as a result of the rulemaking, including certain government agencies that collect this material from schools and labs for disposal.

Response: Unrestricted disposal of source material was never specifically permitted under the § 40.22 general license. Although § 40.22 provided an exemption to the requirements

in 10 CFR part 20, a general licensee was still required to make transfers in accordance with § 40.51, which requires the transfer be to someone authorized to receive the source material. The revised § 40.22 clarifies the disposal requirements and adds an allowance for very small quantities. As a result, schools and laboratories should be able to do direct disposal of their very small quantities of source material rather than requiring state government agencies to collect the source material. There are no restrictions in the general license that prevent the possessor from modifying the form of the source material to place it into a solid form or other appropriate form for the chosen disposal pathway.

In the notice of proposed rulemaking, the NRC proposed in § 40.22(b)(2)(i) that quantities of source material greater than 0.5 kg (1.1 lb) per year would be required to be disposed of as radioactive material through the provisions of § 20.2001 or transferred to another person otherwise authorized to receive the source material. The notice of proposed rulemaking asked if the NRC should consider other disposal alternatives for these larger quantities, such as in U.S. Environmental Protection Agency's Resource Conservation and Recovery Act (RCRA) Subtitle C hazardous waste disposal facilities or RCRA Subtitle D municipal Solid waste landfills. The following comments were provided in response to this question:

Comment: One commenter recommended that given the low radioactivity of source material, the NRC should consider a wide variety of disposal options. These options already include disposal in sanitary sewers and could also include uranium mill tailings impoundments, processing as alternative feed, and other types of disposal sites that can safely contain the material. A different commenter recommended that the NRC should establish guidelines for municipal landfills to accept naturally occurring radioactive material (NORM), not covered by the AEA, and certain forms of source material and byproduct material based on a combination of mass and activity.

Response: Many of the suggested disposal alternatives have been used to dispose of source material from specific licensees, after receiving authorization from the NRC, including disposal at Resource Conservation and Recovery Act subtitle C facilities. The general licensee may request approval for alternative disposals under § 20.2002, “Method for obtaining approval of proposed disposal procedures.”

With the exception of source material and discrete sources of radium-226, all other NORM is currently not subject to the NRC’s regulations. The NRC can only exempt persons from the requirements of NRC’s regulations, including those regulations related to specific disposal requirements for radioactive material, if the material under consideration is subject to the NRC’s jurisdiction. Local jurisdictions have separate authorities that may come into play that may limit the disposal of materials containing source material (and other radioactive materials) at municipal landfills or other locations.

A.6 Contamination Control

In the notice of proposed rulemaking, the NRC requested specific comments on whether the NRC should 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.

Comment: One commenter indicated that the enforcement aspects of the rulemaking needed to be further explored because the proposed requirement in § 40.22(c) had no enforcement value whatsoever. The commenter indicated that because there is no requirement to possess or use survey instruments, much less perform a closeout survey, most general licensees may be long gone before any contamination is located by authorities. The commenter recommended that if the proposed possession limit poses a significant enough contamination hazard, the source material should not be allowed to be possessed under a general license and should instead be required to be possessed under a specific license.

Response: The NRC is hesitant to require all users of source material to formally survey their locations upon cessation of activities because many persons likely conduct activities with source material where there is little concern regarding contamination. The intent of the requirements in § 40.22(c) are to allow a general licensee to consult with the regulator to determine if surveys are necessary. Under the regulations currently in place, there are no clear requirements for a general licensee to take any decommissioning action because of the current exemption to the requirements in 10 CFR part 20. Although the NRC could limit operations under the general license such that contamination is unlikely by limiting the use of source material to only non-dispersible forms and not allowing any processing, such limitations would significantly reduce the benefit of the general license while increasing the costs to licensees who would then require a specific license. The NRC has concluded that the reduced possession limits will satisfactorily limit most contamination concerns while the requirements proposed in § 40.22(c) will allow the regulator to have a specific regulation to enforce in rare circumstances where contamination is detected. As a result, the NRC concluded that no changes to the proposed version of § 40.22(c) are necessary. If highly contaminated, abandoned sites that operated under a general license continue to be identified, the NRC may reconsider this requirement.

A.7 Initial Distribution and Transfer under § 40.22(e)

Comment: Two commenters stated concerns about the requirement proposed in § 40.22(e) that a person, initially transferring or distributing source material to a person receiving the source material under the general license in § 40.22, would be required to obtain a specific license for distribution under the proposed § 40.54. Their concerns were focused on transfers of samples containing source material to analytical laboratories. One of these commenters also voiced concerns about the potential impact on calibrators using depleted uranium sources. The

commenter was concerned that calibrators may encounter additional problems or expense obtaining calibration sources because organizations that distribute calibration disks made of depleted uranium under a general license would be required to obtain a specific license increasing costs to calibrators. The same commenter was also concerned that laboratories that provide standards for use under the general license would also be required to obtain a specific license for distribution thus increasing costs for their customers. The other commenter requested clarification on whether a driller identifying uranium ore deposits would require a specific license to distribute samples for analytical characterization. Both commenters believed this requirement could have significant impacts on the persons exploring for and mining uranium and that it could increase costs to their customers or deal a death warrant to exploration.

Response: The NRC acknowledges that some persons operating under the § 40.22 general license and their customers may have increased costs as a result of needing to obtain a specific license for distribution of their products, including calibration sources. However, the NRC has concluded that the benefit of being able to identify who is distributing source material, and how much material is being distributed, outweighs those increased costs because it will allow the NRC to better ensure that the products do not significantly impact public health and safety.

The NRC acknowledges that the proposed rule would have resulted in an unclear situation concerning the transfer of analytical samples to and/from laboratories, particularly in relation to sampling ores where the source material content level would not be known until the sample is analyzed. Although no laboratories provided comment on the proposed rule, other commenters indicated that some analytical laboratories may currently operate under a general license rather than a specific license and thus a person providing samples to the laboratory may need a distribution license under the proposed requirements. In addition, a laboratory operating under a specific license that returns samples to a general licensee would also have been

required to obtain a distribution license under the proposed requirements. The NRC agrees that this would be overly burdensome for those parties and has revised the final rule to maintain the current limits for laboratories doing sample analyses by creating a separate provision for laboratories in § 40.22(b). The NRC concluded that reporting such common transfers would not provide sufficient benefit versus the burden associated with obtaining a specific license. As a result, § 40.22(e) allows initial transfers of source material to or from a general licensee for the purpose of analytical sampling without a § 40.54 (or equivalent) specific license. However, this would not change the need for a laboratory to obtain a distribution license issued under § 40.54 if the laboratory manufactured and initially transferred standards or calibration sources containing source material for use under the § 40.22 general license.

B. Distribution of Source Material for Possession under a Product Exemption.

B.1 Requirement to Obtain a Specific License for Distribution to Exempt Persons Only from the NRC

Comment: Four commenters questioned the requirement that they may only obtain a specific license from the NRC for distribution of products containing source material to persons receiving them under exemption even if they are located in an Agreement State. The commenters voiced concerns that this would lead to unnecessary dual jurisdiction (having to obtain a possession and use license from the Agreement State and a distribution license from the NRC), result in the need for significant procedure modifications, and could lead to confusion as to which agency's requirements were applicable. Two of these commenters stated that their Agreement State license already authorized them to distribute their products. Further, the commenters were concerned that the additional costs associated with obtaining and maintaining the second license could result in products being noncompetitive, particularly in the international

marketplace. The commenters requested that this requirement be reconsidered to allow the Agreement States to issue such licenses.

Response: When the Agreement State program was implemented with the publication of 10 CFR part 150 (27 FR 1351; February 14, 1962), the authority to regulate distribution of products intended for use by the general public was reserved to the Commission, then the Atomic Energy Commission, in § 150.15. Later, § 150.15(a)(6) was expanded to apply to all products for which the user is exempt from licensing requirements (34 FR 7369; May 7, 1969). However, before the current rulemaking, the NRC had not established any requirements specific to distribution of exempt products for source material; thus, the NRC did not require manufacturers and distributors in Agreement States to obtain NRC licensees. Although the case of distribution of exempt products from Agreement States will require the distributor to get two licenses, one from the NRC and one from the State, there is no dual jurisdiction over the same activities. In this situation, the NRC concerns itself only with what is being distributed and actions necessary to ensure that the product(s) is safe and within any constraints of the exemption, while the State regulates such matters as in-plant safety, emissions, and decommissioning. This regulatory system has been in place and working effectively for decades in the case of byproduct material. In the absence of NRC regulations over the distribution of source material to exempt persons, some States may have included some license conditions that pertain to distribution. If this is the case, these requirements should be removed from the Agreement State license when the distributor comes under an NRC distribution license. Current distributors of source material to persons exempt under § 40.13(c) (and equivalent Agreement State provisions) have a year after the effective date of this rule to apply to NRC for the required license in order to continue distribution. This will allow time to answer questions and resolve any confusion as to which agency's requirements are applicable. This change should not require significant procedural modifications, presuming that the distributor was

already ensuring that its product met any constraints in the exemptions. Furthermore, these requirements only cover domestic distribution and are not applicable to international distribution. Competitors that manufacture or import similar products for distribution will be required to meet the same requirements, thus there should be no competitive disadvantages.

Comment: Three commenters indicated that they already held possession and use licenses issued by an Agreement State. The commenters stated that this rule would add excessive costs by requiring the licensee to prepare and submit an application to the NRC for a specific license to distribute products under exemption and also introduce costs for modifying their procedures and existing programs to accommodate the rule's additional requirements. One of these commenters estimated that these costs (including new annual fees) would add more than \$37,000 per year to their current annual regulatory costs. The costs were broken down to include \$5,000 for preparation of the application, \$7,000 for the application fee, and at least \$25,000 to modify existing procedures to incorporate both NRC and Agreement State regulatory requirements and to train employees accordingly. One additional commenter indicated that it did not currently possess a specific license from an Agreement State and, under the proposed rule changes, would need to bear the new costs of procuring and maintaining a possession license from the Agreement State and an NRC distribution license. Associated costs would include application fees, annual fees, and the cost of developing an Agreement State-focused compliance program.

Response: The NRC acknowledges that some persons currently operating under the current general license will be required to obtain new licenses for both possession and use as well as for initial distribution or transfer. As indicated by the comments, in the case of a person, located in an Agreement State, who initially distributes source material to exempt persons, the person may be required to obtain separate licenses from two regulatory agencies (one from the Agreement State for possession and use, and a separate license from the NRC for distribution).

When proposing the rule, the NRC considered these costs and believes that there are significant benefits to requiring a distribution license. The requirements will better ensure that products being distributed meet the constraints of the exemptions and will allow the NRC to accumulate information about the amount of, and to estimate the impacts of, source material being distributed for use under exemption. This information will then be used to make better informed regulatory decisions concerning the distribution of products to be used under exemption. Some of the costs noted by the commenters are actually onetime costs, such as those costs for preparing and submitting the application, and do not continue annually. However, as a commenter identified, there are new annual fees. Those fees are expected to be significantly less than the \$37,000 described by the commenter. In the past, costs of the resources spent in attempts to gather information about these products and to estimate the extent and the conditions of their use would be recovered from fees for other activities that the NRC regulates. Thus, this rule would also improve the equitability in the charging of fees.

As discussed in the previous response, the need for two licenses cannot be avoided; however, because each agency will have separate roles, there is not expected to be any significant or conflicting duplicative regulation.

B.2 Obligations of the Distributor of Source Material to Persons Receiving it under an Exemption

Comment: Four commenters voiced questions about the obligations of a person initially distributing products to a person for use under the exemption if the recipient subsequently modifies the product (presumably in compliance with the § 40.22 general license). The commenters questioned whether they would be considered as the initial distributors of material for use under the § 40.22 general license and thus obligated to obtain a specific license under § 40.54 (or its Agreement State equivalent) along with their § 40.52 distribution license. One of

the commenters was also concerned that if there is an obligation to determine how a product is used by the recipient, particularly in light of the understandable reticence customers may have with sharing information about their operations, the initial distributor may be forced to undertake undue burdens. One of the commenters stated that this issue could result in increased enforcement risk. The commenters requested that the rule or guidance be written to clearly absolve the initial distributor of products containing source material and received under an exemption of any responsibility of determining the licensing status of the end user of their products. One of the commenters also requested that the proposed rule be modified to clearly specify the limits of a specific licensee's liability with respect to the requirements of § 40.51(c) and (d).

Response: An initial distributor of source material may only transfer source material in accordance with the requirements in § 40.51. If a distributor transfers a product that meets the conditions of an exemption to a recipient that is authorized to receive the source material under an exemption from licensing, then the initial distributor has met its obligations. If the recipient subsequently uses the product in a way that is inconsistent with the exemption (e.g., modifies a product in a way that the exemption does not allow) or contrary to the requirements of other regulations (e.g., a specific license or general license), the recipient would be solely responsible for its misuse. In some cases, persons who receive a product for use under an exemption may modify it under the general license in § 40.22; however, if they subsequently transfer the modified product for use under an exemption, the transfer would be considered an initial transfer of a new product and the person who modified the product would require a specific license for initial distribution under § 40.52.

B.3 Construction and Design Information

Comment: Four commenters indicated concerns with the requirements in the proposed § 40.52(b) which would require a licensee distributing exempt products to provide details of the construction and design of each product as part of the license application. The commenters indicated that submitting such information on every product may be impracticable because they manufacture a large number of different products of similar type (e.g., lenses of different shapes and sizes), many of which may be manufactured infrequently or even on a one-time basis to meet customer specifications and are subject to change during the production process. The commenters are concerned about the excessive burden if they had to amend their license each time they developed a new design. The commenters requested clarification and guidance on whether more generic information about their operations and products, rather than model specific information, would be considered acceptable as a means of avoiding multiple license amendments.

Response: The exemptions in § 40.13(c) cover a wide range of products. Only in limited cases are these manufactured as specific models with model numbers. When such products are distributed, the model information makes the recordkeeping and reporting aspects more efficient; however, the NRC does not intend to create a situation where licensees must amend licenses frequently because of normal variations in products. Because of the variety of product types identified in § 40.13(c), the extent of information to be provided about the details of construction and design may vary depending on the product. If there are significant variations in similar product types planned to be initially distributed, an applicant should provide some general information on the ranges of sizes and weights, or lists of models with more specific information. For some products, such as welding rods; rare earth metals, compounds, and mixtures; and glassware, sufficient information may include a description of the product and variations planned to be distributed. For other products, such as incandescent gas mantles,

electric lamps, and tungsten parts, drawings and other details of the products may be necessary in addition to a description, because such additional information may be important in evaluating the safety of the product. Operating manuals, descriptive sales literature, or similar documents may be submitted as part of an application. If applicable to the type of product, the applicant should describe construction aspects of the product, including components of the product, materials of construction, dimensions, and assembly methods, particularly if a product may depend upon certain design considerations to meet the conditions of the exemption or increase safety. An overall drawing of the product identifying primary components and indicating overall dimensions may be useful as a complement to the written description of the product.

B.4 Labeling

Comment: Three commenters provided comments on the proposed requirement in § 40.52(b)(4) that an applicant or licensee provide the proposed method of labeling or marking for 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. Specifically, the commenters requested clarification if the requirement means that the label can simply state that “this product contains source material” or if the specific source material type (e.g., thorium or uranium) and concentration are required to be on the label. One of the commenters was concerned that specifying the type or concentration of source material on the label could unnecessarily alarm users who may not understand the weight designation or are unable to comprehend that the amount listed on the label is a trivial amount of activity. All three commenters requested that the guidance be modified to provide better clarification regarding the expectation for labeling. Four commenters stated that there would be significant costs associated with designing new packaging that meets the new labeling requirements. One commenter indicated that it would be

difficult to estimate packaging costs in light of the fact that many of their products are small, infrequent and/or “one time only” orders.

Response: Only two of the exemptions currently have labeling requirements specified by the exemption itself: 10 CFR 40.13(c)(5) for counterweights, and 10 CFR 40.13(c)(6) for shipping containers. Paragraph (b) of 10 CFR 40.53, “Conditions of licenses issued under § 40.52: Quality control, labeling, and records and reports,” requires that products be labeled to meet the constraints of the exemptions. In 10 CFR 40.52(b)(4), the NRC requires all applicants to submit information on labeling to identify the manufacturer or distributor and the source material. Similar requirements already exist for the distribution of byproduct material and applicants typically provide samples or copies of labels or packaging, although descriptions could be acceptable. The NRC does not intend to make significant changes to industry practice with this requirement. Many of the products covered by the exemptions are not practical to label; and it is possible that in some cases only the packaging would be labeled. Glassware is typically labeled either with impressions or small stickers to identify the manufacturer. For some products, the initial recipient would need some information about the identity and quantity or concentration of source material. In such cases, packaging or accompanying paperwork would provide the information. In most cases, the identification of the manufacturer or distributor and the fact that thorium or uranium is present should appear on point-of-sale packaging. The term, “source material,” should not be used in lieu of “uranium” or “thorium.”

B.5 Instructions on Safe Handling and Radiation Safety Precautions

Comment: Two commenters requested clarification on what would be considered acceptable in meeting the requirement in § 40.52(b)(5), which requires that the distributor provide information on safe handling and radiation safety precautions. The commenters stated that they currently provide such information in Material Safety Data Sheets (MSDSs). The

commenters were not sure if this requirement meant that the information needed to be placed inside each container or whether the information could be provided as part of other purchase documentation or just referenced as being available for review. In addition, the commenters stated that it was not clear whether this information had to be provided before the purchase or only along with the purchase. One of the commenters requested that the NRC consider requiring only annual submittals to the customer instead of including them with each shipment.

Response: The requirements in § 40.52(b)(5) require the inclusion of radiation safety precautions and instructions relating to handling, use, and storage of products to be used under § 40.13(c)(1)(i) and (iii), which apply only to thorium contained in gas mantles and welding rods. The commenter's concerns appeared to be associated with coated lenses, which the commenter's company manufactured – as such, the requirement in § 40.52(b)(5) will not apply to their products because the products are not welding rods or thorium mantles. In the case of welding rods and thorium mantles, safe handling instructions can aid in significantly reducing exposures associated with usage. Under § 40.52(b)(5), the NRC would expect individual packages to be labeled or include safety instructions because these products may often be sold through intermediary distributors. In the case of welding rods, the MSDS would be an acceptable means of informing users; provided that the radiological aspects of hazards are specifically addressed in the MSDS.

B.6 Quality Control

Comment: Four commenters stated that there would be significant costs for developing and implementing a quality control program as required in § 40.52(b)(3). One commenter estimated the associated costs would add more than \$30,000 to their existing product quality control program. These costs were broken down as \$10,000 per year for sample analysis,

\$10,000 for program development/management, and \$10,000 for data management, verification and reporting.

Response: The new requirement in § 40.52(b)(3) only applies to those products where there is an applicable quantity or concentration limit associated with the product exemption. The information necessary to satisfy this requirement would only need to describe how the manufacturer will ensure that the product does not exceed the limits associated with the exemption and is likely already accomplished under existing quality control programs. The assurance may be shown through calculation, description of existing quality assurance programs, or, if necessary, through batch sampling. The NRC expects that most manufacturers would already have some quality assurance program in place to ensure that the customer is receiving what is advertised and, therefore, it is not anticipated that there would be significant costs associated with providing assurances that the limits are met. For example, the NRC expects that most optics require a relatively high precision on the amount of source material that is contained in a coating in order to achieve the desired optical effect and that procedures are used to ascertain that the amount is correct. A description of these procedures or how this precision is achieved would be sufficient to satisfy the requirement for describing the quality control program. As a result, the NRC expects that, in most cases, the added costs from this requirement would be minimal.

B.7 Annual Reports

Comment: Three commenters indicated that the requirement to provide an annual report to the NRC, as proposed in § 40.53(c), would result in significant burden to their operations. The commenters stated that, contrary to the NRC's conclusion in the notice of proposed rulemaking, the information requested was not part of their existing business recordkeeping practices and therefore the information would not be a minimal burden to

provide. One commenter indicated that they sold optics with thorium coatings and without thorium coatings and that this requirements would result in the commenter needing to institute separate tracking and reporting systems for both types of optics. The commenters indicated that they would have to develop, implement, and staff a data acquisition management system for which they would have no need other than this rulemaking at a cost of significant resources.

Response: The NRC recognizes that a distributor's current data handling system may not be designed to provide the required information; but, with the capabilities of current information technology, the NRC expects information could be readily assembled and provided in a form and content that is acceptable to the NRC without imposing significant burden on the licensee. In the past, the NRC has occasionally requested distributors of source material to general licensees to voluntarily assemble and provide not only product and quantity information, but also to provide information about recipients of the source material. These distributors were able to fulfill requests without significant notice and did not voice concerns about the burden associated with the requests. Under § 40.53(c), distributors of products for use under an exemption are not required to submit as much information, as there is no obligation to submit information about customers. The NRC does not expect the distributor to have to develop, implement, and staff a data acquisition management system to fulfill this requirement and leaves it up to the distributor how best to fulfill the requirement. Byproduct material distributors have been required to submit such reports for decades. Also, source material distributors have one year to apply for a license, and are not required to submit such a report until the year after their specific license is issued, which should allow the distributors sufficient time to develop cost-effective systems to meet the requirement. The information to be provided in these reports is important for the NRC to understand how much source material is distributed for use under exemption and to ensure that the products distributed for use under exemption are and continue

to be safe. The NRC has concluded that these benefits outweigh the costs associated with providing this information.

Comment: Four commenters requested clarification about the level of precision that was expected under the proposed requirements in § 40.53(a) and (c)(3)(ii). The commenters indicated uncertainty as to whether each item had to be assessed individually or if they could provide alternative verifications and indicate that the amount of source material was below the percentage or quantity limit. The commenters were concerned that being required to determine the actual source material content on a per product or batch basis would increase the contamination potential of operations and increase the product costs, delivery times, and personnel exposures. The commenters requested that guidance clarifying these requirements be provided and recommended that the NRC allow the reporting of nominal concentrations (i.e., less than 10 percent) or quantities rather than product specific numbers or per individual product in the annual report. One commenter also requested clarification on whether the reporting units should be weight percent (i.e., ppm) or activity (i.e., Ci or Bq).

Response: Simply providing information that the source material was below a concentration or quantity limit would not generally be acceptable. The better the characterization that can be provided by the distributor, the better the NRC will be able to refine its estimates of impacts to the public from exempt products in the future. However, the intent is not to require additional sampling or any significant analysis that is not already performed. The form of the information that is appropriate will vary for the type of product. Nominal values for specific products and total quantity of source material distributed in those products may be adequate. If products can be categorized by type, one approach may be to give the range of source material content for each type and provide the total quantity for each type distributed. While information on weight percent may be provided, total weight would also be needed to meet the requirement of reporting the total quantity of source material in each type of product.

While it would be more convenient for the NRC to receive information in consistent units from all distributors, the final rule does not specify the units so as to allow distributors to report in whatever units they are currently keeping records.

Comment: Four commenters stated concerns about the requirements in the proposed § 40.53(c) that require the distributor to provide the NRC with annual reports detailing who their customers were and frequency, type, and amount of sales to those customers. The commenters indicated that this was proprietary information which would have to be submitted as such and would be burdensome.

Response: The proposed § 40.53(c) does not contain any language that would require the submittal of customer information or any information specifically related to individual customers. This was not changed in the final rule. The commenters also addressed a similar concern with respect to the annual reporting requirement proposed in § 40.55(d), which applies to initial distributors of source material for use under the general license in § 40.22. The § 40.55(d) reports must include information about certain customers and frequency, type, and amount of sales to those customers. A response to that concern is provided in section III.C.4, of this document.

Comment: One commenter indicated that the reporting requirement in § 40.53(c) appeared to be parallel to the general licensing reporting system currently in place for devices containing byproduct material. The commenter requested clarification on what kind of regulatory oversight is intended for these reports. For example, would the NRC and the Agreement States need to establish databases and tracking systems and would there be inspections in the field?

Response: Although the NRC may develop databases internally to evaluate reports, the NRC does not plan to institute a database capable of tracking materials similar to that currently used for tracking generally licensed devices containing byproduct material. The reporting

requirement in § 40.53(c) parallels the various 10 CFR part 32 reporting requirements concerning distribution of products for use under the exemptions from licensing in 10 CFR part 30. The NRC plans to periodically aggregate the collected information related to distribution of products to exempt persons and assess the information to ensure that the exemptions are being properly used and that the overall impact of all such products is not inappropriate. The data would also be analyzed to determine if additional changes to the regulations are required to improve or verify the safety of the exemption. Although field inspections solely to verify records of transfers are not envisioned as a normal practice, review of a licensee's recordkeeping practices may be included as part of any routine inspection of the specific licensee.

B.8 Cost/Benefit Considerations

Comment: Four commenters provided comments regarding their concerns about costs associated with implementing the proposed new requirements. One commenter argued that the summations of the additional costs will impact the competitive nature of their products in the national and international marketplace. Two commenters stated that they were not convinced that the risks associated with the use of source material under the current regulations, as described in NUREG-1717, justified the significant costs that would be associated with implementing the proposed rule requirements. One of these commenters added that their products, which entailed the use of thorium in finished optics, were estimated to be well within the range of normal background radiation exposures incurred by the U.S. population. Another commenter summarized that it was not clear how the benefits of the proposed rule, in light of the trivial risk of using their products, outweigh the significant increase in cost. This same commenter was also concerned that due to the contractual nature of their business, they may

not be able to recover costs until their current contracts expire thus placing them in financial jeopardy.

Response: The costs of these requirements are projected by the NRC to be less than the costs indicated by the commenters, who mostly represent the optics industry. Some of the costs attributed to the rule by commenters are in fact due to clarification of the existing rules. For example, there was confusion as to the applicability of the exemptions for coated lenses. Because of how the general license in § 40.22 previously stood, it was not always necessary or practical to clarify when someone was covered by an exemption or if they in fact were using a product under the general license.

Although products used under exemptions from licensing generally present low risks, comparison with normal background radiation exposures is not adequate for judging the acceptability of these products. It has been difficult for the NRC to adequately ensure that the products distributed are as they should be, and that the overall impact to the public from all of the products distributed for use under exemption is acceptable. Requiring distributors to be specifically licensed and to provide transfer reports will greatly improve the NRC's ability to do these things and will improve the efficiency and effectiveness of the NRC in carrying out these responsibilities. The NRC has to the extent possible, with only incomplete information available, designed this rule to minimize the impacts on industry while establishing a basic regulatory framework for control of distribution of source material to exempt persons. Finally, although the distributor may undertake some additional costs, they will have one year to submit a license application and additional time until that license may be approved, during which the distributor can potentially alter or implement new contracts with customers. This time is in addition to the advance notice already provided by the proposed rule about these new requirements. Additionally, competitors will equally face similar issues.

C. Distribution of Source Material for Possession under the General License.

C.1 Notifications to Customers

Comment: Four commenters stated that there would be significant costs associated with developing a program to track and distribute applicable regulations and safety instructions to customers (estimated to be \$10,000 annually by one commenter). A separate commenter noted that general licensees have in the past had very few responsibilities other than those related to disposal. The commenter recommended that, because the rulemaking adds significant new requirements to persons possessing source material under the § 40.22 general license, the NRC should place additional responsibilities on the distributor to require the distributor to not only provide the customer with a copy of the applicable regulations, but to also obtain documentation from the general licensee acknowledging their understanding of their responsibilities under the general license.

Response: The NRC is concerned that some persons receiving source material for possession or use under the general license may not be aware of the specific regulatory requirements applicable to their possession and use of that material. This conclusion is borne out even by some of the comments received – for example, one commenter provided an observation that currently unlimited quantities of one percent solutions of both natural thorium and natural uranium analytical metal standards may be purchased by non-licensed facilities. This conclusion may have been reached because some persons have incorrectly assumed that these materials were being possessed under exemption instead of the § 40.22 general license as a result of the lack of specific requirements in the former § 40.22 general license and the fact that no information was provided by the distributor to indicate otherwise. The costs to initial distributors of source material for use under the § 40.22 general license to make and provide copies of applicable safety information and the regulations to recipients of the source material is

justified to ensure that the recipient is aware of the existing regulations that are applicable to its possession and use of the source material. This requirement should help ensure the safe use of the material by the recipient. The NRC is currently aware of only one primary distributor of source material to general licensees and did not receive any comments from this distributor. As indicated by one commenter, general licensees in the past have had very few responsibilities and these notifications would help alert them of the final rule changes in § 40.22. Although one commenter requested that the rule require the distributor to obtain an acknowledgement of receipt of the notifications, at this time, the NRC believes this will place unnecessary burden on the distributor and the general licensee without providing significant additional benefit. After the NRC has these requirements in place for a few years, the NRC will be better able to determine if the additional burden of such a requirement is warranted.

Comment: One commenter requested that the regulations be modified to require that any person who transfers source material to a general licensee, where the person receiving the material also possesses a specific license of any kind issued by an Agreement State or the NRC, be required to report to and receive acknowledgement from the radiation safety officer or other official named on the recipient's license of such transfer.

Response: The commenter is part of an organization that may hold a single specific license but may have numerous, distinct operations that use source material under separate general licenses. Such a requirement would likely be useful in helping an organization to ensure that it does not surpass the possession limits of the general license or face other violations because the exemptions to 10 CFR parts 19 and 20 do not apply to the source material held by a specific licensee. The NRC believes this will place unnecessary burden on the distributor. An organization can implement internal procedures to achieve the same results, such as by allowing purchases of source material to be made only through the radiation safety officer, without the need for NRC to implement new regulations.

C.2 Quality Control

Comment: Four commenters stated that there would be significant costs for developing and implementing a quality control program as required in § 40.55. One commenter estimated the associated costs would add more than \$30,000 to their existing product quality control program. These costs were broken down as \$10,000 per year for sample analysis, \$10,000 for program development/management, and \$10,000 for data management, verification and reporting.

Response: Paragraph (a) in § 40.55 requires that each person licensed under § 40.54 label the immediate container of each quantity of source material with the type of source material and quantity of material. Paragraph (b) in § 40.55 requires that the licensee ensure that the quantities and concentrations of source material are as labeled and as indicated in any transfer records. The information required to meet § 40.54(b), with respect to quality control, should be sufficient if it includes a description of an existing quality control or quality assurance program or how the amount of source material in a material or product will be controlled (e.g., through batch sampling). The NRC expects that most manufacturers would already have some quality assurance program in place to ensure that the customer is receiving what was ordered and that costs to meet this new requirement would therefore be minimal.

C.3 Labeling Requirements

Comment: Four commenters stated that there would be significant costs associated with designing new packaging that meets the new labeling requirements. One commenter indicated that it would be difficult to estimate packaging costs in light of the fact that many of their products are small, infrequent and/or “one time only” orders.

Response: The NRC expects that most products are already delivered in some type of individual packaging or bulk packaging for similar products. It is expected that the manufacturer, in most cases has an idea of the specific amount of material included in the product. For most uses, the recipient would be ordering a specific amount and/or concentration and would expect that the package/container or invoice would tell them what they received. Although there may be some costs associated with modifying the labeling, the NRC believes that the benefit of the customer knowing this information outweighs the costs of modifying the label because the customer will have better knowledge of how to safely deal with the material. Also, existing distributors are being given one year to apply for a license to allow for an easy transition. At that point, the existing distributors would provide plans for meeting the requirements of the license for which they are applying and would not have to implement them until the license is issued.

The NRC acknowledges that some products may fall under a general license only because the source material is contained within an ore that was processed and so exact amounts of uranium or thorium contained within the ore may not be known. Instead, average or maximum concentrations, as approved by the NRC in a specific license, could be used to reduce the costs that would be required by sampling each batch. In many cases, incoming ores may already have such concentrations listed. This labeling is important such that the recipient of the material under a general license can ensure that they are staying within the possession limits.

C.4 Annual Reports

Comment: Under § 40.55(d), the NRC proposed that each initial distributor must provide an annual report to the NRC which is to include certain information as specified in the proposed regulation. Two commenters indicated that this requirement would result in significant burdens

to their operations. The commenters stated that, contrary to the NRC's conclusion in the notice of proposed rulemaking, the information requested is not part of their existing business recordkeeping practices and therefore the information would not be a minimal burden to provide. The commenters indicated that they would have to develop, implement, and staff a data acquisition management system for which they would have no other need than this rulemaking at a cost of significant resources.

Response: The NRC recognizes that a distributor's current data handling may not be designed to instantly provide the required information; but, with the capabilities of current information technology, the NRC expects information could be readily assembled and provided in a form and content that is acceptable to the NRC without incurring significant burden on the licensee. In the past, the NRC has occasionally requested distributors of source material to general licensees to voluntarily assemble and provide not only product and quantity information, but also to provide information about recipients of the source material. These distributors were able to fulfill the requests without significant notice and did not voice concerns about the burden associated with the requests. The only currently identified distributor of source material to general licensees has voluntarily provided similar information in the past and so requiring an annual submission does not seem overly burdensome. The NRC does not expect the distributor to have to develop, implement, and staff a data acquisition management system to fulfill this requirement and leaves it up to the distributor how best to fulfill the requirement. Byproduct material distributors have been required to submit such reports, at least annually, for decades. Also, source material distributors will have one year to apply for a license, and would not be required to submit such a report until the year after their specific license is issued. This should allow sufficient time to develop a cost-effective system to meet the reporting requirement. The NRC has concluded that the information to be provided in these reports is important for the NRC to understand and ensure that products and materials distributed for use

under the general license are, and continue to be, safe. In addition, such reports will help identify who currently is operating under a general license.

Comment: Four commenters stated concerns about requirements in the proposed § 40.55(d) requiring the distributor to provide the NRC with annual reports detailing who their customers were and frequency, type, and amount of sales to those customers. The commenters indicated that this was proprietary information which would have to be submitted to the NRC as such and the process would be burdensome. Two of these commenters indicated it was unclear how this information would be protected. One of these commenters indicated that because their transactions are subject to security restrictions they may be prohibited from submitting the information in such a report. Three of these commenters stated that having to file to protect this information pursuant to § 2.390 for each report would be burdensome and recommended that NRC eliminate the requirements for providing customer specific data from the annual reporting requirement. One of these commenters recommended that the annual report only include generic information transferred on a state basis, while the other two commenters recommended that they be allowed to maintain such records at their site for NRC review during inspections.

Response: The NRC and Agreement States have procedures in place for protecting proprietary information. Similar requirements have applied to the distribution of byproduct material for decades, in most cases on a quarterly basis. The information is pertinent to allow both NRC and the Agreement States to understand who is receiving source material under their jurisdiction to better ensure that the source material is being properly handled. The NRC recognizes that customer information may be considered proprietary and would treat it as such in accordance with the NRC's regulations and procedures. Distributors would need to mark it as such to ensure that it is treated accordingly. For reports related to the distribution of byproduct material, the NRC has typically waived the associated affidavit requirements under § 2.390(b)(ii)

if the report is appropriately marked as proprietary. Thus, the requirements for requesting withholding of such information under § 2.390 are not as burdensome as they may appear. Although the information could be held at the distributor's facility, such a plan would not allow individual Agreement States to be notified of who is receiving source material under their regulatory jurisdiction. Upon the request of a distributor who believes they are prohibited from providing information to the NRC in an annual report because of security restrictions imposed by other agencies, the NRC will evaluate the security restrictions on a case-by-case basis.

Comment: Three commenters identified that the proposed § 40.55(d) only requires the name and address of general licensees who received greater than 50 g (0.11 lb) of source material but that the reporting requirement under § 40.53 have no such threshold. Two of these commenters questioned why there is a difference and requested clarification of why the threshold is only 50 g. These commenters recommended that the threshold be raised to be consistent with the possession limit in § 40.22(a).

Response: As indicated earlier, the reporting requirement in § 40.53(c) does not require the reporting of customer information and so a comparison between the reporting requirements under § 40.53(c) and § 40.55(d) is not appropriate. In § 40.55(d), the NRC is requesting the reporting of customer names who receive source material under the general license to better ensure that persons operating under the § 40.22 general license can be identified by the regulator. This will allow the regulator to better ensure the general licensee meets the requirements of § 40.22. The threshold of 50 g was determined by looking at distribution reports that were voluntarily submitted to the NRC in the past and intended to reduce burden on distributors who distribute significantly smaller quantities of source material which are less likely to result in significant health and safety or contamination issues. Using the possession limit for the cutoff for reporting identities of general licensees would result in no general licensees being identified.

Comment: Three commenters requested clarification as to whether the reports required to be filed with a responsible Agreement State under § 40.55(d)(2) only need to be submitted to the Agreement State in which the distributor was located or to, effectively, all the Agreement States and the NRC.

Response: Paragraph § 40.55(d)(1) requires that the distributor provide a complete report of all distributions to the NRC, including for those transfers made to general licensees in Agreement States. Paragraph (d)(2) in § 40.55 requires that the distributor issue a separate report to each Agreement State into which the material was distributed to provide those Agreement States with a better understanding of who is receiving source material and how much under the equivalent Agreement State regulation. The reports to the Agreement States are only required to identify those persons within that individual Agreement State that received more than 50 g of source material; however, even if each person received less than 50 g within an individual Agreement State, the distributor would still be expected to provide a report of how much source material in total was distributed into the individual Agreement State. If no source material was distributed into an Agreement State in the previous calendar year, the distributor does not need to provide a report to the Agreement State, unless the particular State requests it. In that case, the distributor must provide a report to that Agreement State that indicates that no source material was distributed in the previous calendar year. As a result of comments and to better clarify that reports should be sent to each Agreement State into which source material is transferred, § 40.55(d)(2) was revised.

Comment: The Agreement State commenter indicated that the reporting requirement in § 40.55(d) appeared to be parallel to the general licensing reporting system currently in place for byproduct material devices. The commenter requested clarification on what kind of regulatory oversight the NRC intends for these reports – for example, will the NRC and the

Agreement States need to establish databases and tracking systems and will there be inspections in the field?

Response: Although the NRC may develop databases internally to evaluate reports, the NRC does not plan to institute a database capable of tracking materials similar to that currently used for tracking generally licensed byproduct devices. The NRC plans to periodically aggregate the collected information related to distribution of source material to general licensees. The data would be used to identify general licensees and to determine if additional changes in the regulations are required to improve safety. Identifying general licensees will allow the NRC to contact them to provide or to request information, or to inspect them if it deems it appropriate. Although field inspections solely to verify records of transfers are not envisioned as a normal practice, review of a licensee's recordkeeping practices may be included as part of any routine inspection of the specific licensee.

D. Exemptions.

The notice for proposed rulemaking included a request for comments on whether or not it is appropriate to limit source material on coated lenses through use of a concentration limit.

Comment: One commenter suggested that an activity per unit area (square centimeter) would seem more appropriate. The commenter did not suggest a limit.

Response: The NRC is concerned that a concentration limit may not be the best method to limit uranium and thorium content in the coating of a lens because the activity is concentrated on the outer boundary. Although an activity per unit of surface area is likely a better control, the NRC is hesitant to impose such a limit at this time, without receiving more complete information on the range of products, sizes, quantities of source material, coating thicknesses, etc. Based on the evaluation and findings in the PNNL study, the total source material content is normally

significantly less for a coated lens than a lens with a homogeneous content. As a result, the NRC has concluded that the proposed limit is acceptable. One of the key assumptions for these lenses, however, is that the coating is not easily removable. As the key concern with safety for these lenses is how easily removable the coatings might be, § 40.52(b)(2) will require the manufacturer to submit a description of its manufacturing process, as part of a license application, that would ensure that the coating is not easily removable. After the NRC receives more information regarding the distribution of these lenses as a result of the new reporting requirements, the NRC may reconsider the issue.

E. Fees.

The notice of the proposed rulemaking included a request for comments on whether the proposed categories and fees in § 170.31 and § 171.16 were appropriate and reasonable.

Comment: One commenter indicated that any additional fees would be burdensome. This commenter was concerned that under the proposed rule, a facility providing sample characterization for source and [10 CFR part 30] byproduct material for licensees and non-licensees could potentially be charged greater than \$30,000 annually and more than \$15,000 in applications fees. These costs did not include the cost of preparing an application or implementing the new regulatory programs. The commenter stated that these fees eclipse the cost for both conventional and *in situ* recovery facilities that produce millions of pounds of source material annually.

Response: The commenter is correct that a person distributing source material and byproduct material for use under exemptions and general licenses could be subject to fees under a number of different fee categories. However, the fee categories for byproduct material distribution are not new and should not be addressed as new costs. The commenter is correct

that a person manufacturing and distributing byproduct material and source material for use under exemptions and general licenses (thereby being affected by up to six separate fee categories) could have a total annual fee that exceeds the annual fees for conventional or *in situ* recovery facilities. This is because the NRC handles each of these (possession, distribution, source material, byproduct material, etc.) as a separate activity. In the past, costs of the resources spent in attempts to gather and evaluate information about the use of source material under exemption and the § 40.22 general license and to estimate the extent and the conditions of their use would be recovered from fees for other NRC-regulated activities unrelated to source material activities. Thus, this rule also improves the equitability in the charging of fees. These fees are expected to change periodically based upon the actual amount of effort the NRC spends in actively regulating licensees in these categories. In addition, small businesses are granted some relief from these fees and are allowed to pay significantly lower fees.

F. Miscellaneous.

F.1 Scope of “other glass or ceramic” in § 40.13(c)(2)(iii)

Comment: One commenter requested that the NRC clarify the scope of the term “other glass or ceramic” as it appears in § 40.13(c)(2)(iii). The commenter stated that the scope should extend to industrial use ceramics that are not used in residential or commercial building construction. The commenter stated that the phrase “used in construction” means used in the construction of residential or commercial buildings and not “used in construction” of industrial crucibles, jet engines, chemical manufacturing facilities, or military radar. The commenter discussed the fact that since other forms of ceramics are allowed under other exemptions in § 40.13(c)(2)(i) and (ii), that the exemption in § 40.13(c)(2)(iii) should be considered to include

any other ceramics except those in § 40.13(c)(2)(i) and (ii) and those ceramics used in residential and commercial building construction.

Response: The fact that there are other exemptions that cover specific types of ceramics is in fact evidence that the exemption for glassware in § 40.13(c)(2)(iii) is not meant to cover all ceramics. The exclusionary language at the end of that exemption had previously been associated with the exemptions in § 40.13(c)(i) and (ii) in addition to § 40.13(c)(iii). However, these exemptions are specific enough as to no longer need such clarification. Also, the glaze on some ceramics, such as ceramic tiles, may itself be considered glass. Thus, maintaining the exclusionary language concerning ceramic tile and other tile used in construction is appropriate. The NRC agrees that the phrase “used in construction” means used in the construction of residential or commercial buildings and not “used in construction” of industrial crucibles, jet engines, chemical manufacturing facilities, or military radar. Nevertheless, the exemption in § 40.13(c)(2)(iii) does not cover ceramic material.

F.2 Applicability of Specific Product Exemption vs. Broader 0.05 Percent Exemption

Comment: One commenter indicated that it manufactures a wide variety of “windows” that are nominally 18 inches by 12 inches, in addition to small lenses that are less than 1 inch in diameter. Some of these products contain less than 0.05 percent by weight of uranium and thorium. The commenter requested clarification on whether the product exemption in § 40.13(c)(7) or the broader exemption in § 40.13(a) takes precedence. If the former, the manufacturer would be required to distribute the product under the proposed distribution license in § 40.52. The commenter recommended that this potential point of confusion be addressed in guidance.

Response: Although there is not a stated definition for what constitutes a lens in the NRC's regulations, the Merriam-Webster Dictionary⁶ defines a lens as "a piece of transparent material (as glass) that has two opposite regular surfaces either both curved or one curved and the other plane and that is used either singly or combined in an optical instrument for forming an image by focusing rays of light." Similarly a mirror is intended to reflect waves of light or other radiation. Because a "window" is usually intended to only allow transmittal of light (not reflect or focus it), the NRC does not consider a window to be a lens and thus the exemption in § 40.13(c)(7) would not normally apply to a window. When determining the appropriate exemption, it would be inappropriate to use the exemption limit in § 40.13(a) for a product in which the source material is intentionally applied or included. As a result, for coated lenses, the only applicable exemption would be in § 40.13(c)(7) and thus the initial distribution of all coated lenses would require a license under § 40.52.

F.3 Threshold for Licensable Source Material

Comment: One commenter requested guidance about when uranium or thorium is actually considered source material. In particular, the commenter asked if source material is defined as being controlled by a licensee, or if it includes any material that may contain greater than 0.05 percent by weight of uranium or thorium, including outcrops, mine workings, and cores required to ascertain if material is minable. The commenter also wondered how one handles ores that are being analytically sampled when one doesn't know the concentration of uranium and thorium until the analysis is completed. The commenter was also concerned that some inspectors have indicated that as soon as you add acids to the ore, for analytical sample preservation as required by approved analytical methodologies for uranium testing, that the

⁶ See website <http://www.merriam-webster.com/dictionary/lens>.

material should be classified as source material even if you don't know the concentration in the sample exceeds the 0.05 percent limit.

Response: The NRC acknowledges that because of the ubiquitous nature of uranium and thorium, knowing if a material is an ore or is source material is problematic. As long as the source material remains in its place in nature, the source material is not subject to regulation under the AEA. Furthermore, until the ore is actually processed, because of the exemption in § 40.13(b), a person is not required to obtain a license from the NRC for possession or use of the material nor meet the requirements of 10 CFR part 40. However, once processing occurs, the processor would need a license (either general or specific) to possess and process the source material if the material's content exceeds 0.05 percent by weight of the material. If the processed material is then transferred to someone else for use under a product exemption in § 40.13(c) or the general license in § 40.22, that person would need a distributor license.

Based on comments, the NRC has concluded that transfers of source material to analytical laboratories (and potentially back to the client) for determining concentrations would be extremely burdensome to track and need not be covered by licensing requirements for initial distribution. As a result, the NRC has modified the proposed § 40.22(e) to include a provision specifically to address analytical laboratories and, as such, a specific license for the initial distribution of source material is not required in order to transfer source material to an analytical laboratory operating under a § 40.22 general license for the purpose of determining the source material concentration of the material. Similarly, the laboratory would not be required to obtain a distribution license to return the sample to the person that originally provided the sample for analysis. The NRC expects that most laboratories routinely analyzing radioactive materials are operating under a specific license. However, to the extent that the general license of § 40.22 is used for this purpose, it is not necessary to capture such transfers under a distribution license. Furthermore, the NRC modified § 40.22(a) to allow laboratories receiving uranium and thorium

for the purpose of determining its concentration to essentially maintain the same quantity limits as have been allowed by § 40.22 in the past.

The NRC also acknowledges that there may be issues when handling unprocessed ores when the source material content is not known. To alleviate potential violations where a laboratory may unexpectedly identify source material in an ore that would normally require licensing, a clarifying amendment was made to the definition of “unrefined and unprocessed ore” in § 40.4 to indicate that activities related to the sample analysis of an unprocessed ore are not considered as processing and an analytical laboratory may treat the sample as unprocessed ore under the exemption in § 40.13(b). This change is consistent with Section 65 of the AEA which states that “reports shall not be required with respect to (a) any source material prior to its removal from its place of deposit in nature, or (b) ...or the reporting of which will discourage independent prospecting for new deposits.”

Comment: One commenter stated that the NRC should clarify that compliance assessments for uranium and/or thorium in a material can be reported to three significant figures, if justified by analytical accuracy and precision. The commenter explained that the regulatory language of § 40.13(a) of “one twentieth of one percent” describes a fraction of a fraction and provides a numeral example in parenthesis of 0.05 percent. The commenter further stated that following accepted rounding convention, an analytical value of 0.049 percent rounds to 0.05 percent and thus is considered licensable source material if analysis to only two significant figures is allowed by § 40.13(a). The commenter requested that given that improvement in analytical sensitivity over the years, it is appropriate to clarify that the number of significant figures to which source material content is reported should be limited only by the validated accuracy and precision of the analytical method used.

Response: Although the numeric value in § 40.13(a) is only stated out to one significant figure, the NRC does not require rounding if a more precise analysis is made. Thus if the

analysis indicated that the material was 0.049 percent by weight, the NRC would not consider the material containing the uranium or thorium to require a license.

F.4 Revision of the Exemption in § 40.13(b) for Unrefined Ores

Comment: One commenter stated the exemption for unrefined and unprocessed ore found in § 40.13(b) is a critical part of 10 CFR part 40 and rightfully remains unchanged because it: 1) exempts mining of source material from the regulation; 2) rightfully exempts natural materials from the regulations; and 3) starts the regulatory regime only upon processing of naturally occurring materials thus limiting the regulation to anthropogenic materials.

Response: The NRC has no plans to revise § 40.13(b) in any way that would reduce the benefits identified by the commenter at this time. However, based upon comments received, the NRC has included a clarifying amendment to the definition of “unrefined and unprocessed ore” in § 40.4 in the final rule to indicate that activities related to the sample analysis of an unprocessed ore and a few other specified activities as discussed in more detail in section II.A.8 of this document, are not considered to be processing and that the material would continue to be considered an unprocessed or unrefined ore and thus remain exempt under § 40.13(b).

G. Future Rulemaking Considerations.

The notice of the proposed rulemaking included a request for comments on certain issues that could be considered for future rulemakings. The following comments were provided in response to the NRC’s questions. The NRC would like to thank respondents for taking the time to provide these comments, and will consider them when evaluating the need and scope of future rulemaking in this area. The NRC is not providing a response to these comments at this time.

G.1 Addition of 11e.(2) Byproduct Material to the § 40.22 General License

The notice of proposed rulemaking included a request for comment on whether the general license in § 40.22 should be expanded to cover 11e.(2) byproduct material (mill tailings or waste).

Comment: Three commenters responded positively to expanding the § 40.22 general license to include provisions for 11e.(2) byproduct material. One of the commenters indicated that current regulations are hampering the ability of analytical laboratories to perform necessary testing on waste material generated by an in situ recovery facility because the laboratory requires a specific license. Another of these commenters indicated that such a change would be a boon for laboratories serving the uranium recovery industry. The commenter argued that uranium mill tailings (which are a major component of 11e.(2) byproduct material) are lower in activity than unrefined and unprocessed ores which are considered to be exempt under § 40.13(b). The commenter provided suggested limits for inclusion in any proposed general license expansion to be 150 lb of 11e.(2) byproduct material at one time and receipt of no more than 1,000 lb per year. The third commenter indicated that higher limits were appropriate if the dose limits were not likely to be exceeded but also identified the need that additional provisions for disposition may be needed.

G.2 Sealed Source and Device Registry

The notice of proposed rulemaking included a request for comment on whether explicit provisions should be added to 10 CFR parts 40 and 70 to cover the inclusion of source material and special nuclear material in items in the sealed source and device registry, similar to § 32.210.

Comment: One commenter supported making this revision for devices and specific products.

G.3 Usefulness of Provisions in §§ 40.25 and 40.34

The notice of proposed rulemaking included a request for comment on whether the provisions in §§ 40.25 and 40.34 should be revised to make the general license more useful to the regulatory program, whether the usefulness clause is too subjective and acting as deterrent, and if the exposure limits in § 40.34(a)(2) should be reduced to 1 mSv (100 mrem) per year.

Comment: One commenter indicated that most persons have chosen to possess materials under their specific license instead of under these provisions. The commenter indicated that there are some accelerator/cyclotron facilities that still use material under this general license. The commenter continued that the usefulness of the product should always be a primary consideration in the evaluation process and should be maintained in the rule language. Finally, the commenter indicated that exposure limits should be consistent with those for other generally licensed products.

IV. Discussion of Final Amendments by Section

Section 30.6 Communications.

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

Section 40.4 Definitions

10 CFR 40.4 – Revises the definition of “*Unrefined and unprocessed ore*” to clarify that certain activities are not considered processing in this regard.

Section 40.5 Communications.

10 CFR 40.5(b)(1)(iv) – Adds 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) – Adds sections to the list of information collection requirements.

Section 40.13 Unimportant quantities of source material.

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

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

10 CFR 40.13(c)(2)(iii) – Revises 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) – Removes paragraph (c)(5)(i), as it is redundant with the new paragraph (c)(10), and renumbers the subsequent paragraphs within (c)(5).

10 CFR 40.13(c)(7) – Revises 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 optical lenses 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) – Adds paragraph (c)(10) to prohibit initial distribution for use under the exemptions in § 40.13(c) without a specific license issued under § 40.52.

10 CFR 40.13(d) – Removes 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) – Applies a limit of 1.5 kg (3.3 lb) at any one time to certain forms of uranium and thorium that may be inhaled or ingested during normal working conditions and restricts receipt of these forms to less than 7 kg (15.4 lb) per year. Also, allows a person, currently possessing quantities greater than these limits, one year from the effective date of the rule to reduce possession limits or apply for a specific license for possession and use; however, a person not applying for a specific license has until the end of the calendar year following the effective date of the rule to reduce throughput to the new limits.

10 CFR 40.22 (a)(2) – Allows additional possession of forms of uranium and thorium that are not expected to be normally inhaled or ingested.

10 CFR 40.22(a)(3) – Allows 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(a)(4) – Allows laboratories handling samples for the purpose of determining uranium or thorium content to continue to possess up to 7 kg (15.4 lb) of source material at any one time and up to 70 kg (154 lb) of source material per calendar year.

10 CFR 40.22(b)(1) – Continues 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) – Clarifies that any person who receives, possesses, uses, or transfers source material under § 40.22 may not abandon source material and that the source material must be transferred under § 40.51 or permanently disposed of in accordance with

§ 20.2001. An exception is that a general licensee is 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 and that the recipient is not required to obtain a license from the NRC as long as it was permanently disposed in accordance with local laws.

10 CFR 40.22(b)(3) – Clarifies which provisions in 10 CFR part 40 apply under the general license.

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

10 CFR 40.22(b)(5) – Clarifies that export of source material is subject to 10 CFR part 110.

10 CFR 40.22(c) – Requires 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) – Revises and moves the requirements currently under paragraph (b) of this section to paragraph (d) of this section.

10 CFR 40.22(e) – Restricts 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) – Adds §§ 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 – Establishes 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 – Establishes 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 – Establishes requirements for a license authorizing initial transfer or distribution for use under § 40.22(a) 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 – Establishes requirements for licenses issued under § 40.54, including reporting and recordkeeping requirements for the distribution 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) – Adds sections to the list of provisions that are not subject to criminal sanctions.

Section 70.5 Communications.

10 CFR 70.5(b)(1)(iv) – Adds a reference to the new § 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 and export licenses.

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

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 – Adds three fee categories for distributors of source material to the annual fees.

V. Criminal Penalties

For the purpose of Section 223 of the AEA, the Commission is amending § 40.22 and adding §§ 40.53 and 40.55 under one or more of Sections 161b, 161i, or 161o of the AEA.

Willful violations of the rule will be subject to criminal enforcement.

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 final rule is 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 final 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” (see <http://www.nrc.gov/reading-rm/doc-collections/management-directives/>).

NRC program elements (including regulations) are placed into four compatibility categories (see the 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 AEA, as amended, or provisions of 10 CFR. These program elements are not adopted by Agreement States. The following table lists the parts and sections that have been created or revised and their corresponding categorization under the “Policy Statement on Adequacy and Compatibility of Agreement State Programs.” A bracket around a category means that the section may have been adopted elsewhere, and it is not necessary to adopt it again.

The Agreement States have 3 years from the effective date of the final rule to adopt compatible regulations.

Compatibility Table for Final 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				
40.4	Amend	Definitions <i>Unrefined and unprocessed ore</i>	B	B
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)(5)(i)	Remove	Unimportant quantities of source material	B	B
40.13(c)(5)(ii)	Redesignate	Unimportant quantities of source material (becomes 40.13(c)(5)(i))	B	B
40.13(c)(5)(iii)	Redesignate	Unimportant quantities of source material (becomes 40.13(c)(5)(ii))	B	B
40.13(c)(5)(iv)	Redesignate	Unimportant quantities of source material (becomes 40.13(c)(5)(iii))	B	B
40.13(c)(5)(v)	Redesignate	Unimportant quantities of source material (becomes 40.13(c)(5)(iv))	NRC	NRC
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(a)(4)	New	Small quantities of source material	-	B
40.22(b)	Amend	Small quantities of source material	B	B
40.22(b)(1)	New	Small quantities of source material	-	B
40.22(b)(2)	New	Small quantities of source material	-	B
40.22(b)(3)	New	Small quantities of source material	-	B
40.22(b)(4)	New	Small quantities of source material	-	D
40.22(b)(5)	New	Small quantities of source material	-	B
40.22(c)	New	Small quantities of source material	-	C
40.22(d)	Amend	Small quantities of source material (Previously 40.22(b))	B	B
40.22(e)	New	Small quantities of source material	-	B
40.32(f)	Amend	General requirements for issuance of a specific license	D	D
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 amendments. Agreement States should remove this provision from their regulations.

VII. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, well-organized manner that also follows other best practices

appropriate to the subject or field and the intended audience. The NRC has attempted to use plain language in promulgating this rule consistent with the Federal Plain Writing Act guidelines.

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 final rule, the NRC is establishing requirements for distributors of source material to persons exempt from regulation and to general licensees. In addition, the final amendments 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 revising, clarifying, or deleting certain exemptions from licensing to make the requirements for the use of source material under the exemptions more risk informed. This action does not constitute the establishment of a standard that establishes generally applicable requirements.

IX. 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 final rule because the Commission has concluded on the basis of an environmental assessment that this final rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment.

The determination of this environmental assessment is that there will be no significant impact to the public from this action.

The majority of the provisions in the final rule come within the scope of categorical exclusion in § 51.22, and as such, an environmental review is not necessary. The NRC has also determined that implementation of the remaining provisions of the final rule would not result in any significant impact to the environment. 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 expanding the exemption from licensing in § 40.13(c)(7) to allow coated lenses and mirrors, 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 final rule would be procedural and administrative in nature.

This conclusion was published in the environmental assessment that was posted to the NRC rulemaking Web site, <http://www.regulations.gov> for 75 days after publication of the proposed rule. No comments were received on the content of the environmental assessment.

X. Paperwork Reduction Act Statement

This final rule contains new or amended information collection requirements contained in 10 CFR parts 19, 20, 40, and NRC Form 313, that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, approval numbers 3150-0044, -0014, -0020, and -0120. The final

rule changes to 10 CFR parts 30, 70, 170, and 171 do not contain new or amended information collection requirements.

The burden to the public for these information collections is estimated to average 4.2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of these information collections, including suggestions for reducing the burden, to the Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS.RESOURCE@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0020), Office of Management and Budget, Washington, DC 20503. You may also e-mail comments to [Chad S Whiteman@omb.eop.gov](mailto:Chad_S_Whiteman@omb.eop.gov) or comment by telephone at (202) 395-4718.

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.

XI. Regulatory Analysis

The Commission has prepared a regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The analysis is available for inspection on <http://www.regulations.gov> by searching on Docket ID NRC-2009-0084 and in the NRC's PDR, 11555 Rockville Pike, Rockville, MD 20852.

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 may 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 revisions to the regulatory program will 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 final rule do not involve any provisions that 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 final rule to address these classes of entities. With respect to 10 CFR part 40 licensees, there are no provisions for backfit in 10 CFR part 40. Therefore, a backfit analysis has not been prepared for this final rule to address 10 CFR part 40 licensees.

XIV. Congressional Review Act

In accordance with the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects

10 CFR Part 30

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

10 CFR Part 40

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

10 CFR Part 70

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

10 CFR Part 170

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

10 CFR Part 171

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

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR parts 30, 40, 70, 170, and 171.

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

1. The authority citation for 10 CFR part 30 continues to read as follows:

Authority: Secs. 81, 82, 161, 181, 182, 183, 186, 223, 234 (42 U.S.C. 2111, 2112, 2201, 2231, 2232, 2233, 2236, 2273, 2282); Energy Reorganization Act secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); Government Paperwork Elimination Act sec. 1704 (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 Energy Reorganization Act sec. 211, Pub. L. 95-601, sec. 10, as amended by Pub. L. 102-486, sec. 2902 (42 U.S.C. 5851). Section 30.34(b) also issued under Atomic Energy Act sec. 184 (42 U.S.C. 2234). Section 30.61 also issued under Atomic Energy Act sec. 187 (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 under §§ 32.11 through 32.30 and 40.52 of this chapter to persons exempt from licensing requirements.

* * * * *

PART 40-DOMESTIC LICENSING OF SOURCE MATERIAL

3. The authority citation for 10 CFR part 40 continues to read as follows:

Authority: Atomic Energy Act secs. 11(e)(2), 62, 63, 64, 65, 81, 161, 181, 182, 183, 186, 193, 223, 234, 274, 275 (42 U.S.C. 2014(e)(2), 2092, 2093, 2094, 2095, 2111, 2113, 2114, 2201, 2231, 2232, 2233, 2236, 2243, 2273, 2282, 2021, 2022); Energy Reorganization Act secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); ; Government Paperwork Elimination Act

sec. 1704 (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 Energy Reorganization Act sec. 211, Pub. L. 95-601, sec. 10, as amended by Pub. L. 102-486, sec. 2902 (42 U.S.C. 5851). Section 40.31(g) also issued under Atomic Energy Act sec. 122 (42 U.S.C. 2152). Section 40.46 also issued under Atomic Energy Act sec. 184 (42 U.S.C. 2234). Section 40.71 also issued under Atomic Energy Act sec. 187 (42 U.S.C. 2237).

4. In § 40.4, the definition of *Unrefined and unprocessed ore* is revised to read as follows:

§ 40.4 Definitions.

* * * * *

Unrefined and unprocessed ore means ore in its natural form prior to any processing, such as grinding, roasting or beneficiating, or refining. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.

* * * * *

5. 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 under §§ 32.11 through 32.30 and 40.52 of this chapter to persons exempt from licensing requirements.

* * * * *

6. 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.

* * * * *

7. In § 40.13, the introductory text to paragraph (c) and paragraphs (c)(2)(i), (c)(2)(iii), and (c)(7) are revised; paragraphs (c)(5)(i) and (d) are removed; paragraphs (c)(5)(ii), (c)(5)(iii), (c)(5)(iv), and (c)(5)(v) are redesignated as (c)(5)(i), (c)(5)(ii), (c)(5)(iii), and (c)(5)(iv), respectively; paragraph (c)(10) is added; and footnote 2 is revised 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 DATE THAT IS 90 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, 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 DATE THAT IS 90 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, 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 or mirror does not contain more than 10 percent by weight thorium or uranium or, for lenses manufactured before **[INSERT DATE THAT IS 90 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, 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 DATE THAT IS 90 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** 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 these 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).

* * * * *

²The requirements specified in paragraphs (c)(5)(i) and (ii) of this section need not be met by counterweights manufactured prior to Dec. 31, 1969, provided that such counterweights were manufactured under a specific license issued by the Atomic Energy Commission and were impressed with the legend required by §40.13(c)(5)(ii) in effect on June 30, 1969.

8. 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) No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms (e.g., gaseous, liquid, powder, etc.) at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. 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 uranium and thorium in any one calendar year. Persons possessing source material in excess of these limits as of **[INSERT DATE THAT IS 90 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]** may continue to possess up to 7 kg (15.4 lb) of uranium and thorium at any one time for one year beyond this date, or until the Commission takes final action on a pending application submitted on or before **[INSERT DATE THAT IS 1 YEAR PLUS 90 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]** for a specific license for such material; and receive up to 70 kg (154 lb) of uranium or thorium in any one calendar year until December 31, **[the staff will insert year that is 15 months after publication prior to sending to the Federal Register]**, or until the Commission takes final action on a pending application submitted on or before **[INSERT DATE THAT IS 1 YEAR PLUS 90 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]** for a specific license for such material; and

(2) No more than a total of 7 kg (15.4 lb) of uranium and thorium 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 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under this paragraph unless it is accounted for under the limits of paragraph (a)(1) of this section; or

(3) No 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; or

(4) No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed 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 70 kg (154 lb) of source material in any one calendar year.

(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, 40.56, 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 not 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)(1) or (2) 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. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample. Initial distribution of source material to persons generally licensed by paragraph (a) of this section before **[INSERT DATE THAT IS 90 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** 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 on or before **[INSERT DATE THAT IS 1 YEAR PLUS 90 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

9. 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.

* * * * *

10. 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) 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) and as required by their license. 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 provisions 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 each responsible Agreement State agency that identifies all persons, operating under provisions equivalent to § 40.22, to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single 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.

11. 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

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

Authority: Atomic Energy Act secs. 51, 53, 161, 182, 183, 193, 223, 234 (42 U.S.C. 2071, 2073, 2201, 2232, 2233, 2243, 2273, 2282, 2297f); secs. 201, 202, 204, 206, 211 (42 U.S.C. 5841, 5842, 5845, 5846, 5851);; Government Paperwork Elimination Act sec. 1704 (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 70.21(g) also issued under Atomic Energy Act sec. 122 (42 U.S.C. 2152).
Section 70.31 also issued under Atomic Energy Act sec. 57(d) (42 U.S.C. 2077(d)). Sections 70.36 and 70.44 also issued under Atomic Energy Act sec. 184 (42 U.S.C. 2234). Section 70.81 also issued under Atomic Energy Act secs. 186, 187 (42 U.S.C. 2236, 2237). Section 70.82 also issued under Atomic Energy Act sec. 108 (42 U.S.C. 2138).

13. 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 under §§ 32.11 through 32.30 and 40.52 of this chapter to persons exempt from licensing requirements.

* * * * *

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

14. The authority citation for 10 CFR part 170 continues to read as follows:

Authority: Independent Offices Appropriations Act sec. 501 (31 U.S.C. 9701); Atomic Energy Act sec. 161(w) (42 U.S.C. 2201(w)); Energy Reorganization Act sec. 201 (42 U.S.C. 5841); Chief Financial Officers Act sec. 205 (31 U.S.C. 901, 902); Government Paperwork Elimination Act sec. 1704, (44 U.S.C. 3504 note); Energy Policy Act secs. 623, Energy Policy Act of 2005 sec. 651(e) Pub. L. 109-58, 119 Stat.783 (42 U.S.C. 2201(w), 2014, 2021, 2021b, 2111).

15. Section 170.31 is revised by 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 Schedule of fees for materials licenses and other regulatory services, including inspections, and import and export licenses.

* * * * *

SCHEDULE OF MATERIALS FEES

[See footnotes at end of table]

Categories of materials licenses and type of fees ¹	Fee ^{2,3}
* * * * *	
2. Source material:	
* * * * *	
C. Licenses to distribute items containing source material to persons exempt from the licensing requirements of part 40 of this chapter.	
Application [Program Code(s): 11240]	\$7,000
D. Licenses to distribute source material to persons generally licensed under part 40 of this chapter.	
Application [Program Code(s): 11230 and 11231]	\$2,000
E. Licenses for possession and use of source material for processing or manufacturing of products or materials containing source material for commercial distribution.	
Application [Program Code(s): 11710]	\$5,400
F. All other source material licenses.	
Application [Program Code(s): 11200, 11220, 11221, 11300, 11800, 11810]	\$5,400
* * * * *	

¹ *Types of fees* - Separate charges, as shown in the schedule, will be assessed for preapplication 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, renewals, and amendments to existing licenses, preapplication consultations and 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 nonroutine 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.

²Fees 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.

³Full 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 for 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

16. The authority citation for 10 CFR part 171 continues to read as follows:

Authority: Consolidated Omnibus Budget Reconciliation Act sec. 6101 Pub. L. 99-272, as amended by sec. 5601, Pub. L. 100-203 as amended by sec. 3201, Pub. L. 101-239, as amended by sec. 6101, Pub. L. 101-508, as amended by sec. 2903a, Pub. L. 102-486 (42 U.S.C. 2213, 2214), and as amended by Title IV, Pub. L. 109-103 (42 U.S.C. 2214); Atomic Energy Act sec. 161(w), 223, 234 (42 U.S.C. 2201(w), 2273, 2282); Energy Reorganization Act sec. 201 (42 U.S.C. 5841); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005 sec. 651(e), Pub. L. 109-58 (42 U.S.C. 2014, 2021, 2021b, 2111).

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

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

* * * * *

(d) * * *

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

[See footnotes at end of table]

Category of Materials Licenses	Annual fees ^{1,2,3}
* * * * *	
2. Source Material	
* * * * *	
C. Licenses to distribute items containing source material to persons exempt from the licensing requirements of part 40 of this chapter [Program Code(s): 11240]	\$10,000
D. Licenses to distribute source material to persons generally licensed under part 40 of this chapter [Program Code(s): 11230 and 11231]	\$5,000
E. Licenses for possession and use of source material for processing or manufacturing of products or materials containing source material for commercial distribution. [Program Code(s): 11710]	\$12,400
F. All other source material licenses. [Program Code(s): 11200, 11220, 11221, 11300, 11800, 11810]	\$12,400
* * * * *	

¹Annual 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, 2011, 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.

²Payment 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 10 CFR parts 30, 40, 70, 71, 72, or 76 of this chapter.

³Each 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 _____, 2012.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.

**Regulatory Analysis for Final
Rulemaking – Requirements for Distribution
of Source Material: 10 CFR Parts 30, 40, 70,
170, and 171**

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



REGULATORY ANALYSIS

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1. STATEMENT OF THE PROBLEM

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

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

2. EXISTING REGULATORY FRAMEWORK

The regulations in 10 CFR Part 40 set out the basic requirements for licensing of source material and include a number of exemptions from licensing requirements. The exemptions from licensing requirements are in § 40.13.

The regulations in 10 CFR Part 40 also include a number of general licenses. Of particular interest is § 40.22, which authorizes commercial and industrial firms, research, educational, and medical institutions; and Federal, State, and local governmental agencies to use and transfer not more than 15 pounds (lb) (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 (168 kg) of source material may be received in any one calendar year. Such general licensees are exempt from the provisions of 10 CFR Parts 19, 20, and 21, except for those licensees who also possess source material under a specific license.

3. ALTERNATIVES CONSIDERED

3.1 No action

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

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

This alternative will amend 10 CFR Parts 30, 40, 70, 170, and 171 to resolve several issues related primarily to the goals of ensuring public health and safety in the use of source material under general license and under exemptions from licensing. The regulatory amendments will create a regulatory framework for the initial distribution of source material which will allow for the Commission to be aware of what types and quantities of products containing source material are distributed for use under the exemptions from licensing and to identify persons using significant quantities of source material under the general license in § 40.22. It will also ensure

that general licensees under § 40.22 are informed of applicable regulations before they obtain source material. These changes will affect licensees who distribute source material and future users of some materials currently used under general license or exemption from licensing.

3.3 Other Alternatives

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

4. ANALYSIS OF ALTERNATIVES

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

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

Licensee labor rates were obtained from National Wage Data available on the Bureau of Labor Statistics web site (www.bls.gov). Depending on the industry and the occupation (e.g., manufacturing, health and safety, etc.), an appropriate mean hourly labor rate is selected. The rate is then increased using a multiplier of 1.5 to account for benefits (insurance premiums, pension, and legally required benefits). Because exact hourly rates would be difficult to obtain and may not be sufficiently recent, nationwide mean hourly rates are used.

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

NRC labor rates are determined by the calculation methodology in Abstract 5.2 of NUREG/CR-4627, Rev.1, "Generic Cost Estimates, Abstracts from Generic Studies for Use in Preparing Regulatory Impact Analyses." This methodology considers only variable costs that are directly related to the implementation, operation, and maintenance of the final requirement. Currently, this hourly labor rate for FSME is \$116.

Agreement States' labor rates vary in amount and in how each rate is determined. A survey of a particular industry would reveal a labor rate that can be compared to the NRC's labor rate, or the Bureau of Labor Statistics web site can be used to obtain an hourly labor rate. Either of these methods is likely to yield similar results. For the purpose of this analysis, the average Agreement State hourly labor rate was obtained from the Bureau of Labor Statistics Employer Costs for Employee Compensation data set, "Management, professional, and related

occupations,” limited to State and local government workers¹. This wage was then increased by the same factor of 1.5 described earlier to obtain an hourly labor rate of \$50 and an annual labor rate of \$89,000.

The estimation of costs for rulemaking is based on professional staff full-time equivalent (FTE). Based on actual data from the NRC’s time and labor system, the number of hours in 1 year that directly relate to the implementation of assigned duties is 1,451; this excludes hours on such things as leave, training, and completing administrative tasks. Therefore, an NRC professional staff FTE hour rate is based on 1,451 hours. As described in the Office of Management and Budget (OMB) Circular A-76, “Performance of Commercial Activities,” the number of productive hours in 1 year is 1,776. As this actual value is likely to vary from State to State and no specific data are available, the FTE costs for the Agreement States are based on the number of hours estimated in OMB Circular A-76. Costs are determined by multiplying the number of FTEs by 1,451 hours or 1,776 hours times the hourly labor rate, for the NRC or the Agreement States, as appropriate.

For all licensee labor rates, \$56 per hour is used. This rate is based on the Bureau of Labor Statistics Employer Costs for Employee Compensation data set, “Health and Safety Engineers, Except Mining Safety Engineers and Inspectors”²; however, some of the actions evaluated may be conducted by lower paid employees, such as clerical staff.

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

- Occupational Health (Routine and Accident/Event) – The final rule will reduce likely doses to workers using some types of products under exemptions from license and generally licensed materials distributed in the future.
- Public Health (Routine and Accident/Event) – The final rule will result in some reduction in public doses, and provide greater assurance that exposures received as a result of products being used under exemptions from licensing and materials used under the subject general license do not exceed appropriate levels.
- Safeguards and Security Considerations – The final rule will improve assurance that radionuclides of concern to security are not made available through the general license.
- Industry Implementation -- Costs to industry will result in connection with those manufacturers and distributors who will require new specific licenses for distribution.

¹Department of Labor (U.S.), Bureau of Labor Statistics. Employer Costs for Employee Compensation, September 2011, Table 4 - Employer costs per hour worked for employee compensation and costs as a percent of total compensation: State and local government workers, by major occupational and industry group, September 2011.

² Department of Labor (U.S.), Bureau of Labor Statistics. Occupational Employment Statistics, Occupational Employment and Wages, May 2010, 17-2111 Health and Safety Engineers, Except Mining Safety Engineers and Inspectors. Mean hourly wage is \$37.60 x 1.5 = \$56/hour.

- Industry Operation -- The final rule will improve licensing of distribution of certain source material by making the regulations clearer, more up-to-date, and more risk-informed. Costs to industry will primarily impact those persons who currently operate under general license.
- NRC Implementation and Operation -- The NRC has incurred costs to develop a rule and to revise existing guidance. The final rule will result in effects on operating costs, as an increase in specific licensees will result.
- Other Government -- The Agreement States will need to amend their regulations to maintain compatibility with NRC requirements; impacts to the Agreement State regulatory programs will be minimal. The U.S. Environmental Protection Agency could see reduced costs if instances of significantly contaminated general licensee sites are avoided in the future.
- Environmental Considerations -- The final rule will eliminate or make more restrictive some of the exemptions from licensing. This will result in less source material being disposed of in municipal landfills and incinerators. Changes to the general license in § 40.22 may also impact such disposal.
- Regulatory Efficiency -- The final rule will increase efficiency by improving the regulatory framework for the distribution of source material, removing obsolete provisions, and clarifying some of the regulations.
- Improvements in Knowledge -- The rule will allow the NRC to better track the number and types of products and materials distributed for use under exemptions from license and to better estimate the impacts of these products and materials. The final rule will allow the NRC and the Agreement States to more easily identify general licensees using source material and to improve their knowledge about their activities.
- Other Considerations -- The final rule could increase public confidence in the NRC by making the regulations more protective of public health and safety by allowing the NRC to better evaluate and provide information on exposures of the public and certain workers from source material.

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

The final rule is *not* expected to affect the following attributes:

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

Determining to what extent each of these attributes can be quantified is difficult. For some attributes, like NRC implementation costs, quantifying the impact is relatively straightforward. For many others, it cannot be done due to lack of information or methodological problems. However, NUREG/BR-0058, Revision 4, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," states that "[e]ven inexact quantification with large uncertainties is preferable to no quantification, provided the uncertainties are appropriately considered." In ideal circumstances, dollar amounts are added up and a "net benefit" is given -- the amount by which values exceed impacts. Often, only costs (impacts) can be quantified. In the absence of dollar estimates for benefits and costs, a regulatory analysis may be able to provide some other quantitative information.

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

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

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

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

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

There are no alternatives to rulemaking that could accomplish the same result. However, there are other ways the regulations could be changed to improve the control of distribution and use of such products. One option would be to require specific authorization for distribution without a specific licensing provision. This would be difficult to implement because the authorization to transfer material for use under exemption from licensing is reserved to the NRC under 10 CFR 150.15(a)(6). Use of this NRC-retained authority to require all such distribution to be authorized by specific license issued by the NRC will be significantly more efficient and effective than any other option, and will more consistently provide for adequate control of the materials used under exemption.

Cost Impacts:

Costs to Industry/Licensees (Manufacturers and Distributors)

Costs to distributors will depend on whether they are currently an NRC or an Agreement State specific licensee or are currently operating under § 40.22 or equivalent State provisions, or an importer with no current license.

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

Illustrative estimate of application costs for these assumptions:

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

NRC Exempt-Distribution License Required:

30 applications x 8 hours/application x \$56/hour = ~\$13,400

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

Since hazard and safety information exists (e.g., American Welding Society (AWS) Safety and Health Fact Sheet No. 2 and No. 27), the effort to develop a distributor-specific label or instruction is estimated to take an average of 20 hours.
4 applications x 20 hours/application x \$56/ hour = ~\$4,500

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

Quality control (§ 40.53(a)):

Although there will now be an explicit requirement that distributors must ensure that products meet the applicable exemption limits, the distributors should already be doing this. New costs are limited to those connected with documentation of the program for the NRC. Those are included in the application costs estimated above.

Reporting (§ 40.53(c)):

0.5 hours/licensee x 30 licensees x \$56/hour = ~\$840/year

Recordkeeping (§ 40.53(c)):

1 hour/licensee x 30 licensees x \$56/hour = ~\$1,680/year

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

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

Illustrative estimate for 4 importers providing instructions:

A printed piece of paper is likely to cost \$0.03 per page. For purposes of this analysis, it is assumed that 1,000,000 thoriated welding electrodes are distributed annually in the United States and that they are typically sold in quantities of 10. Larger quantities are also sold, primarily to secondary distributors.

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

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

$$100,000 \text{ sales/year} \times \$0.03/\text{package insert} = \sim\$3,000/\text{year}$$

$$100,000 \text{ sales/year} \times 0.02 \text{ hr/sale} \times \$56/\text{hr} = \sim\$112,000/\text{year}$$

$$\sim\$115,000 \text{ total/year}$$

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

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

Fees

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

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

Importers of finished products will be exempt from 10 CFR Parts 19 and 20. In addition, importers will be exempt from § 40.32(b) and (c), which concern the adequacy of training, experience, facilities, and equipment to protect health and minimize danger to life and property. For importers, the costs of being a specific licensee will be almost exclusively the costs directly involved with requirements covering distribution estimated above. For others, the requirements of 10 CFR Parts 19 and 20 and the additional requirements in 10 CFR Part 40 (and equivalent Agreement State requirements) related to the possession and use of the source material will add to the costs of being specifically licensed.

The costs of being subject to 10 CFR Parts 19 and 20 (and equivalent Agreement State requirements) will depend on a number of factors. New specific licensees, who are not importers of finished products, will be those currently manufacturing a product covered by an exemption in § 40.13(c), including coated lenses being added to the exemption in § 40.13(c)(7),

who are now operating under the general license in § 40.22 (or equivalent Agreement State provisions).

The costs for complying with 10 CFR Part 19 are primarily those associated with training employees; most of this cost is only incurred if workers' exposures are likely to exceed 1 millisievert (mSv) (100 millirem (mrem)) per year. Ongoing costs will routinely result for all licensees from § 19.13, Notifications and reports to individuals.

The primary costs for complying with 10 CFR Part 20 will result from requirements to have and to document a radiation protection program, including having a radiation safety officer, as well as maintaining cognizance of the requirements in order to maintain compliance. The primary applicable requirements related to this are in: § 20.1101, along with applicable limits in 10 CFR Part 20, Subparts C (occupational dose limits), D (radiation dose limits for individual members of the public), and F (surveys and monitoring); § 20.1906 (receipt and opening of packages); and § 20.2102 (records). The complexity of this radiation protection program will depend on the degree of hazard it is intended to control. The more complex the program needs to be, the greater the costs of the program will be.

One-time costs for a general licensee/manufacturer becoming a specific licensee and instituting a radiation protection program, including training, will be on the order of \$10,000 in capital costs and 20 hours of labor (@ \$56 per hr) for roughly an additional \$1,100, totaling ~\$11,100 per entity. Ongoing efforts applicable to all specific licensees are likely to involve 22 hours per year for routine requirements, primarily notification of workers of their exposures (§ 19.13), records of radiation protection program (§ 20.2102), and records of surveys (§ 20.2103). Thus, a minimum of:

$$22 \text{ hr} \times \$56/\text{hr} = \sim \$1,200/\text{year}$$

Other requirements in 10 CFR Part 20 that may result in significant costs are those related to waste disposal in Subpart K, Appendix G, and § 20.2108 (Records of waste disposal).

There are a large number of other specific reporting and recordkeeping requirements within 10 CFR Part 20; however, these types of licensees will have limited circumstances for needing to report under many of them. Reporting requirements that will clearly be applicable include: requirements for labeling of containers (§ 20.1904) and reports of theft or loss (§ 20.2201).

At some point in the future, these licensees are likely to incur costs when they discontinue use of the source material and terminate their license, as they will be subject to Subpart E of 10 CFR Part 20 on criteria for release of the site.

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

A typical manufacturer likely to be currently operating under a general license is someone applying a coating to optical lenses. Typically, these operations involve coating the lenses in vacuum chambers. These chambers and other equipment need to be cleaned periodically to remove residual material, sometimes with sandblasting. Adequate radiation protection may

involve the use of equipment such as glove boxes and some form of respiratory protection. These operations tend to have significant wastes for disposal.

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

Additional provisions in 10 CFR Part 40 that may result in costs being incurred:

General licensees under § 40.22 are not exempted from the regulatory provisions in 10 CFR Part 40; however, certain requirements are only applicable to a specific licensee/applicant and are not applicable to the general licensee. These requirements include particularly: § 40.31, Application for specific licenses; § 40.32, General requirements for issuance of specific licenses; § 40.42, Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas; § 40.43, Renewal of licenses; and § 40.44, Amendment of licenses. Also, § 40.36, Financial assurance for decommissioning, applies only to specific licensees; however, these manufacturers do not have enough source material to meet the criteria for this requirement. In the near term, the most significant costs of these additional 10 CFR Part 40 requirements are from the initial application and any changes that will be needed to obtain the initial license.

Some NRC general licensees are likely to be manufacturing products used under exemption, and will need to obtain specific licenses as a result of this rule. The NRC estimates that fewer than 20 entities nationally are manufacturing such products under a general license and will become NRC § 40.52 licensees as a result of these new requirements. For those in Agreement States, the costs discussed above concerning the applicability of 10 CFR Parts 19 and 20 will mostly come about through equivalent Agreement State regulations as applied to the possession and use licenses they will obtain from the Agreement State where each is conducting business. Given the large variability in costs to individual affected parties and the large uncertainty in the number of affected parties, no attempt has been made to fully quantify the total cost of an applicant obtaining a possession license because they required a specific license for distribution.

Other Costs to Industry

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

Costs to NRC:

One time:

30 applications x 8 hours/application x \$116/staff hour = ~\$28,000

3 include consideration of manufacturing safety

3 x 10 additional hours/application x \$116/staff hour = ~\$3,500

Total: ~\$31,500

Annual:

Small additional ongoing costs for inspections:

Assuming an average of 6 additional inspections per year

6 inspections x 12 hr/inspection x \$116/staff hr = ~\$8,400

Small increase in number of amendments/year:

6 amendments/yr x 5 hr/amendment x \$116/staff hour = ~\$3,500

Total: ~12,000/year

Costs to Agreement States

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

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

Costs to Public

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

Occupational Health/Public Health

Small incremental increases to occupational exposures could occur as a result of the additional labeling, if the process involves workers spending more time in proximity to products. These increases are not expected to be significant, as most such processes are automated, and exposure rates are low in any event.

Benefits:

Benefits to Licensees/Distributors

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

Benefits to Workers

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

Benefits to NRC/Benefits to Agreement States

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

Benefits to Users/Public

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

Environmental Considerations

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

Alternatives Considered

Requiring the labeling of products or point-of-sale containers for all products, even when particular instructions to users are not necessary to enhance safety, was also considered. Such labeling would notify consumers of the presence of radioactive material and clarify that end users are exempt from all regulation. This would provide for greater knowledge concerning the use of radioactivity in such products and limit questions and concerns about appropriate disposal options. However, this option would provide no clear benefit to health and safety.

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

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

Cost Impacts:

Costs to Licensees/Distributors

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

Costs to NRC

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

Costs to Agreement States

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

Costs to Users

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

Benefits:

Benefits to Licensees/Distributors

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

Benefits to NRC/Agreement States

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

Public Health

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

Environmental Considerations

No significant effect is anticipated. There will, however, be greater assurance that glassware manufactured in the future and ultimately disposed of without regard to its radioactivity will have a lower concentration of source material.

Alternatives Considered

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

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

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

Cost Impacts:

Cost to Licensees (Manufacturers and Distributors)

The NRC is not aware of anyone currently manufacturing optical lenses containing greater than 10 percent by weight of thorium. As a result, no changes in direct costs are anticipated. Limited costs could result to licensees if ensuring and demonstrating that products do not exceed the lower limit is more difficult.

Costs to NRC

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

Costs to Agreement States

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

Benefits:

Benefits to Licensees/Distributors

Manufacturers and distributors of lenses that are not currently covered by the exemption or that are not clearly covered will benefit, because there will be greater market opportunity for their lenses and mirrors.

Benefits to NRC/Agreement States

Clarification of the regulatory status of coated lenses will create regulatory efficiency by reducing questions and confusion.

Benefits to Users/Potential Users

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

Alternatives Considered

The Commission also considered developing and providing limits on lenses with coatings that might be more appropriate than a weight percent limit. Although the approach of averaging content with a lens plus coating has its drawbacks, a practical limit on thickness or total quantity of source material was difficult to determine. The only comment on this aspect of the proposed rule was a suggestion that an activity per unit area (square centimeter) would seem more appropriate. However, no additional information was provided as a basis for establishing such a limit. At some point in the future, when the Commission gets more information through licensing the distribution of these products, this may be reconsidered.

4.4 Remove Obsolete Provisions

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

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

Section 40.13(c)(2)(i) contains a provision for glazed ceramic tableware. Based on dose estimates included in NUREG-1717, this is the only exemption identified for source material that could result in significant doses to individual members of the public. Although these products

have not been manufactured in many years, this change will ensure that they are not domestically manufactured or imported in the future.

Cost Impacts:

Costs to Licensees (Manufacturers and Distributors)

There are no known manufacturers or initial distributors for these products.

Costs to NRC and Agreement States

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

Section 40.13 is Compatibility Category B requiring essentially identical wording in Agreement State regulations. Revising § 40.13(c) and removing § 40.13(d) requires comparable changes in Agreement State regulations; however, each State is expected to conduct one rulemaking following this revision of 10 CFR Parts 30, 40, 70, 170, and 171. The cost for the Agreement State rulemaking is discussed in Section 4.9.

Costs to the Public

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

Benefits:

Deleting these unnecessary regulations will simplify the regulations by eliminating extraneous text. This will eliminate the need to reassess the potential exposure of the public from these exemptions for possible future distribution of the products. Also, these exemptions will no longer need to be considered when assessing the total potential doses to the public from multiple sources. Additionally, there is a potential benefit to the public from the elimination of future exposures. Based on dose estimates performed for the exemption for tableware (§ 40.13(c)(2)(i)), potential exposures could be higher than is appropriate for exempt materials. As a result of this action, members of the public will be assured that exposures from products manufactured in the future will not occur.

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

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

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

equivalent Agreement State regulations. The final rule was revised to clarify that transfers to any analytical laboratories that may be operating under the general license in § 40.22 are not to be captured by the new requirements for distribution.

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

Cost Impacts:

Costs to Licensees (Distributors)

Only one initial distributor of source material to § 40.22 general licensees has been identified (the distributor is specifically licensed by an Agreement State). It is assumed that there may be a couple of other Agreement State licensees, previously unidentified by the NRC, that will be required to come under the new licensing requirements when equivalent provisions are added to Agreement State regulations. It is assumed one new NRC licensee will initially distribute source material for use by general licensees.

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

Illustrative estimate of application costs for these assumptions:

4 distributors (1 NRC; 3 Agreement State)

General License-Distribution License Required:

4 applications x 8 hours/application x \$56/hour = ~\$1,800

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

Quality control (§ 40.55(a)):

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

Reporting (§ 40.55(d)):

0.6 hr/licensee (reports to NRC) x 4 licensees x \$56/hr = ~\$130

0.3 hr/report to a State x average 5 States/licensee x 4 licensees x \$56/hr = ~\$340

Recordkeeping (§ 40.55(e)):

$$1 \text{ hour/licensee} \times 4 \text{ licensees} \times \$56/\text{hour} = \sim\$220$$

Labeling (§ 40.55(b)):

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

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

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

Illustrative estimate for 4 distributors providing instructions:

Initial costs associated with providing safety instructions:

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

$$4 \text{ applications} \times 40 \text{ hours/application} \times \$ 56/ \text{ hour} = \sim\$9,000$$

Continuing costs of providing safety instructions:

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

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

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

$$100 \text{ total recipients/year} \times \$0.12/\text{package insert} = \sim\$12/\text{year}$$

$$100 \text{ recipients/year} \times 0.02 \text{ hr/recipient} \times \$56/\text{hr} = \sim\$110/\text{year}$$

$$\sim\$120 \text{ total/year}$$

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

Costs to NRC and Agreement States

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

Illustrative costs for 4 applicants/licensees:

1 application to NRC x 8 hours/application x \$116/staff hour = ~\$900
3 applications to States x 8 hours/application x \$46/staff hour = ~\$1,100

Total: ~\$2,000

There will also be small additional ongoing costs for inspections.

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

Benefits:

Benefits to General Licensees

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

Benefits to NRC/Benefits to Agreement States

These provisions will allow the Commission and the Agreement States to better control the source material used under this general license. It will allow them to identify general licensees receiving significant amounts of source material, so that they can communicate with them and inspect them as needed.

Benefits to Public

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

4.6 Revise the General License in § 40.22

The final rule will revise § 40.22 in a number of ways: (1) to limit the general license to thorium and uranium in their natural isotopic concentrations and depleted uranium; (2) to limit possession to less than 1.5 kg (3.3 lb) of source material at any one time and 7 kg (15.4 lb) per calendar year for dispersible forms, and to continue to allow up to 7 kg (15.4 lb) at any one time and 70 kg (154 lb) per calendar year for most solid forms, for removal of uranium from drinking water, and for laboratories handling samples for the purpose of determining the concentration of the uranium and thorium; (3) to clarify disposal requirements and the applicability of other 10 CFR Part 40 regulations; (4) to require a general licensee to respond to NRC requests for information; and (5) to require the general licensee to minimize contamination at the site and

ensures that the site is cleaned up after use of source material is ended. The specific provision for analytical laboratories is added in the final rule in case such laboratories are operating under the general license, in order to prevent any unintended impacts for the handling of samples.

Cost impacts:

Costs to Industry/Licensees

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

Costs to General Licensees

Some of these explicit requirements should apply because general licensees are not exempt from all of 10 CFR Part 40; for some, these changes are clarifications of general licensee responsibilities. It is expected that most, if not all, general licensees under this provision who are not manufacturing and distributing products to others (who will be required to become specific licensees to continue those activities) use very small quantities and will not have difficulty continuing their current activities within the additional constraints being added. Costs for those remaining under the general license are expected to be small and are difficult to quantify. The most significant may be if activities resulted in a significant contamination of a building or site that ultimately requires a major cleanup effort. However, the reduced limits for dispersible forms will reduce this likelihood for those using materials under the general license in the future.

Costs to Public

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

Benefits:

Benefits to Licensees/Distributors

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

Benefits to General Licensees

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

Benefits to NRC/Benefits to Agreement States

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

Benefits to Public

There will be less probability of general licensees causing unnecessary contamination resulting in future owners being exposed to contaminated sites. Public confidence may be enhanced.

4.7 Minor Clarifying or Administrative Revisions

Other minor revisions are included to better organize, clarify, or update the regulations in these parts, such as the addition of appropriate sections under lists of information collections and clarification of which requirements are subject to criminal penalties. In the final rule this also includes a revision to the definition of “Unrefined and unprocessed ore,” as used in the exemption in § 40.13(b), to clarify what is not considered to be processing; this clarification will assist in preventing unintended impacts for those sending samples of natural materials containing uranium and thorium to analytical laboratories for characterization. Minor conforming amendments are included in 10 CFR Parts 30 and 70 because the delineation of the delegation of licensing programs to the Regions is written broadly in these parts.

Cost Impacts:

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

Benefits:

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

4.8 Development and Implementation Costs

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

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

Federal and State Materials and Environmental Management Programs expended in developing the rule.

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

4.9 Costs to Agreement States of Compatible Regulations

Costs will be incurred by the Agreement States for development and implementation of compatible regulations. The costs will vary significantly by State because of differences in internal procedures for developing regulations. Some rule changes will be required to meet Compatibility Category B for certain revisions. As these revisions will be required to be essentially word-for-word compatible, the process should be relatively simple. For this final rule, the NRC assumes an average of 0.1 FTE at \$89,000 per FTE for each state. There are currently 37 Agreement States; therefore, the total cost for all Agreement States will be approximately \$329,000.

5. DECISION RATIONALE

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

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

A significant cost will be implementation of the final rule by the NRC and the Agreement States. However, by handling several issues together, the Commission is minimizing its costs as well as costs for the Agreement States compared to addressing each of these issues separately.

6. IMPLEMENTATION

The NRC's schedule for implementation of this rulemaking calls for the effective date of the rule to be in 2013 for the NRC's jurisdiction and full implementation by the Agreement States by 2017. The applicable guidance documents are NUREG-1556, Vol. 8, and NUREG-1556, Vol. 16. These have additional updating needs and are being revised as part of a broader update likely to be completed following the issuance of the rule. Some revision to these two documents will be appropriate as a result of this rule in order to expand the scope to include source material distribution. Interim guidance was issued for public comment in the form of Questions and Answers. These will be updated based on revisions in the final rule and as a result of public comments requesting further guidance/clarification, if the applicable NUREG-1556 volumes are not prepared for publication by the time the rule is made effective.

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

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

7. IMPLICATIONS FOR OTHER FEDERAL AGENCIES

Promulgation of this final rule will have no adverse effects on other Federal agencies.

8. EFFECT ON SMALL ENTITIES

The final rule will impact both small and large entities with the largest impact on those persons currently manufacturing and distributing products for use under § 40.13(c) and that are not already specifically licensed. It is not known exactly how many such entities exist, nor what fraction are small entities, but the total of small entities impacted is believed to be fewer than 20. Small entities are provided with relief from the impact of fees through reduced fees amounts.

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

June 2012

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



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1.0 Introduction

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

1.1 Background

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

Other parts are affected by this rulemaking. The regulations in 10 CFR Part 30 provide the basic requirements for possession and use of byproduct material, while 10 CFR Part 70 provides the basic requirements for possession and use of special nuclear material. Both of these parts will be amended to conform to the changes made to 10 CFR Part 40. The regulations in 10 CFR Parts 170 and 171 address fees associated with licensing and will be amended to include the new categories of 10 CFR Part 40 specific licenses for distribution.

The NRC has conducted a systematic reevaluation of the exemptions from licensing in 10 CFR Parts 30 and 40 of the NRC's regulations, which govern the use of byproduct and source material, respectively. A major part of the effort was an assessment of the potential and likely doses to workers and the public under these exemptions. The assessment of doses associated with most of these exemptions can be found in NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," (NRC, June 2001). In the past few years, several issues have been identified where improvements could be made to the regulations governing these products. The amendments to exemptions considered in this document largely stem from this analysis.

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

1.2 Document Organization

This environmental assessment presents a discussion of the basic subjects specified in 10 CFR 51.30 and fulfills the requirements of the National Environmental Policy Act of 1969, as amended. This environmental assessment is organized to best accommodate the rule's complexity. This complexity is due to the Commission's decision to aggregate multiple issues into this single rulemaking, with the purpose of minimizing the cost of the activities. The rule is therefore best understood and discussed as a collection of separate small issues. Many of the amendments meet the criteria for categorical exclusion – as detailed below – and do not require an environmental assessment to be prepared. The amendments not meeting these criteria are discussed issue-by-issue, and are the focus of the environmental assessment.

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

2.0 Need for the Preferred Action

Currently, there are no regulatory mechanisms for the Commission to ensure that products and materials distributed for use under the general license in § 40.22 or an exemption in § 40.13 are maintained within the applicable constraints of the requirements for these uses. Because the staff cannot readily identify who possesses source material under the general license in § 40.22 or how and in what quantities the source material possessed under § 40.22 is being used, the staff cannot fully assess the resultant risks to public health and safety. In addition, some isotopically-separated source material, in particular, thorium-228, has the potential to present significantly higher potential doses. Although the NRC is not aware of large quantities of these isotopes being separated for commercial use, if the separated isotopes were readily available, the current provisions of § 40.22 could allow a person to receive quantities large enough in

terms of activity to present not only a safety concern, but also a security concern, without obtaining a specific license.

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

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

The findings in the PNNL study indicated that the use of source material in products is declining. The results of the evaluation also indicated that most source material possessed under § 40.22 is likely handled in quantities, physical forms, or in uses and under conditions that would justify the continued use of the exemptions to 10 CFR Parts 19 and 20. However, as indicated by PRM-40-27, and by the bounding dose calculations evaluated in the PNNL study, situations can and do occasionally occur that exceed limitations under which 10 CFR Parts 19 and 20 usually apply.

3.0 Applicability of Categorical Exclusion for Certain Amendments

Many of these amendments being made by the final rule belong to a category of actions that the Commission has determined to be a categorical exclusion, having found that these types of actions do not individually or cumulatively have a significant effect on the human environment. Therefore, this EA is not required to evaluate these amendments.

In accordance with § 51.22(c)(1), the amendments to 10 CFR Parts 170 and 171 are categorically excluded, and do not require an environmental assessment. Additionally, under § 51.22(c)(3), amendments to 10 CFR Parts 30, 40, and 70 that relate to procedures for filing and reviewing application for licenses, recordkeeping, and reporting – paragraphs (i), (ii), and (iii), respectively – do not require an environmental assessment. The final §§ 40.13(c)(10) and 40.22(e) will require that affected persons comply with §§ 40.52 and 40.54, respectively. Sections 40.52 and 40.54 provide the requirements for approval of a specific license and are covered by this categorical exclusion. The final recordkeeping and reporting requirements for initial distributors of source material to general licensees and exempt persons in §§ 40.53 and 40.55 are also covered by this categorical exclusion. Finally, the amendments to §§ 30.6, 40.5,

and 70.5 which deal with communications, § 40.8, “Information collection requirements: OMB approval,” and § 40.82, “Criminal penalties,” are also covered by this categorical exclusion.

4.0 The Preferred Federal Action and Alternatives: Generic Discussion

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

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

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

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

The no-action alternative is to maintain the status quo. The no-action alternative would not address the identified concerns. Specific details of the implications of the preferred action and the no-action alternative are discussed below, issue by issue. Because the non-rulemaking

alternatives discussed above do not achieve the goals of the preferred action nor result in any differences from the no-action alternative, they are not discussed further.

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

5.1 Revise 10 CFR 40.22 in its Entirety

Section 40.22 provides the requirements for possession and use of small quantities of source material under a general license. The current regulations in § 40.22 allow possession and use of up to 15 pounds (lb) (~7 kilograms (kg)) of source material at one time and receipt of no more than 150 lb of source material within a calendar year. These requirements have no associated reporting or registration requirements and exempt the user from the health and safety requirements in 10 CFR Part 20 and the training requirements in 10 CFR Part 19, thus effectively allowing the general license to operate similar to those exempt from licensing.

The final rule will revise § 40.22 to:

- limit the general license to natural isotopic concentrations of thorium and uranium and to depleted uranium;
- limit possession to less than 1.5 kg (3.3 lb) of source material at any one time and 7 kg (15.4 lb) per calendar year for dispersible or processed forms, while continuing to allow up to 7 kg (15.4 lb) total of source material at any one time and receipt of no more than 70 kg (154 lb) per calendar year including source material in solid, non-dispersible forms for persons removing uranium from drinking water, or for laboratories handling samples for the purpose of determining the concentration of the uranium and thorium;
- clarify disposal requirements and the applicability of other 10 CFR Part 40 regulations; and
- require the general licensee to minimize contamination at the site and ensure that the site is cleaned up after the use of source material is ended.

The revised § 40.22 will also require a general licensee to respond to NRC written requests and prohibit the initial transfer of source material to a general license without a specific license. The requirement to respond to NRC written requests is considered to be a reporting requirement and the prohibition on the initial transfer of source material is considered to be a procedure related to the filing of an application; both of which fall under the categorical exclusion in § 51.22(c)(3) (see Section 3.0, above). The remaining requirements in § 40.22 are restated from the current requirements in § 40.22.

5.1.1 Revision of 10 CFR 40.22 Possession Limits

Although source material, in particular thorium, has an external radiation impact, the primary concern when dealing with source material is limiting internal uptake. The 2006 PNNL report concluded that certain activities allowed under the current possession limits in § 40.22 could expose workers to almost 5 rem (50 millisieverts (mSv)) per year (both internal and external doses) using conservative assumptions. More realistic scenarios indicated worker exposures could still exceed 800 millirem (mrem) (8 mSv) per year. In both cases, the majority of the exposures were related to inhalation and ingestion which would only result from material that was dispersible in air or processed to create dust. By reducing the possession limit for such material to 1.5 kg (3.3 lb) of source material at any one time and receipt of up to 7 kg (15.4 lb) of source material in dispersible or processed forms in a calendar year, the NRC expects worker exposures to generally be below 100 mrem (1 mSv) per year, which is the limit in § 20.1301 that applies to most NRC licensees for protection of members of the public. Because § 40.22 general licensees are not required to meet the training requirements in 10 CFR Part 19, it is more appropriate to treat their workers similar to members of the general public. Implementation of normal industrial hygiene requirements would further reduce these potential exposures. In addition, by limiting the types of source material to only natural isotopic concentrations of thorium and uranium and depleted uranium, the new possession limits reduces the possibility that a person will accumulate large quantities of isotopes with high specific activities. Possession of large quantities of certain isotopes of source material (in particular thorium-228) could significantly increase the possibility of high exposures.

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

The NRC is retaining the possession limits and annual receipt limits for: (1) solid, unprocessed source material (e.g., ore or uranium metal samples that are used for display); (2) removal of uranium from drinking water; and (3) laboratories handling samples for the purpose of determining the concentration of the uranium and thorium. Because solid, unprocessed source materials will likely not contribute significantly to internal uptakes of source material or significantly result in additional contamination, the NRC has determined that the current limit is sufficient. In the case of water treatment, the primary treatment method that is expected to accumulate concentrations of source material that would fall under the general license would be from ion exchange. In this case, the uranium would be expected to be selectively isolated from its progeny. As a result, exposures from the uranium itself, because the uranium would be imbedded on resin and not readily available for internal uptake, are expected to be minimal. The third exception from the change to possession limits was added in the final rule to avoid potential unintended and inappropriate impacts to these laboratories and to the mining industry. Because there is no change being made to the possession limits for non-dispersible source material, for water treatment activities, or for sample measurement laboratories from the current general license, there will be no significant impact to any environmental resources.

5.1.2 Clarification of Disposal Requirements for 10 CFR 40.22

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

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

By clearly delineating the amount and form of source material allowed to be disposed of without further NRC licensing, the final action will reduce the potential for much greater quantities of source material (conceivably up to 150 lb (~70 kg) per general licensee per year) to be disposed of at an unlicensed facility. The purpose of allowing smaller quantities of source material to continue to be disposed of without further NRC licensing is to allow an economical disposal route for persons (e.g., educational institutions) possessing very small quantities of source material. Continuing to allow these small quantities of source material to be disposed of in landfills is not expected to significantly impact the environment or members of the public because the material is required to be in a solid, non-dispersible form, which would be unlikely to spread to the environment and would not be readily inhaled or ingested. Requiring the disposal of larger quantities of source material in a manner consistent with § 20.2001 will reduce the impact to workers, the public, and the environment resulting from larger disposals at unlicensed facilities that could be construed to be acceptable under the current regulations.

Because of the limited availability of licensed disposal sites, the final action could result in longer transportation routes than disposal at the local landfill. Longer transportation routes have a potential to increase the opportunity for higher exposures to drivers, accidents, exhaust emissions, and use of non-renewable resources (gasoline or diesel). Because the possession limits in § 40.22 will limit disposal of at most 7 kg (15.4 lb) of source material at one time, it is

likely that the general licensee would use either a waste consolidator, or, if Department of Transportation regulations allow, common shippers, in order to limit transportation costs and packaging costs. Waste consolidators and common shippers would likely already be transporting other materials to or near the locales of the licensed disposal site thus limiting these potential adverse effects.

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

5.1.3 Requirements to Minimize Contamination and Adequately Decommission the Site

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

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

Revised § 40.22 will also require that when activities involving source material are permanently ceased at any site, the general licensee does not abandon the site with quantities of source material that could result in exposures exceeding the limits in § 20.1402. Section 20.1402 requires a licensee to restore a site for unrestricted use such that residual radiation that is distinguishable from background will not result in exposures above 25 mrem (0.25 mSv)/year. Because of the current 10 CFR Part 20 exemption, a § 40.22 general licensee is not required to decommission the site. The final action will require the licensee to notify the NRC if significant source material contamination (i.e., there is a potential the residual contamination would exceed the limits in § 20.1402) is identified upon completion of activities. The NRC could then advise the general licensee about decommissioning and surveying options and, if necessary, inspect the facility upon completion of such activities.

Because these amendments will provide greater controls on the eventual disposition of the source material, the final amendments are expected to have an insignificant impact on environmental resources compared to the current contamination control and decommissioning requirements for § 40.22 general licensees.

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

The existing regulation in § 40.13(c)(7) provides an exemption from licensing for the possession of finished optical lenses containing thorium homogeneously distributed throughout the lens at a

concentration of no greater than 30 percent thorium by weight. Shaping, grinding, or polishing of the lenses is specifically prohibited. In addition, the use of lenses in applications where the lens is in close proximity to the eye (e.g., contact lenses, spectacles, or eyepieces in binoculars or other optical instruments) is also prohibited.

Revised § 40.13(c)(7) expands the exemption to clearly cover thorium-coated lenses and mirrors and to allow the use of uranium in and on lenses and mirrors. The concentration of source material allowed on or within the lens will be reduced from 30 percent by weight to 10 percent by weight; however, lenses containing thorium homogeneously distributed throughout the lens and manufactured prior to the effective date of the rule will continue to be exempt at concentrations up to 30 percent by weight of the thorium. The restrictions on processing and uses currently in § 40.13(c)(7) will continue to apply.

5.2.1 Addition of Uranium and Thorium Coated Lenses to Exemption

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

The PNNL report specifically evaluated the use and manufacture of thorium and uranium thin-film optical coatings. Based upon the findings in the report, a lens manufactured with a thin-film of source material contained significantly less source material than those lenses that contained thorium homogeneously distributed throughout the lens. Lenses evaluated in NUREG-1717 incorporated up to 100 grams (g) (0.22 lb) of thorium, while thin-film coated lenses have approximately 0.02 g (0.0007 ounces) of thorium applied to the lens. Routine doses (accounting for external exposures only) from the lenses with thin-film optical coatings of thorium were calculated to be less than 0.004 millirem (mrem) (0.04 microsieverts (μ Sv)) per year to an individual. Doses from uranium coated lenses were found to be even lower. Doses resulting from accidents while using the thin coated lenses were expected to be similarly small. Thin-film coatings of uranium or thorium applied to mirrors would be expected to have similar impacts.

The Commission has a consumer product policy (30 FR 3462, March 16, 1965), which calls for the Commission to monitor the overall impact of its exemptions from licensing. The Commission evaluated the potential exposure impacts from consumer products in the early '60's, again in the late '70's, and more broadly of all of its exemptions in the '90's. The second of these analyses was published as NUREG/CR-1775, "Environmental Assessment of Consumer Products Containing Radioactive Material," in 1980. As noted in the Section 1.1, Background, the dose assessments from the latest of these evaluations were published as NUREG-1717. The Commission's policy is for consumer products to routinely expose users to only a small fraction of the public dose limit. The estimated doses under routine use conditions for lenses having thin-film optical coatings of uranium and thorium results in only a small fraction of the public dose limit (well below 10 μ Sv (1 mrem) per year). As a result, expanding the exemption for lenses to include lenses or mirrors coated with thorium or uranium will not significantly impact public or occupational health.

5.2.2 *Reduction of Allowable Concentration to 10 Percent by Weight*

The final rule establishes a new concentration limit for source material contained in or on finished optical lenses and mirrors of 10 percent by weight, which is a reduction from the previous 30 percent by weight limit that was applicable to lenses containing thorium. The evaluation in NUREG-1717 assumed that a camera operator used a lens system containing 3 lenses, each containing 100 g (0.22 lb) of thorium and concentrations of 10 percent by weight of thorium. The resulting dose was 200 μ Sv (20 mrem) per year to an operator, and is considered higher than a small fraction of the public dose limit. Although this may be considered an industrial use rather than a consumer product use (thus the higher allowable exposure), the reduction in concentration is warranted due to the availability of alternative materials that can be applied or incorporated to lenses to achieve similar effects. Additionally, the NRC has not been able to identify any persons currently manufacturing lenses using concentrations in excess of 10 percent. This is likely because of the increased prevalence of lenses with thin optical coatings or other materials. Lenses containing thorium homogeneously distributed throughout the lens and manufactured prior to the effective date of the rule would continue to be exempt at concentrations up to 30 percent by weight thorium to account for those lenses still possessed that may be in excess of the final limit of 10 percent by weight.

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

5.3 *Revise the definition of “unrefined and unprocessed ore” in 10 CFR 40.4*

The existing regulation in § 40.13(b) provides an exemption from licensing for unrefined and unprocessed ore. A clarifying amendment to the definition of “unrefined and unprocessed ore” in § 40.4 is being made in the final rule in response to comments to indicate that activities related to the sample analysis of an unprocessed ore and a few other specified activities are not considered to be processing and that the ore would remain exempt under § 40.13(b) after these limited types of activities. While this is a clarification, generally in line with the original intent, it somewhat expands the exemption under § 40.13(b). The inclusion of sample analysis of unprocessed ore is primarily to ensure consistency with § 65 of the Atomic Energy Act of 1954, as amended, which states, in part that “reports shall not be required with respect to (a) any source material prior to its removal from its place of deposit in nature, or (b) ...the reporting of which will discourage independent prospection for new deposits.” It is also intended to prevent unintended impacts to analytical laboratories that could be placed in the position of being in violation of NRC regulations because they did not know that a sample contained enough source material to exceed the regulatory limits until after sampling. The rule also clarifies that simple handling of soils/sands such as sieving or encapsulation does not cause the material to come under licensing requirements. The primary intent of the original definition was to allow mines to

transfer ores without having to obtain a specific license. This was accomplished by exempting from licensing those activities where the ore was not physically or chemically changed. Neither sieving nor encapsulation result in physical or chemical changes to the ore itself. Overall, there is expected to be a minimal impact on environmental resources as a result of this clarification.

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

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

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

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

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

The amendment to the introductory paragraph of § 40.13(c) will clearly state that a person possessing a product under an exemption in § 40.13(c) is not only exempt from obtaining a license or meeting the requirements of 10 CFR Part 40, but also is not required to meet the notification and training requirements of 10 CFR Part 19, the health and safety requirements of 10 CFR Part 20, and the reporting requirements in 10 CFR Part 21. Because this is the current practice under the exemption, the addition of this clarifying language will not affect any environmental resources.

5.5 No Action

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

The no-action alternative would not address identified public health and safety concerns. General licensees would continue to possess source material in quantities or isotopic concentrations that could significantly exceed public health and safety limits while still being exempt from 10 CFR Parts 19 and 20. Confusion regarding disposal requirements would continue, thus potentially permitting licensees to dispose of source material in unlicensed disposal facilities. In addition, not implementing contamination controls would allow the licensee to potentially abandon source material in place and thus expose other persons to dose levels normally not allowed for unrestricted use. Although the no-action alternative would not adversely affect any environmental resources, this alternative would not provide the improvements to health and safety that could result from the preferred action.

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

6.0 Conclusion

The NRC has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's implementing regulations in Subpart A of 10 CFR Part 51, not to prepare an environmental impact statement for this rulemaking because the Commission has concluded on the basis of this environmental assessment that this rule is not a major Federal action significantly affecting the quality of the human environment. While most of the revisions fall under a categorical exclusion, the revisions to § 40.22 primarily provide additional limitations on, or clarify what a general licensee is allowed under the general license, thus potentially reducing the impact on environmental resources from the status quo. Similarly, certain exemptions are being revised or deleted to limit the future use of certain products containing source material. Although the NRC is expanding 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 previously authorized under the exemption.

The determination of this environmental assessment is that there will be no significant impact to any environmental resources from this action and therefore the actions do not warrant the preparation of an environmental impact statement. A finding of no significant impact (FONSI) was published in the *Federal Register* concurrently with the publication of the proposed rule for public comment (75 FR 43425, July 26, 2010). No comments were received regarding the EA. The Commission considered the possible impacts from revisions made in the final rule and reaffirms this determination. Accordingly, the FONSI will be restated concurrently with the publication of the final rule.

7.0 List of Agencies and Persons Consulted

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

8.0 Sources Cited

Administrative Procedure Act of 1946, 5 U.S.C § 551 *et seq.* (1946).

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

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

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

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

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

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Code of Federal Regulations, Title 10, Energy, Part 170, "Fees for Facilities, Materials, Import and Export Licenses, and other Regulatory Services Under the Atomic Energy Act of 1954, as Amended."

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