UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

SECRETARY

October 23, 2012

COMMISSION VOTING RECORD

DECISION ITEM: SECY-12-0099

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

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of October 23, 2012.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:
1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Macfarlane
Commissioner Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff
OGC
EDO
PDR

VOTING SUMMARY - SECY-12-0099

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MACFARLANE	X				X	10/5/12
COMR. SVINICKI	X				X	10/4/12
COMR. APOSTOLAKIS	X				X	9/17/12
COMR. MAGWOOD	X				X	9/21/12
COMR. OSTENDORFF	X				X	8/30/12

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Chairman Allison M. Macfarlane

SUBJECT: SECY-12-0099 – FINAL RULE: DISTRIBUTION OF SOURCE MATERIAL TO EXEMPT PERSONS AND TO GENERAL LICENSEES AND REVISION OF GENERAL LICENSE AND EXEMPTIONS (RIN 3150-AH15)

Approved __X__ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached _X__ None ___

SIGNATURE

10/5/12

DATE

Entered on "STARS" Yes _X__ No ___

Chairman Macfarlane's Comments on SECY-12-0099
"Final Rule: Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions (RIN 3150-AH15)"

I approve the staff's proposal to publish the final rule for revisions to source material regulations (10 CFR Parts 30, 40, 70, 170 and 171). I concur with the staff that this rule will not have a significant impact on a substantial number of small entities. I also support the edits proposed by Commissioners Svinicki, Apostolakis, and Ostendorff, and the comment made by Commissioner Magwood that the staff should continue outreach with impacted users, organizations, and the States to build awareness of the changed requirements and new processes we are imposing by this rule.

My additional comments are attached.

10/5/12

Allison M. Macfarlane Date

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. (insert value from Part 171)

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

$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. The NRC's analysis of the costs associated with this rule are contained in the regulatory analysis associated with the rule, which can be found at (insert ML number).

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

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~~ appropriate 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.

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~~ ensures that fees are fair. 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

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER SVINICKI

SUBJECT: SECY-12-0099 – FINAL RULE: DISTRIBUTION OF SOURCE MATERIAL TO EXEMPT PERSONS AND TO GENERAL LICENSEES AND REVISION OF GENERAL LICENSE AND EXEMPTIONS (RIN 3150-AH15)

Approved XX **Disapproved** _____ **Abstain** _____

Not Participating _____

COMMENTS: **Below** XX **Attached** ___ **None** ___

I approve for publication in the *Federal Register* the notice of final rulemaking (Enclosure 1 to SECY-12-0099) to amend Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 30, 40, 70, 170, and 171, subject to the attached edits. I also approve the edits to the notice provided by Commissioners Apostolakis and Ostendorff in their votes, as well as the edit to the draft Congressional letters, provided by Commissioner Apostolakis. I certify that this rule, if promulgated, will not have significant impact on a substantial number of small entities.

I concur with Commissioner Magwood that the regulatory basis for these changes does not provide as clear or quantitative of an analysis as NRC would typically strive to produce, making the direct benefits of these new requirements less evident. This is at least partially due to our lack of data regarding some of the segments of users impacted by the rule. After the notice is published, the staff will need to continue its outreach to this somewhat far-flung community of users and organizations to build awareness of the changed regulatory requirements enshrined in the final rule, as well as the processes for obtaining a specific license and for qualifying for fee relief as a certified, small entity.

SIGNATURE

10/ 4 /12

DATE

Entered on "STARS" Yes ✓ **No** ___

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~~ do not 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

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

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 new § 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 without a specific license for 1 year beyond the effective date of this rule. ~~However~~Additionally, 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

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~~ that 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)

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 that 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,

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 record~~keeping~~ retention requirements for transfers of generally licensed devices in byproduct material regulations. For generally licensed devices containing byproduct material, longer record ~~keeping~~ retention 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 that 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

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

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~~ that 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.

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

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.

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~~The SOC further states, "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,

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

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~~ that 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

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~~ second 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

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,

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

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 – f~~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

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~~ that are less

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

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.

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 $B_{\perp}$ 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

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.

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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

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.

* * * * *

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.

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

[3]Full cost fees will be determined based on the professional staff time multiplied by the appropriate professional hourly rate established in § 170.20 in effect when the service is provided, and the appropriate contractual support services expended. For applications currently on file for which review costs have reached an applicable fee ceiling established by the June 20, 1984, and July 2, 1990, rules, but are still pending completion of the review, the cost incurred after any applicable ceiling was reached through January 29, 1989, will not be billed to the applicant. Any professional staff-hours expended above those ceilings on or after January 30, 1989, will be assessed at the applicable rates established by § 170.20, as appropriate, except for topical reports for which costs exceed $50,000. Costs ~~which~~ that 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

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Apostolakis

SUBJECT: SECY-12-0099 – FINAL RULE: DISTRIBUTION OF SOURCE MATERIAL TO EXEMPT PERSONS AND TO GENERAL LICENSEES AND REVISION OF GENERAL LICENSE AND EXEMPTIONS (RIN 3150-AH15)

Approved X **Disapproved** _____ **Abstain** _____

Not Participating _____

COMMENTS: **Below** ___ **Attached** X **None** ___

SIGNATURE

9/17/12

DATE

Entered on "STARS" Yes ✓ **No** ___

Commissioner Apostolakis' comments on SECY-12-0099 – Final Rule: Distribution of Source Material to Exempt Persons and to General Licensees and Revisions of General License and Exemptions.

I approve the staff's recommendation to publish in the *Federal Register* the final amendments to Parts 30, 40, 70, 170 and 171, subject to the following comments. I concur with staff that this rule will not have significant impact on a substantial number of small entities. I also support the edit proposed by Commissioner Ostendorff.

Proposed *Federal Register* Notice

The staff should make the following edits to the proposed *Federal Register* Notice:

Page 35, first line from the top, delete the word "unlikely";
Page 74, revise this section with engagement of OGC, to clarify that the justification and affidavit required by 2.390 must be provided for the first report and that NRC has typically waved these requirements for all other reports if appropriately marked; and,

at an appropriate location within the Federal Register include the website address that licensees can use to find the contact and mailing information for each Agreement State.

Draft Congressional Letters

Revise the second sentence of the letters as follows: ~~By requiring~~ This amendment requires distributors to obtain specific licenses and imposes new reporting requirements.~~, the amendment will allow NRC to identify how and in what quantities source material is being used under both product exemptions and the general license, as well as help in identifying general licensees~~ This will provide the NRC with timely information on the types and quantities of source material distributed for use under an exemption and general licenses.

George Apostolakis 7/17/12

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MAGWOOD

SUBJECT: SECY-12-0099 – FINAL RULE: DISTRIBUTION OF SOURCE MATERIAL TO EXEMPT PERSONS AND TO GENERAL LICENSEES AND REVISION OF GENERAL LICENSE AND EXEMPTIONS (RIN 3150-AH15)

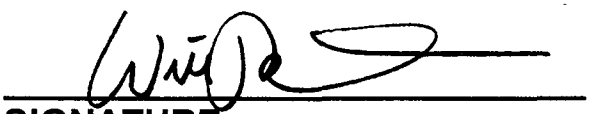
Approved X **Disapproved** _____ **Abstain** _____

Not Participating _____

COMMENTS: **Below** X **Attached** ___ **None** ___

I commend the staff's effort to engage stakeholders that have limited interactions with NRC. I also appreciate the staff's work to provide the Commission a final rule that will enable NRC to assess more accurately the public health and safety risks regarding the distribution and use of certain source material. That said, I am concerned by the lack of a clear, quantitative analysis of the potential health and safety benefits associated with this rulemaking. It would serve us well were we in a better position to explain the direct benefit of this rulemaking and thus assure our stakeholders of the appropriateness of the added burden and costs it will impose.

I encourage staff to continue to have dialogue with organizations that would be most impacted by the final rule to determine whether workshops are needed to explain the process for obtaining a specific license. I also urge that the NRC staff work closely with Agreement States in the implementation of this rule.



SIGNATURE

21 September 2012

DATE

Entered on "STARS" **Yes** X **No** ___

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER OSTENDORFF

SUBJECT: SECY-12-0099 – FINAL RULE: DISTRIBUTION OF SOURCE MATERIAL TO EXEMPT PERSONS AND TO GENERAL LICENSEES AND REVISION OF GENERAL LICENSE AND EXEMPTIONS (RIN 3150-AH15)

Approved X **Disapproved** _____ **Abstain** _____

Not Participating _____

COMMENTS: **Below** X **Attached** X **None** ___

I approve publishing the final rule, which would amend the requirements for the distribution and use of source material in 10 CFR Parts 30, 40, 70, 170, and 171, subject to the attached edit. I certify that this rule, if promulgated, will not have significant impact on a substantial number of small entities. I thank the staff for thoroughly evaluating the concerns raised about radiological exposure associated with source material used under the NRC's regulations and recommending appropriate changes to address these concerns. This rule will provide for better protection of workers and the public from the radiological hazards associated with the use of source material.

SIGNATURE

8/30/12

DATE

Entered on "STARS" Yes X No ___

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.~~ The NRC's analysis of the costs associated with this rule are contained in the regulatory analysis associated with the rule, which can be found at (insert ML Number).

In addition, a~~A~~lthough 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