
**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:

$$30 \text{ applications} \times 8 \text{ hours/application} \times \$56/\text{hour} = \sim\$13,400$$

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)):

$$0.5 \text{ hours/licensee} \times 30 \text{ licensees} \times \$56/\text{hour} = \sim\$840/\text{year}$$

Recordkeeping (§ 40.53(c)):

$$1 \text{ hour/licensee} \times 30 \text{ licensees} \times \$56/\text{hour} = \sim\$1,680/\text{year}$$

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.

References

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