FINAL REGULATORY ANALYSIS

for

AMENDMENTS to

10 CFR Parts 30, 31, 32, and 150

for

EXEMPTIONS FROM LICENSING, GENERAL LICENSES, AND DISTRIBUTION OF BYPRODUCT MATERIAL: LICENSING AND REPORTING REQUIREMENTS

January 2007

FINAL REGULATORY ANALYSIS

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1 STATEMENT OF THE PROBLEM AND OBJECTIVES

The U.S. Nuclear Regulatory Commission (NRC) conducted a systematic reevaluation of the exemptions from licensing in 10 CFR Parts 30 and 40, which respectively govern the use of byproduct material and source material. During this reevaluation, the Commission identified several areas where the regulations could be improved, clarified, or made more flexible and user friendly.

Of particular importance, exempt distribution reports, as previously required at 5-year intervals, did not provide timely information that is necessary for the NRC to assess the health impacts of exempt products on the public health and safety. Difficulties existed in reporting because the required date for reporting by each licensee is different and the information is not necessarily reported by year. It was difficult to estimate the amount or types of products/materials containing byproduct material distributed each year or to see any trends in the market. Additionally, distribution information that was recorded by licensees in Agreement States was not provided to the NRC. In order for the NRC to effectively and efficiently evaluate the overall impact to the public nationally as part of carrying out the Commission's policy on products distributed for use by the general public, timely and complete information is needed.

The Commission has periodically reevaluated the exposure of the general public from all products and materials distributed for use under exemption, in order to ensure that the total contribution of these products to the exposure of the public will not exceed small fractions of the allowable exposure limits. Prior to this rulemaking, regulations regarding exempt quantities did not explicitly prevent combining (bundling) of sources, and the NRC could not provide assurance that exposures would not exceed acceptable levels. Additionally, some of the regulations in § 30.15 and § 30.16 had contained obsolete provisions, i.e., no products are being distributed for use under certain exemptions. This final rule eliminates obsolete exemptions and adds to the assurance that future use of products in these categories will not contribute to exposures of the public.

Some regulations had been overly burdensome or required licensee actions that were not commensurate with the associated risk. For example, adequate information is available concerning the potential doses to the public from the use of smoke detectors, and so the distribution requirements no longer need to include the development and submittal of dose assessments. Residential ionization chamber smoke detectors, and some similar smoke detectors, have been manufactured and used for many years. Current designs are very consistent. Prior to this rule, the licensing of a new initial distributor of smoke detectors had required a dose evaluation to demonstrate that certain safety criteria had been met. The estimated doses under normal, routine conditions are well under the safety criterion for routine use of 5 mrem/year (50 μSv/year) whole body, and the associated individual organ limits. This final rule reduces licensees' and NRC burdens while still maintaining the health and safety of the public and the environment.

There has been some confusion as to the applicability of some requirements with respect to the transfer of a device from a general licensee to a specific licensee when the same entity holds both licenses. Previously, written approval from the NRC had been required for this type of transfer. Clarification in the regulation will improve regulatory efficiency.

The NRC is amending its regulations governing the use of byproduct material to revise reporting of transfers to persons exempt from licensing, simplify the licensing of smoke detector distribution, remove obsolete provisions, and clarify certain regulations. These actions will better ensure the protection of public health and safety in the future, make the licensing of distribution to exempt persons more effective and efficient, and reduce unnecessary regulatory burden to certain general licensees.

2 EXISTING REGULATORY FRAMEWORK

Part 30 sets out the basic requirements for licensing of byproduct material and includes a number of exemptions from licensing requirements. Prior to this final rule, the exemptions were in §§ 30.14, 30.15, 30.16, 30.18, 30.19, 30.20, and 30.21. The two exemptions in §§ 30.19 and 30.20, self-luminous products and gas and aerosol detectors, respectively, are class exemptions and provide for a range of products. Under the class exemptions, new products can be approved if an applicant demonstrates that the new product meets certain safety criteria during the licensing process. This is in contrast to the other exemptions for which the level of safety is controlled through such limits as specification of radionuclides and quantities. Sections 30.14 and 30.18, exempt concentrations and exempt quantities, are broad materials exemptions, which allow the use of a large number of radionuclides. The specific radionuclide limits on the concentrations and quantities are contained in tables in §§ 30.70 and 30.71, respectively. The remainder of the exemptions from licensing are product specific, for which many assumptions can and have been made concerning how the product is distributed, used, and disposed.

Part 31 provides general licenses for the use of certain items containing byproduct material and the requirements associated with these general licenses.

Part 32 sets out requirements for the manufacture or initial transfer (distribution) of items containing byproduct material to persons exempt from licensing requirements and to persons using a general license. The requirements for distributors address such measures as: prototype testing, labeling, quality control, and, in some cases, specific sampling procedures. The requirements for distribution to general licensees include material transfer reports on a quarterly or annual basis. The requirements for distribution to exempt persons include material transfer reports on a five-year interval, and when applying for renewal or termination of a license.

Part 150 sets out regulations for all States that have entered into agreements with the Commission under subsection 274b of the Act (Agreement States).

3 IDENTIFICATION OF ALTERNATIVE APPROACHES TO THE PROBLEM

3.1 No Action

One alternative to enacting rule changes would be to take no action. The no-action alternative would allow current practices to continue. If the NRC does not take action, there would not be

any change in costs or benefits to the public, licensees, or the NRC. The no-action alternative would not address identified concerns.

3.2 Rulemaking to Revise 10 CFR Parts 30, 31, 32, and 150

This alternative will amend 10 CFR Parts 30, 31, 32, and 150 to resolve six issues related primarily to the goals of ensuring public health and safety and increasing regulatory efficiency, effectiveness, realism, and timeliness. The regulatory amendments will improve reporting requirements, improve licensing of distribution of certain byproduct materials, clarify some regulations, eliminate obsolete provisions, as well as establish a specific product exemption. These changes will affect licensees who distribute byproduct material to exempt persons, some users of generally licensed devices, and some exempt persons.

3.3 Other Alternatives

Other alternatives such as developing or revising guidance, issuing generic communications, etc., are not viable because these alternatives would not provide the necessary regulatory basis to mandate particular licensee actions. To maintain regulatory flexibility consistent with current regulatory needs and ensure the protection of public health and safety in the future, changes in the regulations are necessary.

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

Sections 4.1 through 4.6 describe each of the amendments in the rule and provide the costs and benefits to the licensees, NRC, Agreement States, and the public related to each amendment. Section 4.7 presents the costs to the NRC and Section 4.8 presents the costs to Agreement States for their rulemakings necessary to promulgate the amendments.

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

Licensee labor rates are 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 has been selected. The rate is then increased using a multiplier of 1.4 to account for benefits (insurance premiums, pension, and legally required benefits). The 1.4 multiplier was determined by reviewing Employer Costs for Employee Compensation tables for 2004 for the same industries and occupation groups also available on the Bureau of Labor Statistics web site. Because exact hourly rates would be difficult to obtain, nationwide mean hourly rates are used.

Licensee fees are obtained from 10 CFR 170.31 and 171.16. It is recognized that the fees are periodically adjusted, most recently on May 30, 2006 (71 FR 30722), and fluctuate from year to year based on many factors. For the purpose of this analysis, the fees are assumed to remain unchanged over the next three years. In the context of the overall, societal regulatory evaluation, NRC's fees are neither a cost or benefit, but are considered a distributional effect.

To a licensee, however, fees may have a significant impact and therefore they are discussed in detail below.

NRC labor rates are determined per the calculation methodology in Abstract 5.2 of NUREG/CR-4627, Rev.1, "Generic Cost Estimates, Abstracts from Generic Studies for Use in Preparing Regulatory Impact Analyses." This methodology considers only variable costs that are directly related to the implementation, operation, and maintenance of the new requirement. This hourly labor rate for the NRC's material licensing program is $87, with an annual labor rate of $155,000.

Agreement States' labor rates vary in amount and in how each rate is determined. For the purpose of this analysis, the average Agreement State hourly labor rate was obtained from the Bureau of Labor Statistics Employer Costs for Employee Compensation data set, "Management, professional, and related occupations" limited to State and local government workers[1]. This wage was then increased by the same factor of 1.4 described earlier to obtain an hourly labor rate of $44 and an annual labor rate of $79,000.

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

For all other labor rates or fees that are specific to an issue, the reference is provided within the specific issue (Sections 4.1 through 4.6).

This Regulatory Analysis is prepared in accordance with NUREG/BR-0058(4), "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," to support 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 are affected by this final rule:

- Industry Implementation and Operation – The rule improves reporting requirements and improves licensing of distribution of certain byproduct materials. For example, new manufacturers and distributors of smoke detectors will no longer have to perform a dose assessment, and all manufacturers and distributors can avoid certain fees.
- NRC Implementation and Operation – The NRC will incur costs to revise guidance. The rule will result in reductions in operating costs.
- Other Government – Agreement States will need to amend their regulations to maintain compatibility with NRC requirements; impacts to the Agreement State regulatory programs will be minimal.

[1]Department of Labor (U.S.), Bureau of Labor Statistics, Employer Costs for Employee Compensation, 4th Quarter 2005. Series IDs CMU3020000100000D and CMU3020000100000P.

- Regulatory Efficiency – The rule improves regulatory efficiency by simplifying the licensing of smoke detectors, removing obsolete provisions, and clarifying some of the regulations.
- Improvements in Knowledge – The rule allows the NRC to better track products and materials distributed for use under exemptions from license and better estimate the impacts of these products and materials. For certain issues, the rule will improve the general knowledge of licensees (e.g., clarify the required actions for transfers from general license to specific license).
- Other Considerations – The rule is expected to increase public confidence in the NRC by assuring that exempt persons and the public are not being exposed to material that could possibly yield a dose in excess of limits contained in policy guidance for exemptions.

The above attributes are evaluated more fully in Sections 4.1 through 4.6 as they pertain to the individual issues.

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

- Public Health (Accident/Event and Routine)
- Occupational Health (Accident/Event and Routine)
- Offsite Property
- Onsite Property
- General Public
- Antitrust Considerations
- Safeguards and Security Considerations
- Environmental Considerations

4.1 Revise §§ 32.12, 32.16, 32.20, 32.25(c), and 32.29(c) for Reporting Requirements

Sections 32.12, 32.16, 32.20, 32.25(c), and 32.29(c) require that specific licensees (manufacturers and distributors) maintain records of transfer of material to exempt persons and file a report with the Director of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a). Prior to this rule, a copy of the report was also required to be sent to the appropriate NRC Regional Office.

The usefulness of information collected through reports of byproduct material in products and materials being distributed to exempt persons will improve by changing the period of reporting to every calendar year rather than every 5 years (and when filing an application for renewal or termination of the license). This change provides product distribution information that is more useful for evaluating potential individual doses to the public from multiple sources and collective doses to the public from exempt products and materials than under the previous regulations. Because the date of reporting for each licensee was different and the information was not necessarily reported by year, it had been difficult to estimate the amount or types of products/materials containing byproduct material distributed each year or to see any trends. Also, the information was not current. It had been more difficult for the NRC to track when reports are due, particularly now that this type of license is typically issued for 10 years rather than for 5 years. A reporting deficiency was not always noted unless a renewal or termination

of license had been processed. Annual reporting eliminates these difficulties and will not significantly change the reporting burden for these licensees.

In addition to the lengthy period between reports, certain information was not always clear in the reports, making it more difficult to use the information. This final rule makes these reporting provisions more specific, to include the specific exemption provision under which the products/materials are being distributed, the model numbers, when applicable, and clear identification of the specific licensee submitting the report including the license number.

The rule also revises §§ 32.12, 32.16, 32.20, 32.25, and 32.29 to include in the address, "ATTN: Document Control Desk/Exempt Distribution" on the annual reports. The requirement to provide copies to the Regions is eliminated, and the frequency of reporting is changed to annual.

The following number of licensees are likely to be affected by the above changes. The following information (with the exception of § 32.12) was obtained from the Licensing Tracking System as of August 2006. Licensees reporting under § 32.12 were identified through Agencywide Documents Access & Management System (ADAMS) searches for the appropriate type of licenses.

§ 32.12	2	licensees
§ 32.16	43	licensees
§ 32.17	0	licensees
§ 32.20	22	licensees
§ 32.25	10	licensees
§ 32.29	25	licensees

The above numbers sum to 102 licensees. However, four of these licensees distribute products under two sections so there are 98 unique entities affected by these changes.

Cost Impacts:

Costs to Licensees (Manufacturers and Distributors)

> The rule requires annual reports instead of a 5-year reporting period. Efficiency and accuracy in compiling annual reports are expected, because it is likely that less time will be needed to compile annual reports compared to compiling accurate information for five years for current reporting requirements. The period of time that records must be retained is shortened. Thus, the costs to licensees are expected to be minimal or non-existent.

Costs to the NRC and Agreement States

> The NRC's costs are discussed in Section 4.7. Although NRC will receive a greater number of reports per year, the amount of data received in a five-year period will be the same and therefore no costs to NRC are expected. The rule requires more specific information, identification of the specific exemption provision, the model numbers of products, and the license number of the reporting licensee. The handling and use of the information would be more efficient and effective overall.

Section 32.12 is changed to Compatibility Category NRC; the impacts of that are addressed in Section 4.2. Sections 32.16, 32.20, 32.25, and 32.29 are already Compatibility Category NRC. Therefore, this rule change would not result in any costs to the Agreement States.

Costs to the Public

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

Benefits:

The revisions are expected to make the reporting process more efficient and will improve the quality of the information. Annual reporting will also provide information on distribution that is more useful for evaluating potential individual doses to the public from multiple sources and collective doses to the public from exempt products and materials than under the previous regulations. The NRC will have a better basis on which to inform the public concerning these exposures. These changes also provide a better basis for considering any future rulemaking in this area and in allocating NRC resources. Finally, the period of retention for records, though still one year after transfers are included in a report, would be as much as 4 years shorter. The amount of information required to be kept at any one time would be up to 2 years of transfers records rather than up to 6 years of transfers.

4.2 Revise § 30.14 to Make Exempt Concentrations NRC Only

Section 30.14 states that any person is exempt from the requirements for a license to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing byproduct material in concentrations not in excess of those listed in § 30.70. The requirements for a license to introduce exempt concentrations into products are specified in § 32.11. Section 32.12 requires that each person licensed under § 32.11 maintain records of transfer of material and file a report with the Director of Nuclear Material Safety and Safeguards, and send a copy of the report to the appropriate NRC Regional Office.

Paragraph 30.14(c) exempts a manufacturer, processor, or producer of a product or material in an Agreement State from the requirements for an NRC license to the extent that he transfers byproduct material contained in a product or material in concentrations not in excess of those specified in § 30.70 and introduced into the product or material by a licensee holding a specific license issued by an Agreement State, the Commission, or the Atomic Energy Commission expressly authorizing such introduction. Currently, there is no process in place by which Agreement States provide copies of transfer reports to the NRC. The exemption in § 30.14(c) was added specifically for persons in Agreement States, because of the provision in § 150.15(a)(6), which reserves to the NRC the authority for licensing transfers to exempt persons.

Paragraph 30.14(d) and § 32.13 prohibit introduction of byproduct material into products and materials that may be transferred to persons exempt under § 30.14 or equivalent regulations without a specific license authorizing the introduction. Previously, this license could have been an NRC or Agreement State license.

In order for the NRC to effectively evaluate the overall impact to the public from exempt distribution, all distribution for use under exemptions from licensing should be licensed by the NRC. Therefore, the rule makes §§ 32.11 and 32.12 Compatibility Category NRC and revises the wording of the exemption in § 30.14(c), § 150.20, and the prohibition in §§ 30.14(d) and 32.13 accordingly, so that only the NRC may authorize the introduction of byproduct material into products and materials to be distributed for use under § 30.14 and equivalent Agreement State regulations. For clarification, § 30.14(c) is also revised to apply to manufacturers, processors, or producers in non-Agreement States who use a radiotracer firm or other § 32.11 licensee to introduce byproduct material into their products.

Cost Impacts:

Cost to Licensees (Manufacturers and Distributors)

Changing §§ 32.11 and 32.12 to become Compatibility Category NRC requires any entity licensed under equivalent regulations of an Agreement State to obtain an NRC license. The Agreement States and the NRC have not been able to identify any such licensees. However, there is considerable uncertainty as to whether there are any licensees to be impacted. In order to consider the potential impact if there were affected licensees, the costs are estimated based on an assumption that there are three times as many Agreement State licensees as NRC licensees. As there are two NRC licensees, the number of Agreement State licensees is assumed to be six. As a result of this rule, the following costs are projected for six affected licensees in Agreement States:

E-Distribution License Required:

Effort to prepare the application:

7 hours/application[2] x \$45/hour[3] ≅ \$300/application

6 applicants x \$300/application = \$1,800

The estimated effort to prepare an application comes from a generic number that is the average based on all applications submitted to the NRC by applicants for a variety of materials licenses, amendments of licenses, and renewals of licenses over a given time period. Some applications are more complex and require more effort to develop. Others may require less time to develop. Because the licensees considered by this rule are already Agreement State licensees, the effort to become an NRC licensee is assumed to be minimal; therefore, the generic number provided in the OMB supporting statement was used.

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[2]OMB Clearance No. 3150-0120, "Final Supporting Statement for NRC Form 313 Application for Material License and NRC Form 313A Training and Experience and Preceptor Statement."

[3]Department of Labor (U.S.), Bureau of Labor Statistics, Occupational Employment and Wages, May 2005. Standard Occupational Classification (SOC) System Code Number 17-2111 "Health and Safety Engineers, Except Mining Safety Engineers and Inspectors," national hourly mean wage, plus benefits.

Licensees are required to pay a fee for the application:

$8,700 application fee[4] x 6 applicants = $52,200

E-Distribution Annual Fees:

$11,700 annual fee[5] x 6 licensees = $70,200/year

It is noted that some Agreement States charge fees, while others do not. Therefore, for some licensees, the cost of fees to the NRC may be partially offset by fees no longer paid to a State. Also, there are other costs associated with complying with the requirements of an NRC license, but these costs are expected to be essentially the same as currently applicable under Agreement State licenses.

Section 32.12 requires that transfer reports be filed with the NRC. Section 32.12 was previously Compatibility Category C, so reporting requirements may not be identical between State and NRC requirements. However, Agreement State licensees would be expected to be filing transfer reports to their appropriate state government. The rule is not expected to result in significantly different cost for filing of reports.

Costs to the NRC and Agreement States

If there are licensees in Agreement States impacted by this change, the NRC would incur annual costs associated with the review of the E-Distribution license applications, in addition to the review, filing, and retention of reports.

Effort to review the applications:

7 hours/application[6] x $87/hour ≅ $600/application

6 applications x $600/application = $3,600

As discussed above, the effort to review an application is a generic number that is the average based on all applications reviewed by the NRC from applicants for materials licenses over a given time period. Some applications are more complex and require more effort to review. For the purpose of this analysis, the generic number provided in the OMB supporting statement was used.

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[4]§ 170.31, "Schedule of fees for material licensees and other regulatory services, including inspections, and import and export licenses," Item 3.I (Byproduct Material)

[5]§ 171.16, "Annual Fees: Material Licensees, Holders of Certificates of Compliance, Holders of Sealed Source and Device Registrations, Holders of Quality Assurance Program Approvals, and Government Agencies Licensed by the NRC," Item 3.I (Byproduct Material)

[6]OMB Clearance No. 3150-0120, "Final Supporting Statement for NRC Form 313 Application for Material License and NRC Form 313A Training and Experience and Preceptor Statement."

Additional NRC costs are discussed in Section 4.7.

Paragraphs 30.14(c) and 30.14(d) are Compatibility Category B and require essentially identical wording. Revising §§ 30.14(c) and 30.14(d) will require a comparable change in Agreement State regulations; however, each State is expected to conduct one rulemaking following this revision of Parts 30, 31, 32, and 150. The cost for the Agreement State rulemakings is discussed in Section 4.8.

Costs to the Public:

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

Benefits

The benefit of the regulation is that the NRC could more effectively evaluate the overall impact to the public from exempt distribution by having the necessary information on a national level. Additionally, it improves the efficiency, and possibly the consistency, of regulation, because one entity has responsibility for handling all exempt distribution licenses for byproduct material. Currently, there are roughly 100 total NRC licenses for distribution of byproduct material to exempt persons, none in the Agreement States. This change also removes a source of confusion concerning whether an NRC license is required.

4.3 Revise § 30.18 to Preclude Combining Multiple Exempt Quantities

Section 30.18 states that a person is exempt from licensing requirements to the extent that such a person possesses, uses, transfers, owns, or acquires byproduct material in individual quantities, each of which does not exceed the applicable quantity in § 30.71, Schedule B (i.e., an "exempt quantity"). However, prior to this action, there had been no restriction as to the total quantity that may be possessed and used at any one time by the exempt person. The exemption in § 30.18 is based, in part, on the safety properties inherent in a single exempt quantity. The radiological assessment in NUREG-1717, “Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials,” (June 2001) shows there is a potential safety hazard if multiple exempt sources (for some radionuclides) are combined and used in a device.

In 1999, the NRC issued Generic Letter 99-01 to notify materials licensees about an Office of Nuclear Material Safety and Safeguards decision concerning combining (bundling) exempt quantities. The NRC stated that it does not authorize: (a) the bundling of exempt quantities of byproduct material; (b) any program advising persons to combine exempt quantity sources; and (c) the possession and use of bundled exempt sources, in unregistered devices, by persons exempt from licensing. The generic letter also addressed concerns about protection of property, by articulating the preferred labeling and disposal practices. Since that time, the NRC has denied all requests to manufacture and distribute devices that have source holders to accommodate multiple exempt quantity sources, i.e., bundling of exempt quantity sources. Therefore, it is assumed for the purposes of this analysis that since 1999, both manufacturers and distributors and users of exempt devices are in “compliance” with NRC regulations and do not bundle multiple sources for the purpose of use in a device, except in cases previously

approved by the NRC. These latter devices were “grandfathered” by the generic letter, subject to the user maintaining control of these devices.

This final rule clarifies the regulations in § 30.18 to better ensure that persons will not combine or bundle exempt sources in the future. The rule also codifies the “grandfathering” of those devices placed in use before May 3, 1999.

The added language in the rule ensures that bundling is prohibited by the end-user. Although similar information was communicated in a generic letter, generic letters are not enforceable. By amending the regulation, the prohibition against the practice of bundling becomes legally binding and enforceable, which provides the assurance that these practices will not occur. Moreover, a regulation precludes the need for future follow-up communications on the issue.

Cost Impacts:

Costs to Exempt Persons (Users)

Since the issuance of Generic Letter 99-01, it is assumed that licensees and users are complying with the provisions of § 30.18 as interpreted in that notification. In addition, instructions in the generic letter designed to ensure protection of property are assumed to already be adopted by licensees and users of these devices. At least with regard to the manufacture and distribution of unapproved devices designed for the use of bundled exempt quantity sources, it is unlikely that these practices would be ongoing without the NRC becoming aware. The final rule clarifies that bundling of exempt quantity sources for use in a device used by exempt persons is not permitted. Therefore, there are no expected costs to the users of exempt devices using exempt quantity sources from the rule.

Costs to Licensees (Manufacturers and Distributors)

There are no expected costs to manufacturers and distributors from the rule since they are already required to state on a label or in a brochure “Exempt Quantities Should Not be Combined” and this revision reflects current policy.

Costs to the NRC and Agreement States

There are no expected costs to the NRC from this amendment.

Section 30.18 is Compatibility Category B requiring essentially identical wording. Revising § 30.18 requires a comparable change in Agreement State regulations; however, each State is expected to conduct one rulemaking following the planned revision of Parts 30, 31, 32, and 150. The cost for the State’s rulemaking is discussed in Section 4.8.

Costs to the Public

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

Benefits:

The NRC and the Agreement States have regulatory assurance that exempt persons and the public are not being exposed to quantities that could possibly yield a dose in excess of limits contained in policy guidance for exemptions. In addition, as it is preferable not to dispose of devices containing multiple exempt sources through ordinary commercial waste disposal or metal recycling channels because of the presence of radioactive material, this prohibition will ensure that property is protected from inadvertent contamination. The public will benefit from this prohibition due to potentially reduced doses for the device users, and the consideration of property protection.

4.4 Revise Regulations to Remove Obsolete Provisions

The exemptions in § 30.15 provide for persons to receive, possess, use, transfer, own, or acquire certain products containing byproduct material. Of interest are those products 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: automobile lock illuminators (§ 30.15(a)(2)), balances of precision (§ 30.15(a)(3)), automobile shift quadrants (§ 30.15(a)(4)), marine compasses (§ 30.15(a)(5)), thermostat dials and pointers (§ 30.15(a)(6)), spark gap irradiators (§ 30.15(a)(10)), and resins containing scandium-46 for sand consolidation in oil wells (§ 30.16). The Commission is removing exemptions for these products and prohibiting further distribution while allowing for the continued possession and use of previously distributed items.

The final rule prohibits further distribution of products that are no longer being manufactured, but may remain in use. This is the case for certain products included in §§ 30.15(a)(3) and (a)(5). For those products believed to never have been distributed or for which it is otherwise unlikely that any remain in use, the rule removes the provisions entirely, such as §§ 30.15(a)(2), (a)(4), (a)(6), and (a)(10).

Section 30.16 had contained a provision for synthetic plastic resins containing scandium-46 for sand consolidation in oil wells. Based on preliminary dose estimates not included in NUREG-1717, this is the only one of these exemptions that could result in significant doses. The NRC has not been able to find evidence that there is such resin in use. Therefore, this rule removes § 30.16.

Prior to this rule, Part 32 had contained requirements for manufacturers and distributors of these products. This rule removes the associated requirements for prototype test procedures in §§ 32.14(d)(2) and 32.40, and the requirements for a license to produce or initially distribute resins containing scandium-46 in § 32.17.

Cost Impacts:

Costs to Licensees (Manufacturers and Distributors)

There are no manufacturers or distributors for these products.

Costs to the NRC and Agreement States

The NRC's costs are discussed in Section 4.7.

Sections 30.15, 30.16, and 32.17 are Compatibility Category B requiring essentially identical wording. Revising §§ 30.15 and 30.16, and removing § 32.17 requires comparable changes in Agreement State regulations; however, each State is expected to conduct one rulemaking following this revision of Parts 30, 31, 32 and 150. The cost for the Agreement State rulemaking is discussed in Section 4.8.

Costs to the Public

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

Benefits:

Deleting these unnecessary regulations simplifies the regulations by eliminating extraneous text. This eliminates the need to reassess the potential exposure of the public from these exemptions for possible future distributions of the products. Also, these exemptions no longer need to be considered when assessing the total potential doses to the public from multiple sources. There is also a small reduction of effort in the process of renewing OMB clearance for the reporting and recordkeeping requirements contained in Part 32. In a planned future effort, the NRC is considering making revisions to the requirements for distributors with respect to quality control and sampling, and for applicants for distribution licenses to make them less prescriptive and more risk-informed. In that action, the consideration for such changes would not need to address the requirements being removed in this action. Additionally, there is a potential benefit to the public from the elimination of future exposures. Based on preliminary dose estimates performed for the exemption for resins containing scandium-46 for sand consolidation in oil wells (§ 30.16), potential exposures could be higher than is appropriate for exempt materials. As a result of this action, members of the public can be assured that future exposures will not occur.

4.5 Revise § 30.15 to Add a Product-Specific Exemption for Smoke Detectors

Ionization chamber smoke detectors have been manufactured and used for many years. Users of these smoke detectors have been and continue to be exempted from licensing. Section 30.20 exempts persons that receive, possess, use, transfer, own, or acquire byproduct material in gas and aerosol detectors designed to protect life or property from fires from licensing requirements. The specific requirements to obtain a license to manufacture, process, produce, or initially transfer gas and aerosol detectors intended for use under § 30.20 are contained in § 32.26. Specific conditions of licenses are stated in § 32.29 and include requirements for quality control, labeling, recordkeeping, and reporting of transfers. Prior to this rule, § 30.20 was the only exemption applicable to smoke detector end users.

The current designs of residential ionization chamber smoke detectors are very consistent, using 0.9 to 1 μCi of americium-241 (Am-241) contained in a foil, surrounded by an ionization chamber. Based on information in NUREG-1717, as well as other documents, the estimated

doses under normal, routine conditions are well below the safety criterion for routine use of 5 mrem/year (50 μSv/year), and the associated individual organ limits.

This rule establishes a specific exemption from licensing requirements for ionization chamber smoke detectors. Specifically, § 30.15(a)(7) is added to create a specific exemption for ionization chamber smoke detectors containing no more than 1 μCi of Am-241 in the form of a foil and designed to protect life and property from fires. Paragraph 32.15(d) is revised to include more specific labeling requirements for smoke detectors consistent with those currently applicable under the gas and aerosol detector provisions.

The primary difference between the new exemption and the existing class exemption is that an applicant for a license to distribute smoke detectors for use under the new exemption is not required to submit dose assessments to demonstrate that doses from the various stages of the life cycle of the product do not exceed certain values. The applicant is still required to submit basic design information consistent with that required from applicants to distribute products under other product-specific exemptions, specifically for those products used under § 30.15.

The effect of this rule is to reduce the regulatory burden for new applicants for licenses to distribute ionization chamber smoke detectors, including the associated fees, while still providing assurance that the byproduct material is properly contained within the product and will not be released under the most severe conditions encountered in normal use and handling. The fees are lowered because under current licensing practice, a product-specific exemption does not require a Sealed Source and Device (SS&D) certificate for the product. Although license fees fluctuate, typically the fee for a distributor of a product under a class exemption is higher than for a distributor of a product used under a product-specific exemption.

Costs and benefits are estimated below for 10 existing licensees and 3 new applicants per year (based on a review of licensing action data for FY02 through FY04 for Program Code 3255). It is expected that some existing licensees would seek to change the status of their licenses so that they would no longer have to pay certain annual fees. Also, it is assumed that the NRC will receive new applications at the current rate. However, there is uncertainty in these numbers as they are projections of future voluntary actions. Furthermore, the estimations presented below are for large entities; annual fees are different for small entities.

Cost Impacts:

Costs to Licensees (Manufacturers and Distributors)

> There are no expected costs to licensees from the rule. The rule does not impose any new requirements on existing licensees.
>
> However, some current licensees may choose to expend resources to change the regulatory status of their product in order to reduce their annual fees. As this would be a voluntary expenditure in order to obtain an overall benefit, this expenditure is covered under Benefits to Existing Licensees to estimate a net benefit to existing licensees.

Costs to the NRC

From Existing Licensees:

The NRC would incur costs from the review of the license and SS&D certificate amendments that might be submitted by existing licensees. These costs are largely recovered from the annual fees paid by the licensees. If a significant number of licensees choose to change the status of their product as a result of this change to the regulation, annual fees in the future may be affected; however, such an impact is not estimated in this analysis.

In order to illustrate the potential overall impact of this revision, the NRC assumes that 10 current licensees, who are not small entities, amend their license in the first year or two after the rule is effective. The cost for the NRC to review amendments is estimated as follows.

7 hours/amendment[7] x \$87/hour x 10 licensees $\cong$ \$6,000, a one time cost

From Implementation:

The NRC's implementation costs are discussed in Section 4.7.

Costs to Agreement States

Section 30.15 is Compatibility Category B requiring essentially identical wording. Adding § 30.15(a)(7) requires a comparable addition to Agreement State regulations; however, each State is expected to conduct one rulemaking following this revision of Parts 30, 31, 32, and 150. The cost for the Agreement State rulemaking is discussed in Section 4.8. As §§ 32.14 and 32.26 are Compatibility Category NRC, there is no impact on Agreement State licensing.

Costs to the Public

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

Benefits:

Benefit to New Applicants (Manufacturers and Distributors)

The effect of this change is to reduce the regulatory burden for new applicants to distribute ionization chamber smoke detectors, as well as the associated fees.

For the new product-specific exemption, applicants no longer have to perform a dose assessment, as required under the class exemption. OMB Supporting Statement

[7]OMB Clearance No. 3150-0120, "Final Supporting Statement for NRC Form 313 Application for Material License and NRC Form 313A Training and Experience and Preceptor Statement."

3150-0001 estimates that applicants spend an average of 21 hours preparing the required information for a sealed source and device evaluation. A significant fraction of this time is spent on the dose assessment. For the purpose of this analysis, it is assumed that licensees spend approximately 50 percent of their time on dose assessments. Because a dose assessment is no longer required, applicants' burden would be reduced by 50 percent (i.e., roughly 11 hours saved). Thus, 11 hours saved at $45/hour[8] for a cost savings of about $500/applicant for the development of an application. In addition, the fee associated with a device evaluation ($21,000 in 2006),[9] is no longer required. A different application fee would also apply. Using FY 2006 fees, the application fee would be $8,700[10] instead of $14,600.[11] The net reduction in application fees is $26,900 for each applicant. Once labor costs are accounted for, each applicant realizes a total savings of $27,400.

These applicants will also have reduced net annual fees as licensees. Because a device evaluation is no longer required, the change results in a savings equal to the amount of the annual fee for an active SS&D certificate ($25,700/year in 2006),[12] and a saving in the applicable annual fee. The applicable annual fee would be $11,700 (in 2006).[13] The annual fee for a licensee who distributes a device that requires a device evaluation is $19,300 (in 2006).[14] Thus a net reduction in annual fees of $33,300/licensee.

Analysis of a recent three year period shows the NRC has received eight applications for new licenses to manufacture or distribute smoke detectors that meet the product-

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[8]Department of Labor (U.S.), Bureau of Labor Statistics, Occupational Employment and Wages, May 2005. Standard Occupational Classification (SOC) System Code Number 17-2111 "Health and Safety Engineers, Except Mining Safety Engineers and Inspectors," national hourly mean wage, plus benefits.

[9]§ 170.31, "Schedule of fees for material licensees and other regulatory services, including inspections, and import and export licenses," Item 9.A (Devices).

[10]§ 170.31, "Schedule of fees for material licensees and other regulatory services, including inspections, and import and export licenses," Item 3.I.

[11]§ 170.31, "Schedule of fees for material licensees and other regulatory services, including inspections, and import and export licenses," Item 3.H.

[12]§ 171.16, "Annual Fees: Material Licensees, Holders of Certificates of Compliance, Holders of Sealed Source and Device Registrations, Holders of Quality Assurance Program Approvals, and Government Agencies Licensed by the NRC," Item 9.A (Devices).

[13]§ 171.16, "Annual Fees: Material Licensees, Holders of Certificates of Compliance, Holders of Sealed Source and Device Registrations, Holders of Quality Assurance Program Approvals, and Government Agencies Licensed by the NRC," Item 3.I.

[14]§ 171.16, "Annual Fees: Material Licensees, Holders of Certificates of Compliance, Holders of Sealed Source and Device Registrations, Holders of Quality Assurance Program Approvals, and Government Agencies Licensed by the NRC," Item 3.H.

specific exemption criteria.[15] For the purpose of this regulatory analysis, it is assumed that three applications per year would be submitted to the NRC, maintaining the current rate. The annual cost savings to new applicants are estimated to be:

3 applicants/year x 11 hours saved/applicant x $45/hour ≅ $1,500

Additionally, fees of $26,900 are avoided x 3 applicants/year = $80,700

For a total of about $82,200 saved/year by applicants, plus continuing savings as licensees depending on the future rate of the applicable fees.

Benefit to Existing Licensees (Manufacturers and Distributors)

Existing licensees will be afforded the flexibility to change the status of their license (i.e., from § 32.26 to § 32.14), allowing their SS&D registration to be made inactive, if they so choose. For those existing licensees choosing to do so, they would no longer have to pay the annual fee for holding a registration certificate ($25,700 in 2006). A change in the regulatory status of the license would also reduce the annual fees. Annual fees are currently $19,300/year[16] but would decrease to $11,700/year[17] under this change. Using 2006 fees, this result in an annual savings of $33,300.

In order to do so, the licensee would have to get an amendment to the certificate and its license. Although there is no fee for these amendments, a licensee would incur costs to prepare the amendment. OMB Supporting Statement 3150-0120 estimates that an applicant/licensee would spend an average of 7 hours to fill out the health and safety portion of an application, and does not differentiate between an application and an amendment. For current licensees wishing to distribute their smoke detectors under a product-specific exemption, the amendment process would be mostly administrative in nature. Therefore, it is estimated that it would take licensees a total of 7 hours to prepare and submit both the license amendment request and the device registration certificate amendment request. The licensee's effort is estimated as follows:

[15]Number of applications based on review of licensing action data for FY02 through FY04 for Program Code 3255.

[16]§ 171.16, "Annual Fees: Material Licensees, Holders of Certificates of Compliance, Holders of Sealed Source and Device Registrations, Holders of Quality Assurance Program Approvals, and Government Agencies Licensed by the NRC," Item 3.H (Byproduct Material – Require Device Evaluation)

[17]§ 171.16, "Annual Fees: Material Licensees, Holders of Certificates of Compliance, Holders of Sealed Source and Device Registrations, Holders of Quality Assurance Program Approvals, and Government Agencies Licensed by the NRC," Item 3.I (Byproduct Material – Do Not Require Device Evaluation)

7 hours/amendment[18] x $45/hour[19] = $315, a one-time cost

For a rough indication of overall savings to existing licensees:

7 hours/amendment x $45/hour x 10 licensees ≅ $3,200 one-time cost incurred

To obtain an annual savings:
Elimination of an annual fee of $25,700 and a $7,600 decrease in another annual fee for 10 licensees. This would result in a benefit of $333,000 per year for 10 licensees starting roughly one year after promulgation of the final rule; however, these fees would be expected to change from year to year.

Currently there are 25 licensees under § 32.26, most of which distribute smoke detectors. A few of these distributors are small entities. For them, the benefit from changing from a § 32.26 license to a § 32.14 license would be limited to reducing their annual fee either $2,300 or $500 under current licensing policy and the 2006 fee schedule, depending on which size category they fall into, because of inactivating their SS&D certificate. (Fees for small entity categories are provided in § 171.16(c) and size standards are established in § 2.810).

Benefit to the NRC

From New Applicants:

A device evaluation is no longer required. The NRC estimates that it currently takes 34 hours for the NRC to review such an application. Under this change, the reduction in staff burden is estimated by eliminating the 21-hour effort needed to perform a device evaluation, but increasing the NRC effort to review a license application by 6 hours. The net decrease in burden would be 15 hours. The NRC would save:

3 applications/year x 15 hours saved/application x $87/hour ≅ $3,900 saved/year

Benefit to Agreement States

There are no benefits to Agreement States because §§ 32.26 and 32.14 are NRC-only provisions.

Benefits to the Public

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[18]OMB Clearance No. 3150-0120, "Final Supporting Statement for NRC Form 313 Application for Material License and NRC Form 313A Training and Experience and Preceptor Statement."

[19]Department of Labor (U.S.), Bureau of Labor Statistics, Occupational Employment and Wages, May 2005. Standard Occupational Classification (SOC) System Code Number 17-2111 "Health and Safety Engineers, Except Mining Safety Engineers and Inspectors," national hourly mean wage, plus benefits.

There are no expected benefits to the public from this amendment. Savings experienced by manufacturers and distributors may be passed on to the consumer; however, given the large number of detectors sold, this is not expected to have a significant impact on prices.

4.6 Revise § 31.5(c)(8) to Clarify General Licensee Transfer to Specific Licensee Status

Following a revision to the general license in § 31.5 that became effective in February 2001, an increased number of specific licensees transferred their authorization to possess and use some devices under the § 31.5 general license to the authority provided by their specific license. This was primarily to avoid paying the new registration fees for some of these devices.

Although there are provisions in the regulations related to the required actions, there has been some confusion as to the applicability of some requirements with respect to the transfer of a device from a general licensee to a specific licensee when the same entity holds both licenses.

Paragraph 31.5(c)(8) specifies acceptable specifically licensed recipients of devices covered by the general license and lays out requirements for the transfer of the devices. For example, it requires that a general licensee report to the NRC transfers of devices to specific licensees. It had also required written approval from the NRC for transfers to any specific licensee not included in § 31.5(c)(8)(i). Prior to this final rule, the general licensee who wished to transfer a device to any other specific licensee, even if that licensee is the same entity and the effect is only to transfer to a specifically licensed status, could only do so by obtaining approval for the transfer. The Commission could then verify that the specific license authorizes such use, ensure that the licensee is fully aware of its responsibilities under both the general and specific license with respect to the device, and make updates to its tracking system.

This final rule clarifies the required actions for this type of transfer. It would also remove the necessity of obtaining prior written NRC approval under these particular circumstances. Paragraph 31.5(c)(8)(iii) is revised to include details concerning the required actions for a specific licensee to transfer a device held under this general license to the authority provided by its specific license. By including these additional details in the regulation, it is not considered necessary for the specific licensee to obtain prior written approval.

Cost Impacts:

Costs to Licensees (Specific Licensees)

There is no cost to the specific licensees wishing to transfer the regulatory status of their generally licensed devices. The actions described in § 31.5(c)(8)(iii) are necessary to comply with all current applicable requirements related to both the general license and the specific license.

Costs to Specific Licensees (Manufacturers and Distributors)

Those licensed under § 32.51 and equivalent regulations of the Agreement States will have to update the information provided to their customers (i.e., updated copies of § 31.5 and equivalent Agreement State regulations) under § 32.51a(a) and (b). It is assumed that adequate implementation transition time would be allowed by the NRC and the Agreement States. Thus, this change is not expected to cause any incremental cost.

Costs to the NRC and Agreement States

The NRC's costs from the rulemaking are discussed in Section 4.7.

Section 31.5 is Compatibility Category B requiring essentially identical wording. Revising § 31.5(c)(8) requires a comparable revision to Agreement State regulations; however, each State is expected to conduct one rulemaking following this revision of Parts 30, 31, 32, and 150. The cost for the States' rulemaking is discussed in Section 4.8.

Costs to the Public

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

Benefits:

This rule removes the necessity of obtaining prior written NRC approval when a specific licensee transfers a generally licensed device to itself such that it would be covered by the provisions of its specific license. As a result, there would be a reduction in burden to the licensees from obtaining approval, and a reduction in burden to the NRC from granting approval. This scenario is not expected to occur frequently. It is assumed that it occurs approximately five times per year.

Benefit to Licensees

Licensees are relieved of the need to make a request to the NRC to transfer the material. Annual savings are estimated as follows:

5 requests/year x 1 hour saved/request x \$45/hour[20] $\cong$ \$200 saved/year

Additionally, licensees would more easily understand the applicable requirements and procedures and would not need to contact the NRC for clarification.

[20]Department of Labor (U.S.), Bureau of Labor Statistics, Occupational Employment and Wages, May 2005. Standard Occupational Classification (SOC) System Code Number 17-2111 "Health and Safety Engineers, Except Mining Safety Engineers and Inspectors," national hourly mean wage, plus benefits.

Benefit to the NRC and the Agreement States

The NRC and the Agreement States will no longer receive requests from licensees to transfer generally licensed devices under the provisions of their specific license. Therefore, the NRC's burden would be reduced by approximately one hour per request:

5 requests/year x 1 hour/request x $87/hour ≅ $400/year

Similarly, Agreement States will experience a small reduction in burden. For the purpose of this analysis, it is assumed that there are three times as many general licensees in Agreement States as in NRC regulated states. Therefore, the reduction in burden for all Agreement States would be approximately three times as much as for the NRC.

Also, there should be a reduction in phone and email inquiries concerning if and how such a transfer can be made and in problems that arise when licensees misinterpret what needs to be done, are not fully aware of their responsibilities, and possibly omit some of the necessary steps such as reporting under § 31.5(c)(8)(ii). The clarification of licensee responsibilities will also make enforcement of these requirements easier.

Benefit to the Public

There are no expected benefits to the public from this amendment.

4.7 Implementation Costs

The NRC staff intends to update existing guidance in the NUREG-1556 series related to exempt distribution licensing to reflect the revisions to the regulations. NUREG-1556, Vol. 8 requires minor revisions. Because there is an update planned for the NUREGs in this series, there is no cost impact as a result of this rulemaking for implementation.

4.8 Costs to Agreement States of Compatible Regulations

Costs will be incurred by the Agreement States for development and implementation of compatible regulations. The costs are expected to vary significantly by State because of differences in internal procedures for developing regulations. Some rule changes are required to meet Compatibility Category B for certain revisions. As these need to be essentially word-for-word compatible, the process should be relatively simple for this part. For this rule, the NRC assumes an average of 0.1 FTE at $79,000/FTE for each state, to be accomplished within a three-year period. There are currently 34 Agreement States; therefore, the total cost for all Agreement States is approximately $269,000.

4.9 Quantifiable Costs

Table 4.1 presents the quantified impacts of the rule in current dollars. Numbers in parentheses are negative and represent a net benefit. Accordingly, numbers not in parentheses are positive and represent a net cost. As noted in previous sections, this rule may have significant distributional financial effects on certain categories of licensees. Distributional effects are not included in the table below.

Table 4.1 Quantifiable Costs (Benefits) of Final Rule (thousands of $)

Section of RA	Initial (One Time) Costs	Annual Costs
4.1 – Revise Exempt Distribution Reporting Requirements	-	-
4.2 – Change Exempt Concentrations to NRC-Only	6	-
4.3 – Prohibit Combining Exempt Quantities	-	-
4.4 – Remove Obsolete Provisions	-	-
4.5 – Product-Specific Smoke Detector Exemption	9	(5)
4.6 – Clarify General License to Specific License Transfer	-	(1)
4.7 – NRC Rulemaking Activities	-	-
4.8 – Agreement State Rulemaking Activities (3 years)	269	-
Total	284	(6)

The net present value of the costs and benefits in Table 4.1 at a discount rate of 3% for a 10-year period is $222,000. The net present value of the costs and benefits in Table 4.1 at a discount rate of 7% for a 10-year period is $212,000. As discussed in the decision rationale (Section 5), the quantifiable costs and benefits are a small portion of the overall considerations. For example, the data quality gained from revising exempt distribution reporting requirements (Section 4.1) is impossible to obtain under the current regulatory structure. The limitations of the information about the products/materials and quantities distributed for use under exemption greatly impacted the cost of developing the dose assessments in NUREG-1717 and contributed to the uncertainties in the results.

4.10 Uncertainty

There are a number of uncertainties contained in this regulatory analysis. The costs and benefits, where quantified, are based on an assumed number of licensees or applicants. Some of the numbers were obtained from the review of licensing action data, whereas others are assumptions. When possible, specific data was used. Other costs and benefits are not easily

quantifiable, and therefore, are assessed qualitatively. These factors combine to make this regulatory analysis uncertain. However, the uncertainty is not so great as to affect the ability to evaluate this rule. Further study of the variability of the unknown factors would not elucidate any valuable insights, and the conclusions presented are not sensitive to the uncertainty itself.

Estimations of efforts to prepare applications, amendments, dose assessments, reports, etc., are based on current OMB supporting statements. Although OMB supporting statements are based on a few years of licensing action data, they represent averages and not best estimates. The licensing action data itself, i.e., hours charge to TAC numbers, may be inaccurate.

The labor rates are based on national mean (average) wage rates published by the Bureau of Labor Statistics, and then adjusted to account for indirect labor costs. This process for estimating labor rates introduces statistical uncertainty, because of the variability of both wages and indirect labor costs. Further uncertainty is introduced due to time lags. The most current set of wage data available from the Bureau of Labor Statistics was published in May 2006, but is based on older data (May 2005). In addition, another time lag exists between the preparation of this regulatory analysis and the effective date of this rule. These factors collectively contribute to uncertainty in estimating the labor rates.

The annual fees and NRC's labor rate change periodically, and although these numbers are accurate at the present time, they are expected to fluctuate in the future. There is no reliable method to predict the NRC's annual fees in advance of their publication each fiscal year, and none is attempted in this document.

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 rule result in increased assurance of the protection of public health and safety in the future, more effective and efficient licensing of distribution to exempt persons, and a reduction in undue burden to certain general licensees. Changes have been made to this regulatory analysis between the draft and final publications to reflect updated estimates of labor rates, numbers of licensees, and NRC fees. In addition, some changes to the rule text have also been made to what was proposed. However, these minor changes have not impacted the Commission's decision or reasoning. Previously, some of the regulations were unclear, provided for obsolete activities, or required unnecessary procedures relative to the very small risk associated with a product. Although there are apparent costs associated with some of the amendments, the Commission believes that these costs are outweighed by those non-quantifiable costs associated with regulatory efficiency and protection of the health and safety of the public. The largest single cost is to the Agreement States from implementation of the rulemaking. However, by handling several issues together, the Commission has minimized its costs as well as costs for the Agreement States.

6 IMPLEMENTATION

The NRC's schedule for implementation of this rulemaking calls for the effective date of the rule to be in 2008 for the NRC's jurisdiction and full implementation by the Agreement States by 2009 - 2010. The applicable guidance document, NUREG-1556, Vol. 8, will be revised as part of a broader update following the issuance of the rule. Revisions are needed as a result of this rule for consistency with revisions to the exemptions and associated distributor requirements. The only guidance document that needs to be changed to reflect these amendments is NUREG-1556, Vol. 8.

One of the changes requires that persons currently authorized by an Agreement State to introduce byproduct material into a product or material and to transfer ownership or possession of the product or material containing the byproduct material to persons exempt under § 30.14 or equivalent regulations become NRC licensees. It appears that there are no current Agreement State licensees that would be affected by this change. If any such licensees are identified, the Commission will allow adequate time for any Agreement State licensees affected by this amendment to apply for and obtain an NRC license under § 32.11, so that a smooth transition would result without any interference with the conduct of their business.

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

This regulatory action is not expected to present any significant implementation problems. Affected licensees will be sent a copy of the final Federal Register notice.

7 IMPLICATIONS FOR OTHER FEDERAL AGENCIES

Promulgation of this rule has no adverse effects on other Federal agencies.

8 EFFECT ON SMALL ENTITIES

The rule does not significantly impact small or large entities. The rule will result in a net savings to licensees. The maximum number of licensees impacted by a change is 98, many of whom are not small entities. The change for this case is simply limited to a change in reporting requirements (i.e., minimal impact on licensees).

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

Code of Federal Regulations, *Title 10, Energy,* Part 31, "General Domestic Licenses for Byproduct Material."

Code of Federal Regulations, *Title 10, Energy,* Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," Subpart A, "Exempt Concentrations and Items."

Code of Federal Regulations, *Title 10, Energy,* Part 150, "Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters under Section 274."

Code of Federal Regulations, *Title 10, Energy,* Section 170.31, "Schedule of Fees for Materials Licenses and Other Regulatory Services, Including Inspections, and Import and Export Licenses."

Code of Federal Regulations, *Title 10, Energy,* Section 171.16, "Annual Fees: Materials Licensees, Holders of Certificates of Compliance, Holders of Sealed Source and Device Registrations, Holders of Quality Assurance Program Approvals, and Government Agencies Licensed by the NRC."

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