DRAFT REGULATORY ANALYSIS

for

AMENDMENT to

10 CFR Parts 30, 31, 32, and 150

for

CERTAIN EXEMPTIONS AND GENERAL LICENSE PROVISIONS

DRAFT REGULATORY ANALYSIS

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1 STATEMENT OF THE PROBLEM AND OBJECTIVES

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

Of particular importance, exempt distribution reports, as currently required at 5-year intervals, do not provide timely information that is necessary for NRC to assess the health impacts of these programs on the public health and safety. Difficulties exist in reporting because the required date for reporting by each licensee is different and the information is not necessarily reported by year. This makes it 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 is recorded by licensees in Agreement States is not currently being provided to the NRC. In order for 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 limits of exposure for the public. Regulations regarding exempt quantities are not explicit to prevent combining (bundling) of sources, thus the NRC cannot provide assurance that exposures would not exceed the levels originally intended under the exemption. Some of the regulations in § 30.15 and § 30.16 currently contain some obsolete provisions, i.e., no products are being distributed for use under certain exemptions. Eliminating obsolete exemptions adds to the assurance that future use of products in these categories would not contribute to exposures of the public.

Some regulations are overly burdensome or require licensee actions that are 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, that the requirements to distribute these products 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. Licensing a new initial distributor of smoke detectors currently requires a dose evaluation to demonstrate that certain safety criteria are 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. Revision to these requirements can reduce 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. Currently, written approval from the NRC is required for this type of transfer. Clarification in the regulation would improve regulatory efficiency.

The NRC is proposing to amend 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 some of the regulations. These actions are intended to 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. The exemptions are 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, which cover a broad class of products. Under these provisions, new products can be approved for use through the licensing process, if the applicant demonstrates that the specific product meets certain safety criteria. 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 quantities and concentrations are contained in tables in §§ 30.71 and 30.70, 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 proposing rule changes would be to take no action. The no-action alternative would allow current practices to continue. If NRC does not take action, there would not be any change in costs or benefits to the public, licensees or NRC. The no-action alternative would not address identified concerns.

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

This alternative is to 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 proposed regulatory amendments would 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 would 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 PROPOSED PROVISIONS

Sections 4.1 through 4.6 describe each of the proposed amendments in the rule and provide estimates of the costs and benefits to the licensees, NRC, Agreement States, and the public related to each amendment. Section 4.7 estimates the costs to NRC and Section 4.8 estimates costs to Agreement States for rulemakings 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 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 1.4 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 and may not be sufficiently recent, nationwide mean hourly rates are used.

Licensee fees were obtained from 10 CFR 170.31 and 171.16. It is recognized that the fees are periodically adjusted, most recently on May 26, 2005 (70 FR 30527), 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 proposed requirement. Currently, this hourly labor rate for NMSS is $87.

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 workers[1]. This wage was then increased by the same factor of 1.4 described earlier to obtain an hourly labor rate of $43 and an annual labor rate of $76,000.

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

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

This Regulatory Analysis was 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 would be affected by the proposed rule:

- Industry Implementation and Operation – The proposed rule would improve reporting requirements and improve licensing of distribution of certain byproduct materials. For example, manufacturers and distributors of smoke detectors would no longer have to perform a dose assessment, nor pay certain fees.
- NRC Implementation and Operation – The NRC would incur costs to develop a rule and to revise existing guidance. The proposed rule would result in small reductions in operating costs.
- Other Government – Agreement States would need to amend their regulations to maintain compatibility with NRC requirements; impacts to the Agreement State regulatory programs would be minimal.
- Regulatory Efficiency – The proposed rule would improve regulatory efficiency by simplifying the licensing of smoke detectors, removing obsolete provisions, and clarifying some of the regulations.

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[1]Department of Labor (U.S.), Bureau of Labor Statistics, Employer Costs for Employee Compensation, 4th Quarter 2004. Series IDs CMU3020000100000D and CMU3020000100000P.

- Improvements in Knowledge – The proposed rule would allow 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 proposed rule may improve the general knowledge of licensees (e.g., clarify the required actions for transfers from general license to specific license).
- Other Considerations – The proposed rule could 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 proposed rule would *not* be 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). A copy of the report must also 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 could be improved 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 would provide 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 existing regulations. Because the date of reporting for each licensee is different and the information is not necessarily reported by year, it is difficult to estimate the amount or types of products/materials containing byproduct material distributed each year or to see any trends. Also, the information is not current. It is more difficult for NRC to track when reports are due, particularly now that this type of license is typically issued for 10 years rather than 5 years. The deficiency may not always be noted unless a renewal or termination of license is being processed. Reporting annually would eliminate these difficulties and would not significantly change the reporting burden for these licensees.

In addition to the lengthy period between reports, certain information is not always clear in the reports, making it more difficult to use the information. The proposed rule would make 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 proposed rule would also revise §§ 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 would be eliminated, and the frequency of reporting would be 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 December 2004. Licensees reporting under § 32.12 were identified through ADAMS searches for the appropriate type of licenses.

§ 32.12	2	licensees
§ 32.16	43	licensees
§ 32.17	0	licensees
§ 32.20	25	licensees
§ 32.25	11	licensees
§ 32.29	27	licensees

The above numbers sum to 108 licensees. However, five of these licensees distribute products under two sections.

<u>Cost Impacts</u>:

Costs to Licensees (Manufacturers and Distributors)

The proposed rule would require 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 would be needed to compile annual reports compared to locating and compiling accurate information for five years for current reporting requirements. Thus, the costs to licensees are expected to be minimal or non-existent.

Costs to NRC and Agreement States

The NRC would incur costs from the rulemaking which are discussed in Section 4.7. Although NRC would receive a greater number of reports per year, the amount of data would be similar and no additional costs to NRC are expected. The proposed rule would require 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 would become 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 proposed 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 the proposed rule.

Benefits:

The revisions are expected to make the reporting process more efficient and could improve the quality of the information. Annual reporting would 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 existing regulations. The NRC would have a better basis on which to inform the public concerning these exposures. These changes would 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 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 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. Currently this license may be an NRC or Agreement State license.

In order for 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 NRC. Thus, the proposed rule would make §§ 32.11 and 32.12 Compatibility Category NRC and revise 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 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) would also be 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)

If §§ 32.11 and 32.12 become Compatibility Category NRC, then any entity licensed under equivalent regulations of an Agreement State would be required to obtain an NRC license. The NRC has been unable 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 proposed change, 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 $44/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 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 proposed change 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 2004. 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:

$8,000 application fee[4] x 6 applicants — $48,000

E-Distribution Annual Fees:

$11,100 annual fee[5] x 6 licensees = $66,600/year

It is noted that some Agreement States charge fees, while others do not. Therefore, for some licensees, the cost of fees to 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 is currently Compatibility Category C, so reporting requirements may not be identical. However, Agreement State licensees would be expected to be filing transfer reports to their appropriate state government. The proposed rule would not be expected to result in significantly different cost for filing of reports.

Costs to NRC and Agreement States

If there are licensees in Agreement States impacted by this proposed 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."

The NRC would also incur the cost from this rulemaking process, which is discussed in Section 4.7.

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

Costs to the Public:

There are no expected costs to the public from the proposed rulemaking.

Benefits

The benefits of the proposed regulation would be 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 would improve the efficiency, and possibly the consistency, of regulation, because one entity, the NRC, would have responsibility for handling exempt distribution licenses for byproduct material. Currently, there are approximately 100 total NRC licenses for distribution of byproduct material to exempt persons, none known amongst all the Agreement States. This change would also remove 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, there is no restriction as to the total quantity that may be possessed and used at any one time. 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 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.

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

The added language in the rule would ensure that bundling is prohibited. 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 would not occur. Moreover, a regulation would preclude the need for future follow-up generic letters 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 NRC becoming aware. The proposed rule would clarify 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 proposed rule.

Costs to Licensees (Manufacturers and Distributors)

There are no expected costs to manufacturers and distributors from the proposed 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 NRC and Agreement States

There are no expected costs to the NRC from the proposed rule, except the cost of rulemaking, which is discussed in Section 4.7.

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

Costs to the Public

There are no expected costs to the public from the proposed rule.

Benefits:

The NRC and the Agreement States would 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 due 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. Candidate 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 Sc-46 for sand consolidation in oil wells (§ 30.16). The Commission is proposing to delete exemptions for these products or to prohibit further distribution while allowing for the continued possession and use of previously distributed items.

For products no longer being manufactured, but for which some products may remain in use, the proposed rule would prohibit further distribution, i.e., §§ 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 proposed rule would remove the provisions, i.e., §§ 30.15(a)(2), (a)(4), (a)(6), and (a)(10).

Section 30.16 contains 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. Based on recent information, there is no such resin in use. Therefore, the proposed rule would remove § 30.16.

Part 32 contains regulations specifically for manufacturers and distributors of these products. Therefore, the proposed rule would remove 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 NRC and Agreement States

The NRC would incur costs from the rulemaking which 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 would require comparable changes in Agreement State regulations; however, each State would conduct one rulemaking following the planned revision of Parts 30, 31, 32 and 150. The cost for the rulemaking is discussed in Section 4.8.

Costs to the Public

There are no expected costs to the public from the proposed rulemaking.

Benefits:

Deleting these unnecessary regulations would simplify the regulations by eliminating extraneous text. This would eliminate the need to reassess the potential exposure of the public from these exemptions for possible future distributions of the products. Also, these exemptions would no longer need to be considered when assessing the total potential doses to the public from multiple sources. There would also be 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 Sc-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 proposed action, members of the public would be assured that future exposures would 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 currently qualify under an exemption at § 30.20. Specifically, § 30.20 exempts from licensing requirements persons that receive, possess, use, transfer, own, or acquire byproduct material, in gas and aerosol detectors designed to protect life or property from fires. 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.

The current designs of residential ionization chamber smoke detectors are very consistent, using 0.9 to 1 FCi 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 FSv/year), and the associated individual organ limits.

The proposed rule would establish a specific exemption from licensing requirements for ionization chamber smoke detectors. Specifically, § 30.15(a)(7) would be added to create a specific exemption for ionization chamber smoke detectors containing no more than 1 FCi of Am-241 in the form of a foil and designed to protect life and property from fires. Paragraph 32.15(d) would be 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 this proposed exemption and the existing class exemption is that an applicant for a license to distribute smoke detectors for use under this exemption would not be 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 would still be 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 proposed 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 would be reduced 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 (a significant savings). Also, it is assumed that the NRC would continue to 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.

<u>Cost Impacts</u>:

Costs to Licensees (Manufacturers and Distributors)

> There are no expected costs to licensees from the proposed rule. The proposed rule would 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 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 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 proposed 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, 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 — $6,000, a one time cost

From the Rulemaking:

The NRC would incur costs from the rulemaking which 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) would require a comparable addition to Agreement State regulations; however, each State would conduct one rulemaking following the revision of Parts 30, 31, 32, and 150. The cost for the rulemaking is discussed in Section 4.8. As §§ 32.14 and 32.26 are Compatibility Category NRC, there would be no impact on Agreement State licensing.

Costs to the Public

There are no expected costs to the public from the proposed rulemaking.

<u>Benefits</u>:

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 this product-specific exemption, applicants would no longer have to perform a dose assessment as previously required. OMB Supporting Statement 3150-0001 estimates

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[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."

that applicants spend an average of 21 hours preparing the required information for a sealed source and device evaluation. A majority 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 would no longer be required, applicants' burden would be reduced by 50 percent (i.e., roughly 11 hours saved). Thus, 11 hours saved at $44/hour[8] for a cost savings of $440/applicant for the development of an application. In addition, the fee associated with a device evaluation ($19,300 in 2005),[9] would no longer be required. A different application fee would also apply. Using FY 2005 fees, the application fee would be $8,000[10] instead of $13,500.[11] This would be a net reduction in application fees of $24,800 for each applicant and a total of $25,240 saved at the time of application once labor costs are accounted for.

These applicants would also have reduced net annual fees as licensees. Because a device evaluation would no longer be required, the proposed change would result in a savings equal to the amount of the annual fee for an active SS&D certificate ($24,600/year in 2005),[12] and a saving in the applicable annual fee. The applicable annual fee would be $11,100 (in 2005).[13] The annual fee for a licensee who distributes a device that requires a device evaluation is $18,300 (in 2005).[14] Thus, a net reduction in annual fees of $31,800/licensee.

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[8]Department of Labor (U.S.), Bureau of Labor Statistics, Occupational Employment and Wages, May 2004. 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.

Over the past three fiscal years, the NRC has received eight applications for new licenses to manufacture or distribute smoke detectors.[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 $44/hour — $1,500

Plus, $24,800 x 3 applicants/year = $74,400

For a total of about $75,900 saved/year by applicants, plus continuing savings as licensees depending on the fluctuation of the applicable fees.

Benefit to Existing Licensees (Manufacturers and Distributors)

Existing licensees would 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 ($24,600 in 2005). A change in the regulatory status of the license would also reduce the annual fees. Annual fees are currently $18,300/year[16] but would decrease to $11,100/year[17] under this change. Using 2005 fees, this would be a resultant annual savings of $31,800.

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:

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[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 $44/hour[19] = $308, a one-time cost

For a rough indication of overall savings to existing licensees:

7 hours/amendment x $44/hour x 10 licensees ─ $3,000 one-time cost incurred

To obtain an annual savings:
Elimination of an annual fee of $24,600 and a $7,200 decrease in another annual fee for 10 licensees. This would result in a benefit of $318,000 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 27 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 2005 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 NRC

From New Applicants:

A device evaluation would no longer be required; however, the time expended by the NRC staff to review a future license application of this type would increase slightly because the license reviewer would now also have to review and verify certain information about the device that would otherwise be included in the SS&D review. NRC estimates that it currently takes 34 hours for 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 NRC effort to review a license application by 6 hours. The net decrease in burden would be 15 hours. NRC would save:

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

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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 2004. 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 Agreement States

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

Benefits to the Public

There are no expected benefits to the public from the proposed rule. 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 also requires written approval from the NRC for transfers to any specific licensee not included in § 31.5(c)(8)(i). Thus, the general licensee who wishes 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, shall obtain approval for the transfer. The Commission can 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.

The proposed amendment would clarify the required actions for this type of transfer. It would also remove the necessity of obtaining prior written NRC approval under these circumstances. Paragraph 31.5(c)(8)(iii) would be 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 his 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 proposed revised § 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 would 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 NRC and Agreement States

The NRC would incur costs from the rulemaking which are discussed in Section 4.7.

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

Costs to the Public

There are no expected costs to the public from the proposed rulemaking.

Benefits:

The proposed rule would remove 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 his 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 would be relieved of the need to make a request to NRC to transfer the material. Annual savings are estimated as follows:

5 requests/year x 1 hour saved/request x $44/hour[20] ─ $200 saved/year

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

Benefit to NRC and the Agreement States

The NRC and the Agreement States would 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 would 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 would also make enforcement of these requirements easier.

Benefit to the Public

There are no expected benefits to the public from the proposed rule.

4.7 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; they may arise from the necessity of 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.

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[20]Department of Labor (U.S.), Bureau of Labor Statistics, Occupational Employment and Wages, May 2004. 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.

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 Nuclear Material Safety and Safeguards expended in developing the rule.

The estimated total cost of the rulemaking is 1.1 professional staff years (FTE) and $50,000 in contractor assistance. One NRC professional staff member costs $156,600/FTE. The total cost of development for the NRC is estimated to be approximately $220,000. These are “sunk” costs for developing the proposed rule. Approximately 0.3 FTE remain for the development of the final rule ($47,000).

NRC staff would need 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 would require minor revisions. Because there is a routine update planned for the NUREGs in this series, there is no cost impact as a result of this proposed rulemaking for implementation.

4.8 Costs to Agreement States of Compatible Regulations

Costs would be incurred by the Agreement States for development and implementation of compatible regulations. The costs would vary significantly by State because of differences in internal procedures for developing regulations. Some rule changes would be 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 proposed rule, the NRC assumes an average of 0.1 FTE at $76,000/FTE for each state. There are currently 33 Agreement States; therefore, the total cost for all Agreement States would be approximately $250,000.

4.9 Quantifiable Costs

Table 4.1 presents the quantified impacts of the proposed 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 Proposed 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	47	-
4.8 – Agreement State Rulemaking Activities	251	-
Total	313	(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 $261,000. The net present value of the costs and benefits in Table 4.1 at a discount rate of 7% per year for a 10-year period is $270,000. 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 highly 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 2005, but is based on older data (May 2004). In addition, another time lag exists between the preparation of this regulatory analysis and the effective date of this rule, approximately 2007 - 2008. 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 (FY05), they are expected to fluctuate in the future. There is no reliable method to predict NRC's annual fees in advance of their publication each fiscal year, and none is attempted in this document. Because the annual fees are a significant factor in this regulatory analysis and they vary greatly from year to year, it should be recognized that there is considerable uncertainty in the overall analysis.

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 proposed rulemaking would be 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. Currently, some of the regulations are unclear, provide for obsolete activities, or contain unnecessary burden 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 will be outweighed by those non-quantifiable costs associated with regulatory efficiency and protection of the health and safety of the public. The largest single cost would be to the NRC and to Agreement States from implementation of the proposed rulemaking. However, by handling several issues together, the Commission would minimize its costs as well as costs for the Agreement States.

6 IMPLEMENTATION

NRC's schedule for completion of this rulemaking calls for a final rule to be published in 2006 or 2007. The applicable guidance document, NUREG-1556, Vol. 8, would be revised as part of its routine updating following the issuance of the rule. Revisions are needed for consistency with revisions to the exemptions and associated distributor requirements. No new guidance is needed.

One of the proposed changes would require 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 would add transition provisions to allow adequate time for any Agreement State licensees affected by this proposed change 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 proposed changes that affect Compatibility Category B requirements, Agreement States have three years to make changes to their affected regulations.

The proposed 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 proposed rule would have no adverse effects on other Federal agencies.

8 EFFECT ON SMALL ENTITIES

The proposed rule would not significantly impact small or large entities. The proposed rule would result in a net savings to licensees. The maximum number of licensees impacted by a proposed change is 103, many of which are not small entities. The proposed change for this case is simply limited to a change in reporting requirements (i.e., minimal impact on licensees).

REFERENCES

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

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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Nuclear Regulatory Commission (U.S.)(NRC). NUREG/CR-4627 Revision 1, “Generic Cost Estimates: Abstracts from Generic Studies for Use in Preparing Regulatory Impact Analyses,” NRC: Washington, D.C. February 1989.

Nuclear Regulatory Commission (U.S.)(NRC). SECY-02-0196, “Recommendations Stemming from the Systematic Assessment of Exemptions from Licensing in 10 CFR Parts 30 and 40; and a Rulemaking Plan for Risk-informing 10 CFR Parts 30, 31, and 32.” NRC: Washington, D.C. November 1, 2002.