

DRAFT REGULATORY ANALYSIS

for

AMENDMENT to

10 CFR Parts 30, 31, 32, and 150

for

CERTAIN EXEMPTIONS AND
GENERAL LICENSE PROVISIONS

DRAFT REGULATORY ANALYSIS

TABLE OF CONTENTS

1	STATEMENT OF THE PROBLEM AND OBJECTIVES	1
2	EXISTING REGULATORY FRAMEWORK	2
3	IDENTIFICATION OF ALTERNATIVE APPROACHES TO THE PROBLEM	3
	3.1 No Action	3
	3.2 Proposed Rulemaking to Revise 10 CFR Parts 30, 31, 32, and 150	3
	3.3 Other Alternatives	3
4	DESCRIPTION, DISCUSSION, AND ANALYSIS OF VALUES AND IMPACTS OF PROPOSED PROVISIONS	3
	4.1 Revise §§ 32.12, 32.16, 32.20, 32.25(c), and 32.29(c) for Reporting Requirements	5
	4.2 Revise § 30.14 to Make Exempt Concentrations NRC Only	7
	4.3 Revise § 30.18 to Preclude Combining Multiple Exempt Quantities	10
	4.4 Revise Regulations to Remove Obsolete Provisions	12
	4.5 Revise § 30.15 to Add a Product-Specific Exemption for Smoke Detectors ..	13
	4.6 Revise §§ 31.5 and 31.7 to Exempt Some General Licensees from Immediate Notification Requirement in § 20.2201(a)(1)(i)	18
	4.7 Revise § 31.5(c)(8) to Clarify General Licensee Transfer to Specific Licensee Status	22
	4.8 Development and Implementation Costs	24
	4.9 Costs to Agreement States of Compatible Regulations	25
	4.10 Uncertainty	25
5	DECISION RATIONALE	25
6	IMPLEMENTATION	26
7	IMPLICATIONS FOR OTHER FEDERAL AGENCIES	26
8	EFFECT ON SMALL ENTITIES	26
	REFERENCES	27

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 μ Sv/year) whole body, and the associated individual organ limits. In addition, general licensees under §§ 31.5 and 31.7 are required to immediately notify the NRC if devices containing certain quantities of radionuclides are lost or stolen. For certain radionuclides, the quantities of materials requiring immediate notification under § 20.2201(a)(1)(i) may be lower than warranted given the associated radiological risk. Revision to these requirements can reduce licensees' and NRC and Agreement States' 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 seven issues related primarily to the goals of ensuring public health and safety and increasing regulatory efficiency, effectiveness, and realism. 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, users of some 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 4.7 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 4.8 estimates the costs to NRC and Section 4.9 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 and 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 and Statistics web site. Because exact hourly rates would be difficult to obtain and may not be sufficiently recent, 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. However, for the purpose of this analysis, the fees are assumed to remain unchanged over the next three years.

NRC labor rates are based on the current rates published in § 170.20 for the Nuclear Materials and Nuclear Waste Program. The labor rate is determined per the calculation methodology in Abstract 5.2 of NUREG/CR-4627, and considers only variable costs that are directly related to the implementation, and operation and maintenance of the proposed requirement. Currently, this hourly labor rate for NMSS is \$87 per staff-hour.

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 and 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 hourly labor rate was obtained from the Bureau of Labor and Statistics Employer Costs for Employee Compensation tables for State and local government workers by major occupation group for 2004 and increased by the same factor of 1.4 described earlier. This yields an hourly labor rate of \$60.

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 4.7).

This Regulatory Analysis was prepared under NUREG/BR-0058(6) 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 the *Regulatory Analysis Technical Evaluation Handbook*, NUREG/BR-0184. The following attributes would be affected by the proposed rule:

- C 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.
- C 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; the only impacts to the Agreement State regulatory program would be a small reduction in reports received.
- 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.

- C 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 4.7 as they pertain to the individual issues.

The proposed rule would *not* be expected to affect the following attributes:

- C Public Health (Accident/Event and Routine)
- C Occupational Health (Accident/Event and Routine)
- C Offsite Property
- C Onsite Property
- C General Public
- C Antitrust Considerations
- C Safeguards and Security Considerations
- C 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 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," as well as a requirement to submit a report on Form XXX--"Report of Transfers to Exempt Persons" or a clear and legible report containing all of the data required by the form. 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.

Cost Impacts:

Costs to Licensees (Manufacturers and Distributors)

The proposed rule would require annual reports instead of a five year reporting period. Efficiency and accuracy in compiling annual reports are expected because the proposed rule would require more specific information, primarily identification of the specific exemption provision and the license number of the reporting licensee. Therefore, 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 4.8. 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 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:

Providing a standard format or a form could 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. Additionally, the rule would provide an effective date by which Agreement State licensees would no longer be authorized to continue with these activities.

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/application¹ x \$46/hour – \$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.

Licensees are required to pay a fee for the application:

¹OMB 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."

\$4,300 application fee² x 6 applicants – \$26,000

E-Distribution Annual Fees:

\$6,000 annual fee³ x 6 licensees = \$36,000/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/application⁴ x \$87/hour⁵ – \$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

²§ 170.31, “Schedule of fees for material licensees and other regulatory services, including inspections, and import and export licenses,” Item 3.I (Byproduct Material)

³§ 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)

⁴OMB 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.”

⁵Internal NRC correspondence, email from Brian J. Richter to James Morris dated July 15, 2004, Subject: NMSS/NRR/NRC Labor Rates

more effort to review. For the purpose of this analysis, the generic number provided in the OMB supporting statement was used.

The NRC would also incur the cost from this rulemaking process, which is discussed in Section 4.8.

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 4.9.

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. 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. 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.

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. 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 4.8.

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 4.9.

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. Similarly, the public would benefit from potentially reduced doses.

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 4.8.

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 4.9.

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 are variable, typically fees 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.

Cost Impacts:

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/amendment⁶ 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 4.8.

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 4.9. 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.

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

⁶OMB 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."

percent (i.e., roughly 11 hours saved). Thus, 11 hours saved at \$42/hour⁷ for a cost savings of \$460/applicant for the development of an application. In addition, the fee associated with a device evaluation (\$5,600 in 2004),⁸ would no longer be required. A different application fee would also apply. Using 2004 fees, the application fee would be \$4,300⁹ instead of \$4,200.¹⁰ This would be a net reduction in application fees of \$5,500 for each applicant and a total of \$5,960 saved at the time of application.

These applicants would also have reduced 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 (\$6,700/year in 2004),¹¹ with a slight offsetting increase in the applicable annual fee. The applicable annual fee would be \$6,000 (in 2004).¹² The annual fee for a licensee who distributes a device that requires a device evaluation is \$5,800 (in 2004).¹³ Thus, a net reduction in annual fees of \$6,500/licensee. This may be significantly different by the time this rule becomes effective, as the fees are revised each year.

Over the past three fiscal years, the NRC has received eight applications for new licenses to manufacture or distribute smoke detectors.¹⁴ For the purpose of this regulatory analysis, it is assumed that the NRC would continue to receive new

⁷Bureau of Labor and Statistics, November 2003 National Industry-Specific Occupational Employment and Wage Estimates, North American Industry Classification System (NAICS) 334200 – Communications Equipment Manufacturing, Standard Occupational Classification (SOC) System Code Number 17-2111 – Health and Safety Engineers, Except Mining Safety Engineers and Inspectors hourly mean wage.

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

⁹§ 170.31, “Schedule of fees for material licensees and other regulatory services, including inspections, and import and export licenses,” Item 3.I.

¹⁰§ 170.31, “Schedule of fees for material licensees and other regulatory services, including inspections, and import and export licenses,” Item 3.H.

¹¹§ 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).

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 3.I.

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.H.

¹⁴Number of applications based on review of licensing action data for FY02 through FY04 for Program Code 3255.

applications approximately at this same rate (three applications per year). The annual cost savings to new applicants are estimated to be:

3 applicants/year x 11 hours saved/applicant x \$42/hour – \$1,400

Plus, \$5,500 x 3 applicants/year = \$16,500

For a total of about \$18,000 saved/year by applicants, plus continuing savings as licensees depending on how the applicable fees evolve.

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 (\$6,700 in 2004).

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 seven 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 seven 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:

7 hours/amendment¹⁵ x \$42/hour¹⁶ = \$294, a one-time cost

In addition, a change in the regulatory status of the license would slightly increase the annual fees. Annual fees are currently \$5,800/year¹⁷ but would increase to

¹⁵OMB 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."

¹⁶Bureau of Labor and Statistics, November 2003 National Industry-Specific Occupational Employment and Wage Estimates, North American Industry Classification System (NAICS) 334200 – Communications Equipment Manufacturing, Standard Occupational Classification (SOC) System Code Number 17-2111 – Health and Safety Engineers, Except Mining Safety Engineers and Inspectors hourly mean wage.

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.H (Byproduct Material – Require Device Evaluation)

\$6,000/year¹⁸ under this change. Using 2004 fees, this would be a resultant annual savings of \$6,500.

For a rough indication of overall savings to existing licensees:

7 hours/amendment x \$42/hour x 10 licensees – \$3,000 one-time cost incurred

To obtain an annual savings:

Elimination of an annual fee of \$6,700 and \$200 increase in another annual fee for 10 licensees. This would result in a benefit of \$65,000 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 2004 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

Benefit to Agreement States

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

¹⁸§ 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)

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 and 31.7 to Exempt Some General Licensees from Immediate Notification Requirement in § 20.2201(a)(1)(i)

Currently §§ 31.5(c)(10) and 31.7(b) require that general licensees comply with the provisions of §§ 20.2201 and 20.2202 for reporting the theft or loss of licensed material and radiation incidents, but exempt them from the remainder of the requirements of 10 CFR Parts 19, 20, and 21. In particular, § 20.2201(a)(1)(i) requires that each licensee must notify NRC by phone immediately after its occurrence becomes known to the licensee of any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C to Part 20 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas. The licensee must report to NRC by phone within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, all licensed material in a quantity greater than 10 times the quantity specified in Appendix C to Part 20 that is still missing at this time (§ 20.2201(a)(1)(ii)). In addition, a written report is required within 30 days of making the phone call (§ 20.2201(b)).

This proposed rule would exempt general licensees under §§ 31.5 and 31.7 from the requirement in § 20.2201(a)(1)(i) for immediate notification, except with regard to devices meeting the requirements for registration in § 31.5(c)(13)(i). For those devices for which immediate notification is no longer required, the 30-day telephone notification requirement in § 20.2201(a)(1)(ii) would still apply. The proposed devices for which the general licensee would be exempted would be devices containing 1 Ci or more of tritium (mostly exit signs), 1 Ci or more of Kr-85, 10 mCi or more of Pm-147, 0.1 mCi or more of Po-210, and 1 mCi or more of Cd-109, as well as a small number of devices containing a few other radionuclides. The number of devices for which the timing for reporting losses or thefts would be affected by the proposed rule is estimated to be over 500,000. However, only roughly 20 immediate reports of losses and thefts of devices are made by general licensees per year, according to NMED (Nuclear Material Event Reports), the database that includes information on these reports.

The proposed revision would serve to give general licensees more time to report. In the case where a device is found or recovered before the making of the 30-day telephone report, no call nor followup written report would be required.

Cost Impacts:

Costs to General Licensees (Users)

There are no expected costs to the general licensees from the proposed rule.

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). However, the NRC would allow a reasonable time for these licensees to start doing so and would not expect this to cause any incremental cost. Also, this would be a single action, though necessary because of both this issue and the issue discussed in section 4.7 below.

Costs to NRC and Agreement States

The NRC would incur costs from the rulemaking which are discussed in Section 4.8.

Sections 31.5 and 31.7 are Compatibility Category B requiring essentially identical wording. Revising §§ 31.5(c)(10) and 31.7(b) 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 4.9.

Impacts to Public Health (Accident/Event)

Although timely notification of NRC or the Agreement States is intended to provide an opportunity for taking action to recover devices to prevent unnecessary exposure to radiation as well as prevent sources from ending up in scrap, this revision is not expected to have a negative impact on public health. None of the generally licensed devices present an imminent danger to health and safety. Most are required to meet a safety criterion of no person likely to receive a dose in excess of 15 rem (150 mSv) whole body under severe accident conditions. Reporting for the devices presenting the most significant, though still small, risks are not being revised. Also, generally licensed devices do not contain the types and quantities of radioactive material that are considered to be of concern for possible intentional misuse in a radiological dispersion device. The change in notification requirements is not expected to have a significant impact on the recovery of affected lost or stolen devices. Thus, elimination of the requirement for immediate notification for certain lost or stolen generally licensed devices would not impose additional health concerns on the public or affect the environment.

Costs to the Public

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

Benefits:

The proposed rule seeks to eliminate the burden associated with immediate notifications commensurate with the associated risk. Approximately 20 immediate reports of losses and thefts per year are made by general licensees (including Agreement State general licensees). This number does not include specific licensee reports concerning devices they possess under a general license, because these reports are identified in the data base by the specific license. It should be noted that the practice of immediate notification is when the licensee becomes

aware that the device is missing, often much longer after the actual loss occurred. General licensees are likely to have different methods for internal audits and inventorying than specific licensees, such that the time before losses are discovered may be longer. As a result, the likelihood of devices being found because of more timely reporting is smaller than for specifically licensed devices.

Two of the most widely distributed devices under § 31.5 are EXIT signs and static eliminators. Many of the 20 annual reports are likely to involve one of these devices. (General licensees that possess devices that are required to be registered are more likely to be the ones reporting losses, even though they represent a smaller fraction of generally licensed devices than those covered by this proposed rule.) Therefore, for the purpose of the regulatory analysis, it is estimated that there would be 12 fewer reports per year required on an immediate basis as a result of the proposed rule (3 by NRC licensees and 9 by Agreement State licensees). Historically, the portion of devices reported lost or stolen in immediate reports and reported found or recovered in 30-day follow-up reports is roughly one third. Thus, in roughly 4 instances per year, neither a telephone call nor written report would be required. In 8 more instances, more time would be provided to make the required reports.

Benefit to Licensees

Licensees would experience savings for no longer making 4 immediate phone calls and 4 written reports per year, each of which has been estimated to take 3 hours effort.¹⁹ Annual savings are estimated as follows:

8 reports/year x 3 hours/report x \$46/hour²⁰ – \$2,100/year; roughly \$500 for NRC and \$1,600 for Agreement States

This does not account for instances where reports are still required, though not immediately. It is considered a further benefit to the licensees to have more time before being required to make a report. It may also be somewhat easier on an ongoing basis for “responsible individuals” (required by § 31.5(c)(12)) to not concern themselves with having to report immediately rather than within 30 days.

¹⁹OMB Clearance No. 3150-0014, “Final OMB Supporting Statement For 10 CFR Part 20 ‘Standards for Protection Against Radiation’ Revision to Clearance Extension,” Table 1.

²⁰Bureau of Labor and Statistics, November 2003 National Industry-Specific Occupational Employment and Wage Estimates, North American Industry Classification System (NAICS) 334500 – Navigational, Measuring, Electromedical, and Control Instruments Manufacturing, Standard Occupational Classification (SOC) System Code Number 17-2111 – Health and Safety Engineer mean hourly wage

Benefit to NRC and Agreement States

NRC and the Agreement States would experience savings as a result of no longer receiving and acting on 4 immediate reports per year and 4 written reports. The annual savings are estimated as follows:

$$8 \text{ reports/year} \times 3 \text{ hours/report}^{21} \times \$87/\text{hour} = \$2,100/\text{year}$$

Additionally, the NRC and Agreement States would benefit from not having to do a resource-intensive response if the device is found/recovered by the licensee within the 30-day window. Follow-up investigations depend heavily on the nature of the incident and resources spent vary widely; therefore, they are not quantified for this analysis.

Benefit to the Public

There is no expected benefit to the public from the proposed rule.

4.7 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

²¹OMB Clearance No. 3150-0014, "Final OMB Supporting Statement For 10 CFR Part 20 'Standards for Protection Against Radiation' Revision to Clearance Extension," Table 3.

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). However, the NRC would allow a reasonable time for these licensees to start doing so. The Agreement States would not be expected to be unreasonable in this regard. Thus, this change is not expected to cause any incremental cost. Also, this would be a single action, though necessary because of both this issue and the issue discussed above in section 4.6.

Costs to NRC and Agreement States

The NRC would incur costs from the rulemaking which are discussed in Section 4.8.

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 4.9.

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:

$$5 \text{ requests/year} \times 1 \text{ hour saved/request} \times \$46/\text{hour}^{22} = \$200 \text{ saved/year}$$

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:

$$5 \text{ requests/year} \times 1 \text{ hour/request} \times \$87/\text{hour} = \$400/\text{year}$$

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.

4.8 Development and Implementation Costs

NRC development costs are the costs of preparation of a regulation before its promulgation and implementation. Such costs may include expenditures for research in support of this regulatory action, publishing notices of rulemaking, holding public meetings, responding to public comments, and issuing a final rule. NRC implementation costs are those "front-end" costs

²²Bureau of Labor and Statistics, November 2003 National Industry-Specific Occupational Employment and Wage Estimates, North American Industry Classification System (NAICS) 334500 – Navigational, Measuring, Electromedical, and Control Instruments Manufacturing, Standard Occupational Classification (SOC) System Code Number 17-2111 – Health and Safety Engineer mean hourly wage.

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.

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 cost of the rulemaking is 1.3 professional staff years and \$50,000 in contractor assistance. One NRC professional staff member costs \$156,600/staff-yr. The total cost of development for the NRC is estimated to be approximately \$250,000.

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.

4.9 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 \$106,500/FTE for each state. There are currently 33 Agreement States; therefore, the total cost for all Agreement States would be approximately \$350,000.

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.

The labor rates are based on mean hourly rates from November 2003 and adjusted to account for benefits. These rates are slightly outdated and may underestimate the actual rates that are experienced in the industry and the Agreement States.

The annual fees and NRC’s labor rate change periodically, and although these numbers are currently accurate, they soon will be updated.

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.

Other costs and benefits are not easily quantifiable, and therefore, are assessed qualitatively. These factors combine to make this regulatory analysis highly uncertain.

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. 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 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

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