RULEMAKING ISSUE
(Affirmation)

July 6, 2007 SECY-07-0113

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations /RA/

SUBJECT: FINAL RULE: 10 CFR PARTS 30, 31, 32, AND 150 – EXEMPTIONS FROM LICENSING, GENERAL LICENSES, AND DISTRIBUTION OF BYPRODUCT MATERIAL: LICENSING AND REPORTING REQUIREMENTS (RIN 3150-AH41)

PURPOSE:

To request Commission approval for the publication of a final rule. This final rule amends Parts 30, 31, 32, and 150, and affects distributors of byproduct material to exempt persons, some general licensees, and some users of exempt products. The staff has developed this final rule to improve regulatory efficiency, and ensure public health and safety and protection of the environment. This paper does not address any new commitments.

SUMMARY:

This final rule will amend several regulations governing the distribution of byproduct material. The reporting requirements for licensees distributing byproduct material to persons exempt from licensing are being changed, obsolete provisions are being deleted, certain regulatory requirements are being clarified, and smoke detector distribution regulations are being simplified. In addition, this final rule clarifies the process for transferring a generally licensed

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device for use under a specific license. Aspects of this rule will affect all distributors of exempt byproduct material who submit transfer reports, some general licensees, and some users of exempt products. These actions are intended to better ensure the protection of public health and safety, make the licensing of distribution to exempt persons more effective and efficient, and reduce unnecessary regulatory burden to certain general licensees. Individually and collectively these amendments have been found to have no adverse environmental impacts, and have no significant additional regulatory burden.

BACKGROUND:

The staff provided the Commission with recommendations for possible improvements to the regulations governing the exemptions from licensing for both byproduct and source material in 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," dated November 1, 2002. The rulemaking plan included in SECY-02-0196 addressed only the regulations governing byproduct material. The staff recommended a number of issues to be considered in the rulemaking process, including some related to the general licenses in Part 31. The plan also discussed the possible need to make adjustments or add issues during the rulemaking process.

In SECY-05-0151, "Proposed Rule: 10 CFR Parts 30, 31, 32, and 150 – Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements (RIN 3150-AH41)," dated August 23, 2005, the staff presented a proposed rule, which included the resolution of five of the issues approved by the Commission in the staff requirements memorandum (SRM) to SECY-02-0196 (November 17, 2003; ADAMS Accession No. ML033210570), and two others that had been identified by the staff in the interim.

In an SRM dated November 3, 2005, responding to SECY-05-0151, the Commission approved publication of the subject proposed rule, with the elimination of one of the amendments. The proposed rule was published in the *Federal Register* on January 4, 2006 (71 FR 275). The comment period closed March 20, 2006, and nine comment letters were received. One comment letter was submitted by a smoke detector manufacturer, and another by a manufacturer of sources used in smoke detectors. One comment was received from the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR), representing manufacturers and distributors of exempt quantities of byproduct material. One comment was received from the Radiation Safety Officer (RSO) of a university. Officials from two States (Alabama and Texas) and staff from two others (Illinois and Georgia) also submitted comments. These comments are discussed in detail in the *Federal Register* notice (Enclosure 1). As a result of consideration of the comments, minor changes were made to what was proposed in order to eliminate unanticipated burdens on licensees and to clarify some of the regulatory text.

DISCUSSION:

The final rule will make a number of revisions to the regulations regarding the use of byproduct material under exemptions from licensing and under general licenses, and regarding the requirements for those who distribute products and materials for use under exemptions from licensing. These improvements are part of the overall commitment to systematically assess the Nuclear Regulatory Commission's (NRC's) regulatory program to ensure the safe use and

management of byproduct material. Implementing these final amendments to Parts 30, 31, 32, and 150 will ensure that the NRC's regulatory actions are more effective, efficient, and realistic, and enhance NRC's ability to protect public health and safety.

Issues Included in this Final Rule

This final rule amends the regulations in Parts 30, 31, 32, and 150. The amendments address six goals: (1) improving the reporting of exempt product/material distribution; (2) requiring NRC-only licensing of introduction of exempt concentrations; (3) explicitly prohibiting bundling of exempt quantities; (4) removing obsolete provisions; (5) simplifying the licensing of smoke detector distribution; and (6) clarifying requirements in § 31.5 for transfer of generally licensed devices for use under a specific license.

Improving the Reporting of Exempt Product/Material Distribution

Distributors of exempt products had previously submitted reports to the NRC on a 5-year cycle. This final rule replaces this requirement with an annual reporting requirement. The longer reporting period between reports has had detrimental effects on the quality and timeliness of data available to the NRC. In addition, minor changes to the content of reports will also be made to improve the NRC's ability to assess the full impact on public health and safety from exempt products and materials. Despite the fact that licensees will have to submit more reports, these licensees' net regulatory burden will not significantly change because each report will be shorter, and the record retention period will be shorter as well. The only concern expressed in the comments on the proposed rule regarding this revision pertained to the inclusion of chemical and physical data reported by distributors of exempt quantities. The final rule has been clarified in order to address this concern. Other comments received on this subject were supportive of the proposed rule.

NRC Licensing of Introduction of Exempt Concentrations

Paragraph 150.15(a)(6) reserves to the NRC the authority for licensing the transfers to persons exempt from licensing and regulatory requirements. Notwithstanding § 150.15(a)(6), § 30.14 allows Agreement States to license those who introduce byproduct material into products or materials for transfer as exempt concentrations. This exemption predates the Agreement State program. This anomaly creates a gap in the information available to assess the impact of exempt products, may introduce inconsistencies in the licensing process, and results in confusion concerning whether such activities require an NRC license. It is also more efficient for one jurisdiction to license this activity than for each State to expend resources and maintain capabilities for this exceptional authority. The final rule will provide that only the NRC may authorize such introduction and transfer.

This issue garnered comments from some States. The comment submitted by Texas was strongly worded in opposition to this change. The staff notes, however, that no previous objection had been raised by Texas or any other State during the development of either the proposed rule or the rulemaking plan. Prior to publication of the proposed rule, the Agreement States were polled as to whether they had any such licensees, and additional searches were made by the staff to identify potentially affected licensees, however, none were found. Since

publication of the proposed rule, Texas has not identified any licensee who would be affected by the rule and no current Agreement State licensees of this type have been identified.

Bundling of Exempt Quantities

The final rule codifies the Commission's position that multiple exempt quantities should not be combined, or "bundled." This practice circumvents the basic safety considerations relied on in issuing the exemption and is not consistent with the required label provided by the manufacturer, which must state that "exempt quantities should not be combined." This final rule amends the NRC's regulations to specifically prohibit the combination of exempt quantities for the purpose of producing an increased radiation level. Comments received on this amendment were supportive.

Obsolete Exemption Provisions

Obsolete exemptions will be deleted. These exemptions are no longer beneficial to the public, and address products no longer commercially distributed. Some exemptions deleted by this final rule have never been used. Comments received were unanimously supportive of the NRC deleting these exemptions.

Most of these exemptions are contained in § 30.15, "Certain items containing byproduct material." The exemptions for automobile lock illuminators and shift quadrants, thermostat dials and pointers, and spark gap irradiators containing cobalt-60 will be removed completely. The exemptions for balances of precision and marine compasses and other navigational instruments will be limited to previously distributed products, because there is the possibility that some of these products may still be functional and in use. Additionally, the relevant distributor requirements in Part 32 that reference obsolete products will be removed.

In addition to the obsolete exemptions in § 30.15, the exemption in § 30.16, "Resins containing scandium-46 and designed for sand-consolidation in oil wells," will be deleted. The exemption for resins containing scandium-46 has a potential for significant doses if used. Removing this exemption will further ensure that this obsolete product will not be used without a specific license in the future.

Smoke Detector Product-Specific Exemption

This final rule will simplify licensing for applicants to initially distribute smoke detectors by establishing a new product-specific exemption for ionization chamber smoke detectors containing no more than 1 μCi of americium-241 in the form of a foil. These widely distributed and greatly beneficial devices are currently being used under the class exemption for gas and aerosol detectors. Current-day smoke detectors are consistently designed and the NRC has developed extensive licensing experience.

Because the existing class exemption is not being deleted, the remaining smoke detector models that do not qualify for the new exemption may still be distributed to exempt persons, so there will be no negative impacts on any existing business. An analysis of the sealed source and device registry showed that 92 percent (97 out of 106) of existing smoke detector models will potentially qualify for the new product specific exemption. The establishment of a new

product-specific exemption for these products will also reduce fees for initial distributors of smoke detectors. The only issue raised in the comments on this revision concerned allowance for variation in the activity of sources that normally result from the manufacturing process.

Transfer of Generally Licensed Devices to Specifically Licensed Status

Licensing and enforcement experience indicates that a clarification is needed to § 31.5 to address the transfer of a device from the authority provided by the general license to that of a specific license. Some specific licensees possess devices that are generally licensed and, recently, an increased number of these licensees have transferred their authorization to possess and use a device held under the general license to that of a specific license. Doing so allows the specific licensee to avoid paying registration fees on some devices, and is allowed under § 31.5(c)(8). Such a transfer continues to be at the licensee's discretion. This rule clarifies the responsibilities of licensees seeking such a transfer. For example, the appropriate labeling, testing, and disposal requirements are different for general licensees than for specific licensees. Additionally, such transfer currently requires prior written approval from the NRC. The regulations will be amended to eliminate the requirement for a licensee to seek prior approval, and to state exactly what the licensee must do. This will enhance regulatory clarity and improve the ease of transfer of devices held under a general license to a specific license. This proposed revision resulted in stakeholder interest during the public comment period. Concerns came mainly from States, who raised additional issues related to this general license. Some of these issues are the subject of a petition submitted by the Organization of Agreement States (OAS). The OAS petition recommends that some currently generally licensed devices should only be possessed by specific licensees. The staff believes that the changes made in this rule are warranted, regardless of the outcome of the petition. This rule will apply to the remaining generally licensed devices. These comments have been addressed in the *Federal Register* notice.

Outcome of this Final Rule: Advancing the NRC's Strategic Goals

Some of the revisions improve NRC's ability to ensure the protection of public health and safety and the environment through the availability of more current and useful data on distributions of byproduct material. Additionally, these amendments will help to ensure that NRC actions are effective, efficient, realistic, and timely. Better data collection will improve the effectiveness and efficiency of NRC actions through the addition of certain new provisions and the elimination of certain requirements that are no longer necessary. Based on regulatory, licensing, and enforcement experience, the staff has also identified the need to clarify regulations in response to unanticipated interpretations of certain existing regulations. Finally, the goal of ensuring openness in our regulatory process will be advanced because the NRC will have a better basis on which to inform the public about exposures resulting from the distribution of consumer products.

Agreement State Issues

In addition to being represented on the working group for the final rule, the Agreement States had an early opportunity to review a copy of the draft final rule. On February 22, 2007, a copy of the draft final rule was posted on NRC's Technical Conference Forum so that the Agreement States (as well as New Jersey, Pennsylvania, and Virginia) could review it and provide

comments. Written comments were received only from the State of Washington. These comments related primarily to compatibility categories and multiple licensing jurisdictions.

The State of Washington expressed several concerns in its comments. One concern was that, since § 30.14(c) requires all manufacturers, processors, and producers to be NRC licensees, this will lead to additional Federal licensing in addition to Agreement State licensing. The staff notes that this provision, in fact, exempts manufacturers, processors, and producers from NRC licensing for the transfer of products and materials containing exempt concentrations, although this exemption is contingent on the "introducer" being an NRC licensee. The State of Washington did support NRC licensing of the introduction of exempt concentrations.

The State of Washington also suggested that all parts of the rule be categorized as Compatibility Category C, and objected to parts of the rule being Category B and Category NRC. This rule contains regulations that are classified as Category NRC, Category B, Category C, and Category D in accordance with the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997 (62 FR 46517), and for the various reasons set forth in the Statement of Considerations. Consistent with what had been proposed, this final rule will change § 32.11 from Categories C/B to Category NRC, and § 32.12 will change from Category C to Category NRC. These sections involve exempt product distribution licensing, a regulatory area that is reserved to the NRC, and therefore Category NRC is appropriate. For the rest of the amendments made in this final rule, the compatibility category is not being changed.

Another comment from the State of Washington was that specific licensees producing or distributing exempt materials will now report directly to the NRC and this could lead to "information gaps." Most distributors of byproduct material to exempt persons already must be NRC licensees who make certain reports to the NRC. One additional category of licensee ("introducers" of exempt concentrations) will now need an NRC license and will report to the NRC. This fills a gap for the NRC.

There was also a concern expressed by the State of Washington that the requirements would be relaxed to allow companies to make some physical and/or informational changes to generally licensed device labels without having to report these to NRC, and that this could adversely affect the realistic control of generally licensed materials, possibly leading to missing, lost or abandoned sources. However, labels will only be allowed to be changed by specific licensees and only on devices no longer generally licensed; the change in status will be required to be reported to the NRC.

RECOMMENDATIONS:

That the Commission:

1. Approve for publication in the *Federal Register* the final amendments to Parts 30, 31, 32, and 150 (Enclosure 1).

2. Certify that this rule, if adopted, will not have a significant impact on a substantial number of small entities, to satisfy the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

3. Note:

a. The final rule will be published in the *Federal Register* and will be effective 60 days after publication.

b. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification that this rule does not have a significant economic impact on a substantial number of small entities, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b).

c. A final Regulatory Analysis has been prepared for this rulemaking (Enclosure 2).

d. A final Environmental Assessment has been prepared for this rulemaking (Enclosure 3).

e. The staff has determined that this action is not a "major rule," as defined in the Congressional Review Act of 1996 (CRA) [5 U.S.C. 804(2)] and has confirmed this determination with the Office of Management and Budget (OMB). The appropriate Congressional and Government Accountability Office contacts will be informed (Enclosure 4).

f. NUREG-1556, Volume 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses," will require minor revisions for consistency with these final amendments to the regulations.

g. Appropriate Congressional committees will be informed of this action.

h. A press release will be issued by the Office of Public Affairs when the final rule is filed with the Office of the *Federal Register*.

I. This final rule amends information collection requirements. However, the burden for these revisions to information collection is insignificant and OMB clearance is not required.

RESOURCES:

The resources for completing action on this final rule are estimated at 0.1 full time equivelent and are in the fiscal year 2007 budget for the Office of Federal and State Materials and Environmental Management Programs.

COORDINATION:

The Office of the General Counsel has no legal objection to the final rulemaking. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

/RA William F. Kane Acting for/

Luis A. Reyes
Executive Director
for Operations

Enclosures:
1. Draft *Federal Register* Notice
2. Regulatory Analysis
3. Environmental Assessment
4. CRA Forms

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR PARTS 30, 31, 32, AND 150

RIN: 3150-AH41

Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements.

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending several regulations governing the distribution of byproduct material. The reporting requirements for licensees distributing byproduct material to persons exempt from licensing are being changed, obsolete provisions are being deleted, certain regulatory provisions are being clarified, and smoke detector distribution regulations are being simplified. In addition, this final rule modifies the process for transferring a generally licensed device for use under a specific license. Aspects of this rule will affect distributors of exempt byproduct material, some general licensees, and some users of exempt products. These actions are intended to make the licensing of distribution to exempt persons more effective and efficient, reduce unnecessary regulatory burden to certain general licensees, and better ensure the protection of public health and safety.

EFFECTIVE DATE: This final rule is effective on **[insert 60 days from date of publication in the Federal Register].**

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SUPPLEMENTARY INFORMATION:

I. Background.

A. Introduction.

The Commission has authority to issue both specific and general licenses for the use of byproduct material, and also to exempt byproduct material from regulatory control under section 81 of the Atomic Energy Act of 1954, as amended (hereafter, “the Act” or the AEA). In considering its exemptions from licensing, the Commission is directed by the Act to make "a finding that the exemption of such classes or quantities of such material or such kinds of uses or users will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public." To ensure that its exemptions meet the requirements of the Act, the Commission specifies limits for the radiological properties of what is distributed to persons exempt from licensing, and carefully oversees the manufacture and distribution of the approved products and materials.

As beneficial uses of byproduct material were developed and experience grew, new products intended for use by the public were invented, and the regulations were amended to accommodate their use under various exemptions from licensing. These products and materials present very low risks of significant individual doses. However, a substantial portion of the public uses these products – more than 100 million smoke detectors are in use in this country – and as a result, is routinely exposed to some ionizing radiation. Therefore, in the 1990s, the Commission conducted a systematic reevaluation of the exempt materials and products, most of which had been approved before 1970. A major part of the effort was an assessment of the potential and likely doses to workers and the public under the existing regulations governing the distribution of exempt products.

Dose assessments associated with most exempt products can be found in NUREG-1717,[1] "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," June 2001. Generally, the systematic assessment of exemptions determined that no significant problems exist with the current uses of byproduct materials under the exemptions from licensing. Actual exposures of the public likely to occur are in line with Commission policy concerning acceptable doses from exempt products and materials. For some exempt products,

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[1]NUREG-1717 is a historical document developed using the models and methodology available in the 1990s. The NUREG provides the estimate of the radiological impacts of the various exemptions from licensing based on what was known about distribution of material under the exemptions in the early 1990s. NUREG-1717 was used as the initial basis for evaluating the regulations for exemptions from licensing requirements and determining whether those regulations adequately ensured that the health and safety of the public were protected consistent with NRC policies related to radiation protection. The agency will not use the results presented in NUREG-1717 as a sole basis for any regulatory decisions or future rulemaking without additional analysis.

Copies of NUREGs may be purchased from the Superintendent of Documents, U. S. Government Printing Office, P.O. Box 37082, Washington, DC 20013-7082. Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. A copy is also available for inspection and/or copying for a fee at the NRC public Document Room, One White Flint North, 11555 Rockville Pike, Public File Area O1-F21, Rockville, MD.

there was a significant difference between potential and likely doses because the use of the exempt product is limited (or nonexistent) or significantly lower quantities are used in products than is potentially allowed under the exemption.

The Commission is also revising a certain general license within this final rule. General licenses are provided by regulation, grant authority to a person for certain activities involving byproduct material, and are effective without the filing of an application with the Commission or the issuance of licensing documents to particular persons. Separate and distinct from either exemptions or specific licenses, general licenses are designed to be commensurate with the specific circumstances covered by each general license. However, the NRC has determined that its regulations were not clear with respect to certain transfers of generally licensed devices. This has led to inefficiencies in licensing oversight and may negatively impact public confidence. Thus, the NRC is clarifying and simplifying its regulations related to this issue.

This final rule reflects the Commission's goals to make its regulations more flexible, user-friendly, and performance-based, and to improve its ability to risk-inform its regulatory program. These concepts continue to be considered in developing potential revisions to the regulatory program in the area of distribution of byproduct material to exempt persons. To make optimal use of rulemaking resources, both for the NRC and the States who must develop conforming regulations, several issues have been combined into this final rule.

A proposed rule containing these amendments was published for public comment in the *Federal Register* on January 4, 2006 (71 FR 275). The public comment period closed March 20, 2006. Nine comment letters were received. The NRC has considered these comments in this final rule.

B. Regulatory Framework.

The Commission's regulations in Part 30 contain the basic requirements for licensing of byproduct material. Part 30 includes a number of regulations that exempt the end user from licensing requirements, so-called “exemptions.” Many of these exemptions are product-specific, intended only for specific purposes which are narrowly defined by regulation. More broadly defined are the general materials exemptions, which allow the use of many radionuclides in many chemical and physical forms subject to limits on activity, and which are specified in §§ 30.14 and 30.18 for exempt concentrations and exempt quantities, respectively. The Commission’s regulations also include two class exemptions – for self-luminous products and gas and aerosol detectors, in §§ 30.19 and 30.20, respectively – which cover a broad class of products not limited to certain quantities or radionuclides. Under the class exemptions, many products can be approved for use through the licensing process if the applicant demonstrates that the specific product is within the class and meets certain radiation dose criteria.

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

Part 32, Subpart A, 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.

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

II. Discussion.

This final rule makes a number of revisions to the regulations governing the use of byproduct material under exemptions from licensing and under general license, and to the requirements for those who distribute products and materials for use under exemptions from licensing. The changes are intended to better ensure the protection of public health and safety and improve the efficiency and effectiveness of certain licensing actions.

A. Improved Reporting of Distribution to Persons Exempt from Licensing Requirements.

The reporting and recordkeeping requirements for distributors of products containing byproduct material to persons exempt from licensing in Part 30 are being amended to improve the quality of data available to the NRC. The changes set forth in this rule have been made in such a way that there is an insignificant effect on these licensees' reporting and recordkeeping burdens. The reporting and recordkeeping requirements for these distributors are found in §§ 32.12, 32.16, 32.20, 32.25(c), and 32.29(c).

Before 1983, reporting of transfers of exempt byproduct material was required on an annual basis. The NRC amended its regulations in 1983 to change the reporting requirement to once every 5 years to minimize administrative burden. The 1983 reporting regulations required that an additional materials transfer report be submitted when filing for license renewal or notifying the NRC of a decision to cease licensed activities. However, subsequent experience with the 5-year reporting frequency has shown that it does not provide the NRC with complete, accurate, or timely information on products and materials containing byproduct material distributed for use under exemptions from licensing.

A 5-year reporting cycle does not produce timely information for the NRC to fully determine the products and amount of byproduct material distributed annually for exempt use. The lack of timely information limits the NRC's ability to evaluate the overall net impact of such distribution on public health and safety. 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 exempt products containing byproduct material distributed each year or to detect emerging trends. A 5-year reporting period also negatively affects the availability of current information. The limitations of the information about the products and materials and quantities distributed for use under exemption greatly impacted the effort involved in developing the dose assessments in NUREG-1717 and contributed to uncertainties in the results.

Reevaluation of the reporting requirements suggests that annual reporting may also be administratively more efficient than a 5-year cycle for both the NRC and licensees. There have been more implementation problems with the longer cycle than with annual reporting. For example, because of the long interval between reports, licensees frequently neglect to file reports in compliance with the regulations. This lapse sometimes results in the need for the NRC to request that additional information be sent so that an application for renewal or termination of license can be processed. The long interval between reports also may lead to licensee inefficiencies in collecting the data. Routine annual reporting should be more straightforward and easier for licensees to comply with than consolidating and reporting 5 years of distribution information.

This final rule requires that material transfer reports covering transfers made during the calendar year be submitted annually by January 31 of the following year. In the first report made after the change, licensees are being required to submit information on transfers made since the previous report, so that there are no gaps in coverage. The requirements added in 1983 for

licensees to file a special material transfer report when filing for license renewal (contained in the existing §§ 32.12, 32.16, 32.20, 32.25, and 32.29) are being deleted. Another change is being made to the same sections so that material transfer reports are required 30 days after ceasing authorized activities, rather than at the point of notifying the Commission of the decision to cease authorized activities.

In addition to the lengthy period between the 5-year reports, the manner in which product information and licensee information has been submitted in the reports has not always been clear, making the data more difficult to use. This final rule modifies how information is to be provided, improving clarity by making the reporting provisions more specific. Under the revised provisions, as specified in §§ 32.12(a)(1), 32.16(a)(1), 32.20(b)(1), 32.25(c)(1), and 32.29(c)(1), the report must clearly identify the specific licensee submitting the report, including the license number. In addition, as specified in §§ 32.12(a)(2), 32.16(a)(2), 32.20(b)(2), 32.25(c)(2), and 32.29(c)(2), the report is required to reference the specific exemption provision under which the products or materials are being distributed.

The current regulations require that the licensee must identify the distributed product; however, different licensees have complied with this requirement in a number of ways, some of which necessitated that the NRC obtain additional information to fully interpret what was being distributed. Licensees have frequently included model numbers in the reports, but often as the only identification of the type of product being transferred. This final rule adds the requirement to report model numbers, when applicable, as part of the required information.

Other changes are being made to reduce the licensees' reporting and recordkeeping burden. Under the prior framework, licensees were required to send a copy of the transfer reports to both the NRC headquarters and the appropriate Regional office. The requirement to send a copy of the reports to the Regional offices will be removed. Instead, the information will

be distributed by the NRC internally to the appropriate personnel. To make the NRC's internal document handling more efficient, the address to which reports are to be sent will contain the line, "ATTN: Document Control Desk/Exempt Distribution." The addressee also has been changed from that specified in the proposed rule to be consistent with the recent reorganization of the NRC's materials programs. Finally, the period for which licensees must retain records, i.e. one year after transfers are included in a report, will be up to four years shorter than under the existing requirements. These factors are expected to make the reporting process more efficient and to improve the quality of the information submitted.

As a result of these changes, the NRC expects to receive information on distribution to exempt persons that is more useful for evaluating both potential individual doses to the public from multiple sources and collective doses to the public from these products and materials than that provided under the previous requirements. The NRC will have a stronger basis for informing the public about these exposures. These changes also will provide a better basis for considering any future regulatory changes in this area and for allocating NRC resources.

B. NRC Licensing of the Introduction of Exempt Concentrations.

For most exemptions from licensing in Part 30, distributors must have an NRC license even if they are in Agreement States. There are two exemptions for which this is not the case. One obsolete exemption, § 30.16, "Resins containing scandium-46 and designed for sand-consolidation in oil wells," is being removed by this final rule, as discussed in section II.D of this document. The other exception to NRC-only licensing of distribution of exempt byproduct material is in § 30.14, "Exempt concentrations."

The exempt concentration exemption in § 30.14 is a general materials exemption, broadly defined and not limited to a particular use. The exemption allows for various practices to be evaluated on a case-by-case basis through the licensing process. Section 30.14, paragraph (c), contains an exemption from licensing by the NRC for manufacturers, processors, or producers in Agreement States if the introduction of byproduct material into their product or material is conducted by an NRC specific licensee whose license authorizes this introduction.

Previously, there were provisions in the NRC's regulations that allowed Agreement State licensing of the introduction of exempt concentrations. Agreement State licensing was added in 1963, soon after the regulations governing the Agreement State program were established the previous year (10 CFR Part 150 was established in 1962). At the time, the only practices being regulated under these provisions related to quality control procedures and other radiotracer activities. Byproduct material was permitted to be introduced into oil, gasoline, plastics, and similar commercial and industrial materials. Also, at the time these provisions were added, it was expected that the NRC and the Agreement States would develop a system to obtain copies of the transfer reports submitted to the different regulatory bodies by licensees so that the NRC would have national information on distribution. Such a system was never implemented.

All practices involving exempt concentrations result in increased radioactivity in the products. A number of different practices have been evaluated and conducted under § 32.11, including the neutron irradiation of gemstones, silicon semiconductor materials, and luggage and cargo in explosive detection systems. These practices did not exist in the early 1960s, and involve consideration of issues including extensive national distribution. These practices involve a more complex dose evaluation than did the earlier practices, which were characterized by a single radionuclide dispersed within a product. For the case of irradiation of gemstones, the NRC has since required authorization only by an NRC license.

It is important for the NRC to obtain information on all distributions of byproduct material to exempt persons in order to effectively and efficiently assess the overall impact of such distributions on the public. NRC licensing of all such distribution will facilitate this goal. Also, the concentration limits in § 30.70 do not provide the sole assurance of protection of public health and safety. The evaluation done in connection with the licensing process is also important. The previous regulatory framework allowing multiple licensing jurisdictions to have the authority to issue these licenses had the potential to result in inconsistency in the licensing process.

A regulatory framework in which there is one licensing authority is inherently more efficient than a framework with multiple jurisdictions from an administrative standpoint. A sole licensing authority automatically would possess data on the nationwide amount of byproduct material introduced into products distributed to the general public. In addition, because the introduction of exempt concentrations is a rarely-used exemption, NRC-only licensing would avoid a situation in which every Agreement State would have to maintain resources, regulations, and procedures to license this practice, despite the fact that it would be unlikely for any individual State to have a significant number of these licensees.

This final rule requires that the entity introducing byproduct material into products and materials for use under the exempt concentration provisions must have an NRC license specifically authorizing this practice. Specifically, the final rule changes §§ 32.11 and 32.12 to compatibility category NRC. Compatibility categories and their meanings are explained, in Section VI, “Agreement State Compatibility.” This change necessitates conforming amendments to related paragraphs (§§ 30.14(c), 30.14(d), 32.11, 32.13, and 150.20) so that only NRC may authorize the introduction of byproduct material into products and materials to be distributed for use under § 30.14.

Consistent with the practice for other exempt byproduct material distribution, a person introducing byproduct material into products and materials for use under the exempt concentration provision may have possession and use of the byproduct material authorized by an Agreement State and a distribution license from the NRC. To accommodate this framework, § 32.11 is revised to exempt Agreement State licensees from § 30.33(a)(2) and (3), so as not to duplicate the licensee's Agreement State license conditions associated with possession and use.

Currently, the only known entities licensed under § 32.11 (or equivalent Agreement State regulations) are a small number of radiotracer firms, licensed by the NRC, who introduce byproduct material into material like gas and oil, and steel companies who use sources to monitor refractory lining wear in blast furnaces. No Agreement State licensees of these types were identified by the NRC in 2002, when the States were asked to comment on the rulemaking plan, or in 2005, when the NRC was assessing potential effects of this rule.

Changing the licensing of introduction of exempt concentrations to NRC-only in this regulation will allow the NRC to obtain complete national data on products and materials containing byproduct material distributed to persons exempt from licensing and regulation. In addition, because the NRC licenses all other distributions of exempt material, NRC-only licensing of introduction of exempt concentrations will be consistent with the other types of exempt distribution. Since no Agreement State licensees have been identified who introduce byproduct material into products received by persons exempt from licensing under § 30.14, there should be no impact on distributors as a result of this change.

A person who introduces byproduct material into materials or products distributed to persons exempt from licensing under § 30.14 must, as a result of this rule, hold a license from the NRC under § 32.11. Under § 30.14, the byproduct material activity concentration applicable

to this practice must be less than the limits established by § 30.70, “Schedule A – Exempt concentrations.”

C. Bundling of Exempt Quantities.

In accordance with § 30.18, “Exempt quantities,” a person is exempt from the requirements for a license to the extent that the person receives, 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. This exemption is being amended to explicitly prohibit the end user from combining, or “bundling” multiple sources. Commercial distributors of exempt quantities are presently prohibited from incorporating the exempt byproduct material into any manufactured or assembled commodity, product, or device by regulation (under § 32.18, “Manufacture, distribution and transfer of exempt quantities of byproduct material”). However, until this final rule, there had been no regulation prohibiting the end-user from bundling sources.

The NRC became aware that some persons holding byproduct material under the general materials exemption in § 30.18 had been combining (bundling) multiple exempt quantities within an individual device that had not been evaluated or approved by the NRC. The devices were manufactured without any radioactive material, but were designed to be used with multiple exempt quantity sources of byproduct material. After becoming aware of this issue, the NRC originally determined in June 1994 that, under certain limited circumstances, the bundling of exempt sources did not present a health and safety hazard and therefore no action was taken. Later, the NRC became concerned that the number of exempt sources bundled in unlicensed devices could reach a point where a general or specific license would otherwise be required. As long as the bundled sources were considered exempt, the NRC would have no

mechanism to ensure their safe possession, use, and disposal. As a result, the NRC issued Generic Letter 99-01, "Recent Nuclear Material Safety and Safeguards Decision on Bundling Exempt Quantities", on May 3, 1999, to clarify that bundling was not appropriate under the existing regulation. This position was supported by the language in § 32.19(d)(2), which directs the distributor to provide a label or accompanying brochure with any distributed exempt quantities that includes the statement "Exempt Quantities Should Not be Combined." However, the NRC has since concluded that the regulations in § 30.18 should be amended to specifically prohibit bundling by the end user under the exemption. This final rule revises the exempt quantities provision in § 30.18 to explicitly prohibit combining sources to create an increased radiation level.

The original basis for the quantities chosen for the exemption in § 30.18 was the more restrictive of: (1) the quantity of material inhaled by a reference individual exposed for 1 year at the highest average concentration permitted in air for members of the general public in unrestricted areas, or (2) for gamma emitters, the quantity of material that would produce a radiation level of 1 mR/hr at 10 cm from a point source. This basis provides reasonable assurance of protection because, under the conditions of the exemption, it is unlikely that any individual would inhale (or ingest) more than a very small fraction of any radioactive material being used or receive excessive doses of external radiation when realistic source-to-receptor distances and exposure times are assumed. Should bundling be permitted, the NRC could not assure that the exposures would not exceed the levels originally intended under the exemption. In addition, there would be the potential for other undesirable consequences, such as the disposal of devices containing multiple exempt sources through ordinary commercial waste streams or metal recycling channels resulting in inappropriate contamination of property.

Because of the NRC's 1994 determination that, under certain limited circumstances, bundling of exempt sources did not present a health and safety hazard, the May 3, 1999, generic letter affirmed that the NRC did not plan to take any action regarding the devices initially produced for use with a limited number of exempt quantity sources or their users unless a radiological safety hazard were to be identified. The NRC has no indication that significant exposures are resulting or will result from the continued use of the devices evaluated in 1994, therefore this rule will allow continued exempt use of those devices distributed before 1999. This exclusion is intended to avoid imposing a regulatory burden on those persons (if any are still using the devices) who otherwise might be impacted by this clarification in the regulation who are continuing to use devices in use before the generic letter was issued. Additionally, this regulation is not intended to impact normal storage methods of the materials held under the exemption in § 30.18.

D. Obsolete Provisions.

Some exemptions from licensing are considered obsolete in that no products are being distributed for use under the exemption. In some cases, no products covered by the exemption remain in use. In others, there are no records of any products ever having been used. Generally, this has occurred because new technologies have made the use of radioactive material unnecessary or less cost-effective.

The Commission is deleting exemptions for products that are no longer being used or manufactured, or revising the regulations to restrict further distribution while allowing for the continued possession and use of previously distributed items. Obsolete exemptions in Part 30 were for: automobile lock illuminators (formerly § 30.15(a)(2)), balances of precision

(§ 30.15(a)(3)), automobile shift quadrants (formerly § 30.15(a)(4)), marine compasses (§ 30.15(a)(5)), thermostat dials and pointers (formerly § 30.15(a)(6)), spark gap irradiators[2] (formerly § 30.15(a)(10)), and resins containing scandium-46 for sand consolidation in oil wells (formerly § 30.16).

Of these, the exemption for resins containing scandium is the only one that could have resulted in significant doses, based on preliminary dose assessments. Because the exemption was no longer being used, the preliminary dose assessments were not refined or included in NUREG-1717. These preliminary estimates indicated a potential for exposures higher than are appropriate for materials being used under an exemption from licensing. The removal of this exemption, as a result of this final rule, provides assurance that health and safety are adequately protected from possible future exempt distribution.

With the exception of resins covered by § 30.16, only the NRC has licensed distributors of these products. The primary bases for determining that products are obsolete are the NRC's records on its licensees. Industry contacts were also used to collect historical information concerning the use of the various products.

For these obsolete exemptions, the specific requirements for manufacturers and initial distributors are being removed in their entirety. These include regulations for the manufacture or distribution of resins containing scandium-46 (formerly § 32.17) and the prototype test procedures for automobile lock illuminators formerly specified in § 32.40 and formerly required by § 32.14(d)(2).

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[2]This particular exemption is for a product designed to minimize spark delay in some electrically ignited commercial fuel-oil burners, and is different than some products referred to as "spark gaps" or "spark gap tubes," which are a category of electron tube and exempted by § 30.15(a)(8). No change is being made to § 30.15(a)(8) at this time.

The NRC's research has shown that the distribution of thermostat dials or pointers, spark gap irradiators, and resins containing scandium-46 for sand consolidation in oil wells ceased so long ago that it is highly unlikely that any remain in use. Therefore, the complete removal of these exemptions is not expected to have any negative effect on any persons. In the unlikely event that a person currently possesses any of these products for which the governing regulations have been removed, this action is not intended to change the regulatory status of any products previously distributed in conformance with the provisions of the regulations applicable at the time the device was distributed: the user remains exempt. The distribution of balances of precision and marine compasses has ceased; however, some devices may still be in use. Therefore, these exemptions will not be completely removed. Instead, the regulations have been changed to limit exempt use to previously distributed products.

Deleting these unnecessary and obsolete provisions will simplify the regulations. This action will also eliminate the need for the Commission to reassess the potential exposure of the public from possible future distributions of these products. Agreement State regulations will be shortened as well. Most importantly, eliminating obsolete exemptions adds assurance that future use of products in these categories will not contribute to exposures of the public.

E. New Product-Specific Exemption for Smoke Detectors.

One of the most widely distributed products used under an exemption from licensing is the ionization chamber smoke detector. From April 1969 until this final rule, smoke detectors have been used under the class exemption for gas and aerosol detectors in § 30.20 (and equivalent regulations of the Agreement States). The Commission established this class exemption so that detectors with similar purposes could be licensed for distribution without the

need for establishing many product-specific exemptions through extensive rulemaking procedures. For example, the class exemption in § 30.20 has also been successfully used to cover new chemical agent detectors.

Modern ionization chamber smoke detectors have been manufactured and used for many years, with consistency in the design of products. Earlier smoke detector designs sometimes incorporated larger amounts of radioactive material than what is typical today, and in some cases incorporated other radionuclides – such as radium-226 – whereas americium-241 is the only radionuclide that is widely used in these devices today. Current designs are very consistent, in that they almost always entail using 1 μCi or less of americium-241, contained in a foil, and surrounded by an ionization chamber.

Potential doses from the distribution, use, handling, and disposal of these detectors have been estimated in NUREG/CR-1156, "Environmental Assessment of Ionization Chamber Smoke Detectors Containing Am-241," November 1979, and more recently in NUREG-1717 (2001). Dose assessments have been performed in numerous license applications under the existing class exemption structure. The estimated doses under normal, routine conditions are well under the safety criterion for routine use of 5 mrem/year (5 μSv/year) whole body, and the associated individual organ limits.

Because the doses from smoke detectors are well understood, and modern designs are very consistent, this rule establishes a product-specific exemption from licensing requirements for smoke detectors. This is intended to apply to ionization chamber smoke detectors containing no more than 1 μCi (37 kBq) of americium-241 in the form of a foil, and whose primary function is the protection of life and property. Based on records of currently active device designs,[3] there are 106 smoke detector models that are approved for distribution under the class exemption. Of

[3]Data taken from the sealed source and device (SS&D) registry September 2006.

these, 92 percent (97 out of 106) appear to qualify for the new product-specific exemption because those devices are limited to no more than the amount 1 μCi of americium-241 in the form of a foil. The new product-specific exemption for ionization chamber smoke detectors is established as § 30.15(a)(7).[4] The requirements for licensees (and applicants) to distribute these products are contained in §§ 32.14, 32.15, and 32.16, as revised by this final rule.

The primary difference between this new exemption and the existing class exemption in § 30.20 is that an applicant for a license to distribute smoke detectors for use under the new 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 for use under other product-specific exemptions, specifically for those products used under § 30.15. The specific requirements for obtaining a license to manufacture, process, produce, or initially transfer gas and aerosol detectors intended for use under the existing class exemption in § 30.20 are contained in § 32.26. Conditions of these licenses are contained in § 32.29, and include requirements for quality control, labeling, recordkeeping, and the reporting of transfers. The safety criteria (contained in §§ 32.27 and 32.28) for the existing class exemption include: (1) radiation dose limits for individuals from normal handling, storage, use, and disposal of these products; and (2) radiation dose limits for individuals, in conjunction with approximate associated probabilities of occurrence, for accidents.

[4]Section 30.15(a)(7) had been used before to provide an exemption for a different product. A product-specific exemption from licensing was provided in § 30.15(a)(7) for "glow lamps" in the 1960s. Later, it was determined that glow lamps should be exempted along with other types of electron tubes under § 30.15(a)(8), and § 30.15(a)(7) was removed. See 34 FR 6651 (April 18, 1969). Because § 30.15(a)(7) has not been used in such a long time, no confusion is expected from this designation for the product-specific exemption for smoke detectors.

The primary emphasis of the new requirements imposed on the applicant is to provide 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. Requirements for those licensed to distribute smoke detectors to be used under the new product-specific exemption are contained in §§ 32.15 and 32.16. These regulations denote the quality assurance, labeling, recordkeeping, and reports of transfer. The labeling requirements for the existing class exemption are found in § 32.29(b), and to make the product specific labeling requirements equivalent to those of the class exemption, minor amendments were made to § 32.15.

The NRC believes that an applicant who wishes to distribute a qualifying smoke detector will find the process easier and less expensive under the new product-specific exemption than under the class exemption. Compared with the existing class exemption, under the new exemption, license applicants are not required to perform and submit dose assessments to demonstrate that doses from the various stages of the life cycle of the product do not exceed certain values. It is the NRC staff's licensing practice to issue licenses for the distribution of products to be used under a class exemption only after a sealed source and device (SS&D) review and registration of the model in the SS&D registry. Detectors to be used under the new product-specific exemption will not be required to undergo the SS&D review, and devices qualifying for a product-specific exemption may be distributed without a SS&D certificate. As a result, distributors of qualifying smoke detectors will be in a different fee category for the application and annual fees, and likely will be charged lower fees. Relevant application fees both with or without SS&D review and registration are published in § 170.31. Annual fees for licensees distributing devices both with or without SS&D registration are published in § 171.16. Although the fees vary, and future fees are difficult to project with accuracy, the fees are typically

more expensive if an SS&D review and registration is needed. Consistent with the requirements of the other product-specific exemptions, the applicant for a license to distribute under the new exemption is required to submit basic design information. However, compared with the process established for the existing class exemption, under the new exemption a sealed source and device certificate need not be obtained (or maintained) to distribute smoke detectors that meet the requirements of the new exemption.

The new product-specific exemption allows licensees a new option for distributing smoke detectors to the public that is less costly. It is not compulsory for all smoke detectors to be manufactured and distributed for use only under the new product-specific exemption. Furthermore, this final rule does not modify the existing regulation exempting users of smoke detectors from licensing (§ 30.20). A smoke detector manufacturer that produces devices that do not conform with the product-specific exemption (for example, if the devices contain 4 μCi, or another radionuclide such as nickel-63) may distribute them under the broader class exemption for gas and aerosol detectors.

The net effect of this new product-specific exemption is that the regulatory burden and fees are reduced for applicants for licenses to distribute qualifying ionizing chamber smoke detectors. Licensees who currently distribute qualifying smoke detectors (1 μCi or less of americium-241 in the form of a foil) for use under the class exemption, may also realize benefits if they amend their licenses to distribute the devices under the new product-specific exemption. Additionally, the change is expected to reduce the NRC staff time needed to review these applications, because an evaluation of dose assessments is no longer necessary. Given the wide distribution these products have already experienced, this change is not expected to affect the overall number of smoke detectors distributed in the future. Thus, this change improves the

efficiency of the regulatory process, without any impacts to the health and safety of the public or the environment.

F. Specific Licenses and Generally Licensed Devices – Clarification.

A device possessed and used under § 31.5 is a generally licensed device. An entity who holds a specific license may use and possess such a device under the authority of the general license provided by regulation, or, if certain requirements are met, the entity may transfer the device to the authority provided by its specific license. This final rule amends § 31.5 to explicitly state the actions necessary to successfully perform this type of transfer, and eliminates the need to obtain prior NRC approval.

Following a revision to the general license provided by § 31.5 (65 FR 79161; December 18, 2000) 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. Licensees were motivated to transfer their devices in this way primarily to avoid the newly established registration fees. There are also other, non-fee-related reasons why one would make such a transfer. It should be noted that this final rule does not compel eligible licensees to make this type of transfer.

There has been some confusion about the licensee's responsibilities in enacting such a transfer. A major issue when transferring a generally licensed device to the authority of a specific license has been the label of the device. The general license in § 31.5, under paragraph (c)(1), requires that the original label on the device be maintained. This label, among other things, indicates the regulatory status (as a generally licensed device), provides safety instructions, and may refer to operating and service manuals. Retaining the label is problematic

because, once the device is transferred to the authority of a specific license, instructions to the general licensee may be inappropriate. For example, instructions may indicate that the licensee may not conduct its own leak tests, which is an unnecessary restriction once the device is transferred to the authority of a specific license. Another problem with the label of the transferred device is that the labels of all devices held by a specific licensee must conform with § 20.1904, “Labeling containers,” whereas, before the transfer, these requirements were not applicable. It is not acceptable for a device being held under a specific license to be labeled in accordance with § 32.51(a)(3); i.e., a general license label. Thus, if a device is transferred from generally licensed status to the authority of a specific license, the licensee must consider what changes should be made to the labeling and how those changes are to be made. The licensee is responsible for ensuring that the label of the transferred device meets the content requirements of § 20.1904, that any inappropriate restrictions that may have been on the label are resolved, and that any changes to the label are done in a manner that does not damage the device. The licensee should also ensure that the information on the manufacturer, model number, and serial number is retained on the labeling. Persons who have previously transferred generally licensed devices to the authority of their specific license should review the status of the label of the device, to ensure compliance with § 20.1904 and to resolve any inappropriate restrictions that may have been left on the label.

A second issue when transferring a generally licensed device to the authority of a specific license concerns maintenance. A specific licensee would conduct its own maintenance activities, including required leak tests, but may need information concerning the appropriate methods particular to the device. This information would have been provided if the device had been distributed as specifically licensed. However, because the device was generally licensed and, in some cases, the end user was not permitted to perform certain maintenance, this

information may not have been provided when the device was obtained. A specific licensee who wishes to transfer a generally licensed device to the authority of its specific license must have any information developed by the manufacturer on specific maintenance procedures. If the licensee does not already have this information, it could contact the manufacturer, a service provider, another knowledgeable licensee, or a regulatory agency to obtain information on the proper procedures for conducting leak testing and other required maintenance activities.

A necessary condition for this type of transfer is that the licensee must verify that the conditions of the specific license authorize the possession and use of the device. If the specific license does not authorize the possession of the particular radionuclides or activity, the licensee is unable to transfer a generally licensed device to its specific license. For example, the generally licensed device to be transferred may contain americium-241, but the specific license does not authorize the possession of transuranic radionuclides (americium is a transuranic element). If this is the case, the specific licensee must apply for an appropriate amendment to the specific license before transferring the device.

Finally, this final rule simplifies reporting requirements for this type of transfer. Before this rulemaking, two reports were required: a report before the transfer (requesting permission), and a report concurrent with the transfer (reporting the transfer). The NRC believes that there is little benefit in requesting written approval from the NRC before the transfer; therefore, the regulations have been revised. To maintain the integrity of the general license tracking systems operated by the NRC, any transfer of a generally licensed device must be reported, but two reports are not needed. Therefore, § 31.5(c)(8)(iii) is amended so that the pre-transfer report (requesting permission) is no longer required. To keep the appropriate tracking systems up-to-date, it is still necessary for the licensee to file a transfer report per § 31.5(c)(8)(ii).

III. Summary of Public Comments on the Proposed Rule.

The proposed rule on Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements, was published on January 4, 2006 (71 FR 275). The comment period ended on March 20, 2006. Nine letters were received commenting on the proposed rule. One comment letter was submitted by a smoke detector manufacturer, and another by a manufacturer of sources used in smoke detectors. One comment was received from the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR), representing manufacturers and distributors of exempt quantities of byproduct material. One comment was received from the Radiation Safety Officer (RSO) of a university. One comment was received from a member of the public who did not identify an affiliation. Officials from two Agreement States (Alabama and Texas) and staff from two others (Illinois and Georgia) also submitted comments. A discussion of the comments and the NRC's responses follow.

A. *Meaning of the Term "Byproduct Material."*

Comment: One commenter noted that the Energy Policy Act of 2005 changed the definition of "byproduct material" in the AEA. It was suggested that the NRC explain how "byproduct material" is defined in this rule.

Response: The definition of byproduct material that applies to this rule is in 10 CFR 30.4: "*Byproduct material* means any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material." As noted in the comment, the Energy Policy Act

of 2005 (EPAct) expanded and revised the definition of byproduct material under the NRC's jurisdiction by incorporating certain naturally occurring and accelerator produced radioactive material. The EPAct required that the NRC promulgate revisions to its regulations to incorporate the new byproduct material. The NRC published its proposed rule on July 28, 2006 (71 FR 42952) in response to this requirement, to revise its regulations and revise the definition of byproduct material in certain of its regulations, including 10 CFR 30.4. When the revised definition becomes effective, the new definition will apply. Distributors of the newly defined byproduct material will be regulated by the NRC, and therefore required to follow the regulations as amended by this final rule. However, as these distributors are already licensed by the NRC for distribution of other radioactive materials, the impact of this final rule on these distributors will be no greater than the impact on other NRC exempt distribution licensees.

B. Exempt Quantity Distribution Reports.

Comment: One commenter submitted a comment on the NRC's new reporting requirements in § 32.20(c) for distributors and manufacturers of materials distributed to persons exempt under § 30.18, "Exempt quantities." The commenter noted that a requirement for a report that indicates the chemical and physical form of each exempt quantity could be excessively burdensome. The commenter suggested that the NRC should specify the names that may be used by licensees to describe commonly distributed materials.

Response: The final rule was changed as a result of this comment. The NRC has evaluated the impact of exempt quantities on the public health and safety and the environment to weigh the effectiveness and appropriateness of its regulatory program for this exemption. The NRC does this for all exempt products and materials. During the last evaluation of exempt

distribution, it was believed that knowledge of both the chemical and physical form of material distributed as “exempt quantities” would provide information that could increase the NRC's ability to estimate the impacts of this exemption on public health and safety and the environment. The proposed rule language, therefore, required that distributors of exempt quantities of radioactive material must report, among other things, both the chemical and physical form of the radioactive material. However, the NRC agrees that providing chemical information would be excessively burdensome for licensees, and that the NRC can perform the necessary evaluations based on the information provided on physical form.

The Commission has changed the final rule language to address the commenter’s concerns. The language in the final rule retains the annual reporting requirement for exempt quantity distribution and the requirement to report physical form. However, the NRC will not require reporting of the chemical form.

The NRC notes that while terms such as "solid," "liquid," or "gas" are appropriate to use for reporting the physical form of exempt quantities, other descriptive terms such as “metal” or “powder” are also acceptable. The NRC does not intend to restrict licensees to use of particular terms; doing so may impose additional burden in reporting. If a licensee has made a substantial number of distributions, and has documentation that more quickly and easily provides essentially the same information and allows the NRC to determine the physical form of the distributed material, a licensee may choose to report using its own terminology instead (e.g., "solution" instead of "liquid" or "sealed source" instead of "solid"). However, terms that are ambiguous (e.g., "calibration standard," or "radiolabeled research compounds") do not specify the physical form and are not acceptable for reporting exempt quantity distribution.

Reports covering any time period before the effective date of this final rule are only required to contain data on the total quantity of each radionuclide distributed. Although a report

of physical form would be useful for historical distributions, there is no requirement to report the physical form before the effective date of this rule. This was clarified in the final rule text.

C. Transfer of a Generally Licensed Device.

Comment: Some commenters noted that the rule language as proposed in § 31.5(c)(8)(iii)(C) would have required that the licensee obtain maintenance information from the manufacturer to transfer the device to its specific license, which would be impossible if the manufacturer is no longer in business or otherwise unwilling to provide maintenance information.

Response: The final rule was changed in response to this comment. The intent in the proposed rule was that a specific licensee is responsible for maintenance activities, but the maintenance instructions may not have been provided to the licensee when the device was first purchased. Although the specific licensee should have sufficient expertise to conduct adequate maintenance activities, in some cases there are procedures developed by the manufacturer (and reviewed and approved by the NRC or Agreement State) that are unique to the device. There is no universal requirement for manufacturers to provide this information to general licensees, because general licensees are only allowed to perform maintenance activities in limited circumstances, and at the time of distribution it was not known that the device would eventually be used under the authority of a specific license. Therefore, it was proposed that a licensee must obtain maintenance information that would be applicable under the specific license. The language in the proposed rule could have been interpreted to limit licensees to obtaining this information directly from the device manufacturer (or initial transferor). This would be problematic if the manufacturer were no longer in business.

The final rule has been changed to clarify that the needed information on maintenance is that originated by the manufacturer (or initial distributor), and that it need not be obtained directly. The information may be obtained from not only the device manufacturer, but a service provider, a regulatory agency, or another knowledgeable licensee. The NRC believes that service providers, in particular, should have the maintenance information readily available, and there should be an established relationship between a service provider and the general licensee for the devices in question. The important goal is that the specific licensee is aware of any device-specific maintenance instructions important to safety.

Comment: Several commenters noted potential problems with the proposed labeling procedure in § 31.5(c)(8)(iii)(B) that would require a licensee to remove and replace the label before the transfer of a generally licensed device to the authority of a specific license. One commenter indicated that the proposed requirement may conflict with the requirement in § 31.5(c)(1) that prohibits a general licensee from removing the label, and it was suggested that a specifically licensed third party would be needed to complete the transaction. It was also noted that the NRC's labeling requirements could lead to the loss of additional safety warnings or leak testing instructions from generally licensed devices, or that the provenance of the device would be lost. Other commenters identified potential problems, such as damage to the device that could occur during the process of removing the old label. One commenter recommended that the NRC consider that when a generally licensed device is added to a specific license, the conditions of the specific license supersede the general license requirements. For instance, a specific license condition specifying leak tests would supersede the general license label limitations.

Response: The final rule was changed in response to this comment. The proposed rule addressed the labeling procedure that would accompany the transfer of a generally licensed

device to the authority of a specific license to address the case where an old label was unnecessarily restrictive on the end user, or where the old label would not comply with the requirements of § 20.1904, or any circumstance where the old label would conflict with the device's new status and the licensee's new responsibilities, such as if the original label of the device continued to indicate that it was a generally licensed device. In addition, as noted by one commenter, some labels on generally licensed devices contain stipulations that restrict actions by the end user, such as indications that the licensee shall not conduct its own leak tests. This prohibition would be in force as long as the device is held under a general license; however, once the device is transferred to the authority of a specific license, this restriction would be inappropriate.

The intent of the labeling change in the proposed rule was not to remove safety information, but to remove inappropriate restrictions that may be on some labels and to reflect the change in status from generally licensed to specifically licensed. As noted in one comment, the conditions of the specific license supercede the requirements of the general license once the device is transferred to the authority of the specific license. To address this and other potential conflicts, the NRC proposed that the licensee remove the existing label and replace it with another.

The final rule has been changed to allow licensees several acceptable options – including those suggested by commenters – for the labeling procedure that will accompany the transfer of a generally licensed device to the authority of a specific license. As originally stated in the proposed rule, the old label may be removed entirely. However, the final rule provides an additional option that the old label may be covered or altered in whole or in part. Alternatively, the specific licensee may leave the old label on the device and conspicuously affix a new label, so long as the resulting arrangement makes it clear (to an inspector, for example) that the old

label is superceded. If a licensee believes that the process of removing the old label would affect the integrity of a device's shielding or would otherwise damage the device, the licensee must use another method to comply with the labeling requirement, such as covering the old label.

The final rule has also been changed to specifically identify the information that must be on a device that is transferred from generally licensed to specifically licensed status. The final rule has been clarified to require that the device's manufacturer, model number, and serial number be retained. In any case, the new label must comply with the requirements for all containers of specifically licensed radioactive material (in this case, a device) in § 20.1904, and also include the device's manufacturer, model number, and serial number. The requirement that the device be labeled in accordance with § 20.1904 is not a new requirement, as that section applies to all devices held under the authority of a specific license; however, the requirement has been clarified in the final rule. The device's manufacturer, model number, and serial number is information that is not required by § 20.1904; however, the final rule clarifies that this information must be retained for tracking purposes and so that the provenance, or origin, of the device is not lost.

Concerning the comment that an existing regulation (§ 31.5(c)(1)) prohibits a general licensee from removing a label, the regulation would no longer apply once the device is transferred to the authority of a specific license. It is also not necessary for a specifically licensed third party (such as a vendor) to change the label to accompany the change in status; a specific licensee who possesses the device is authorized to remove the label.

Comment: A commenter objected to removing the requirement in § 31.5(c)(iii) for prior approval for this category of transfer, as prior approval would ensure appropriate tracking and licensing of the device.

Response: The NRC disagrees with this comment and the final rule is not changed. As part of transferring the device to the specific license, the licensee must still report the transfer under the existing requirement in § 31.5(c)(8)(ii). The NRC believes this report is sufficient to allow for appropriate tracking and licensing and that prior approval of the transfer is unnecessary.

Comment: Some commenters suggested additional regulatory provisions with regard to the transfer of a generally licensed device to the authority of a specific license. One commenter suggested that, along with the proposed simplified mechanism for transferring a generally licensed device to a specific license (GL to SL transfer), there should also be a mechanism for transferring a device from a specific licensee *back* to generally licensed status (SL to GL transfer). A separate suggestion was made that a requirement be added to § 31.5(c)(8)(iii)(C) requiring the general licensee to initiate a program to leak test the device at a frequency specified under conditions of the specific license. A third suggestion was made that the NRC "consider" that when a generally licensed device is added to a specific license, the conditions of the specific license, such as the leak test condition, would supercede the conditions in the general license.

Response: No change has been made to the final rule as a result of these comments. This final rule only affects the transfer of generally licensed devices to specifically licensed status, and does not address the transfer of a device from a specific license back to its original status as generally licensed. The general license in § 31.5 only applies to devices received from a § 32.51 specific licensee (or Agreement State equivalent) to ensure that the device may be used by persons with no radiological training, and for tracking purposes.

With regard to the suggestion to add a provision to § 31.5(c) to require the general licensee to leak test the device at a frequency specified under conditions of a specific license,

once the device is transferred to the authority of a specific license, the regulations in Part 31 do not apply, because the device is no longer generally licensed. Therefore, any rule change to this part will be ineffective in governing licensee actions after the device is transferred. No rule change is necessary, moreover, because the commenter's concerns that the device continue to be leak tested in accordance with the terms of the specific license will be addressed on the specific license following the transfer. The NRC recognizes that the conditions of the specific license supersede the requirements of the general license once the device is transferred to the authority of the specific license. The rule language does not need to be changed to ensure that conditions of the specific license supersede the conditions in the general license.

Comment: One commenter stated that the proposed revision to § 31.5(c)(8)(iii) "is requiring additional regulation not required of general licensees who do not possess a specific license." The commenter indicated that an alternative approach might be "to separately list GL products in a distinct license condition on specific licenses." The commenter warned that the proposed rule would ignore the "safety properties of GL products and abandon their inherent safety features and relegate them to the same requirements imposed on specifically licensed products."

Response: No changes to the final rule are being made as a result of these comments. This regulation provides licensees who hold both a generally licensed device and a specific license the option to more easily transfer a generally licensed device to the authority of a specific license. This transfer is not mandatory for all specific licensees who possess a generally licensed device. No additional regulation is being imposed on general licensees who do not possess a specific license, and no additional regulation is being imposed on general licensees who do possess a specific license, unless the licensee chooses to transfer its generally licensed devices to the authority of its specific license.

This final rule does not require specific licensees to list generally licensed devices on their specific licenses. Requiring this would negate a characteristic feature of the general license, which is valid without the issuance of a licensing document to a particular person. The commenter's approach – listing generally licensed devices held by a specific license as a license condition on a specific license – may lead to ambiguities with respect to the responsibilities of the licensee with regard to recordkeeping (such as device tracking). For example, generally licensed devices under § 31.5 are tracked by the NRC, but cease to be tracked once the device is transferred to the authority of a specific license. A misinterpretation of the regulatory status of the device may result in errors in the tracking systems. Additionally, when the generally licensed device is disposed of or otherwise transferred to a specific licensee, there would be extra costs associated in amending the license. Therefore, the NRC does not believe that generally licensed devices should be required to be listed on specific licensing documents.

Comment: One commenter stated that "the transfer of the GL device to an end-user, in this case a specific licensee, would need to be reported, but not because it is being transferred as a specifically licensed device; it is not, it is still a GL device."

Response: The NRC agrees that the transfer should be reported, under § 31.5(c)(8)(iii)(D). However, the NRC disagrees with the commenter's statement that the transferred device remains under a general license. Although a device that may be used under a general license may also be used under a specific license if the specific license authorizes the byproduct material, there should be a distinction as to which license is providing the authority for the possession and use of each device. This distinction determines which requirements apply to the licensee, such as reporting and maintenance.

D. New Product-Specific Exemption for Smoke Detectors.

Comment: Two commenters were concerned about the potential impact of a literal interpretation of the language in the proposed rule exempting smoke detectors. The proposed new product-specific exemption in § 30.15(a)(7) was limited to smoke detectors containing no more than 1 µCi of americium-241. Both commenters noted that, due to small variations caused by the manufacturing process, it is impractical (if not impossible) to produce smoke detectors that always contain no more than 1 µCi of americium-241. It was noted that this small variation is acceptable in current licensing practices and does not present any health, safety, or security risk. These commenters suggested that a statement should be added to the final rule allowing for nominal variation in the activity level of the source incorporated into the smoke detector.

Response: No change to the final rule is being made as a result of these comments. The product-specific exemption for smoke detectors is intended to apply to detectors that contain sources in which the expected activity is 1 µCi of americium-241 or less. This expected quantity is also the activity that is put on the label. The NRC believes that variation is to be expected as a result of the manufacturing process, and that a degree of variation is acceptable. Considerations for ensuring the quality of products and the adequacy of measurement in various circumstances are separate from the stated activity, or quantity, limit for an exemption. The interpretation of the quantity limit of 1 µCi is only that the expected, labeled quantity or activity may not exceed this limit. This is consistent with the historical interpretation of existing quantity limits in other exemptions. It should be noted that this is different from the stated “maximum activity” on the SS&D registration certificate. For a product-specific exemption, a SS&D certificate is not needed, and other information besides the dose assessment are available to ensure that the device may be safely used under an exemption from licensing.

Comment: One commenter urged revision of the appropriate guidance document (NUREG-1556, Vol. 3, Rev. 1) as soon as possible to reflect changes to methods for approving sources and devices.

Response: NUREG-1556, Vol. 3, Rev. 1 addresses the procedures for SS&Ds, and will not be updated as a result of this rule because the SS&D procedures are not being amended. However, NUREG-1556, Vol. 8, Rev. 1, which provides program specific guidance about exempt distribution products, will be revised to reflect the revisions made by this final rule, and relevant changes brought about by other recent rulemakings concerning byproduct material. The changes to the guidance needed as a result of this rulemaking are relatively minor and will be made to eliminate inconsistencies with the revised regulations.

E. NRC – Agreement State Jurisdictional Issues.

Comment: One commenter stated that it would be helpful to clarify why the regulations for exempt quantities refer to equivalent Agreement State regulations.

Response: No change to the final rule is needed as a result of this comment. The final rule refers to Agreement State regulations because different agencies may have jurisdiction before, during, and after the distribution of exempt quantities of byproduct material. For example, prior to distribution, the possession of byproduct material requires a license, either by the NRC or an Agreement State depending on which regulatory body has jurisdiction. The commercial distribution of exempt quantities of byproduct material must be in accordance with a license issued by the NRC under § 32.18, since the NRC has the sole authority for authorizing commercial transfers. After the transfer, the recipient of the byproduct material is exempt from

regulatory requirements either from those of the NRC or an Agreement State, depending on the location of the recipient.

Comment: One commenter raised objections to the NRC being the only licensing authority for exempt concentrations in § 30.14 and objected to reclassification of §§ 32.11 and 32.12 as Compatibility Category NRC. The commenter reasoned that organizations of State regulators, such as the Organization of Agreement States and the Conference of Radiation Control Program Directors could be used to facilitate data exchanges on exempt concentration distribution nationwide, and that the change to NRC-only licensing would not be justified on the basis of common defense and security.

Response: The NRC disagrees with this comment and the final rule retains the proposed language and compatibility category. All distribution of byproduct material to exempt persons is presently solely licensed by the NRC, with the only exception being provided in § 30.14, "Exempt concentrations." (Previously, § 30.16, which is now being removed, had also provided for Agreement State licensing.) This discrepancy in the Commission's regulations was identified as a result of the NRC's systematic evaluation of exemptions performed in the 1990's, and has been discussed with the Agreement States since that time. The distribution of radioactive materials to the public for uncontrolled use – which includes exempt concentrations – and the release of these materials into the environment involve questions of national policy that are best addressed by the Commission. The NRC has determined that this discrepancy is not warranted.

The regulations controlling the introduction of radioactive material into products subsequently distributed under the exempt concentration exemption (§ 30.14) is the NRC's oldest exemption for byproduct material. It predates the Agreement State program. As the commenter notes, organizations of State regulators exist now, and could be used to facilitate the exchange of data on exempt concentrations. However, as explained below, the lack of a data

exchange is not the only factor that the NRC considered in determining that exempt concentration distribution should be changed to NRC-only licensing.

There is no administrative benefit in providing authority to States to license exempt concentrations of byproduct material, and in fact, such licensing would likely be very costly to maintain. No Agreement State has identified any licensees authorized to introduce byproduct material into materials or products that are exempt from licensing under this regulation. The only businesses nationwide that are involved in this practice are already NRC licensees. Continuing with the current multi-jurisdictional structure would require States to train qualified license reviewers, update and maintain regulations, produce guidance documents, and develop a data exchange process among the States and with the NRC, which would involve an unnecessary use of resources, considering that there are no licensees in State jurisdictions. NRC-only licensing avoids these complications and costs, and a transition to NRC-only licensing at this time will have no regulatory impact on any business. It is administratively more efficient for there to be one licensing authority (NRC) rather than for each jurisdiction to maintain a licensing capability that is little used and unlike any other programmatic function.

Among other reasons, the Commission has retained regulatory authority for exempt distribution (consumer products) to remove any possibility that population exposure from these products would be inconsistent with Commission policies. The Commission has long retained the position that the distribution of radioactive materials to the general public for uncontrolled use and the eventual disposition of these materials involve questions of national policy that are best addressed by the NRC (March 16, 1965; 30 FR 3462). The NRC's retaining sole licensing authority over the distribution of exempt byproduct material does not have to be justified under common defense and security.

F. Disposal of Exempt and Generally Licensed Devices.

Comment: One commenter stated that disposal costs should be factored into the original cost of the exempt devices, and that a mechanism should be established to return exempt devices to a vendor for recycling or disposal. This commenter also stated that disposal costs should be factored into the original costs of generally licensed devices.

Response: The issue of disposal costs is outside the scope of this rulemaking.

IV. Amendments By Section.

10 CFR 30.14(c) – Revises the exemption for manufacturers, processors, and producers to require that the licensed entity must be an NRC licensee, and clarifies that the exemption applies in all jurisdictions.

10 CFR 30.14(d) – Revises the prohibition on introducing exempt concentrations to apply to all persons except those authorized by an NRC license.

10 CFR 30.15(a) – Removes obsolete exemptions (automobile lock illuminators, automobile shift indicators, thermostat dials and pointers, and spark gap irradiators). Limits certain exemptions (balances of precision and marine compasses and other navigational instruments) to previously distributed products. Creates a new exemption for smoke detectors containing no more than 1 μCi of americium-241 in a foil.

10 CFR 30.16 – Removes the exemption for resins containing scandium-46 for sand consolidation in oil wells.

10 CFR 30.18 – Revises the exempt quantities provision by adding an explicit prohibition against combining sources to create an increased radiation level.

10 CFR 31.5(c)(8)(ii) – Resolves an ambiguity with respect to addressing reports submitted to the NRC. Changed to reflect a reorganization within the NRC.

10 CFR 31.5(c)(8)(iii) – Revises transfer provisions to explicitly state actions necessary for transfer of devices from generally licensed status to specifically licensed status. Removes the need for written NRC approval before transfer in that case.

10 CFR 32.8 – Removes § 32.17 from the list of information collection requirements.

10 CFR 32.11(a) – Exempts Agreement State licensees from the requirements of § 30.33(a)(2) and (3).

10 CFR 32.12 – Revises the reporting period for material transfers to annual. Revises the content of the reports and removes the requirement to send copies to the Regional offices. Changed to reflect a reorganization within the NRC.

10 CFR 32.13 – Prohibits the introduction of exempt concentrations by all persons except for those authorized by an NRC license.

10 CFR 32.14(d) – Removes reference to deleted § 32.40.

10 CFR 32.15(d) – Adds labeling requirements for smoke detectors distributed for use under the new product-specific exemption in § 30.15.

10 CFR 32.16 – Revises the reporting period for material transfers to annual. Makes minor changes to the content of the reports and removes the requirement to send copies to the Regional offices. Removes reference to deleted § 32.17. Changed to reflect a reorganization within the NRC.

10 CFR 32.17 – Removes obsolete distributor requirements for resins containing scandium-46 for sand consolidation in oil wells.

10 CFR 32.20 – Revises the reporting period for material transfers to annual. Makes minor changes to the content of the reports and removes the requirement to send copies to the Regional offices. Changed to reflect a reorganization within the NRC.

10 CFR 32.25(c) – Revises the reporting period for material transfers to annual. Makes minor changes to the content of the reports and removes the requirement to send copies to the Regional offices. Changed to reflect a reorganization within the NRC.

10 CFR 32.29(c) – Revises the reporting period for material transfers to annual. Makes minor changes to the content of the reports and removes the requirement to send copies to the Regional offices. Changed to reflect a reorganization within the NRC.

10 CFR 32.40 – Removes the prototype test requirements for automobile lock illuminators.

10 CFR 150.20(b) – Removes the provision for transfers to persons exempt under § 30.14 from the reciprocity provision for Agreement State licensees.

V. Criminal Penalties.

For the purpose of Section 223 of the Atomic Energy Act of 1954, as amended, the Commission is issuing the final rule to amend 10 CFR Parts 30, 31, 32, and 150 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule will be subject to criminal enforcement.

VI. Agreement State Compatibility.

In accordance with the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997 (62 FR 46517), NRC program elements (including regulations) are placed into Compatibility Categories A, B, C, D, or NRC, or Adequacy Category H&S. This rule does not amend any regulation classified as compatibility category A or adequacy category H&S. Compatibility Category B are those program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. Compatibility Category C are those program elements that do not meet the criteria of Categories A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a national basis. An Agreement State should adopt the essential objectives of the Category C program elements. Compatibility Category D are those program elements that do not meet any of the criteria of Category A, B, or C, and, thus, do not need to be adopted by Agreement States for purposes of compatibility. Compatibility Category NRC are those program elements that address areas of regulation that cannot be relinquished to the Agreement States under the AEA or provisions of 10 CFR. These program elements should not be adopted by the Agreement States.

Despite being amended in terms of substance, the compatibility category will not change for many regulations as a result of this final rule. Sections 32.14, 32.15, 32.16, 32.20, 32.25, 32.29, and 32.40 will continue to be classified as Category NRC. Amendments made by this rule to regulations in Parts 30 and 31, as well as § 32.17, will continue to be classified as Category B. Sections 32.13 and 150.20 will continue to be classified as Category C.

Section 32.8 will continue to be classified as Category D. Consistent with what was proposed, § 32.11 is changed from Categories C/B to Category NRC and § 32.12 is changed from Category C to Category NRC.

VII. Voluntary Consensus Standards.

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. This action does not constitute the establishment of a standard that establishes generally applicable requirements.

VIII. Environmental Assessment and Finding of No Significant Environmental Impact: Availability.

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule is not a major Federal action significantly affecting the quality of the human environment and therefore an environmental impact statement is not required. The Commission has prepared an environmental assessment for this final rule and has made a finding of no significant impact as a result of this final rule.

Many of the individual amendments in this rule belong to a category of actions which the Commission, by §§ 51.22(c)(1) and 51.22(c)(3)(ii) and (iii), has declared to be a categorical exclusion. The amendments to §§ 30.14, 32.11, and 32.13 related to NRC licensing of the

introduction of exempt concentrations do not change any provision that regulates the physical nature of the products. The amendments to §§ 30.15, 30.16, 32.17, and 32.40 related to deleting obsolete provisions do not constitute a significant change to current practices. Similarly, the amendment to § 30.18 which prohibits combining exempt quantities does not change current practices. The new product specific exemption for smoke detectors in § 30.15(a)(7) does not change any provision that regulates the physical nature of the products and is not likely to affect any environmental resources.

The detailed environmental assessment supporting this final rule is available for public inspection at the NRC Public Document Room, O–1F23, 11555 Rockville Pike, Rockville, MD. Single copies of the Environmental Assessment may be obtained from Andy Imboden, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, (301) 415-2327, asi@nrc.gov.

IX. Paperwork Reduction Act Statement.

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This final rule makes minor revisions to the burden on existing and future licensees for reporting and recordkeeping under §§ 31.5, 32.12, 32.16, 32.20, 32.25(c), and 32.29(c). New licensees under § 32.14 will find their burden reduced as compared to the existing licensing under § 32.26. The public burden for this information collection is estimated to average 1 hour per request. Because the burden for this information collection is insignificant, Office of Management and Budget (OMB) clearance is not required. Existing requirements were approved by OMB under numbers 3150-0001, 3150-0014, 3150-0016, and 3150-0120.

Public Protection Notification.

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

X. Regulatory Analysis.

The Commission has prepared a regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The analysis is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD. Single copies of the regulatory analysis are available from Andy Imboden, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, (301) 415-2327, asi@nrc.gov.

XI. Regulatory Flexibility Certification.

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. The majority of companies that are affected by this rule do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards established by the NRC in 10 CFR 2.810.

XII. Backfit Analysis.

The NRC has determined that the backfit rule (§§ 50.109, 70.76, 72.62, or 76.76) does not apply to this final rule because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR Chapter 1. Therefore, a backfit analysis is not required.

XIII. Congressional Review Act.

In accordance with the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

Lists of Subjects

10 CFR Part 30

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 31

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, scientific equipment.

10 CFR Part 32

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 150

Criminal penalties, Hazardous materials transportation, Intergovernmental relations, Nuclear materials, Reporting and recordkeeping requirements, Security measures, Source material, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR Parts 30, 31, 32, and 150.

PART 30 - RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

1. The authority citation for part 30 continues to read as follows:

Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 30.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102-486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

2. In § 30.14, paragraphs (c) and (d) are revised to read as follows:

§ 30.14 Exempt concentrations.

* * * * *

(c) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in this part and parts 31 through 36 and 39 of this chapter to the extent that this person 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 the Commission expressly authorizing such introduction. This exemption does not

apply to the transfer of byproduct material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(d) No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.11 of this chapter.

3. In § 30.15, paragraphs (a)(2), (a)(4), (a)(6), and (a)(10) are removed and reserved, paragraphs (a)(3) and (a)(5) are revised, and paragraph (a)(7) is added to read as follows:

§ 30.15 Certain items containing byproduct material.

(a) * * *

(2) [Reserved]

(3) Balances of precision containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part manufactured before **(insert effective date of final rule)**.

(4) [Reserved]

(5) Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas manufactured before **(insert effective date of final rule)**.

(6) [Reserved]

(7) Ionization chamber smoke detectors containing not more than 1 microcurie (μCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

* * * * *

(10) [Reserved]

* * * * *

§ 30.16 [Removed]

3. Section 30.16 is removed.

4. In § 30.18, paragraph (a) is revised and paragraph (e) is added to read as follows:

§ 30.18 Exempt quantities.

(a) Except as provided in paragraphs (c) through (e) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 30 through 34, 36, and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in individual quantities, each of which does not exceed the applicable quantity set forth in § 30.71, Schedule B.

* * * * *

(e) No person may, for purposes of producing an increased radiation level, combine quantities of byproduct material covered by this exemption so that the aggregate quantity exceeds the limits set forth in § 30.71, Schedule B, except for byproduct material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the regulations in this part.

PART 31 - GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

5. The authority citation for part 31 continues to read as follows:

Authority: Secs. 81, 161, 183, 68 Stat. 935, 948, 954, as amended (42 U.S.C. 2111, 2201, 2233); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

6. In § 31.5, the introductory text of paragraph (c)(8)(ii) and paragraph (c)(8)(iii) are revised to read as follows:

§ 31.5 Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.[2]

* * * * *

(c) * * *

(8) * * *

(ii) Shall, within 30 days after the transfer of a device to a specific licensee or export, furnish a report to the Director of the Office of Federal and State Materials and Environmental Management Programs by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/GLTS. The report must contain --

[2]Persons possessing byproduct material in devices under a general license in Sec. 31.5 before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of Sec. 31.5 in effect on January 14, 1975.

* * * * *

(iii) Shall obtain written NRC approval before transferring the device to any other specific licensee not specifically identified in paragraph (c)(8)(i) of this section; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:

(A) Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(B) Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by paragraph (c)(1) of this section) so that the device is labeled in compliance with § 20.1904 of this chapter; however the manufacturer, model number, and serial number must be retained;

(C) Obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and

(D) Reports the transfer under paragraph (c)(8)(ii) of this section.

* * * * *

PART 32 - SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

6. The authority citation for part 32 continues to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note), Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 594 (2005).

7. In § 32.8, paragraph (b) is revised to read as follows:

§ 32.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 32.11, 32.12, 32.14, 32.15, 32.16, 32.18, 32.19, 32.20, 32.21, 32.21a, 32.22, 32.23, 32.25, 32.26, 32.27, 32.29, 32.51, 32.51a, 32.52, 32.53, 32.54, 32.55, 32.56, 32.57, 32.58, 32.61, 32.62, 32.71, 32.72, 32.74, and 32.210.

* * * * *

8. In § 32.11, paragraph (a) is revised to read as follows:

§ 32.11 Introduction of byproduct material in exempt concentrations into products or materials, and transfer of ownership or possession: Requirements for license.

* * * * *

(a) Satisfies the general requirements specified in § 30.33 of this chapter; *provided, however,* that the requirements of § 30.33(a)(2) and (3) do not apply to an application for a license to introduce byproduct material into a product or material owned by or in the possession of the licensee or another and the transfer of ownership or possession of the product or material containing the byproduct material, if the possession and use of the byproduct material to be introduced is authorized by a license issued by an Agreement State;

* * * * *

9. Section 32.12 is revised to read as follows:

§ 32.12 Same: Records and material transfer reports.

(a) Each person licensed under § 32.11 shall maintain records of transfer of byproduct material and file a report with the Director of the Office of Federal and State Materials and Environmental Management Programs by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the byproduct material is transferred for use under § 30.14 of this chapter or equivalent regulations of an Agreement State.

(b) The report must identify the:

(1) Type and quantity of each product or material into which byproduct material has been introduced during the reporting period;

(2) Name and address of the person who owned or possessed the product or material, into which byproduct material has been introduced, at the time of introduction;

(3) The type and quantity of radionuclide introduced into each product or material; and

(4) The initial concentrations of the radionuclide in the product or material at time of transfer of the byproduct material by the licensee.

(c)(1) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after **(Insert the effective date of this final rule)**, the licensee shall separately include data for transfers in prior years not previously reported to the Commission or to an Agreement State.

(2) Licensees who permanently discontinue activities authorized by the license issued under § 32.11 shall file a report for the current calendar year within 30 days after ceasing distribution.

(d) If no transfers of byproduct material have been made under § 32.11 during the reporting period, the report must so indicate.

(e) The licensee shall maintain the record of a transfer for one year after the transfer is included in a report to the Commission.

10. Section 32.13 is revised to read as follows:

§ 32.13 Same: Prohibition of introduction.

No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under § 30.14 of this chapter or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.11.

11. In § 32.14, paragraph (d) is revised to read as follows:

§ 32.14 Certain items containing byproduct material; Requirements for license to apply or initially transfer.

* * * * *

(d) The Commission determines that the byproduct material is properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling.

12. In § 32.15, paragraph (d) is revised to read as follows:

§ 32.15 Same: Quality assurance, prohibition of transfer, and labeling.

* * * * *

(d)(1) Label or mark each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified.

(2) For ionization chamber smoke detectors, label or mark each detector and its point-of-sale package so that:

(i) Each detector has a durable, legible, readily visible label or marking on the external surface of the detector containing:

(A) The following statement: "CONTAINS RADIOACTIVE MATERIAL";

(B) The name of the radionuclide (“americium-241" or “Am-241") and the quantity of activity; and

(C) An identification of the person licensed under § 32.14 to transfer the detector for use under § 30.15(a)(7) of this chapter or equivalent regulations of an Agreement State.

(ii) The labeling or marking specified in paragraph (d)(2)(i) of this section is located where it will be readily visible when the detector is removed from its mounting.

(iii) The external surface of the point-of-sale package has a legible, readily visible label or marking containing:

(A) The name of the radionuclide and quantity of activity;

(B) An identification of the person licensed under § 32.14 to transfer the detector for use under § 30.15(a)(7) or equivalent regulations of an Agreement State; and

(C) The following or a substantially similar statement: "THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS."

(iv) Each detector and point-of-sale package is provided with such other information as may be required by the Commission.

13. Section 32.16 is revised to read as follows:

§ 32.16 Certain items containing byproduct material: Records and reports of transfer.

(a) Each person licensed under § 32.14 shall maintain records of all transfers of byproduct material and file a report with the Director of the Office of Federal and State Material and Environmental Management Programs by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the products are transferred for use under § 30.15 of this chapter, giving the specific paragraph designation, or equivalent regulations of an Agreement State.

(b) The report must include the following information on products transferred to other persons for use under § 30.15 or equivalent regulations of an Agreement State:

(1) A description or identification of the type of each product and the model number(s), if applicable;

(2) For each radionuclide in each type of device and each model number, if applicable, the total quantity of the radionuclide; and

(3) The number of units of each type of product transferred during the reporting period by model number, if applicable.

(c)(1) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after **(Insert the effective date of this final rule)**, the licensee shall separately include data for transfers in prior years not previously reported to the Commission.

(2) Licensees who permanently discontinue activities authorized by the license issued under § 32.14 shall file a report for the current calendar year within 30 days after ceasing distribution.

(d) If no transfers of byproduct material have been made under § 32.14 during the reporting period, the report must so indicate.

(e) The licensee shall maintain the record of a transfer for one year after the transfer is included in a report to the Commission.

§ 32.17 [Removed]

14. Section 32.17 is removed.

15. Section 32.20 is revised to read as follows:

§ 32.20 Same: Records and material transfer reports.

(a) Each person licensed under § 32.18 shall maintain records of transfer of material identifying, by name and address, each person to whom byproduct material is transferred for use under § 30.18 of this chapter or the equivalent regulations of an Agreement State and stating the kinds, quantities, and physical form of byproduct material transferred.

(b) The licensee shall file a summary report with the Director of the Office of Federal and State Materials and Environmental Management Programs by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the materials are transferred for use under § 30.18 or equivalent regulations of an Agreement State.

(c) For each radionuclide in each physical form, the report shall indicate the total quantity of each radionuclide and the physical form, transferred under the specific license.

(d)(1) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after **(Insert the effective date of this final rule)**, the licensee shall separately include the total quantity of each radionuclide transferred for transfers in prior years not previously reported to the Commission.

(2) Licensees who permanently discontinue activities authorized by the license issued under § 32.18 shall file a report for the current calendar year within 30 days after ceasing distribution.

(e) If no transfers of byproduct material have been made under § 32.18 during the reporting period, the report must so indicate.

(f) The licensee shall maintain the record of a transfer for one year after the transfer is included in a summary report to the Commission.

16. In § 32.25, paragraph (c) is revised to read as follows:

§ 32.25 Conditions of licenses issued under § 32.22: Quality control, labeling, and reports of transfer.

* * * * *

(c) Maintain records of all transfers and file a report with the Director of the Office of Federal and State Materials and Environmental Management Programs by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the products are transferred for use under § 30.19 of this chapter or equivalent regulations of an Agreement State.

(3) The report must include the following information on products transferred to other persons for use under § 30.19 or equivalent regulations of an Agreement State:

(i) A description or identification of the type of each product and the model number(s);

(ii) For each radionuclide in each type of product and each model number, the total quantity of the radionuclide;

(iii) The number of units of each type of product transferred during the reporting period by model number.

(4)(i) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after **(Insert the effective date of this final rule)**, the licensee shall separately include data for transfers in prior years not previously reported to the Commission.

(ii) Licensees who permanently discontinue activities authorized by the license issued under § 32.22 shall file a report for the current calendar year within 30 days after ceasing distribution.

(5) If no transfers of byproduct material have been made under § 32.22 during the reporting period, the report must so indicate.

(6) The licensee shall maintain the record of a transfer for one year after the transfer is included in a report to the Commission.

17. In § 32.29, paragraph (c) is revised to read as follows:

§ 32.29 Conditions of licenses issued under § 32.26: Quality control, labeling, and reports of transfer.

* * * * *

(c) Maintain records of all transfers and file a report with the Director of the Office of Federal and State Materials and Environmental Management Programs by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the products are transferred for use under § 30.20 of this chapter or equivalent regulations of an Agreement State.

(3) The report must include the following information on products transferred to other persons for use under § 30.20 or equivalent regulations of an Agreement State:

(i) A description or identification of the type of each product and the model number(s);

(ii) For each radionuclide in each type of product and each model number, the total quantity of the radionuclide;

(iii) The number of units of each type of product transferred during the reporting period by model number.

(4)(i) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after **(Insert the effective date of this final rule)**, the licensee shall separately include data for transfers in prior years not previously reported to the Commission.

(ii) Licensees who permanently discontinue activities authorized by the license issued under § 32.26 shall file a report for the current calendar year within 30 days after ceasing distribution.

(5) If no transfers of byproduct material have been made under § 32.26 during the reporting period, the report must so indicate.

(6) The licensee shall maintain the record of a transfer for one year after the transfer is included in a report to the Commission.

§ 32.40 [Removed]

18. Section 32.40 is removed.

PART 150 - EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274

19. The authority citation for part 150 continues to read as follows:

Authority: Sec. 161, 68 Stat. 948, as amended, sec. 274, 73 Stat. 688 (42 U.S.C. 2201, 2021); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Sections 150.3, 150.15, 150.15a, 150.31, 150.32 also issued under secs. 11e(2), 81, 68 Stat. 923, 935, as amended, secs. 83, 84, 92 Stat. 3033, 3039 (42 U.S.C. 2014e(2), 2111, 2113, 2114). Section 150.14 also issued under sec. 53, 68 Stat. 930, as amended (42 U.S.C. 2073). Section 150.15 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 150.17a also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 150.30 also issued under sec. 234, 83 Stat. 444 (42 U.S.C. 2282).

20. In § 150.20, paragraph (b)(3) is revised to read as follows:

§ 150.20 Recognition of Agreement State licenses.

* * * * *

(b) * * *

(3) Shall not, in any non-Agreement State, in an area of exclusive Federal jurisdiction within an Agreement State, or in offshore waters, transfer or dispose of radioactive material possessed or used under the general licenses provided in this section, except by transfer to a person who is specifically licensed by the Commission to receive this material.

* * * * *

Dated at Rockville, Maryland, this_____ day of_____, 2007.

For the Nuclear Regulatory Commission.

_____
Annette Vietti-Cook,
Secretary of the Commission.

FINAL REGULATORY ANALYSIS

for

AMENDMENTS to

10 CFR Parts 30, 31, 32, and 150

for

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

January 2007

FINAL REGULATORY ANALYSIS

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1 STATEMENT OF THE PROBLEM AND OBJECTIVES

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

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

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

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

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

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

2 EXISTING REGULATORY FRAMEWORK

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

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

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

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

3 IDENTIFICATION OF ALTERNATIVE APPROACHES TO THE PROBLEM

3.1 No Action

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

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

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

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

3.3 Other Alternatives

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

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

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

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

Licensee labor rates are obtained from National Wage Data available on the Bureau of Labor Statistics web site (www.bls.gov). Depending on the industry and the occupation (e.g., manufacturing, health and safety, etc.), an appropriate mean hourly labor rate has been selected. The rate is then increased using a multiplier of 1.4 to account for benefits (insurance premiums, pension, and legally required benefits). The 1.4 multiplier was determined by reviewing Employer Costs for Employee Compensation tables for 2004 for the same industries and occupation groups also available on the Bureau of Labor Statistics web site. Because exact hourly rates would be difficult to obtain, nationwide mean hourly rates are used.

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

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

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

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

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

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

This Regulatory Analysis is prepared in accordance with NUREG/BR-0058(4), "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," to support NRC's regulatory action and examine the costs and benefits of the alternatives considered by the Commission. The NRC staff has evaluated each attribute listed in Chapter Five of NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook." The following attributes are affected by this final rule:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Cost Impacts:

Costs to Licensees (Manufacturers and Distributors)

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

Costs to the NRC and Agreement States

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

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

Costs to the Public

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

Benefits:

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

4.2 Revise § 30.14 to Make Exempt Concentrations NRC Only

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

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

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

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

Cost Impacts:

Cost to Licensees (Manufacturers and Distributors)

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

E-Distribution License Required:

Effort to prepare the application:

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

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

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

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

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

Licensees are required to pay a fee for the application:

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

E-Distribution Annual Fees:

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

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

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

Costs to the NRC and Agreement States

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

Effort to review the applications:

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

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

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

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

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

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

Additional NRC costs are discussed in Section 4.7.

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

Costs to the Public:

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

Benefits

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

4.3 Revise § 30.18 to Preclude Combining Multiple Exempt Quantities

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

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

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

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

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

Cost Impacts:

Costs to Exempt Persons (Users)

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

Costs to Licensees (Manufacturers and Distributors)

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

Costs to the NRC and Agreement States

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

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

Costs to the Public

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

Benefits:

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

4.4 Revise Regulations to Remove Obsolete Provisions

The exemptions in § 30.15 provide for persons to receive, possess, use, transfer, own, or acquire certain products containing byproduct material. Of interest are those products no longer being used or manufactured. The general reason for their obsolescence is because of new technologies that have made the use of radioactive material unnecessary or less cost-effective. Obsolete exemptions are: automobile lock illuminators (§ 30.15(a)(2)), balances of precision (§ 30.15(a)(3)), automobile shift quadrants (§ 30.15(a)(4)), marine compasses (§ 30.15(a)(5)), thermostat dials and pointers (§ 30.15(a)(6)), spark gap irradiators (§ 30.15(a)(10)), and resins containing scandium-46 for sand consolidation in oil wells (§ 30.16). The Commission is removing exemptions for these products and prohibiting further distribution while allowing for the continued possession and use of previously distributed items.

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

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

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

Cost Impacts:

Costs to Licensees (Manufacturers and Distributors)

There are no manufacturers or distributors for these products.

Costs to the NRC and Agreement States

The NRC's costs are discussed in Section 4.7.

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

Costs to the Public

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

Benefits:

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

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

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

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

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

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

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

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

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

Cost Impacts:

Costs to Licensees (Manufacturers and Distributors)

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

Costs to the NRC

From Existing Licensees:

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

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

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

From Implementation:

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

Costs to Agreement States

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

Costs to the Public

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

Benefits:

Benefit to New Applicants (Manufacturers and Distributors)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Benefit to Existing Licensees (Manufacturers and Distributors)

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

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

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

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

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

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

For a rough indication of overall savings to existing licensees:

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

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

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

Benefit to the NRC

From New Applicants:

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

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

Benefit to Agreement States

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

Benefits to the Public

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

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

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

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

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

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

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

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

Cost Impacts:

Costs to Licensees (Specific Licensees)

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

Costs to Specific Licensees (Manufacturers and Distributors)

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

Costs to the NRC and Agreement States

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

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

Costs to the Public

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

Benefits:

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

Benefit to Licensees

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

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

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

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

Benefit to the NRC and the Agreement States

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

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

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

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

Benefit to the Public

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

4.7 Implementation Costs

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

4.8 Costs to Agreement States of Compatible Regulations

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

4.9 Quantifiable Costs

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

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

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

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

4.10 Uncertainty

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

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

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

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

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

5 DECISION RATIONALE

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

6 IMPLEMENTATION

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

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

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

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

7 IMPLICATIONS FOR OTHER FEDERAL AGENCIES

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

8 EFFECT ON SMALL ENTITIES

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

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."

Department of Labor (U.S.), Bureau of Labor Statistics, Employer Costs for Employee Compensation. Management, professional, and related occupations, State and local government wages. Series IDs CMU3020000100000D and CMU3020000100000P, 4th Quarter 2005. <www.bls.gov>.

Department of Labor (U.S.), Bureau of Labor Statistics, May 2004 National Occupational Employment and Wage Estimates. Standard Occupational Classification (SOC) System Code Number 17-2111 "Health and Safety Engineers, Except Mining Safety Engineers and Inspectors." <www.bls.gov>.

Executive Office of the President, Office of Management and Budget (OMB). Circular A-76, "Performance of Commercial Activities." May 29, 2003, including technical correction made August 15, 2003.

Executive Office of the President, Office of Management and Budget (OMB). Clearance No. 3150-0001, "Final Supporting Statement for 10 CFR Part 32 "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material."

Executive Office of the President, Office of Management and Budget (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."

Nuclear Regulatory Commission (U.S.) (NRC). Generic Letter 99-01, "Recent Nuclear Material Safety and Safeguards Decision on Bundling Exempt Quantities." NRC: Washington, D.C. May 3, 1999.

Nuclear Regulatory Commission (U.S.)(NRC). NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," NRC: Washington, D.C. June 2001.

Nuclear Regulatory Commission (U.S.)(NRC). NUREG/BR-0058 Revision 4, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," NRC: Washington, D.C. September 2004.

Nuclear Regulatory Commission (U.S.)(NRC). NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook, Final Report," NRC: Washington, D.C. January 1997.

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.

Environmental Assessment for Final Rulemaking – Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements (10 CFR Parts 30, 31, 32, and 150)

U.S. Nuclear Regulatory Commission

Table of Contents

1.0 Introduction.

The Nuclear Regulatory Commission (NRC) is amending its regulations governing the use of byproduct material in 10 CFR Parts 30, 31, 32, and 150. These amendments revise reporting of transfers to persons exempt from licensing, simplify the licensing of smoke detector distribution, remove obsolete provisions, and make some clarifications to the regulations in these parts. 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 on certain general licensees. These changes affect licensees who distribute byproduct material to exempt persons, some users of generally licensed devices, and some exempt persons. The NRC has prepared this environmental assessment (EA) to determine whether the promulgation of this rule will have any significant environmental impact.

1.1 Background.

The Commission's regulations for byproduct material are in 10 CFR Part 30, which sets out the basic requirements for licensing of byproduct material and includes a number of exemptions from licensing. These exemptions allow for certain products and materials containing byproduct material to be used without any regulatory requirements imposed on the user. These 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, for 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 limits such as specification of radionuclides and quantities. Sections 30.14 and 30.18, exempt concentrations and exempt quantities, are broad materials exemptions, which allow the use of a large number of radionuclides. The specific radionuclide limits on the concentrations and quantities are contained in tables in §§ 30.70 and 30.71, respectively. The remainder of the exemptions from licensing are product specific, for which many assumptions can and have been made concerning how the product is distributed, used, and disposed.

Other parts are affected by this rulemaking. Part 31 provides general licenses for the use of certain items containing byproduct material and the requirements associated with these general licenses. The general licenses are established in §§ 31.3, 31.5, 31.7, 31.8, 31.10, and 31.11. 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. Part 150 provides regulations for all States that have entered into agreements with the Commission in accordance with subsection 274b of the Atomic Energy Act, and is also being amended to conform with the changes made in Parts 30 and 32.

The NRC has conducted a systematic reevaluation of the exemptions from licensing in Parts 30 and 40 of the NRC’s regulations, which govern the use of byproduct and source material. A major part of the effort was an assessment of the potential and likely doses to workers and the public under these exemptions. The assessment of doses associated with most of these exemptions can be found in NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," June 2001. Also in the past few years, several issues have been identified where improvements could be made to the regulations governing these products. The amendments considered in this document largely stem from this analysis.

1.2 Document Organization.

This environmental assessment presents a discussion of the basic subjects specified in 10 CFR 51.30. It is organized to best accommodate the rule's complexity. This complexity is due to the Commission's decision to aggregate multiple issues into this single rulemaking, with the purpose of minimizing the costs of its activities. The rule is therefore best understood and discussed as a collection of autonomous small issues. If taken independently, many of the amendments meet the criteria for categorical exclusion – as detailed below – and do not require an environmental assessment to be prepared. The amendments not meeting these criteria are discussed issue-by-issue, and are the focus of the environmental assessment.

A discussion of the need for the actions is contained in Section 2.0. The applicability of categorical exclusions to certain amendments is discussed in Section 3.0. For those issues where a categorical exclusion does not apply, a discussion of the actions and their alternatives is presented generically in Section 4.0, and specifically on an issue-by-issue basis in Section 5.0 along with their environmental impacts. The conclusion is in Section 6.0. A list of agencies and persons consulted and an identification of sources used are contained in Sections 7.0 and 8.0, respectively.

2.0 Need for the Preferred Action.

Based on the NRC's review of regulations that govern the licensing, manufacture, use, and disposal requirements for byproduct material as contained in 10 CFR Parts 30, 31, 32, and 150, it was determined that several of its regulations are in need of revision. Internal analyses have identified regulations that can be improved because they are less effective than intended, or unnecessarily burdensome. Additionally, interactions with the licensed community have identified regulations that require additional clarification. Therefore, Federal action is needed to address the need for the NRC to update and clarify certain regulations and to improve efficiency in the licensing of material transfer to exempt persons. Changes to these regulations are needed to better ensure the protection of public health and safety in the future and improve the effectiveness and efficiency of certain licensing actions.

3.0 Applicability of Categorical Exclusion for Certain Amendments.

Many of these amendments, if taken independently, belong to a category of actions that the Commission has determined to be a categorical exclusion, having found that these types of actions do not individually or cumulatively have a significant effect on the human environment. Therefore, this EA is not required to evaluate these amendments further.

The categorical exclusion in § 51.22(c)(1) includes amendments to Part 150 as not requiring an environmental assessment.

The categorical exclusion in § 51.22(c)(3) provides that amendments to Parts 30, 31, and 32 that relate to recordkeeping and reporting – paragraphs (ii) and (iii), respectively – do not require an environmental assessment. The amendments that revise the reporting for material transfers from a 5-year period to annual are therefore covered by this categorical exclusion. Amendments to these affected recordkeeping and reporting requirements are in §§ 32.12, 32.16, 32.20, 32.25(c), and 32.29(c). The amendment to § 31.5(c)(8) eliminates a reporting requirement for general licensees who transfer a device from a general to a specific license, and is covered by this categorical exclusion.

4.0 The Preferred Federal Action and Alternatives: Generic Discussion.

Under this federal action, the NRC is amending certain sections of 10 CFR Parts 30, 31, 32, and 150 by rulemaking in accordance with the Administrative Procedure Act of 1946, as amended. The alternatives to rulemaking would be to take no action, or to take various non-rulemaking actions. Non-rulemaking alternatives include: generic letters, information notices, guidance documents, and direct one-on-one contact with licensees.

Rulemaking is the NRC's preferred alternative because it best resolves the need for action for these issues consistent with the Commission's goals of protecting the public health and safety, increasing regulatory effectiveness, efficiency, and realism, and ensuring openness in the regulatory process. In general for these issues, rulemaking establishes regulations which can be made enforceable; affords opportunity for public involvement; and are readily available to regulators, licensees, and the general public.

For issues inherent in the regulations themselves – such as obsolete provisions – no non-rulemaking alternatives can realistically address the issue. For other issues, there may be realistic non-rulemaking solutions, but these have drawbacks as explained below.

The no-action alternative is to keep the status quo. The no-action alternative would not address identified concerns. Specific details of the implications of the rulemaking, non-rulemaking alternatives, and the no-action alternative are discussed below, issue by issue.

5.0 The Preferred Federal Actions, Alternatives, and Environmental Impacts: Discussion of Specific Issues.

5.1 Revise 10 CFR 30.14 to Make Exempt Concentrations NRC Only.

Section 30.14 provides that any person is exempt from the requirements for a license to the extent that this 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. Licenses to transfer or introduce byproduct material for commercial distribution in a product or material may be issued by the NRC or one of the more than 30 Agreement States. With respect to exempt products, the ability for an Agreement State to authorize these distributors is relatively unique, whereas the NRC routinely reviews applications for licenses to distribute products containing byproduct material to exempt persons.

The provision allowing Agreement State licensing of products and materials used under the § 30.14 exemption was promulgated with the intent that the States and the NRC would develop a system whereby the NRC would obtain information on distribution and the NRC would still be able to track nationwide distribution. No such process has been developed; as a result there is a gap in NRC information on nationwide distribution of exempt products. The no-action alternative would leave this gap in NRC information. Similarly, although non-rulemaking methods could improve communication of information on distribution, there is no other alternative to rulemaking as effective in obtaining data that is complete, comprehensive, and timely. For example, guidance documents could be used to recommend communication methods to be used between the States and the NRC, such as using the services of established State organizations, but the NRC can not enforce compliance with the guidance documents. The no-action and non-rulemaking alternatives do not address any potential inconsistencies in licensing approach or confusion caused by this exception to the otherwise NRC-only licensing of byproduct material distribution to exempt persons.

The no-action and non-rulemaking alternatives would continue current licensing practices; licenses for introducing exempt concentrations could be issued by either the NRC or an Agreement State. There is no difference in standards for a license from the NRC or from an Agreement State, licenses from both jurisdictions are essentially equivalent, and all users regardless of location are exempt from licensing.

The preferred action would consolidate, within the NRC, all distributor licensing of byproduct material to exempt persons. Therefore, all information regarding nationwide distribution would be in one place and would be more easily and efficiently tracked. The existing concentration limits and prohibitions are being retained for these products and materials. Because no changes are being made to any provision that regulates the physical nature of this category of products, the preferred action does not affect any environmental resources.

5.2 Revise 10 CFR 30.18 to Preclude Combining Multiple Exempt Quantities.

Section 30.18 provides an exemption from licensing for a person who receives, possesses, uses, transfers, owns, or acquires byproduct material in individual quantities each of which does not exceed the applicable quantity set forth in § 30.71, Schedule B. The material limits in § 30.71 were established for individual sources. The combining or "bundling" of multiple sources into devices to make use of an increased radiation field was not anticipated in the development of the byproduct material limits. A person wishing to commercially distribute or initially transfer these products containing byproduct material must obtain an exempt distribution license from NRC in accordance with § 32.18. Paragraph (c) of § 32.18 prohibits the distributor from incorporating the exempt byproduct material into any manufactured or assembled commodity, product, or device intended for commercial distribution. Also, a license condition is imposed on the distributor in § 32.19(d)(2) to label the byproduct material to include the words, "Exempt Quantities Should Not Be Combined." However, prior to this rulemaking, there was no provision in § 30.18 to explicitly prohibit the user from combining multiple exempt quantities.

The NRC staff determined that the bundling of exempt quantities is "inconsistent with existing regulations" (NRC Generic Letter 99-01: Recent Nuclear Material Safety and Safeguards Decision on Bundling Exempt Quantities, May 3, 1999). The letter indicated that the NRC would consider rulemaking to clarify the regulatory status of combined exempt quantities and to assure the protection of the public health and safety with consideration of property protection. Because the generic letter has already been issued, and the users are exempt from licensing, there is no realistic non-rulemaking alternative available for this issue. The no-action alternative would be to continue to rely on the generic letter to communicate the NRC's position on this issue. However, generic letters are not binding or enforceable for non-licensees and may be less effective over time.

This rule clarifies the regulations in § 30.18 to better ensure that persons will not combine or bundle exempt sources in the future. To the NRC's knowledge, no person exempt from licensing has combined multiple exempt quantities in devices for purposes of creating an increased radiation level since the issuance of the generic letter in 1999. The preferred action would prevent the past practice of bundling from recurring. It would provide better assurance that devices with bundled sources (equivalent to larger quantity sources than permitted under the exemption) would not be created and ultimately disposed of in landfills and metals recycling waste streams. The bundling prohibition is therefore protective of the environment, but is not a significant change to current practices. There is no environmental impact from the preferred action compared to the no-action alternative and the rulemaking is not likely to affect any environmental resources.

5.3 Revise 10 CFR 30.15 and 30.16 to Remove Obsolete Provisions.

The existing § 30.15 establishes an exemption from licensing for many products containing byproduct material. The specific provisions of § 30.15 evaluated in this document are: § 30.15(a)(2) – automobile lock illuminators, § 30.15(a)(3) – balances of precision, § 30.15(a)(4) – automobile shift quadrants, § 30.15(a)(5) – marine compasses and other marine navigational instruments, § 30.15(a)(6) – thermostat dials and pointers, and § 30.15(a)(10) – spark gap irradiators. The existing § 30.16 establishes an exemption from licensing for resins containing scandium-46 and designed for sand-consolidation in oil wells. These provisions are for products that have never been used, are no longer being used, or are no longer being manufactured.

The NRC's preferred action is to delete exemptions and distributor requirements for the above products. No non-rulemaking alternatives can feasibly attain this purpose. The preferred action is not intended to change the regulatory status of any products previously distributed in conformance with the provisions of the regulations applicable at the time. Therefore, the rule retains the exemptions for balances of precision and marine compasses and other navigational instruments, but the exemption would be constrained to products that were distributed before the effective date of the final rule.

All other obsolete exemptions considered in this rulemaking are eliminated in full. Although thermostat dials or pointers, spark gap irradiators, and resins containing scandium-46 for sand consolidation in oil wells have been distributed in the past, their distribution ceased so long ago that it is highly unlikely that any are still being used. These products are no longer in use because their function has been replaced by other products due to external factors such as economic considerations or technical advances, making their future use unlikely. Automobile lock illuminators and automobile shift quadrants were never distributed commercially. A regulatory exemption was pursued for these products before a market could be developed; none ever materialized.

Because the exemptions removed by this action are obsolete, and in all cases no products are currently being distributed, the only notable distinction between the no-action alternative and the rulemaking is that the latter would prohibit future distribution without NRC reevaluation. However, future distribution is unlikely in the no-action alternative because the products are outmoded. Therefore, it is unlikely that the rulemaking will affect any environmental resources.

5.4 Revise 10 CFR 30.15 to Add a Product-Specific Exemption for Smoke Detectors.

The existing § 30.20 provides an exemption from licensing for a person to receive, possess, use, transfer, own, or acquire a gas and aerosol detector. One of the most widely distributed consumer products containing byproduct material is the ionization chamber smoke detector, currently used under this class exemption. These products have been used for fire protection purposes for many years and have demonstrated through extensive licensing experience that they meet adequate design and safety criteria. The vast majority of U.S. homes have one or more ionization chamber smoke detectors, and the total number in use is likely to be considerably more than 100 million (NUREG-1717, p. 2-217).

Under the no-action alternative, the requirements for a specific license to initially transfer, manufacture, process, or produce smoke detectors, as well as other gas and aerosol detectors containing byproduct material used under § 30.20, are located in § 32.26. New applicants must demonstrate that their device meets the safety requirements of §§ 32.26, 32.27, and 32.28. Once a license is issued, all manufacturing must be done in accordance with § 32.29. Because

this issue has no realistic non-rulemaking alternative, the no-action alternative is the only alternative to rulemaking.

Under the preferred action, the NRC is establishing a product-specific exemption under § 30.15(a)(7) for ionization chamber smoke detectors that contain no more than 1 microcurie (μCi) of americium-241 (Am-241) in the form of a foil. New applicants seeking to manufacture or initially distribute these devices under § 30.15(a)(7) have to meet the application requirements of § 32.14. Once the application requirements have been met and a license issued, all manufacturing must be done in accordance with the requirements of § 32.15. Under the preferred action, the current regulatory structure remains for the class of gas and aerosol detectors: smoke detector licensees/applicants may choose for their product to be distributed for use under either the class exemption in § 30.20 or the product-specific exemption under § 30.15(a)(7).

For the purposes of assessing environmental impact, the primary difference between the two regulatory schemes (preferred vs. no-action) would be regarding new applicants. Under the preferred action, new applicants are not required to submit dose assessments as part of the application process. These dose assessments are intended to demonstrate the doses that result during various life stages of the product do not exceed certain values. This has been thoroughly evaluated in NUREG/CR-1156, "Environmental Assessment of Ionization Chamber Smoke Detectors Containing Am-241," November 1979, and in NUREG-1717. The applicant will still be required to submit basic device design information for the product consistent with product-specific distribution regulations under § 32.14 (which are similar to § 32.26). Specific requirements applicable to the licensed distributor are similar to § 32.29 and are contained in § 32.15. However, the labeling requirements for smoke detectors under the previous regulation are more specific than those in § 32.15(d). In order that the more specific labeling requirement be retained, essentially the same details have been added to § 32.15(d) for ionization chamber smoke detectors. The preferred action is unlikely to have any effect on the design of the device compared to the no-action alternative.

The preferred action is not expected to result in any significant changes in the number of ionization chamber smoke detectors on the market. Because the dose assessment and its review will not be performed, a new applicant under the new rule will have a lower regulatory burden. However, given the very large number of smoke detectors distributed annually, the difference in regulatory cost per unit between the past and future regulations is negligible, and therefore unlikely to appreciably affect the number of smoke detectors on the market.

There is no identifiable environmental impact from the preferred action compared to the no-action alternative. Therefore, the rule is not likely to affect any environmental resources.

6.0 Conclusion.

The NRC is amending its regulations governing the use of byproduct material in 10 CFR Parts 30, 31, 32, and 150. This document was prepared so that environmental impacts would be considered as part of the decision-making process. This assessment discusses the impacts of the final rulemaking under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51. Many of the individual amendments in this rule belong to a category of actions which the Commission, by § 51.22(c)(1) and § 51.22(c)(3)(ii) and (iii), has declared to be a categorical exclusion and found that it is not possible for these types of actions to individually or cumulatively have a significant effect on the human environment. The other amendments in this rulemaking will not affect any environmental

resources, and therefore this rulemaking does not warrant the preparation of an environmental impact statement. Accordingly and appropriately, a finding of no significant impact (FONSI) was published in the *Federal Register* concurrently with the publication of the proposed rule for public comment (71 FR 275, January 4, 2006) and will be restated concurrently with the publication of the final rule.

7.0 List of Agencies and Persons Consulted.

The NRC staff has determined that the preferred Federal action is not a type of activity that has potential to cause effects on historic properties because it is a procedural action. Therefore, no further consultation is required under Section 106 of the National Historic Preservation Act. Additionally, the NRC staff has determined that Section 7 consultation with the U.S. Fish and Wildlife Service is not required because the preferred Federal action is procedural in nature and will not affect listed species or critical habitat.

8.0 Sources Cited.

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 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," Subpart A, "National Environmental Policy Act – Regulations Implementing Section 102(2)."

Nuclear Regulatory Commission (U.S.) (NRC). Generic Letter 99-01, "Recent Nuclear Material Safety and Safeguards Decision on Bundling Exempt Quantities." NRC: Washington, D.C. May 3, 1999.

Nuclear Regulatory Commission (U.S.) (NRC). NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," NRC: Washington, D.C. June 2001.

Nuclear Regulatory Commission (U.S.) (NRC). NUREG/CR-1156, "Environmental Assessment of Ionization Chamber Smoke Detectors Containing Am-241," November 1979.

24722

Submission of Federal Rules Under the Congressional Review Act

☒ President of the Senate ☐ Speaker of the House of Representatives ☐ GAO

Please fill the circles electronically or with black pen or #2 pencil.

1. Name of Department or Agency	2. Subdivision or Office
U.S. Nuclear Regulatory Commission	**Ofc. of Fed. & State Matl's and Env. Mgmt. Prog.**

3. Rule Title

10 CFR Parts 30, 31, 32, and 150 -- Exemptions from licensing, general licenses, and distributions of byproduct material: licensing and reporting requirements

4. Regulation Identifier Number (RIN) or Other Unique Identifier (if applicable)

RIN 3150-AH41

5. ◯ Major Rule ◉ Non-major Rule

6. ◉ Final Rule ◯ Other _____

7. With respect to this rule, did your agency solicit public comments? ◉ Yes ◯ No ◯ N/A

8. Priority of Regulation (fill in one)

◉ Economically Significant; or Significant; or Substantive, Non Significant ◯ Routine and Frequent or Informational/Administrative/Other (Do not complete the other side of this form if filled in above.)

9. Effective Date (if applicable)

10. Concise Summary of Rule (fill in one or both) ◯ attached ◉ stated in rule

Submitted by: _____ (signature)

Name: **Andy Imboden**

Title: **Project Manager, Division of Intergovernmental Liaison and Rulemaking**

Submitted by: _____ (signature)

Name: Andy Imboden

Title: Project Manager, Division of Intergovernmental Liaison and Rulemaking

For Congressional Use Only:

Date Received: _____

Committee of Jurisdiction:
For Congressional Use _____

Only: Date Received:

3/23/99

Committee of Jurisdiction:

	Yes	No	N/A
A. With respect to this rule, did your agency prepare an analysis of costs and benefits?	◉	○	○
B. With respect to this rule, by the final rulemaking stage, did your agency			
1. certify that the rule would not have a significant economic impact on a substantial number of small entities under 5 U.S.C.§ 605(b)?	◉	○	○
2. prepare a final Regulatory Flexibility Analysis under 5 U.S.C. § 604(a)?	◉	○	○
C. With respect to this rule, did your agency prepare a written statement under § 202 of the Unfunded Mandates Reform Act of 1995?	○	○	◉
D. With respect to this rule, did your agency prepare an Environmental Assessment or an Environmental Impact Statement under the National Environmental Policy Actg (NEPA)?	◉	○	○
E. Does this rule contain a collection of information requiring OMB approval under the Paperwork Reduction Act of 1995?	○	◉	○
F. Did you discuss any of the following in the preamble to the rule?	○	○	◉
• E.O. 12612, Federalism	○	○	◉
• E.O. 126630, Government Actions and Interference with Constitutionally Protected Property Rights	○	○	◉
• E.O. 12866, Regulatory Planning and Review	○	○	◉
• E.O. 12875, Enhancing the Intergovernmental Partnership	○	○	◉
• E.O. 12988, Civil Justice Reform	○	○	◉
• E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks	○	○	◉
• Other statutes or executive orders discussed in the preamble concerning the rulemaking process (please specify)	○	○	◉

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A. With respect to this rule, did your agency prepare an analysis of costs and benefits?
B. With respect to this rule, by the final rulemaking stage, did your agency
1. certify that the rule would not have a significant economic impact on a substantial number of small entities under 5 U.S.C.§ 605(b)?
2. prepare a final Regulatory Flexibility Analysis under 5 U.S.C. § 604(a)?
C. With respect to this rule, did your agency prepare a written statement under § 202 of the Unfunded Mandates Reform Act of 1995?
D. With respect to this rule, did your agency prepare an Environmental Assessment or an Environmental Impact Statement under the National Environmental Policy Actg (NEPA)?
E. Does this rule contain a collection of information requiring OMB approval under the Paperwork Reduction Act of 1995?
F. Did you discuss any of the following in the preamble to the rule?
• E.O. 12612, Federalism
• E.O. 126630, Government Actions and Interference with Constitutionally Protected Property Rights
• E.O. 12866, Regulatory Planning and Review
• E.O. 12875, Enhancing the Intergovernmental Partnership
• E.O. 12988, Civil Justice Reform
• E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks
• Other statutes or executive orders discussed in the preamble concerning the rulemaking process (please specify)

3/23/99

24722

Submission of Federal Rules Under the Congressional Review Act

☐ President of the Senate ☒ Speaker of the House of Representatives ☐ GAO

Please fill the circles electronically or with black pen or #2 pencil.

1. Name of Department or Agency
U.S. Nuclear Regulatory Commission

2. Subdivision or Office
Ofc. of Fed. & State Matl's and Env. Mgmt. Prog.

3. Rule Title
10 CFR Parts 30, 31, 32, and 150 -- Exemptions from licensing, general licenses, and distributions of byproduct material: licensing and reporting requirements

4. Regulation Identifier Number (RIN) or Other Unique Identifier (if applicable)
RIN 3150-AH41

5. Major Rule ◯ Non-major Rule ◉

6. Final Rule ◉ Other ◯

7. With respect to this rule, did your agency solicit public comments? Yes ◉ No ◯ N/A ◯

8. Priority of Regulation (fill in one)
◉ Economically Significant, or Significant, or Substantive, Non Significant
◯ Routine and Frequent or Informational/Administrative/Other (Do not complete the other side of this form if filled in above.)

9. Effective Date (if applicable)

10. Concise Summary of Rule (fill in one or both) attached ◯ stated in rule ◉

Submitted by: _____ (signature)

Name: Andy Imboden

Title: Project Manager, Division of Intergovernmental Liaison and Rulemaking

For Congressional Use Only:

Date Received:

Committee of Jurisdiction:

Submitted by: _____ (signature)

3/23/99

Name: Andy Imboden

Title: Project Manager, Division of Intergovernmental Liaison and Rulemaking

24722

For Congressional Use Only: Date

Received:

Committee of Jurisdiction:

	Yes	No	N/A
A. With respect to this rule, did your agency prepare an analysis of costs and benefits?	◉	○	○
B. With respect to this rule, by the final rulemaking stage, did your agency			
1. certify that the rule would not have a significant economic impact on a substantial number of small entities under 5 U.S.C.§ 605(b)?	◉	○	○
2. prepare a final Regulatory Flexibility Analysis under 5 U.S.C. § 604(a)?	◉	○	○
C. With respect to this rule, did your agency prepare a written statement under § 202 of the Unfunded Mandates Reform Act of 1995?	○	○	◉
D. With respect to this rule, did your agency prepare an Environmental Assessment or an Environmental Impact Statement under the National Environmental Policy Act (NEPA)?	◉	○	○
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• E.O. 12866, Regulatory Planning and Review	○	○	◉
• E.O. 12875, Enhancing the Intergovernmental Partnership	○	○	◉
• E.O. 12988, Civil Justice Reform	○	○	◉
• E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks	○	○	◉
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3/23/99

C. With respect to this rule, did your agency prepare a written statement under § 202 of the Unfunded Mandates Reform Act of 1995?

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F. Did you discuss any of the following in the preamble to the rule?

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" E.O. 12612, Federalism

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Protected E.O. 126630, Property Government Rights Actions and

Interference with Constitutionally

0 0

" E.O. 12866, Regulatory Planning and Review

" E.O. 12875, Enhancing the Intergovernmental Partnership

" E.O. 12988, Civil Justice Reform

" EDO. 13045, Protection of Children from Environmental Health Risks and Safety Risks

" Other statutes or executive orders discussed in the preamble concerning the rulemaking process (please specify)

24722

Submission of Federal Rules Under the Congressional Review Act

☐ President of the Senate ☐ Speaker of the House of Representatives ☒ GAO

Please fill the circles electronically or with black pen or #2 pencil.

1. Name of Department or Agency	2. Subdivision or Office
U.S. Nuclear Regulatory Commission	**Ofc. of Fed. & State Matl's and Env. Mgmt. Prog.**

3. Rule Title

10 CFR Parts 30, 31, 32, and 150 -- Exemptions from licensing, general licenses, and distributions of byproduct material: licensing and reporting requirements

4. Regulation Identifier Number (RIN) or Other Unique Identifier (if applicable) **3/23/99**

RIN 3150-AH41

5. Major Rule ◯ Non-major Rule ◉

6. Final Rule ◉ Other ◯ _____

7. With respect to this rule, did your agency solicit public comments? Yes ◉ No ◯ N/A ◯

8. Priority of Regulation (fill in one)

◉ Economically Significant; or Significant; or Substantive, Non Significant

◯ Routine and Frequent or Informational/Administrative/Other (Do not complete the other side of this form if filled in above.)

9. Effective Date (if applicable)

10. Concise Summary of Rule (fill in one or both) attached ◯ stated in rule ◉

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24722

Submission of Federal Rules Under the Congressional Review Act

☐ President of the Senate ☒ Speaker of the House of Representatives

Submitted by: _____ (signature)

Name: **Andy Imboden**

Title: **Project Manager, Division of Intergovernmental Liaison and Rulemaking**

Please fill the circles electronically or with black pen or #2 pencil.

1. Name of Department or Agency: U.S. Nuclear Regulatory Commission

2. Subdivision or Office: Ofc. of Fed. & State Mat's and Env. Mgmt. Prog.

3. Rule Title

10 CFR Parts 30, 31, 32, and 150 -- Exemptions from licensing, general licenses, and distributions of byproduct material: licensing and reporting requirements

For Congressional Use Only:

Date Received: _____

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RIN 3150-AH41

Committee of Jurisdiction: _____

5. Major Rule Q Non-major Rule (

3/23/99

6. Final Rule ® Other Q_

	Yes	No	N/A
A. With respect to this rule, did your agency prepare an analysis of costs and benefits?	◉	○	○
B. With respect to this rule, by the final rulemaking stage, did your agency			
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2. prepare a final Regulatory Flexibility Analysis under 5 U.S.C. § 604(a)?	◉	○	○
C. With respect to this rule, did your agency prepare a written statement under § 202 of the Unfunded Mandates Reform Act of 1995?	○	○	◉
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• E.O. 126630, Government Actions and Interference with Constitutionally Protected Property Rights	○	○	◉
• E.O. 12866, Regulatory Planning and Review	○	○	◉
• E.O. 12875, Enhancing the Intergovernmental Partnership	○	○	◉
• E.O. 12988, Civil Justice Reform	○	○	◉
• E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks	○	○	◉
• Other statutes or executive orders discussed in the preamble concerning the rulemaking process (please specify)			

7. With respect to this rule, did your agency solicit public comments? Yes) No Q N/A Q

8. Priority of Regulation (fill in one)

Economically Significant, or Semi-significant or Significant, or Informational/Administrative/Other Substantive, Non Significant (Do not complete the other side of this form if filled in above.)

9. Effective Date (if applicable)

10. Concise Summary of Rule (this rule and by our agency prepare an Environmental)

Submitted by: (J (signature)

Name: Andy Imboden

Title: Project Manager, Division of Intergovernmental Liaison and Rulemaking

For Congressional Use Only: Date Received:

Committee of Jurisdiction:

3/23/99

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B. With respect to this rule, by the final rulemaking stage, did your agency

1. certify that the rule would not have a significant economic impact on a substantial number of small entities under 5 U.S.C.§ 605(b)?

3/23/99

2. prepare a final Regulatory Flexibility Analysis under 5 U.S.C. § 604(a)?

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Yes No N/A

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F. Did you discuss any of thefollowing in the preamble to the rule? Q0 ®

- E.O. 12612, Federalism 1 ®
- " E.O. 126630, Government Actions and Interference with Constitutionally Protected Property Rights 1 ®
- " E.O. 12866, Regulatory Planning and Review
- E.O. 12875, Enhancing the Intergovernmental Partnership
- " **E.O.** .12988, Civil Justice Reform 1 ®
- " E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks 1 ®
- " Other statutes or executive orders discussed in the preamble concerning the rulemaking process (please specify) 1 ®

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Yes No N/A

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