Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

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: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations governing the use of byproduct material to revise requirements for reporting transfers to persons exempt from licensing, simplify the licensing of smoke detector distribution, remove obsolete provisions, and clarify certain regulatory provisions. These actions are intended to better ensure the protection of public health and safety in the future, make the licensing of distribution to exempt persons more effective and efficient, and reduce unnecessary regulatory burden to certain general licensees. These changes would affect licensees who distribute byproduct material to exempt persons, users of some generally licensed devices, and some exempt persons.

DATES: Submit comments by March 20, 2006. Submit comments specific to the information collection aspects of this rule by February 3, 2006. Comments received after these dates will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before these dates.

ADDRESSES: You may submit comments by any of the following methods. Please include the number RIN 3150–AH41 in the subject line of your comments. Comments on rulemakings submitted in writing or in electronic form will be made available to the public in their entirety on the NRC rulemaking Web site. Personal information will not be removed from your comments.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: *SECY@nrc.gov.* If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415–1966. You may also submit comments via the NRC's rulemaking Web site at *http://ruleforum.llnl.gov.* Address questions about our rulemaking Web site to Carol Gallagher at (301) 415–5905; e-mail *cag@nrc.gov.* Comments can also be submitted via the Federal eRulemaking Portal at *http://www.regulations.gov.*

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. Federal workdays. (Telephone (301) 415–1966).

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415–1101.

You may submit comments on the information collections by the methods indicated under Paperwork Reduction Act Statement.

Publicly available documents related to this rulemaking may be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), Room O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee. Selected documents, including comments, may be viewed and downloaded electronically via the NRC rulemaking Web site at *http://ruleforum.llnl.gov.*

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html.* From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC PDR Reference staff at 1–800–397–4209, 301–415–4737 or by e-mail to *pdr@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Catherine R. Mattsen, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Mail Stop T8F3, Washington, DC 20555–0001, telephone (301) 415–6264, e-mail, *crm@nrc.gov.*

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I. Background

A. Introduction

The Commission has authority to issue both general and specific 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''). A general license is provided by regulation, grants authority to a person for certain activities involving byproduct material, and is effective without the filing of an application with the Commission or the issuance of a licensing document to a particular person. Requirements for general licensees appear in the regulations and are designed to be commensurate with the specific circumstances covered by each general license.

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.'' As beneficial uses of licensed material were developed and experience grew, new products intended for use by the general public were invented and the regulations were amended to accommodate the use of new products. The Commission currently has 15 exemptions from licensing for byproduct material in its regulations, most of which were added by 1970.

The Commission has conducted a systematic reevaluation of the exemptions from licensing in parts 30 and 40 of NRC's regulations (in Title 10 of the Code of Federal Regulations), which govern the use of byproduct and source materials. 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,[1] ''Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials,'' June 2001. For some exemptions, the difference between potential (possible under the conditions of the exemption) and likely doses is significant because actual use of the exemption is limited or nonexistent, or significantly lower quantities are used in products than is potentially allowed under the exemption.

This proposed action concerns only conclusions of the reevaluation of regulations governing byproduct material. Any potential revisions to the regulations governing source material would be addressed in the future. In addition to the exemptions themselves, the NRC has reviewed the existing regulations governing the distribution of byproduct material to persons for use under the exemptions.

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 be occurring are in line with Commission policy concerning acceptable doses from products and materials used under exemptions from licensing. However, in some cases, the regulatory constraints and controls in place may not be adequate to fully ensure that the health and safety of the public will continue to be protected to the extent considered appropriate for practices occurring under exemptions from licensing.

Although presenting very low risks of significant individual doses to members of the general public, exempt products are a source of routine exposure to the public. A substantial portion of the population uses and enjoys benefits from exempt products, such as smoke detectors, but, at the same time, receives some radiation exposure from those products.

The Commission has also decided to make the regulations more flexible, user-friendly, and performance-based, and to improve its ability to risk-inform its regulatory program. These concepts have been considered in developing potential revisions to the regulatory program in the area of distribution of byproduct material to exempt persons.

The Commission is also proposing a revision to a certain general license within this same rulemaking. There are some areas where the regulations are not clear or explicit. This leads to inefficiencies in the regulatory process and can lower public confidence. Thus, a clarification is being proposed.

In addition to the issues addressed by this proposed rule, the Commission is considering other issues that may be addressed in a future rulemaking to further amend parts 30, 31, and 32.

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 exemptions from licensing requirements in §§ 30.14, 30.15, 30.16, 30.18, 30.19, 30.20, and 30.21. These exemptions allow for certain products and materials containing byproduct material to be used without any regulatory requirements on the user. 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 is within the class and meets certain radiation dose criteria. This contrasts with 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 these concentrations and quantities are contained in tables in §§ 30.70 and 30.71, respectively. The remaining 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. 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 sets out regulations for all States that have entered into agreements with the Commission under subsection 274b of the Act (Agreement States).

II. Proposed Actions

This proposed rule would make 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 in the future and improve the efficiency and effectiveness of certain licensing actions.

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

The current reporting and recordkeeping requirements for distributors of products and materials to persons exempt from licensing in part 30 (contained in §§ 32.12, 32.16, 32.20, 32.25(c), and 32.29(c)) require these licensees to maintain records of these transfers and to submit reports to NRC once every five years. The reports must

[1] NUREG–1717 is a historical document development 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.

indicate the total quantity of byproduct material and/or the total number of exempt units listed by type transferred during the reporting period. The breakdown of the information by year is not required. These reports are also required when filing for license renewal or notifying the Commission of a decision to cease authorized activities.

The resulting reports are not timely and informative enough for NRC to fully determine the products and amount of byproduct material distributed annually for exempt use. This limits the NRC's ability to evaluate the overall net impact of these practices 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 products/materials containing byproduct material distributed each year or to see any trends. Also, the information is not very current. The limitations of the information about the products/materials and quantities distributed for use under exemption greatly impacted the effort involved in developing the dose assessments in NUREG–1717 and contributed to the uncertainties in the results.

Before 1983, reporting of transfers of exempt byproduct material was required on an annual basis. The regulations were amended in 1983 to change the reporting requirement to once every 5 years to minimize administrative burden. However, subsequent experience with the 5-year reporting frequency has shown that it does not provide NRC with complete, accurate, or timely information on products and materials containing byproduct material distributed for use under exemptions from licensing. Reevaluation of the reporting requirements also suggests that annual reporting may be administratively more efficient for both the NRC and affected licensees than the current requirement. Experience shows that there have been more implementation problems under the current scheme than with annual reporting. For example, because of the long interval between reports, licensees frequently forget to file reports in compliance with the regulations. This lapse sometimes results in the need for requests for additional information to be sent so that an application for renewal or termination of license can be processed. The long interval between reports also leads to licensee inefficiencies in collecting the data.

The proposed rule would require that material transfer reports covering transfers made during the calendar year be submitted annually by January 31 of the following year. These reports would also be required 30 days after ceasing authorized activities, rather than at the point of notifying the Commission of the decision to cease authorized activities. The reports would no longer be required when filing for license renewal. In the first report made after the proposed change, licensees would also be required to submit information on transfers made since the previous report. Routine annual reporting should be more straightforward and easier for licensees to comply with than consolidating and reporting five years of distribution information. This approach is expected to impose a minimal burden and be more efficient for both the NRC and licensees, particularly given the current state of information technology. A recent change to the Commission's regulations allows electronic submission as an alternative to standard mail submission, which reduces administrative costs.

In addition to the lengthy period between the current reports, certain information is not always clear in the reports, making it more difficult to use the information. The proposed rule would make these reporting provisions more specific. The report would be required to include reference to the specific exemption provision under which the products/materials are being distributed and clearly identify the specific licensee submitting the report, including the license number.

The current regulations require the licensee to identify the product distributed. However, this is done in a number of ways, some of which require the NRC to refer to other documents to obtain the information needed to fully interpret what is being distributed. The proposed rule would add model numbers, when applicable, to the required information. Licensees have frequently included model numbers in the reports, but often as the only identification of the type of product being transferred. The proposed rule would eliminate these inefficiencies without making a significant change to licensees' reporting burden. The address to which reports are to be sent would also contain the line, ''ATTN: Document Control Desk/Exempt Distribution,'' to make the internal distribution of the documents within NRC more efficient. The requirement for licensees to send an additional copy of the reports to the appropriate Regional office would be removed. Under NRC's internal procedures, the information would be electronically distributed to the Regional offices. 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 proposed changes, the NRC would 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 existing regulations. The NRC would have a stronger basis for informing the public concerning such exposures. These changes would also provide a better basis for considering any future regulatory changes in this area and in allocating NRC resources. Finally, the period of retention for records, proposed to remain at one year after transfers are included in a report, would be up to four years shorter than under existing requirements.

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. Reporting requirements for these licensees provide the NRC with national data on products and materials containing byproduct material distributed to persons exempt from licensing and regulation. There are two exemptions for which this is not the case. The first of these, § 30.16, ''Resins containing scandium-46 and designed for sand-consolidation in oil wells,'' would be removed, as noted below, because it is obsolete. The second is § 30.14, ''Exempt concentrations,'' for which those who introduce byproduct material into products or materials are licensed under § 32.11 or similar Agreement States regulations. The concentration limits applicable to this exemption from licensing are contained in § 30.70, ''Schedule A—Exempt concentrations,'' and equivalent Agreement State regulations.

The provisions that allow Agreement State licensing of the introduction of byproduct material into products and materials in exempt concentrations for transfer to persons exempt from licensing were added to NRC regulations in 1963, soon after the regulations governing the Agreement State program were established in 1962 (10 CFR part 150). At the time, the only practices being regulated under these provisions related to quality control procedures and other radiotracer activities. Exempt concentrations were permitted to be introduced into oil, gasoline, plastics, and similar commercial and industrial items. Also, at the time these provisions were added, it was expected that the NRC would

develop a system with the Agreement States to obtain copies of the transfer reports submitted to the Agreement States by their licensees so that NRC would have national information on distribution. Such a system was never implemented.

The exempt concentration provision in § 30.14 is a general materials exemption that is not limited to a particular use. It allows for various practices to be evaluated by the NRC or an Agreement State on a case-by-case basis through the licensing process. 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 an airport explosive detection system, resulting in induced radioactivity in the products. These practices involved consideration of issues not anticipated in the early 1960's, including the extensive national distribution of the products. For the case of irradiation of gemstones, the NRC has since required authorization by an NRC license.

Section 30.14 also contains an exemption from licensing by NRC (in paragraph (c)) for manufacturers, processors, or producers in Agreement States if the introduction of byproduct material into their product or material is conducted by a specific licensee whose license authorizes this introduction. Currently, this authority may be provided under either an NRC license or an Agreement State license.

Information on all distributions to exempt persons is important for NRC to effectively and efficiently assess the overall impact to the public nationally. NRC licensing of all such distribution would facilitate this process. 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 current situation of multiple jurisdictions potentially issuing these licenses may allow for some inconsistency in the licensing process.

The proposed rule would require that the entity introducing byproduct material into products and materials for use under the exempt concentration provisions have an NRC license specifically authorizing this introduction. Specifically, the proposed rule would make §§ 32.11 and 32.12 Compatibility Category NRC (i.e., reserved to NRC). (For a brief explanation of compatibility categories see the Agreement State Compatibility section.) This change to NRC-only licensing would also require amendment of other provisions in the regulations. Thus, the proposed rule would revise the wording of the exemption in § 30.14(c), § 32.11, the prohibition in §§ 30.14(d) and 32.13, and the reciprocity provision in § 150.20 accordingly, so that only NRC may authorize the introduction of byproduct material into products and materials to be distributed for use under § 30.14 and equivalent Agreement State regulations.

Section 32.11 would be revised to exempt Agreement State licensees from § 30.33(a)(2) and (3). Consistent with the practice for other distributors of byproduct material to exempt persons in Agreement States, who have possession and use of the material authorized by an Agreement State license and distribution authorized by an NRC license, the possession and use of the byproduct material to be introduced could remain under an Agreement State license. In that case, provisions similar to § 30.33(a)(2) and (3) would apply under the Agreement State license.

Currently, the only known entities licensed under § 32.11 or equivalent regulations of the Agreement States are a small number of radiotracer firms, who introduce byproduct material into such materials as gas and oil, and steel companies, who use sources to monitor the wear of refractory lining in blast furnaces resulting in infrequent but expected instances of slight contamination of some steel. The Agreement States were requested to provide information on the number of licensees of this type in 2002 and 2005. No licensees were identified.

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 for NRC the authority for licensing transfers to exempt persons. The proposed rule would further revise the exemption in § 30.14(c) to also 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. The intent of the regulations in § 32.11 is to allow a licensee to introduce byproduct material into products and materials held by others who are not required to have a license, thus, there is no reason to limit this provision to persons in Agreement States. Therefore, § 30.14(c) would be amended to delete the reference to the Agreement States.

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 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. However, a person who commercially distributes materials to another person for use under § 30.18 must first obtain a distribution license from NRC in accordance with § 32.18, ''Manufacture, distribution and transfer of exempt quantities of byproduct material: Requirements for license.''

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. However, there is no stated prohibition regarding such application by the end-user who is not commercially distributing the product.

NRC became aware that some persons holding byproduct material under the exemption in § 30.18 had been combining (bundling) multiple exempt quantities within an individual device that had not been evaluated and approved by the NRC. The devices were manufactured without radioactive material, but were designed to use multiple exempt quantity sources of byproduct material. After first becoming aware of the bundling issue, NRC originally determined in June 1994, that, under certain limited circumstances, 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 these devices could reach a point where a general or specific license would normally be required. If the bundled sources were considered exempt, NRC would have no mechanism to ensure their safe possession, use, and disposal. As a result, NRC issued a generic letter in 1999, ''NRC Generic Letter 99–01: Recent Nuclear Material Safety and Safeguards Decision on Bundling Exempt Quantities, May 3, 1999,'' to clarify that bundling was not appropriate under the existing regulation. This position is 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 believes that the regulations in § 30.18 should be amended to specifically prohibit bundling under the exemption. The proposed rule would revise 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 one year at the highest average concentration permitted in air for members of the general public in unrestricted areas at the time; 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. It was reasoned that 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, NRC cannot assure that the exposures would not exceed the levels originally intended under the exemption. In addition, there would be some potential that disposal of devices containing multiple exempt sources through ordinary commercial waste streams or metal recycling channels could result 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 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. Because NRC has no indication that significant exposures are resulting or will result from the continued use of the devices evaluated in 1994, the proposed amendment would allow continued use of those devices. This exclusion is intended to avoid imposing a regulatory burden on those persons 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. Generally, this has occurred because new technologies have made the use of radioactive material unnecessary or less cost-effective.

The Commission is proposing to delete exemptions for products that are no longer being used or manufactured, or to restrict further distribution while allowing for the continued possession and use of previously distributed items. These exemptions in part 30 are for: 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 (Sc-46) for sand consolidation in oil wells (§ 30.16). Of these, only the exemption for resins containing scandium could result in significant doses, which might be of concern, if it were used.

NUREG–1717 describes the various products covered by the individual exemptions in the second subsection of each section for a particular exemption. Some of the conclusions in that report concerning distribution are:

(1) On § 30.15(a)(2): It is believed that automobile lock illuminators containing H–3 (tritium) or promethium-147 have never been manufactured for commercial use;

(2) On § 30.15(a)(3): Tritium is not currently being used on balances of precision;

(3) On § 30.15(a)(4): It is believed that automobile shift quadrants containing tritium are not being manufactured, nor have they ever been manufactured, for commercial use;

(4) On § 30.15(a)(5): Apparently, domestic manufacture and import of marine compasses and other navigational instruments that contain tritium has ceased;

(5) On § 30.15(a)(6): Tritiated paint is not currently being used on thermostat dials and pointers, primarily because electronic displays are now available for illumination purposes. Neither are gaseous tritium light sources used for thermostat dials or pointers;

(6) On § 30.15(a)(10): Spark gap irradiators containing cobalt are designed to minimize spark delay in some electrically ignited commercial fuel-oil burners by generating free electrons in the spark gap. The irradiators are no longer being manufactured, only about 100 irradiators were in stock in 1994, and no plans had been made to distribute them for use. The original manufacturer is no longer in business. The number of irradiators actually distributed is unknown, but is not thought to be significant. [Note: there are products referred to as ''spark gaps'' or ''spark gap tubes,'' a category of electron tube, covered by the exemption in § 30.15(a)(8), which should not to be confused with the specific product covered by § 30.15(a)(10)]; and

(7) On § 30.16: Resins as the primary cementing media are no longer used.

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

The NRC expects that the distribution of thermostat dials or pointers, spark gap irradiators, and resins containing Sc-46 for sand consolidation in oil wells ceased so long ago that it is highly unlikely that any remain in use. This may or may not be the case for balances of precision and marine compasses distributed for use under § 30.15(a)(3) and (5). As noted, automobile lock illuminators and automobile shift quadrants were likely never commercially distributed for use under exemption. The exemptions for automobile lock illuminators, automobile shift quadrants, thermostat dials or pointers, spark gap irradiators, and resins containing Sc-46 for sand consolidation in oil wells would be removed. The exemptions for balances of precision and marine compasses and other navigational instruments would be retained for previously distributed products only. This language is not being retained for the other five exemptions considered obsolete. However, in the unlikely event that persons still possess any of these products, 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.

Specific requirements for manufacturers and initial distributors of products that are no longer being manufactured or distributed would also be deleted. These include § 32.17 for the manufacture or distribution of resins containing Sc-46 and the prototype test procedures for automobile lock illuminators specified in § 32.40 and required by § 32.14(d)(2).

In the case of the resins containing Sc-46 for sand consolidation, this action would provide assurance that health and safety are adequately protected from possible future distribution. Only preliminary dose estimates were made for this exemption. These preliminary estimates indicated a potential for exposures higher than is appropriate for materials being used under an exemption. However, the preliminary dose estimates were not refined or included in NUREG–1717, because the exemption was no longer being used.

Deleting these unnecessary provisions would simplify the regulations by eliminating extraneous text. Also, the Commission periodically reevaluates the exposure of the general public from all products and materials distributed for use under exemption, to ensure that the total contribution of these products to the exposure of the public will not exceed small fractions of the allowable limits. Eliminating obsolete exemptions would add to the assurance that future use of products in these categories would not contribute to exposures of the public and would also eliminate the need to reassess the potential exposure of the public from possible future distributions of the products.

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 commonly used in residences. These smoke detectors are currently used under the class exemption in § 30.20 for gas and aerosol detectors and equivalent regulations of the Agreement States. This class exemption was established in April 1969. Section 30.20 also covers chemical agent detectors and allows for new detectors with similar purposes to be licensed for distribution without a new exemption from licensing being established by rulemaking.

The specific requirements for obtaining a license to manufacture, process, produce, or initially transfer gas and aerosol detectors intended for use under § 30.20 are currently contained in § 32.26. Conditions of licenses are contained in § 32.29 including requirements for quality control, labeling, recordkeeping, and reporting of transfers. NRC's licensing of a new initial distributor of smoke detectors involves an evaluation to determine that certain safety criteria (contained in §§ 32.27 and 32.28) are met. The safety criteria for gas and aerosol detectors 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.

Residential ionization chamber smoke detectors and some similar smoke detectors have been manufactured and used for many years. Current designs are very consistent, using 0.9 to 1 μCi (33 to 37 kBq) of americium-241 (Am-241) contained in a foil, surrounded by an ionization chamber. Earlier designs used larger quantities of americium and, in some cases, other radionuclides. Residential ionization chamber smoke detectors (and similar detectors) represent a well established practice with consistency in the design of products and with extensive licensing experience. Potential doses from the distribution, use, handling, and disposal of these detectors has been estimated in NUREG/CR–1156, ''Environmental Assessment of Ionization Chamber Smoke Detectors Containing Am-241,'' November 1979, in NUREG–1717, and in various license applications. 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.

This proposed rule would establish a specific exemption from licensing requirements for ionization chamber smoke detectors containing no more than 1 μCi (37 kBq) of Am-241 in the form of a foil and designed to protect life and property from fires. This is intended to apply to ionization smoke detectors whose primary function is the protection of life and property. The exemption for ionization chamber smoke detectors would be added to § 30.15(a) as § 30.15(a)(7). The primary difference between this proposed exemption and the existing class exemption in § 30.20 is that an applicant for a license to distribute smoke detectors for use under this exemption would not be required to submit dose assessments to demonstrate that doses from the various stages of the life cycle of the product do not exceed certain values. The applicant would still be required to submit basic design information consistent with that required from applicants to distribute products for use under other product-specific exemptions, specifically for those products used under § 30.15. The requirements for applicants to distribute these products are contained in § 32.14. The primary emphasis of these requirements 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 under § 32.14 are contained in §§ 32.15 and 32.16. These latter requirements address quality assurance, labeling, recordkeeping, and reports of transfer. The labeling requirement for smoke detectors under the current regulation in § 32.29(b) is more specific than those in § 32.15(d). In order that the more specific labeling requirement be retained, essentially the same details would be added to § 32.15(d) as applicable specifically to ionization chamber smoke detectors. A minor change (*i.e.*, not referring to 10 CFR 32.27) would be made to be consistent with the new regulatory requirements.

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 in the SS & D. This is not the practice for products to be distributed for use under a product-specific exemption. Because of this, the proposed revision would also reduce both application and annual fees for distributors of smoke detectors. There is a separate application fee in § 170.31, associated with device review and registration, which would no longer apply. Also, in § 171.16, there are different annual fees based on whether a device has been evaluated for registration in the SS & D. The primary difference is the elimination of the fee for holding a registration certificate. For small entities, reduced fees apply; therefore, the affect of this change on fees would be smaller.

The effect of this change would be to reduce the regulatory burden and the fees for new applicants for licenses to distribute ionization chamber smoke detectors. Additionally, the change would reduce the NRC staff time needed to review these applications, because an evaluation of dose assessments would no longer be included. Current distributors of ionization chamber smoke detectors using no more than 1 μCi of Am-241 (37 kBq) may also amend their licenses and SS & D registrations to change the regulatory status of their products in order to reduce their annual fees. Given the wide distribution this product has already experienced, this change is not expected to affect the overall number of ionization chamber smoke detectors distributed in the future. Thus, a more efficient regulatory process would be used without any impacts to the health and safety of the public or the environment.

F. Specific Licensees and Generally Licensed Devices—Clarification

Following a revision to the general license provided by § 31.5 (65 FR 79161; Dec. 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. These transfers were made primarily to avoid the cost of the new registration fees for some of these devices in addition to their specific

license fees. There are also other, non-fee-related reasons why one would make such a transfer. 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, and as to exactly what is necessary to comply with existing requirements related to both types of license.

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 general license regulatory status of the device and provides safety instructions or reference to operating and service manuals. Instructions to the general licensee may not be appropriate for the use of the device under a specific license. For example, instructions may indicate that the general licensee may not conduct its own leak tests, but must have an appropriate specifically licensed service company do so. Also, under a specific license, different labeling requirements are applicable (§ 20.1904, ''Labeling containers''). It is not acceptable for a device being held under a specific license (SL) to be labeled in accordance with § 32.51(a)(3), i.e., a general license (GL) label. Thus, if a device is to be transferred from GL status to SL status, the label needs to be changed to comply with the appropriate labeling requirement.

A specific licensee would conduct its own maintenance activities including required leak tests, but may need information from the manufacturer concerning the appropriate methods for the particular device. This information may not have been provided to the entity as a general licensee, depending on the device and what has been determined to be appropriate activities for a general licensee. Thus, a specific licensee may need to contact the manufacturer to obtain the proper procedures for conducting required leak tests and other activities.

A specific licensee may have provisions in its license that authorize the quantities of the radionuclides used in a generally licensed device. The licensee needs to verify that the conditions of the specific license authorize the possession and use of the device or apply for an appropriate amendment to the license.

Paragraph (c)(8) of § 31.5 specifies acceptable specifically licensed recipients of devices covered by this general license and requires that a general licensee report to the NRC transfers of devices to specific licensees. The address for reporting includes an attention line to Document Control Desk/GLTS. GLTS refers to the General License Tracking System, which includes information on devices in use under §§ 31.5 and 31.7. In order for this database to be kept up-to-date, transfers to specific licensees must be reported and the devices removed from the database. Paragraph (c)(8)(iii) of § 31.5 requires written approval from the NRC for transfers to any specific licensee not identified in paragraph (c)(8)(i). Thus, a general licensee who wishes to transfer a device to any other specific licensee, even if that licensee is the same entity and the effect is only to transfer to a specifically licensed status, must obtain approval for the transfer. In this way, the NRC can verify that the specific license authorizes this use and can ensure that the licensee is fully aware of its responsibilities under both the general and specific license with respect to the device. In addition, the NRC can update the GLTS.

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

III. Early Agreement State Participation

The working group involved in the preparation of this proposed rule included a member who was appointed by the Organization of Agreement States (OAS), as well as the Conference of Radiation Control Program Directors (CRCPD). This proposed rule and its draft Environmental Assessment were also provided to the Agreement States during their development via the use of the NRC Technical Conference Forum Web site and notification to the States of their availability.

Two States provided comments. Both supported most of the proposed revisions but were concerned with NRC making revisions to the general license requirements in § 31.5. The State of Wisconsin noted particularly the revision to § 31.5(c)(8) and suggested that the NRC suspend the proposed revision of § 31.5 until the Commission has evaluated a recently submitted OAS petition for rulemaking to determine if the petition offers a better alternative. Illinois supported the revision of § 31.5(c)(8), but disagreed with another amendment to § 31.5 included in the draft proposed rule posted for Agreement state comment, which has not been retained in this proposed rule. Illinois also suggested revising the labeling requirements (in § 32.19(d)(2)) so that the label would state that exempt quantities ''shall'' not be combined (rather than ''should'').

The OAS petition referred to by Wisconsin suggests that those devices used under general license and covered by the registration requirement in § 31.5(c)(13), be required to be specifically licensed instead. If the Commission decides to grant the OAS petition, unregistered devices would still remain under a general license that may be transferred to the authority of a specific license. If the Commission decides to deny the OAS petition, both registered and unregistered devices would remain under a general license that may be transferred to the authority of a specific license. As a result, the NRC has determined that the actions suggested by the OAS petition, if taken, would not negatively impact the proposed change in this action; the issues are sufficiently independent that the NRC does not believe this change should await resolution of the petition.

The labeling requirement in § 32.19(d) is a notification from a licensee to a non-licensee. The label provides information to the user; however, this direction is not enforceable. A revision to the exemption in § 30.18 itself is being proposed in order to make the intent demonstrated by the labeling requirement more enforceable. Amending the labeling requirement would not do so and would impose a cost on licensees who commercially distribute exempt quantities with no real effect.

IV. Summary of Proposed Amendments by Section

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

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

10 CFR 30.15(a)—Would (1) remove exemptions for automobile lock illuminators, automobile shift quadrants, thermostat dials and pointers, and spark gap irradiators; (2) limit the exemptions for balances of precision and marine compasses and other navigational instruments to products previously distributed; and (3)

add an exemption for ionization chamber smoke detectors containing no more than 1 μCi of Am-241 in a foil.

10 CFR 30.16—The exemption for resins containing Sc-46 for sand consolidation in oil wells would be removed.

10 CFR 30.18—Would revise the exempt quantities provision by adding an explicit prohibition in a new paragraph (e) against combining sources to create an increased radiation level.

10 CFR 31.5(c)(8)(ii)—Would resolve a minor ambiguity with respect to addressing reports.

10 CFR 31.5(c)(8)(iii)—Would revise transfer provisions to explicitly state actions necessary for transfer of devices from general license to specific license status and remove the need for written NRC approval in that case.

10 CFR 32.11(a)—Would be revised to exempt Agreement State licensees from § 30.33(a)(2) and (3).

10 CFR 32.12—Would revise the period of reporting for material transfers to annual and make minor changes to the content of reports.

10 CFR 32.13—Would revise the prohibition on introducing exempt concentrations to apply to all persons except those authorized by an NRC license.

10 CFR 32.14(d)—Would remove the reference to § 32.40.

10 CFR 32.15(d)—Would add specific labeling requirements for smoke detectors distributed for use under § 30.15 consistent with that currently applicable under the gas and aerosol detector provisions in § 32.29.

10 CFR 32.16—Would revise the period of reporting for material transfers to annual, make minor changes to the content of reports, and remove reference to § 32.17.

10 CFR 32.17—Requirements for distribution of resins containing Sc-46 for sand consolidation in oil wells would be removed.

10 CFR 32.20—Would revise the period of reporting for material transfers to annual and make minor changes to the content of reports.

10 CFR 32.25(c)—Would revise the period of reporting for material transfers to annual and make minor changes to the content of reports.

10 CFR 32.29(c)—Would revise the period of reporting for material transfers to annual and make minor changes to the content of reports.

10 CFR 32.40—Prototype test requirements for automobile lock illuminators would be removed.

10 CFR 150.20(b)—Would remove 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 (AEA), the Commission is proposing 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 would be subject to criminal enforcement.

VI. Agreement State Compatibility

Under the ''Policy Statement on Adequacy and Compatibility of Agreement State Programs'' which became effective on September 3, 1997 (62 FR 46517), NRC program elements (including regulations) are placed into compatibility categories A, B, C, D, NRC or adequacy category H&S. Compatibility Category A are those program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt category A program elements in an essentially identical manner in order to provide uniformity in the regulation of agreement material on a nationwide basis. 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 Category 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, above, 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 Atomic Energy Act of 1954, as amended, or provisions of Title 10 of the Code of Federal Regulations. These program elements should not be adopted by the Agreement States. Health and Safety (H&S) are program elements that are required because of a particular health and safety role in the regulation of agreement material within the State and should be adopted in a manner that embodies the essential objectives of the NRC program.

The proposed rule would be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements. The revisions to parts 30 and 31 would be classified as Compatibility Category B and the revisions to §§ 32.13 and 150.20 would be classified as Category C. Sections 32.11 and 32.12 would be changed from Compatibility Categories C/B and C respectively to Category NRC. Section 32.17 is Compatibility Category B. Sections 32.15, 32.16, 32.20, 32.25, and 32.29 are classified as Compatibility Category NRC. The existing compatibility designation for these regulations are not affected.

Specific information about the compatibility or health and safety components assigned to this rule may be found at the Office of State and Tribal Programs Web site, *http://www.hsrd.ornl.gov/nrc/home.html.*

VII. Plain Language

The Presidential Memorandum dated June 1, 1998, entitled, ''Plain Language in Government Writing'' directed that the Government's writing be in plain language. This memorandum was published on June 10, 1998 (63 FR 31883). The NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the **ADDRESSES** heading above.

VIII. 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. In this proposed rule, the NRC would amend its regulations governing the use of byproduct material to revise reporting of transfers to persons exempt from licensing, simplify the licensing of smoke detector distribution, remove obsolete provisions, and make some clarifications to the regulations. None of these actions constitute the establishment of a standard that establishes generally applicable requirements.

IX. 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, not to prepare an environmental impact statement for this proposed rule because the Commission has concluded on the basis of an environmental assessment that this proposed rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment. The following is a summary of the Environmental Assessment: Many of the individual actions being proposed are the type of actions described in the categorical exclusions of § 51.22(c)(1) and (3). In addition, the proposed rule would remove provisions applicable to practices that no longer exist, establish a separate exemption from licensing for ionization smoke detectors containing no more than 1 μCi of americium-241, explicitly prohibit combining exempt quantity sources, and require NRC licensing of the introduction of exempt concentrations into products and materials. The removal of unused provisions would not result in a change to any practices except to ensure that these activities do not resume in the future without reconsideration by the Commission. The new exemption for smoke detectors is not expected to have any impact on the design or number of smoke detectors distributed to the public. The prohibition on combining exempt quantities reinforces the intent of existing regulations. The safety standards related to the exempt concentration provisions would not change. The Commission has concluded that none of these actions would have any significant impacts to the environment or otherwise include any condition requiring consultation under section 102(2)(C) of NEPA.

The determination of the Environmental Assessment for this proposed rule is that there will be no significant impact to the public or the environment from this action. However, the general public should note that the NRC welcomes public participation. Comments on any aspect of the Environmental Assessment may be submitted to the NRC as indicated under the **ADDRESSES** heading.

The NRC has sent a copy of the Environmental Assessment and this proposed rule to every State Liaison Officer and requested their comments on the Environmental Assessment. The Environmental Assessment may be examined at the NRC Public Document Room, O–1F23, 11555 Rockville Pike, Rockville, MD. Single copies of the Environmental Assessment are available from Andy Imboden of the Office of Nuclear Material Safety and Safeguards, telephone (301) 415–6128, e-mail, *asi@nrc.gov.*

X. Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The proposed rule makes minor revisions to the burdens on licensees for reporting and recordkeeping under §§ 31.5, 32.12, 32.16, 32.20, 32.25(c), and 32.29(c). It reduces the burden for new applicants to distribute ionization chamber smoke detectors by allowing them to obtain licenses under § 32.14 rather than § 32.26. The public burden for this information collection is estimated to average 1 hour. Because the burden for these revisions to the information collections is insignificant, Office of Management and Budget (OMB) clearance is not required. Existing requirements were approved by the Office of Management and Budget, approval numbers 3150–0001, 3150–0014, 3150–0016, and 3150–0120.

Send comments on any aspect of this collection of information, including suggestions for reducing the burden, to the Information and Records Management Branch (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by e-mail to *bjs1@nrc.gov*.

XI. 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.

XII. Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission.

The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the **ADDRESSES** heading. The analysis is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD. The regulatory analysis can also be viewed and downloaded electronically via the NRC rulemaking Web site at *http://ruleforum.llnl.gov*. Single copies of the regulatory analysis are available from Catherine R. Mattsen, telephone (301) 415–6264, e-mail, *crm@nrc.gov* of the Office of Nuclear Material Safety and Safeguards.

XIII. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. A significant number of the licensees affected by this action would meet the definition of ''small entities'' set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121. However, none of the proposed revisions to the regulatory program would result in a significant economic impact on the affected entities.

XIV. Backfit Analysis

NRC has determined that the backfit rule does not apply to this proposed rule; therefore, a backfit analysis is not required for this proposed rule because it does not involve any provisions that would impose backfits as defined in Chapter I.

List 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. 553; the NRC is proposing to adopt 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 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 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]

4. Section 30.16 is removed.

5. 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

6. 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).

7. In § 31.5, paragraphs (c)(8)(ii) and (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.

* * * * *

(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 Nuclear Material Safety and Safeguards 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—

(A) The identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number;

(B) The name, address, and license number of the person receiving the device (license number not applicable if exported); and

(C) The date of the transfer.

(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 and obtains an amendment to the license authorizing the possession and use;

(B) Removes the label otherwise required by paragraph (c)(1) of this section and replaces it with an appropriate label to comply with § 20.1904 of this chapter;

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

8. 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).

9. 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;

* * * * *

10. 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 Nuclear Material Safety and Safeguards 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 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 a period of one year after the transfer is included in a report to the Commission.

11. 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.

12. 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.

13. 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.

14. 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 Nuclear Material Safety and Safeguards 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;

(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 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 a period of one year after the transfer is included in a report to the Commission.

§ 32.17 [Removed]

15. Section 32.17 is removed.

16. 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 chemical and physical form of byproduct material transferred.

(b) The licensee shall file a summary report with the Director of Nuclear Material Safety and Safeguards 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 chemical and physical form, the report shall indicate the total quantity of each radionuclide and the chemical and 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 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 § 32.18 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 a period of one year after the transfer is included in a summary report to the Commission.

17. 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 Nuclear Material Safety and Safeguards 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 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 a period of one year after the transfer is included in a report to the Commission.

18. 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 Nuclear Material Safety and Safeguards 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 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 a period of one year after the transfer is included in a report to the Commission.

§ 32.40 [Removed]

19. Section 32.40 is removed.

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

20. 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).

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

§ 150.20 Recognition of Agreement State licensing.

* * * * *

(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 28th day of December, 2005.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 06–19 Filed 1–3–06; 8:45 am]

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DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Chapter I

[Docket No. 05–22]

Office of Thrift Supervision

12 CFR Chapter V

[No. 2005–53]

FEDERAL RESERVE SYSTEM

12 CFR Chapter II

[Docket No. R–1243]

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Chapter III

Request for Burden Reduction Recommendations; Rules Relating to Prompt Corrective Action and the Disclosure and Reporting of CRA-Related Agreements; Economic Growth and Regulatory Paperwork Reduction Act of 1996 Review

AGENCIES: Office of the Comptroller of the Currency (OCC), Treasury; Board of Governors of the Federal Reserve System (Board); Federal Deposit Insurance Corporation (FDIC); and Office of Thrift Supervision (OTS), Treasury.

ACTION: Notice of regulatory review; request for comments.

SUMMARY: The OCC, Board, FDIC and OTS (''we'' or ''the Agencies'') are reviewing our regulations to identify outdated, unnecessary, or unduly burdensome regulatory requirements pursuant to the Economic Growth and Regulatory Paperwork Reduction Act of 1996 (EGRPRA). Today, we request your comments and suggestions on ways to reduce burden with respect to rules regarding Prompt Corrective Action and the Disclosure and Reporting of CRA-Related Agreements, which are in the Capital and Community Reinvestment Act categories of regulations. All comments are welcome. We specifically invite comment on the following issues: whether statutory changes are needed; whether the regulations contain requirements that are not needed to serve the purposes of the statutes they implement; the extent to which the regulations may adversely affect competition; whether the cost of compliance associated with reporting, recordkeeping, and disclosure requirements, particularly on small institutions, is justified; whether any regulatory requirements are inconsistent or redundant; and whether any regulations are unclear.

This is our last request for comment on categories of regulations in the first 10-year cycle of regulatory review under EGRPRA. We will analyze the comments received and propose burden-reducing changes to our regulations where appropriate. Some of your suggestions for burden reduction might require legislative changes. Where legislative changes would be required, we will consider your suggestions in recommending appropriate changes to Congress.

DATES: Written comments must be received no later than April 4, 2006.

ADDRESSES: You may submit comments by any of the following methods:

EGRPRA Web site: *http://www.EGRPRA.gov*

- Comments submitted at the Agencies' joint Web site will automatically be distributed to all the Agencies. Comments received at the EGRPRA Web site and by other means will be posted on the Web site to the extent possible.

Individual agency addresses: You are also welcome to submit comments to the Agencies at the following contact points (due to delays in paper mail delivery in the Washington area, commenters may prefer to submit their comments by alternative means):

OCC: You should include OCC and Docket Number 05–22 in your comment. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *OCC Web Site: http://www.occ.treas.gov.* Click on ''Contact the OCC,'' scroll down and click on ''Comments on Proposed Regulations.''
- *E-mail address: regs.comments@occ.treas.gov.*
- *Fax:* (202) 874–4448.
- *Mail:* Office of the Comptroller of the Currency, 250 E Street, SW., Mail Stop 1–5, Washington, DC 20219.
- *Hand Delivery/Courier:* 250 E Street, SW., Attn: Public Information Room, Mail Stop 1–5, Washington, DC 20219.

Instructions: All submissions must include the agency name (OCC) and docket number or Regulatory Information Number (RIN) for this notice of proposed rulemaking. In general, OCC will enter all comments received into the docket without change, including any business or personal information that you provide. You may review comments and other