considered that in the absence of an initial recommendation from the NOSB to permit the addition of nonsynthetic colors as a broad category that they could not continue to permit the exemption of nonsynthetic colors on § 205.605(a). As a result, the NOSB voted not to renew the exemption of nonsynthetic colors on § 205.605(a).

F. Effective Date

This final rule reflects recommendations submitted to the Secretary by the NOSB for the purpose of fulfilling the requirements of 7 U.S.C. 6517(e) of the OFPA. 7 U.S.C. 6517(e) requires the NOSB to review each substance on the National List within 5 years of its publication. The substances being reauthorized for use on the National List were initially authorized for use or prohibition in organic agriculture on October 21, 2002. Because these substances are critical to organic production and handling operations, producers and handlers should be able to continue to use them beyond their 5-year expiration date of October 21, 2007. Accordingly, this rule shall be effective on October 21, 2007.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

■ For the reasons set forth in the preamble, 7 CFR part 205, Subpart G is amended as follows:

PART 205—NATIONAL ORGANIC PROGRAM

■ 1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501–6522.

■ 2. Section 205.603 is revised to read as follows:

§ 205.603 Synthetic substances allowed for use in organic livestock production.

In accordance with restrictions specified in this section the following synthetic substances may be used in organic livestock production:

(a) As disinfectants, sanitizer, and medical treatments as applicable.

(1) Alcohols.

(i) Ethanol-disinfectant and sanitizer only, prohibited as a feed additive.

(ii) Isopropanol-disinfectant only.

(2) Aspirin-approved for health care use to reduce inflammation.

(3) Biologics—vaccines.

(4) Chlorhexidine—allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

(5) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite.

(ii) Chlorine dioxide.

(iii) Sodium hypochlorite.

(6) Electrolytes—without antibiotics.

(7) Glucose.

(8) Glycerine—allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.

(9) Hydrogen peroxide.

(10) Iodine.

(11) Magnesium sulfate.

(12) Oxytocin—use in postparturition therapeutic applications.

(13) Paraciticides. Ivermectin-prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.

(14) Phosphoric acid—allowed as an equipment cleaner, *Provided,* That, no direct contact with organically managed livestock or land occurs.

(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(1) Copper sulfate.

(2) Iodine.

(3) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

(4) Lime, hydrated—as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes.

(5) Mineral oil—for topical use and as a lubricant.

(6) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

(c) As feed supplements. None.

(d) As feed additives.

(1) DL–Methionine, DL–Methionine-hydroxy analog, and DL–Methionine-hydroxy analog calcium (CAS #59–51–8; 63–68–3; 348–67–4) for use only in organic poultry production until October 21, 2008.

(2) Trace minerals, used for enrichment or fortification when FDA approved.

(3) Vitamins, used for enrichment or fortification when FDA approved.

(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or a synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(1) EPA List 4—Inerts of Minimal Concern.

(2) [Reserved]

(f)–(z) [Reserved]

§ 205.605 [Amended]

■ 3. In § 205.605, substances ''colors, nonsynthetic sources only'' is removed from paragraph (a) and the substance ''Potassium tartrate made from tartaric acid'' is removed from paragraph (b).

Dated: October 10, 2007.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E7–20326 Filed 10–15–07; 8:45 am]

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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.

DATES: *Effective Date:* This final rule is effective on December 17, 2007.

FOR FURTHER INFORMATION CONTACT: 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.*

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, 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

[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.

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.

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., 1 year after transfers are included in a report, will be up to 4 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

[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.

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).

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 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.

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

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

[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.

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 an 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 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.

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 must 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.

Another issue when transferring a generally licensed device to the authority of a specific license concerns maintenance. A specific licensee who plans to conduct its own maintenance activities, including required leak tests, must have information concerning the appropriate methods particular to the device. This information may 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 transfers a generally licensed device to the authority of its specific license and does not already have this information, 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.

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 Materia''

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, which currently reads: ''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. The final rule was published October 1, 2007 (72 FR 55863). When the revised definition becomes effective November 30, 2007, 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 Generally Licensed Devices

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 must 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 change 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 provides program-specific guidance about exempt distribution products. Interim staff guidance to supplement NUREG–1556, Vol. 8 is to be provided to reflect the revisions made by this final rule. The changes to the guidance needed as a result of this rulemaking are relatively minor and will be provided in the interim staff guidance 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, and the reference to § 30.14(d).

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); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

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 December 17, 2007.

(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 December 17, 2007.

(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); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

■ 7. In § 31.5, paragraph (c)(8)(ii) introductory text 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.[5]

* * * * *

(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—

* * * * *

(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

■ 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); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

■ 9. 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,

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

32.54, 32.55, 32.56, 32.57, 32.58, 32.61, 32.62, 32.71, 32.72, 32.74, and 32.210.

* * * * *

■ 10. 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;

* * * * *

■ 11. 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 December 17, 2007, 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.

■ 12. 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.

■ 13. 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.

■ 14. 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.

■ 15. 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 product 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 December 17, 2007, 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]

■ 16. Section 32.17 is removed.

■ 17. 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 December 17, 2007, 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.

■ 18. 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 December 17, 2007, 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.

■ 19. 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 December 17, 2007, 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]

■ 20. Section 32.40 is removed.

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

■ 21. 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); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

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).

■ 22. In § 150.20, paragraph (b) introductory text, and paragraph (b)(3) are revised to read as follows:

§ 150.20 Recognition of Agreement State licenses.

* * * * *

(b) Notwithstanding any provision to the contrary in any specific license issued by an Agreement State to a person engaging in activities in a non-Agreement State, in an area of exclusive Federal jurisdiction within an Agreement State, or in offshore waters under the general licenses provided in this section, the general licenses provided in this section are subject to all the provisions of the Act, now or hereafter in effect, and to all applicable rules, regulations, and orders of the Commission including the provisions of §§ 30.7(a) through (f), 30.9, 30.10, 30.34, 30.41, and 30.51 through 30.63 of this chapter; §§ 40.7(a) through (f), 40.9, 40.10, 40.41, 40.51, 40.61 through 40.63, 40.71, and 40.81 of this chapter; §§ 70.7(a) through (f), 70.9, 70.10, 70.32, 70.42, 70.52, 70.55, 70.56, 70.60 through 70.62 of this chapter; §§ 74.11, 74.15, and 74.19 of this chapter; and to the provisions of 10 CFR parts 19, 20 and 71 and subparts C through H of part 34, §§ 39.15 and 39.31 through 39.77 of this chapter. In addition, any person engaging in activities in non-Agreement States, in areas of exclusive Federal jurisdiction within Agreement States, or in offshore waters under the general licenses provided in this section:

* * * * *

(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 3rd day of October 2007.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. E7–19944 Filed 10–15–07; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2007–28922; Directorate Identifier 2007–NM–132–AD; Amendment 39–15225; AD 2007–21–07]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A310 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

An incident occurred on one A300–600 aircraft at parking brake application. Both engines were running, the aircraft started moving again despite parking brake application. Captain tried to stop the aircraft via the pedals but, as the parking brake selector valve was selected, the aircraft could not be stopped (as per design, activation of the parking brake inhibits the other braking modes, and consequently prevents the recovery of the normal braking through the pedals). As part of the investigation, the pressure limiter was removed and examined. The expertise revealed a metallic wire aimed at reducing the section of one port of this equipment was found broken. A part of this wire partially obstructed the hole receiving this wire, thus delaying the build up of parking brake pressure.

We are issuing this AD to require actions to correct the unsafe condition on these products.

DATES: This AD becomes effective November 20, 2007.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of November 20, 2007.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tom Stafford, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–1622; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on August 16, 2007 (72 FR 45976). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

An incident occurred on one A300–600 aircraft at parking brake application. Both engines were running, the aircraft started moving again despite parking brake application. Captain tried to stop the aircraft via the pedals but, as the parking brake selector valve was selected, the aircraft could not be stopped (as per design, activation of the parking brake inhibits the other braking modes, and consequently prevents the recovery of the normal braking through the pedals). As part of the investigation, the pressure limiter was removed and examined. The expertise revealed a metallic wire aimed at reducing the section of one port of this equipment was found broken. A part of this wire partially obstructed the hole receiving this wire, thus delaying the build up of parking brake pressure. In order to avoid recurrence of the failure mode described above, EASA issued Airworthiness Directive (AD) 2006–0178 to require the replacement of the parking brake pressure limiter (FIN 323292).

During embodiment of SB (Service Bulletin) 32–2133 on an A310 as per AD 2006–0178 (EASA AD 2006–0178 corresponds to FAA AD 2007–02–21, amendment 39–14908), an operator reported that the modified pressure limiter could not be fitted. Subsequent investigation concluded that A310 installation being slightly different from A300–600 aircraft, the approved solution was not directly adaptable to A310 aircraft.