[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 31, 32, 40, and 70

RIN 3150-AH91

[NRC-2008-0338]

Requirements for Distribution of Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U. S. Nuclear Regulatory Commission (NRC or the Commission) is amending its regulations to make requirements for distributors of byproduct material clearer, less prescriptive, and more risk-informed and up to date. The Commission is also redefining categories of devices to be used under exemptions, adding explicit provisions regarding the sealed source and device registration process, and adding flexibility to the licensing of users of sealed sources and devices. This action is primarily intended to make licensing processes more efficient and effective. These changes will affect manufacturers and distributors of sources and devices containing byproduct material and future users of some products currently used under a general or specific license.

DATES: *Effective Date:* This final rule is effective on **[INSERT DATE 90 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*].**

ADDRESSES: Please refer to Docket ID NRC-2008-0338 when contacting the NRC about the availability of information for this final rule. You may access information and comment submittals related to this final rulemaking, which the NRC possesses and are publicly available, by any of the following methods:

- **Federal Rulemaking Web Site:** Go to http://www.regulations.gov and search for Docket ID NRC-2008-0338.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may access publicly available documents online in the NRC Library at http://www.nrc.gov/reading-rm/adams.html. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

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SUPPLEMENTARY INFORMATION:

I. Background.

A. Introduction.

The Commission has authority to issue both general and specific licenses for the use of byproduct material and also to exempt byproduct material from regulatory control under Section 81 of the Atomic Energy Act of 1954, as amended (hereafter, "the Act" or the AEA). A general license is provided by regulation, grants authority to a person for particular activities involving byproduct material as described within the general license, and is effective without the filing of an application with the Commission or the issuance of a licensing document to a particular person. Requirements for general licensees appear in the regulations and are designed to be commensurate with the specific circumstances covered by each general license.

A specific license is issued to a named person who has filed an application with the Commission.

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." (Section 81(a) of the Act, 42 U.S.C. 2111.) As beneficial uses of radioactive material were developed and experience grew, new products intended for use by the general public were invented and the regulations were amended to accommodate the use of new products.

Although presenting very low risks of significant individual doses to members of the general public, exempt products are a source of routine exposure to the public. A substantial portion of the population uses and enjoys benefits from exempt products, such as smoke detectors, but also receives some radiation exposure from those products. In keeping with its consumer product policy, which calls for the Commission to evaluate the total effect of consumer products on the public, the Commission conducted a systematic reevaluation of the exemptions from licensing. A major part of the effort was an assessment of the potential and likely doses to workers and the public under these exemptions. Dose assessments for most of these exemptions can be found in NUREG-1717[1], "Systematic Radiological Assessment of

[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 or see: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1717/.

Exemptions for Source and Byproduct Materials," June 2001. Actual exposures of the public likely to occur are in line with Commission policy concerning acceptable doses from products and materials used under exemptions. For some exemptions, there was a significant difference between potential and likely doses because the use of the exemption is limited or nonexistent, or significantly lower quantities are used in products than is potentially allowed under the exemption.

The NRC has reviewed the regulations governing the distribution of byproduct material to persons for use under the exemptions, as well as other regulations governing distribution of products containing byproduct material. The Commission decided to make these regulations more flexible, user-friendly, and performance-based, and to improve its ability to risk-inform its regulatory program. These concepts were considered in developing potential revisions to the regulatory program in the area of distribution of byproduct material.

In a final rule published October 16, 2007 (72 FR 58473), some of these revisions that could be more readily completed were made, including the removal of obsolete exemptions. This action is a follow-on to that effort for revisions that required more detailed development. To make optimal use of rulemaking resources, both for the NRC and the Agreement States who must develop conforming regulations, several issues have been combined into this rule. The proposed rule containing these amendments was published for public comment in the *Federal Register* on June 24, 2010 (75 FR 36212). The public comment period closed September 7, 2010. Ten comment letters were received. The NRC has considered these comments in this final rule.

B. Regulatory Framework.

The Commission's regulations in part 30 of Title 10 of the *Code of Federal Regulations* (10 CFR) contain the basic requirements for licensing of byproduct material. Part 30 includes a number of provisions that exempt the end user from licensing requirements, so-called "exemptions." Some exemptions are product-specific, intended only for specific purposes which are narrowly defined by regulation. More broadly defined are the general materials exemptions, which allow the use of many radionuclides in many chemical and physical forms subject to limits on activity, and which are specified in §§ 30.14 and 30.18 for exempt concentrations and exempt quantities, respectively. The Commission's regulations currently 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. In the case of class exemptions, many products can be approved for use through the licensing process if the applicant for a distribution license demonstrates that the specific product is within the class and meets certain radiation dose criteria.

Part 31 of 10 CFR provides general licenses for the use of certain items containing byproduct material and the requirements associated with these general licenses.

Part 32 of 10 CFR sets out requirements for the manufacture or initial transfer (distribution) of items containing byproduct material to persons exempt from licensing requirements and to persons using a general license. It also includes requirements applicable to certain manufacturers and distributors of products and materials to be used by specific licensees. The requirements for manufacturers and initial transferors (distributors) address such measures as prototype testing, labeling, reporting and recordkeeping, quality control, and, in some cases, specific sampling procedures.

II. Discussion.

This final rule is making 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. The changes are intended to improve the efficiency and effectiveness of certain licensing actions.

A. Actions Related to Sealed Source and Device Registration.

A.1 Updating Regulations to Add Registration Requirements

Section 32.210 provides for the registration of sealed sources and devices containing sealed sources intended for use under a specific license. Manufacturers or distributors may submit a request to the NRC for an evaluation of radiation safety information for a product and for registration of the product. After satisfactory completion of the evaluation, the NRC issues a certificate of registration to the person making the request. Subsequently, under § 30.32(g), specific licensees or applicants for a specific license who wish to use the registered product need only identify the source or device by manufacturer and model number, as registered with the Commission under § 32.210 or with an Agreement State, in their applications. Because the source or device has already been evaluated and its safety information is a matter of record, the users are not required to submit the detailed radiation safety information for the source or device in their license applications. This greatly simplifies the licensing process for the users of specifically licensed sources and devices. The registration system is referred to as the Sealed Source and Device (SS & D) Registry. Many Agreement States have a similar registration process. Registration certificates for the sources and devices reviewed and approved by the

Agreement States are also added to the national SS & D Registry. However, some Agreement States do not include the evaluation and registration of sealed sources and devices in their agreements; in these cases, authority for these reviews remains under NRC regulatory jurisdiction.

A definition of the registry is included in § 35.2 as follows: "*Sealed Source and Device Registry* means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product." This definition is being added to part 32 by this action, as the information requirements for the SS & D review and registration are in part 32. The SS & D Registry is maintained in a computer database, which is available to the Agreement States, as well as U. S. government agencies and some foreign regulators. While this process, in which the manufacturer or initial distributor obtains a registration certificate for the source or device, is generally used for most specifically licensed sources and devices, in some cases of custom-made sources or devices, the planned user will sometimes submit the detailed radiation safety information. As a matter of licensing practice, such a custom device, if containing more than certain quantities of radioactive material, is also registered; however, it only allows for the use of the custom-made source or device by the specified user. As § 30.32(g) requires the radiation safety information to be submitted by applicants to use sealed sources and devices if they are not registered, manufacturers and distributors generally register the sources and devices that are to be used under a specific license. Sealed source or device review and registration are conducted for most sealed sources and devices to be used under a specific license.

This registration process has also been extended to many generally licensed and some exempt products. The regulations in part 32 contain requirements for submittal of radiation

safety information concerning these products by the manufacturer or initial distributor. Although registration of these products by the manufacturer or initial distributor was not previously addressed by the regulations, the NRC's licensing practice has been to issue registration certificates for certain of these products based on the radiation safety information submitted. Also, fees are assessed based on whether or not a "sealed source and/or device review" is required.

The products in each of these categories for which the registration process has been used as part of the licensing process have been indicated in guidance, e.g., NUREG-1556, Vol. 3, Rev. 1, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration"; NUREG-1556, Vol. 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses"; and NUREG-1556, Vol. 16, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees." For a number of categories of specifically licensed sources and devices, an explicit requirement for registration is included in the regulations. Existing specific requirements include §§ 35.400, 35.500, 35.600, 36.21, and 39.41(f). These concern certain medical use products, sealed sources installed in irradiators after July 1, 1993, and energy compensation sources (a specific type of reference source used in well logging).

The only products used under exemption from licensing for which the NRC issues registration certificates are those distributed for use under a "class exemption." As noted earlier, a class exemption allows for the use under exemption of a category of products with the safety decision for individual products made through the licensing process. The safety review for these products includes evaluating the product against specific safety criteria contained in the regulations in part 32. The regulations currently contain two class exemptions. These are found in § 30.19, Self-luminous products containing tritium, krypton-85, or promethium-147, and

§ 30.20, Gas and aerosol detectors containing byproduct material, and equivalent Agreement State regulations. As discussed later in this document, this rule establishes a third class exemption for certain industrial products.

In the case of generally licensed products, sealed source and device registration certificates have been issued for products distributed for use under §§ 31.3, 31.5, 31.7, and 31.10, and equivalent Agreement State regulations. (Note that this registration is distinct and different in scope and purpose from the registration of devices by some general licensees under § 31.5(c)(13).)

Neither general licensees nor persons exempt from licensing requirements need to submit any safety information in order to obtain a product. For these products, however, the registration process also serves the important purpose of providing information to the regulators in all jurisdictions. Products are approved by the NRC and, in some cases, by the various Agreement States for distribution to all jurisdictions. For those products that are registered by the manufacturer or distributor, the registration information is available to the NRC and to the Agreement States through the SS & D Registry. In this way, the various jurisdictions can be assured of the radiation safety of the products being used under their regulations that have been evaluated by another jurisdiction. The registration of products by model number also assists in the tracking of generally licensed devices by the NRC and the Agreement States. In some cases, a secondary distributor of a generally licensed device may refer to the registration certificate obtained by the manufacturer, or more frequently a source to be installed in a generally licensed device may be manufactured by a different entity who has registered the source separately.

For those products used under a product-specific exemption, for which registration certificates are not issued, the safety of the product has been evaluated based primarily on the constraints contained in the regulations, such as a quantity limit for a specific radionuclide, and

what can be projected about the life cycle of the product and how it is used. Some of these evaluations are documented in NUREG/CR-1775, "Environmental Assessment of Consumer Products Containing Radioactive Material," October 1980 (ADAMS Accession No. ML082910862), and NUREG-1717. The applicable requirements in § 32.14(b) require information to be submitted to allow an evaluation of the potential radiation exposure and, in accordance with § 32.14(d), the NRC makes a determination 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." But the information to support this evaluation of the particular product is not considered necessary to routinely provide to the Agreement States through the SS & D Registry.

No sealed source and device review is conducted for the products used under the general licenses in §§ 31.8 or 31.11. The general license in § 31.8 is specifically for no more than 0.185 MBq (5 μCi)[1] of americium-241 or radium-226 in the form of calibration and reference sources, and applies only to specific licensees. The safety of these sources is also well established, with the individual product being reviewed and approved in the licensing process. The general license in § 31.11 pertains to in-vitro clinical or laboratory testing using prepackaged units containing certain limited quantities of byproduct material, e.g., iodine-125 in units not exceeding 10 μCi (0.37 MBq). These in-vitro kits are not sealed sources or devices. They can be used only by physicians, clinical laboratories, hospitals, and practitioners of veterinary medicine who preregister with the Commission and by part 35 licensees. There is also no SS & D registration for the recently added general license in § 31.12, which covers only items produced prior to the NRC gaining jurisdiction over radium-226. Because there is no

[1] The NRC's policy on units calls for new and amended regulations to use the International System of Units (SI) with the English unit equivalent following in parentheses. In this document, a number of references are made to existing regulations that are currently in English units; in referencing such values, the actual regulatory value is given first with the SI unit equivalent, sometimes a rounded approximation, following in parentheses. Also, when discussing comments, units used by the commenter are used.

allowance for future production of items to be used under this general license, there are no associated distributor requirements and thus, no requirement for a product to be registered in the SS & D Registry. These products are mostly antiquities produced before States had regulations similar to NRC's.

Registration certificates are issued for most specifically licensed sealed sources and devices. The exceptions are for small calibration and reference sources and for sources and devices to be used by 1) broad scope licensees under 10 CFR part 33 and equivalent Agreement State regulations, 2) research and development licensees, and 3) licensees for whom the source or device was built to their unique specifications and contain no more than 740 GBq (20 Ci) of tritium or 7.4 GBq (200 mCi) of any other radionuclide. These three categories of licensees must be qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form as indicated in their license(s). Under these circumstances, licensing these three types of users does not rely on the inherent safety features of the source or device; users will be evaluated under the criteria in § 30.33(a)(2) and (3) and licensed to handle equivalent quantities of the materials in any form. If the source is registered but not the device, the users must be licensed to handle equivalent quantities of the materials in unshielded form.

For specifically licensed calibration and reference sources, the quantity cutoffs being established for small sources excluded from the requirement for registration are 0.37 MBq (10 μCi) for alpha emitters and 37 MBq (1 mCi) for beta and/or gamma emitters. This is a simplification from previous licensing practice, which used a limit of 3.7 MBq (100 μCi) or 10 times the quantity specified in § 30.71, whichever is greater, for beta and/or gamma emitters. The limits using that guidance for beta/gamma emitters range from 3.7 MBq (100 μCi) to 370 MBq (10 mCi). Thus, for any particular radionuclide, the new criterion is no more than 10 times higher to 10 times lower than previous practice. As certificates typically cover a large

number of radionuclides for this type of sealed source, this change is not expected to affect the overall number of registration certificates issued.

This final rule explicitly adds registration requirements to the regulations for byproduct material in products used under certain general licenses and under certain exemptions from licensing requirements, as well as for additional specifically licensed sources and devices for which this is not currently addressed by the regulations. This will make it easier for potential applicants for a license to distribute these products to determine the applicable requirements and associated fees. These provisions are in large part consistent with previous licensing practice and appear in §§ 32.22(a)(3)(ii), 32.26(c)(2), 32.30(c)(3), 32.51(a)(6), 32.53(f), 32.61(g), 32.74(a)(4), and 32.210.

A.2 Adding Provisions for Amendment, Modification and Revocation, Review, and Inactivation of Registration Certificates

The Commission is adding a number of other explicit provisions to the regulations concerning sealed source and device registration certificates. Many certificates are revised and updated from time to time as a result of amendment requests made by manufacturers or distributors to accommodate desired changes in a product or associated procedures or to add new products to a registration certificate covering a series of models. Sections 30.38 and 30.39, which previously addressed only amendment of licenses, are being revised to also address amendment of registration certificates. The final rule is also revising § 30.38 to remove the requirement to use Form NRC-313 for requesting amendments to licenses, because as a practical matter, many amendments are requested and obtained without use of the form.

Unlike specific licenses, registration certificates are not issued with expiration dates. If a significant safety issue arises with a product, regulatory means are available to address it, such

as an order issued to a distributor to cease distribution until the safety issue is resolved. The Commission has had authority to request additional information or to modify requirements under the general provisions in §§ 2.204, 30.34(e), and 30.61. In addition, since the Commission has authority to revoke a license, and registration is used as part of the licensing process, the Commission has had the authority to revoke a registration certificate, if, for example, it determined that the registration was inconsistent with regulatory standards or the certificate had been obtained by providing falsified information. However, the regulations have not referenced this authority. Therefore, § 30.61 is being revised to explicitly implement the Commission's authority to modify or revoke registration certificates.

As a registration certificate, in conjunction with a license, authorizes distribution of a product, a certificate may be reevaluated at the time of license renewal. Generally, this has not been the practice of the NRC, but may be the case for some Agreement States. In the case of licenses authorizing distribution to exempt persons, a limited review of the certificate(s), when applicable, has typically been conducted to ensure that the information is complete and accurate with respect to any changes that may have occurred since issuance of the certificate. For all types of certificates, it is important that there be consistency between the license and the certificate(s).

The Commission does not believe that it is necessary to conduct a complete reevaluation of sealed sources and devices at the time that distribution licenses are renewed, usually every 10 years, since generally, there are fewer safety significant aspects that are likely to change reflected in the registration certificate than those addressed in the license. The Commission does recognize a need to update registration certificates and relies, for the most part, on certificate holders to request amendments of certificates, as appropriate. One factor is that the NRC is required to consider the application of industry standards, for example, as reflected in § 32.210(d). These industry standards may be revised to provide improved safety.

Also, licensees are required by § 20.1101 to implement radiation protection programs and to use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA). Thus, it is appropriate for licensees to consider new developments in technology and standards as they may impact ALARA in the design of products. However, because § 32.210(f) requires the certificate holder to manufacture and distribute products in accordance with the provisions of the registration certificate and any statements made in the request for registration, and no reevaluation of a source or device, once approved, is normally required, the regulatory structure may limit rather than encourage industry improvement.

There may be reasons to reevaluate a sealed source or device in some circumstances with regard to either the actual design of a source or device, or such other aspects as quality assurance or information provided to the user on safe use. While the current regulations provide adequate authority to do so, recalling a registration certificate for review and reissuance in the absence of a significant safety problem with the product is an activity very rarely conducted by the NRC in the past. This final rule also includes an explicit provision to specifically address such a process in § 32.210(h). The Commission will complete such an evaluation in accordance with the criteria specified in § 32.210. As noted under Section II. A.1, “Updating Regulations to Add Registration Requirements,” of this document, this final rule adds specific provisions delineating which sealed sources and devices must be registered in the SS & D Registry, broadening the applicability of § 32.210 to some generally licensed and exempt products. The Commission may use the new provision in § 32.210(h) to update the certificate with respect to applicable current regulatory standards or to ensure the quality of the summary of safety information and the information on conditions of use contained in the registration certificate that is available to the various jurisdictions.

Generally, the Commission has not made standards more restrictive with regard to products to be used under a general license or under an exemption from licensing, so as to restrict further distribution of a previously approved product. However, such a decision in the future may necessitate a reevaluation of a registration certificate.

Registrations in the SS & D Registry are kept active until a distributor who is no longer distributing the particular sources or devices, requests to change the status. At this point, the registration is changed to inactive status, meaning that the covered products are no longer authorized to be distributed. Annual fees are assessed by the NRC only for active registration certificates. The SS & D registrations are kept indefinitely in inactive status after authorization to distribute has ceased, so that the registration information is available for sources and devices previously distributed and possibly still in use.

Because some States do not have annual fees for maintaining active SS & D certificates, distributors do not consistently request inactivation of certificates, leaving active certificates in the database that do not reflect any continued distribution. This somewhat limits the information available to other jurisdictions as to what sources and devices are authorized for continued distribution. This rule includes a provision for inactivation (§ 32.211), which will require distributors to request inactivation of certificates normally within 2 years after distribution of the source(s) or device(s) covered by the certificate has ceased. Two years was chosen to minimize any impact on certificate holders. NRC certificate holders typically request inactivation of certificates within about a year. The inactivation provision has been modified in the final rule from the proposed wording of that section to recognize that a decision to cease distribution may occasionally occur more than 2 years after the last initial transfer of a covered source or device has been made. In this situation, a distributor must provide a brief explanation of the circumstances that led to requesting inactivation of the certificate after more than 2 years of no transfers. This provision is expected to improve the consistency of this approach across

jurisdictions through the addition of equivalent provisions to Agreement State regulations, and thus, the quality of the information concerning current distribution available to regulators.

A.3 Adding Flexibility for Licensing Users of Sealed Sources and Devices

As noted, the safety information for every sealed source and device to be used under a specific license is not included in the SS & D Registry. However, the wording of § 30.32(g) has not allowed as much flexibility as was expected when this provision was added to the regulations. In some circumstances, it has been impractical or impossible for users to provide all of the information required by § 30.32(g). This has caused some applicants and licensees renewing their licenses to seek exemptions from § 30.32(g) for the use of products for which the manufacturer or distributor has not obtained an SS & D registration.

In addition to providing criteria in a revision to § 32.210 for situations where an SS & D registration is not required, revisions to § 30.32(g) are also being made to accommodate exceptions made in the SS & D registration process. In order to better accommodate the new provisions clearly, paragraph (g) of § 30.32 has been slightly restructured in the final rule.

A new § 30.32(g)(3) (which appeared as § 30.32(g)(4) in the proposed rule) provides that limited information is required for the smaller calibration and reference sources that are not registered. Also included is a provision to allow for licenses to be issued without the need for every individual sealed source or device to be used to be identified by the applicant. A new § 30.32(g)(4) (which appeared in § 30.32(g)(5) in the proposed rule) allows an applicant to propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used as an alternative to identifying each sealed source and device individually when it is not feasible to do so.

This latter provision is not intended as a broadly applied change in the approach to licensing the use of sealed sources and devices. This change is intended to accommodate certain expected situations in which having to identify each sealed source or device presents an undue burden. For example, military applicants are sometimes unable to identify exactly which product they may be procuring. This provision could also be used by the types of applicants/licensees identified in § 32.210(g)(2), namely those licensed for research and development (R & D), those licensed under part 33, and certain custom users who have adequate training and experience and facilities and equipment to handle comparable quantities of material in other forms. It may also be reasonable to use such an approach to provide some flexibility in the case of calibration and reference sources. The words, “If it is not feasible to identify each sealed source and device individually,” have been included in the final rule text to clarify the limited applicability of this provision.

It is anticipated that except for the R & D licensees, part 33 licensees, and certain custom users, one of the constraints would be that the sealed sources and devices are registered, as it is generally not practical for an applicant to supply adequate information to demonstrate that the radiation safety properties of unspecified sources or devices are inherently adequate to protect health and minimize danger to life and property.

The use of the SS & D registration process as a tool for licensing was intended to provide a more efficient and effective licensing process than to have all users provide detailed information about the sources and devices to be used, and for license reviewers to evaluate the safety of the sources and devices in conjunction with the evaluation of the applicant’s training and experience and facilities and equipment. The changes to §§ 30.32(g) and 32.210(g) are intended to further improve the efficiency and effectiveness of the licensing process by eliminating the need for unnecessary exemptions for recognized situations that are not unique to a particular applicant.

A.4 Extending requirements concerning legacy sources and devices to all byproduct material covered by part 30

In the final rule published October 1, 2007 (72 FR 55863), which amended the Commission's regulations to incorporate the new categories of byproduct material added by the Energy Policy Act of 2005 (EPAct), a revision was made to § 30.32(g) to facilitate licensing the use of legacy sealed sources and devices. These are older sources and devices for which the manufacturer is no longer in existence and for which it may be impossible to provide all of the categories of information identified in § 32.210(c), as required by § 30.32(g)(1)(ii), formerly § 30.32(g)(2). Generally, that amendment was intended to cover sources and devices manufactured before the promulgation of § 32.210. This provision, formerly in § 30.32(g)(3), delineates additional information that is required to license the use of a sealed source or device for which all of the information previously required is not available. The information must include a description of the source or device, a description of radiation safety features, intended use and associated operating experience, and results of a recent leak test. The NRC licensing staff will review the submitted information to make a licensing decision regarding possession and use of the source or device. However, that amendment limited the provision to sealed sources and devices containing naturally occurring and accelerator-produced radioactive material (NARM), because the scope of that rule was limited to such materials. There are, however, a number of legacy sealed sources and devices containing pre-EPAct byproduct material, i.e., byproduct material as defined in section 11e.(1) of the AEA, for which it may also be impossible to provide all of the information required under § 32.210(c). This final rule is extending that provision to legacy sources and devices containing any byproduct material, as defined in part 30; it is now designated § 30.32(g)(2).

B. Establish a New Class Exemption for Certain Industrial Products.

As noted in Section I.B., "Regulatory Framework," class exemptions allow the Commission to exempt categories of products or devices with similar characteristics and purposes, rather than requiring individual exemptions for each product. For example, the class exemption in § 30.20 for gas and aerosol detectors was established in April 1969. Since that time, new products possessing similar attributes were allowed to be licensed for distribution under § 30.20 as they were developed. This regulatory structure allowed the new detectors to be used without product-specific exemptions, which would have required additional rulemaking. The health and safety of the public is ensured by evaluating each specific product against safety criteria contained in the regulations that apply to all products in a class.

There are a number of products used under the general license in § 31.5 that could meet similar safety criteria but do not come under either of the existing classes, i.e., §§ 30.19 and 30.20. Certain industrial devices were identified by the NRC staff for possible use under an exemption from licensing requirements because of their low risk; i.e., static eliminators and ion generators containing polonium-210, beta backscatter and transmission devices, electron capture detectors for gas chromatographs, x-ray fluorescence analyzers, and calibration and reference sources. Dose assessments were conducted for these categories of products assuming use under an exemption from licensing and included in NUREG-1717. For each of the types of licensed products suggested for possible use under an exemption and included in the dose evaluations of NUREG-1717, some of the products clearly result in doses so low that requiring use under a license could be considered an unnecessary regulatory burden and an unnecessary expenditure of user and NRC resources. However, it is not clear that each type of device would necessarily qualify for exemption for all of the radionuclides and quantities used. Therefore, the NRC is adding a new class exemption, rather than attempting to create a number

of additional product-specific exemptions with appropriate limitations, such as radionuclide-specific quantity limits.

The new class exemption in § 30.22, covering a broad range of industrial devices, will maintain protection of public health and safety and, at the same time, relieve regulatory burden. Presently, most of these products are licensed under the general license in § 31.5 and equivalent Agreement State regulations. In order for a product to be distributed for use under the new class exemption, the manufacturer or importer will be required to demonstrate that a particular device meets certain safety criteria, with NRC review and approval. This class exemption will also allow for the development of new products within the class or category of industrial devices that could be approved for use under exemption without the need for additional rulemaking to add product-specific exemptions.

This approach allows for a broader number of devices to be exempted and for variations on a product or new products in the class to be approved for use under exemption from licensing without further need for rulemaking. The exemption may lead to more devices being developed with appropriately low risk that meet the criteria for the exemption. Thus, additional benefit to society may accrue if more people make use of the types of products in this class.

Although some calibration and reference sources are currently licensed under § 31.5, a clarification is included in the new exemption that such sources are not covered, since it is more difficult to assess likely scenarios of handling and use for sources not incorporated into a specific device with a specific purpose; in particular, the number of sources that might be used or stored in close proximity is apt to be greater and more uncertain. Also, calibration and reference sources are frequently used by persons using other radioactive materials under a license, minimizing the benefit of an exemption in this case. Many of these are already used under the exemption in § 30.18. Some containing americium-241 and radium-226 are also

covered by the general license in § 31.8. Therefore, it is not believed that the type of exemption being added is an appropriate regulatory approach for calibration and reference sources.

The exemption covers industrial devices with the same list of purposes as are covered by the general license in § 31.5 with the exception of that of producing light. The class exemption for self-luminous products is considered adequate and appropriate to provide for exempt use of products of this type.

The new exemption for industrial products has a lower dose criterion for routine use than that associated with the general license and includes consideration of potential doses from disposal. Devices used under § 31.5 must be returned to a specific licensee, such as a vendor (distributor) or waste broker, and ultimately disposed of as low-level radioactive waste. Under the new exemption from licensing requirements, there are no controls on disposal; the devices will be disposed without regard to their radioactivity. Thus, the potential impacts of uncontrolled disposal need to be evaluated in the licensing process for each particular device.

The information to be submitted by an applicant to distribute a device for use under this new class exemption is delineated in § 32.30; these requirements are very similar to those for applications to distribute a product for use under the other class exemptions, for example, under § 32.26 for gas and aerosol detectors.

The safety criteria are similar to the criteria for licensing the manufacture or distribution of gas and aerosol detectors (contained in §§ 32.27 and 32.28). However, those criteria include more organ-specific limits, because they were based on the dose limitation methodology recommended by the International Commission on Radiation Protection (ICRP) in 1959 in ICRP-2, “Report of ICRP Committee II on Permissible Dose for Internal Radiation,” whereas more recently developed approaches to radiation protection rely less on individual organ dose limits or constraints, particularly when doses are low, and include weighting organ dose contributions to overall dose. These newer approaches involve calculating doses in total

effective dose equivalent as in 10 CFR part 20, based on ICRP-26, “Recommendations of the International Commission on Radiological Protection,” or effective dose, based on the subsequent recommendations of the ICRP. The safety criteria for the new class exemption will not require that the exposures be estimated specifically in terms of total effective dose equivalent (TEDE) or effective dose.

The intent is to provide flexibility so that the most up-to-date dose calculation methodology may be used. However, the staff will normally accept the use of the current approved methodology such as that now reflected in part 20.

The NRC notes that the ICRP issued its latest recommendations in ICRP-103, “The 2007 Recommendations of the International Commission on Radiological Protection.” The specific dose conversion factors based on those recommendations have not yet been calculated. However, as the safety criteria for the class exemption are design criteria, it is preferable to have the flexibility to use the latest information for considering risk during design.

For the purposes of these provisions, a definition of a generic term for internal dose, “committed dose,” is being added to § 32.2 to encompass this approach, which includes weighting of organ and tissue doses, but not strictly under one system. The definition of “committed dose” has been changed in the final rule to remove the reference to specific definitions in part 20 and of ICRP, but maintain the basic approach. The revised definition includes the term “tissue weighting factors.” The NRC would normally accept dose estimates based on the weighting factors in part 20 or the tissue weighting factors in ICRP-60, “1990 Recommendations of the International Commission on Radiological Protection,” or ICRP-103.

The dose criterion for routine use of these devices is 200 μSv (20 mrem)/year, which is significantly higher than that for gas and aerosol detectors (5 mrem (50 μSv)/year). This exemption covers industrial type devices, used almost exclusively on the job, meaning that routine doses will normally be occupational, i.e., doses received by individuals in the course of

employment in which the individual's assigned duties involve exposure to radiation or to radioactive material. In a small proportion of cases, a user might not be a worker, but a student, for example. However, these instances are likely to involve a limited amount of time for exposure over the year, reducing doses to these types of users. Due to the industrial purpose of the devices, these products are not expected to be sold in the large quantities possible for consumer products, such as smoke detectors. Therefore, these products will contribute to the exposures of many fewer people. Doses to members of the public would generally be smaller, usually much less than that to the user.

In order to provide reasonable assurance that members of the public are not routinely exposed to more than a few mrem/year (few 10's of μSv/year), the regulation also includes a criterion that the device is unlikely to be routinely used by members of the general public in a non-occupational environment. The Commission's policy for consumer products is for the general public to receive no more than a small fraction of the public dose limit from exempt products, so that their exposures from all sources are not likely to routinely exceed the public dose limit, which is now 100 mrem (1 mSv)/year.

The fact that industrial products are not as widely used as items commonly used in the home will tend to limit the contribution by these products to disposal doses; e.g., the exposures of landfill workers. Nonetheless, the safety criteria include a separate criterion for disposal, 10 μSv (1 mrem)/year. This criterion is lower than the criterion for routine use, because the same individuals are apt to be exposed to all products disposed in any particular landfill or municipal incinerator.

Accident criteria are similar to those for products to be used under §§ 30.19 and 30.20. The higher of these limits, that for the lowest probability accident, is also used in the safety criteria for the general license in § 31.5, under which many of the devices potentially covered by the new class exemption are currently used (§ 32.51(a)(2)(iii)). However, the safety criteria for

the new class exemption include an additional criterion to ensure that the radionuclide quantities allowed for use under the exemption are limited, such that the maximum possible dose is controlled, even if the circumstances leading to such a dose are extremely improbable.

The accident criteria currently in § 32.23(d), § 32.24, Column IV, § 32.27(c), § 32.28, Column III, and § 32.51(a)(2)(iii) were expected to limit the total amount of radioactive material likely to be approved for use under the relevant exemption or general license, irrespective of the design to contain or shield the material. However, designs to contain the material even under severe conditions of use or accident have resulted in relatively large quantities of materials being approved in some cases. Although the radiological risk is well controlled by these designs, possible scenarios of misuse are not required to be evaluated.

For this new exemption, a criterion is included requiring that specific scenarios of misuse be analyzed and shown to meet certain dose limits. The analysis required to meet this misuse criterion will be relatively simple. Evaluating actual risk from possible misuse would be much more difficult, but such risks will be limited by this misuse criterion. The basis for this criterion is to ensure public health and safety. The criterion is 100 mSv (10 rem), plus an additional skin dose criterion. This criterion is slightly lower than the accident criterion of 15 rem (150 mSv) applicable to products covered by the existing class exemptions and the general license in § 31.5. This criterion is considered to be a more appropriate value given the high level of uncertainty in estimates of doses under accident conditions.

Limiting the radionuclide quantities allowed for use under the exemption, even if well contained, has the additional benefits of: 1) minimizing risks associated with devices becoming subject to scrap metal recycling, such as property damage due to contamination resulting from smelting; 2) further controlling overall impacts to waste disposal workers; 3) minimizing overall impacts to the environment from uncontrolled disposal of products used under exemptions from licensing; and 4) minimizing the potential problems of products exempted by the NRC being

detected at and sometimes rejected for disposal in landfills and municipal incinerators by State and local restrictions.

In the proposed rule, an additional fixed limit for radionuclides of concern, in terms of a small fraction of the Category 2 threshold as listed in Appendix E of part 20, was also included (as proposed § 32.30(c)(4)). This additional limit is not included in the final rule. The Commission has determined that there is no safety or security basis for a quantity limit, that the safety criteria will adequately protect public health and safety from products approved for use under the new class exemption, and that the misuse criterion in particular will adequately control the quantities of material that will be approved for use in such products to obtain the additional benefits described above.

Except for the removal of this specific quantity limit and the change to the definition of "committed dose," the rule is essentially identical to the proposed regulatory text related to this new class exemption with one minor change made in response to public comment. That change involves the specific distances at which applicants will measure the radiation field around devices they seek to distribute for use under the exemption. This is discussed further under Section III, "Summary and Analysis of Public Comments on the Proposed Rule."

C. Remove Unnecessary Limitations from the Class Exemption for Gas and Aerosol Detectors.

The class exemption in § 30.20 is for gas and aerosol detectors "designed to protect life or property from fires and airborne hazards." At the time that this exemption was added to the regulations, the applications of these types of devices under consideration were smoke detectors and devices to detect chemicals that would constitute an airborne hazard if inhaled. The words "designed to protect life or property from fires and airborne hazards" were included

to ensure that the products provided a clear societal benefit. Products similar to those allowed, but not quite fitting the "class," cannot be approved for use under this exemption. For example, drug detectors were rejected for distribution for use under this exemption because they do not specifically protect life or property from fires or airborne hazards. The NRC believes that there is a clear societal benefit from this application and allowing its use under the exemption is justified, as long as a particular device meets the applicable safety standards. A minor modification, therefore, is being made to allow for a slightly broader class of product without eliminating the expectation of a societal benefit. "Designed to protect life or property from fires and airborne hazards" is replaced with, "designed to protect health, safety, or property." This will allow other potential applications under an existing regulatory framework, which has safety criteria designed to adequately protect public health and safety.

D. Update the Regulations on Certain Static Eliminators and Ion Generating Tubes.

Section 31.3 provided a general license for certain static eliminators and ion generating tubes. The static eliminators distributed for use under this provision include those intended for use by the general public. There were no requirements associated with this general license; however, the provision did not explicitly contain an exemption from 10 CFR parts 19, 20, and 21. Nonetheless, the Commission has generally treated products covered by this provision as if the users were exempt from licensing. Distribution had to be authorized only by the NRC and not by the Agreement States. There were no distribution requirements specified in part 32. Distributors were licensed under part 30, with particular license conditions related to distribution determined on a case-by-case basis. Reporting requirements in licenses were similar to exempt distribution reporting requirements.

This inconsistency resulted from the fact that the use of the static eliminators covered by this general license predated the regulations in parts 19, 20, 21, 31, and 32. The general license for static eliminators was first issued in part 30 in the 1950s shortly before the formalization of radiation protection requirements was completed by issuance of part 20. Therefore, the original general license did not include an exemption from part 20. Training requirements were separated from part 20 and issued in part 19 at a later date. The ion generating tubes covered by paragraph (d) of § 31.3 were also covered by the general license in part 30 prior to the recodification of byproduct material regulations into 10 CFR parts 30, 31, 32, 33, 34, 35, and 36 in 1965. The general licenses for byproduct material were moved from part 30 to part 31 at that time.

In 1971 (36 FR 6015; April 1, 1971), the Commission proposed to change this general license to an exemption, and also to expand it into a class exemption under which additional static elimination devices and ion generating tubes with differing radionuclides and quantities could be approved for use under the exemption through licensing actions. As a result of competing priorities for staff effort at the time, that rule was never finalized.

Although these products have a long history of use, there have been relatively few licensed distributors. Nonetheless, this situation caused some confusion in the licensing process. The Commission is changing this general license into an exemption from licensing in § 30.15(a)(2). The current licensed distributor will not be required to amend its license in order to continue distribution, but any future distributors will come under the distributor provisions associated with §§ 30.15; i.e., §§ 32.14, 32.15, and 32.16. This change is intended to have no effect on any current distributor or user of these products, only to remove an inconsistency in the regulations and to make any future licensing decisions in this regard more efficient and effective.

With respect to the issue of requirements for sealed source and device review, this change removes the need for a registration certificate if these products are distributed under the authority of a license issued under § 32.14. The licensing practice of using the sealed source and device review and registration process for products to be used under the general license in § 31.3 primarily resulted from the lack of specific requirements for a distribution license in the regulations. Thus, § 32.210 provided the types of information to be provided concerning the product for NRC review.

E. Remove Prescriptive Requirements for Distributors of Generally Licensed Devices and Exempt Products.

The Commission determined that the requirements for manufacturers or initial distributors of exempt and generally licensed products were in some cases overly prescriptive, particularly in the areas of prototype testing and acceptance sampling/quality control (QC) procedures. Such a prescriptive approach is easy to implement and regulate, but is relatively inflexible. When evaluating a new or redesigned product, the NRC requires prototype testing to validate the design of products and their ability to contain byproduct material. Acceptance sampling (a specific QC process) monitors the effectiveness of the manufacturing process for safety-significant parts to minimize the likelihood of failures and events caused by inadequate manufacturing quality.

This rule is intended to focus the regulations on performance, rather than procedures. The regulations retain general requirements and provide general standards by which performance may be judged, rather than specifying detailed procedures that must be followed, except for products for which oversight of these activities would no longer be required as discussed under Section II. F., “Make the Requirements for Distributors of Exempt Products

More Risk-Informed." The NUREG-1556 series of documents provides guidance to licensees and applicants on acceptable approaches to meeting these requirements.

The procedures being removed from the regulations are generally acceptable to meet the new performance-based requirements. Safety benefits of the changes being made in this area will primarily be gained indirectly by removing overly burdensome and possibly counterproductive procedures and, more importantly, by accommodating the use of new technologies. The intent is for the revised regulatory requirements to be equivalent to previous practices (except as noted), so that existing licensees will not have to change their procedures as a result of this rulemaking. However, the revised provisions are written so that applicants and licensees have flexibility in the methods that they use to determine the design quality (prototype tests) and manufacturing quality (acceptance sampling/QC) of these products. In keeping with national and international best manufacturing standards, manufacturers and the distributors that represent them are expected to maintain a quality management system that stresses continual improvement. Examples of such system requirements can be found in the International Organization for Standardization standard, ISO 9001:2008, "Quality Management Systems – Requirements." While the focus of ISO 9001:2008 is on customer satisfaction, it contains some quality management concepts that are appropriate to the distribution of generally licensed and exempt products containing byproduct material.

Prototype Test Procedures

This final rule simplifies the prescriptive regulations for prototype testing for new products proposed for use under general license. The revised provisions include only those aspects that are results-oriented, rather than specifying detailed procedures that must be followed. An applicant may choose to follow current prototype test procedures, as they would satisfy the outcomes required by this rule in every situation. The specific procedures are being

removed from the regulations and included as example acceptable procedures in guidance documents.

In the case of generally licensed products, regulations that had contained prescriptive requirements for prototype testing were:

- Paragraph (d)(4) of § 32.53, “Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer,” standard to pass tests described in § 32.101;
- Paragraph (d)(2) of § 32.57, “Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer,” standard to pass tests described in § 32.102;
- Paragraph (e)(4) of § 32.61, “Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer,” standard to pass tests described in § 32.103;
- Section 32.101, “Schedule B--prototype tests for luminous safety devices for use in aircraft”;
- Section 32.102, “Schedule C--prototype tests for calibration or reference sources containing americium-241 or radium-226”; and
- Section 32.103, “Schedule D--prototype tests for ice detection devices containing strontium-90.”

No prescriptive prototype testing requirements pertaining to manufacturers of exempt products remained in the regulations, as they had been previously removed. Most recently, §§ 32.14(d)(2) and 32.40 were removed by a rule published October 16, 2007 (72 FR 58473).

Acceptance Sampling and Quality Control Procedures

In the case of generally licensed products, regulations that contained prescriptive requirements for acceptance sampling/quality control procedures were:

- Paragraphs (a) though (d) of § 32.55, “Same: Quality assurance; prohibition of transfer” (“Same” refers to “Luminous safety devices for use in aircraft”);
- Section 32.59, “Same: Leak testing of each source” (“Same” refers to “Calibration or reference sources containing americium-241 or radium-226”);
- Paragraphs (a) through (e) of § 32.62, “Same: Quality assurance; prohibition of transfer” (“Same” refers to “Ice detection devices containing strontium-90”); and
- Section 32.110, “Acceptance sampling procedures under certain specific licenses.”

The prescriptive requirements for acceptance sampling/quality control procedures pertaining to manufacturers of exempt products were paragraphs (a)(2), (a)(3), and (c)(2) of § 32.15, “Same: Quality assurance, prohibition of transfer, and labeling.” (“Same” refers to “Certain items containing byproduct material.”)

These all included specified procedures; §§ 32.15(a) and (c), 32.55(b) and (d), and 32.62(c) and (e) specifically referred to § 32.110.

The NRC intends to allow acceptance sampling to be performance-based, rather than specifying procedural details. Section 32.110 provided that a random sample shall be taken from each inspection lot of specified devices for which testing is required in accordance with the appropriate sampling table in that section. If the number of defectives in the sample does not exceed the acceptance number in the appropriate sampling table, the lot was not to be accepted, while if the number of defectives exceeds the acceptance number, the entire inspection lot was to be rejected. There is no longer a need for the NRC to maintain the acceptance sampling tables that were in § 32.110, which provided the number of acceptable defective units in various lot sizes for a variety of Lot Tolerance Percent Defective values. Note:

Lot Tolerance Percent Defective is defined in § 32.2 as the poorest quality in an individual inspection lot that should be accepted. The table in § 32.110(b)(6), Lot Tolerance Percent Defective 5.0 percent, correlated with the standard in the above cited regulations. However, the other seven tables in § 32.110 apparently had been little used since their publication in 1974, as there were no specific standards in part 32 requiring Lot Tolerance Percent Defectives other than 5 percent. Licensees can now easily use widely available computer software to determine their own acceptance sampling procedures to best monitor their manufacturing processes. This final rule removes § 32.110. Acceptance sampling criteria continue to be specified in §§ 32.15, 32.55, and 32.62, specifying the values required for quality (Lot Tolerance Percent Defective) and confidence. Section 32.59 requires leak testing of each source for calibration or reference sources containing americium-241 or radium-226 generally licensed under § 31.8, rather than sampling of lots. This final rule does not change that provision other than providing minor clarifications.

Previously, the NRC required the affected categories of licensees to perform acceptance sampling in accordance with § 32.110 or propose alternative procedures (under § 32.15(b), § 32.55(c), or § 32.62(d)) which provided a Lot Tolerance Percent Defective of 5.0 percent at a consumer's risk of 0.10. This "consumer's risk" criterion is equivalent to 90 percent confidence that the Lot Tolerance Percent Defective will not be exceeded. The applicant's quality control procedures, including any alternate procedures proposed, are reviewed and approved by the NRC. This final rule does not change the 5 percent criterion for Lot Tolerance Percent Defective (i.e., 95 percent acceptance). The value of consumer risk of 10 percent was more relaxed than others used by the NRC, such as in inspections, which use standards of no more than 5 percent defective at 5 percent risk. The final rule revises the acceptance sampling standard to no more than 5 percent risk, expressed as "95 percent confidence," for those

categories of products for which the acceptance criteria are specified in the regulations. The term “confidence” is now more commonly used in this context.

Most of NRC’s statistical acceptance criteria today - such as in inspections – are, at least, 95 percent acceptance with 95 percent confidence. Raising the required confidence level from 90 percent to 95 percent may be an increase in burden, but is justified, because the 90 percent standard was inconsistent with other agency practices, as well as industry standards. However, it is expected that because of the nature of the products covered by these regulations, the lot sizes apt to be used, and other factors, the revision is unlikely to change the approaches used by the limited number of current licensees under these provisions.

Another change in NRC’s acceptance sampling regulations is a clarification of the prohibition on the transfer of any defective lot. The prohibition of transfer of rejected *lots*, previously appearing in §§ 32.15(c)(2), 32.55(d)(2), and 32.62(e)(2), is being revised. The prohibition of transfer appeared to apply only to individual items found to be defective, rather than addressing all items in a sampled lot that do not meet the acceptance standard. These revisions concerning rejected lots appear in §§ 32.15(b)(2), 32.55(d)(2), and 32.62(e)(2). From a statistical standpoint, unless a lot is sampled and tested in such a way as to demonstrate compliance with the required measures of quality assurance, the entire lot should be rejected. The final rule requires that distribution of any part, or sub-lot, of a rejected lot must be in accordance with procedures spelled out in the license, and that testing after repairs must be performed by an independent reviewer. The provision for an independent reviewer is a new requirement, but it is a recommendation of the International Atomic Energy Agency (IAEA), and may have been used voluntarily as an industry best practice. The IAEA recommends that, based on sound statistical theory, depending on the safety significance of the defective item or lot, the independent reviewer may be a different inspector from the one that performed the original sampling, or an inspector from a third party. In the case of the products for which these

changes are being made, the risk is low and it is sufficient for the independent inspector to simply be another qualified employee. Individual worker accountability plays an important role in an effective quality assurance (QA) program, and an independent reviewer, besides adding another layer of assurance that the sub-lot or part is acceptable, will add accountability to the program.

The sampling plan will normally be detailed in the license, which will ensure that the quality assurance program is systematic and planned where justified, such as for lot sizes, sample sizes, criteria, and procedures. The primary source of guidance on quality control and quality assurance is NUREG-1556, Vol. 3, Rev. 1. This guidance indicates that the NRC may accept a certificate of accreditation in lieu of a full set of QA/QC plans or procedures. The vendor providing certification must, however, make the commitment that the generic QA/QC program includes provisions that address the specific requirements in the regulations for the fabrication of the sealed sources or devices. Depending on the specific requirements of the fabrication process, such provisions would include:

- Verifying that the design conforms fully with the statements and commitments submitted in support of the application (including materials, dimensions within stated tolerances, manufacturing methods, assembly methods, labeling), using sampling methods that meet applicable provisions, such as § 32.55.
- Leak testing all units to 185 Bq (0.005 µCi).
- Testing all units for proper operation of all safety features.
- Verifying that, for all units, the radiation levels do not exceed the maximum values stated in the application.

The proper treatment and definition of lots is essential from a statistical perspective, and relevant to acceptance sampling procedures. For the purposes of acceptance sampling, a “lot” should consist of homogeneous products manufactured from the same or similar machines,

interchangeable in terms of their intended use or function. Similarly, from a statistical perspective, a sampling plan must demonstrate certain characteristics to sufficiently guarantee quality:

- Manufacturer compliance with predetermined lot sizes, sample sizes, sampling methodology, and acceptance criteria.
- Agreement with a one-time decision to accept or reject a lot in its entirety.
- Separate, predetermined treatment of sub-lots.
- The calculation and reporting of separate measures for quality and for confidence.

It should be emphasized, however, that the regulatory requirement for acceptance sampling is not an attempt to control overall product quality, but to minimize the possibility that a distributed product has inadequate or malfunctioning safety features.

In summary, this final rule revises the cited paragraphs concerning prototype testing and quality control, including specific sampling requirements, to make these requirements for distributors more flexible and performance-based rather than prescriptive. Guidance on quality assurance methods is included in NUREG-1556, Vol. 3, Rev. 1, including specifically Appendix G.

Less prescriptive, more flexible, performance-based regulations will continue to specify performance requirements. Generally, the specific procedures being removed from the regulations continue to be considered acceptable. The NRC normally evaluates products using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the NRC formulates reasonable standards and criteria in consultation with the manufacturer or distributor. References to appropriate industry and consensus standards are included in NUREG-1556, Vol. 3, Rev. 1, Appendix F. Updated guidance will be provided when a new or revised industry standard becomes available that the NRC considers more appropriate. The licensee will be free to propose alternative methods to

those presented in industry standards and guidance, provided that the methods provide sufficient evidence that all safety related components are capable of performing their intended functions.

Current licensees will need to make any necessary upgrades to their QC programs when this rule becomes effective. However, because license conditions are written broadly, it is not expected that any such changes in the QC programs will be inconsistent with an existing license (or registration certificate). Any changes needed in the license to better ensure consistency with the revised requirements will likely be made at the time of the next license renewal or related amendment of the license.

F. Make the Requirements for Distributors of Exempt Products More Risk-Informed.

To a large extent, the NRC has applied similar requirements throughout part 32 on manufacturers and distributors of all categories of products, irrespective of the quantity of byproduct material within or the risk of a product. However, given the low risk of some exempt products, some of the requirements are believed to be unnecessary, and not commensurate with the associated risk. This was particularly true in the areas of prototype testing and quality control requirements for products to be used under exemptions from licensing.

The NRC considered whether some of the products used under an exemption from licensing present such low levels of radiation exposures, both routinely and in the event of accidents, that continued NRC oversight of the specific prototype tests and/or the quality control/quality assurance to be applied by the manufacturer or distributor would not be warranted.

Although many products distributed under the class exemptions would likely meet such a low-risk standard, the Commission does not believe it prudent to eliminate any of these

requirements for the class exemptions. The safety criteria for each class exemption are intended to ensure that the risks associated with any product approved for use under the associated exemption are quite low. Nonetheless, because of the nature of a class exemption to allow for new products to be approved, it is not possible to conclude that elimination of oversight of prototype testing or quality control procedures for an entire class of products is prudent. The evaluation of the safety of the individual product may depend on knowledge of such procedures.

The NRC evaluated the inherent potential for radiation exposures from products containing byproduct material used under product-specific exemptions and the likelihood of increases in risks if oversight of the subject procedures were removed. The product-specific exemptions appear in § 30.15. There were four types of products listed in that provision for which future distribution is allowed, specifically timepieces, ionization chamber smoke detectors, electron tubes, and ionizing radiation measuring instruments. (Note that in the discussion under Section II. D., "Update the Regulations on Certain Static Eliminators and Ion Generating Tubes," the Commission is adding another exemption to § 30.15.) The requirements of this type for manufacturers and distributors of products used under § 30.15 were contained in:
§ 32.14(b)(4), on submittal of information on prototype test procedures used and the results;
§ 32.14(b)(5), on submittal of quality control procedures to be used; and §§ 32.15(a)(2) and (a)(3) and 32.110, on specific sampling procedures for quality control. Paragraph 32.15(c) also contained a prohibition on transferring any defective lot or item to exempt persons.

Even without the NRC's continuing oversight of these procedures, licensees would be motivated to retain them as good business practices. There are a number of factors that will likely cause manufacturers and distributors to continue to conduct prototype testing and at least some form of quality control/assurance. In some cases, functionality testing closely aligns with testing for containment of radioactive material. The consideration of risk for these products,

however, did not rely on this expectation, beyond some reasonable bounding assumptions about the likelihood and consequences of distributing defective products. For example, failures that result in functional failure may happen more frequently, but it is not reasonable to assume that manufacturers would continue to distribute a large percentage of defective devices over long periods.

The NRC used NUREG-1717 as a primary resource concerning estimates of doses that result from the distribution, use, maintenance and repair, disposal, and accidents involving these products. The NRC considered the extent to which these doses might be affected if the lack of oversight over prototype testing resulted in a product design that was less effective in containing or shielding the byproduct material. The NRC also considered the extent that doses or probability of accidents could be affected if the lack of oversight of quality control/quality assurance significantly reduced the effectiveness of licensees' programs in this area. This assessment was semi-qualitative as there is no data available on products used without regulatory control, which could support a quantitative probabilistic risk assessment.

This final rule eliminates NRC oversight for these types of activities for a few of the exempt products as not justified, based on risk. Requirements to submit information on prototype tests in § 32.14(b)(4) are eliminated for products exempt under § 30.15(a)(7) and (8), ionization chamber smoke detectors and electron tubes respectively. This requirement is also removed for timepieces under § 30.15(a)(1) containing promethium-147 or tritium in the form of gaseous tritium light sources. Oversight of quality control/quality assurance is eliminated for these same products as well as for products to be used under the new exemption in § 30.15(a)(2), static eliminators and ion generating tubes formerly covered by the general license in § 31.3. This is in revised § 32.14(b)(5), which now requires that quality control procedures be submitted for approval only for ionizing radiation measuring instruments and timepieces containing tritium in the form of paint. Other requirements in the application for a

license to distribute these products remain, such as the submittal (under § 32.14(b)) and evaluation (§ 32.14(d)) of basic design features intended to contain the byproduct material.

Based on the assessment of the inherent safety of these products, it is estimated that even if a lack of appropriate prototype testing resulted in lower quality product designs in the future or poor quality control resulted in degradation of production quality, the potential increases in individual doses would be less than 10 μSv (1 mrem)/year in any situation where significant numbers of products could be affected. Also, in the extreme case of a significant change in future distributor behavior, some individual doses could be increased by somewhat higher amounts in non-routine situations. Overall, considering both potential increases in doses and the probability of circumstances resulting in those increases, the potential incremental risk is estimated to be insignificant.

Unnecessary regulatory burden on distributors of these products is reduced. Because, as noted above, licensees are not likely to eliminate such procedures as a result of discontinued NRC oversight, the benefits assumed are only those associated with eliminating the submittal of testing/sampling procedures for review and approval, eliminating the submittal of prototype testing results, and allowing added flexibility to change procedures in response to other factors, including competitive demands for continuous quality improvement, without NRC permission.

Current licensees authorized to distribute products affected by this change will need to amend their license in order to not be held accountable for continuing to follow the QC/QA program as delineated in their license. This will be a simple amendment as the regulations will be clear that this license condition is no longer required.

G. Minor Clarifying or Administrative Revisions.

Other minor revisions are being made to better organize, clarify, or update the regulations in these parts, such as the renaming of subparts C and D and the movement of §§ 32.72 and 32.74 from subpart B to subpart C. These two sections are being moved because they do not cover generally licensed items. Minor conforming amendments are included in parts 40 and 70 because the delineation of the delegation of licensing programs to the Regions is written broadly in these parts. Such revisions are noted in Section IV., "Summary of Final Amendments by Section."

III. Summary and Analysis of Public Comments on the Proposed Rule.

The NRC reviewed the public comments received on the June 24, 2010 (75 FR 36212), proposed rule. The comment period ended on September 7, 2010. Ten comment letters were received. The commenters included the Organization of Agreement States (OAS), the State of Wisconsin, the radiation safety officer of a university, and an individual. The remainder were manufacturers and distributors and organizations representing manufacturers and distributors. Two commenters requested an extension to the comment period. Although an extension was not granted, all comments were considered. In addition to inviting comments on any aspects of the proposed rule, the NRC posed specific questions for consideration. A discussion of the comments and the NRC's responses follow.

A. Actions Related to Sealed Source and Device Registration.

A.1 Updating Regulations to Add Registration Requirements

Comment: While only one commenter specifically supported the overall change to add requirements for registration of the various categories of sources and devices and to add the definition of the sealed source and device registry to part 32, most appeared to generally support these changes. One commenter specifically noted the importance of the Compatibility Category B for SS & D related changes in order to ensure consistency throughout all jurisdictions.

Response: No changes to this aspect of the rule have been made. The Commission agrees with the importance of national consistency in this regard. Compatibility Category B applies as proposed to the paragraphs in part 32 relevant to requirements to obtain SS & D registration (except for those sections that are NRC only because the NRC retains authority over all distribution to exempt persons). Also as proposed, Compatibility Category D continues to apply to § 32.210 for those States that do not issue registration certificates.

A.2 Adding Provisions for Amendment, Modification and Revocation, Review, and Inactivation of Registration Certificates

A large portion of the comments received on the proposed rule concerned the provisions for inactivation of certificates and for reevaluation of certificates. There were four specific questions raised in the notice of proposed rulemaking concerning the updating of registration certificates. The following comments relate primarily to these two questions:

Q. 1 Updating of registration certificates in the SS & D Registry:

(a) Under what circumstances should proposed § 32.210(h) be used to require a reevaluation? How should such a reevaluation be conducted with minimum impact to industry?

Q.1 (d) In general, how might the NRC use the proposed provision for review in § 32.210(h) in relation to changes in standards for products or limits in addressing continued distribution and the timing for changes to the authority to distribute tied to the registration certificate?

Comment: Commenters on this subject were manufacturers and distributors and representatives of the industry. These commenters recommended that a re-evaluation of registration certificates be conducted: 1) upon request by the manufacturer or initial distributor due to changes [that would affect regulatory compliance]; 2) to ensure compliance with regulations; 3) based on indications of radiological safety concerns or when new regulations implement more restrictive dose constraints; or 4) when the regulations that apply to those sealed sources or devices change to an extent that compliance with the regulation could require modification of the conditions of the registration. One commenter supported the recommendation that no reevaluation was needed except to ensure compliance with the regulations or if there are reports of defects that would affect regulatory compliance, by indicating that the fundamentals of radiation protection or technology are not likely to undergo any change significant enough to create a compelling need for reevaluation of a device certificate.

Response: Generally, the NRC agrees with the circumstances recommended by the various commenters for reevaluation of a registration certificate. Another possible situation in which a review might be required would be in the case of an older certificate that has not been revised by request of the holder and that has limited information related to the original demonstration of safety. However, at this time, the NRC does not envision the routine auditing of certificates for adequacy of information.

Comment: One commenter recommended that if the regulations for sealed sources and devices change to an extent that compliance with the regulation could require modification of the conditions of the registration, then the affected licensees should be notified of those requirements, and the date by which compliance is required. Likewise, licensees could be required to make a notification that no design changes are required.

Response: The approach suggested by the commenter is a reasonable one for the NRC to take in such a circumstance; however, such an occurrence is rare and implementation details would be decided on a case-by-case basis.

Comment: One commenter agreed that it is not necessary to conduct a complete reevaluation of sealed sources and devices at the time that distribution licenses are reviewed, but also stated that the NRC should change NUREG-1556 guidance to explicitly require a review of certificates at the time of license renewal to ensure that the information is complete, accurate, and that the source or device remains current considering the application of the current industry standards.

Response: The NRC agrees that it is not necessary to conduct a complete reevaluation of sealed sources and devices at the time that distribution licenses are reviewed for renewal, although some review of certificates for consistency with the license is appropriate at that time. The NRC staff is currently updating the guidance in NUREG-1556 series concerning such matters.

Comment: One commenter suggested that the NRC conduct a comprehensive audit of all certificates in the registry and reconcile them with NRC and Agreement States Distribution License issued. This commenter noted problems, such as licenses being amended without amendment of the accompanying registration certificates and the existence of certificates still listed for active vendors when the company's distribution license had been previously terminated.

Response: This is not something to be addressed in rulemaking. The NRC sometimes identifies such problems as the commenter has noted and corrects them. The NRC could not conduct a complete audit of all certificates, as the Agreement States have responsibility for ensuring the consistency of their distributor licenses with the relevant certificates. The addition of the inactivation provision in § 32.211 is intended to improve the consistency in this aspect of the SS & D registration process.

Comment: The NRC should monitor changes to relevant ANSI [American National Standards Institute] and ISO standards for reference during the review process.

Response: The NRC generally keeps current with respect to such standards, in some cases participating on the committees making the revisions. This comment did not call for any particular change to the current rulemaking language in this final rule.

Comment: Two commenters expressed the opinion that § 32.210(h) was redundant and therefore not necessary, given that the NRC already has authority under § 30.61 to request additional information or to modify requirements, if necessary, to revoke a license and registration certificate. One stated that § 32.210(h) would not ensure consistency between licenses and certificates and that instead of adding this provision, §§ 30.34(e) and 30.61 should be designated Compatibility Category B or A for Agreement States because of the transboundary implications associated with source or device registrations, which could be distributed in all fifty states and worldwide. This commenter also suggested that this would grant Agreement States the ability to review, revoke, inactivate, or modify certificates based on significant safety issues.

Response: The NRC disagrees that § 32.210(h) is duplicative of the general authority provided under § 30.61. The intent of this rule concerning sealed source and device registration certificates is to make the regulations more explicit as to how the registration process is used in the licensing process. The details of this process should be specified in part 32. It would not be

appropriate to designate §§ 30.34(e) and 30.61 Compatibility Category B for Agreement States, which is the program element assigned when there are significant direct transboundary implications, in order to address the transboundary implications associated with source or device registrations. These provisions cover a broad range of licenses for which there are no transboundary implications. The importance of national consistency for sealed source and device registrations is more appropriately handled in the categorization of the appropriate part 32 provisions, such as §§ 32.210 and 32.211. However, the Commission has decided that the transboundary implications of § 32.210(h) are not significant enough to require identical treatment by each jurisdiction, so this one paragraph within § 32.210 has been assigned Compatibility Category C (for Agreement States who perform SS & D evaluations); thus, those States would adopt the essential objectives of § 32.210(h), rather than essentially the same language.

Comment: One commenter suggested that § 32.210(h) include a backfit provision, suggesting an approach where certificate holders would be given a certain amount of time to reevaluate their source or device to determine whether it meets new dose criteria. This suggested approach also included actions that could be taken to control user doses if the source or device does not meet the criteria.

Response: Requiring previously approved products to meet new standards established in the regulations is not an action the NRC would anticipate taking very often, particularly given that overall standards for radiation protection are not expected to change dramatically in the foreseeable future. There are no new dose criteria in this rule to be applied to previously approved products. It is not appropriate to incorporate an implementation provision into this rule as suggested by the commenter to cover potential future changes in regulations concerning dose criteria. Specific implementation provisions of this type can only reasonably be provided in

the regulations in connection with a specific regulatory change being implemented. The NRC deals with such circumstances within the rulemaking process which makes such a change.

The following comments respond to this question posed:

Q 1. (b) How might registration certificates best be updated so as not to discourage improvement in the design of sources or devices, more readily allow for the application of updated industry standards, and ensure that information in the certificates is fully consistent with current practices? (For example, in addition to the proposed provision in § 32.210(h), other options could include reviewing certificates at the time of license renewal, in part or in whole; adding separate expiration dates to certificates with typically longer terms than licenses, e.g., 10 to 20 years; and explicitly allowing licensees to make changes without NRC approval, if these changes do not reduce safety margins.)

Comment: Two of the commenters suggested that device certificates should expire and be renewed at intervals of 10 years or longer, and that at the time of renewal, the certificate be updated to meet current industry standards. One of these commenters thought that this could be done in lieu of requiring inactivation of a device certificate after 2 years, stating that the inactivation provision would severely restrict business and put an undue burden on both the State and NRC programs, and companies with small distributions. The other stated that expiration dates should be specific to each device, based on its certificate approval date, and that the renewal should be easily performed requiring only a request to renew and an explanation of any changes needed to comply with current radiation safety standards. In contrast, one commenter stated that requiring reviews of certificates in conjunction with license renewal or placing expiration dates on certificates is unnecessary.

Response: The option of adding expiration dates and then conducting a renewal process would not appropriately replace the inactivation process. If a distributor is no longer distributing products covered by a certificate, there would be no reason to renew the certificate. The inactivation provision is discussed further later in this section.

If the NRC were to institute a policy of adding expiration dates to registration certificates, the expiration date would be specific to the certificate and the sources or devices covered by the certificate based on the issuance date as suggested by the commenter. Although the Commission agrees there is value in using an expiration/renewal process for registration certificates, instituting such a system nationally would be a significant change from the process in place for some time and would put additional burdens on the Agreement States that issue certificates at a time when resources are limited. There are other means to deal with changes that should be made to certificates, such as the use of the new provision in § 32.210(h).

Comment: One commenter suggested that the NRC should explicitly list which criteria constitute an amendment such as change in product name, company name, or any component directly related to radiation safety. Another commenter suggested that if certificates are not written in an overly specific manner, most minor product changes or improvements could be handled by submittals regarding the change which show that the device meets the original requirements. Additionally, the NRC could amend the certificate's tie-down condition to reference the registrant's revised submissions by date.

Response: Paragraph (f) of § 32.210 requires the certificate holder to manufacture and distribute products in accordance with the provisions of the registration certificate and any statements made in the request for registration. It would be complicated and not feasible for this provision to be revised to indicate exactly which aspects must be followed. Such an approach could increase risks that a distributor may make changes with unintended impacts on safety. The NRC has modified administrative practices concerning the content of registration

certificates so as to minimize the inclusion of details not important to safety on the certificate. The NRC does amend certificates to reference new submissions as appropriate.

Comment: Another commenter also recommended that the NRC add amendment criteria to § 32.210 providing suggested regulatory text which is similar to the approach in 10 CFR 50.59. This suggested approach would allow distributors to make changes based on their own evaluation as to the potential impact on safety and require them to keep records of the changes and report them to the NRC within 24 months.

Response: The NRC staff did consider recommending such a provision in part 30 in particular when conducting the systematic assessment of exemptions. However, because of the difficulties expected developing such a provision for the broad range of products and facilities involved in the use of byproduct material, the staff did not recommend such a provision for parts 30 and/or 32. The approach suggested by the commenter included the need for complex analyses by the distributor concerning safety that would not be reported to the NRC for up to 24 months. The NRC believes that this may lead to compromises in safety. Also, at one time, fees charged for amendment of licenses and registration certificates were a deterrent to licensees proposing changes; however, changes were made to the fee structure, so that this is no longer the case.

The following comments respond to this question posed:

Q.1 (c) How should certificates for previously approved devices be handled if the device does not meet current standards, such as in the case of the separately proposed (August 3, 2009; 74 FR 38372) quantity limit in the general license in § 31.5 (and comparable Agreement State provisions)? How should registration certificates be handled in this situation? (For example, in some cases, the distributor may be able to limit the quantity of affected radionuclides, rather than change its certificate to one for specifically licensed devices.)

Comment: A few commenters recommended that previously approved devices be grandfathered when standards are changed, one recommending this for devices in use, others for future distributions under existing active certificates as well. One of those supporting allowing continued distribution of previously approved devices recommended that the grandfathering of previously approved devices should be a Compatibility Category B for Agreement States. Generally, these commenters did not believe it justified to change the status of previously approved devices unless there was a significant impact on health, safety, security, or the environment. One of these commenters stated that such actions should only be taken if well justified in terms of benefit versus cost and that revised standards should only apply to devices distributed after a certain date. Related to the referenced proposed rule, which would have added an activity limit to the general license in § 31.5, two of the commenters indicated that the registration certificates would have to be revised to address distribution to both general and specific licensees. One commenter stated that it disagrees with the content of the proposed rule on limiting the amount of byproduct material in generally licensed devices.

Response: The Commission has decided against adopting a final rule based on the referenced proposed rule. That proposed rule would not have grandfathered devices already in use under the general license. The impact that the rule would have had on current users played a role in the decision not to adopt a final rule on that subject.

Generally, the NRC agrees with the comment that it would not be justified to change the status of previously approved devices unless there was a significant impact on health, safety, security, or the environment. The NRC recognizes that the appropriate regulatory action may be different when considering a change for 1) products to be approved in the future, 2) the continued distribution of products previously approved, and 3) products previously manufactured and already in use.

Comment: A few commenters recommended that new and re-distributed devices, devices manufactured after a certain date, or devices with significant changes, should require a new or updated certificate that complies with current or revised standards.

Response: Because of existing requirements in § 32.210(f), a certificate would have to be amended before devices with significant changes could be distributed. As to changes made to regulatory requirements that may necessitate a change to an existing certificate, the NRC makes decisions on implementation of a revised regulation on a case-by-case basis considering the risks involved and benefits associated with the particular change.

Comment: One commenter proposed that an independent screening review be performed to identify the set of devices likely to result in occupational dose in excess of 500 mrem TEDE and a public dose of 50 mrem in 1 year, and then establish notification or review criteria for the certificate holders accordingly. This commenter suggested that the NRC notify each certificate holder with devices exceeding the dose criteria and request a factual accuracy review, comments regarding the calculations, and the cost to recall and make changes to ensure compliance with the dose values. This recommendation went on to suggest that, if occupational doses could exceed 500 mrem/year, the distributor should be required to notify users that they should comply with part 20 (or the Agreement State regulations), and that if public doses could exceed 50 mrem, but not 100 mrem, the NRC should require an ALARA review similar to that required by 10 CFR 20.1101(d).

Response: This proposal did not suggest revising the regulations. However, in looking at a possible screening process, it should be noted that acceptable potential doses that workers and the general public may receive from a device depends on whether it is to be used under an exemption from licensing, a general license, or a specific license. Devices to be used under certain exemptions and the general license in § 31.5 are evaluated against specific safety criteria in part 32. There are no specific criteria for devices used under specific license; the

safety of workers and the public being primarily protected by part 20, which applies to all specific licensees. Applying such a process as suggested by the commenter across the board would be inappropriate. In particular, the recommended criteria would be inappropriate for evaluating products used under exemptions from licensing. Also, in the absence of an indication of a problem or adverse operational experience, the NRC does not believe it necessary to conduct a screening for all previously approved devices.

The Inactivation Provision in § 32.211

The only issue that received a significant number of objections was the proposed inactivation requirement. However, much of this reaction resulted from apparent misinterpretation of the intent of the provision and because of unforeseen impacts that could result if devices are transferred only occasionally with two years passing without a transfer of a device for which some continued distribution is anticipated.

Comment: A few commenters indicated that it was not uncommon for 2 years to pass between transfers of particular devices and that the requirement to inactivate in this instance would be burdensome to business. Comments were that compliance with this proposed rule would not be practical, that licensees may not know in advance when their last manufacture or transfer of a sealed source or device will take place, and that the certificate holders should decide when to inactivate certificates based on their business needs and intentions. Commenters specifically suggested that one may anticipate new applications for a product, development of new markets, etc., and that it might force inactivation of a certificate for a device which may be required again in another few months. Two commenters noted that the costs of maintaining the certificate, including the fees, provide incentive to inactivate a certificate when there are no prospects of future sales; one of these commenters recognized the rationale for desiring registrations to be inactivated if there is no intent to manufacture and/or distribute within

a reasonable period. One commenter stated that the existing certificates already must be renewed periodically. This commenter suggested a 5-year time limit to apply for inactivation.

Response: The primary intent of the amendments concerning the sealed source and device registry, including the inactivation provision, is to make the regulations more explicit and transparent with respect to the use of registration certificates as part of the licensing process and also to improve national consistency in the processes used, thus improving the quality of the information in the registration database. This provision was not intended to interfere with business decisions or processes, but rather was proposed to alleviate any confusion as to which sources and devices are authorized for continued distribution, as well as providing a mechanism for regulators to help ensure the continued availability of qualified device service providers. The NRC would not want distributors to unnecessarily inactivate a certificate as a result of this provision and then need to apply for an active certificate again in the case of product with a limited market.

The intent of the language of the proposed rule text was that the request would be made when two conditions are met: 1) There is no ongoing intent to distribute and 2) 2 years have passed since distribution has ceased. However, the Statement of Considerations for the proposed rule did not address the condition in the regulation that the distributor must have no intention to make further transfers. As the commenters have noted, an unintended consequence of the rule as proposed might have been that if a distributor does not make the decision to make no further transfers more than 2 years after the last transfer, it could be in noncompliance with the regulations.

The text in this final rule has therefore been revised to clarify that no action need be taken after 2 years without a transfer until it is determined that there will be no future transfers. However, within 90 days of such a determination, inactivation must be requested and some brief

explanation must be provided if more than 2 years has elapsed since distribution of any source or device covered by the certificate has ceased.

If a licensee is concerned that an inspection could identify a certificate that it is being kept active in anticipation of future sales, even though no sale has been made in 2 years, it may document its intent to continue sales; however, this would not be required. There may be existing evidence available of an expectation to continue to distribute. In some cases, there are capabilities that must be maintained in order to continue to be able to and/or be authorized to distribute, particularly for a manufacturer. There may be such documents as marketing materials, including catalogues of available products, or internal memos, which indicate either an ongoing intent to sell or a decision to cease distribution.

In addition, the situation of not transferring any source or device for more than 2 years with the intent to continue sales is expected to be relatively rare, particularly because individual certificates frequently include numerous models that have been approved for distribution. While distributors should update certificates to indicate which models are no longer being sold, the NRC did not make doing so a requirement or set a deadline for this type of amendment of certificates. The text of § 32.211 has also been revised to clarify that inactivation is necessary when all sources or devices covered by a certificate are no longer being distributed and to clarify that certificates must be inactivated before the associated distribution license is terminated. The specific address for submitting inactivation requests is also added.

Comment: Some commenters expressed concern that the proposed language of § 32.211 did not appear to allow redistributions or other transfers of sources or devices after inactivation of a certificate. Two commenters specifically suggested that the proposed wording of the fourth sentence in proposed § 32.211 should be changed to include the word “initially” so that it reads: “A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to *initially* transfer such

sources or devices for use." Another commenter was also concerned about redistribution, stating that it should be authorized even if the certificate is inactive. This commenter believed that an inactive certificate does not allow for the transfer or redistribution of registered sources or devices by specific licensees and noted that a source or device no longer being initially distributed is nonetheless safe for use by persons authorized to use the source in accordance with the conditions of the registration certificate.

Response: The intent of proposed § 32.211 in this regard is that only the unique authority provided to the distributor by the registration certificate (along with the associated license) to initially transfer a source or device ceases, without any effect on any other transfers of the covered source(s) or device(s). The suggested addition of the word, "initially," has been made for clarification. The inactivation of a certificate does not limit the use or transfer of previously manufactured sources and devices. The Commission agrees that a source or device that is no longer being distributed is nonetheless safe for use by persons authorized to use it in accordance with the conditions of the certificate. The only concern after the inactivation of a certificate is that proper servicing continues to be available. The inactivation provision clarifies that a device shall be serviced as provided in the certificate and the inactivation process alerts the regulator that servicing may not be available from the original distributor.

A.3 Adding Flexibility for Licensing Users of Sealed Sources and Devices

Two specific questions were posed in the proposed rule concerning this issue:

Q.5 Proposal in § 30.32(g)(5) to allow some licenses to specify only constraints on the number and type of sealed sources and devices to be used and the conditions under which they are to be used:

(a) In view of the expectation that this authorization would only be granted in limited situations and due to special circumstances, how can NRC make it clear that approval of this approach would be at the NRC's discretion, rather than this being an open-ended option for anyone, or should the regulation specify when this approach is acceptable?

Comment: In response to this question, two commenters requested that the NRC be as clear and detailed or practical as possible when imposing new requirements. Additionally, one commenter suggested that the NRC add an example of an exemption in NUREG-1556.

Response: The text of the final rule has been revised to clarify that this approach may be used if it is not feasible to identify each sealed source and device individually. Examples of situations where use of this approach is acceptable were discussed in the proposed rule as well as in the discussion of this issue in Section II. A.3., "Adding Flexibility for Licensing Users of Sealed Sources and Devices." Such examples and additional guidance are being provided in the interim guidance [Docket ID NRC-2012-0074] developed for this rulemaking, and will ultimately be included in the revisions to applicable volumes of NUREG-1556. A notice concerning the availability of the interim guidance for comment was published in the Proposed Rules section of this issue of the *Federal Register*. However, one situation that is not considered appropriate for this approach is in applying for the renewal of a license that had been previously issued without identification of individual sources and devices where it is simply inconvenient to provide an inventory of currently held sources and devices.

Q.5(b) Are there other situations besides those discussed, when identifying all of the sealed sources and devices to be licensed is particularly impractical?

Comment: Two commenters responded to this question. One comment concerned not applying any limits on the quantities distributed to generally licensed or exempt devices. The other commenter suggested that the definition of "sealed source" in § 30.4 (and part 70) lacks specificity and should be revised to focus on only those sources manufactured and distributed pursuant to an SS & D registration. This commenter indicated that this would address confusion as to the applicability of certain requirements, in particular, leak testing requirements, to sources that are contained in ways that could be construed to constitute a sealed source, under the current definition. The suggested revision would have limited sealed sources to those that are registered in the SS & D Registry.

Response: The provision proposed in § 30.32(g)(5) and in the final rule as § 30.32(g)(4) is not applicable to generally licensed or exempt devices, which do not have to be listed on a specific license. Addressing concerns related to the applicability of leak testing requirements for specifically licensed sources is outside of the scope of this rule. Limiting the definition of "sealed source" to registered sources would be inconsistent with aspects of this rule (in particular § 32.210(g)) and other provisions in NRC regulations.

B. Establish a New Class Exemption for Certain Industrial Products.

Only about half of the commenters made any statements about the proposed new class exemption. The comments received were mostly supportive, although some concerns were noted. Support for the proposed exemption came primarily from a major manufacturer and from the OAS. The manufacturer indicated that research and development of new devices is expensive and time-consuming, that the uncertainty in the regulatory outcome and the lengthy rulemaking process to obtain a product-specific exemption made exempt product development risky, and that creating a class exemption for industrial devices with risk-informed, performance-

based criteria would reduce uncertainty, speed approvals, and lower barriers to innovation, and would provide a nationwide standard. This manufacturer also pointed out the difficulties of general licensing for low-risk devices with inconsistencies in Agreement State licensing of portable devices even though the SS & D Registry authorizes distribution to general licensees. This commenter noted the complications of marketing and distribution of such products on a nationwide basis as well as those for users who may be authorized to use a device under a general license in State A, but if they transport the device to State B, a specific license is required. Both this manufacturer and the OAS suggested that manufacturers would be more inclined to develop products using lower quantities of radioactive materials in order to meet the criteria for exemption, with one commenter suggesting that this would result in a reduction in some hazards to workers, members of the public, and the environment.

Comment: One manufacturer/distributor expressed concern that the health and safety of the public or the environment might not be adequately protected, noting the possibility that the increased number of devices allowed to be disposed of in landfills and scrap metal reprocessing streams would potentially increase the number of alarms at landfills, scrap metal facilities, and metal recycling facilities and ultimately create a burden on State regulatory authorities as a result. However, this commenter also said that the number of devices exempted by this provision would be very small and that this could be handled on an individual source or device basis and that the exception could be included in the NUREG-1556 guidance.

Response: Granting an exemption from licensing and all of the associated requirements is not appropriately handled through guidance. Although an individual can request specific exemptions under § 30.11, it is not practical for a manufacturer to distribute a product to be used by persons who individually have to request an exemption from licensing. The NRC normally does not issue exemptions from all of the licensing requirements of part 30 except through rulemaking to establish a broadly applicable exemption from licensing.

Although the NRC cannot ensure that exempt products do not occasionally cause alarms at such places as landfills, scrap metal facilities, and metal recycling facilities, the NRC does not believe that this possibility alone would justify not exempting products for which the safety of the public is adequately protected. This would unnecessarily limit the benefits society may derive from the uses of radioactive material.

This new exemption has been designed to ensure that quantities of byproduct materials approved for use in products are well controlled. This includes the misuse scenario in § 32.31(b), which ensures that relatively high quantities are not approved based on the material being well contained and well shielded. One of the benefits of such criteria is limiting the possibility that quantities of material in any products approved for use under the new class exemption are sufficient to cause such problems during disposal as raised by the commenter.

In addition, labeling requirements help to minimize the efforts that are ultimately spent toward resolving what to do in these cases. When a product is identified in the waste that caused the alarm, the label should be intact in most cases and this provides the information necessary to determine if the product can be accepted or what the disposal options are for it. Most products covered by an exemption do not contain quantities of byproduct material large enough to set off alarms, particularly when shielded within a quantity of waste. How much byproduct material can result in an alarm depends on the practices at the site for handling and sorting waste and when the waste passes any alarm system.

Comment: A few commenters discussed the values in the safety criteria in § 32.31, particularly the 20 mrem/year routine use criterion, although not all specifically in response to the following question related to this issue:

Q.2 New class exemption for industrial products in § 30.20:

(a) Is the 20 mrem/year routine dose criterion appropriate, given that users are workers, but there is no control of conditions of use once a product is distributed for use under an exemption from license?

A manufacturer and an organization representing manufacturers and distributors suggested that the 20 mrem/year criterion was unnecessarily low. These commenters suggested that the criterion should be 50 mrem/year or 100 mrem/year. The commenter suggesting 50 mrem/year argued that 20 mrem/year would be overly burdensome, that the median dose would be lower than the criterion, because of the requirement to estimate the likely number of devices likely to be in one place, and that the most likely scenario of exposure to the public was disposal and that has a separate limit of 1 mrem/year. The commenter supporting 100 mrem/year did not see any reason for the criterion to be lower than the public dose criterion, but also asked how the NRC would monitor compliance with the new criterion given that members of the public are not typically issued dosimetry.

Another commenter suggested that the 20 mrem/year criterion should be lower, also stating that the discussion of a 10 rem misuse scenario is inconsistent with the 25 mrem/year value in 10 CFR 20.1402 and the 10 mrem/year constraint imposed by 10 CFR 20.1101(d), since misuse could result in an airborne intake of radioactive material. This commenter suggested that a more consistent argument might be made for a criterion of 10 mrem/year TEDE for all scenarios.

Response: The safety criteria for a class exemption such as the new industrial product exemption are design criteria. Demonstrating that a product meets these criteria depends on projections of future events. There is no monitoring of actual user exposures. As products used under exemption are used without any further regulatory control, the agency cannot ensure that users will not be exposed to a number of different products. They may also be exposed to other sources of radiation. Given the uncertainty in the ultimate exposures and the fact that

individuals may be exposed to multiple sources, using the public dose limit of 1 mSv (100 mrem)/year is not adequate or appropriate.

Using the same dose criterion for all scenarios would be inconsistent on a risk basis as the various scenarios have different probabilities of occurrence, particularly in the case of accident scenarios. In addition, the lower criterion for disposal is used because individuals who are impacted by the uncontrolled disposal of exempt products are exposed to all radioactive material going to the same disposal facility, such as a landfill.

With regard to the commenter's comparisons to other existing regulations, "practice-specific" limits such as the criteria for unrestricted release in § 20.1402, constraints on air emissions in § 20.1101(d), and the safety criterion for routine use of "exempt" industrial products do not need to be numerically consistent. The two cited provisions in part 20 are essentially the fraction of the overall public dose limit considered appropriate for that particular source of exposure to the public. Such practice-specific limits are chosen based on cost/benefit considerations and other factors related to each specific practice.

Given the cost/benefit considerations and the likelihood of the same workers being exposed to a number of different types of devices falling under this and other exemptions, the Commission believes that 200 μSv (20 mrem)/year is an appropriate criterion for worker exposures from a device used under exemption, particularly given that the applicant must estimate the number of the same device likely to be present in the location of use and show that the total exposure from that number of devices is unlikely to exceed this criterion.

The argument for raising the routine use criterion to 50 mrem (500 μSv)/year is also not compelling. Although some individuals using a single or small number of devices would incur a lower than 20 mrem (200 μSv)/year dose, the NRC does not agree that the median dose would be significantly below the criterion. Also, estimating the median dose and regulating on that

basis is not the appropriate way to control exposures, as it would not control well the maximum likely dose.

Comment: One commenter noted that the requirement in § 32.30(b)(6) to submit information including the maximum radiation levels at 5 and 25 centimeters (cm) was inconsistent with other sections of the regulations, regulatory guidance documents, and consensus standards and recommended that the latter distance be changed to 30 centimeters. Regulations and guidance documents referenced included: 1) the definition of radiation areas and high radiation areas in 10 CFR 20.1003; 2) the exception to posting requirements in 10 CFR 20.1903(c); 3) the ANSI/ Health Physics Society standard, ANSI/HPS N43.8-2008, "Classification of Industrial Ionizing Radiation Gauging Devices" (which uses the distances 5 cm, 30 cm, and 100 cm for developing the classification of devices); and 4) NUREG-1556, Vol. 3, Rev. 1 (which provides for making radiation measurements at 5 cm, 30 cm, and 100 cm from the product). This commenter also recommended that similar changes be made to §§ 32.22 and 32.26.

Response: The NRC agrees that consistency with ANSI/HPS N43.8-2008 and NUREG-1556, Vol. 3, Rev. 1 is appropriate for this situation, although the other references are not particularly relevant, as they deal with different types of requirements. The final rule has been changed to require that measurements be taken at 5 and 30 cm. Note this change in distances for measurements does not affect the safety criteria for devices. The measurements are designed to characterize the radiation profile around the device for use in evaluating the safety of the device. However, the measurements are not used directly in determining acceptability. For a particular device, the applicant must describe how it would be used and the scenarios in which people are exposed during the entire life cycle of the device. This includes estimating distances at which one would typically be exposed. The radiation profile can be used to estimate the radiation field at various distances for use in the analysis.

Changes to §§ 32.22 and 32.26 are outside the scope of this rulemaking.

While not applicable to the new class exemption itself, the proposed rule also posed this question in connection with the new class exemption:

Q. 2(b) Would it be appropriate to apply certain aspects of the proposed standards for this class exemption to the safety criteria (§§ 32.23 and 32.27) for the existing class exemptions (§§ 30.19 and 30.20), namely, the use of more up-to-date methodology for dose assessment as reflected in the proposed definition of the term, "committed dose," the inclusion of a misuse scenario and/or a specific quantity limit to control quantities that may meet the safety criteria when a source is well contained and shielded, and the consideration of the number of products likely to accumulate in one place in the dose assessments for all scenarios?

Comment: One commenter specifically supported making such changes to the safety criteria for the two class exemptions established in 1969 provided they are also changed to reflect the Federal Radiation Council (FRC)/ Environmental Protection Agency (EPA) guidance on use of ICRP-26 in the setting of radiation safety regulations. Another commenter indicated that manufacturers in any industry cannot typically be held responsible for the intentional misuse of any product, but gave examples of safety features that can be incorporated in the products to help prevent improper use.

Response: The Commission posed this question in order to obtain input for any future rulemaking in this area. The NRC plans to consider such changes in the future to the other two class exemptions; however, the approach may not be specifically tied to ICRP-26 methodology. The NRC is currently evaluating what changes to its regulatory program should be considered in connection with achieving better alignment with ICRP-103 recommendations. The basic recommended limit for exposures of the public is consistent in the various versions of the basic safety standards in ICRP-26, ICRP-60, and ICRP-103. The details of calculating doses have

been evolving. In the case of design standards such as the subject regulations, it is appropriate to allow for the use of the latest methodology.

The misuse scenario as used in the safety criteria for the new class exemption has been developed to limit the quantity of byproduct material in products used under the exemption so as to limit the potential harm that can be created with the product in any situation, not to attribute responsibility (for example, to a manufacturer) in actual cases of intentional misuse.

C. Remove Unnecessary Limitations from the Class Exemption for Gas and Aerosol Detectors.

The only comments on this issue were in response to the three specific questions posed:

Q.3 Expanding the class exemption for gas and aerosol detectors in § 30.20 by revising the requirement of "designed to protect life or property from fires and airborne hazards" to instead be "designed to protect health, safety, or property":

(a) Are there additional products that may be exempted under this expanded definition of the class not specifically considered by the NRC?

Comment: One commenter suggested that the revision could inspire new products alleged to protect property from all sorts of airborne hazards, such as, detectors to detect chemical contaminates in air at ultra clean nano fabrication facilities as well as to sniff airline passengers for drugs.

Response: Detectors for maintaining ultra clean nano fabrication facilities would appear to be a type of product with a reasonable benefit to society. The NRC considers it reasonable to allow such a product to be used under exemption, if it is adequately shown to meet the safety criteria in part 32 for evaluation of such products. As the change in scope of the class of

products covered by this exemption is relatively limited, the NRC does not expect to see the development of a large number of new products as a result of this change and most are likely to be products used in moderate numbers.

Q.3(b) Are these words adequate to ensure that products present a clear societal benefit?

Comment: One commenter simply agreed. Another disagreed, indicating that using detectors to sniff for drugs might not be considered "a clear societal benefit" by many and that use in nano technology to manufacture “cool but frivolous products,” might not be considered a clear societal benefit.

Response: If detectors were developed that could be approved for use under this exemption for use in nano technology, they would not be exclusively used for the production of frivolous products, but might also be used for more important applications. Overall some reasonable societal benefit would be expected to balance the limited impact from exempting the detectors. Similarly, the detection of drugs is generally accepted as presenting an overall benefit to society, but NRC recognizes that there could be situations in which the determination of societal benefit is a matter of judgment. Under the final regulations, the NRC will look to see whether the product provides a benefit in protecting health, safety, or property, and if it does, the NRC will find there is a societal benefit.

Q.3(c) Are there any potential problems with approving additional products for use under this exemption and later reevaluating the safety criteria associated with this exemption for potential alignment with newer recommendations of the ICRP?

Comment: One commenter expressed general agreement with expanding the scope of exempt device approvals, and also stated that it endorsed the position taken by the Canadian Nuclear Safety Commission, certain European countries, and Japanese regulators to allow the complete exemption without device registration or distribution license of products with activities below IAEA exemption "clearance" levels. The commenter who questioned whether the revised words for the purpose of the devices ensured products with a clear societal benefit in response to Question 3(b) also stated that creating exemptions consistent with world markets is good for U.S. consumers and manufacturers.

Response: With regard to the suggestion to allow complete exemption of products with activities below IAEA exemption “clearance” levels, this comment is not specifically responsive to the question posed. However, the NRC does not agree that there should be a “complete exemption” such as the commenter suggested. The NRC notes that, related to this issue, the NRC’s regulations in §§ 30.14 and 30.70 exempt materials based on the concentration of the byproduct material contained within it. Although this is not considered a “clearance” provision, distribution licenses are only required by § 32.11 for products and materials into which byproduct material is introduced by an intentional action. The regulations in §§ 30.18 and 30.71 exempt materials based on the quantity of the byproduct material. In this case, distribution licenses are required in the case of commercial distribution. These are the circumstances for which the NRC considers it appropriate to exercise oversight of the processes to ensure that the materials transferred for use under these general material exemptions in fact meet the constraints of the exemption.

D. Remove Prescriptive Requirements for Distributors of Generally Licensed Devices and Exempt Products.

Comments received responded to the questions posed related to this issue:

Q.4 Changes to certain quality control requirements in §§ 32.15, 32.55, and 32.62 to (i) raise the statistical acceptance criteria; i.e., increasing the required confidence that the Lot Tolerance Percent Defective will not be exceeded from the current 90 percent (consumer risk of 0.10) to 95 percent; and (ii) require that distribution of any part, or sub-lot, of a rejected lot must be in accordance with procedures spelled out in the license and that testing after repairs must be performed by an independent reviewer. These proposed revisions are in § 32.15(a) and (b) for certain exempt items, § 32.55(b) and (d) for luminous safety devices used in aircraft, and § 32.62(c) and (e) for ice detection devices.:

(a) Would any actual changes in practice need to be made by affected licensees? The NRC would welcome information that would aid in evaluating any impact.

Comment: One commenter stated that licensees would be required to change their procedures, retrain their work force and incur additional cost.

Response: The commenter provided no support for this statement. The commenter was contacted and did not provide any additional supporting information on this comment. Most licensees authorized under the distribution provisions for which the sampling/quality control standards are being revised in fact test all products rather than using a sampling procedure. The NRC does not believe that these changes will result in such a significant burden as the commenter is suggesting.

Q.4(b) Would there be any impact on manufacturers or distributors of products for which oversight of quality control practices are proposed to be removed, if the new provisions were applied to these products instead, i.e., if all of the exceptions in § 32.14(b)(5) were not made effective as proposed? (As discussed under Section III. F. "Make the Requirements for Distributors of Exempt Products More Risk-Informed," products for which quality control oversight may be removed are: ionization chamber smoke detectors, electron tubes, and timepieces containing promethium-147 or tritium in the form of gaseous tritium light sources, covered by exemptions in § 30.15, and for products to be used under the proposed new exemption in § 30.15(a)(2), static eliminators and ion generating tubes formerly covered by the general license in § 31.3.)

Comment: One commenter stated that many manufacturers are ISO 9001 certified and their current procedures are adequate to address any quality control issues.

Response: Although this statement is not responsive to the particular question posed, the NRC agrees with the comment.

E. Other Issues.

There were no specific comments received on the issues of updating the regulations on certain static eliminators and ion generating tubes or making the requirements for distributors of exempt products more risk-informed, or on the proposed minor clarifying and administrative revisions. Some additional minor clarifying changes have been made to the final amendments.

F. Comments on Issues Outside of the Scope of the Rule.

In addition to those comments noted above, there were a few other comments made that are outside of the scope of the rule.

Comment: One commenter stated that the NRC should require manufacturers to take back exempt products after their useful life has expired, without charge to the user of the device, to reduce the amount of material disposed in landfills and released to the environment.

Response: The impacts from disposal of products used under the exemptions from licensing have been fully evaluated and determined to be acceptable. Requiring manufacturers to take back exempt products would unnecessarily increase costs to consumers and create problems when distributors have gone out of business and terminated their license. Also, the collection of large numbers of products in one place results in larger exposures to those handling the products than when they are disposed in numerous municipal disposal facilities across the country.

Comment: One commenter requested that the NRC make clear the requirements for inventory, leak testing, and reporting in parts 30, 40, and 70.

Response: Besides being outside the scope of this rule, the resolution of this issue would be complicated and the commenter did not provide an adequate approach for doing so.

Comment: The OAS restated its concerns about the quantities of material used in generally licensed devices being too high and the current general license program not providing adequate accountability for registered material.

Response: These concerns were presented in a petition for rulemaking (PRM-31-5), which has been handled separately from this action. The Commission considered the issues raised in a separate rulemaking, but decided against issuing a final rule. Final action on that petition was published January 25, 2012 (77 FR 3640).

IV. Summary of Final Amendments by Section.

10 CFR 30.6(b)(1)(iv) – Adds a reference to new 10 CFR 32.30 as a licensing category not delegated to the NRC Regions.

10 CFR 30.8(c)(1) – Removes reference to 10 CFR 30.38 as a section that contains NRC Form 313.

10 CFR 30.15(a)(2) – Adds an exemption for certain static eliminators and ion generators in place of the general license formerly in 10 CFR 31.3.

10 CFR 30.19(b) – Clarifies that applicants under 10 CFR 32.22 should also apply for a registration certificate.

10 CFR 30.20 – Slightly expands the class of products covered under this exemption from licensing; clarifies that applicants under 10 CFR 32.26 should also apply for a registration certificate; updates the parts of the regulations from which persons are exempt to include 10 CFR part 19.

10 CFR 30.22 – Establishes a new class exemption for industrial devices initially transferred from 10 CFR 32.30 licensees.

10 CFR 30.32(g) – Restructured for clarity.

10 CFR 30.32(g)(2) – Extends and redesignates the provision for providing alternative information on NARM legacy sealed sources and devices to all legacy sealed sources and devices.

10 CFR 30.32(g)(3) – Adds a provision for providing limited information for certain calibration and reference sources.

10 CFR 30.32(g)(4) – Adds a provision to allow for constraints on the number and type of sealed sources and devices to be used and the conditions under which they are to be used

rather than requiring complete identification of all sealed sources and devices to be licensed in certain cases.

10 CFR 30.38 – Revises the heading and adds an explicit provision for amendment of registration certificates and removes reference to NRC Form 313.

10 CFR 30.39 – Adds registration certificates to clarify that the same requirements are applicable to amendment of a registration certificate as for issuance of a new certificate.

10 CFR 30.61 – Revises the heading and adds registration certificates to provisions for modification and revocation of licenses and updates reference to parts under which licenses are issued.

10 CFR 31.3 – General license is removed, section reserved, and replaced by a new exemption in 10 CFR 30.15(a)(2).

10 CFR 31.23(b) – Removes reference to 10 CFR 31.3 and makes other minor corrections.

10 CFR 32.1(a) – Expands the description of the scope of 10 CFR part 32 to cover additional requirements and makes clarifications.

10 CFR 32.2 – Adds definitions of “committed dose” and “sealed source and device registry.” The definition of “committed dose” was modified from the proposed rule to remove an improper incorporation by reference.

10 CFR 32.8(b) – Adds to the list of information collection requirements: 10 CFR 32.30 on application requirements for distributors of exempt industrial devices, 10 CFR 32.31 on safety criteria to be addressed in the application for license under 10 CFR 32.30, 10 CFR 32.32 on reporting and recordkeeping requirements for distributors of exempt industrial devices, and 10 CFR 32.211 on requesting inactivation of registration certificates.

10 CFR 32.14(b)(4) – Makes exceptions to prototype testing requirements.

10 CFR 32.14(b)(5) – Makes exceptions to quality control requirements.

10 CFR 32.15(a), (b), and (c) – Removes the specific procedural requirements for quality assurance, revises the acceptance criterion, and limits these requirements to products for which such procedures will be required under 10 CFR 32.14.

10 CFR 32.22(a)(3) – Adds an explicit requirement for sealed source and device registration.

10 CFR 32.26 – Revises the introductory text to expand the limitation of “from fires or airborne hazards,” for the purpose of the detectors, thus, expanding the class of products covered; and adds an explicit requirement for sealed source and device registration.

10 CFR 32.30 – Establishes requirements for an application to manufacture, process, produce, or initially transfer for sale or distribution exempt industrial devices.

10 CFR 32.31 – Establishes safety criteria for approving industrial devices to be distributed for use under 10 CFR 30.22 and equivalent Agreement State regulations.

10 CFR 32.32 – Establishes specific conditions of license for distribution of exempt industrial devices, including quality control, labeling, and reporting and recordkeeping requirements.

10 CFR 32.51(a)(6) – Adds an explicit requirement for sealed source and device registration for devices to be transferred for use under 10 CFR 31.5 and equivalent Agreement State regulations.

10 CFR 32.53 – Removes the reference to 10 CFR 32.101 and adds requirements for prototype testing without details of procedures to be followed; revises the requirement for information to be submitted on quality control/quality assurance to be consistent with less prescriptive approach in 10 CFR 32.55; and adds an explicit requirement for sealed source and device registration.

10 CFR 32.55 – Revises the requirement to conduct quality assurance to be clearer and less prescriptive and revises the acceptance criterion.

10 CFR 32.56 – Adds ATTN: GLTS to address for reporting, explicitly requires reports to Agreement States, and clarifies the need for reporting even if no transfers were made during the reporting period.

10 CFR 32.57(d)(2) and (e) – Removes reference to 10 CFR 32.102 and adds less prescriptive requirement for prototype testing in paragraph (e).

10 CFR 32.59 – Makes minor clarifying amendments to testing requirements for calibration and reference sources to be used under 10 CFR 31.8 and equivalent Agreement State regulations.

10 CFR 32.61(e)(4) and (f) – Revises the prototype test requirement by removing reference to 10 CFR 32.103 and adding less prescriptive requirement for prototype testing in paragraph (f).

10 CFR 32.61(g) – Adds an explicit requirement for sealed source and device registration.

10 CFR 32.62(c), (d), and (e) – Revises and clarifies quality assurance requirements, acceptance criterion, and associated prohibition of transfer.

Heading of subpart C is changed to “Specifically Licensed Items.”

10 CFR 32.72 and 10 CFR 32.74 are moved from subpart B to renamed subpart C.

10 CFR 32.74(a)(4) – Adds an explicit requirement for sealed source and device registration for sealed sources and devices for medical use.

10 CFR 32.101 – Specific prototype test procedures for luminous safety devices for use in aircraft are removed.

10 CFR 32.102 – Specific prototype test procedures for calibration and reference sources containing americium-241 or radium-226 are removed.

10 CFR 32.103 – Specific prototype test procedures for ice detection devices containing strontium-90 are removed.

10 CFR 32.110 – Specific acceptance sampling procedures are removed.

Heading of subpart D is changed to “Sealed Source and Device Registration.”

10 CFR 32.201 is moved from subpart D to renamed subpart C.

10 CFR 32.210(a) and (e) – Remove restriction of applicability to specifically licensed items.

10 CFR 32.210(b) – Adds ATTN: SSDR to address for requests.

10 CFR 32.210(d) – Adds reference to other criteria that apply to various categories of sealed sources and devices.

10 CFR 32.210(g) – Adds criteria for sources and devices not requiring SS & D registration.

10 CFR 32.210(h) – Adds an explicit provision for additional review of registration certificates.

10 CFR 32.211 – Adds an explicit provision for inactivation of sealed source and device registration certificates.

10 CFR 32.303(b) – Adds reference to new requirements not issued under section 223 of the AEA, as well as correcting previous omissions.

10 CFR 40.5(b)(1)(iv) – Adds reference to new 10 CFR 32.30 as a licensing category not delegated to the NRC Regions.

10 CFR 70.5(b)(1)(iv) – Adds reference to new 10 CFR 32.30 as a licensing category not delegated to the NRC Regions.

V. Criminal Penalties.

For the purpose of Section 223 of the Atomic Energy Act (AEA), the Commission is amending 10 CFR parts 30 and 32 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.

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the *Federal Register* (62 FR 46517; September 3, 1997), this final rule would be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among the Agreement States and the NRC requirements. The NRC staff analyzed the final rule in accordance with the procedure established within Part III, "Categorization Process for NRC Program Elements," of Handbook 5.9 to Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs" (a copy of which may be viewed at http://www.nrc.gov/reading-rm/doc-collections/management-directives/).

NRC program elements (including regulations) are placed into four compatibility categories (See the Compatibility Table in this section). In addition, the NRC program elements can also be identified as having particular health and safety significance or as being reserved solely to the NRC. Compatibility Category A are those program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Category A program elements in an essentially identical manner to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B are those program

elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. Compatibility Category C are those program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide 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.

Health and Safety (H&S) are program elements that are not required for compatibility but are identified as having a particular health and safety role (i.e., adequacy) in the regulation of agreement material within the State. Although not required for compatibility, the State should adopt program elements in this H&S category based on those of the NRC that embody the essential objectives of the NRC program elements because of particular health and safety considerations. Compatibility Category NRC are those program elements that address areas of regulation that cannot be relinquished to Agreement States under the Atomic Energy Act, as amended, or provisions of 10 CFR. These program elements are not adopted by Agreement States. The following table lists the parts and sections that would be revised and their corresponding categorization under the “Policy Statement on Adequacy and Compatibility of Agreement State Programs.”

The final rule is a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements. The compatibility categories are designated in the following table:

Compatibility Table for Final Rule

Section/Paragraph	Change	Subject	Compatibility	
			Existing	New
30.6(b)(1)(iv)	Amend	Communications	D	D
30.8(c)(1)	Amend	Information collection requirements: OMB approval	D	D
30.15(a)(2)	Add	Certain items containing byproduct material	…….	B
30.19(b)	Amend	Self-luminous products containing tritium, krypton-85, or promethium-147	B	B
30.20	Amend	Gas and aerosol detectors containing byproduct material	B	B
30.22	New	Certain industrial devices	…….	B
30.32(g)	Amend	Application for specific licenses	C	C
30.38	Amend	Application for amendment of licenses and registration certificates	D	D
30.39	Amend	Commission action on applications to renew or amend	D	D
30.61	Amend	Modification and revocation of licenses and registration certificates	D	D
31.3	Remove	[Existing title - Certain devices and equipment]	B	★
31.23(b)	Amend	Criminal penalties	D	D
32.1(a)	Amend	Purpose and scope	D	D
32.2	Add	Definition: Committed dose	…….	D
32.2	Add	Definition: Sealed source and device registry	……..	D
32.8(b)	Amend	Information collection requirements: OMB approval	D	D
32.14(b)(4) & (b)(5)	Amend	Certain items containing byproduct material; requirements for license to apply or initially transfer	NRC	NRC
32.15(a), (b), & (c)	Amend	Same: Quality assurance, prohibition of transfer, and labeling	NRC	NRC
32.22(a)(3)	Add	Self-luminous products containing tritium, krypton-85 or promethium-147: Requirements for license to manufacture, process, produce, or initially transfer	NRC	NRC
32.26	Amend	Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer	NRC	NRC
32.30	New	Certain industrial devices containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer	…….	NRC
32.31	New	Certain industrial devices containing byproduct material: Safety criteria	……..	NRC
32.32	New	Conditions of licenses issued under § 32.30: Quality control, labeling, and reports of transfer	……..	NRC
32.51(a)(6)	Add	Byproduct material contained in devices for use under § 31.5; requirements for license to manufacture, or initially transfer	……..	B
32.53(b)(5) & (d)(4)	Amend	Luminous safety devices for use in aircraft: Requirements for license to manufacture,	B	B

Section/Paragraph	Change	Subject	Compatibility	
			Existing	New
		assemble, repair or initially transfer		
32.53(e) & (f)	Add	Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer	B	B
32.55	Amend	Same: Quality assurance, prohibition of transfer	B	B
32.56	Amend	Same: Material transfer reports	B	B
32.57(d)(2)	Amend	Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer	B	B
32.57(e)	Add	Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer	B	B
32.59	Amend	Same: Leak testing of each source	B	B
32.61(e)(4)	Amend	Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer	B	B
32.61(f) & (g)	Add	Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer	……..	B
32.62(c), (d), & (e)	Amend	Same: Quality assurance; prohibition of transfer	B	B
32.74(a)(4)	Add	Manufacture and distribution of sources or devices containing byproduct material for medical use	……..	B
32.101	Remove	[Existing title - Schedule B--prototype tests for luminous safety devices for use in aircraft]	B	★
32.102	Remove	[Existing title - Schedule C—prototype tests for calibration or reference sources containing americium-241 or radium-226]	B	★
32.103	Remove	[Existing title - Schedule D--prototype tests for ice detection devices containing strontium-90]	B	★
32.110	Remove	[Existing title - Acceptance sampling procedures under certain specific licenses]	B	★
32.210(a), (b), (d), & (e)	Amend	Registration of product information	B ★★	B ★★
32.210(g)	Add	Registration of product information	……..	B ★★
32.210(h)	Add	Registration of product information	……..	C ★★
32.211	New	Inactivation of certificates of registration of sealed sources and devices	……..	B ★★
32.303(b)	Amend	Criminal penalties	D	D
40.5(b)(1)(iv)	Amend	Communications	D	D
70.5(b)(1)(iv)	Amend	Communications	D	D

★ Denotes regulations that are designated Compatibility Category B but which will be removed from the regulations as a result of these proposed amendments. Agreement States should remove these provisions from their regulations when the regulations become final.

★★ D – for States that do not perform SS & D evaluations.

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. In this final rule, the NRC is making the requirements for distributors of byproduct material clearer, less prescriptive, and more risk-informed and up to date. The Commission is also redefining categories of devices to be used under exemptions, adding explicit provisions regarding the sealed source and device registration process, and adding flexibility to the licensing of users of sealed sources and devices. This action does not constitute the establishment of a standard that establishes generally applicable requirements. However, the regulations being amended concerning sealed source and device reviews, in particular § 32.210(d), will continue to indicate that the NRC uses accepted industry standards, if applicable, in its evaluations.

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

The Commission has determined under the National Environmental Policy Act (NEPA) of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, not to prepare an environmental impact statement for this final rule because the Commission has concluded on the basis of an environmental assessment that this final rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment. The following is a summary of the Environmental Assessment: Many of the individual actions being taken are the type of actions described in the categorical exclusions of §§ 51.22(c)(2) and

51.22(c)(3)(i) and (iii). In addition, the rule will remove prescriptive procedural provisions, add a new class exemption and a new product-specific exemption, broaden an existing class exemption, add flexibility to the basis for licensing the use of sealed sources and devices, and remove some requirements for the distributors of low risk exempt products. The Commission has concluded that none of these actions would have significant impacts to the environment or otherwise include any condition requiring consultation under section 102(2)(C) of NEPA.

The determination of the environmental assessment is that there will be no significant impact to the public from this action.

This conclusion was published in the environmental assessment that was posted to the Federal rulemaking Web site, http://www.regulations.gov, for 75 days after publication of the proposed rule. There were no comments received on the content of the environmental assessment.

IX. Plain Writing.

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, "Plain Language in Government Writing," published June 10, 1998 (63 FR 31883).

X. Paperwork Reduction Act Statement.

This final rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements

were approved by the Office of Management and Budget, control numbers 3150-0017; 3150-0001; and 3150-0120.

The burden to the public for these information collections is estimated to average 16.39 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of these information collections, including suggestions for reducing the burden, to the Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS.Resource@nrc.gov; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0017; -0001; -0120), Office of Management and Budget, Washington, DC 20503, or by Internet electronic mail to Chad_S_Whiteman@omb.eop.gov.

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.

XI. 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 on http://www.regulations.gov by searching on Docket ID NRC-2008-0338 and in the NRC's PDR, 11555 Rockville Pike, Rockville, MD 20852.

XII. Regulatory Flexibility Certification.

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

XIII. Backfit Analysis.

The NRC's backfit provisions are found in the regulations at §§ 50.109, 52.39, 52.63, 52.83, 52.98, 52.145, 52.171, 70.76, 72.62, and 76.76. The requirements contained in this final rule do not involve any provisions that will impose backfits on nuclear power plant licensees as defined in 10 CFR parts 50 or 52, or on licensees for gaseous diffusion plants, independent spent fuel storage installations or special nuclear material as defined in 10 CFR parts 70, 72 and 76, respectively, and as such a backfit analysis is not required. Therefore, a backfit

analysis need not be prepared for this final rule to address these classes of entities. With respect to licenses issued under parts 30, 31, and 32, the NRC has determined that there are no applicable provisions for backfit. Therefore, a backfit analysis need not be prepared for this rule to address parts 30, 31, or 32 licensees.

XIV. 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.

List of Subjects

10 CFR Part 30

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

10 CFR Part 31

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

10 CFR Part 32

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

10 CFR Part 40

Criminal penalties, Government contracts, Hazardous materials transportation, Nuclear materials, Reporting and recordkeeping requirements, Source material, Uranium.

10 CFR Part 70

Criminal penalties, Hazardous materials transportation, Material control and accounting, Nuclear materials, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, 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, 40, and 70.

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: Atomic Energy Act secs. 81, 82, 161, 181, 182, 183, 186, 223, 234 (42 U.S.C. 2111, 2112, 2201, 2231, 2232, 2233, 2236, 2273, 2282); Energy Reorganization Act secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 549 (2005).

Section 30.7 also issued under Energy Reorganization Act sec. 211, Pub. L. 95-601, sec. 10, as amended by Pub. L. 102-486, sec. 2902 (42 U.S.C. 5851). Section 30.34(b) also issued under Atomic Energy Act sec. 184 (42 U.S.C. 2234). Section 30.61 also issued under Atomic Energy Act sec. 187 (42 U.S.C. 2237).

2. In § 30.6, paragraph (b)(1)(iv) is revised to read as follows:

§ 30.6 Communications.

* * * * *

(b) * * *

(1) * * *

(iv) Distribution of products containing radioactive material under §§ 32.11 through 32.30 of this chapter to persons exempt from licensing requirements.

* * * * *

3. In § 30.8, paragraph (c)(1) is revised to read as follows:

§ 30.8 Information collection requirements: OMB approval.

* * * * *

(c) * * *

(1) In §§ 30.32 and 30.37, NRC Form 313 is approved under control number 3150-0120.

* * * * *

4. In § 30.15, paragraph (a)(2) is added to read as follows:

§ 30.15 Certain items containing byproduct material.

(a) * * *

(2)(i) Static elimination devices which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 μCi) of polonium-210 per device.

(ii) Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 μCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.

(iii) Such devices authorized before **[INSERT DATE 90 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]** for use under the general license then provided in § 31.3 and equivalent regulations of Agreement States and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Commission.

* * * * *

5. In § 30.19, paragraph (b) is revised to read as follows:

§ 30.19 Self-luminous products containing tritium, krypton-85, or promethium-147.

* * * * *

(b) Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for

use under paragraph (a) of this section, should apply for a license under § 32.22 of this chapter and for a certificate of registration in accordance with § 32.210 of this chapter.

* * * * *

6. Section 30.20 is revised to read as follows:

§ 30.20 Gas and aerosol detectors containing byproduct material.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 19, 20, 21, and 30 through 36 and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect health, safety, or property, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under § 32.26 of this chapter, which license authorizes the initial transfer of the product for use under this section. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by a State under comparable provisions to § 32.26 of this chapter authorizing distribution to persons exempt from regulatory requirements.

(b) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use under paragraph (a) of this section, should apply for a license under § 32.26 of this chapter and for a certificate of registration in accordance with § 32.210 of this chapter.

7. Section 30.22 is added under the undesignated heading Exemptions to read as follows:

§ 30.22 Certain industrial devices.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 19, 20, 21, 30 through 36, and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under § 32.30 of this chapter, which license authorizes the initial transfer of the device for use under this section. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

(b) Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under paragraph (a) of this section, should apply for a license under § 32.30 of this chapter and for a certificate of registration in accordance with § 32.210 of this chapter.

8. In § 30.32, paragraph (g) is revised to read as follows:

§ 30.32 Application for specific licenses.

* * * * *

(g)(1) Except as provided in paragraphs (g)(2), (g)(3), and (g)(4) of this section, an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either--

(i) Identify the source or device by manufacturer and model number as registered with the Commission under § 32.210 of this chapter, with an Agreement State, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a State under provisions comparable to § 32.210 of this chapter; or

(ii) Contain the information identified in § 32.210(c) of this chapter.

(2) For sources or devices manufactured before **[INSERT DATE 90 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]** that are not registered with the Commission under § 32.210 of this chapter or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in § 32.210(c) of this chapter, the application must include:

(i) All available information identified in § 32.210(c) of this chapter concerning the source, and, if applicable, the device; and

(ii) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

(3) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with § 32.210(g)(1) of this chapter, the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

(4) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

* * * * *

9. Section 30.38 is revised to read as follows:

§ 30.38 Application for amendment of licenses and registration certificates.

Applications for amendment of a license must be filed in accordance with § 30.32 and must specify the respects in which the licensee desires its license to be amended and the grounds for the amendment. Applications for amendment of sealed source and device registration certificates must be filed in accordance with § 32.210 of this chapter and any other applicable provisions and must specify the respects in which the certificate holder desires its certificate to be amended and the grounds for the amendment.

10. Section 30.39 is revised to read as follows:

§ 30.39 Commission action on applications to renew or amend.

In considering an application to renew or amend a license or to amend a sealed source or device registration certificate, the Commission will apply the applicable criteria set forth in § 30.33 and parts 32 through 36 and 39 of this chapter.

11. Section 30.61 is revised to read as follows:

§ 30.61 Modification and revocation of licenses and registration certificates.

(a) The terms and conditions of each license and registration certificate issued under the regulations in this part and parts 31 through 36 and 39 of this chapter shall be subject to amendment, revision, or modification by reason of amendments to the Act, or by reason of rules, regulations, and orders issued in accordance with the terms of the Act.

(b) Any license or registration certificate may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or in any statement of fact required under section 182 of the Act, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means that would warrant the Commission to refuse to grant a license or registration certificate on an original application, or for violation of, or failure to observe any of the terms and provisions of the Act or of any rule, regulation, or order of the Commission.

(c) Except in cases of willfulness or those in which the public health, interest, or safety requires otherwise, no license or registration certificate shall be modified, suspended, or

revoked unless, before the institution of proceedings therefor, facts or conduct that may warrant such action shall have been called to the attention of the licensee or certificate holder in writing and the licensee or certificate holder shall have been given an opportunity to demonstrate or achieve compliance with all lawful requirements.

PART 31 - GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

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

AUTHORITY: Atomic Energy Act secs. 81, 161, 183, 223, 234 (42 U.S.C. 2111, 2201, 2233, 2273, 2282); Energy Reorganization Act secs. 201, 202 (42 U.S.C. 5841, 5842); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, sec. 651(e), Pub. L. No. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

§ 31.3 [Removed and Reserved]

13. Section 31.3 is removed and reserved.

14. In § 31.23, paragraph (b) is revised to read as follows:

§ 31.23 Criminal penalties.

* * * * *

(b) The regulations in part 31 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 31.1, 31.2, 31.4, 31.9, 31.22, and 31.23.

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

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

AUTHORITY: Atomic Energy Act secs. 81, 161, 181, 182, 183, 223, 234 (42 U.S.C. 2111, 2201, 2231, 2232, 2233, 2273, 2282); Energy Reorganization Act sec. 201 (42 U.S.C. 5841); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, sec. 651(e), Pub. L. No. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

16. In § 32.1, paragraph (a) is revised to read as follows:

§ 32.1 Purpose and scope.

(a)(1) This part prescribes requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing byproduct material for sale or distribution to:

(i) Persons exempted from the licensing requirements of part 30 of this chapter, or equivalent regulations of an Agreement State, or

(ii) Persons generally licensed under part 31 of this chapter or equivalent regulations of an Agreement State.

(iii) Persons licensed under part 35 of this chapter.

(2) This part prescribes requirements for the issuance of specific licenses to persons who introduce byproduct material into a product or material owned by or in the possession of a licensee or another, and regulations governing holders of such licenses.

(3) This part prescribes certain requirements governing holders of licenses to manufacture or distribute items containing byproduct material.

(4) This part describes procedures and prescribes requirements for the issuance of certificates of registration (covering radiation safety information about a product) to manufacturers or initial transferors of sealed sources or devices containing sealed sources.

* * * * *

17. In § 32.2, the definitions of *Committed dose* and *Sealed Source and Device Registry* are added in alphabetical order to read as follows:

§ 32.2 Definitions.

* * * * *

Committed dose for the purposes of this part means the radiation dose that will accumulate over time as a result of retention in the body of radioactive material. Committed dose is a generic term for internal dose and must be calculated by summing the projected dose over the 50 years after intake for all irradiated organs or tissues multiplying the doses to individual organs and tissues by applicable tissue weighting factors.

* * * * *

Sealed Source and Device Registry means the national registry that contains all the registration certificates, generated by both the NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

18. 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, 32.30, 32.31, 32.32, 32.51, 32.51a, 32.52, 32.53, 32.54, 32.55, 32.56, 32.57, 32.58, 32.61, 32.62, 32.71, 32.72, 32.74, 32.201, 32.210, and 32.211.

* * * * *

19. In § 32.14, paragraphs (b)(4) and (b)(5) are revised to read as follows:

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

* * * * *

(b) * * *

(4) Except for electron tubes and ionization chamber smoke detectors and timepieces containing promethium-147 or tritium in the form of gaseous tritium light sources, procedures for and results of prototype testing to demonstrate that the byproduct material will not become detached from the product and that the byproduct material will not be released to the environment under the most severe conditions likely to be encountered in normal use of the product;

(5) In the case of ionizing radiation measuring instruments and timepieces containing tritium in the form of paint, quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet;

* * * * *

20. In § 32.15, paragraph (c) is removed and reserved and paragraphs (a) and (b) are revised to read as follows:

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

(a) Each person licensed under § 32.14 for products for which quality control procedures are required shall:

(1) Maintain quality assurance systems in the manufacture of the part or product, or the installation of the part into the product, in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed products are capable of performing their intended functions;

(2) Subject inspection lots to acceptance sampling procedures, by procedures specified in the license issued under § 32.14, to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded; and

(3) Visually inspect each unit in inspection lots. Any unit which has an observable physical defect that could adversely affect containment of the byproduct material must be considered a defective unit.

(b) No person licensed under § 32.14 shall transfer to other persons for use under § 30.15 of this chapter or equivalent regulations of an Agreement State:

(1) Any part or product tested and found defective under the criteria and procedures specified in the license issued under § 32.14, unless the defective part or product has been repaired or reworked, retested, and found by an independent inspector to meet the applicable acceptance criteria; or

(2) Any part or product contained within any lot that has been sampled and rejected as a result of the procedures in paragraph (a)(2) of this section, unless:

(i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under § 32.14; and

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with the procedures specified in paragraphs (a)(2) and (b)(2)(i) of this section and any other criteria that may be required as a condition of the license issued under § 32.14.

(c) [Reserved]

* * * * *

21. In § 32.22, paragraph (a)(3) is added to read as follows:

§ 32.22 Self-luminous products containing tritium, krypton-85 or promethium-147: Requirements for license to manufacture, process, produce, or initially transfer.

(a) * * *

(3)(i) The Commission determines that the product meets the safety criteria in § 32.23; and

(ii) The product has been evaluated by the NRC and registered in the Sealed Source and Device Registry.

* * * * *

22. In § 32.26, the introductory text is revised and paragraph (c) is added to read as follows:

§ 32.26 Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.

An application for a specific license to manufacture, process, or produce gas and aerosol detectors containing byproduct material and designed to protect health, safety, or property, or to initially transfer such products for use under § 30.20 of this chapter or equivalent regulations of an Agreement State, will be approved if:

* * * * *

(c)(1) The Commission determines that the product meets the safety criteria in § 32.27; and

(2) The product has been evaluated by the NRC and registered in the Sealed Source and Device Registry.

23. Section 32.30 is added under subpart A to read as follows:

§ 32.30 Certain industrial devices containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.

An application for a specific license to manufacture, process, produce, or initially transfer for sale or distribution devices containing byproduct material for use under § 30.22 of this chapter or equivalent regulations of an Agreement State will be approved if:

(a) The applicant satisfies the general requirements of § 30.33 of this chapter: However, the requirements of § 30.33(a)(2) and (a)(3) do not apply to an application for a license to

transfer byproduct material in such industrial devices manufactured, processed, or produced under a license issued by an Agreement State;

(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the industrial devices to demonstrate that the device will meet the safety criteria set forth in § 32.31. The information should include:

(1) A description of the device and its intended use or uses;

(2) The type and quantity of byproduct material in each unit;

(3) Chemical and physical form of the byproduct material in the device and changes in chemical and physical form that may occur during the useful life of the device;

(4) Solubility in water and body fluids of the forms of the byproduct material identified in paragraphs (b)(3) and (b)(12) of this section;

(5) Details of construction and design of the device as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the device;

(6) Maximum external radiation levels at 5 and 30 centimeters from any external surface of the device, averaged over an area not to exceed 10 square centimeters, and the method of measurement;

(7) Degree of access of human beings to the device during normal handling and use;

(8) Total quantity of byproduct material expected to be distributed in the devices annually;

(9) The expected useful life of the device;

(10) The proposed methods of labeling or marking the device and its point-of-sale package to satisfy the requirements of § 32.32(b);

(11) Procedures for prototype testing of the device to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the device;

(12) Results of the prototype testing of the device, including any change in the form of the byproduct material contained in the device, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features;

(13) The estimated external radiation doses and committed doses resulting from the intake of byproduct material in any one year relevant to the safety criteria in § 32.31 and the basis for these estimates;

(14) A determination that the probabilities with respect to the doses referred to in § 32.31(a)(4) meet the criteria of that paragraph;

(15) Quality control procedures to be followed in the fabrication of production lots of the devices and the quality control standards the devices will be required to meet; and

(16) Any additional information, including experimental studies and tests, required by the Commission.

(c)(1) The Commission determines that the device meets the safety criteria in § 32.31.

(2) The device is unlikely to be routinely used by members of the general public in a non-occupational environment.

(3) The device has been registered in the Sealed Source and Device Registry.

24. Section 32.31 is added under subpart A to read as follows:

§ 32.31 Certain industrial devices containing byproduct material: Safety criteria.

(a) An applicant for a license under § 32.30 shall demonstrate that the device is designed and will be manufactured so that:

(1) In normal use, handling, and storage of the quantities of exempt units likely to accumulate in one location, including during marketing, distribution, installation, and servicing of the device, it is unlikely that the external radiation dose in any one year, or the committed dose resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the device will exceed 200 μSv (20 mrem).

(2) It is unlikely that the external radiation dose in any one year, or the committed dose resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from disposal of the quantities of units likely to accumulate in the same disposal site will exceed 10 μSv (1 mrem).

(3) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the device from wear and abuse likely to occur in normal handling and use of the device during its useful life.

(4) In use, handling, storage, and disposal of the quantities of exempt units likely to accumulate in one location, including during marketing, distribution, installation, and servicing of the device, the probability is low that the containment, shielding, or other safety features of the device would fail under such circumstances that a person would receive an external radiation dose or committed dose in excess of 5 mSv (500 mrem), and the probability is negligible that a

person would receive an external radiation dose or committed dose of 100 mSv (10 rem) or greater.[1]

(b) An applicant for a license under § 32.30 shall demonstrate that, even in unlikely scenarios of misuse, including those resulting in direct exposure to the unshielded source removed from the device for 1,000 hours at an average distance of 1 meter and those resulting in dispersal and subsequent intake of 10^{-4} of the quantity of byproduct material (or in the case of tritium, an intake of 10 percent), a person will not receive an external radiation dose or committed dose in excess of 100 mSv (10 rem), and, if the unshielded source is small enough to fit in a pocket, that the dose to localized areas of skin averaged over areas no larger than 1 square centimeter from carrying the unshielded source in a pocket for 80 hours will not exceed 2 Sv (200 rem).

25. Section 32.32 is added under subpart A to read as follows:

§ 32.32 Conditions of licenses issued under § 32.30: Quality control, labeling, and reports of transfer.

Each person licensed under § 32.30 shall:

(a) Carry out adequate control procedures in the manufacture of the device to ensure that each production lot meets the quality control standards approved by the Commission;

[1] It is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates that are to be made. The following values may be used as guides in estimating compliance with the criteria: Low--not more than one such failure/incident per year for each 10,000 exempt units distributed. Negligible--not more than one such failure/incident per year for each one million exempt units distributed.

(b) Label or mark each device and its point-of-sale package so that:

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

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

(ii) The name of the radionuclide(s) and quantity(ies) of activity;

(iii) An identification of the person licensed under § 32.30 to transfer the device for use under § 30.22 of this chapter or equivalent regulations of an Agreement State; and

(iv) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information).

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

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

(ii) An identification of the person licensed under § 32.30 to transfer the device for use under § 30.22 of this chapter or equivalent regulations of an Agreement State; and

(iii) The following or a substantially similar statement: “THIS DEVICE CONTAINS RADIOACTIVE MATERIAL AND HAS BEEN MANUFACTURED IN COMPLIANCE WITH U.S. NUCLEAR REGULATORY COMMISSION SAFETY CRITERIA IN 10 CFR 32.31. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS.”

(3) Each device and point-of-sale package contains such other information as may be required by the Commission; and

(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 devices are transferred for use under § 30.22 of this chapter or equivalent regulations of an Agreement State.

(3) The report must include the following information on devices transferred to other persons for use under § 30.22 or equivalent regulations of an Agreement State:

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

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

(iii) The number of units of each type of device 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.

(ii) Licensees who permanently discontinue activities authorized by the license issued under § 32.30 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 § 32.30 during the reporting period, the report must so indicate.

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

26. In § 32.51, paragraph(a)(6) is added to read as follows:

§ 32.51 Byproduct material contained in devices for use under § 31.5; requirements for license to manufacture, or initially transfer.

(a) * * *

(6) The device has been registered in the Sealed Source and Device Registry.

* * * * *

27. In § 32.53, paragraphs (b)(5) and (d)(4) are revised and paragraphs (e) and (f) are added to read as follows:

§ 32.53 Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer.

* * * * *

(b) * * *

(5) Quality assurance procedures to be followed that are sufficient to ensure compliance with § 32.55;

* * * * *

(d) * * *

(4) Prototypes of the device have been subjected to and have satisfactorily passed the tests required by paragraph (e) of this section.

(e) The applicant shall subject at least five prototypes of the device to tests as follows:

(1) The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could

adversely affect the effective containment of tritium or promethium-147, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.

(2) The devices are inspected for evidence of physical damage and for loss of tritium or promethium-147, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (e)(3) of this section.

(3) Device designs are rejected for which the following has been detected for any unit:

(i) A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device; or

(ii) Surface contamination of tritium or promethium-147 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or

(iii) Any other evidence of physical damage.

(f) The device has been registered in the Sealed Source and Device Registry.

28. Section 32.55 is revised to read as follows:

§ 32.55 Same: Quality assurance, prohibition of transfer.

(a) Each person licensed under § 32.53 shall visually inspect each device and shall reject any that has an observable physical defect that could adversely affect containment of the tritium or promethium-147.

(b) Each person licensed under § 32.53 shall:

(1) Maintain quality assurance systems in the manufacture of the luminous safety device in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and

(2) Subject inspection lots to acceptance sampling procedures, by procedures specified in paragraph (c) of this section and in the license issued under § 32.53, to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded.

(c) The licensee shall subject each inspection lot to:

(1) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as absolute pressure and water immersion.

(2) Inspection for evidence of physical damage, containment failure, or for loss of tritium or promethium-147 after each stage of testing, using methods of inspection adequate for applying the following criteria for defective:

(i) A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device;

(ii) Levels of radiation in excess of 5 microgray (0.5 millirad) per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber, if the device contains promethium-147; and

(iii) Any other criteria specified in the license issued under § 32.53.

(d) No person licensed under § 32.53 shall transfer to persons generally licensed under § 31.7 of this chapter, or under an equivalent general license of an Agreement State:

(1) Any luminous safety device tested and found defective under any condition of a license issued under § 32.53, or paragraph (b) of this section, unless the defective luminous safety device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

(2) Any luminous safety device contained within any lot that has been sampled and rejected as a result of the procedures in paragraph (b)(2) of this section, unless:

(i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under § 32.53; and

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with paragraphs (b)(2) and (d)(2)(i) of this section and any other criteria that may be required as a condition of the license issued under § 32.53.

29. Section 32.56 is revised to read as follows:

§ 32.56 Same: Material transfer reports.

(a) Each person licensed under § 32.53 shall file an annual report with the Director, Office of Federal and State Materials and Environmental Management Programs, ATTN: Document Control Desk/GLTS, by an appropriate method listed in § 30.6(a) of this chapter, which must state the total quantity of tritium or promethium-147 transferred to persons generally licensed under § 31.7 of this chapter. The report must identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. Each report must cover the year ending June 30 and must be filed within thirty (30) days thereafter. If no transfers have been made to persons generally licensed under § 31.7 of this chapter during the reporting period, the report must so indicate.

(b) Each person licensed under § 32.53 shall report annually all transfers of devices to persons for use under a general license in an Agreement State's regulations that are equivalent to § 31.7 of this chapter to the responsible Agreement State agency. The report must state the total quantity of tritium or promethium-147 transferred, identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium

or promethium-147 in each kind of device. If no transfers have been made to a particular Agreement State during the reporting period, this information must be reported to the responsible Agreement State agency upon request of the agency.

30. In § 32.57, paragraph (d)(2) is revised and paragraph (e) is added to read as follows:

§ 32.57 Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer.

* * * * *

(d) * * *

(2) The source has been subjected to and has satisfactorily passed appropriate tests required by paragraph (e) of this section.

(e) The applicant shall subject at least five prototypes of each source that is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 to tests as follows:

(1) The initial quantity of radioactive material deposited on each source is measured by direct counting of the source.

(2) The sources are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment or binding of americium-241 or radium-226, such as physical handling, moisture, and water immersion.

(3) The sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (e)(4) of this section.

(4) Source designs are rejected for which the following has been detected for any unit: removal of more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 from the source or any other evidence of physical damage.

31. Section 32.59 is revised to read as follows:

§ 32.59 Same: Leak testing of each source.

Each person licensed under § 32.57 shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee under § 31.8 of this chapter or under equivalent regulations of an Agreement State. This test must be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the filter paper must be measured using methods capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If a source has been shown to be leaking or losing more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 by the methods described in this section, the source must be rejected and must not be transferred to a general licensee under § 31.8 of this chapter, or equivalent regulations of an Agreement State.

32. In § 32.61, paragraph (e)(4) is revised and paragraphs (f) and (g) are added to read as follows:

§ 32.61 Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer.

* * * * *

(e) * * *

(4) Prototypes of the device have been subjected to and have satisfactorily passed the tests required by paragraph (f) of this section.

* * * * *

(f) The applicant shall subject at least five prototypes of the device to tests as follows:

(1) The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of strontium-90, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.

(2) The devices are inspected for evidence of physical damage and for loss of strontium-90 after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (f)(3) of this section.

(3) Device designs are rejected for which the following has been detected for any unit:

(i) A leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device; or

(ii) Surface contamination of strontium-90 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or

(iii) Any other evidence of physical damage.

(g) The device has been registered in the Sealed Source and Device Registry.

33. In § 32.62, paragraphs (c), (d), and (e) are revised to read as follows:

§ 32.62 Same: Quality assurance; prohibition of transfer.

* * * * *

(c) Each person licensed under § 32.61 shall:

(1) Maintain quality assurance systems in the manufacture of the ice detection device containing strontium-90 in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and

(2) Subject inspection lots to acceptance sampling procedures, by procedures specified in paragraph (d) of this section and in the license issued under § 32.61, to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded.

(d) Each person licensed under § 32.61 shall subject each inspection lot to:

(1) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could possibly affect the effective containment of strontium-90, such as absolute pressure and water immersion.

(2) Inspection for evidence of physical damage, containment failure, or for loss of strontium-90 after each stage of testing, using methods of inspection adequate to determine compliance with the following criteria for defective: a leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device and any other criteria specified in the license issued under § 32.61.

(e) No person licensed under § 32.61 shall transfer to persons generally licensed under § 31.10 of this chapter, or under an equivalent general license of an Agreement State:

(1) Any ice detection device containing strontium-90 tested and found defective under the criteria specified in a license issued under § 32.61, unless the defective ice detection device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

(2) Any ice detection device containing strontium-90 contained within any lot that has been sampled and rejected as a result of the procedures in paragraph (c)(2) of this section, unless:

(i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under § 32.61; and

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with paragraphs (c)(2) and (e)(2)(i) of this section and any other criteria as may be required as a condition of the license issued under § 32.61.

Subpart C - Specifically Licensed Items

34. The heading of subpart C is revised to read as previously set out.

35. Sections 32.72 and 32.74 are transferred from subpart B to subpart C; § 32.74 is amended by adding paragraph (a)(4) to read as follows:

§ 32.74 Manufacture and distribution of sources or devices containing byproduct material for medical use.

(a) * * *

(4) The source or device has been registered in the Sealed Source and Device Registry.

* * * * *

§ 32.101 [Removed]

36. Section 32.101 is removed.

§ 32.102 [Removed]

37. Section 32.102 is removed.

§ 32.103 [Removed]

38. Section 32.103 is removed.

§ 32.110 [Removed]

39. Section 32.110 is removed.

Subpart D - Sealed Source and Device Registration

40. The heading of subpart D is revised to read as previously set out.

41. Section 32.201 is transferred from subpart D to subpart C.

42. In § 32.210, paragraphs (a), (b), (d), and (e) are revised, and paragraphs (g) and (h) are added to read as follows:

§ 32.210 Registration of product information.

(a) Any manufacturer or initial distributor of a sealed source or device containing a sealed source may submit a request to the NRC for evaluation of radiation safety information about its product and for its registration.

(b) The request for review must be sent to the NRC's Office of Federal and State Materials and Environmental Management Programs, ATTN: SSDR by an appropriate method listed in § 30.6(a) of this chapter.

* * * * *

(d) The NRC normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the NRC formulates reasonable standards and criteria with the help of the manufacturer or distributor. The NRC shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property. Subpart A of this part includes specific criteria that apply to certain exempt products and subpart B includes specific criteria applicable to certain generally licensed devices. Subpart C includes specific provisions that apply to certain specifically licensed items.

(e) After completion of the evaluation, the Commission issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of

the product, or concerning use under an exemption from licensing or general license as applicable for the category of certificate.

* * * * *

(g) Authority to manufacture or initially distribute a sealed source or device to specific licensees may be provided in the license without the issuance of a certificate of registration in the following cases:

(1) Calibration and reference sources containing no more than:

(i) 37 MBq (1 mCi), for beta and/or gamma emitting radionuclides; or

(ii) 0.37 MBq (10 μCi), for alpha emitting radionuclides; or

(2) The intended recipients are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form in the case of unregistered sources or, for registered sealed sources contained in unregistered devices, are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form, as specified in their licenses; and

(i) The intended recipients are licensed under part 33 of this chapter or comparable provisions of an Agreement State; or

(ii) The recipients are authorized for research and development; or

(iii) The sources and devices are to be built to the unique specifications of the particular recipient and contain no more than 740 GBq (20 Ci) of tritium or 7.4 GBq (200 mCi) of any other radionuclide.

(h) After the certificate is issued, the Commission may conduct an additional review as it determines is necessary to ensure compliance with current regulatory standards. In conducting its review, the Commission will complete its evaluation in accordance with criteria specified in this section. The Commission may request such additional information as it considers

necessary to conduct its review and the certificate holder shall provide the information as requested.

43. Section 32.211 is added under subpart D to read as follows:

§ 32.211 Inactivation of certificates of registration of sealed sources and devices.

(a) A certificate holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) covered by a particular certificate issued by the Commission shall request inactivation of the registration certificate. Such a request must be made to the NRC's Office of Federal and State Materials and Environmental Management Programs, ATTN: SSDR by an appropriate method listed in § 30.6(a) of this chapter and must normally be made no later than two years after initial distribution of all of the source(s) or device(s) covered by the certificate has ceased. However, if the certificate holder determines that an initial transfer was in fact the last initial transfer more than two years after that transfer, the certificate holder shall request inactivation of the certificate within 90 days of this determination and briefly describe the circumstances of the delay.

(b) If a distribution license is to be terminated in accordance with § 30.36 of this chapter, the licensee shall request inactivation of its registration certificates associated with that distribution license before the Commission will terminate the license. Such a request for inactivation of certificate(s) must indicate that the license is being terminated and include the associated specific license number.

(c) A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to initially transfer such sources or

devices for use. Servicing of devices must be in accordance with any conditions in the certificate, including in the case of an inactive certificate.

44. In § 32.303, paragraph (b) is revised to read as follows:

§ 32.303 Criminal penalties.

* * * * *

(b) The regulations in part 32 that are not issued under subsections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 32.1, 32.2, 32.8, 32.11, 32.14, 32.18, 32.21, 32.22, 32.23, 32.24, 32.26, 32.27, 32.28, 32.30, 32.31, 32.51, 32.53, 32.57, 32.61, 32.71, 32.72, 32.74, 32.301, and 32.303.

PART 40 - DOMESTIC LICENSING OF SOURCE MATERIAL

45. The authority citation for part 40 continues to read as follows:

AUTHORITY: Atomic Energy Act secs. 11(e)(2), 62, 63, 64, 65, 81, 161, 181, 182, 183, 186, 193, 223, 234, 274, 275 (42 U.S.C. 2014(e)(2), 2092, 2093, 2094, 2095, 2111, 2113, 2114, 2201, 2231, 2232, 2233, 2236, 2243, 2273, 2282, 2021, 2022); Energy Reorganization Act secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. No. 109-59, 119 Stat. 594 (2005).

Section 40.7 also issued under Energy Reorganization Act sec. 211, Pub. L. 95-601, sec. 10, as amended by Pub. L. 102-486, sec. 2902 (42 U.S.C. 5851). Section 40.31(g) also issued under Atomic Energy Act sec. 122 (42 U.S.C. 2152). Section 40.46 also issued under

Atomic Energy Act sec. 184 (42 U.S.C. 2234). Section 40.71 also issued under Atomic Energy Act sec. 187 (42 U.S.C. 2237).

46. In § 40.5, paragraph (b)(1)(iv) is revised to read as follows:

§ 40.5 Communications.

* * * * *

(b) * * *

(1) * * *

(iv) Distribution of products containing radioactive material under §§ 32.11 through 32.30 of this chapter to persons exempt from licensing requirements.

* * * * *

PART 70 - DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

47. The authority citation for part 70 continues to read as follows:

AUTHORITY: Atomic Energy Act secs. 51, 53, 161, 182, 183, 193, 223, 234 (42 U.S.C. 2071, 2073, 2201, 2232, 2233, 2243, 2273, 2282, 2297f); secs. 201, 202, 204, 206, 211 (42 U.S.C. 5841, 5842, 5845, 5846, 5851); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 194 (2005).

Sections 70.1(c) and 70.20a(b) also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

Section 70.21(g) also issued under Atomic Energy Act sec. 122 (42 U.S.C. 2152). Section 70.31 also issued under Atomic Energy Act sec. 57(d) (42 U.S.C. 2077(d)). Sections 70.36 and 70.44 also issued under Atomic Energy Act sec. 184 (42 U.S.C. 2234). Section 70.81 also issued under Atomic Energy Act secs. 186, 187 (42 U.S.C. 2236, 2237). Section 70.82 also issued under Atomic Energy Act sec. 108 (42 U.S.C. 2138).

48. In § 70.5, paragraph (b)(1)(iv) is revised to read as follows:

§ 70.5 Communications.

* * * * *

(b) * * *

(1) * * *

(iv) Distribution of products containing radioactive material under §§ 32.11 through 32.30 of this chapter to persons exempt from licensing requirements.

* * * * *

Dated at Rockville, Maryland, this 13th day of July, 2012.

For the Nuclear Regulatory Commission.

/RA/

Annette Vietti-Cook,
Secretary of the Commission.