[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:** Proposed rule.

**SUMMARY:** The Nuclear Regulatory Commission (NRC) is proposing to amend 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 proposing to ~~improve safety criteria for approving products through licensing actions,~~ redefine categories of devices to be used under exemptions, add explicit provisions regarding the sealed source and device registration process, and add flexibility to the licensing of users of sealed sources and devices. This action is primarily intended to make licensing processes more efficient and effective. ~~It is also intended to improve assurance that appropriate quantities of radionuclides are approved for use under the general license and under exemptions from license.~~ These changes would 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:** The comment period expires [**INSERT DATE 75 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER**]. Submit comments specific to the information collections aspects of this rule by [**INSERT DATE 30 DAYS AFTER PUBLICATION**]. Comments received after these dates will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before these dates.

**ADDRESSES** ~~:~~: Please include Docket ID NRC-2008-0338 in the subject line of your comments. For instructions on submitting comments and accessing documents related to this action, see Section I, "Submitting Comments and Accessing Information" in the SUPPLEMENTARY INFORMATION section of this document. You may submit comments by any one of the following methods. ~~Comments submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.~~

**Federal ~~e-~~Rulemaking ~~Portal~~Web Site:** Go to http://www.regulations.gov and search for documents filed under Docket ID ~~[~~NRC-2008-0338~~]~~. Address questions about NRC dockets to Carol Gallagher, telephone 301- 492-3668; e~~-~~mail Carol.Gallagher@nrc.gov.

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

**E~~-~~mail comments to:** Rulemaking.Comments@nrc.gov~~Rulemaking.Comments@nrc.gov.~~. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at 301-415-196~~77~~6.

**Hand ~~d~~Deliver comments to**: 11555 Rockville Pike, Rockville, Maryland 20852~~,~~ between 7:30 ~~am~~a.m. and 4:15 ~~pm~~p.m. during Federal workdays~~.~~ (Telephone 301-415-

196~~776~~).

**Fax comments to:** Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.

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

~~You can access publicly available documents related to this document using the following methods:~~

~~**NRC's Public Document Room (PDR):** The public may examine and have copied for a fee publicly available documents at the NRC's PDR, Public File Area O1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.~~

~~**NRC's Agencywide Documents Access and Management System (ADAMS):** Publicly available documents created or received at the NRC are available electronically at the NRC's Electronic Reading Room at . From this page, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to .~~

**FOR FURTHER INFORMATION CONTACT:** Catherine R. Mattsen, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone 301-415-6264, e-mail, Catherine.Mattsen@nrc.gov.

**SUPPLEMENTARY INFORMATION:**

I. Submitting Comments and Accessing Information

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A. Introduction.

XII. Regulatory Flexibility Certification.

XIII. Backfit Analysis.

## I. Submitting Comments and Accessing Information

Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site http://www.regulations.gov. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

You can access publicly available documents related to this document using the following methods:

**NRC's Public Document Room (PDR):** The public may examine and have copied for a fee, publicly available documents at the NRC's PDR, Room O-1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

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**Federal Rulemaking Web Site:** Public comments and supporting materials related to this proposed rule can be found at http://www.regulations.gov by searching on Docket ID NRC-2008-0338.

## II. 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." 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 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 have been considered in developing potential revisions to the regulatory program in the area of distribution of byproduct material.

[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.

In a final rule published October 16, 2007 (72 FR 58473), some of these revisions were made, including the removal of obsolete exemptions. This action is a follow-on to that effort. To make optimal use of rulemaking resources, both for the NRC and the States who must develop conforming regulations, several issues have been combined into this proposed rule.

**B. Regulatory Framework.**

The Commission's regulations in Part 30 contain the basic requirements for licensing of byproduct material. Part 30 includes a number of 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 also include two class exemptions – for self-luminous products and gas and aerosol detectors, in §§ 30.19 and 30.20, respectively – which cover a broad class of products not limited to certain quantities or radionuclides. Under the class exemptions, many products can be approved for use through the licensing process if the applicant demonstrates that the specific product is within the class and meets certain radiation dose criteria.

Part 31 provides general licenses for the use of certain items containing byproduct material and the requirements associated with these general licenses. The general licenses are established in §§ 31.3, 31.5, 31.7, 31.8, 31.10, 31.11, and 31.12.

Part 32 sets out requirements for the manufacture or initial transfer (distribution) of items containing byproduct material to persons exempt from licensing requirements and to persons using a general license. It also includes requirements applicable to certain manufacturers and distributors of products and materials to be used by specific licensees. The

requirements for distributors address such measures as prototype testing, labeling, reporting and recordkeeping, quality control, and, in some cases, specific sampling procedures.

## ~~I~~IIII. Proposed Actions

This proposed rule would make a number of revisions to the regulations governing the use of byproduct material under exemptions from licensing and under general license, and to the requirements for those who distribute products and materials. The changes are intended to improve the efficiency and effectiveness of certain licensing actions. ~~Some amendments are also being proposed to improve assurance that appropriate quantities of radionuclides are approved for use under the general license in § 31.5 and under exemptions from license.~~

### 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 NRC for an evaluation of radiation safety information for a product and for registration of the product. After satisfactory completion of the evaluation, the ~~Commission~~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 similar registration procedures. Registration certificates for the sources and devices reviewed 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; 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 same definition would be added to 10 CFR 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. 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 10 CFR 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 is not addressed by the regulations, the NRC's licensing practice is 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 is used as part of the licensing process are 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 Licenses." 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 10 CFR 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 proposed rule would establish a third class exemption for certain industrial products.

In the case of generally licensed products, sealed source and device registration certificates are 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 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 NRC and all of 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 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 (available at the NRC's electronic Reading Room, ADAMS Accession No. ML082910862), and NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," June 2001. 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 $\mu$Ci) 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 $\mu$Ci (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 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 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 proposed quantity cutoffs for small sources excluded from the requirement for registration are 0.37 MBq (10 $\mu$Ci) for alpha emitters and 37 MBq (1 mCi) for beta and/or gamma emitters. This is a simplification from current licensing practice, which uses a limit of 3.7 MBq (100 $\mu$Ci) or ten times the quantity specified in § 30.71, whichever is greater, for beta and/or gamma emitters. The limits using current guidance for beta/gamma emitters range from 3.7 MBq (100 $\mu$Ci) to 370 MBq (10 mCi). Thus, for any particular radionuclide, the proposed criterion is no more than ten times higher to ten times lower than current practice. As certificates typically cover a large number of

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

The proposed rule would explicitly add registration requirements to the regulations for byproduct material in products used under general licenses and under 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 proposed provisions are in large part consistent with present licensing practice. They would 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 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 currently address only amendment of licenses, would be revised to also address amendment of registration certificates.

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 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 the authority to revoke a registration certificate, if for example, it determines that the registration is inconsistent with current regulatory standards. However, the current regulations do not reference 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 the 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 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 currently 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 updated 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 current 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 ~~would be~~is an activity ~~not previously~~very rarely conducted by NRC in the past. This proposed rule also includes an explicit provision to specifically address such a process in § 32.210(h). The Commission would complete its evaluation in accordance with the criteria specified in § 32.210. As noted under Section III. A.1, "Updating Regulations to Add Registration Requirements," of this document, this proposed rule would add specific provisions delineating which sealed sources and devices must be registered in the SS & D, broadening the applicability of § 32.210 to some generally licensed and exempt products. The Commission may use the proposed provision in § 32.210(h) to update the certificate with respect to applicable industry standards or current security concerns 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. The Commission specifically seeks comment on the circumstances under which such a reevaluation should be made and also on how such a reevaluation may be conducted with minimum impact to industry.

The Commission requests comment on how it might best provide for the update of registration certificates 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. 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.

Generally, the Commission has not previously made standards more restrictive with regard to products to be used under a general license or under an exemption from licensing, such as to restrict further distribution of a previously approved product. However, in a separate action, the Commission ~~is proposing~~has proposed to revise § 31.5 to restrict quantities of certain radionuclides that are authorized under the general license ~~**[Insert date and cite if published before this notice]**.~~(August 3, 2009; 74 FR 38372). That action would impact the authority to distribute certain devices. ~~In this proposed rule, the Commission is also proposing to revise § 32.51 on criteria for approving devices to be used under § 31.5.~~ The Commission therefore seeks comment on how certificates for devices previously approved for use under the general license in § 31.5 (and equivalent Agreement State provisions) should be reevaluated and required to meet ~~the revised criteria in § 32.51 for continued distribution. Proposed revisions to § 32.51 are discussed under Section II. E., "Revise the Safety Criteria for Devices to be Used under the General License in § 31.5." That section further discusses how the~~ such new limits. In addition, the Commission ~~may~~seeks comments on how the NRC might use the proposed provision for review in § 32.210(h) in relation to ~~the proposed revisions to § 32.51~~any changes in standards for products or applicable limits with respect to continued distribution, such as under what circumstances distribution of a product should be stopped by a certain

date, or under what circumstances changes to individual certificates might be considered on a case-by-case basis.

~~This proposed rule also contains revisions to the safety standards for the class exemptions (§§ 30.19 and 30.20). In the case of devices approved for use under §§ 30.19 and 30.20, it is expected that all currently authorized products would meet the revised safety standards discussed under Section II. C., "Revise the Safety Criteria for the Existing Class Exemptions." Thus, dose assessments would not be required to be submitted by current certificate holders to demonstrate compliance with the revised standards.~~

Currently, registrations in the SS & D Registry are kept active until a distributor who is no longer distributing a particular source or device, 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 NRC only for active registrations. 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 proposed provision for inactivation (§ 32.211), which would require distributors to request inactivation of certificates within 2 years following the last initial transfer of a source or device covered by the certificate. Two years was chosen to minimize any impact on certificate holders. NRC certificate holders typically request inactivation of certificates within about a year. 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 proposed revision to § 32.210 for situations where an SS & D registration would not be required, revisions to § 30.32(g) are also being proposed which would accommodate exceptions made in the SS & D registration process. In particular, a proposed § 30.32(g)(4) would provide that limited information would be required for the smaller calibration and reference sources that are not registered. Also included is a proposed 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 proposed § 30.32(g)(5) would allow 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.

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 proposed § 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. 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 proposed 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)(2). Generally, that amendment was intended to cover sources and devices manufactured before the promulgation of § 32.210. This provision, 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 rule proposes to extend that provision to legacy sources and devices containing any byproduct material, as defined in Part 30.

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

As noted in the introduction on 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 existing 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 proposing 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 proposed § 30.22, covering a broad range of industrial devices, would 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 would be required to demonstrate that a particular device meets certain safety criteria, with NRC review and

approval. Such a class exemption would 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. ~~In addition, for some devices used under general license or proposed for general license use, there have been difficulties in maintaining accountability for devices in order to comply with the requirements of the general license. Some industrial devices are good candidates for being rented, for example, by contractors who have short term needs for certain devices. An exemption from regulatory requirements would make this more feasible. Such an exemption may also allow for the use of devices by "first responders," such as fire and police personnel, under conditions in which the accountability appropriate for use under § 31.5 is impractical.~~The exemption may lead to more devices being developed with appropriately low risk that could 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 proposed 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 proposed is an appropriate regulatory approach for calibration and reference sources.

The proposed exemption would cover 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 existing class exemption for self-luminous products is considered adequate and appropriate to provide for exempt use of products of this type.

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

The proposed safety criteria are similar to the current 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~~. As discussed later in this document, the safety criteria for the existing class exemptions are proposed to be changed, in part, to allow for the use of more up-to-date dose calculation methodology.~~, 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 proposed safety criteria for the new class exemption would not require that the exposures be estimated specifically in terms of total effective dose equivalent (TEDE) or effective dose.

The intent is that generally the most up-to-date dose calculation methodology would be used, and that the approach would allow for future updates. However, the staff would normally accept the use of another method such as that now reflected in 10 CFR Part 20, as long as it did not result in a significantly different level of safety.

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 on estimating risks.

For the purposes of these provisions, a definition of a generic term for internal dose, "committed dose" would be added to § 32.2 to encompass this approach, which includes weighting of organ doses, but not strictly under one system.

The proposed dose criterion for routine use of these devices is 200 $\mu$Sv (20 mrem)/year, which is significantly higher than that for gas and aerosol detectors (5 mrem (50 $\mu$Sv)/year). This exemption would cover 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 would contribute to the doses 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 $\mu$Sv/year), the proposal would also include 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 would tend to limit the contribution by these products to disposal doses; e.g., the exposures of landfill workers. Nonetheless, the proposal includes a separate criterion for disposal, 10 $\mu$Sv (1 mrem)/year. This criterion is lower than the proposed 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 would be 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 proposed new class exemption are currently used [§ 32.51(a)(2)(iii)]. However, the proposed safety criteria for the new class exemption include additional criteria 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 risk is well controlled by these designs, possible scenarios of misuse or malicious use are not ~~currently~~ required to be evaluated.

~~A~~For this new exemption, a proposed criterion would require that specific scenarios of misuse be analyzed and shown to meet certain dose limits. The analysis required to meet this misuse criterion would be relatively simple. Evaluating actual risk from possible misuse or malicious use would be much more difficult, but such risks would be limited by this proposed criterion. The proposed criterion is 100 mSv (10 rem), plus an additional skin dose criterion. This criterion is slightly lower than ~~current~~the accident criterion of 15 rem (150 mSv) ~~now~~ applicable to products covered by the existing class exemptions and the general license in § 31.5. The proposed 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 NRC being detected at and sometimes rejected for disposal in landfills and municipal incinerators by State and local restrictions.

In addition, a fixed limit for radionuclides of concern for security, in terms of a small fraction of the Category 2 threshold as listed in Appendix E of Part 20 (which is based on the International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources), is also included (in proposed § 32.30(c)(4)) to further ensure that the quantities of these radionuclides in exempt products are not such that they would be a practical source of obtaining radioactive materials in quantities sufficient to cause significant harm. In a separate action, the Commission has proposed expanding the applicability of national source tracking requirements to other categories of sources (73 FR 19749; April 11, 2008). If that rule becomes effective, this proposed criterion would be reworded to reference a category with lower thresholds and adjustment of the fraction of the threshold.

**C. Revise the Safety Criteria for the Existing Class Exemptions.**

In developing the new class exemption for industrial devices, the NRC determined that the safety criteria in §§ 32.26 and 32.27 for the gas and aerosol detectors could be improved by adding the same type of provisions (§§ 32.30(c)(4) and 32.31(b)) as proposed for the new class exemption to better ensure that ever increasing quantities of radionuclides are not approved for use under the exemption as a result of designs that well contain and shield sources. Although there is no concern with any of the detectors approved to date for use under § 30.20, "Gas and aerosol detectors containing byproduct material," significantly larger quantities of byproduct material could potentially pass the existing safety criteria. Thus, the proposed rule would add the misuse criterion derived for the new class exemption for industrial devices to the safety criteria in § 32.27 for gas and aerosol detectors, and the explicit quantity limit related to IAEA categorization of sources proposed for that exemption to § 32.26. As noted in the discussion of the proposed new class exemption for industrial products, the constraint on quantities tied to

the categorization of sources for the national source tracking system (NSTS) would be reworded if the NSTS is expanded as proposed.

The potential problem of increasing quantities of radionuclides being proposed for use under the class exemption, § 30.19, "Self-luminous products containing tritium, krypton-85, or promethium-147," is not a concern, as this exemption is limited to three specific radionuclides, and self-luminous products by their nature do not involve major shielding.

However, the safety criteria for both of these class exemptions were developed in the late 1960's, and as a result, are written consistent with the dose limitation methodology from the ICRP recommendations of 1959 contained in ICRP-2. This approach includes limits on many individual organs, while more recent recommendations involve weighting organ dose contributions to overall dose and calculating 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 proposed revised safety criteria would eliminate most individual organ limits and would not specify that the dose be in total effective dose equivalent (TEDE) or effective dose.

**C.** The intent is that generally the most up-to-date dose calculation methodology would be used, and that the approach would allow for future updates. However, the staff would normally accept the use of other methods such as that now reflected in 10 CFR Part 20, as long as it did not result in a significantly different level of safety. ICRP has recently issued its latest recommendations in ICRP-103. The specific dose conversion factors based on those recommendations have not yet been calculated. As the safety criteria in 10 CFR Part 32 for class exemptions and the general license in § 31.5 are design criteria, it is preferable to have the flexibility to use the latest information on estimating risks, rather than try to maintain consistency in evaluations made for various products over time. For the purposes of these

provisions, the definition of "dose commitment" in § 32.2 would be revised to encompass this approach that includes weighting of organ doses, but not strictly under one system.

The safety criteria for these two exemptions (in §§ 32.23 and 32.27) would be somewhat changed in other ways. The current safety criteria for self-luminous products includes a table of dose limits with four columns (in § 32.24). The proposed revision would combine the aspects covered by the two sets of criteria in Columns I and II and require all routine doses to meet the limit of 10 $\mu$Sv (1 mrem)/year considering the number of products likely to accumulate in one place. Currently, the 1 mrem limit applies to normal use and disposal of one unit with an additional limit of 10 mrem (100 $\mu$Sv)/year for the normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product. While the proposed approach to these scenarios is somewhat more restrictive, removing individual organ limits also makes the criteria somewhat less restrictive. Overall, this is not considered a significant change. The results in NUREG-1717 for the example products used under the self-luminous product exemption provide estimated doses of no more than 1 mrem (10 $\mu$Sv)/year for all non-accident scenarios, for which the numbers of products likely to be in one place were considered. For both of these revised provisions, the calculation of doses from disposal would have to consider the number of products likely to accumulate in one place; for disposal, this would be the number of products likely to be disposed in one landfill, municipal incinerator, or other disposal site.

The accident criterion for the rare event (roughly 1 per million devices) would be reduced from 15 rem (150 mSv) to 100 mSv (10 rem) to be consistent with the equivalent criterion proposed for the new class exemption for industrial devices.

These changes would only affect the approval of products in the future under these provisions. Products currently authorized to be distributed under these exemptions will continue to be authorized for distribution without additional analyses being required to show that the new

~~criteria would be met. It is expected that the proposed revised criteria would ultimately lead to improvement in the efficiency of this aspect of the licensing process, and contribute to public confidence.~~

**~~D.~~ 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 would be justified, as long as a particular device meets the applicable safety standards. A minor modification, therefore, is proposed 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" would be replaced with, "designed to protect health, safety, or property." This would allow other potential applications under an existing regulatory framework, which has safety criteria designed to adequately protect public health and safety. ~~As discussed in the previous section, some modification of the safety criteria is also proposed.~~

**E. Revise the Safety Criteria for Devices to be Used under the General License in § 31.5.**

Section 31.5 provides a general license for the use of certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere. The requirements for a specific license to manufacture or initially transfer devices containing byproduct material to persons generally licensed under § 31.5 and equivalent Agreement State regulations appear in § 32.51. Paragraphs (a)(2) and (c) of this section essentially establish the safety criteria for approving such devices. The Commission is proposing some changes to these criteria. These contemplated changes would primarily update the criteria in a number of respects, specifically, dose calculation methodology, standards for training of workers, and concerns about the amount of material that can be obtained without the need for the approval of NRC or another regulatory body in the Agreement States. These changes are intended to improve the safety of workers at general licensees' facilities, limit quantities of certain radioactive material that may be obtained from persons licensed under § 32.51, and improve the efficiency and effectiveness of licensing distributors in this category. The revised criteria would also be more consistent with other NRC regulations.

Paragraph (a)(2)(iii) contains the accident criteria, which currently tie into the accident criteria for § 30.19 by using a specific reference to Column IV of the table in § 32.24, the criteria for the lower probability accident. As noted under Section II. C., "Revise the Safety Criteria for the Existing Class Exemptions," these criteria include a large number of individual organ limits and terminology consistent with ICRP-2. The dose criteria for ordinary conditions of handling, use, and storage in paragraph (a)(2)(ii) are 10 percent of the limits in § 20.1201(a), the occupational dose limits for adults. The dose limitation methodology currently reflected in 10 CFR Part 20 is based on ICRP-26. Thus, the two criteria require the use of two different methodologies by applicants.

A more significant issue concerning the safety criteria in § 32.51(a)(2) and (c) is an inconsistency with respect to the training requirements in 10 CFR Part 19 and the doses allowed for persons untrained in radiological safety under the general license. The criterion in § 32.51(a)(2)(i) is that the device can be safely operated by persons not having training in radiological protection (as there are no training requirements applicable to the general license in § 31.5). The primary dose criterion in § 32.51(a)(2)(ii) for ordinary conditions of handling, storage, and use of the device translates to 500 mrem/year (5 mSv/year) TEDE, with additional criteria for lens of eye, skin, and other organs. However, for specific licensees, § 19.12, "Instruction to workers," requires that individuals be trained in radiation safety if, in the course of employment, they are likely to receive an occupational dose in excess of 100 mrem (1 mSv) in a year. When the criteria for approving devices for use under the general license now in § 31.5 (then appearing as § 30.21(c)) were originally codified, the public dose limit on which some of the Commission's regulations had been based was 500 mrem/year (5 mSv/year) and the criterion for requiring training of workers if their exposures were likely to exceed 100 mrem (1 mSv) in a year did not exist.

The Commission is proposing to revise the criteria in § 32.51(a)(2) and (c). The proposed revision would reduce the criterion for conditions of ordinary use to 1 mSv/year (100 mrem/year), simplify the analysis required by eliminating the discrepancy in the dose methodologies to be used, and allow more recently developed methodologies to be used. The accident criteria would be clarified to require the consideration of the number of devices that might be in one location. The maximum allowable dose from an accident would be reduced from 15 rem (150 mSv) to 100 mSv (10 rem) and most of the separate organ limits would be eliminated. The change to the accident criteria recognizes the relatively low level of precision of dose estimates for accidents and represents essentially the same level of risk as the current

provision. The skin dose limit for accidents would remain at 200 rem (2 Sv) averaged over no more than 1 $cm^2$.

In addition, a criterion would be added to provide an explicit quantity limit related to IAEA categorization of sources. The Commission is concerned that significant quantities of the radionuclides of concern to security can be obtained directly from a § 32.51 licensee without applying for a license from the NRC. The proposed new criterion would limit the quantity of a radionuclide of concern that can be contained in a device approved for use under the general license in § 31.5 to 0.01 times the applicable value listed in Appendix E to Part 20 as a Category 2 quantity. This is equivalent to 10 percent of IAEA Category 3 limits. The proposed criterion in § 32.51(a)(2)(v) would also apply a "rule of ratios" in the case where more than one radionuclide is used in a device, i.e., that the sum of the ratios of the quantity of each radionuclide to the individual radionuclide quantity limit must not exceed one. In a separate action [**Add reference if the proposed GL restriction rule is published first**.], the Commission is proposing a quantity limit directly in § 31.5. Such a limit, if made effective, would affect the regulatory status of devices previously approved and previously transferred for use under the general license. Although that rule would not modify § 32.51, it would also limit the quantity of certain radionuclides that may be contained in devices to be transferred in the future regardless of whether such devices were previously approved for use under § 31.5. This action proposes a similar change, as well as the others discussed here, for future approvals of devices to be used under the general license in § 31.5 and equivalent Agreement State regulations. These quantities are considered adequate to allow for many devices in the category of products to be developed, while limiting the quantity of material that may be obtained without having to apply for and obtain a specific license. It is expected that the quantity limit proposed in § 32.51(a)(2)(v) would be applied to the approval of devices even if the same limit is not made effective in § 31.5 for existing devices. Any comment on the

appropriateness of this limit for future approvals should be made in response to this proposed rulemaking, even if a similar comment is submitted on the separate proposed rulemaking to establish a limit for devices previously approved and transferred for use under the general license in § 31.5.

The Commission does not believe it necessary to apply the revised criteria immediately after this rule becomes effective to the distribution of previously approved products. However, allowing such devices to be distributed indefinitely may not be appropriate. The Commission is requesting comment on the application of the revised standards, in particular, the reduced criterion for routine use, to the continued distribution of previously approved devices. The Commission would not require all distributor licensees in this category to demonstrate that previously approved devices comply with the revised safety criteria. For some devices, it may be apparent from the current information in the registration certificate that the devices are likely to comply with these standards. Other instances would be considered on a case-by-case basis, using the proposed provisions in § 32.210(h) for review of registration certificates discussed under Section II. A.2, "Adding Provisions for Amendment, Modification and Revocation, Review, and Inactivation of Registration Certificates." In some cases, the distributor may be able to limit the quantity of certain radionuclides, further clarify that the use of multiple radionuclides would not exceed the "rule of ratios" in proposed revised § 32.51(a)(2)(v), or provide additional analyses of likely doses to users. In limited cases, devices may need to be redesigned in order to meet the proposed revised criteria. Using a case-by-case approach after the effective date of the rule is intended to minimize the impacts of the revision of the safety criteria, allowing time for adjustments to be made without revoking the authority to distribute.

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

Section 31.3 provides 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 are no requirements associated with this general license; however, the provision does not explicitly contain an exemption from 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 must be authorized only by NRC and not by the Agreement States. There are no distribution requirements specified in Part 32. Distributors are licensed under Part 30, with particular license conditions related to distribution determined on a case-by-case basis. Reporting requirements in licenses have been similar to exempt distribution reporting requirements.

This inconsistency results from the fact that the use of the static eliminators covered by this general license predated the regulations in 10 CFR Parts 19, 20, 21, 30, 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 has caused some confusion in the licensing process. The Commission is proposing to change this general license into an exemption from licensing in § 30.15(a)(2). The current licensed distributor would not be required to amend its license, but any future distributors would 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 would remove 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.

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

The Commission has determined that the requirements for manufacturers or initial distributors of exempt and generally licensed products are in some cases overly prescriptive, particularly in the areas of prototype testing and acceptance sampling/quality control (QC) procedures. The current prescriptive approach is easy to implement and regulate, but is relatively inflexible. ~~The~~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 proposed rule is intended to focus the regulations on performance, rather than procedures. The regulations would 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. H~~III. 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 included in the current regulatory requirements are generally acceptable to meet the proposed performance-based requirements. Safety benefits of the proposed changes in this area would 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 proposed regulatory requirements to be equivalent to the current practices (except as noted), so that existing licensees would not have to change their procedures as a result of this rulemaking. However, the provisions are written so that applicants and licensees would 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 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 ISO 9001:2000, "Quality Management Systems – Requirements," and, unique to the nuclear safety field, IAEA Safety Series No. 50-C/SG-Q, "Quality Assurance

for Safety in Nuclear Power Plants and Other Nuclear Installations, Code and Safety Guides Q1–Q14." While the focus of ISO 9001:2000 is on customer satisfaction, and the primary focus of the IAEA series is on nuclear facility safety, these documents contain some quality management concepts that are appropriate to the distribution of generally licensed and exempt products containing byproduct material.

Prototype Test Procedures.

This rule proposes to simplify current prescriptive regulations for prototype testing for new products proposed for use under general license. The proposed 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 proposed rule in every situation. The specific procedures would be removed from the regulations and included as example acceptable procedures in guidance documents.

In the case of generally licensed products, regulations that contain prescriptive requirements for prototype testing are:

- 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 remain in the regulations, as they have 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 contain prescriptive requirements for acceptance sampling/quality control procedures are:

- 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 are 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 include specified procedures; §§ 32.15(a) and (c), 32.55(b) and (d), and 32.62(c) and (e) specifically refer to § 32.110.

The NRC intends to allow acceptance sampling to be performance-based, rather than specifying procedural details. Section 32.110 provides that a random sample shall be taken from each inspection lot of specified licensed 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 shall be accepted, while if the number of defectives exceeds the acceptance number, the entire inspection lot shall be rejected. There is no longer a need for NRC to maintain the acceptance sampling tables in § 32.110, which provides 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 correlates with the standard in the above cited regulations. However, the other seven tables in § 32.110 apparently have been little used since their publication in 1974, as there are 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 rule would remove § 32.110. Acceptance sampling criteria would 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 rule does not propose to change that provision other than providing minor clarifications.

Presently, the NRC requires 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 provide 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 NRC. The proposed rule would not change the 5 percent criterion for Lot Tolerance Percent Defective (i.e., 95 percent acceptance). The current value of consumer risk of 10 percent is more relaxed than others used by NRC, such as in inspections, which use standards of no more than 5 percent defective at 5 percent risk. The proposed rule would revise 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 current standard is 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 proposed revision is unlikely to change the approaches used by the limited number of current licensees under these provisions.

Another proposed 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, currently appearing in §§ 32.15(c)(2), 32.55(d)(2), and 32.62(e)(2), would be revised. Currently, the prohibition of transfer appears 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. As

proposed, these revisions concerning rejected lots would 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 proposed rule would 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. The provision for an independent reviewer is a proposed new requirement, but it is an IAEA recommendation, and may have been used voluntarily as an industry best practice. 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 proposed, 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, would 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 current guidance on quality control and quality assurance is NUREG-1556, Volume 3, Rev. 1, “Consolidated Guidance About Materials Licenses, Applications for Sealed Source and Device Evaluation and Registration.” This guidance indicates that 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 which 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; and 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 proposed rule would revise 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, Volume 3, Revision 1, including specifically Appendix G.

Less prescriptive, more flexible, performance-based regulations would continue to specify performance requirements. Generally, the specific procedures being removed from the regulations would 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, 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, Volume 3, Rev. 1, Appendix F. Updated guidance would be provided when a new or revised industry standard becomes available that NRC considers more appropriate. The licensee would 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.

~~H.~~ Current licensees would need to make any necessary upgrade to their QC programs when the rule becomes effective. However, because license conditions are written broadly, it is not expected that any such changes in the QC program would be inconsistent with an existing license (or registration certificate). Any changes needed in the license to better ensure consistency with the revised requirements would 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, NRC applies 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 existing requirements may be unnecessary, and not commensurate with the associated risk. This is 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.

Although it may be possible to develop an explicit approach to allow for removal of oversight of these types of procedures for some of the products distributed under the class exemptions, the burden of these requirements is not so great that the effort to develop a specific procedure for this did not seem worthwhile. Applicants and licensees do nonetheless

have the option to seek an individual specific exemption under § 30.11 from any requirement applicable to the use of byproduct material.

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 are currently 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. F~~III. D., "Update the Regulations on Certain Static Eliminators and Ion Generating Tubes," the Commission is proposing to add another exemption to § 30.15.) The requirements of this type for manufacturers and distributors of products used under § 30.15 are 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 contains a prohibition on transferring any defective lot or item to exempt persons.

Even without 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 would 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 proposed rule would eliminate 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) would be eliminated for products exempt under § 30.15(a)(7) and (8), ionization chamber smoke detectors and electron tubes respectively. This requirement would also be eliminated 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 would be 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 a proposed revised § 32.14(b)(5), which would require 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 would 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 $\mu$Sv (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 would be 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 would 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 would be a simple amendment as the regulations would be clear that this license condition is no longer required.

The ~~Commission~~NRC does not currently believe that any similar requirements for submitting information on such procedures for generally licensed devices are candidates for revocation based on risk, as the safety of these devices generally relies on the design and manufacturing process quality to a greater degree than for these exempt products. This is less so in the case of calibration and reference sources used under § 31.8 and the risk directly

associated with these sources may be sufficiently low to consider removing oversight of prototype testing or quality control, particularly given the general license's applicability only to specifically licensed persons. However, problems with leakage or significant variation of quantities would affect the use of these sources so as to indirectly affect health and safety of other activities.

~~**I. Minor clarifying or administrative revisions.**~~

**G. Specific Questions for Comment.**

The NRC invites comments on any aspect of this proposed rule, but has these specific questions for consideration:

1. Updating of registration certificates in the SS & D Registry (Discussed in Section III. A.2):

(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?

(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.)

(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.)

(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?

2. New class exemption for industrial products in § 30.20 (Discussed in Section III. B.):

(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?

(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?

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” (Discussed in Section III. C.):

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

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

(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?

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 (Discussed in Section III. E.). 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.

(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.)

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 (Discussed in Section III. A.3):

(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?

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

**H. Minor Clarifying or Administrative Revisions.**

Other minor revisions are proposed 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 would be 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. All such revisions are noted in the following section.

## ~~III.~~IV. Summary of Proposed Amendments by Section.

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

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

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

10 CFR 30.20 – Would slightly expand the class of products covered under this exemption from licensing; would clarify that applicants under 10 CFR 32.26 should also apply for a registration certificate; would update parts of the regulations from which persons are exempt to include 10 CFR Part 19.

10 CFR 30.22 - Would establish a new class exemption for industrial devices initially transferred from 10 CFR 32.30 licensees.

10 CFR 30.32(g)(3) - Would extend 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)(4) – Would add a provision for providing limited information for certain calibration and reference sources.

10 CFR 30.32(g)(5) – Would add 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.

10 CFR 30.38 - Would add an explicit provision for amendment of registration certificates.

10 CFR 30.39 - Would add 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 – Would add registration certificates to provisions for modification and revocation of licenses and update reference to Parts under which licenses are issued.

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

10 CFR 31.23 – Would remove reference to 10 CFR 31.3 and make other minor corrections.

10 CFR 32.1 – Would expand the description of the scope of 10 CFR Part 32 to cover additional requirements and make clarifications.

10 CFR 32.2 - Would add ~~a definition~~definitions of "committed dose" and "sealed source and device registry~~"; would revise the definition of "dose commitment." ~~."

10 CFR 32.8 - Would add 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) – Would make exceptions to prototype testing requirements.

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

10 CFR 32.15(a), (b), and (c) - Would remove the specific procedural requirements for quality assurance, revise the acceptance criterion, and limit these requirements to ~~those established in the license to allow~~products for ~~the exceptions made in~~which such procedures would be required under 10 CFR 32.14~~(b)(5).~~.

10 CFR 32.22 - Would add an explicit requirement for sealed source and device registration.

~~10 CFR 32.23 - Would revise safety criteria by removing organ dose limits and terminology derived from ICRP-2 dose limitation methodology, combining criteria in columns I and II of the existing table in 10 CFR 32.24, requiring consideration of the number of products likely to accumulate in one place in all scenarios, and changing the negligible probability accident criterion.~~

~~10 CFR 32.24 - Would be removed, as a table is not needed for the simplified approach to 10 CFR 32.23.~~

10 CFR 32.26 – Would revise 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 would add an explicit requirement for sealed source and device registration ~~and a specific quantity limit related to radionuclides of concern~~.

~~10 CFR 32.27 - Would revise safety criteria by removing organ dose limits (except for skin) and terminology derived from ICRP-2 dose limitation methodology, requiring consideration of the number of products likely to accumulate in one place in all scenarios, changing the negligible probability accident criterion, and adding specific misuse criteria.~~

~~10 CFR 32.28 - Would be removed, as a table is not needed for the simplified approach to 10 CFR 32.27.~~

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

10 CFR 32.31 - Would establish 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 - Would establish specific conditions of license for distribution of exempt industrial devices, including quality control, labeling, and reporting and recordkeeping requirements.

~~10 CFR 32.51(a)(2) and (c) - Would revise the safety criteria for devices used under 10 CFR 31.5 and equivalent Agreement State regulations to change routine dose limit to 1 mSv (100 mrem)/yr and accident criterion to 100 mSv (10 rem); would add an explicit requirement to consider multiple devices; would add a specific quantity limit related to radionuclides of concern; and would remove references to 10 CFR 32.24 and 10 CFR 20.1201(a).~~

10 CFR 32.51(a)(6) - Would add 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 - Would remove the reference to 10 CFR 32.101 and add requirements for prototype testing without details of procedures to be followed; would revise the requirement for information to be submitted on quality control/quality assurance to be consistent with less prescriptive approach in 10 CFR 32.55; would add an explicit requirement for sealed source and device registration.

10 CFR 32.55 - Would revise the requirement to conduct quality assurance to be clearer and less prescriptive and revise the acceptance criterion.

10 CFR 32.56 - Would add ATTN:  GLTS to address for reporting, explicitly require reports to Agreement States, and clarify the need for reporting even if no transfers were made during the reporting period.

10 CFR 32.57(d)(2) and (e) - Would remove reference to 10 CFR 32.102 and add less prescriptive requirement for prototype testing in paragraph (e).

10 CFR 32.59 – Would make 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) - Would revise 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) – Would add an explicit requirement for sealed source and device registration.

10 CFR 32.62(c), (d), and (e) - Would revise and clarify quality assurance requirements, acceptance criterion, and associated prohibition of transfer.

Heading of Subpart C would be changed to “Specifically Licensed Items.”

10 CFR 32.72 and 10 CFR 32.74 would be moved from Subpart B to renamed Subpart C.

10 CFR 32.74(a)(4) - Would add 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 would be removed.

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

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

10 CFR 32.110 - Specific acceptance sampling procedures would be removed.

Heading of Subpart D would be changed to “Sealed Source and Device Registration.”

10 CFR 32.201 - Would be moved from Subpart D to renamed Subpart C.

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

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

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

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

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

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

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

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

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

## ~~IV~~V. Criminal Penalties.

For the purpose of Section 223 of the Atomic Energy Act (AEA), the Commission is proposing to amend 10 CFR Parts 30 and 32 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

## ~~V.~~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 on September 3, 1997 (62 FR 46517), NRC program elements (including regulations) are placed into compatibility categories A, B, C, D, NRC or adequacy category Health and Safety (H&S). Compatibility Category A are those program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Category A program elements in an essentially identical manner in order to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B are those program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement

State should adopt Category B program elements in an essentially identical manner. Compatibility Category C are those program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a national basis. An Agreement State should adopt the essential objectives of the Category C program elements. Compatibility Category D are those program elements that do not meet any of the criteria of Category A, B, or C, above, and, thus, do not need to be adopted by Agreement States for purposes of compatibility. Compatibility Category NRC are those program elements that address areas of regulation that cannot be relinquished to the Agreement States under the Atomic Energy Act of 1954, as amended, or provisions of Title 10 of the Code of Federal Regulations (CFR). These program elements should not be adopted by the Agreement States. H&S are program elements that are required because of a particular health and safety role in the regulation of agreement material within the State and should be adopted in a manner that embodies the essential objectives of the NRC program.

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

~~The regulations in Subpart A of Part 32 (§§ 32.11 through 32.32) are classified as Compatibility Category "NRC," with the exception of the unaffected § 32.13 and the current § 32.24, which would be removed. Compatibility is not required for Category "NRC" regulations. Exemptions from licensing, including §§ 30.15, 30.19, 30.20, and the new § 30.22, are classified as Compatibility Category B, as is § 31.3. The regulations in Subpart B of Part 32 (§§ 32.51 through 32.103) are classified as Compatibility Category B, as is § 32.24, with respect to its use in connection to § 32.51, and § 32.110. Section 32.210 is classified as~~

Compatibility Category B for States that perform SS & D evaluations and Compatibility Category D for States that do not perform SS & D evaluations; the same would be true for the new § 32.211. Paragraph 30.32(g) is classified as Compatibility Category C. Sections 30.6, 30.38, 30.39, 30.61, 31.23, 32.8, 32.303, 40.5, and 70.5, § 32.1(a), and the definition of *Sealed Source and Device Registry* in § 32.2 are classified as Compatibility Category D. Existing compatibility designations for these regulations are not to be affected. For sections currently designated Compatibility Category B that are being removed, the equivalent provisions in Agreement State regulations would need to be removed concurrent with making related revisions.

The definition of *Dose commitment* is currently Compatibility Category A, but with the note that this term and definition are superseded by the new term and definition in 10 CFR Part 20, "committed dose equivalent," and that the Part 20 term and definition should be used for purposes of compatibility and States should adopt this terminology consistently throughout their requirements. This rule proposes that the revised definition of *Dose commitment* should remain Compatibility Category A, but with this term and its revised definition included for the purposes of Part 32 equivalent regulations.

## VI.
## Compatibility Table

| Section | Change | Subject | Compatibility | |
|---|---|---|---|---|
| | | | Existing | New |
| 30.6(b)(1)(iv) | Amend | Communications | 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)(3) | Amend | Application for specific licenses | C | C |
| 30.32(g)(4) | Add | Application for specific licenses | …….. | C |
| 30.32(g)(5) | Add | Application for specific licenses | …….. | C |
| 30.38 | Amend | Application for amendment of licenses and | D | D |

| Section | Change | Subject | Compatibility | |
|---|---|---|---|---|
| | | | Existing | New |
| | | registration certificates | | |
| 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 | …….. | NRC |
| 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) and (b)(5) | Amend | Certain items containing byproduct material; requirements for license to apply or initially transfer | NRC | NRC |
| 32.15(a), (b), and (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) and (d)(4) | Amend | Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer | B | B |
| 32.53(e) and (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 | B | B |

| Section | Change | Subject | Compatibility | |
|---|---|---|---|---|
| | | | Existing | New |
| | | for license to manufacture or initially transfer | | |
| 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) and (g) | Add | Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer | …….. | B |
| 32.62(c), (d), and (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), and (e) | Amend | Registration of product information | B ★★ | B ★★ |
| 32.210(g) and (h) | Add | Registration of product information | …….. | B ★★ |
| 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. Plain Language.

The Presidential Memorandum “Plain Language in Government Writing” published June 10, 1998 (63 FR 31883), directed that the Government’s documents be in clear and accessible language. The NRC requests comments on this proposed rule specifically with

respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the "ADDRESSES" heading.

## VIII. Voluntary Consensus Standards.

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC would make the requirements for distributors of byproduct material clearer, less prescriptive, and more risk-informed and up to date. The Commission is also proposing to ~~improve safety criteria for approving products through licensing actions,~~ redefine categories of devices to be used under exemptions, add explicit provisions regarding the sealed source and device registration process, and add 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), would continue to indicate that the NRC uses accepted industry standards, if applicable, in its evaluations.

## ~~VIII.~~IX. Finding of No Significant Environmental Impact: Availability.

The Commission has determined under the National Environmental Policy Act of 1969, as amended (NEPA), and the Commission's regulations in subpart A of 10 CFR Part 51, not to prepare an environmental impact statement for this proposed rule because the Commission has concluded on the basis of an environmental assessment that this proposed rule, if adopted,

would not be a major Federal action significantly affecting the quality of the human environment. The following is a summary of the Environmental Assessment: Many of the individual actions being proposed are the type of actions described in the categorical exclusions of §§ 51.22(c)(2) and 51.22(c)(3)(i) and (iii). In addition, the proposed rule would remove prescriptive procedural provisions, add a new class exemption and a new product-specific exemption, broaden an existing class exemption, ~~revise safety criteria for the class exemptions and the general license in § 31.5,~~ 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 this Environmental Assessment is that there will be no significant impact to the public from this action. However, the general public should note that the NRC welcomes public participation. Comments on any aspect of the Environmental Assessment may be submitted to the NRC as indicated under the ADDRESSES heading.

The NRC has sent a copy of the Environmental Assessment and this proposed rule to every State Liaison Officer and requested their comments on the Environmental Assessment. The Environmental Assessment may be examined on http://www.regulations.gov and at the NRC Public Document Room, O-1F21, 11555 Rockville Pike, Rockville, MD 20852. Single copies of the Environmental Assessment may be obtained from Catherine R. Mattsen**,** Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone 301-415-6264, e-mail, Catherine.Mattsen@nrc.gov.

## ~~IXX~~. Paperwork Reduction Act Statement.

This proposed rule ~~contains~~would contain new ~~and~~or amended information collection requirements ~~contained in 10 CFR Parts 30 and 32~~ that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq). ~~While a small increase in burden is estimated for this~~This proposed rule~~, over the longer term, an overall reduction of information collection burden is anticipated. The future overall reduction is expected because the proposed rule would expand the categories of products allowed to be used under an exemption from licensing under which no information collections would be required. These information collection requirements have~~ has been submitted to the Office of Management and Budget ~~(OMB)~~ for review and approval~~. The proposed changes to 10 CFR Parts 31, 40, and 70 do not contain new or amended~~ of the information collection requirements. ~~Existing requirements were approved by the OMB, approval number(s) 3150-0001, 3150-0017, and 3150-0120.~~

Type of submission, new or revision: Revision.

The title of the information collection: 10 CFR Parts 30, 31, 32, 40, and 70~~;~~, Requirements for Distribution of Byproduct Material, Proposed Rule

The form number if applicable: NRC Form 313

How often the collection is required: One time; annual; and occasional.

Who will be required or asked to report: Applicants and licensees who manufacture or initially distribute sealed sources and devices, and some users of those sources and devices.

An estimate of the number of annual responses: 58 ~~(52~~ [(10 CFR Part 32 – 37 responses ~~and~~+ 6 recordkeepers) + (NRC Form 313 – 15 responses)]

The estimated number of annual respondents: 44 (25 NRC ~~25;~~ licensees + 19 Agreement ~~States 19)~~State licensees)

An estimate of the total number of hours needed annually to complete the requirement or request: 951 ~~(957~~ hours [10 CFR Part 32~~;~~ – 957 (351 reporting + 606 recordkeeping) + (NRC Form 313 – decrease of 6 ~~Form 313)~~ hours reporting)]

Abstract: The NRC is proposing to amend 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 proposing to ~~improve safety criteria for approving products through licensing actions,~~ redefine categories of devices to be used under exemptions, add explicit provisions regarding the sealed source and device registration process, and add flexibility to the licensing of users of sealed sources and devices. This action is primarily intended to make licensing processes more efficient and effective. ~~It is also intended to improve assurance that appropriate quantities of radionuclides are approved for use under the general license and under exemptions from license.~~ These changes would affect manufacturers and distributors of sources and devices containing byproduct material and future users of some products currently used under general or specific license.

The NRC is seeking public comment on the potential impact of the information collections contained in ~~the~~this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the ~~proper performance of the~~NRC to properly perform its functions ~~of the NRC, including whether~~? Does the information ~~will~~ have practical utility?

2. Is the burden estimate ~~of burden~~ accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the OMB clearance package may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O~~-1 F21 -~~1F21, Rockville, MD 20852. The OMB clearance package and rule are available at the NRC worldwide Web site: http://www.nrc.gov/public-involve/doc-comment/omb/index.html for 60 days after the signature date of this notice.

Send comments on any aspect of these proposed regulations related to information collections, including suggestions for reducing the burden and on the above issues, by (INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER) to ~~the Records and FOIA/Privacy~~ Information Services Branch (T~~-~~5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by ~~e-~~Internet electronic mail to Infocollects.Resource@NRC.gov, and to the Christine J. Kymn, Desk Officer, ~~Nathan Frey,~~ Office of Information and Regulatory Affairs, NEOB-10202~~,~~ (3150-~~0001, 3150-~~0017, 3150-0001, and 3150-0120), Office of Management and Budget, Washington, DC 20503. Comments on the proposed information collections may also be submitted via the Federal eRulemaking Portal https://www.regulations.gov, ~~docket ID~~ Docket No. NRC-2008-0338. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date. You may also ~~e-mail~~email comments to Christine_J._Kymn@omb.eop.gov or comment by telephone at (202-) 395~~-7345-~~4638.

Public Protection Notification

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

## ~~X.~~XI. Regulatory Analysis.

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

The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading. The analysis is available for inspection on http://www.regulations.gov and in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852. Single copies of the Regulatory Analysis may be obtained from Catherine R. Mattsen**,** Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone 301-415-6264, e-mail, Catherine.Mattsen@nrc.gov.

## ~~XI~~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 would not, if promulgated, have a significant economic impact on a substantial number of small entities. A significant number of the licensees affected by this action would meet the definition of "small entities" set forth in the Regulatory Flexibility

Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121. However, none of the proposed revisions to the regulatory program would result in a significant economic impact on the affected entities.

## XIII. Backfit Analysis.

The ~~NRC has determined that the~~ NRC's backfit ~~rule (§§~~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, ~~or~~ and 76.76~~) does not apply to~~. The requirements contained in this proposed rule ~~because this amendment would~~do not involve any provisions that would impose backfits on nuclear power plant licensees as defined in 10 CFR ~~Chapter I.~~ 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 ~~is not required.~~ need not be prepared for this proposed 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 proposed rule to address Parts 30, 31, or 32 licensees.

**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. 553; the NRC is proposing to adopt 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:** Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

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

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

**§ 30.6 Communications.**

* * * * *

(b) * * *

(1) * * *

(iv) Distribution of products containing radioactive material to persons exempt under §§ 32.11 through 32.30.

* * * * *

3. 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 $\mu$Ci) 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 $\mu$Ci) 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 effective date of this rule) 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.

* * * * *

4. 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.

* * * * *

5. 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.

(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.

6. 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.

7. In § 30.32, paragraph (g)(3) is revised and paragraphs (g)(4) and (g)(5) are added to read as follows:

**§ 30.32 Application for specific licenses.**

* * * * *

(g) * * *

(3) For sources or devices manufactured before (insert effective date of this rule) 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 applicant must provide:

(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; or

(4) 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; or

(5) 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.

* * * * *

8. 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 shall be filed on Form NRC-313 in accordance with § 30.32 and shall 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 shall be filed in accordance with § 32.210 of this chapter and any other applicable provisions and shall specify the respects in which the licensee desires its certificate to be amended and the grounds for the amendment.

9. 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.

10. 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 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 in writing and the licensee shall have been given an opportunity to demonstrate or achieve compliance with all lawful requirements.

## PART 31 - GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

11. The authority citation for Part 31 continues to read as follows:

**Authority:** Secs. 81, 161, 183, 68 Stat. 935, 948, 954, as amended (42 U.S.C. 2111, 2201, 2233); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), P. Law 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

### § 31.3 [Removed and Reserved]

12. Section 31.3 is removed and reserved.

13. 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

14. The authority citation for Part 32 continues to read as follows:

**Authority:** Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

15. 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.

* * * * *

16. In § 32.2, the definitions of ~~*Dose commitment* is revised~~*Committed dose* and ~~the definition of~~ *Sealed Source and Device Registry* ~~is~~are added in alphabetical order to read as follows:

**§ 32.2 Definitions.**

* * * * *

~~*Dose commitment*~~ *Committed dose* means the radiation dose that will accumulate over time as result of retention in the body of radioactive material. For the purposes of this part, committed dose ~~commitment~~ is a generic term for internal dose and means committed effective

dose equivalent, as defined in part 20 of this chapter, or committed effective dose as defined by the International Commission on Radiation Protection.

* * * * *

*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.

17. 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.

* * * * *

18. 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;

* * * * *

19. 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 ~~assurance programs~~control procedures are ~~addressed in the license~~required must:

(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 shall 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]

* * * * *

20. 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 device meets the safety criteria in § 32.23; and

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

* * * * *

~~21. Section 32.23 is revised to read as follows:~~

~~**§ 32.23 Same: Safety criteria.**~~

~~An applicant for a license under § 32.22 must demonstrate that the product is designed and will be manufactured so that:~~

~~(a) In normal 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 product, it is unlikely that the external radiation dose in any one year, or the dose commitment 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 product will exceed 10 $\mu$Sv (1 mrem).~~

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

~~(c) 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 product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of 5 mSv (500 mrem), and the probability is negligible that a person would receive an external radiation dose or dose commitment of 100 mSv (10 rem) or greater.[1]~~

**~~§ 32.24 [Removed]~~**

~~22. Section 32.24 is removed.~~

~~23.~~21. 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:

[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 which 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 per year for each 10,000 exempt units distributed. Negligible--not more than one such failure per year for each one million exempt units distributed.

*  *  *  *  *

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

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

~~(3) The quantity of byproduct material in the device does not exceed $10^{-4}$ times the value listed in Appendix E to part 20 of this chapter as a Category 2 quantity.~~

~~24. Section 32.27 is revised to read as follows:~~

**~~§ 32.27 Same: Safety criteria.~~**

~~(a) An applicant for a license under § 32.26 must demonstrate that the product is designed and will be manufactured so that:~~

~~(1) In normal 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 product, it is unlikely that the external radiation dose in any one year, or the dose commitment 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 product will exceed 50 $\mu$Sv (5 mrem).~~

~~(2) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.~~

~~(3) 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 product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of 5 mSv (500 mrem), and the probability is negligible that a person would receive an external radiation dose or dose commitment of 100 mSv (10 rem) or greater.[1]~~

~~(b) An applicant for a license under § 32.26 shall demonstrate that even in unlikely scenarios of misuse, including those resulting in direct exposure to the unshielded source removed from the product 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), that a person will not receive an external radiation dose or dose commitment 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).~~

**~~§ 32.28 [Removed]~~**

~~25. Section 32.28 is removed.~~

~~26.~~22. Section 32.30 is added under Subpart A to read as follows:

[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 which 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 per year for each 10,000 exempt units distributed. Negligible--not more than one such failure per year for each one million exempt units distributed.

**§ 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 25 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 ~~dose commitments~~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.

(4) The quantity of byproduct material in the device does not exceed $10^{-4}$ times the value listed in Appendix E to part 20 of this chapter as a Category 2 quantity.

~~27.~~23. 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 ~~commitment~~ 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 $\mu$Sv (20 mrem).

(2) It is unlikely that the external radiation dose in any one year, or the committed dose ~~commitment~~ 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 $\mu$Sv (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 ~~commitment~~ in excess of 5 mSv (500 mrem), and the probability is negligible that a person would receive an external radiation dose or committed dose ~~commitment~~ 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 ~~commitment~~ 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).

~~28.~~24. 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.**

[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 which 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.

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;

(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.

~~29.~~25. In § 32.51, ~~paragraphs (a)(2)(ii), (a)(2)(iii) and (c) are revised and paragraphs (a)(2)(iv), (a)(2)(v), and~~ paragraph(a)(6) ~~are~~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) * * *

~~(2) * * *~~

~~(ii) In normal use, handling, and storage of the quantities of devices likely to accumulate in one location, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to any individual will exceed 1 mSv (100 mrem);~~

~~(iii) 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 under the conditions likely to occur in normal handling and use of the device during its useful life;~~

~~(iv) Under accident conditions (such as fire and explosion involving the number of devices likely to accumulate in one location) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of 100 mSv (10 rem) or a dose to localized areas of skin averaged over areas no larger than 1 square centimeter in excess of 2 Sv (200 rem); and~~

~~(v) The total quantity of byproduct material in the device does not exceed 0.01 times the applicable value listed in Appendix E to part 20 of this chapter as a Category 2 quantity (or does not exceed the applicable value listed in Appendix E as a 1/10 of Category 3 if that addition is made effective as proposed). If the device contains more than one radionuclide, the sum of the~~

~~ratios of the quantity of each radionuclide to the individual radionuclide quantity limit must not exceed one.~~

~~* * * * *~~

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

* * * * *

~~(c) If the applicant desires that the general licensee under § 31.5 of this chapter, or under equivalent regulations of an Agreement State, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated doses associated with such activity or activities, and the basis for these estimates. The submitted information must demonstrate that performance of this activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose or dose commitment in excess of 1 mSv (100 mrem) per year.~~

~~30.~~26. 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 must 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.

~~31.~~27. Section 32.55 is revised to read as follows:

**§ 32.55 Same: Quality assurance, prohibition of transfer.**

(a) Each person licensed under § 32.53 must visually inspect each device and must 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 must:

(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 must 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.

~~32.~~28. 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 or from 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 shall be reported to the responsible Agreement State agency upon request of the agency.

~~33.~~29. 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 must 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.

~~34.~~30. Section 32.59 is revised to read as follows:

**§ 32.59 Same: Leak testing of each source.**

Each person licensed under § 32.57 must 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.

~~35.~~31. 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 must 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.

~~36.~~32. 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 must:

(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 must 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**

~~37.~~33. The heading of Subpart C is revised to read as previously set out.

~~38.~~34. 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]**

~~39.~~35. Section 32.101 is removed.

**§ 32.102 [Removed]**

~~40.~~36. Section 32.102 is removed.

**§ 32.103 [Removed]**

~~41.~~37. Section 32.103 is removed.

**§ 32.110 [Removed]**

~~42.~~38. Section 32.110 is removed.

**Subpart D - Sealed Source and Device Registration**

~~43.~~39. The heading of Subpart D is revised to read as previously set out.

~~44.~~40. Section 32.201 is transferred from Subpart D to Subpart C.

~~45.~~41. 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 $\mu$Ci), 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 Agreement State provisions; 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.

~~46.~~42. 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 specific licensee who no longer intends to manufacture or initially transfer a sealed source or device registered with the Commission shall request inactivation of the registration certificate. Such a request shall be made no later than two years after the last initial transfer of a source or device covered by the certificate. If this cessation of activity is associated with the termination of a specific license, the request for inactivation of registration should state the intent to terminate a license giving the specific license number. A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to 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.

~~47.~~43. 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

~~48.~~44. The authority citation for part 40 continues to read as follows:

**Authority:** Secs. 62, 63, 64, 65, 81, 161, 182, 183, 186, 68 Stat. 932, 933, 935, 948, 953, 954, 955, as amended, secs. 11e(2), 83, 84, Pub. L. 95–604, 92 Stat. 3033, as amended, 3039, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2014(e)(2), 2092, 2093, 2094, 2095, 2111, 2113, 2114, 2201, 2232, 2233, 2236, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688 (42 U.S.C. 2021); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 275, 92 Stat. 3021, as amended by Pub. L. 97–415, 96 Stat. 2067 (42 U.S.C. 2022); sec. 193, 104 Stat. 2835, as amended by Pub. L. 104–134, 110 Stat. 1321, 1321–349 (42 U.S.C. 2243); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note). Section 40.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 40.31(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 40.46 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 40.71 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

~~49.~~45. 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 to persons exempt under §§ 32.11 through 32.30 of this chapter.

* * * * *

**PART 70 - DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL**

~~50.~~46. The authority citation for part 70 continues to read as follows:

**Authority:** Secs. 51, 53, 161, 182, 183, 68 Stat. 929, 930, 948, 953, 954, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2201, 2232, 2233, 2282, 2297f); secs. 201, as amended, 202, 204, 206, 88 Stat. 1242, as amended, 1244, 1245, 1246 (42 U.S.C. 5841, 5842, 5845, 5846). Sec. 193, 104 Stat. 2835, as amended by Pub. L. 104–134, 110 Stat. 1321, 1321–349 (42 U.S.C. 2243); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

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 70.7 is also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851). Section 70.21(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 70.31 also issued under sec. 57d, Pub. L. 93–377, 88 Stat. 475 (42 U.S.C. 2077). Sections 70.36 and 70.44 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 70.81 also issued under secs. 186, 187, 68 Stat. 955 (42 U.S.C. 2236, 2237). Section 70.82 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138).

~~51.~~47. 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 to persons exempt under §§ 32.11 through 32.30 of this chapter.

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Dated at Rockville, Maryland, this day of , 2010~~9~~.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.