RULEMAKING ISSUE
NOTATION VOTE

February 26, 2009 SECY-09-0035

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: PROPOSED RULE: REQUIREMENTS FOR DISTRIBUTION OF BYPRODUCT MATERIAL, PARTS 30, 31, 32, 40, and 70 (RIN 3150-AH91)

PURPOSE:

To request Commission approval to publish a proposed rule, in the *Federal Register*, that would amend 10 CFR Parts 30, 31, 32, 40, and 70. This proposed rule includes miscellaneous amendments to Parts 30, 31, and 32 regarding the requirements for distributors of products containing byproduct material and regarding the use of byproduct material under exemptions from licensing and under general licenses, and minor conforming amendments to Parts 40 and 70.

SUMMARY:

The proposed amendments would revise the regulations to make the requirements for distributors of byproduct material clearer, less prescriptive, and more risk-informed and up-to-date. The proposed rule would also 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 rule would make licensing processes

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more efficient and effective, and increase 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.

BACKGROUND:

The staff provided the Commission with recommendations for possible improvements to the regulations governing the exemptions from licensing for both byproduct and source material in SECY-02-0196, "Recommendations Stemming from the Systematic Assessment of Exemptions from Licensing in 10 CFR Parts 30 and 40; and a Rulemaking Plan for Risk-Informing 10 CFR Parts 30, 31, and 32," dated November 1, 2002. The rulemaking plan included in SECY-02-0196 addressed only the regulations governing byproduct material. The staff recommended a number of issues to be considered in the rulemaking process, including some issues related to the general licenses in Part 31. The plan also discussed the possible need to make adjustments or to add issues during the rulemaking process. In SECY-02-0196, the staff also committed to further examine the issue of adequate control of generally licensed devices if quantities of byproduct material approved for use in generally licensed devices approached levels presenting security concerns.

The Commission issued a staff requirements memorandum (SRM) on November 17, 2003, which approved 12 of the individual issues for consideration in rulemaking. Subsequently, during the initial development of the planned proposed rule, the staff determined that the complexity of the rule warranted more than one rulemaking. This approach, presented in a briefing of the Commissioners' technical assistants on February 10, 2005, was selected because the staff determined that: (1) the criteria for approving products for use under general licenses or under exemptions from licensing warranted further evaluation; (2) the reevaluation of these criteria and other issues required significant additional development of their technical bases; (3) specific immediate benefits could be gained from separately addressing many of the issues for which the technical basis was more straightforward; and (4) a single rule could be overly complex, making it difficult to understand all the issues involved.

In SECY-05-0151, which presented the first proposed rule, the staff also discussed ongoing efforts to prepare this follow-on rule. As noted there, the staff was developing additional technical analyses to support revising the safety criteria for approving products to be used under general license or under exemption from licensing, as well as establishing safety criteria for the planned class exemption for industrial products. The staff also noted plans to expand the considerations of the Sealed Source and Device (SS & D) registration requirements beyond those originally contemplated in developing the rulemaking plan. Additional considerations include alternatives to better ensure that the registration certificates are reviewed and updated as needed to ensure protection of public health and safety, as well as to provide sufficient information to all jurisdictions. These issues have been considered in addition to the issues remaining from the rulemaking plan in developing this proposed rule.

Related to the safety criteria for devices to be used under the general license (GL) in § 31.5 (and equivalent Agreement State provisions), a separate rule, GL restrictions, was initiated in response to the SRM on SECY-06-0094 to establish quantity limits in § 31.5. While SECY-06-0094 suggested revisions to Part 32 would likely be included in the GL restrictions

rule, the issues related to these safety criteria are broader than the security concerns that the GL restrictions rule is intended to address. Changes to § 32.51 are instead included in this proposed rule.

Although the Commission, in SRM-SECY-02-0196, disapproved revising the safety criteria for the class exemptions at that time, the approach now proposed is broader in scope and more flexible than that presented in SECY-02-0196 and the reasons for recommending changes to those provisions have expanded. Additionally, the International Commission on Radiation Protection (ICRP) has since completed and issued its latest recommendations as ICRP-103; anticipation that ICRP's recommendations were again being revised contributed to the Commission's disapproval to proceed at that time.

DISCUSSION:

The proposed rule would make a number of revisions to the regulations regarding the requirements for those who distribute products and materials containing byproduct material, and regarding the use of byproduct material under exemptions from licensing and under general licenses. These improvements are part of the overall commitment to systematically assess the U. S. Nuclear Regulatory Commission's (NRC's) regulatory program to ensure the safe use and management of byproduct material. Implementing these amendments to Parts 30, 31, 32, 40, and 70 would ensure that the NRC's regulatory actions are more effective and efficient, and enhance NRC's ability to protect public health and safety. The following discusses the various amendments included in the proposed rule on an issue-by-issue basis.

Sealed Source and Device Registration – Update Regulations by Adding Explicit Provisions

The requirement in § 32.210 provides only for voluntary registration of safety information for specifically licensed products. However, as a matter of licensing practice, applicants/licensees obtain sealed source and device registration certificates for most, but not all, specifically and generally licensed sealed sources and devices, and for exempt products to be distributed for use under a class exemption. 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 registration certificates are issued are indicated in guidance. For specifically licensed products, the users must supply safety information if the manufacturer or distributor has not registered the source or device. Although explicit requirements for registration are not currently in the regulations, the regulations contain requirements for the submittal of information upon which the sealed source and device review and resultant registration is based.

The rule proposes to make the registration requirements more explicit, so that it is easier for potential applicants to determine the applicable requirements and associated fees. The rule proposes to revise the sections of Part 32 applicable to specific categories of sealed sources and devices to explicitly require that products be included in the SS & D registry, namely §§ 32.22, 32.26, new 32.30 (discussed below), 32.51, 32.53, 32.61, 32.74, and 32.210. The changes would be consistent with current licensing practices except for a simplification of the criteria for exclusion of small specifically licensed calibration and reference sources from registration.

The proposed rule would also add explicit provisions for amendment, modification, and revocation of certificates of registration to §§ 30.38, 30.39, and 30.61. In addition, a provision

allowing for review and reissuance of certificates is included in § 32.210(h). Review of certificates absent an identified safety problem has not been staff practice to date, except in limited ways at the time of license renewal. This provision would primarily be used when certificates need to be updated because of a change to industry or NRC standards. A new provision § 32.211 explicitly addressing inactivation of registration certificates would also be added.

Sealed Sources and Devices – Add Flexibility in the Licensing of Users

The current requirement in § 30.32(g) for licensing the use of sealed sources and devices requires applicants to identify which sealed sources and devices they will use and to provide either (1) the manufacturer and model number as registered by the manufacturer or distributor or (2) all of the same safety information that the manufacturer or distributor would have provided if the source or device had been registered. A recent exception to this requirement was made for legacy sealed sources and devices containing naturally occurring and accelerator-produced radioactive material (NARM). In some cases, it is difficult, or even impossible, for a user to provide some required information if the source or device is not registered, such as what prototype tests were conducted and the results of those prototype tests. Although the criterion in § 32.210(c) is that there is sufficient information to provide reasonable assurance that the radiation safety properties of the sealed source or device are adequate to protect health and minimize danger to life and property, this provision has been interpreted to mean that information in all of the listed categories must be submitted to support the finding, irrespective of the risk or complexity of determining that the standard has been met.

The proposed rule includes the following provisions: Paragraph 30.32(g)(3) would be revised to extend the provision for legacy sealed sources and devices containing NARM to 11e(1) byproduct material (byproduct material covered by Part 30 prior to the addition of NARM). This allows alternative information (to that specified in § 32.210(c)) to be provided to support the safety finding on the product. A provision would also be added as § 30.32(g)(4) to provide that only limited information would be required for certain smaller calibration and reference sources. Another provision would be added as § 30.32(g)(5) to allow for certain constraints to be proposed and approved as a basis for licensing the use of sealed sources and devices in lieu of identifying all individual items in some cases.

Establish a New Class Exemption for Certain Industrial Products

A new provision, § 30.22, would be created to establish a new class exemption for certain types of industrial products, such as static eliminators. Licensing requirements for distribution of devices for use under the new exemption would be similar to those imposed on specifically licensed distributors of gas and aerosol detectors used under § 30.20. These regulations would be: § 32.30, requirements for application to manufacture or distribute industrial devices under the exemption; § 32.31, safety criteria for the design of the devices; and § 32.32, conditions of the license (quality control, labeling, and reporting).

Under these proposed provisions, some manufacturers and distributors of generally licensed devices may apply to have their current products approved for use under the new exemption. These licensing provisions would apply to distributors nationally, as licensing the distribution of products used under an exemption from license is reserved to the NRC.

Revise Safety Criteria for the Existing Class Exemptions

The safety criteria for the current class exemptions are based on an outdated dose calculation methodology, are limited to addressing the dose from a single unit in the case of disposal, and, in the case of the criteria for gas and aerosol detectors, §§ 32.26, 32.27, and 32.28, do not adequately control the maximum quantities of byproduct material that could be approved for use under the exemption in § 30.20 (and equivalent Agreement State provisions).

The following revisions would be made: § 32.23, the safety criteria for self-luminous products, and § 32.27 would be revised by removing most organ dose limits and terminology derived from ICRP-2 dose limitation methodology, changing the negligible probability accident criterion, and requiring the consideration of the number of units likely to accumulate in one place for all scenarios (including disposal); §§ 32.24 and 32.28 would be removed, as tables of organ doses would no longer be needed; the criteria in § 32.23, would combine those from columns I and II of the existing table in § 32.24; a specific quantity limit related to radionuclides of concern would be added to § 32.26; and a misuse criterion with a specified scenario would be added to § 32.27. In connection with these changes, the definition of "dose commitment" in § 32.2 would be revised. These changes would make these regulations simpler, more up-to-date, more flexible, and more protective of the environment.

Broaden the Class Exemption for Gas and Aerosol Detectors

The exemption in § 30.20 provides for persons without a license to receive, possess, use, transfer, own, or acquire byproduct material, in gas and aerosol detectors *designed to protect life or property from fires and airborne hazards*, provided that the detectors are manufactured, processed, produced, or initially transferred in accordance with a specific license. Products similar to those allowed under this exemption, but not quite fitting the "class," cannot be approved under this exemption. One example is drug detectors, which were rejected for distribution under this exemption because they do not specifically address fire or airborne hazard.

The proposed rule would replace the wording in § 30.20 concerning the purposes to which the class is restricted with "designed to protect health, safety, or property." This would allow a broader range of potential applications under the existing framework, while maintaining the assurance of significant societal benefit.

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

This proposal would amend § 32.51 to make the safety criteria simpler, allow for the use of more up-to-date dose calculation methodology, reduce the dose criterion for untrained workers, require the consideration of the number of units likely to accumulate in one place, and limit the quantities of radionuclides of concern that can be obtained from § 32.51 licensees in devices approved in the future.

The proposed rule would revise the safety criteria to change the routine dose limit to 1 mSv (100 mrem)/yr and accident criterion to 100 mSv (10 rem), add an explicit requirement to consider multiple devices, add a specific quantity limit related to radionuclides of concern, and remove references to § 32.24 and § 20.1201(a). These changes are for approval of new products for future distribution to § 31.5 general licensees and those under equivalent

regulations of the Agreement States. However, the provision in § 32.210(h) discussed above, on review and update of registration certificates on a case-by-case basis, could be used to require consideration of the revised safety criteria in a reevaluation of the safety information in the certificate for continued distribution of previously approved devices. There is a specific request for comment in this regard in the proposed rule.

A separate rulemaking to put a quantity limit into § 31.5 (see SECY-08-0137) would change the regulatory status of some currently held devices, as well as restrict all future distribution of devices exceeding that quantity limit to persons generally licensed under § 31.5. Minor editorial changes to this rule will be necessary before its publication to reflect the status of that rulemaking.

Update Regulations on Certain Static Eliminators and Ion Generating Tubes

This proposal would update the regulations by replacing the general license in § 31.3 with an exemption from licensing in § 30.15(a)(2), because the products are consumer products and have essentially been regulated in the past as if users were exempt from regulation. However, specific distributor requirements for these products do not appear in the regulations and were previously established in licensing on a case-by-case basis. As a result of this change, there would be clear requirements in existing regulations for any applicant to distribute such products in the future (under §§ 32.14, 32.15, and 32.16).

Make Requirements for Distributors of Certain Products Less Prescriptive

The requirements for manufacturers of exempt and generally licensed products are in some cases, very prescriptive, particularly in the areas of prototype testing and quality control requirements. The regulations would be made less prescriptive but continue to contain general requirements and, in these cases, provide standards by which performance may be judged rather than specifying details of procedures that must be followed. Regulatory guidance on acceptable approaches to meeting the requirements would be expanded to include the procedural details being removed from the regulations in these areas.

Details of required prototype test procedures for generally licensed products would be removed (§§ 32.101, 32.102, and 32.103). Details would also be removed concerning specified sampling or testing procedures as a means of quality control for both certain exempt products and generally licensed products (§§ 32.15(a) through (c), 32.55, 32.62, and 32.110). The standards for acceptance sampling would be revised to better assure control of the number of defective units likely to be distributed for use under the product-specific exemptions in § 30.15 and some of the general licenses in Part 31 (and equivalent Agreement State regulations). Oversight of how licensees conduct these procedures, however, may be completely removed in the case of some of the products covered by § 30.15.

Risk-Informing the Requirements for Distributors of Exempt Products

The level of control on the distribution of the various exempt products and materials is not commensurate with the associated risk, particularly in the areas of prototype testing and quality assurance/quality control. Some existing requirements may be unnecessary given the risk associated with the particular product. The products for which requirements would be removed have been evaluated as to their inherent risk and how much this risk could change if adequate

prototype testing is not performed or an appropriate level of quality assurance/quality control is not used by the manufacturer. This proposal would revise § 32.14(b)(4) to make exceptions to prototype testing requirements. This proposal would revise § 32.14(b)(5) to make exceptions to requirements to submit quality control procedures for review, and § 32.15, to accommodate the exceptions made in § 32.14(b)(5).

Minor Clarifying or Administrative Revisions

Other proposed revisions include renaming two subparts in Part 32 and minor conforming amendments in Parts 40 and 70.

Outcome of this Proposed Rule: Advancing NRC's Strategic Goals and Objectives

The staff recommends this rulemaking because it best resolves the need for action for these issues consistent with the agency's goals of ensuring adequate protection of public health and safety and the environment and adequate protection in the secure use and management of radioactive materials, as well as its objectives of effectiveness and openness in the regulatory process. In general for these issues, rulemaking establishes regulations which are enforceable; affords opportunity for public involvement; and are readily available to regulators, licensees, and the general public.

AGREEMENT STATE ISSUES:

The proposed rule was prepared with participation of an Agreement State representative. A copy of the draft proposed rule was provided to the 35 Agreement States and the three States with letters of intent so that they could have an early opportunity for review. A considerable amount of input was received. Enclosure 1 discusses highlights of these comments.

The NRC staff has analyzed the proposed rule in accordance with the procedures established within Part III of the Handbook to Management Directive 5.9, "Categorization Process for NRC Program Elements." 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.

Revisions to Subpart A of Part 32 (§§ 32.11 through 32.32) are classified as Compatibility Category "NRC." 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. Revisions to Subpart B of Part 32 (§§ 32.51 through 32.103) are classified as Compatibility Category B, as is § 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 the case 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 would not be affected. 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. The rule proposes

that the definition of *Dose commitment* should remain Compatibility Category A with this term and its revised definition included for the purposes of Part 32 equivalent regulations.

The Standing Committee on Compatibility reviewed the proposed rule and agreed that these amendments are a matter of compatibility between the NRC and the Agreement States and agreed with the proposed compatibility designations, with the exception of that for § 32.210(h). The Committee's response recommended that § 32.210(h) should be Compatibility Category D, since it is "already covered in the regulations that NRC may require additional information as necessary at any time." However, the staff believes that all of § 32.210 should be Compatibility Category B for those States that perform SS & D evaluations and notes that there are no other regulations that explicitly provide such authority with respect to SS & D registration certificates. Also, although § 30.61 would be revised by this rulemaking to explicitly address registration certificates, that provision is Compatibility Category D, as it applies to all byproduct material licensees, while Part 32 applies only to distributors of byproduct material.

COMMITMENTS:

Three volumes of the NUREG-1556 series (cited on page 10 of the draft FRN) should be updated or supplemented as a result of this rulemaking, but all three have other updating needs. The staff plans to provide revisions or supplements to these guidance documents at or about the time the rule is made effective. The proposed rule generally makes changes to existing procedures and does not include any unique provisions for which new draft guidance would be needed earlier.

RECOMMENDATIONS:

That the Commission:

1. Approve for publication in the *Federal Register* the proposed amendments to 10 CFR Parts 30, 31, 32, 40, and 70 (Enclosure 2).

2. Note:

   a. That the proposed amendments will be published in the *Federal Register*, allowing 75 days for public comment.

   b. That the Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b).

   c. That a draft Regulatory Analysis has been prepared for this rulemaking (Enclosure 3).

   d. That a draft Environmental Assessment has been prepared for this rulemaking (Enclosure 4). It will be sent to every State Liaison officer, when the rule is published.

   e. That appropriate Congressional committees will be informed of this action.

f. That a press release will be issued by the Office of Public Affairs when the proposed rulemaking is filed with the Office of the Federal Register.

g. That the Office of Management and Budget (OMB) review is required and a clearance package will be submitted electronically to OMB on or immediately after the date the proposed rule is published in the *Federal Register*.

RESOURCES:

To complete and implement the rulemaking, no more than 1 full-time equivalent position will be required. These resources are included in the FY 2009 budget and FY 2010 Performance Budget Request. The effort will depend on the extent and nature of comments received. The rule is planned to be completed in FY 2010 and there is no impact on other planned work.

COORDINATION:

The Office of the General Counsel has no legal objection to the proposed rulemaking. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections. The rule suggests changes in information collection requirements that must be submitted to OMB on or immediately after the date the proposed rule is published in the *Federal Register*.

/RA Martin Virgilio for/

R. W. Borchardt
Executive Director
for Operations

Enclosures:
1. Discussion of State Comments
2. *Federal Register* Notice
3. Draft Regulatory Analysis
4. Draft Environmental Assessment

Discussion of State Comments

Seven Agreement States (Pennsylvania, Minnesota, Louisiana, Washington, Illinois, Texas, and California) provided comments on the draft *Federal Register* Notice (FRN). The State of Michigan also provided a minor correction and numerous suggested revisions to the regulatory text intended to apply plain language guidelines. Comments were generally supportive with a few questions and concerns. A number of the comments were outside of the scope of the proposed rule, such as a suggestion to eliminate general licenses. Other comments were a result of misreading some of the draft proposed provisions. In some cases, States were contacted to clarify their concerns. These concerns and comments were considered and reflected in the draft FRN.

One substantive revision of rule text was made as a result of State comment. A State commenter recommended that the Sealed Source and Device (SS & D) certificate inactivation provision should be mandatory and have a time limit, such as 2 years after the last transfer. While the NRC's fee structure creates incentive for licensees to seek inactivation of certificates, all States do not have fees for registration certificates. The text of proposed § 32.211 was revised to strengthen the requirement and add the suggested time limit. The staff recommends Compatibility Category B for those States that issue SS & D certificates, so that all such States will have a provision and process for inactivation and distributors would be required to notify the respective regulator and request inactivation of certificates for products no longer being distributed.

Some State commenters seemed more comfortable with product-specific exemptions than with class exemptions as they had concerns about what products and quantities would be covered by the new class exemption. There were recommendations as to what factors should be considered in evaluating products for use under an exemption from licensing, or which products should or should not be exempted. One State commenter specifically noted that the ingestion annual limit of intake in Part 20 for polonium-210 (Po-210) was low compared to the amount of Po-210 proposed for the exemption being added for static eliminators to § 30.15 and that Po-210 had been used as a poison. The staff notes that the proposed exemption in § 30.15, which would replace § 31.3, is for Po-210 in sealed sources contained in devices. The potential for ingestion is greatly reduced because of the form and the containment of the Po-210. This change would make an existing regulatory framework (which includes evaluation of chemical and physical form and containment) applicable for this product, improving assurance that the appropriate evaluations are made in licensing the distribution of such products in the future. As to the proposed class exemption, it would be restricted to devices manufactured, processed, produced, or initially transferred from a § 32.30 licensee. The provisions in proposed §§ 32.30, 32.31, and 32.32 would provide NRC staff with adequate tools to ensure that only those products that can be safely used under an exemption will be allowed to be distributed to persons exempt under proposed § 30.22. Also, information on the particular products approved for use under class exemptions is made available to the States through inclusion in the SS & D registry.

One State commenter suggested that the wording of the accident criteria for class exemptions may be more appropriate for use in the § 32.51 accident criteria. However, there are reasons for differences between the safety criteria for exempt products and those for generally licensed products related to the different status of users. The accident analysis for the general license was intended to be essentially a single "worst case" where a fire and explosion would result in release of the material. Because there are no controls once a product is transferred for use

under an exemption, the safety criteria for the class exemptions are intended to involve a more complete assessment of overall risk from various scenarios which might occur.

One State commenter noted that some States review SS & D registration certificates at the time of license renewal and recommended that this be standard practice. One State commenter recommended that all sealed sources and devices undergo a safety review before being distributed. One State indicated that it does not have the staff to keep registration certificates up to date. With regard to SS & D registration certificates, this rule would primarily codify current licensing practices. At this time, the staff desires to maintain flexibility as to approaches for updating certificates, being careful not to add to resource needs. As to any sealed sources and devices not required to be included in the SS & D registry, safety reviews are nonetheless conducted in the licensing process.

One State commenter questioned whether the provision in § 30.32(g)(5), which would allow some devices to not be specifically identified in the license, would affect tracking in the National Source Tracking System (NSTS). Another questioned whether this would allow devices to be distributed without identifying marks. Another disagreed with § 30.32(g)(5) without a stated reason. However, the staff notes that this provision would not affect the applicability of labeling requirements or that of NSTS requirements, under which the distributor would normally provide the initial transaction report. This provision would not be used in a renewal process for currently held sources subject to NSTS.

One State commenter suggested that § 32.56 be changed to quarterly reporting (rather than annual) and to include automatic null reports to all jurisdictions. As this would require 144 reports per year (and more as the number of Agreement States increase) for a relatively low risk device, the staff does not believe that this is warranted, and would not significantly improve tracking of § 31.7 generally licensed devices.

[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: 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: 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 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. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at 301-415-1677.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays. (Telephone 301-415-1677).

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 http://www.nrc.gov/reading-rm/adams.html. 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 pdr.resource@nrc.gov.

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. 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

[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

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.

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

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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,

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.

II. Proposed Actions

This proposed rule would make a number of revisions to the regulations governing the use of byproduct material under exemptions from licensing and under general license, and to the requirements for those who distribute products and materials. The changes are intended to improve the efficiency and effectiveness of certain licensing actions. Some amendments are

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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.

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 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 μCi) of americium-241 or radium-226 in the form of calibration and reference sources, and applies only to specific licensees. The safety of these sources is also well established, with the individual product being reviewed and approved in the licensing process. The general license in § 31.11 pertains to in-vitro clinical or laboratory testing using prepackaged units containing certain limited quantities of byproduct material, e.g., iodine-125 in units not exceeding 10 μCi (0.37 MBq). These in vitro kits are not sealed sources or devices. They can be used only by physicians, clinical laboratories, hospitals, and practitioners of veterinary medicine who preregister with the Commission and by Part 35 licensees. There is also no SS & D registration for the recently added general license in § 31.12, which covers only items produced prior to the NRC gaining jurisdiction over radium-226. Because there is no 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 μCi) 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 μCi) 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 μCi) 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 an activity not previously conducted by NRC. 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 II. 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 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**]. 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 seeks comment on how 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 Commission may use the proposed provision for review in § 32.210(h) in relation to the proposed revisions to § 32.51.

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; 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.

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.

The proposed dose criterion for routine use of these devices is 200 μSv (20 mrem)/year, which is significantly higher than that for gas and aerosol detectors (5 mrem (50 μSv)/year). This exemption 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 μSv/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 μSv (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 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 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. 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 μSv (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 μSv)/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 μSv)/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. 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. 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 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., "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 products 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. 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., "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 μSv (1 mrem)/year in any situation where significant numbers of products could be affected. Also, in the extreme case of a significant change in future distributor behavior, some individual doses could be increased by somewhat higher amounts in non-routine situations. Overall, considering both potential increases in doses and the probability of circumstances resulting in those increases, the potential incremental risk is estimated to be insignificant.

Unnecessary regulatory burden on distributors of these products 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.

The Commission 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.

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. 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 of “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 acceptance criterion, and limit these requirements to those established in the license to allow for the exceptions made in 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. 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. 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 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. 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.

VII. Voluntary Consensus Standards.

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this 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. 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.

IX. Paperwork Reduction Act Statement.

This proposed rule contains new and 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 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 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 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

The form number: NRC Form 313

How often the collection is required: One time; annual; 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 responses and 6 recordkeepers)

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

An estimate of the total number of hours needed annually to complete the requirement or request: 951 (957 Part 32; decrease of 6 Form 313)

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 proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?

2. Is the 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?

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, 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 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 Services Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to INFOCOLLECTS.RESOURCE@NRC.GOV and to the Desk Officer, Nathan Frey, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0001, 3150-0017, 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 *http://www.regulations.gov*, docket ID 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 comments to Nathan_J_Frey@omb.eop.gov or comment by telephone at 202-395-7345.

Public Protection Notification

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

X. Regulatory Analysis.

The Commission has prepared a 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. 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.

XII. Backfit Analysis.

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

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 μCi) of polonium-210 per device.

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

(iii) Such devices authorized before (insert 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 definition of *Dose commitment* is revised and the definition of *Sealed Source and Device Registry* is added in alphabetical order to read as follows:

§ 32.2 Definitions.

* * * * *

Dose commitment 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, 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 which quality assurance programs are addressed in the license 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 μSv (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]

[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.

§ 32.24 [Removed]

22. Section 32.24 is removed.

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

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

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

* * * * *

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

(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 μSv (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]

[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.

(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. Section 32.30 is added under Subpart A to read as follows:

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

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

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

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

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

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

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

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

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

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

(6) Maximum external radiation levels at 5 and 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 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. 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 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 μSv (20 mrem).

(2) 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 disposal of the quantities of units likely to accumulate in the same disposal site will exceed 10 μSv (1 mrem).

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

(4) In use, handling, storage, and disposal of the quantities of exempt units likely to accumulate in one location, including during marketing, distribution, installation, and servicing of the device, the probability is low that the containment, shielding, or other safety features of the device would fail under such circumstances that a person would receive an external radiation dose or 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 § 32.30 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 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. Section 32.32 is added under Subpart A to read as follows:

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

Each person licensed under § 32.30 shall:

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

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

[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.

(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. In § 32.51, paragraphs (a)(2)(ii), (a)(2)(iii) and (c) are revised and paragraphs (a)(2)(iv), (a)(2)(v), and (a)(6) are 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. 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. 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. 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. 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. 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. 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. 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. The heading of Subpart C is revised to read as previously set out.

38. 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. Section 32.101 is removed.

§ 32.102 [Removed]

40. Section 32.102 is removed.

§ 32.103 [Removed]

41. Section 32.103 is removed.

§ 32.110 [Removed]

42. Section 32.110 is removed.

Subpart D - Sealed Source and Device Registration

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

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

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

§ 32.210 Registration of product information.

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

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

* * * * *

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

apply to certain exempt products and Subpart B includes specific criteria applicable to certain generally licensed devices. Subpart C includes specific provisions that apply to certain specifically licensed items.

(e) After completion of the evaluation, the Commission issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product, or concerning use under an exemption from licensing or general license as applicable for the category of certificate.

* * * * *

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

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

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

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

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

(i) The intended recipients are licensed under part 33 of this chapter or comparable 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. 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. 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. 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. 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. 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. 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.

* * * * *

Dated at Rockville, Maryland, this day of , 2009.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.

Draft Regulatory Analysis for Proposed Rulemaking – Requirements for Distribution of Byproduct Material: (10 CFR Parts 30, 31, 32, 40, and 70)

U.S. Nuclear Regulatory Commission
Office of Federal and State Materials and Environmental Management Programs

DRAFT REGULATORY ANALYSIS

Table of Contents

1. STATEMENT OF THE PROBLEM

The U. S. Nuclear Regulatory Commission (NRC) conducted a systematic reevaluation of the exemptions from licensing in 10 CFR Parts 30 and 40, which govern the use of byproduct and source materials. During this reevaluation, the Commission identified several areas in which the regulations could be improved, clarified, or made more flexible, less prescriptive, up to date, and user friendly. Subsequently, the Commission also determined that certain regulations were overly burdensome or required licensee actions that are not commensurate with the associated risk. Some of these issues were addressed in an earlier rulemaking. That final rule was published October 16, 2007 (72 FR 58473).

The NRC is proposing to amend its regulations governing the use of byproduct material to make requirements for distributors of byproduct material clearer, less prescriptive, and more risk-informed. The Commission is also proposing to improve safety criteria for approving products through licensing actions, and redefine categories of devices to be used under exemption. 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 in 10 CFR 31.5 and under exemptions from licensing requirements. It would affect manufacturers and distributors of sealed sources and devices containing byproduct material and future users of some products currently used under general and specific license.

2. EXISTING REGULATORY FRAMEWORK

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

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

3. ALTERNATIVES CONSIDERED

3.1 No action

One alternative to proposing rule changes would be to take no action. The no-action alternative would allow current practices to continue. If NRC does not take action, there would not be any change in costs or benefits to the public, licensees or NRC. The no-action alternative would not address identified concerns.

3.2 Proposed Rulemaking to Revise 10 CFR Parts 30, 31, 32, 40, and 70

This alternative would amend 10 CFR Parts 30, 31, 32, 40, and 70 to resolve several issues related primarily to the goals of ensuring public health and safety and increasing regulatory efficiency, effectiveness, realism, and timeliness. The regulatory amendments would improve the safety criteria for approving products through licensing actions, improve the licensing of distribution of certain byproduct materials, add flexibility to the licensing of users of sealed sources and devices, clarify and update some regulations, as well as establish a new class exemption. These changes would affect licensees who distribute byproduct material and future users of some devices currently used under general license.

3.3 Other Alternatives

Other alternatives, such as developing or revising guidance or issuing generic communications, are not viable because these alternatives would not provide the necessary regulatory basis to mandate particular licensee actions and cannot adequately address concerns directly related to the regulations themselves. To maintain regulatory flexibility consistent with current regulatory needs, improve efficiency and effectiveness in certain licensing actions, and ensure the protection of public health and safety in the future, changes in the regulations are necessary.

4. ANALYSIS OF ALTERNATIVES

Sections 4.1 through 4.10 describe each of the proposed amendments in the rule and provide discussion and in some cases, quantitative estimates of the costs and benefits to the licensees, NRC, Agreement States, and the public related to each amendment. Section 4.11 estimates the costs to NRC and Section 4.12 estimates costs to Agreement States for rulemakings to promulgate the amendments.

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

Licensee labor rates were obtained from National Wage Data available on the Bureau of Labor Statistics web site (www.bls.gov). Depending on the industry and the occupation (e.g., manufacturing, health and safety, etc.), an appropriate mean hourly labor rate is selected. The rate is then increased using a multiplier of 1.4 to account for benefits (insurance premiums, pension, and legally required benefits). Because exact hourly rates would be difficult to obtain and may not be sufficiently recent, nationwide mean hourly rates are used.

In the context of the overall, societal regulatory evaluation, NRC's fees are neither a cost nor benefit, but are considered a distributional effect. To a licensee, however, fees may have a significant impact and therefore they are mentioned, but not quantified, below in situations where they may be a significant factor.

NRC labor rates are determined per the calculation methodology in Abstract 5.2 of NUREG/CR-4627, Rev.1, "Generic Cost Estimates, Abstracts from Generic Studies for Use in Preparing Regulatory Impact Analyses." This methodology considers only variable costs that are directly related to the implementation, operation, and maintenance of the proposed requirement. Currently, this hourly labor rate for FSME is $93.

Agreement States' labor rates vary in amount and in how each rate is determined. A survey of a particular industry would reveal a labor rate that can be compared to the NRC's labor rate, or the Bureau of Labor Statistics web site can be used to obtain an hourly labor rate. Either of these methods is likely to yield similar results. For the purpose of this analysis, the average Agreement State hourly labor rate was obtained from the Bureau of Labor Statistics Employer Costs for Employee Compensation data set, "Management, professional, and related occupations" limited to State and local government workers[1]. This wage was then increased by the same factor of 1.4 described earlier to obtain an hourly labor rate of $45 and an annual labor rate of $80,000.

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

For all licensee labor rates, $43/hour is used, which is from Bureau of Labor Statistics Employer Costs for Employee Compensation data set, "Health and Safety Engineers, Except Mining Safety Engineers and Inspectors"; however, some of the actions evaluated may be conducted by lower paid employees, such as clerical staff.

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

- Industry Implementation and Operation – The proposed rule would improve licensing of distribution of certain byproduct materials by making the regulations more explicit, less prescriptive, clearer, more up-to-date, and in limited cases, more risk-informed. It would

[1]Department of Labor (U.S.), Bureau of Labor Statistics, Employer Costs for Employee Compensation, 4th Quarter 2007. Series IDs CMU3020000100000D and CMU3020000100000P.

also allow some industrial products to be used under exemption from license instead of a general license, which could increase the use of some products.

- NRC Implementation and Operation – The NRC would incur costs to develop a rule and to revise existing guidance. The proposed rule would result in minor effects on operating costs, improving efficiency in some regards, but adding review and reissuance of sealed source and device registration certificates.
- Other Government – Agreement States would need to amend their regulations to maintain compatibility with NRC requirements; impacts to the Agreement State regulatory programs would be minimal.
- Environmental Considerations – The proposed rule would add a new class exemption and slightly broaden the scope of another class exemption resulting in additional products being disposed of in municipal landfills and incinerators.
- Occupational Health (Accident/Event and Routine) – The proposed rule would reduce likely doses to workers using some types of generally licensed devices distributed in the future. It may expand the use of some types of industrial devices by providing an exemption from licensing, thus increasing the number of people exposed, but at lower levels of exposure than allowed under the general license.
- Public Health (Accident/Event and Routine) – The removal of oversight for certain exempt products could result in small incremental increases in public doses.
- Regulatory Efficiency – The proposed rule would improve regulatory efficiency by improving and simplifying the safety criteria, removing prescriptive provisions and some unnecessary provisions, and clarifying some of the regulations. Also, adding a new class exemption and broadening another would eliminate the application of unnecessary regulatory requirements to low risk devices.
- Improvements in Knowledge – For certain issues, the proposed rule may improve the general knowledge of potential licensees/applicants.
- Other Considerations – The proposed rule could increase public confidence in the NRC by making the regulations clearer and more consistent and up-to-date. However, the risk-informing aspect could potentially have a negative impact on public confidence, since it entails reduction of regulatory control.

The above attributes are evaluated more fully in Sections 4.1 through 4.10 as they pertain to the individual issues.

The proposed rule would *not* be expected to affect the following attributes:

- Offsite Property
- Onsite Property
- General Public
- Antitrust Considerations
- Safeguards and Security Considerations

A major issue here is to what extent these can be quantified. For some attributes, like NRC implementation costs, this is relatively easy. For many others, it cannot be done due to lack of information or methodological problems. However, the Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, NUREG/BR-0058, Revision 4, states: "Even inexact quantification with large uncertainties is preferable to no quantification, provided the uncertainties are appropriately considered." In ideal circumstances, dollar amounts are added up and a "net benefit" is given -- the amount by which values exceed impacts. Often, only costs

(impacts) can be quantified. In the absence of dollar estimates for benefits and costs, a regulatory analysis may be able to provide some other quantitative information, such as number of licensees likely to be affected.

Valuable information on estimating costs and benefits can be found in the Regulatory Analysis Technical Evaluation Handbook, NUREG/BR-0184.

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

4.1 Sealed Source and Device Registration

The definition of "Sealed Source and Device Registry" currently appearing in § 35.2, and to be added to § 32.2, reads "*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." In accordance with this definition, the certificates are to provide a sufficient summary of the safety information of the sealed source or device and the licensing and use conditions approved for the product. This information is important to the regulators in the various jurisdictions, as most sealed sources and devices are distributed into a number of jurisdictions and many are distributed nationally. This is the primary source of safety information for the regulatory bodies about products in the various categories (exempt, generally licensed, specifically licensed) manufactured outside of each jurisdiction.

4.1.1 Revise § 32.210 and Other Regulations to Make Registration Requirement Explicit

The requirements in § 32.210 provide only for voluntary registration of safety information for specifically licensed products, yet registration of many specifically and generally licensed and exempt products is conducted under current licensing practice, and 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 this is applicable are indicated in guidance.

The regulations governing distribution of products to be used under general license and under exemptions include requirements for information concerning safety information to be submitted by applicants and for determinations to be made by the NRC staff. This information forms the basis of the sealed source and device (SS & D) review and resultant registration. However, as a matter of licensing practice, applicants/licensees obtain sealed source and device registration certificates for most, but not all, specifically and generally licensed sealed sources and devices, and for exempt products to be distributed for use under a class exemption. For specifically licensed products, the users must supply safety information if the manufacturer or distributor has not registered the source or device.

The rule proposes to revise § 32.210 to make the registration requirement concerning specifically licensed devices more explicit, so that it is easier for potential applicants to determine the applicable requirements and associated fees. The rule also proposes to revise the sections of Part 32 applicable to specific categories of sealed sources and devices to explicitly require that products be included in the SS & D registry, namely §§ 32.22, 32.26, new

32.30, 32.51, 32.53, 32.61, and 32.74. Also, §§ 30.19 and 30.20 would direct an applicant for a license under §§ 32.22 and 32.26 respectively to also apply for a registration certificate.

Cost Impacts:

Currently, those products for which a device evaluation and registration would be required are being evaluated and registered. The proposed rule would make this an explicit requirement rather than an administrative practice. This change is not expected to result in new or different devices requiring an evaluation and registration. The requirements are consistent with present licensing practice except for a minor change with respect to specifically licensed calibration and reference sources. This change is not expected to affect the overall number of registration certificates issued. Therefore, there are no expected costs to the manufacturers and distributors, or to the NRC from this aspect of the proposed rule. The effect of the addition of a new class exemption in proposed § 30.22 and the requirement for registration for those products (§ 32.30(c)(3)) is covered in Section 4.3.

Costs for NRC implementation for the overall rule are discussed in Section 4.11.

Section 32.210 would remain Compatibility Category B requiring strict compatibility for those States that evaluate sealed sources and devices and Compatibility Category D for those states that do not evaluate sealed sources and devices. Revising § 32.210 and Subpart B of Part 32 would require a comparable change in some Agreement State regulations; however, each State would conduct one rulemaking following the planned revision of Parts 30, 31, 32, 40, and 70. The cost for the rulemaking is discussed in Section 4.12.

Benefits:

Not only would the regulations be more explicit and understandable, but there would be better assurance that there is a sound basis for the inclusion of devices and sealed sources in the registration process. Transparency in the regulations in this regard should contribute to the efficiency and effectiveness of relevant licensing actions.

4.1.2 Revise regulations to explicitly allow for amendment, modification and revocation, review, and inactivation of SS & D registration certificates

Other provisions would be amended so as to explicitly apply to registration certificates in addition to licenses. The proposed rule would add certificates of registration to §§ 30.38, 30.39, and 30.61 concerning amendment, and modification and revocation of licenses. These actions are currently generally authorized by these provisions and others in the regulations. A new provision § 32.211 explicitly addressing inactivation of registration certificates would be added. Inactivation means that no further distribution is authorized, but information about previously distributed products is maintained in the database. Because distributors would be required to request inactivation of certificates for sources and devices no longer being distributed, a proposed time limit of 2 years after the last initial transfer is included.

In addition, a provision for explicitly addressing review and reissuance of certificates is being proposed (§ 32.210(h)). The proposed provision in § 32.210(h) may be used to update the certificate with respect to applicable industry or NRC 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 NRC has not generally conducted reevaluations of sealed sources or devices unless an amendment of a registration certificate has been requested or a significant problem with a product has been identified. While the current regulations provide adequate authority to do so, recalling a registration certificate for review and possible reissuance in the absence of a significant safety problem with the product would be an activity not previously conducted by NRC. An explicit provision in § 32.210 is considered preferable to relying on other general provisions in Part 30 such as § 30.61, for taking such an action.

Discussion of alternatives

The sealed source and device registration process is a licensing tool. However, sealed source and device registrations, unlike specific licenses, have not been issued with expiration dates. The NRC currently relies, for the most part, on certificate holders to request amendments of certificates, as appropriate, when changes are to be made. 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. The NRC's process does not include conducting a complete reevaluation of sealed sources and devices at the time that distribution licenses are renewed. Generally, there are fewer safety significant aspects likely to change reflected in the registration certificate than those addressed in the license. Limited reviews are sometimes conducted to ensure consistency of a certificate with the license.

Many certificates are revised and updated from time to time as a result of the certificate holder requesting amendments to accommodate desired changes in a product or associated procedures or to add new products to a registration certificate covering a series of models. Corrections to update information in the certificate are also occasionally made. Certificates are also inactivated, when the distributor no longer intends to distribute a particular source or device. However, no routine NRC procedure is in place to ensure that the information is current and complete and that the licensee (certificate holder) is continuing to manufacture the product in complete compliance with the statements made at the time of issuance, or to require that certificate holders consider changes to their products or manufacturing procedures to implement improvements in technology or revised industry standards. Some certificates have been active, allowing for continued distribution, for very long periods without being reevaluated.

There may be reasons for NRC 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. 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 achieving 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 tend to limit, rather than encourage, industry improvement.

The Commission considered how it might best provide for the update of registration certificates so as not to discourage improvement in the design of sources or devices, to more readily allow for the application of revised industry or NRC standards, and to ensure that information in the certificates is fully consistent with current practices. Related to the overall issues concerning improving products and manufacturer/distributor procedures and updating of registration certificates, the Commission also considered a number of other alternatives.

Other options considered included 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.

Another option considered was to explicitly require applicants/licensees to demonstrate ALARA in the design of their products. As noted, licensees are required by § 20.1101 to implement ALARA in their radiation protection programs. However, with limited exceptions, the consideration or review of the concept of ALARA in the design of products is not specifically addressed in the regulations. Demonstration of achieving ALARA in the design of products is difficult and is not specifically required to be addressed in licensing in most cases. Such a process may be too burdensome and too arbitrary; however, under existing requirements, licensees should consider new developments in technology as they may impact ALARA in the design of products (and manufacturing procedures) and make improvements, as appropriate.

The Commission also considered adding separate expiration dates to new registration certificates with longer terms than the typical term for licenses, e.g.,10 to 20 years, and having current active certificates expire through a provision in the regulations at some date (15 or 20 years) following the last issuance date on the certificate. However, problems identified with the approach of causing expiration of certificates by regulation include the fact that numerous certificates could expire within a short time of each other, especially in cases where a major distributor had updated many certificates at the same time. Additionally, without the expiration date appearing on the certificate itself, distributors may more easily miss the date for submitting timely renewal requests. The Commission does not believe it justified to terminate a distributor's authorization to distribute as a result of missing a date for timely renewal under this circumstance.

Conducting complete reevaluations of sealed sources and devices at the time of license renewal or requiring renewal of certificates through adding separate expiration dates to certificates has the advantage of providing an anticipated timeframe for reconsideration of devices/sources and the associated documentation by both the certificate holder and the NRC. Either of these approaches would likely contribute to accountability on the part of manufacturers/distributors and to the application of ALARA to product designs, although longer time frames for renewal than the typical 10-year license term would be more likely to lead to actual improvements in products or processes versus more routine updating of documentation only. However, the timing of any renewal process may not be optimal with respect to changes that occur. Also, overall resources required for both distributors and the NRC would be greater than for the limited number of reevaluations envisioned under the proposed approach of § 32.210(h).

Consideration was also given to allowing manufacturers and distributors to make improvements without obtaining prior NRC approval. If any of the information provided in the original

application is to be modified, the licensee/certificate holder must submit an application for an amendment before the change takes place. This may be an impediment to making changes, which could be safety improvements or changes that maintain the existing level of safety but reduce costs. However, it was considered difficult to develop such a provision which would not be overly complex, while both improving flexibility and ensuring that safety is maintained. In addition, eliminating some unnecessary impediments to a licensee/certificate holder making changes that do not adversely affect safety has previously been addressed in licensing practice, e.g., by keeping to a minimum, information included in the certificate concerning aspects with no safety significance.

Cost Impacts:

These proposed revisions would not change NRC's authority or specifically require any new actions on the part of certificate holders or others, except to propose that certificate holders request inactivation within two years after ceasing distribution of covered sources or devices. For most of these actions, including the requirement to request inactivation, the proposed rule would not affect the number or type of actions that occur. The provision in § 32.210(h) may be used for some additional reevaluation of registration certificates. The number of such reevaluations would vary from year to year but is expected to average 4 reviews per year, mostly dealing with certificates for devices. There are now approximately 240 active NRC certificates, of which about 145 are for devices. Many of these now cover a number of models.

The average effort involved in a review of an existing certificate would be less than that for a new certificate. The number of hours involved in any particular case would depend on the completeness and availability of all of the documentation on which the last issuance of the certificate was based and whether any applicable standards or industry practices have changed since that time. Only in rare cases would a sealed source or device need to be redesigned in order for the registration certificate to be reissued. Other aspects, such as quality assurance/quality control, labeling, or the operation and safety instructions to be provided to users, may occasionally need upgrading.

<u>Costs to licensees:</u>

The preparation of a request to register a sealed source or device or amend a certificate is estimated to average 21 hours (OMB Supporting Statement for Part 32). If the licensee's response to NRC's review/reevaluation of a certificate averages 12 hours, the average annual cost to licensees would be:

4 reviews/year x 12 hr/review x $43/hour = ~$2,100

Other potential costs are more difficult to quantify. However, consideration of licensee costs would be made on a case-by-case basis in requiring any changes to be made beyond documentation, so as not to impose any unreasonable costs.

A small number of licensees who are certificate holders in Agreement States may be impacted by equivalent requirements for inactivation.

Costs to NRC:

The number of reissuances per year is estimated to average approximately 4; however, as these would selectively involve mostly certificates for devices (for which the review is more complex), the average number of hours per action would be greater than the overall average for both sources and devices, and is estimated for purposes of this Regulatory Analysis at 24 hours. The annual cost would be approximately:

4 reviews and reissuances x 24 hours/reissuance x $93/staff hour = ~$9,000

NRC could also incur minor administrative costs associated with replacing SS & D registrations with a somewhat increased number of updated or inactivated SS & D certificates from Agreement States that issue certificates in the SS & D database.

Costs for NRC implementation are discussed in Section 4.11.

Costs to Agreement States:

Some of the Agreement States have some process in place to review the certificates, typically at the time of license renewal, at least to ensure that the information contained is complete and consistent with current distribution. (Although manufacturers and distributors are required to manufacture, distribute, and service sources and devices in compliance with any statements made in the request for registration and the provisions in the certificate (§ 32.210(f)), sometimes a licensee may make a change resulting in an inconsistency with its previous commitments.) In some cases, information from inspections or other reports concerning failures or compliance concerns are also considered with respect to the need for revising the certificate.

Some form of reevaluation of SS & D certificates by the Agreement States that issue them would be encouraged. A limited number of actions may result from changes being made in this action and others to the general license program. Sections 30.38, 30.39, and 30.61 are currently Compatibility Category D and are anticipated to remain Compatibility Category D. Therefore, no specific cost to Agreement States is attributed to this change, although some costs would result for Agreement States that issue registration certificates if they increase efforts to review and reissue, or inactivate certificates. Of the proposed amendments related to this issue, only § 32.210 and the new § 32.211 involving inactivation of certificates are a Compatibility Category B for those States that conduct evaluations of sealed sources and devices. NRC is seeking to establish consistency in the practice of inactivation of certificates, so that it is clear to all of the jurisdictions which sealed sources and devices are authorized for continued distribution. Inactivation can be a simple administrative action, once the cessation of distribution is identified. In some cases, time might be spent evaluating such things as the availability of authorized servicers for devices currently in use; however, the issue of maintaining the adequacy of service providers exists irrespective of an inactivation process. These provisions would require a comparable change in some Agreement State regulations; however, each State would conduct one rulemaking following the planned revision of Parts 30, 31, 32, 40, and 70. The cost for the rulemaking is discussed in Section 4.12.

Benefits:

These explicit provisions concerning review and inactivation of registration certificates and the addition of registration certificates to the provisions for amendment and revocation would provide a clearer basis for these Commission actions, contributing to the efficiency and effectiveness of the regulatory program concerning manufacture and distribution of sealed sources and devices. The addition of inactivation provisions to Agreement State regulations would improve the information on currently authorized distribution in the registry and may improve the identification of issues concerning the availability of authorized servicers.

An SS & D certificate review process would provide an orderly approach to ensuring that the industry adjusts to a changing environment and/or standards. It would be less disruptive to industry (both distributor and user industries) than revoking or invalidating certificates on a certain date. For example, it was determined that devices that had been approved for use under the general license in § 31.5 in some cases contained inappropriately high amounts of a radionuclide of concern than is currently acceptable given the change in the security environment. One certificate that allowed for a Category 2 quantity of americium-241 was revoked. Others may be invalidated by a separate rulemaking to restrict quantities of materials in devices authorized under § 31.5. Also, in another aspect of this proposed rule, discussed under Section 4.6 of this document, the Commission is proposing to revise the safety criteria in § 32.51 for approval of devices to be used under § 31.5 (and equivalent Agreement State regulations). The Commission is planning to apply these revised criteria to devices approved in the future and not immediately (or in a specific time frame) require all current distributors of such devices to demonstrate that their products meet the revised criteria. The Commission would instead expect to use the provision in proposed § 32.210(h) to consider whether changes are needed on a case-by-case basis. A specific request for comment on this is included in the proposed rule notice.

The process of reviewing certificates could make distributors more accountable. It would allow case-by-case consideration of the impacts of requiring an actual change to the design of a sealed source or device and time for the distributor to propose acceptable changes. The authority to distribute would continue while the review process was ongoing.

Other possible improvements may result from review and updating of registration certificates. These could include: improvement in a product design or associated required procedures, including greater consideration of the ALARA philosophy in the design of devices, potentially leading to exposure averted, and improvements in 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 (NRC and the States), potentially contributing to confidence in the regulatory program. Any improvement in the information provided to users as instructions on the safe use of a product could also provide benefits in terms of exposure averted.

4.2 Revisions to § 30.32(g) for Sealed Sources and Devices Not Registered by the Manufacturer or Distributor or Not Identified by the User

The current § 30.32(g) assumes that either (1) sealed sources and devices are registered by the manufacturer or distributor or (2) the user can specify which sealed sources and devices it

intends to use and provide all of the same safety related information that the manufacturer or distributor would have provided if the products had been registered. A recent exception to this was made for legacy sealed sources and devices containing naturally occurring and accelerator-produced radioactive material (NARM). That provision, in § 30.32(g), also requires applicants to specify which sealed sources and devices it will use before the license (or amendment to license) is obtained.

There are a number of reasons that a manufacturer or distributor may not have registered a sealed source or device, i.e., (1) it was manufactured before the SS & D registry was fully implemented; (2) guidance in NUREG-1556, Vol. 3, Rev. 1, excepts it from the need for a SS & D registration process; or (3) it is a source or device being developed for a custom user.

If a sealed source or device is not registered, the user must provide the information listed in § 32.210(c). In some cases, it is difficult, or even impossible, for a user to provide some of the types of information required, such as what prototype tests were conducted and the results of those prototype tests. Although the criterion in this provision (§ 32.210(c)) is that there is sufficient information to provide reasonable assurance that the radiation safety properties of the sealed source or device are adequate to protect health and minimize danger to life and property, this provision has been interpreted to mean that information in all of the listed categories must be submitted to support the finding, irrespective of the risk or complexity of determining that the standard has been met.

The proposed rule includes the following provisions:

§ 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 containing byproduct material.

§ 30.32(g)(4) – would add a provision for limited information for certain smaller unregistered calibration and reference sources.

§ 30.32(g)(5) – would add a provision to allow for constraints to be proposed and approved as a basis for licensing the use of sealed sources and devices in lieu of identifying all individual items.

The change to § 30.32(g)(3) extends a provision for legacy sealed sources and devices with 11e.(1) byproduct material (byproduct material covered by Part 30 prior to the addition of NARM). This simply allows alternative information (to that specified in § 32.210(c)) to be provided to support the safety finding on the product.

The addition of § 30.32(g)(4) would provide that smaller calibration and reference sources can be licensed for use under a specific license without an evaluation of the safety properties. Sealed source registration certificates have sometimes not been issued for small sources of this type under current licensing practice. (The exact criteria proposed for the exclusion is somewhat different than those in the current guidance.) Although some review of the proposed design and manufacturing methods would be part of licensing a manufacturer/distributor of such sealed sources, the degree of evaluation does not rise to the level of needing registration of the safety information of the sealed source.

The addition of § 30.32(g)(5) would also provide some flexibility to applicants and license reviewers in the licensing of the use of sealed sources and devices. It would provide an option whereby the exact sealed sources or devices to be used need not be identified in all cases.

Cost Impacts:

There are no costs anticipated beyond that for NRC implementation of the rule and Agreement State rulemakings for compatibility. Paragraph 30.32(g) is classified as Compatibility Category C. Both the NRC and Agreement States would incur costs associated with the rulemaking. These are discussed in Sections 4.11 and 4.12.

These changes are not expected to increase occupational doses. Paragraph 30.32(g)(3) has the same standard for approval using alternative information to support the approval. With respect to § 30.32(g)(4), calibration and reference sources meeting the criteria of exclusion from registration (in proposed § 32.210(g)(1), i.e., 37 MBq (1 mCi) of β/γ-emitters; or 0.37 MBq (10 μCi) of α-emitters) should be able to be handled safely by any specific licensee. Under § 30.32(g)(5), adequate constraints would be added to the license to assure that the safety properties of the sealed sources and devices are adequate given the training and experience and facilities and equipment of the licensee.

Benefits:

These amendments would simplify the licensing of users of sealed sources and devices under certain circumstances.

It may prevent some licensees from disposing of and replacing some sources or devices when renewing their licenses because they cannot supply the information identified in § 32.210(c).

It would eliminate the need in some cases of issuing exemptions from § 30.32(g) and the associated preparation of environmental assessments.

For licensees/applicants, it is estimated that an average of 10 hours would be saved if an exemption from § 30.32(g) is not needed as a result of these provisions.

For NRC, it is estimated that an average of 10 hours per licensing action, plus an additional 10 hours for the environmental assessment, would be saved as a result of not needing an exemption from § 30.32(g).

In the case of small unregistered calibration and reference sources licensed for use under § 30.32(g)(4), it is estimated that an average of 5 hours would be saved by the applicant and a similar amount for NRC.

For situations where the new § 30.32(g)(5) is used, the complexity of this aspect of the license review process might be somewhat increased, but for some cases for which it is currently very difficult for the applicant to identify all sealed sources and devices they intend to use, a significant simplification would result. Overall, a significant savings in time for both applicants and the NRC is expected.

Under Compatibility Category C, Agreement States do not have to have exactly the same requirements. At least some of the States may not have had the same lack of flexibility in this area that developed at NRC. However, some savings to Agreement States and their applicants may result, if the States incorporate similar provisions.

4.3 Create § 30.22 for New Class Exemption and §§ 32.30, 32.31, and 32.32, Requirements for a License, Safety Criteria, and Conditions of a License to Distribute Devices

A new provision, § 30.22, would be created to establish a new class exemption for certain industrial products initially transferred from a § 32.30 licensee. Licensing requirements for distribution of devices for use under the new exemption would be comparable to those imposed on specifically licensed distributors of gas and aerosol detectors used under § 30.20 (and equivalent Agreement state provisions). These regulations would be:

§ 32.30 would be created to establish distributor requirements for exempt industrial devices.
§ 32.31 would be created to establish new safety criteria.
§ 32.32 would be created to establish the specific conditions of the license.

Under these proposed provisions, some manufacturers and distributors of generally licensed devices would apply to have their current products approved for use under the new exemption. In the future, there may be some expansion of markets for these types of products as a result of the elimination of regulatory requirements on the users, particularly given the uncertainty in future costs of radioactive waste disposal. These licensing provisions would apply to distributors nationally, as licensing the distribution of products used under an exemption from license is reserved to NRC. Distributors of products used under a general license may be licensed by the Agreement States. As some States have not taken over the review of sealed sources and devices for registration, some of the Agreement State licensees distributing generally licensed devices for use under § 31.5 may already have obtained an SS & D certificate from NRC.

It is expected that some existing licensees would seek to change the status of their devices so that their future customers would be exempt from licensing. It is estimated that approximately 10 existing licensees would apply in the 2-3 years following the rule change and an additional 3 new applicants for exempt distribution licenses per year would result. However, there is uncertainty in these numbers as they are projections of future voluntary actions. The requirements would be the same for those in Agreement States as those in NRC States. However, there may be some additional cost for those in Agreement States as a result of dealing with two different regulatory bodies. Distributors of exempt products in Agreement States must also have a license from the State authorizing possession and use. For some distributors who currently do not distribute any products for use under an exemption, NRC fees may be a factor in deciding whether to distribute a product under an exemption or continue to distribute it as a generally licensed device. Annual fees are significantly less for small entities than for large entities; thus, this would be less of a factor for small entities.

There are no non-rulemaking alternatives that could accomplish the same result. However, there are other approaches in changing the regulations that could be used to reduce the burden on users of industrial devices and allow for the expanded use of such products. These include establishing a number of product-specific exemptions, revising the general license to reduce requirements for certain devices, or establishing a new general license with more limited requirements commensurate with the level of risk of the devices covered.

One should note that the cost/benefit situation for exempting an industrial product is different than that for exempting a consumer product. In the case of a consumer product, the practice

(the manufacture and use of a particular product) does not occur in the absence of a regulatory provision reasonably available to the general public. Thus, all exposures (and any other impacts) from the potential practice, including those during manufacture of a product, are attributable to the provision, as are all benefits to society from the use of the product. In the case of industrial products, considerations include: How practical is the use of the product under the specific provisions of the general license? What is the burden of the particular requirements of the general license? Will more benefit to society result with a reduction in the burden to users? What additional impacts would occur if used under an exemption, for example, from 100% uncontrolled disposal of the products? In either case, it is difficult to quantify many of the impacts and benefits with any certainty, in part, because most depend on the projection of quantities of products to be distributed. However, most impacts and benefits are in fact proportional to the number distributed, i.e., when larger numbers of a product are used, more people are exposed, but more benefit to society results.

Cost Impacts:

Costs to Licensees (Manufacturers and Distributors)

There are no projected costs to licensees from the rule. The rule does not impose any new requirements on existing licensees.

However, some current licensees may choose to expend resources to change the regulatory status of their product. Also, manufacturers and distributors who do not apply for a license to distribute their products under the exemption may lose some market share to those who do.

Products would be evaluated for use under the exemption and a new certificate would be issued. The affect on fees would depend on whether an NRC SS & D certificate is replaced or only a new one is obtained, as there is a significant annual fee for each certificate. The average time for preparation and review of an SS & D certificate has been previously estimated (OMB Supporting Statement for 10 CFR Part 32) at 21 hours for the applicant and 21 hours for NRC. These vary depending on the nature of the action, whether it is a sealed source or a device, and whether a dose assessment is required. The products involved here are devices with relatively low risk but a complex set of exposure scenarios to evaluate; a somewhat above average estimate of 24 hours per submittal by the applicant is used. The estimate for preparing the license application is also higher than the average estimated in the OMB Supporting Statement for NRC Form 313.

For those specifically licensed distributors who choose to apply for a license under § 32.30, the following costs are estimated.

This would be a voluntary expenditure in order to obtain an overall benefit. This one-time expenditure combined with Benefits to Existing Licensees/Distributors would result in a net benefit to existing licensees.

Illustrative estimate of application costs for these assumptions:

8 licensees in Agreement States
2 current NRC licensees
Average of 2 device certificates per licensee

NRC Exempt-Distribution License Required:
10 applications x 8 hours/application x $43/hour = ~$3,400

Device Evaluation Required:
20 registrations x 24 hours/device x $43/hour = ~$21,000

Total: ~$24,000

Fees associated with these licenses and registration certificates could be more significant costs than those estimated.

Costs to NRC:

10 applications x 8 hours/application x $93/staff hour = ~$7,400

20 evaluations x 21 hours/evaluation x $93/staff hour = ~$39,100

Total: ~$46,500

Costs to Agreement States

Agreement State licensing and inspection programs would only be impacted to the extent that a few of their general license distributors might possibly change completely over to exempt distribution, which would be covered by an NRC license. Even in this case, their possession and use would still be under an Agreement State license.

In addition, both the NRC and Agreement States will incur costs associated with a rulemaking. These are discussed in Sections 4.11 and 4.12.

Costs to public

There are some limited expected costs to the public from this aspect of the proposed rule due to contaminated scrap; however, due to the uncertainty in the probability and extent of such incidents, an actual cost is not estimated.

Occupational Health/Public Health

As this would likely increase the market in affected devices, and would ultimately lead to the development of additional devices, potential increases in the number of persons exposed would result. The safety criteria associated with this exemption would limit routine exposures to no more than 20 mrem (200 μSv)/year (in a work environment) and also control disposal and accident risks. Actual exposures would typically be expected to be lower than those in the safety criteria.

This proposed class exemption, like the two existing class exemptions, requires applicants to estimate the quantity of byproduct material to be distributed annually, and the quantities of units likely to be in one location. This aids in the estimation of doses likely to occur in a number of the scenarios required to be analyzed, including specifically doses from disposal of the product.

Environmental Considerations

This provision would increase the number of products allowed to be disposed as ordinary trash. The new exemption would minimize residential use, by limiting it to products normally used in an industrial setting. Because of this, broadly distributed consumer products would not be included. Increases in the number of "exempt" devices containing byproduct material of about 10 percent might be expected.

The safety criteria would ensure that future doses from disposal are unlikely to exceed 1 mrem (10 μSv)/year from as many items of one product likely to be disposed at one landfill or municipal incinerator. This should minimize environmental effects of increased numbers of products being disposed in landfills and at incinerators.

Benefits:

Benefits to Licensees/Users

There would be no direct effect on current licensees general or specific. However, future users of devices approved for use under the exemption would benefit from not having the requirements of the general license or, in some cases, a specific license. Some current general licensees would be expected to return generally licensed devices to the vendor and obtain devices covered under the exemption, when they become available. Also, NRC may choose to exempt previously distributed items when a model is approved for use under the exemption.

The following discusses typical costs for general licensees which would no longer be incurred by users under the exemption

Currently, generally licensed devices are required to be disposed of as low-level radioactive waste, although some with shorter-lived materials may be allowed to decay instead (after return to the distributor). The proposed rule would allow certain industrial devices to become exempt from licensing, and therefore, disposal of such devices would be as ordinary trash. Users would benefit by no longer having to pay for disposal (usually indirectly as they usually transfer devices back to vendors or may also transfer to waste brokers). The affected devices would not need disposal for some time in the future, after distributors have applied for and obtained exempt status for their devices and sold devices for use under the exemption, and after those devices have subsequently been used for their useful life, which in some cases is more then 10 years. Currently, disposal options for low level radioactive material are limited. As of June 30, 2008, the Barnwell site can only accept waste from organizations located in South Carolina, Connecticut, and New Jersey, the three states that make up the Atlantic Interstate Low-Level Radioactive Waste Management Compact. The costs of low level waste disposal several and more years in the future is highly uncertain; thus no quantification of this benefit has been conducted, but may be substantial. Also, the uncertainty in the cost of future disposal in itself affects the market for such devices; thus, eliminating the requirement for controlled disposal may allow for more people to enjoy the benefits of the products.

Under the proposed solution, future users (including some current general licensees) would no longer have to leak test the devices. However, only approximately 10 percent of these devices are estimated to require a leak test and/or operational test. It is assumed that a leak or

operational test is performed every six months, if required. Six-month testing intervals are the default unless the manufacturer requests otherwise. Typically, the licensee swipes the device, then sends the swipe to be analyzed. Analysis services range in price from $35 - $40 per kit depending on the number of kits. The savings from not performing leak tests are estimated to be:

2 leak tests/device-year x ($40/kit/2 wipes) = $40/device-year

It is assumed that sources that require leak tests are in devices that need to be checked for proper operation. The savings from no longer having to perform this activity is estimated to be:

2 tests/device-year x 0.1 hour/test/operational check x $43/hour = $8.60/device-year

Currently, general licensees are required to maintain records of leak tests and device operation tests performed. The records are required to be maintained for three years. It is assumed that it takes approximately 0.1 hour per device to file and maintain the appropriate records. The time saved from no longer having to perform this activity is estimated to be:

2 leak tests/device-year x 0.1 hour/record x $43/hour = $8.60/device-year

In addition, users (currently generally licensed) would no longer have to file the required transfer reports with the NRC (under § 31.5(c)(8) and (9)). Agreement States are likely to require similar reports under compatibility requirements. The total annual amount saved from no longer having to file reports is estimated below. Based on information from the current OMB clearance for 10 CFR Part 31, it takes 0.6 hours per report. Therefore the reduction in cost, or savings, is estimated to be:

0.6 hour/transfer report x $43/hour = $26/transfer report

As static eliminators containing polonium-210, which need replacing annually, are a type of device likely to be affected, the number of transfer reports relative to the number of devices in use would be higher than the overall ratio currently under § 31.5.

There are a few additional reporting requirements such as change of address (§ 31.5(c)(14)), bankruptcy (§ 30.34(h)), accidents (§ 31.5(c)(5)), and loss or theft of sources (§§ 20.2201 and 20.2202). However, since these are likely to be less frequent events (requiring reports), the impact would be small by comparison with the above quantified costs.

A current requirement in§ 31.5(c)(12) is that general licensees must appoint an individual responsible for having knowledge of appropriate regulations, and that person is to assure day-to-day compliance with the regulations. This requirement would no longer apply under the proposed solution. Therefore, future users, including some current general licensees, would save by not having to pay a person to perform these duties. It is recognized that this person performs other duties that would require his/her employ for those duties; however, it is assumed that this person spends 4 hours/year attending to the required duties.

4 hours/year x $43/hour = $172/user-year

As § 31.5 is now a Compatibility Category B, the Agreement States should have equivalent requirements. Any new exemption would also require equivalent provisions in Agreement State regulations. Thus, the change in status should result in similar cost savings per licensee.

Illustrative annual cost savings to future users for the following assumptions:

50,000 devices used by 5000 users;
10,000 transfers (those currently reportable under § 31.5)/year;
10% of devices require semiannual leak testing
10% of devices require semiannual operational testing

5,000 leak test kits x $40 =	$200,000
5,000 devices tested/year x $8.60 =	$43,000
5,000 devices tested for operation/year x $8.60 =	$43,000
10,000 transfer reports/year x $26 =	$260,000
5,000 responsible individuals x $172 =	$860,000
Total	~$1,400,000

This does not include the unquantified savings in disposal costs, which may be quite significant.

The proposed rule is likely to change user prices slightly. Currently, some manufacturers and distributors of generally licensed devices offer to take back the devices for replacement of the decayed source or disposal. This disposal service is sometimes reflected in the initial sale price. If such devices become exempt from regulation, this disposal service would no longer be required. As such, there may be a slight decrease in the price of the device. A major portion of the cost of the device is for materials (radioactive source and other). Another large contributor to the cost of the device is from insurance and bonding. These portions of the cost would remain, whether the device is generally licensed or exempt. Therefore, there may only be a slight decrease in the cost of the devices.

Benefits to Licensees/Distributors

Distributors are likely to have slightly reduced reporting and recordkeeping costs. Currently, licensees are required to submit quarterly transfer reports under § 32.52, both to NRC and to any Agreement States into which they are transferring devices. Manufacturers and distributors of these products would be required to submit reports of transfer to the NRC annually (proposed § 32.32(c)). Additionally, records of the transfers for exempt products are required to be maintained for 1 year versus 3 years for generally licensed devices (under § 31.5). Reporting requirements for the new class exemption would be less than for generally licensed devices.

A significant reporting and recordkeeping cost for distributors is labeling. This would also be a requirement for the proposed class exemption. Therefore, there would not be a savings associated with this aspect of the recordkeeping. Although there are a number of distributor requirements that would change relative to reporting and recordkeeping, as noted above, the annual costs after the initial changes are made when revising the license would be very similar to current costs.

The most significant benefit to manufacturers and distributors would be increased sales. The extent that the changed status of the product affects future sales will vary depending on the type

of device and the circumstances of its use. This benefit cannot be quantified in any realistic manner.

Benefits to NRC/Benefits to Agreement States

The NRC and the Agreement States would benefit from the proposed provision by a reduction in paperwork (reviewing reports, tracking devices, etc.) associated with generally licensed devices. If this change resulted in 10,000 fewer devices sold per year for use under § 31.5 and equivalent Agreement State provisions, a total time saved by NRC and Agreement State staff would be approximately 500 hours annually dealing with reports associated with potentially impacted generally licensed devices. NRC has approximately 20 percent of general licensees. Therefore, the regulatory agencies would save approximately the following annual amount:

100 hours/year x $93/staff hour = $9,300/year

400 hours/year x $45/hour = $18,000/year

Benefits to Public

It is likely that persons previously not obtaining and using the subject devices under general license would now purchase some of the devices for use. Examples of such persons would be garage/car repair shop owners, photo finishing establishments, laboratories and analytical services, and others. Costs associated with general licenses to possess and use the devices might have been an issue that prevented such persons from owning a device. The use of these products by these types of businesses should lead to benefits to society as a whole.

4.4 Revise the Safety Criteria for the Existing Class Exemptions

The safety criteria for the current class exemptions are based on outdated dose calculation methodology, are limited to addressing the dose from a single unit in the case of disposal, and, in the case of the criteria for gas and aerosol detectors, §§ 32.26, 32.27, and 32.28 do not adequately control the maximum quantities of byproduct material that could be approved for use under the exemption in § 30.20 (and equivalent Agreement State provisions).

The following revisions to the safety criteria are proposed:

Revise § 32.23 by removing organ dose limits and terminology derived from the International Commission on Radiation Protection (ICRP) 2 dose limitation methodology, combining criteria in columns I and II of the existing table in § 32.24, changing the negligible probability accident criterion, and requiring consideration of the likely number of units present for all scenarios.

Remove § 32.24, as a table is not needed for the simplified approach to § 32.23.

Revise § 32.26 to add a specific quantity limit related to radionuclides of concern.

Revise § 32.27 by removing organ dose limits (except for skin from misuse) and terminology derived from ICRP-2 dose limitation methodology; changing the negligible probability accident criterion; adding a misuse criterion with a specified scenario, and requiring consideration of the likely number of units present for all scenarios.

Remove § 32.28, as a table is not needed for the simplified approach to § 32.27.

Cost Impacts:

These changes would affect future distribution and not require reevaluation of any devices currently approved for distribution. Thus, they would have no direct cost on any current licensees. They may limit future development of such products, with associated impacts on distributor and user industries.

Both the NRC and Agreement States will incur costs associated with a rulemaking. These are discussed in Sections 4.11 and 4.12.

Benefits:

These changes would simplify the criteria by eliminating most separate organ dose limits, and provide more flexibility for applying the latest dose calculation methodology based on ICRP recommendations. These changes should improve the efficiency and effectiveness of future NRC licensing actions under these provisions, although no specific cost savings can be quantified.

Some factors in the revisions would tend to be somewhat less restrictive, others, more restrictive. Overall, for the common scenarios of exposure, risk levels would be essentially unchanged. However, the addition of a specific quantity limit in § 32.26 for radionuclides of concern and the specific misuse scenario would improve assurance that gas and aerosol detectors approved in the future do not contain more than an appropriate quantity of byproduct material for use under exemption from licensing. The benefits of controlling quantities are: (1) assuring that exempt products do not present a practical source of radioactive material for malicious use; (2) minimizing risks associated with devices becoming subject to scrap metal recycling, such as property damage due to contamination resulting from smelting, (3) further controlling overall impacts to waste disposal workers, (4) minimizing overall impacts to the environment from uncontrolled disposal of products used under exemptions from licensing, and (5) 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.

4.5 Revise § 30.20 Wording to be Less Restrictive on Purpose of Detectors

The exemption in § 30.20 provides for persons without a license to receive, possess, use, transfer, own, or acquire byproduct material, in gas and aerosol detectors *designed to protect life or property from fires and airborne hazards*, provided that the detectors are manufactured, processed, produced, or initially transferred in accordance with a specific license. Products similar to those allowed under this exemption, but not quite fitting the “class,” cannot be approved under this exemption. One example is drug detectors which were rejected for distribution under this exemption because they were not “designed to protect life or property from fires and airborne hazards.”

The proposed rule would replace the wording in § 30.20, “designed to protect life or property from fires and airborne hazards,” with less restrictive wording to allow other potential applications under an existing framework, which has safety criteria that adequately protect public health and safety.

Cost Impacts:

Currently, devices such as drug detectors are generally licensed for use per the requirements of § 31.5 (and equivalent Agreement State provisions). A change to § 30.20 would allow such devices to be used by persons exempt from licensing requirements. Some manufacturers and distributors of generally licensed devices may apply to have their current products approved for use under the expanded exemption. In the future, there may also be some expansion of markets for these types of products as a result of the elimination of regulatory requirements on the users, particularly given the uncertainty in future costs of radioactive waste disposal. The licensing provisions in §§ 32.26, 32.27, 32.28, and 32.29 apply to distributors nationally, as licensing the distribution of products used under an exemption from license is reserved to the NRC. Distributors of products used under a general license may be licensed by the Agreement States. As some States have not taken over the review of sealed source and devices for registration, some of the Agreement State licensees distributing generally licensed devices for use under § 31.5 may already have obtained an SS & D certificate from NRC. Products would be evaluated for use under the exemption and a new certificate would be issued. The affect on fees would depend on whether an NRC SS & D certificate is replaced or only a new one is obtained, as there is a significant annual fee for each certificate. The average time for preparation and review of an SS & D certificate has been previously estimated (OMB Supporting Statement for 10 CFR Part 32) at 21 hours for the applicant and 21 hours for NRC. These times vary depending on the nature of the action, whether the certificate is for a sealed source or a device, and whether a dose assessment is required. The products involved here are devices with relatively low risk but a complex set of exposure scenarios to evaluate; a somewhat above average estimate of 24 hours per submittal by the applicant is used. The estimate for preparing the license application in this case is also higher than the average estimated in the OMB supporting Statement for NRC Form 313.

<u>Costs to Licensees/Distributors</u>

There are no projected costs to licensees from the rule. The rule does not impose any new requirements on existing licensees.

For those specifically licensed distributors who choose to apply for a license under § 32.26 as a result of this change, the following costs would be expended:

Illustrative estimate of application costs for these assumptions:

3 Agreement State licensees
1 current NRC licensee

NRC E-Distribution License Required:

4 applications x 8 hours/application x $43/hour = ~$1,400

Device Evaluation Required:

4 registrations x 24 hours/device x $43/hour = ~$4,100

Total/year: ~$5,500

Fees associated with these licenses and registration certificates could present more significant costs than those estimated.

Costs to NRC:

4 applications x 8 hours/application x $93/staff hour = ~$3,000

4 evaluations x 21 hours/evaluation x $93/staff hour = ~$7,800

Total/year: ~$11,000

There are no costs to Agreement States other than the rulemaking. Both the NRC and Agreement States will incur costs associated with a rulemaking. These are discussed in Sections 4.11 and 4.12.

Costs to Public

There are some limited potential costs to the public from this aspect of the proposed rule due to contaminated scrap; however, due to the uncertainty in the probability and extent of such incidents, an actual cost is not estimated.

Occupational Health/Public Health

As this would likely increase the market in affected devices, some increases in the number of persons exposed are expected. The safety criteria associated with this exemption would limit routine exposures to no more than 5 mrem (50 μSv)/year and also control disposal and accident risks. Actual exposures are typically lower than those in the safety criteria. The proposed revised scope of purposes for the detectors is “designed to protect health, safety, or property.” This ensures that any product approved for use under the expanded scope of the exemption would be expected to provide a significant benefit to society, thus ensuring a reasonable cost/benefit for the individual product.

Environmental Considerations

This provision would increase the number of devices allowed to be disposed as ordinary trash. However, the safety criteria would also be improved to ensure that future doses from disposal are unlikely to exceed 5 mrem (50 μSv)/year from as many items of one product likely to be disposed at one landfill or municipal incinerator. This should minimize increases in environmental effects of increased numbers of detectors being disposed.

Benefits:

Benefits to Licensees/Users

There would be no direct effect on current general or specific licensees. However, future users of devices approved for use under the exemption would benefit from not having the requirements of the general license, or in some cases, a specific license. Some current general licensees would be expected to return generally licensed devices to the vendor and obtain devices covered under the exemption, when they become available.

As discussed in Section 4.3, there are a number of costs incurred by general licensees, which would not be incurred by future users under an exemption from licensing. The following discusses typical costs for general licensees, which would no longer be incurred by users under the exemption. Costs per device, per general licensee, and per report are the same as assumed under Section 4.3.

Currently, generally licensed devices are disposed of as low-level radioactive waste, although some with shorter-lived materials may be allowed to decay instead (after return to the distributor). The proposed rule would allow certain devices to become exempt from licensing, and therefore, disposal of such devices would be as ordinary trash. Users would benefit by no longer having to pay for disposal (usually indirectly as they usually transfer devices back to vendors or may also transfer to waste brokers). The affected devices would not need disposal for some time in the future, after distributors have applied for and obtained exempt status for their devices and sold devices for use under the exemption, and after those devices have subsequently been used for their useful life, which in some cases is more then 10 years. Currently, disposal options for low level radioactive material are limited. As of June 30, 2008, the Barnwell site can only accept waste from organizations located in South Carolina, Connecticut, and New Jersey, the three states that make up the Atlantic Interstate Low-Level Radioactive Waste Management Compact. The costs of low level waste disposal several and more years in the future is highly uncertain; thus no quantification of this benefit has been conducted, but may be substantial. Also, the uncertainty in the cost of future disposal in itself affects the market for such devices; thus, eliminating the requirement for controlled disposal may allow for more people to enjoy the benefits of the products.

Under the proposed solution, users exempt from regulation would no longer have to leak test the sources. It is assumed that a leak test, if required, is performed every six months. Six-month testing intervals are the default unless the manufacturer requests otherwise. Typically, the licensee swipes the device, then sends the swipe to be analyzed. Analysis services typical price is $35 to $40 per kit depending on the number of kits.

$$\frac{\text{2 tests/kit}}{\text{2 test/year}} \times \$40/\text{kit} = \$40/\text{device-year}$$

Some devices are also checked for proper operation if used under the general license. The savings from no longer having to perform this activity is estimated to be:

2 tests/device-year x 0.1 hour/operational check x $43/hour = $8.60/device-year

Currently, general licensees are required to maintain records of leak tests and device operation tests performed. The records are required to be maintained for 3 years. It is assumed that it takes approximately 0.1 hour per device to file and maintain the appropriate records. The time saved from no longer having to perform this activity is estimated to be:

2 leak tests/device-year x 0.1 hour/record x $43/hour = $8.60/device-year

In addition, users would no longer have to file the required transfer reports with the NRC. Agreement States mostly require similar reports, as a result of compatibility requirements.

0.6 hour/transfer report x $43/hour = $26/transfer report

There are a few additional reporting requirements such as change of address (§ 31.5(c)(14)), bankruptcy (§ 30.34(h)), accidents (§ 31.5(c)(5)), and loss or theft of sources (§§ 20.2201 and 20.2202). However, since these are likely to be infrequent events (requiring reports), the impact would be small by comparison.

A current requirement in § 31.5(c)(12) is that general licensees must appoint an individual responsible for having knowledge of appropriate regulations, and that person is to assure day-to-day compliance with the regulations. This requirement would no longer apply under the proposed solution. It is recognized that this person normally performs other duties that would require his/her employ for those duties; however, it is assumed that this person spends 4 hours/year attending to the required duties. Therefore, current general licensees and other future users would save by not having to pay a person to perform these duties.

4 hours/year x $43/ hour = $172/user-year

As § 31.5 is now a Compatibility Category B, the Agreement States should have equivalent requirements. Any new exemption would also require equivalent provisions in Agreement State regulations. Thus, the change in status should result in similar cost savings per user in Agreement States.

Illustrative annual cost savings to future users for the following assumptions:

5,000 devices used by 1,000 users;
500 transfers/year;
10% of devices require semiannual leak testing
10% of devices require semiannual operational testing

500 leak test kits x $40 =	$20,000
500 devices tested/year x $8.60 =	$4,300
500 devices checked for operation/year x $8.60 =	$4,300
500 transfer reports/year x $26 =	$13,000
1,000 responsible individuals x $172 =	$172,000
Total	~$214,000

This does not include the unquantified savings in disposal costs which may be quite significant.

The proposed solution is likely to change prices to users slightly. Currently, manufacturers and distributors of generally licensed devices offer to take back the devices for replacement of the decayed source or disposal. This disposal service is sometimes reflected in the initial sale price, or sometimes recouped in the price of devices replacing the ones being returned. If such devices become exempt from regulation, this disposal service would no longer be required. As such, there may be a slight decrease in the price of the device. A major portion of the cost of the device is for materials (radioactive source and other). However, another large contributor to the cost of the device is from insurance and bonding. These portions of the cost would remain, whether the device is generally licensed or exempt. Therefore, there may only be a slight decrease in the cost of the device.

Benefits to Licensees/Distributors

Distributors are likely to have slightly reduced reporting and recordkeeping costs. Currently, NRC licensees distributing devices for use under § 31.5 are required to submit quarterly transfer reports under § 32.52, both to NRC and to any Agreement States into which they are transferring devices. In addition, they are required to provide information to customers prior to transfers of devices by § 32.51a (and equivalent Agreement state provisions). Manufacturers and distributors of exempt products, including gas and aerosol detectors (§ 30.20) are required to submit reports of transfer to the NRC annually (§ 32.29). Additionally, records of the transfers for exempt products are required to be maintained for 1 year versus 3 years for generally licensed devices (under § 31.5). Distributors may also benefit from an increase in sales. No attempt has been made to quantify this benefit.

A significant reporting and recordkeeping cost for distributors is labeling. However, similar labeling requirements apply to distributors of gas and aerosol detectors. Therefore, there would not be a savings associated with this aspect of the recordkeeping. Although there are a number of distributor requirements that would change relative to reporting and recordkeeping, as noted above, the annual costs after the initial changes are made when revising the license, and for applicants for products to be used in the future, would be similar to current costs, although somewhat reduced.

Benefits to NRC/Agreement States

The NRC and the Agreement States would benefit from the proposed solution by a reduction in paperwork (e.g., reviewing reports, tracking devices) associated with devices now required to be used under the general license. Also, a limited savings in inspection costs could result, but is unlikely to be significant. General licensees are subject to inspections, but not routinely inspected. Those using the types of devices likely to change to an exempt status are unlikely candidates for inspection.

Benefits to Public

As noted, markets for such devices might expand. Costs associated with general licenses to possess and use the devices might have been an issue that prevented some potential users from obtaining the devices. As more of these devices are apt to be used in the future as a result of the elimination of regulatory requirements on users, more benefit would accrue to the public from the use of the devices. The products would be required to provide some protection to health, safety, or property.

4.6 Revise the Safety Criteria for Devices to be Used under the General License in § 31.5

This proposal would be to amend § 32.51 to make the safety criteria simpler, allow for the use of more up-to-date dose calculation methodology, reduce the dose criterion for untrained workers, and limit the quantities of radionuclides of concern that can be obtained from § 32.51 licensees (and Agreement State equivalent licensees) in devices approved in the future.

This proposal would revise the safety criteria to change the routine dose limit to 1 mSv (100 mrem)/yr and accident criterion to 100 mSv (10 rem); add an explicit requirement to

consider multiple devices; add a specific quantity limit related to radionuclides of concern; and remove references to § 32.24 and § 20.1201(a). These changes are only for approvals of new products for future distribution to § 31.5 general licensees and those under equivalent regulations of the Agreement States. However, as noted under Section 4.1.2, the Commission may on a case-by-case basis require consideration of the revised safety criteria for continued distribution of devices approved for use some time in the past during a reevaluation of the safety information in the registration certificate. There is a specific question for comment in this regard in the proposed rule.

The separate rulemaking to put a quantity limit into § 31.5 would restrict all future distribution to persons generally licensed under § 31.5.

Cost Impacts:

These changes would affect future distribution. The Commission would not require reevaluation of any devices currently approved for distribution, unless reevaluation of older device registration certificates are conducted as discussed under Section 4.1.2. Thus, it would have no immediate direct cost on any current licensees. It may, however, limit future development of these types of products, with associated impacts on distributor and user industries.

Benefits:

This proposal would provide for improved health and safety of persons who use generally licensed devices under § 31.5 and equivalent Agreement State regulations. In addition, reducing the criterion for routine use to 1 mSv (100 mrem)/year and clarifying that contributions to dose from multiple devices must be considered would reduce acceptable radiation fields around the devices, thus, tending to reduce doses to others besides the direct users.

This proposal would simplify the safety criteria, such that licensing actions under this section would be more efficient and effective.

This proposal may contribute to the development of devices with better safety features, such as better shielding or less hazardous radionuclides, as distributors attempt to achieve a generally licensed status for devices developed in the future.

If a less restrictive limit is made effective in § 31.5, the quantity limit in proposed § 32.51(a)(2)(v) would limit the quantity of radionuclides of concern approved for use in the future for use under § 31.5 (and equivalent Agreement State provisions). As proposed, it is only more restrictive than the separate limit proposed for § 31.5 for devices using more than one radionuclide, as it would apply a “rule of ratios” to the quantity limit.

4.7 Update the Regulations on Certain Static Eliminators and Ion Generating Tubes

This proposal would be to replace the general license in § 31.3 with an exemption from licensing in § 30.15(a)(2); thus, there would be clear requirements in the regulations for any applicant to distribute such products in the future (under §§ 32.14, 32.15, and 32.16). The products are consumer products and have essentially been regulated in the past as if they were exempt from regulation, in spite of there being no exemption from Parts 19, 20, and 21 stated in § 31.3.

Cost impacts:

This change is intended to have no effect on current distributors or users of these products. No costs are anticipated beyond the overall costs of the NRC rulemaking and implementation, discussed in Section 4.11, and Agreement State rulemaking discussed in Section 4.12.

It is, however, possible that the one NRC licensee would choose to amend its license to reduce its fees, resulting in one time costs to that licensee and the NRC.

Benefits:

Removing the inconsistency in regulating these products and clarifying the regulations should contribute to public confidence and make any future licensing decisions in this regard more efficient and effective.

4.8 Revise Part 32 to Remove Prescriptive Requirements for Distributors of Certain Generally Licensed Devices and Exempt Products

The requirements for manufacturers of exempt and generally licensed products are in some cases very prescriptive, particularly in the areas of prototype testing and quality control requirements. The regulations would be made less prescriptive and continue to contain general requirements and may provide standards by which performance may be judged rather than specifying details of procedures that must be followed. Regulatory guidance would be provided on acceptable approaches to meeting the requirements. It may also be possible to allow licensees to submit assurance programs that verify product integrity in lieu of specific quality control procedures.

In the case of generally licensed products, regulations that are candidates for modification include those for prototype test procedures (§§ 32.53(d)(4), 32.57(d)(2), 32.61(e)(4), 32.101, 32.102, and 32.103). There are specified sampling or testing procedures as a means of quality control for certain exempt products and generally licensed products (§§ 32.15(a)(2) and (3) and (c)(2), 32.55(a) through (d), 32.59, 32.62(a) through (e), and 32.110).

The following revisions are proposed:
Revise § 32.15(a), (b), and (c) to remove specific procedures.
Revise § 32.53(b)(5) to remove the reference to § 32.55.
Revise § 32.53(d)(4) to remove reference to § 32.101 and add § 32.53(e) to add prototype testing requirement without details of procedures to be followed.
Revise § 32.55 to remove specified acceptance sampling procedures and revise the acceptance criterion.
Revise § 32.57(d)(2) to remove reference to § 32.102 and add § 32.57(e) to add prototype testing requirement without details of procedures to be followed.
Revise § 32.59 for clarification.
Revise § 32.61(e)(4) to remove reference to § 32.103 and add § 32.61(f) to add prototype testing requirement without details of procedures to be followed.
Revise § 32.62(c), (d), and (e) to revise and clarify quality assurance requirements and revise the acceptance criterion.

Remove § 32.101.
Remove § 32.102.
Remove § 32.103.
Remove § 32.110.

The revision or supplementation of the following guidance documents would include example acceptable approaches: NUREG-1556, Vol. 16, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Licenses Authorizing Distribution to General Licensees" and NUREG-1556, Vol. 8, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Licenses Authorizing Distribution to Exempt Person."

Cost Impacts:

Cost to applicants/licensees

The only change that affects existing licensees is the revision of the acceptance criterion from 10% risk of more than 5% defectives to 5% risk, expressed as 95 percent confidence. Current licensees are likely achieving this as a result of other factors. There are no current NRC licensees under §§ 32.53, 32.57, or 32.61. A very small number are expected to be in the Agreement States under any of these provisions. The NRC has 46 licensees under § 32.14; some of these would no longer have NRC oversight of their quality assurance/quality control requirements as a result of changes discussed in Section 4.9.2. There are no Agreement State licensees equivalent to § 32.14, as NRC retains authority over exempt distribution licensing.

It is not expected that the revisions would significantly affect the cost to the applicants, although there might be a small increase as a result of having to address more specifics of the procedures to be followed.

Cost to NRC

Some additional effort would be involved in updating the two relevant guidance documents. Some additional time may be required of NRC license reviewers for a very small number of license applications.

Cost to Agreement States

Some additional time may be required of Agreement State license reviewers for a very small number of license applications.

Benefits:

Less prescriptive, more flexible regulations would be more performance-based. Applicants would be free to propose alternative methods to those presented in guidance to satisfy the requirements in the regulations. The requirements would continue to provide adequate assurance that the products being distributed meet performance standards. The performance standard would be somewhat revised to reduce the risk of defective products being distributed. Any new industry standards would more easily be accommodated.

The Code of Federal Regulations would be reduced by several pages.

4.9 Make the Requirements for Distributors of Exempt Products More Risk-informed

The level of control over the distribution of the various exempt products and materials is not commensurate with the associated risk, particularly in the areas of prototype testing and quality assurance/quality control. Some existing requirements may be unnecessary given the risk associated with the particular product. The products for which requirements would be removed have been evaluated as to their inherent risk and how much this risk could change if adequate prototype testing is not performed or an appropriate level of quality assurance/quality control is not used by the manufacturer.

4.9.1 Revise § 32.14 to Make the Requirements for Prototype Tests for Distribution of Exempt Products More Risk-Informed

Some existing requirements may be unnecessary given the risk associated with the particular product. In this rule, the NRC proposes to revise Part 32 requirements for prototype tests for exempt products to be more risk-informed by eliminating some of the individual requirements. These requirements are in § 32.14(b)(4) and relate to the product-specific exemptions under § 30.15 (and equivalent regulations of the Agreement States).

This proposal would revise § 32.14(b)(4) to make exceptions to prototype testing requirements.

Cost Impacts:

No costs are anticipated for applicants/licensees. There would be no costs to NRC beyond rulemaking and implementation costs discussed in Section 4.11. There would be no costs to Agreement States, as these are NRC only provisions.

Minimal additional incremental increases in doses to the public could result, if a larger number of products experience failure. Minimal potential for increases in doses to a fraction of users could result, usually no more than a fraction of 1 mrem (10 μSv)/year. Overall, an insignificant risk to the public would result even if removal of oversight results in lower quality designs.

Benefits:

Unnecessary regulatory burden during the application process on distributors of certain types of exempt products containing byproduct material would be reduced.

It is estimated that 3 hours would be saved per future applicant. A similar amount would be saved by NRC per application. Typically, it is estimated that eight applicants per year would be affected.

Using those assumptions, $43/hour for applicants, and $93/staff hour for NRC, savings to applicants would be approximately $1,000/year and for NRC, approximately $2,200.

The applicants would also have more flexibility in determining the approach to any prototype testing.

4.9.2 Revise § 32.14 to Make the Requirements for Quality Control for Distribution of Certain Exempt Products More Risk-Informed

Existing requirements for distributors of byproduct material to exempt persons include: specified sampling procedures (§§ 32.15(a)(2) and (3), and 32.110) and submittal of quality control procedures (§ 32.14(b)(5)). These are requirements related to the product-specific exemptions under § 30.15 (and equivalent regulations of the Agreement States).

This proposal would eliminate individual requirements if not justified, based on risk as follows:
Revise § 32.14 (b)(5) to make exceptions to requirements to submit quality control procedures for review.
Revise § 32.15, to qualify the quality assurance requirements so as to limit them to those procedures established in the license. This accommodates the exceptions made in § 32.14(b)(5).

Cost Impacts:

No costs to applicants/licensees are anticipated. There would be no costs to NRC beyond rulemaking and implementation costs discussed in Section 4.11. There would be no costs to Agreement States as these are NRC only provisions.

Minimal potential for increases in doses to a fraction of users could result, usually no more than a fraction of 1 mrem (10 μSv)/year, as well as potential for increases in the probability of failures sometimes resulting in somewhat higher exposures. Overall, an insignificant risk to the public would result even in the unlikely event that removal of oversight results in poor quality control activities.

Benefits:

Unnecessary regulatory burden on distributors of certain products containing byproduct material would be reduced.

It is estimated that 3 hours would be saved per future applicant. A similar amount would be saved by NRC per application. Typically, it is estimated that eight applicants per year would be affected.

Using those assumptions, $43/hour for applicants, and $93/staff hour for NRC, savings to applicants would be approximately $1,000/year and for NRC, approximately $2,200.

There are currently 46 licensees under § 32.14, many of whom would be free to make adjustments in their quality assurance/ quality control procedures without amending their license. No attempt has been made to quantify this benefit. However, as this is an ongoing effect, the overall benefit for this change would be greater than that concerning prototype tests discussed in Section 4.9.1.

NRC inspection costs would be slightly reduced or time would be allotted to more risk-significant activities.

4.10 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.

Cost Impacts:

No costs are anticipated beyond the costs of inclusion in the rulemaking. Overall costs for NRC and Agreement State implementation are discussed in Sections 4.11 and 4.12. Such changes constitute a small portion of the implementation costs.

Benefits:

Improvements of this type in the regulations contribute to efficiency and effectiveness and to public confidence.

4.11 Development and Implementation Costs

NRC development costs are the costs of preparation of a regulation before its promulgation and implementation. Such costs may include expenditures for research in support of this regulatory action, publishing notices of rulemaking, holding public meetings, responding to public comments, and issuing a final rule. NRC implementation costs are those “front-end” costs necessary to effectuate the action; they may arise from the necessity of developing procedures and guidance to assist licensees in complying with the final action. All costs associated with pre-decisional activities are viewed as “sunk” costs and are excluded from NRC implementation costs.

Developmental and implementation costs within the scope of this analysis are the costs of proceeding with a rulemaking, as well as efforts on guidance development associated with this rule. These are mainly costs of the effort of NRC professional staff members in the Office of Federal and State Materials and Environmental Management Programs expended in developing the rule.

Approximately 1 FTE is estimated for the analysis of comments and development of the final rule. One NRC professional staff member costs $165,200/FTE

NRC staff would need to update existing guidance in the NUREG-1556 series related to distribution licensing to reflect the revisions to the regulations. 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” would require minor revisions or supplementation. If the changes for this rule are made within overall revisions of these

NUREGs, the additional updating needs should be relatively limited cost impact as a result of this proposed rulemaking.

4.12 Costs to Agreement States of Compatible Regulations

Costs would be incurred by the Agreement States for development and implementation of compatible regulations. The costs would vary significantly by State because of differences in internal procedures for developing regulations. Some rule changes would be required to meet Compatibility Category A or B for certain revisions. As these need to be essentially word-for-word compatible, the process should be relatively simple. One provision, § 30.32(g), is a Compatibility Category C; this may also result in some revision of the Agreement State regulations. For this proposed rule, the NRC assumes an average of 0.1 FTE at $80,000/FTE for each state. There are currently 35 Agreement States; therefore, the total cost for all Agreement States would be approximately $280,000.

5. DECISION RATIONALE

The assessment of costs and benefits discussed above, quantitatively when possible and qualitatively otherwise, leads the Commission to the conclusion that the overall impacts of the proposed rulemaking would be assurance of the protection of public health and safety in the future, more effective and efficient licensing of distribution to exempt persons and to generally licensed persons, and a reduction in undue burden to certain distributor licensees. Currently, some of the regulations are unclear or contain unnecessary burden relative to the very small risk associated with a product. Although there are apparent costs associated with some of the amendments, the Commission believes that these costs will be outweighed by those non-quantifiable costs associated with regulatory efficiency and protection of the health and safety of the public. This rule would advance to varying degrees the Commissions goals concerning safety, efficiency, timeliness, security, and openness.

The largest single cost would be implementation of the proposed rulemaking by the NRC and the Agreement States. However, by handling several issues together, the Commission minimizes its costs as well as costs for the Agreement States.

6. IMPLEMENTATION

The NRC's schedule for implementation of this rulemaking calls for the effective date of the rule to be in 2010 for the NRC's jurisdiction and full implementation by the Agreement States by 2013. The applicable guidance documents are 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." These all have additional updating needs and should be revised as part of a broader update following the issuance of the rule. There are no changes requiring entirely new guidance; i.e., nothing that would necessitate having guidance available in draft for comment along with the proposed rule. Details of procedures being

removed from the regulations would be added to the applicable guidance when revised as examples of acceptable approaches; however, these details are currently in the regulations. Some revisions to these three documents are needed as a result of this rule for consistency with revisions to the exemptions and requirements for the various categories of distributors.

For all changes that affect Compatibility Category B or Compatibility Category C requirements, Agreement States have 3 years to make changes to their affected regulations.

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

7. IMPLICATIONS FOR OTHER FEDERAL AGENCIES

Promulgation of this proposed rule would have no adverse effects on other Federal agencies.

8. EFFECT ON SMALL ENTITIES

The proposed rule would not significantly impact small or large entities.

References

Department of Labor (U.S.), Bureau of Labor Statistics, Employer Costs for Employee Compensation. Management, professional, and related occupations, State and local government wages. Series IDs CMU3020000100000D and CMU3020000100000P, 4th Quarter 2007. <www.bls.gov>.

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

Draft Environmental Assessment for Proposed Rulemaking – Requirements for Distribution of Byproduct Material: (10 CFR Parts 30, 31, 32, 40, and 70)

U.S. Nuclear Regulatory Commission
Office of Federal and State Materials and Environmental Management Programs

Table of Contents

1.0 Introduction

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations governing the use of byproduct material in 10 CFR Parts 30, 31, 32, 40, and 70. These amendments 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 for the use of 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. The NRC has prepared this environmental assessment (EA) to determine whether the promulgation of this rule will have any significant environmental impact.

1.1 Background

The Commission's regulations for byproduct material are in Part 30 (in Title 10 of the Code of Federal Regulations), which sets out the basic requirements for the domestic licensing of byproduct material and includes a number of exemptions from licensing. These exemptions allow for certain products and materials containing byproduct material to be used without any regulatory requirements imposed on the user. These exemptions are in §§ 30.14, 30.15, 30.18, 30.19, 30.20, and 30.21. The two exemptions in §§ 30.19 and 30.20, for self-luminous products and gas and aerosol detectors, respectively, are class exemptions, which cover a broad class of products. Under these provisions, new products can be approved for use through the licensing process, if the applicant demonstrates that the specific product meets certain safety criteria. This is in contrast to the other exemptions for which the level of safety is controlled through such limits as specification of radionuclides and quantities. Sections 30.14 and 30.18, exempt concentrations and exempt quantities, are broad materials exemptions, which allow the use of a large number of radionuclides. The specific radionuclide limits on the concentrations and quantities are contained in tables in §§ 30.70 and 30.71, respectively. The remainder of the exemptions from licensing are product specific, for which many assumptions can and have been made concerning how the product is distributed, used, and disposed.

Other parts of the Commission’s regulations in Title 10 would be affected by this rulemaking. Part 31 provides general licenses for the use of certain items containing byproduct material and the requirements associated with these general licenses. The general licenses are established in §§ 31.3, 31.5, 31.7, 31.8, 31.10, 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.

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

1.2 Document Organization

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

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

2.0 Need for the Proposed Action

Based on the NRC's review of regulations that govern the licensing, manufacture, use, and disposal requirements for byproduct material as contained in 10 CFR Parts 30, 31, and 32, it was determined that several of its regulations are in need of revision. Internal analyses have identified regulations that can be improved because they are less effective than intended, or unnecessarily burdensome. Additionally, interactions with the licensed community have identified regulations that require additional clarification. Therefore, Federal action is needed to address the need for the NRC to update and clarify certain regulations and to improve efficiency in the licensing of material transfer to exempt persons and to licensees. If enacted, changes to these regulations would better ensure the protection of public health and safety in the future and improve the effectiveness and efficiency of certain licensing actions. Parts 40 and 70 of the Commission's regulations would contain minor conforming amendments.

3.0 Applicability of Categorical Exclusion for Certain Amendments

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

The categorical exclusion in § 51.22(c)(3)(i) provides that amendments to Parts 30, 31, and 32 that relate to procedures for filing and reviewing applications for licenses or other forms of permission do not require an environmental assessment. Paragraph 51.22(c)(3)(iii) provides a categorical exclusion for amendments to Parts 30, 31, 32, 40, and 70 that relate to reporting. Paragraph 51.22(c)(2) provides a categorical exclusion for amendments which are corrective or of a minor or non-policy nature. Thus, such amendments do not require an EA. The proposed amendments related to when a registration certificate is issued in addition to a license to provide the authority for distribution of a sealed source or device and whether and how such certificates should be amended, revoked, reviewed, or inactivated fall into the categorical exclusion in

§ 51.22(c)(3)(i). The proposed revisions to §§ 30.6, 32.56, 40.5, and 70.5 fall under the categorical exclusion in § 51.22(c)(3)(iii). Proposed revisions to §§ 31.23, 32.1, 32.8, 32.59, and 32.303 fall under the categorical exclusion in § 51.22(c)(2), as do renaming Subparts C and D of Part 32 and moving §§ 32.72 and 32.74 to a different subpart.

4.0 The Proposed Action and Alternatives: Generic Discussion

Under the proposed action, the NRC would amend certain sections of 10 CFR Parts 30, 31, 32, 40, and 70 by rulemaking in accordance with the Administrative Procedure Act of 1946, as amended. The alternatives to rulemaking would be to take no action, or to take various non-rulemaking actions. Non-rulemaking alternatives include: generic letters, information notices, guidance documents, and direct one-on-one contact with licensees.

Rulemaking is the NRC's preferred alternative because it best resolves the need for action for these issues consistent with the Agency's goals of ensuring adequate protection of public health and safety and the environment and adequate protection in the secure use and management of radioactive materials, as well as its objectives of effectiveness and openness in the regulatory process. In general for these issues, rulemaking establishes regulations which can be made enforceable; affords opportunity for public involvement; and are readily available to regulators, licensees, and the general public.

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

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

5.0 The Proposed Actions, Alternatives, and Environmental Impacts: Discussion of Specific Issues

5.1 Revisions to § 30.32(g) for Sources and Devices Not Registered by the Manufacturer or Distributor or Not Identified by the User

The proposed rule would provide flexibility in the licensing of sealed sources and devices. Sealed sources and devices present relatively limited potential for leading to any releases to the environment. The attribute most likely to be affected by these changes would be occupational exposure. As discussed briefly below, the limited changes being made in this section are unlikely to have a significant effect.

The provision in § 30.32(g)(3) provides for substituting some categories of information with other information to demonstrate the sealed source or device meets the same safety standard. This rule would extend this provision to materials covered by Part 30 prior to the final rule published October 1, 2007 (72 FR 55863).

The provision in § 30.32(g)(4) allows for the use of small calibration and reference sources for which a registration certificate has not been issued to the manufacturer or distributor without detailed safety information being submitted by the applicant. There are basic requirements

applicable to all specific licensees, such that any specific licensee should be capable of using these calibration and reference sources safely. Requiring detailed safety information from the user for such sources is unlikely to have a significant effect on occupational safety.

The provision in § 30.32(g)(5) also provides flexibility to licensing the use of sealed sources and devices by allowing for constraints on the number and type of sealed sources and devices and the conditions under which they will be used to provide the basis for licensing the user in lieu of identifying each specific sealed source and device to be used. This provision is also not expected to significantly affect occupational doses for workers at licensed facilities, or any other environmental factors.

There are no reasonable alternatives to amending the regulations to add such flexibility. There is not a significant environmental impact from the preferred action compared to the no-action alternative and this aspect of the rulemaking is not likely to affect any environmental resources.

5.2 Establish a New Class Exemption for Certain Industrial Products

A new provision, § 30.22, would be created to establish a new class exemption for certain industrial products initially transferred from a § 32.30 licensee. Licensing requirements for distribution of devices for use under the new exemption would be comparable to those imposed on specifically licensed distributors of gas and aerosol detectors used under § 30.20 (and equivalent Agreement state provisions). These regulations would be:

§ 32.30 would be created to establish distributor requirements for exempt industrial devices.
§ 32.31 would be created to establish new safety criteria.
§ 32.32 would be created to establish the specific conditions of the license issued under § 32.30.

The creation of §§ 32.30, 32.31, and 32.32 would establish the requirements for manufacturers and distributors of certain industrial devices to be used under the new exemption.

Of the various revisions in this proposed rule, this provision has the most potential for producing environmental impacts. Creating an exemption from licensing results in products being released from any further regulatory control. This results in these products being disposed of without regard to radioactivity. While many devices of the types likely to be distributed under this exemption are currently being used under the general license in § 31.5 (and equivalent Agreement State provisions), these are required to be disposed of as low level radioactive waste (and usually, though not uniformly are). Also, providing an exemption from licensing is likely to significantly increase the number of these types of devices distributed in the future. The ultimate disposal of these devices is the most significant factor in evaluating the environmental impacts of this action.

The limitation of this exemption to industrial products unlikely to be routinely used in the home and the provisions in §§ 32.30, 32.31, and 32.32 are key to whether the resulting environmental impacts could be significant. The proposed requirements to approve a device for use under the proposed exemption include the analysis of numerous scenarios through which exposures are expected to occur. These include those expected in various routine situations, as well as accident scenarios. Each of the criteria related to these scenarios limits the potential for significant risks from some aspect of the marketing, distribution, installation, use, servicing and disposal of the devices. Of particular importance with regard to environmental considerations

are: (1) the requirement that it is unlikely that the dose to a suitable sample of the group of individuals expected to be most highly exposed from disposal of the quantities of products likely to accumulate in the same disposal site will exceed 10 μSv (1 mrem) in any one year; (2) the limitation of quantity allowed to be in any device to no more than 10^{-4} times the Category 2 limit in Appendix E of Part 20 (related to the International Atomic Energy Agency (IAEA) categorization of sources of radionuclides of concern); (3) the requirement that certain doses would not be exceeded in specified misuse scenarios involving the unshielded source.

With respect to the first of these, the total quantity expected to be distributed annually must be provided and this would be considered in the projection of the total number of devices likely to accumulate in a single landfill, municipal incinerator, or, if applicable, recycling center. This limit is very low because persons exposed to radioactive material through disposal scenarios are exposed to all materials which end up in ordinary trash. The intent is that the combined effect of the disposal of all materials exempt from regulatory control will not result in exposures to persons, such as waste collectors and waste workers at municipal incinerators, of more than 1 mSv (100 mrem)/year. It is also intended to control exposures to others such as people who may live at the site of a closed landfill in the future; however, waste collectors or waste workers are typically the most exposed population as a result of uncontrolled disposal.

The proposed limit noted in item (2) above is to provide added assurance that quantities of byproduct material in exempt devices would not provide a realistic source of radioactive material for persons with malicious purposes.

The misuse scenario in item (3) above is intended to essentially limit the quantity of any radionuclide which could be in any device, regardless of any shielding and containment designed to limit the exposures from the source in the device. This has a number of intended benefits including minimizing impacts to the environment.

In addition to the specific provisions being proposed with this new exemption, there are a number of other factors which contribute to the conclusion that adding this exemption would not lead to significant impacts to the environment. The Commission has a consumer product policy which calls for the Commission to monitor the overall impact of its exemptions from licensing. The Commission evaluated the potential exposure impacts from consumer products in the early ’60’s, again in the late ‘70’s, and more broadly of all of its exemptions in the ‘90’s. The second of these analyses was published as NUREG/CR-1775, “Environmental Assessment of Consumer Products Containing Radioactive Material,” in 1980. As noted in the Background section of this document, the dose assessments from the latest of these evaluations were published as NUREG-1717 in 2001. NUREG-1717 also includes dose assessments for some devices which are likely candidates for being approved for use under this new class exemption; these assessments estimated exposures from these devices if they were used under an exemption from license.

Related to the consumer product policy, the Commission has reporting requirements for the distribution of byproduct material nationally, through which it can monitor the amount of byproduct material distributed under the exemptions from licensing, which will ultimately be disposed as ordinary trash. Although currently there are no equivalent reporting requirements for the distribution of source material, the Commission has obtained more limited information on the types and quantities of source material being distributed for use under exemptions as input for these types of evaluations.

The intent of this monitoring of distribution is to be able to ensure that members of the public are unlikely to be routinely exposed to more than 1 mSv (100 mrem)/year from the net effect of various sources of materials released from regulatory control. The Commission's policy (March 16, 1965; 30 FR 3462) is for consumer products to routinely expose users to only a small fraction of this limit such that the net effect of multiple exempt products should still be a fraction of the public dose limit, so that those who live on decommissioned sites or are exposed to effluents from licensed facilities are still unlikely to be routinely exposed to more than 1 mSv (100 mrem)/year. The proposed dose criterion for routine use conditions is 200 μSv (20 mrem)/year; however, this exemption, unlike most of the Commission's exemptions, is limited to industrial devices, not including commonly used consumer products.

The conclusion of each of the evaluations of the overall effects of the Commission's exemptions was that the Commission's policy on consumer products has been adequate to maintain routine exposures from exempt products to a fraction of the public dose limit. (That limit was 500 mrem (5 mSv)/year at the time of the first two evaluations.)

The results of the systematic assessment of exemptions, of which NUREG-1717 was a part, showed that many of the earlier established exemptions had declined in use or become completely obsolete. For a number of the source material exemptions, non-radioactive lanthanum has been replacing thorium in large part. These exemptions for thorium-containing products were relatively large contributors to the exposures of the public (in some cases occupationally exposed populations) at one time. Although some products, such as smoke detectors are currently distributed in the millions per year, for many exemptions, there has been a downward trend in distribution. Also, in a recent final rule published October 16, 2007 (72 FR 58473), several obsolete exemptions were removed further assuring that the covered products will no longer be distributed. In that rule, the Commission also improved the reporting requirements in Part 32 in order to improve the ability of the Commission to ensure compliance with the constraints in the exemptions and with the conditions of the license and to see trends in the future. Therefore, the Commission has enhanced its ability to ensure that the net effects of products distributed for use without regulatory control are consistent with the intent of the Commission's consumer product policy.

There are no viable alternatives to rulemaking to establish a broadly applicable exemption from licensing. The conclusion of the Commission is that this new class exemption, if established with the additional provisions noted here, would not result in significant potential for leading to inappropriate exposures to members of the public from the net effect of materials released from regulatory control, and is unlikely to significantly affect other environmental resources.

5.3 Revise the Safety Criteria for the Existing Class Exemptions

The safety criteria for the current class exemptions are based on outdated dose calculation methodology, are limited to addressing the dose from a single unit in the case of disposal, and, in the case of the criteria for gas and aerosol detectors, § 32.26, 32.27, and 32.28 do not adequately control the maximum quantities of byproduct material that could be contained in a detector approved for use under the exemption in § 30.20 (and equivalent Agreement State provisions). The regulations governing the approval of products for use under the class exemption (in § 30.19 and equivalent Agreement State provisions) for self-luminous products

are in §§ 32.22, 32.23, and 32.24. The proposed changes would apply to new products approved in the future under these provisions.

The following revisions are proposed:
Revise definition of "*dose commitment*" in § 32.2.
Revise § 32.23 by removing organ dose limits and terminology derived from International Commission on Radiological Protection (ICRP) 2 dose limitation methodology, combining criteria in columns I and II of the existing table in § 32.24, changing the negligible probability accident criterion, and requiring consideration of the likely number of units present for all scenarios.
Remove § 32.24, as a table is not needed for the simplified approach to § 32.23.
Revise § 32.26 to add a specific quantity limit related to radionuclides of concern.
Revise § 32.27 by removing organ dose limits (except for skin from misuse) and terminology derived from ICRP-2 dose limitation methodology; changing the negligible probability accident criterion; adding a misuse criterion with a specified scenario, and requiring consideration of the likely number of units present for all scenarios.
Remove § 32.28, as a table is not needed for the simplified approach to § 32.27.

Removing some of the individual organ limits would be somewhat less restrictive than the current criteria, but other changes would be more restrictive. In particular, the applicant would now have to estimate the potential doses resulting from disposal of its products to be used under § 30.20 to show that it is unlikely that the dose to a suitable sample of the group of individuals expected to be most highly exposed from disposal of the quantities of units likely to accumulate in the same disposal site will exceed 50 μSv (5 mrem) in any one year. The existing requirement contains a 5 mrem/year dose criterion (with additional organ dose limits) but it applies only to the disposal of a single unit. In addition, a provision to evaluate certain misuse scenarios involving the unshielded source and show that certain exposure limits would not be exceeded is also intended to control the quantity of byproduct material that may be contained in a detector approved for use under § 30.20. In the proposed revision to § 32.23, the disposal criterion of 10 μSv (1 mrem)/year would also now apply to disposal of the quantities of units likely to accumulate in the same disposal site rather than disposal of a single unit.

Overall these changes are expected to be more restrictive as to the quantities of materials that could be approved for use in a detector to be used under §§ 30.19 and 30.20 (and equivalent Agreement State regulations) without unduly limiting the development of new products in the future that may provide significant benefits to the public. These revisions are therefore protective of the environment, but do not result in a significant change to current practices. There is no environmental impact from the preferred action compared to the no-action alternative and this aspect of the rulemaking is not likely to affect any environmental resources.

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

The exemption in § 30.20 and equivalent Agreement State regulations provide for persons without a license to receive, possess, use, transfer, own, or acquire byproduct material, in gas and aerosol detectors *designed to protect life or property from fires and airborne hazards*, provided that the detectors are manufactured, processed, produced, or initially transferred in accordance with a specific license issued under § 32.26. Products similar to those allowed under this exemption, but not quite fitting the "class" cannot be approved under this exemption.

One example is drug detectors, which were rejected for distribution under this exemption because they were not "designed to protect life or property from fires and airborne hazards."

The proposed rule would replace the wording in § 30.20, "designed to protect life or property from fires and airborne hazards," with less restrictive wording to allow other potential applications under an existing framework, which has safety criteria that protect public health and safety.

As discussed under Section 5.3, the safety criteria for this exemption are also being revised. Although a wider class of products would be covered by the exemption, potentially leading to increased numbers of products being distributed under this provision in the future, and ultimately disposed without regard to radioactivity, the revisions to §§ 32.26 and 32.27 should provide improved assurance that the quantities of byproduct material distributed for use under this exemption (and equivalent Agreement State provisions) will be adequately controlled.

The additional considerations discussed under Section 5.2 concerning the Commission's consumer product policy, the evaluations of the overall impact of distribution of products for use under exemptions from licensing, and the fact that distribution under many other exemptions has declined are also applicable to considering the impacts of the potential increase in the types of products being approved for use under § 30.20 and equivalent Agreement State regulations.

The conclusion of the Commission is that expanding the scope of this exemption, while also adding the provisions discussed under 5.3, would not significantly increase the potential for inappropriate exposures to members of the public from the net effect of materials released from regulatory control, would not significantly increase occupational or public exposures, and is unlikely to significantly affect other environmental resources.

5.5 Revise the Safety Criteria for Devices to be Used under the General License in § 31.5 (and equivalent provisions of the Agreement States)

The requirements for a license to manufacture or initially transfer devices containing byproduct material to persons generally licensed under § 31.5 and equivalent Agreement State regulations are established in § 32.51. This proposal would amend § 32.51 to make the safety criteria simpler, allow for the use of more up-to-date dose calculation methodology, reduce the dose criterion for untrained workers, and limit the quantities of radionuclides of concern that can be obtained from § 32.51 licensees (and Agreement State equivalent licensees) in devices approved in the future.

This proposal would revise the safety criteria to reduce the routine dose limit to 1 mSv (100 mrem)/yr and the accident criterion to 100 mSv (10 rem); add an explicit requirement to consider multiple devices; add a specific quantity limit related to radionuclides of concern; and remove references to § 32.24 and § 20.1201(a). These changes are for approvals of new products for future distribution to § 31.5 general licensees and those under equivalent regulations of the Agreement States.

A quantity limit similar to the one proposed here for future approvals is being considered separately by the Commission for direct application in § 31.5. If that provision is not enacted, or a less restrictive provision is made effective, the proposed limitation on quantity in § 32.26 would specifically control quantities of "radionuclides of concern" in devices approved in the future.

The most significant change in these revised provisions is the reduction to the standard for acceptable dose for use of devices under the general license in § 31.5 (and equivalent Agreement State provisions). This would affect both occupational and public doses from devices approved under the revised regulation.

While these devices are required to be returned to a vendor or transferred to a waste broker and ultimately disposed as radioactive waste, it is believed that there is less compliance with disposal requirements for devices used under general license than for those used under specific license, i.e., a larger fraction of general licensees than specific licensees are projected to dispose of devices improperly. Thus, improvements to reduce quantities or exposure rates from generally licensed devices may result in a small reduction to the environmental effects of improper disposal.

This aspect of the proposed rule is therefore protective of the environment. There are no non-rulemaking alternatives to accomplish this result. There is no environmental impact from the preferred action compared to the no-action alternative and the rulemaking is not likely to affect any other environmental resources.

5.6 Update the Regulations on Certain Static Eliminators and Ion Generating Tubes

This proposal would be to replace the general license in § 31.3 with an exemption from licensing in § 30.15(a)(2). As a result, there would be clear requirements in the regulations for any applicant to distribute such products in the future (under §§ 32.14, 32.15, and 32.16). The products are consumer products and have essentially been regulated in the past as if they were exempt from regulation.

Although this is also adding a new exemption to the regulations, these products have been distributed essentially without further regulatory control for use under the general license in § 31.3 (and equivalent Agreement State provisions). The only difference is that there are, in fact, some regulatory requirements applicable to any general license and thus more readily available recourses available to NRC with use under a general license; however, given that no mechanism exists in the regulations to directly identify users of products under this general license, the difference in regulatory status of the products presents little practical difference in the level of control. The potential doses from the use of the covered products under exemption from licensing have been estimated to be very low; dose estimates for some of these products are also presented in NUREG-1717. The important aspect under the existing provisions and under the proposed action is the licensing requirements placed on the distributor. The requirements would remain essentially the same as in current practice, but would be explicit to ensure consistency. Achieving this noted benefit cannot be accomplished under any non-rulemaking alternative.

There is no environmental impact from the preferred action compared to the no-action alternative and the rulemaking is not likely to affect any environmental resources.

5.7 Revise Part 32 to Remove Prescriptive Requirements for Distributors of Certain Generally Licensed Devices and Exempt Products

The requirements for manufacturers of exempt and generally licensed products are in some cases very prescriptive, particularly in the areas of prototype testing and quality control requirements. The regulations would be made less prescriptive, but continue to contain general requirements and provide standards by which performance may be judged rather than specifying details of procedures that must be followed (except for the specific requirements being removed in connection with the risk-informing issue discussed in section 5.8 of this document). Regulatory guidance would be provided on acceptable approaches to meeting the requirements. It may also be possible to allow licensees to submit assurance programs that verify product integrity in lieu of specific quality control procedures.

In the case of generally licensed products, regulations that are candidates for modification include prototype test procedures in §§ 32.53(d)(4), 32.57(d)(2), 32.61(e)(4), 32.101, 32.102, and 32.103. Specified sampling or testing procedures as a means of quality control are in §§ 32.15(a)(2) and (3) and (c)(2), 32.55(a) through (d), 32.59, 32.62(a) through (e), and 32.110.

The following revisions are proposed:
Revise § 32.15(a), (b), and (c) to remove specific procedures.
Revise § 32.53(b)(5) to remove the reference to § 32.55.
Revise § 32.53(d)(4) to remove reference to § 32.101 and add § 32.53(e) to add prototype testing requirement without details of procedures to be followed.
Revise § 32.55 to remove specified acceptance sampling procedures and revise the acceptance criterion.
Revise § 32.57(d)(2) to remove reference to § 32.102 and add § 32.57(e) to add prototype testing requirement without details of procedures to be followed.
Revise § 32.59 for clarification.
Revise § 32.61(e)(4) to remove reference to § 32.103 and add § 32.61(f) to add prototype testing requirement without details of procedures to be followed.
Revise § 32.62(c), (d), and (e) to revise and clarify quality assurance requirements and revise the acceptance criterion.
Remove § 32.101.
Remove § 32.102.
Remove § 32.103.
Remove § 32.110.

These revisions would primarily remove details of procedures to be followed from the regulations. The standards for acceptance sampling would also be revised to reduce the number of defective units likely to be distributed for use under the product-specific exemptions in § 30.15 and some of the general licenses in Part 31 (and equivalent Agreement State regulations). Oversight of how licensees conduct these procedures, however, may be completely removed in the case of some of the products covered by § 30.15 as discussed in the following section.

No impacts to environmental resources would be expected from taking a more performance-based approach for exercising oversight over these procedures.

5.8 Make the Requirements for Distributors of Exempt Products More Risk-informed

The level of control on the distribution of the various exempt products and materials is not commensurate with the associated risk, particularly in the areas of prototype testing and quality assurance/quality control. Some existing requirements may be unnecessary given the risk associated with the particular product. The products for which requirements would be removed have been evaluated as to their inherent risk and how much this risk could change if adequate prototype testing is not performed or an appropriate level of quality assurance/quality control is not used by the manufacturer.

Prototype tests:
In this rule, the NRC proposes to revise Part 32 requirements for prototype tests for exempt products to be more risk-informed by eliminating some of the individual requirements. These requirements are in § 32.14(b)(4) and relate to the product-specific exemptions under § 30.15 (and equivalent regulations of the Agreement States). This proposal would revise § 32.14(b)(4) to make exceptions to prototype testing requirements.

Quality Control:
Existing requirements for distributors of byproduct material to exempt persons include specified sampling procedures (§§ 32.15(a)(2) and (3), and 32.110) and submittal of quality control procedures (§§ 32.14(b)(5)). These are requirements related to the product-specific exemptions under § 30.15 (and equivalent regulations of the Agreement States). This proposal would eliminate individual requirements if not justified, based on risk, by revising § 32.14 (b)(5) to make exceptions to requirements to submit quality control procedures for review, and § 32.15, to accommodate the exceptions made in § 32.14(b)(5).

Removing oversight of prototype testing could have negative effects on the quality of product designs. Removing oversight of quality control could have negative effects on manufacturing quality, i.e., a larger number of items distributed for use under these exemptions may not be manufactured exactly as designed. However, the Commission has evaluated the inherent risk of these products and how much this risk could change if adequate prototype testing is not performed or an appropriate level of quality assurance/quality control is not used by the manufacturer. The Commission has concluded that the potential increase in doses to the public are very small, usually less than 10 μSv (1 mrem)/year, even if removing oversight results in significant changes to the conduct of manufacturers in these areas. No other environmental resources are expected to be affected by this aspect of the proposed rule.

6.0 Conclusion

The NRC is proposing to amend its regulations governing the use of byproduct material in 10 CFR Parts 30, 31, 32, 40, and 70. This document was prepared so that environmental impacts would be considered as part of the decision-making process. This assessment discusses the impacts of the proposed rulemaking under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51. Many of the individual amendments being proposed belong to a category of actions which the Commission, by §§ 51.22(c)(2) and 51.22(c)(3)(i) and (iii), has declared to be a categorical exclusion and found that it is not possible for these types of actions to individually or cumulatively have a significant effect on the human environment. The other proposed amendments in this overall rulemaking would not significantly affect any environmental

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

7.0 List of Agencies and Persons Consulted

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

8.0 Sources Cited

Code of Federal Regulations, Title 10, Energy, Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material."

Code of Federal Regulations, Title 10, Energy, Part 31, "General Domestic Licenses for Byproduct Material."

Code of Federal Regulations, Title 10, Energy, Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material."

Code of Federal Regulations, Title 10, Energy, Part 40, "Domestic Licensing of Source Material."

Code of Federal Regulations, Title 10, Energy, Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," Subpart A, "National Environmental Policy Act – Regulations Implementing Section 102(2)."

Code of Federal Regulations, Title 10, Energy, Part 70, "Domestic Licensing of Special Nuclear Material."

Atomic Energy Commission (U.S.) (AEC). Washington, D.C., "Use of Byproduct Material and Source Material, Products Intended for Use by General Public (Consumer Products)." *Federal Register*: Vol. 30, No. 50, pp. 3462–3463. March 16, 1965.

Nuclear Regulatory Commission (U.S.) (NRC). NUREG/CR-1775, "Environmental Assessment of Consumer Products Containing Radioactive Material," prepared by D. W. Buckley, R. Belanger, P. E. Martin, K. M. Nicholaw, and J. B. Swenson, Science Applications, Inc., October 1980.

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