RULEMAKING ISSUE
AFFIRMATION

September 15, 2011 SECY-11-0129

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: FINAL RULE: REQUIREMENTS FOR DISTRIBUTION OF BYPRODUCT MATERIAL, 10 CFR PARTS 30, 31, 32, 40, AND 70 (RIN 3150-AH91)

PURPOSE:

To request Commission approval to publish a final rule, in the *Federal Register*, that would amend Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 30, 31, 32, 40, and 70. The staff is also requesting that the Commission reconsider and approve development of a proposed rule that would revise the safety criteria for products to be used under the existing class exemptions and the general license in 10 CFR 31.5.

SUMMARY:

This final rule includes 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. The final rule also includes minor conforming amendments to Parts 40 and 70. The final rule will revise the regulations to make the requirements for distributors of byproduct material clearer, less prescriptive, and more risk-informed and up to date. The final rule will also 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

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sealed sources and devices. This rule will make licensing processes more efficient and effective. These changes will affect manufacturers and distributors of sources and devices containing byproduct material and future users of some products currently used under license.

The staff is also proposing for Commission consideration the development of a proposed rule to revise existing safety criteria in Part 32.

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 byproduct material regulations and recommended a number of issues to be considered in rulemaking, including some related to the general licenses in Part 31.

In the staff requirements memorandum (SRM) for SECY-02-0196 dated November 17, 2003, the Commission approved 12 of the individual issues for consideration in rulemaking. During the initial development of the proposed rule, additional related issues were identified and the staff determined that the complexity of the rule warranted more than one rulemaking and briefed the Commissioners' Technical Assistants on February 10, 2005, on the need for the revised approach.

The first proposed rule was submitted to the Commission as part of SECY-05-0151,"Proposed Rule: 10 CFR Parts 30, 31, 32, and 150 – Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements (RIN 3150-AH41)," on August 23, 2005.[1] In SECY-05-0151, the staff also discussed ongoing efforts related to the second rulemaking including certain new issues that the staff identified and were beyond those items discussed in the 2002 rulemaking plan. 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 proposed rule for the second rulemaking was submitted to the Commission in SECY-09-0035, "Proposed Rule: Requirements for Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70 (RIN 3150-AH91)," dated February 26, 2009. In the SRM on SECY-09-0035, dated February 3, 2010, the Commission approved publication of a proposed rule on Requirements for Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70. However, the Commission also disapproved certain aspects of the draft rule presented in SECY-09-0035; namely, revisions to the existing safety criteria in Part 32. The proposed rule was revised by the staff as directed by the SRM and published in the *Federal Register* on June 24, 2010 (75 FR 36211). The comment period closed September 7, 2010, and 10 comment letters were received. The commenters included States, licensees, industry organizations, and an individual. The comments are discussed in detail in the *Federal Register* notice (FRN) (Enclosure 1).

[1] That proposed rule was published January 4, 2006 (71 FR 275) and the final rule was published October 16, 2007 (72 FR 58473).

DISCUSSION:

The final rule will 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 U.S. Nuclear Regulatory Commission's (NRC's) systematic assessment and regulatory program to ensure the safe use and management of byproduct material. Implementing these amendments to Parts 30, 31, 32, 40, and 70 will ensure that the NRC's regulatory actions are more effective and efficient, while protecting the public health and safety. The following discusses the various amendments included in the final rule on an issue-by-issue basis.

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

The current regulations address the sealed source and device (SS & D) registration process and resulting certificates in a limited way and do not clearly reflect the extent of how the registration process is used in the licensing process. The rule will make the registration requirements more explicit, so that it is easier for potential applicants to determine the applicable requirements and associated fees. It revises 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. The changes are largely consistent with previous licensing practices. The rule also adds certificates of registration to the existing provisions for amendment, modification, and revocation of a license. Also, new provisions are added on review and reissuance of certificates (§ 32.210(h)) and inactivation of certificates (§ 32.211). The inactivation provision was revised in the final rule to address commenter concerns.

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 distributor or (2) all of the same safety information that the distributor would have provided if the source or device had been registered. This is difficult in some circumstances. The final rule restructures § 30.32(g) for clarity and includes the following provisions: 1) § 30.32(g)(2), an extension of the provision for legacy sealed sources and devices containing naturally occurring and accelerator-produced radioactive material (previously in § 30.32(g)(3)) to cover all Part 30 byproduct material, which allows alternative information to be provided to support the safety finding on the product; 2) new § 30.32(g)(3) to provide that only limited information will be required for certain smaller calibration and reference sources; and 3) § 30.32(g)(4) 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. This last provision was modified slightly from the proposed rule to clarify that this approach may only be used if identifying all sources and devices presents a particular difficulty.

Establish a New Class Exemption for Certain Industrial Products

A new provision, § 30.22, will establish a new class exemption for certain types of industrial products, such as static eliminators. This will allow additional products to be used under exemption from licensing, if the associated risk does not justify imposing the requirements of a license. Licensing requirements for distribution of devices for use under the new exemption are similar to those imposed on specifically licensed distributors of gas and aerosol detectors used under § 30.20. These regulations will 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 provisions, some manufacturers and distributors of generally licensed devices may apply to have their current products approved for use under the new exemption. Only one minor change was made to the provisions in § 32.30 as a result of public comment.

Although the Commission disapproved revising existing safety criteria in this rulemaking and deferred such considerations to be incorporated into the larger effort for aligning the regulatory program with the 2007 Recommendations of the International Commission on Radiological Protection (ICRP-103), the Commission approved the proposed new class exemption. Absent specific direction for revising the draft safety criteria associated with the new exemption, the staff published the proposed rule and has prepared this final rule explicitly allowing for dose assessments provided in applications to utilize a dose-calculation methodology consistent with 10 CFR Part 20 or ICRP's newer methodologies such as ICRP-103. The definition of "committed dose" in the final rule was revised to remove specific reference to an ICRP definition, which would have been subject to change by ICRP.

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

Update Regulations on Certain Static Eliminators and Ion Generating Tubes

The rule will 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, there will be clear requirements in existing regulations for any applicant to distribute such products in the future.

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 will be made less prescriptive, removing specific procedural details, and continue to contain general requirements and provide standards by which performance may be judged rather than specifying details of procedures that must be followed. Interim regulatory guidance will be issued on acceptable approaches to meeting the requirements, which will include sample procedural details. The standards for acceptance sampling are being revised to better control the number of defective units likely to be distributed for use under the exemptions in § 30.15 and some of the general licenses in Part 31.

Risk-Informing the Requirements for Distributors of Exempt Products

Some existing requirements for prototype testing and quality control are unnecessary given the risk associated with particular products. The products for which requirements are being 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 rule establishes requirements regarding exceptions to prototype testing and submission of quality control procedures.

Minor Clarifying or Administrative Revisions

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

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

The staff recommends approval and publication of this rulemaking because it accomplishes 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.

Follow on Proposed Rule to Revise Safety Criteria

The staff recommends that a separate proposed rule be developed based on the draft proposals included in the proposed rule presented to the Commission in SECY-09-0035 concerning revision of existing safety criteria in Part 32. In the SRM on that paper, the Commission disapproved including these changes in the proposed rule and directed the staff to consider them as part of its effort to develop the technical basis for possible revision of NRC's radiation protection regulations to be consistent with ICRP-103.

The development of the technical basis for the possible revision of Part 20 will not be completed for years. The recommended changes to Part 32 should not await the resolution of issues related to Part 20. The existing criteria for the approval of devices under § 31.5 present both safety and security concerns. In the realm of safety, they are inconsistent with the training

requirements in Part 19, as they allow untrained workers to be routinely exposed to up to 5 mSv (500 mrem)/year. In addition, the safety criteria are dose standards and do not include a limit on the quantity of byproduct material in a device, allowing for risk significant quantities to be approved if the material in a device is well shielded and contained. Given that persons can obtain such devices without interaction with the regulator, this is of concern for security. Applying a quantity limit on the radionuclides of concern to the criteria for approval of new devices would reduce future issues with relatively large quantities of these radionuclides being available without an individual licensing action.

Similarly, the safety criteria for gas and aerosol detectors do not adequately control the maximum quantities of byproduct material that could be approved for use under the exemption in § 30.20. However, the staff found that products currently authorized for distribution to exempt persons would meet the envisioned revised criteria. Changing the safety criteria for the existing class exemptions will avoid the possibility that additional products developed and approved under the existing criteria may need to be reevaluated.

Such a proposed rule could be developed with limited resources as the draft rule text and basis have been previously developed. The staff anticipates that the rule text would be similar to that in the proposed rule presented in SECY-09-0035 for §§ 32.23, 32.24, 32.26(c)(3), 32.27, 32.28, and 32.51. It would also include a minor improvement to §§ 32.22(a)(2)(vi) and 32.26(b)(6) by revising one of the distances at which maximum radiation levels are measured as suggested by a commenter.

AGREEMENT STATE ISSUES:

The final rule was prepared using a working group that included a member from an Agreement State. A copy of the draft final rule was provided to the 37 Agreement States and the one State that has submitted a letter of intent so that they could have an early opportunity for review. Enclosure 1 discusses highlights of these comments.

The NRC staff has analyzed the final 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 final rule will be a matter of compatibility between the NRC and the Agreement States, thereby providing compatible Agreement State and NRC requirements.

Revisions to Subpart A of Part 32 (§§ 32.11 through 32.32) are classified as Compatibility Category “NRC.” 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, except that new paragraph (h) will be Compatibility Category C for States that perform SS & D evaluations. New § 32.211 will be Compatibility Category B for States that perform SS & D evaluations. 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 new definitions for “Committed dose” and “Sealed Source and Device Registry” in § 32.2 are classified as Compatibility Category D. Existing compatibility designations for these regulations will not be affected.

The Standing Committee on Compatibility reviewed the proposed rule; there was one point of disagreement at that time as noted in SECY-09-0035. There was one definition added to the proposed rule as a result of changes made in response to the SRM. When the Committee reviewed the draft final rule, they recommended two changes of categories from the proposed rule, which the staff adopted.

COMMITMENTS:

The staff has prepared interim draft guidance (ML112150558) for use with this rule, which will be published for public comment after Commission action on this final rule.

RECOMMENDATIONS:

That the Commission:

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

2. To satisfy the requirement of the Regulatory Flexibility Act, 5 U.S.C. 605 (b), certify that this rule, if promulgated, will not have significant impact on a substantial number of small entities. This certification is included in the enclosed *Federal Register* notice.

3. Approve the staff's recommendation that an additional proposed rule be drafted to revise the safety criteria in Part 32.

4. Note that:

   a. 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);

   b. A final Regulatory Analysis has been prepared for this rulemaking (Enclosure 2);

   c. A final Environmental Assessment has been prepared for this rulemaking (Enclosure 3);

   d. The staff has determined that this action is not a "major rule," as defined in the Congressional Review Act of 1996 [5 U.S.C 804(2)] and has confirmed this determination with the Office of Management and Budget (OMB). The appropriate Congressional and Government Accountability Office contacts will be informed;

   e. Appropriate Congressional committees will be informed of this action;

   f. A press release will be issued by the Office of Public Affairs when the final rulemaking is filed with the Office of the Federal Register;

g. This final rule contains amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.) that must be submitted to the OMB for its review and approval before publication of the final rule in the *Federal Register*.

RESOURCES:

To complete and implement this final rule, no more than 0.1 full-time equivalent (FTE) position will be required. These resources are within existing budget allocations. If the Commission also approves the recommended development of a proposed rule, that action is projected to require approximately 0.4 FTE. Papers involving resources of less than 1 FTE do not require concurrence from the Office of the Chief Financial Officer.

COORDINATION:

The Office of the General Counsel has no legal objection to the final rulemaking.

/RA by Michael F. Weber for/

R. W. Borchardt
Executive Director
for Operations

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

Discussion of State Comments on Draft Final Rule

The Organization of Agreement States (OAS), Virginia, and Washington submitted comments. OAS' and Virginia's comments were the same and involved mostly suggested editorial revisions for rule text with the intent of achieving consistency with other regulations. For various reasons, most of these changes were not made. For example, the suggestion of using English units first (with International System of Units (SI)) following in parentheses) in new dose standards would be contrary to the Commission's policy on use of the SI units. Also, these comments suggested being more uniform in using the terminology, "equivalent regulations of an Agreement State." However, this terminology is generally used when there is a requirement for or an expectation of equivalency based on compatibility requirements. The rule retains the use of "comparable" in place of "equivalent" when referring to Agreement State regulations, in some instances where there are limited or no compatibility requirements for the subject regulations and equivalency is not important to the applicability of the particular regulation.

One comment from OAS and Virginia dealt with the annual transfer reporting requirements for luminous aircraft safety devices (§ 32.56), which is being revised to require transfer reports to Agreement States and clarify that a report must be provided even when there are no transfers into NRC jurisdiction, i.e., a "null report." The draft rule would also require a null report to an Agreement State if they request it. The comment was that the States should not have to make such a request. However, the null report serves the purpose of verifying to the agency issuing the license that the licensee has not failed to comply with reporting requirements, eliminating any need to follow-up with the licensee concerning the possible noncompliance. It is not necessary for all jurisdictions to receive such a report, just the agency that issued the license, nor is it justified for the licensee to have to generate numerous such reports every year, particularly for this device for which tracking beyond the initial report is not required. Consequently, no change was made by the staff.

Washington's comments were very supportive of the rule with support specifically stated for 1) issuing guidance concurrent with the final rule, 2) prompt reporting and making inactive SS & D certificates for products no longer being initially distributed, 3) the concept of grandfathering, 4) not issuing SS & D certificates with expiration dates, and 5) exemptions for sources without a significant health and safety, environmental, or security hazard. With regard to item 4, Washington believes that licensees should be required to confirm that SS & D certificates are accurate and current at the time of license renewal. No change was made to the draft rule in this regard; however, under the existing requirement in § 32.210(f), the certificate holder has an ongoing responsibility to manufacture and distribute in accordance with the certificate and statements made in obtaining the certificate. Each State has flexibility as to the degree to which it will verify that this is being complied with on an ongoing basis and at the time of license renewal.

With regard to item 5, Washington was concerned about the NRC ensuring that landfill disposal impacts are limited and suggested that EPA's Toxicity Characteristic Leaching Procedure (TCLP) be part of the exemption process. TCLP is a test for certain toxic chemicals in waste and the extent to which they might leach out in a landfill. Requiring such a test on a product would be beyond NRC's jurisdiction. To the extent that there is a concern about byproduct material leaching out in landfills, there are existing provisions in NRC regulations and in these draft regulations that address containment under conditions of use and in the case of class exemptions, criteria for exposures from uncontrolled disposal. Because of the uncertainties involved, assessments for potential exposures from disposal of products authorized for use under exemption are conservative and do not assume that the byproduct material is retained in

the products after disposal. The staff believes that the potential impacts of uncontrolled disposal of products used under exemptions have been and are being adequately addressed in our regulatory program, including the provisions in this rule.

With regard to licensing flexibility for unspecified models of sources and devices, Washington supports this concept *only* for manufacturers and distributors and service provider licensees, and provided that licensee staff are trained and experienced with the product type, and are trained how to recognize and get help for emergency or unfamiliar situations. In response to this comment, the staff notes that the regulation does not provide such a specific limitation, but limits it to when it is not feasible to identify each source and device individually. The statement of considerations and NRC's draft interim guidance include limited additional circumstances acceptable to the NRC staff; however, the Agreement States will be free to determine what is reasonable and acceptable to them in licensing within their jurisdiction.

A significant comment made by Washington that is outside of rulemaking was a suggestion for the NRC to establish a database of information on "problem products." Specifically, Washington stated that "licensees, jurisdictions, emergency responders, and Homeland Security agencies, may need prompt access to a single 'problem products' reference list of radioactive material products that have suffered failures or leaks." This would include details of the radiation hazard (such as failures or leaks) and brief emergency response and radiation hazard abatement directions for use during an incident. While SS & D certificates may be updated to include such warnings, Washington believes it is impractical for the SS & D Registry to serve as a database of information for that purpose and the staff agrees. The Nuclear Material Events Database (NMED) does have information about reportable issues with sources and devices and the various required reports would also form the primary basis of any such new database. However, NMED and the SS & D Registry are not available to some of the entities referred to by Washington, including licensees. Recommendations about the appropriate response and hazards abatement for a particular source or device are best provided by manufacturers and such information is at least in part included in operating manuals and similar documents that are required to be provided to licensees by manufacturers and distributors.

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

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

RIN 3150-AH91

[NRC-2008-0338]

Requirements for Distribution of Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

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

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

ADDRESSES: 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, O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- **NRC's Agencywide Documents Access and Management System (ADAMS):** Publicly available documents created or received at the NRC are available online in the NRC Library 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 the 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*.
- **Federal Rulemaking Web Site:** Public comments and supporting materials related to this final rule can be found at *http://www.regulations.gov* by searching on Docket ID NRC-2008-0338. Address questions about NRC dockets to Carol Gallagher, telephone: 301-492-3668; e-mail: *Carol.Gallagher@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." (Section 81(a) of the Act, 42 U.S.C. 2111.) As beneficial uses of radioactive material were developed and experience grew, new products intended for use by the general public were invented and the regulations were amended to accommodate the use of new products.

Although presenting very low risks of significant individual doses to members of the general public, exempt products are a source of routine exposure to the public. A substantial portion of the population uses and enjoys benefits from exempt products, such as smoke detectors, but also receives some radiation exposure from those products. In keeping with its consumer product policy, which calls for the Commission to evaluate the total effect of consumer products on the public, the Commission conducted a systematic reevaluation of the exemptions from licensing. A major part of the effort was an assessment of the potential and likely doses to workers and the public under these exemptions. Dose assessments for most of these exemptions can be found in NUREG-1717[1], "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," June 2001. Actual exposures of the public likely to occur are in line with Commission policy concerning acceptable doses from products

[1] NUREG-1717 is a historical document developed using the models and methodology available in the 1990s. The NUREG provides the estimate of the radiological impacts of the various exemptions from licensing based on what was known about distribution of material under the exemptions in the early 1990s. NUREG-1717 was used as the initial basis for evaluating the regulations for exemptions from licensing requirements and determining whether those regulations adequately ensured that the health and safety of the public were protected consistent with NRC policies related to radiation protection. The agency will not use the results presented in NUREG-1717 as a sole basis for any regulatory decisions or future rulemaking without additional analysis. Copies of NUREGs may be purchased from the Superintendent of Documents, U. S. Government Printing Office, P.O. Box 37082, Washington, DC 20013-7082. Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. A copy is also available for inspection and/or copying for a fee at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Public File Area O1-F21, Rockville, MD.

and materials used under exemptions. For some exemptions, there was a significant difference between potential and likely doses because the use of the exemption is limited or nonexistent, or significantly lower quantities are used in products than is potentially allowed under the exemption.

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

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

B. Regulatory Framework.

The Commission's regulations in Part 30 of Title 10 of the *Code of Federal Regulations* (10 CFR) contain the basic requirements for licensing of byproduct material. Part 30 includes a number of provisions that exempt the end user from licensing requirements, so-called

"exemptions." Some exemptions are product-specific, intended only for specific purposes which are narrowly defined by regulation. More broadly defined are the general materials exemptions, which allow the use of many radionuclides in many chemical and physical forms subject to limits on activity, and which are specified in §§ 30.14 and 30.18 for exempt concentrations and exempt quantities, respectively. The Commission's regulations currently also include two "class exemptions" – for self-luminous products and gas and aerosol detectors, in §§ 30.19 and 30.20, respectively – which cover a broad class of products not limited to certain quantities or radionuclides. In the case of class exemptions, many products can be approved for use through the licensing process if the applicant for a distribution license demonstrates that the specific product is within the class and meets certain radiation dose criteria.

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

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

II. Discussion.

This final rule is making a number of revisions to the regulations governing the use of byproduct material under exemptions from licensing and under general license, and to the

requirements for those who distribute products and materials. The changes are intended to improve the efficiency and effectiveness of certain licensing actions.

A. Actions Related to Sealed Source and Device Registration.

A.1 Updating Regulations to Add Registration Requirements

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

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

This registration process has also been extended to many generally licensed and some exempt products. The regulations in Part 32 contain requirements for submittal of radiation safety information concerning these products by the manufacturer or initial distributor. Although registration of these products by the manufacturer or initial distributor was not previously addressed by the regulations, the NRC's licensing practice has been to issue registration certificates for certain of these products based on the radiation safety information submitted.

Also, fees are assessed based on whether or not a “sealed source and/or device review” is required.

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

The only products used under exemption from licensing for which the NRC issues registration certificates are those distributed for use under a “class exemption.” As noted earlier, a class exemption allows for the use under exemption of a category of products with the safety decision for individual products made through the licensing process. The safety review for these products includes evaluating the product against specific safety criteria contained in the regulations in Part 32. The regulations currently contain two class exemptions. These are found in § 30.19, Self-luminous products containing tritium, krypton-85, or promethium-147, and § 30.20, Gas and aerosol detectors containing byproduct material, and equivalent Agreement State regulations. As discussed later in this document, this rule establishes a third class exemption for certain industrial products.

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

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

For those products used under a product-specific exemption, for which registration certificates are not issued, the safety of the product has been evaluated based primarily on the constraints contained in the regulations, such as a quantity limit for a specific radionuclide, and what can be projected about the life cycle of the product and how it is used. Some of these evaluations are documented in NUREG/CR-1775, “Environmental Assessment of Consumer Products Containing Radioactive Material,” October 1980 (ADAMS Accession

No. ML082910862), and NUREG-1717. The applicable requirements in § 32.14(b) require information to be submitted to allow an evaluation of the potential radiation exposure and, in accordance with § 32.14(d), the NRC makes a determination that the byproduct material is "properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling." But the information to support this evaluation of the particular product is not considered necessary to routinely provide to the Agreement States through the SS & D Registry.

No sealed source and device review is conducted for the products used under the general licenses in §§ 31.8 or 31.11. The general license in § 31.8 is specifically for no more than 0.185 MBq (5 μCi)[2] 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

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

the SS & D Registry. These products are mostly antiquities produced before States had regulations similar to NRC's.

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

For specifically licensed calibration and reference sources, the quantity cutoffs being established for small sources excluded from the requirement for registration are 0.37 MBq (10 μCi) for alpha emitters and 37 MBq (1 mCi) for beta and/or gamma emitters. This is a simplification from previous licensing practice, which used a limit of 3.7 MBq (100 μCi) or 10 times the quantity specified in § 30.71, whichever is greater, for beta and/or gamma emitters. The limits using that guidance for beta/gamma emitters range from 3.7 MBq (100 μCi) to 370 MBq (10 mCi). Thus, for any particular radionuclide, the new criterion is no more than 10 times higher to 10 times lower than previous practice. As certificates typically cover a large number of radionuclides for this type of sealed source, this change is not expected to affect the overall number of registration certificates issued.

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

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

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

Unlike specific licenses, registration certificates are not issued with expiration dates. If a significant safety issue arises with a product, regulatory means are available to address it, such as an order issued to a distributor to cease distribution until the safety issue is resolved. The Commission has had authority to request additional information or to modify requirements under

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

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

The Commission does not believe that it is necessary to conduct a complete reevaluation of sealed sources and devices at the time that distribution licenses are renewed, usually every 10 years, since generally, there are fewer safety significant aspects that are likely to change reflected in the registration certificate than those addressed in the license. The Commission does recognize a need to update registration certificates and relies, for the most part, on certificate holders to request amendments of certificates, as appropriate. One factor is that the NRC is required to consider the application of industry standards, for example, as reflected in § 32.210(d). These industry standards may be revised to provide improved safety. Also, licensees are required by § 20.1101 to implement radiation protection programs and to use, to the extent practical, procedures and engineering controls based upon sound radiation

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

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

Generally, the Commission has not made standards more restrictive with regard to products to be used under a general license or under an exemption from licensing, so as to

restrict further distribution of a previously approved product. However, such a decision in the future may necessitate a reevaluation of a registration certificate.

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

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

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

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

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

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

This latter provision is not intended as a broadly applied change in the approach to licensing the use of sealed sources and devices. This change is intended to accommodate certain expected situations in which having to identify each sealed source or device presents an undue burden. For example, military applicants are sometimes unable to identify exactly which

product they may be procuring. This provision could also be used by the types of applicants/licensees identified in § 32.210(g)(2), namely those licensed for research and development (R & D), those licensed under Part 33, and certain custom users who have adequate training and experience and facilities and equipment to handle comparable quantities of material in other forms. It may also be reasonable to use such an approach to provide some flexibility in the case of calibration and reference sources. The words, "If it is not feasible to identify each sealed source and device individually," have been included in the final rule text to clarify the limited applicability of this provision.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

the new class exemption include 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 radiological risk is well controlled by these designs, possible scenarios of misuse or malicious use are not required to be evaluated.

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

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

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

In 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 § 32.30(c)(4)) to further ensure that the quantities of these radionuclides in exempt products are not such that they will be a practical source of obtaining radioactive materials in quantities sufficient to cause significant harm.

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

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

The class exemption in § 30.20 is for gas and aerosol detectors "designed to protect life or property from fires and airborne hazards." At the time that this exemption was added to the regulations, the applications of these types of devices under consideration were smoke detectors and devices to detect chemicals that would constitute an airborne hazard if inhaled. The words "designed to protect life or property from fires and airborne hazards" were included to ensure that the products provided a clear societal benefit. Products similar to those allowed, but not quite fitting the "class," cannot be approved for use under this exemption. For example,

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

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

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

This inconsistency resulted from the fact that the use of the static eliminators covered by this general license predated the regulations in Parts 19, 20, 21, 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 caused some confusion in the licensing process. The Commission is changing this general license into an exemption from licensing in § 30.15(a)(2). The current licensed distributor will not be required to amend its license in order to continue distribution, but any future distributors will come under the distributor provisions associated with §§ 30.15; i.e., §§ 32.14, 32.15, and 32.16. This change is intended to have no effect on any current distributor or user of these products, only to remove an inconsistency in the regulations and to make any future licensing decisions in this regard more efficient and effective.

With respect to the issue of requirements for sealed source and device review, this change removes the need for a registration certificate if these products are distributed under the authority of a license issued under § 32.14. The licensing practice of using the sealed source and device review and registration process for products to be used under the general license in

§ 31.3 primarily resulted from the lack of specific requirements for a distribution license in the regulations. Thus, § 32.210 provided the types of information to be provided concerning the product for NRC review.

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

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

This rule is intended to focus the regulations on performance, rather than procedures. The regulations retain general requirements and provide general standards by which performance may be judged, rather than specifying detailed procedures that must be followed, except for products for which oversight of these activities would no longer be required as discussed under Section II. F., “Make the Requirements for Distributors of Exempt Products More Risk-Informed.” The NUREG-1556 series of documents provides guidance to licensees and applicants on acceptable approaches to meeting these requirements.

The procedures being removed from the regulations are generally acceptable to meet the new performance-based requirements. Safety benefits of the changes being made in this

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

Prototype Test Procedures

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

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

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

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

Acceptance Sampling and Quality Control Procedures

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

- Paragraphs (a) though (d) of § 32.55, “Same: Quality assurance; prohibition of transfer” (“Same” refers to “Luminous safety devices for use in aircraft”);

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

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

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

The NRC intends to allow acceptance sampling to be performance-based, rather than specifying procedural details. Section 32.110 provided that a random sample shall be taken from each inspection lot of specified devices for which testing is required in accordance with the appropriate sampling table in that section. If the number of defectives in the sample does not exceed the acceptance number in the appropriate sampling table, the lot was not to be accepted, while if the number of defectives exceeds the acceptance number, the entire inspection lot was to be rejected. There is no longer a need for the NRC to maintain the acceptance sampling tables that were in § 32.110, which provided the number of acceptable defective units in various lot sizes for a variety of Lot Tolerance Percent Defective values. Note: *Lot Tolerance Percent Defective* is defined in § 32.2 as the poorest quality in an individual inspection lot that should be accepted. The table in § 32.110(b)(6), Lot Tolerance Percent Defective 5.0 percent, correlated with the standard in the above cited regulations. However, the other seven tables in § 32.110 apparently had been little used since their publication in 1974, as there were no specific standards in Part 32 requiring Lot Tolerance Percent Defectives other

than 5 percent. Licensees can now easily use widely available computer software to determine their own acceptance sampling procedures to best monitor their manufacturing processes. This final rule removes § 32.110. Acceptance sampling criteria continue to be specified in §§ 32.15, 32.55, and 32.62, specifying the values required for quality (Lot Tolerance Percent Defective) and confidence. Section 32.59 requires leak testing of each source for calibration or reference sources containing americium-241 or radium-226 generally licensed under § 31.8, rather than sampling of lots. This final rule does not change that provision other than providing minor clarifications.

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

Most of NRC's statistical acceptance criteria today - such as in inspections – are, at least, 95 percent acceptance with 95 percent confidence. Raising the required confidence level from 90 percent to 95 percent may be an increase in burden, but is justified, because the 90 percent standard was inconsistent with other agency practices, as well as industry

standards. However, it is expected that because of the nature of the products covered by these regulations, the lot sizes apt to be used, and other factors, the revision is unlikely to change the approaches used by the limited number of current licensees under these provisions.

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

The sampling plan will normally be detailed in the license, which will ensure that the quality assurance program is systematic and planned where justified, such as for lot sizes,

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

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

The proper treatment and definition of lots is essential from a statistical perspective, and relevant to acceptance sampling procedures. For the purposes of acceptance sampling, a “lot” should consist of homogeneous products manufactured from the same or similar machines, interchangeable in terms of their intended use or function. Similarly, from a statistical perspective, a sampling plan must demonstrate certain characteristics to sufficiently guarantee quality:

- Manufacturer compliance with predetermined lot sizes, sample sizes, sampling methodology, and acceptance criteria.
- Agreement with a one-time decision to accept or reject a lot in its entirety.

- Separate, predetermined treatment of sub-lots.
- The calculation and reporting of separate measures for quality and for confidence.

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

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

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

Current licensees will need to make any necessary upgrades to their QC programs when this rule becomes effective. However, because license conditions are written broadly, it is not expected that any such changes in the QC programs will be inconsistent with an existing license

(or registration certificate). Any changes needed in the license to better ensure consistency with the revised requirements will likely be made at the time of the next license renewal or related amendment of the license.

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

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

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

Although many products distributed under the class exemptions would likely meet such a low-risk standard, the Commission does not believe it prudent to eliminate any of these requirements for the class exemptions. The safety criteria for each class exemption are intended to ensure that the risks associated with any product approved for use under the associated exemption are quite low. Nonetheless, because of the nature of a class exemption to allow for new products to be approved, it is not possible to conclude that elimination of oversight of prototype testing or quality control procedures for an entire class of products is

prudent. The evaluation of the safety of the individual product may depend on knowledge of such procedures.

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

Even without the NRC's continuing oversight of these procedures, licensees would be motivated to retain them as good business practices. There are a number of factors that will likely cause manufacturers and distributors to continue to conduct prototype testing and at least some form of quality control/assurance. In some cases, functionality testing closely aligns with testing for containment of radioactive material. The consideration of risk for these products, however, did not rely on this expectation, beyond some reasonable bounding assumptions about the likelihood and consequences of distributing defective products. For example, failures that result in functional failure may happen more frequently, but it is not reasonable to assume that manufacturers would continue to distribute a large percentage of defective devices over long periods.

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

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

Based on the assessment of the inherent safety of these products, it is estimated that even if a lack of appropriate prototype testing resulted in lower quality product designs in the future or poor quality control resulted in degradation of production quality, the potential

increases in individual doses would be less than 10 μSv (1 mrem)/year in any situation where significant numbers of products could be affected. Also, in the extreme case of a significant change in future distributor behavior, some individual doses could be increased by somewhat higher amounts in non-routine situations. Overall, considering both potential increases in doses and the probability of circumstances resulting in those increases, the potential incremental risk is estimated to be insignificant.

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

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

G. Minor Clarifying or Administrative Revisions.

Other minor revisions are being made to better organize, clarify, or update the regulations in these parts, such as the renaming of Subparts C and D and the movement of §§ 32.72 and 32.74 from Subpart B to Subpart C. These two sections are being moved because they do not cover generally licensed items. Minor conforming amendments are included in Parts 40 and 70 because the delineation of the delegation of licensing programs to

the Regions is written broadly in these parts. Such revisions are noted in Section IV., "Summary of Final Amendments by Section."

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

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

A. Actions Related to Sealed Source and Device Registration.

A.1 Updating Regulations to Add Registration Requirements

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

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

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

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

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

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

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

Comment: Commenters on this subject were manufacturers and distributors and representatives of the industry. These commenters recommended that a re-evaluation of registration certificates be conducted: 1) upon request by the manufacturer or initial distributor due to changes [that would affect regulatory compliance]; 2) to ensure compliance with

regulations; 3) based on indications of radiological safety concerns or when new regulations implement more restrictive dose constraints; or 4) when the regulations that apply to those sealed sources or devices change to an extent that compliance with the regulation could require modification of the conditions of the registration. One commenter supported the recommendation that no reevaluation was needed except to ensure compliance with the regulations or if there are reports of defects that would affect regulatory compliance, by indicating that the fundamentals of radiation protection or technology are not likely to undergo any change significant enough to create a compelling need for reevaluation of a device certificate.

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

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

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

Comment: One commenter agreed that it is not necessary to conduct a complete reevaluation of sealed sources and devices at the time that distribution licenses are reviewed,

but also stated that the NRC should change NUREG-1556 guidance to explicitly require a review of certificates at the time of license renewal to ensure that the information is complete, accurate, and that the source or device remains current considering the application of the current industry standards.

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

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

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

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

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

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

Response: The NRC disagrees that § 32.210(h) is duplicative of the general authority provided under § 30.61. The intent of this rule concerning sealed source and device registration certificates is to make the regulations more explicit as to how the registration process is used in the licensing process. The details of this process should be specified in Part 32. It would not be appropriate to designate §§ 30.34(e) and 30.61 Compatibility Category B for Agreement States, which is the program element assigned when there are significant direct transboundary implications, in order to address the transboundary implications associated with source or device registrations. These provisions cover a broad range of licenses for which there are no transboundary implications. The importance of national consistency for sealed source and device registrations is more appropriately handled in the categorization of the appropriate Part 32 provisions, such as §§ 32.210 and 32.211. However, the Commission has decided that the transboundary implications of § 32.210(h) are not significant enough to require identical

treatment by each jurisdiction, so this one paragraph within § 32.210 has been assigned Compatibility Category C (for Agreement States who perform SS & D evaluations); thus, those States would adopt the essential objectives of § 32.210(h), rather than essentially the same language.

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

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

The following comments respond to this question posed:

Q 1. (b) How might registration certificates best be updated so as not to discourage improvement in the design of sources or devices, more readily allow for the application of updated industry standards, and ensure that information in the certificates is fully consistent with current practices? (For example, in addition to the proposed provision in § 32.210(h), other options could include reviewing certificates at the time of license renewal, in part or in whole;

adding separate expiration dates to certificates with typically longer terms than licenses, e.g., 10 to 20 years; and explicitly allowing licensees to make changes without NRC approval, if these changes do not reduce safety margins.)

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

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

If the NRC were to institute a policy of adding expiration dates to registration certificates, the expiration date would be specific to the certificate and the sources or devices covered by the certificate based on the issuance date as suggested by the commenter. Although the Commission agrees there is value in using an expiration/renewal process for registration certificates, instituting such a system nationally would be a significant change from the process in place for some time and would put additional burdens on the Agreement States that issue

certificates at a time when resources are limited. There are other means to deal with changes that should be made to certificates, such as the use of the new provision in § 32.210(h).

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

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

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

Response: The NRC staff did consider recommending such a provision in Part 30 in particular when conducting the systematic assessment of exemptions. However, because of the difficulties expected developing such a provision for the broad range of products and

facilities involved in the use of byproduct material, the staff did not recommend such a provision for Parts 30 and/or 32. The approach suggested by the commenter included the need for complex analyses by the distributor concerning safety that would not be reported to the NRC for up to 24 months. The NRC believes that this may lead to compromises in safety. Also, at one time, fees charged for amendment of licenses and registration certificates were a deterrent to licensees proposing changes; however, changes were made to the fee structure, so that this is no longer the case.

The following comments respond to this question posed:

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

Comment: A few commenters recommended that previously approved devices be grandfathered when standards are changed, one recommending this for devices in use, others for future distributions under existing active certificates as well. One of those supporting allowing continued distribution of previously approved devices recommended that the grandfathering of previously approved devices should be a Compatibility Category B for Agreement States. Generally, these commenters did not believe it justified to change the status of previously approved devices unless there was a significant impact on health, safety, security, or the environment. One of these commenters stated that such actions should only be taken if well justified in terms of benefit versus cost and that revised standards should only apply to devices distributed after a certain date. Related to the referenced proposed rule, which would

have added an activity limit to the general license in § 31.5, two of the commenters indicated that the registration certificates would have to be revised to address distribution to both general and specific licensees. One commenter stated that it disagrees with the content of the proposed rule on limiting the amount of byproduct material in generally licensed devices.

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

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

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

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

Comment: One commenter proposed that an independent screening review be performed to identify the set of devices likely to result in occupational dose in excess of 500 mrem TEDE and a public dose of 50 mrem in 1 year, and then establish notification or

review criteria for the certificate holders accordingly. This commenter suggested that the NRC notify each certificate holder with devices exceeding the dose criteria and request a factual accuracy review, comments regarding the calculations, and the cost to recall and make changes to ensure compliance with the dose values. This recommendation went on to suggest that, if occupational doses could exceed 500 mrem/year, the distributor should be required to notify users that they should comply with Part 20 (or the Agreement State regulations), and that if public doses could exceed 50 mrem, but not 100 mrem, the NRC should require an ALARA review similar to that required by 10 CFR 20.1101(d).

Response: This proposal did not suggest revising the regulations. However, in looking at a possible screening process, it should be noted that acceptable potential doses that workers and the general public may receive from a device depends on whether it is to be used under an exemption from licensing, a general license, or a specific license. Devices to be used under certain exemptions and the general license in § 31.5 are evaluated against specific safety criteria in Part 32. There are no specific criteria for devices used under specific license; the safety of workers and the public being primarily protected by Part 20, which applies to all specific licensees. Applying such a process as suggested by the commenter across the board would be inappropriate. In particular, the recommended criteria would be inappropriate for evaluating products used under exemptions from licensing. Also, in the absence of an indication of a problem or adverse operational experience, the NRC does not believe it necessary to conduct a screening for all previously approved devices.

The Inactivation Provision in § 32.211

The only issue that received a significant number of objections was the proposed inactivation requirement. However, much of this reaction resulted from apparent misinterpretation of the intent of the provision and because of unforeseen impacts that could

result if devices are transferred only occasionally with two years passing without a transfer of a device for which some continued distribution is anticipated.

Comment: A few commenters indicated that it was not uncommon for 2 years to pass between transfers of particular devices and that the requirement to inactivate in this instance would be burdensome to business. Comments were that compliance with this proposed rule would not be practical, that licensees may not know in advance when their last manufacture or transfer of a sealed source or device will take place, and that the certificate holders should decide when to inactivate certificates based on their business needs and intentions. Commenters specifically suggested that one may anticipate new applications for a product, development of new markets, etc., and that it might force inactivation of a certificate for a device which may be required again in another few months. Two commenters noted that the costs of maintaining the certificate, including the fees, provide incentive to inactivate a certificate when there are no prospects of future sales; one of these commenters recognized the rationale for desiring registrations to be inactivated if there is no intent to manufacture and/or distribute within a reasonable period. One commenter stated that the existing certificates already must be renewed periodically. This commenter suggested a 5-year time limit to apply for inactivation.

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

provision and then need to apply for an active certificate again in the case of product with a limited market.

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

The text in this final rule has therefore been revised to clarify that no action need be taken after 2 years without a transfer until it is determined that there will be no future transfers. However, within 90 days of such a determination, inactivation must be requested and some brief explanation must be provided if more than 2 years has elapsed since distribution of any source or device covered by the certificate has ceased.

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

In addition, the situation of not transferring any source or device for more than 2 years with the intent to continue sales is expected to be relatively rare, particularly because individual

certificates frequently include numerous models that have been approved for distribution. While distributors should update certificates to indicate which models are no longer being sold, the NRC did not make doing so a requirement or set a deadline for this type of amendment of certificates. The text of § 32.211 has also been revised to clarify that inactivation is necessary when all sources or devices covered by a certificate are no longer being distributed and to clarify that certificates must be inactivated before the associated distribution license is terminated. The specific address for submitting inactivation requests is also added.

Comment: Some commenters expressed concern that the proposed language of § 32.211 did not appear to allow redistributions or other transfers of sources or devices after inactivation of a certificate. Two commenters specifically suggested that the proposed wording of the fourth sentence in proposed § 32.211 should be changed to include the word “initially” so that it reads: "A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to *initially* transfer such sources or devices for use." Another commenter was also concerned about redistribution, stating that it should be authorized even if the certificate is inactive. This commenter believed that an inactive certificate does not allow for the transfer or redistribution of registered sources or devices by specific licensees and noted that a source or device no longer being initially distributed is nonetheless safe for use by persons authorized to use the source in accordance with the conditions of the registration certificate.

Response: The intent of proposed § 32.211 in this regard is that only the unique authority provided to the distributor by the registration certificate (along with the associated license) to initially transfer a source or device ceases, without any effect on any other transfers of the covered source(s) or device(s). The suggested addition of the word, “initially,” has been made for clarification. The inactivation of a certificate does not limit the use or transfer of previously manufactured sources and devices. The Commission agrees that a source or device

that is no longer being distributed is nonetheless safe for use by persons authorized to use it in accordance with the conditions of the certificate. The only concern after the inactivation of a certificate is that proper servicing continues to be available. The inactivation provision clarifies that a device shall be serviced as provided in the certificate and the inactivation process alerts the regulator that servicing may not be available from the original distributor.

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

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

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

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

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

Response: The text of the final rule has been revised to clarify that this approach may be used if it is not feasible to identify each sealed source and device individually. Examples of situations where use of this approach is acceptable were discussed in the proposed rule as well as in the discussion of this issue in Section II. A.3., "Adding Flexibility for Licensing Users of Sealed Sources and Devices." Such examples and additional guidance are being provided in

the interim guidance developed for this rulemaking, which is being made available for comment concurrent with the publication of this final rule, and ultimately in the revisions to applicable volumes of NUREG-1556. However, one situation that is not considered appropriate for this approach is in applying for the renewal of a license that had been previously issued without identification of individual sources and devices where it is simply inconvenient to provide an inventory of currently held sources and devices.

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

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

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

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

Only about half of the commenters made any statements about the proposed new class exemption. The comments received were mostly supportive, although some concerns were noted. Support for the proposed exemption came primarily from a major manufacturer and from the OAS. The manufacturer indicated that research and development of new devices is expensive and time-consuming, that the uncertainty in the regulatory outcome and the lengthy rulemaking process to obtain a product-specific exemption made exempt product development risky, and that creating a class exemption for industrial devices with risk-informed, performance-based criteria would reduce uncertainty, speed approvals, and lower barriers to innovation, and would provide a nationwide standard. This manufacturer also pointed out the difficulties of general licensing for low-risk devices with inconsistencies in Agreement State licensing of portable devices even though the SS & D Registry authorizes distribution to general licensees. This commenter noted the complications of marketing and distribution of such products on a nationwide basis as well as those for users who may be authorized to use a device under a general license in State A, but if they transport the device to State B, a specific license is required. Both this manufacturer and the OAS suggested that manufacturers would be more inclined to develop products using lower quantities of radioactive materials in order to meet the criteria for exemption, with one commenter suggesting that this would result in a reduction in some hazards to workers, members of the public, and the environment.

Comment: One manufacturer/distributor expressed concern that the health and safety of the public or the environment might not be adequately protected, noting the possibility that the increased number of devices allowed to be disposed of in landfills and scrap metal reprocessing streams would potentially increase the number of alarms at landfills, scrap metal facilities, and

metal recycling facilities and ultimately create a burden on State regulatory authorities as a result. However, this commenter also said that the number of devices exempted by this provision would be very small and that this could be handled on an individual source or device basis and that the exception could be included in the NUREG-1556 guidance.

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

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

This new exemption has been designed to ensure that quantities of byproduct materials approved for use in products are well controlled. This includes the misuse scenario in § 32.31(b), which ensures that relatively high quantities are not approved based on the material being well contained and well shielded. There is also an absolute limit for some radionuclides included in § 32.30(c)(4) related to the quantities in Appendix E to 10 CFR Part 20. One of the benefits of such criteria is limiting the possibility that quantities of material in any products approved for use under the new class exemption are sufficient to cause such problems during disposal as raised by the commenter.

In addition, labeling requirements help to minimize the efforts that are ultimately spent toward resolving what to do in these cases. When a product is identified in the waste that

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

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

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

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

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

Another commenter suggested that the 20 mrem/year criterion should be lower, also stating that the discussion of a 10 rem misuse scenario is inconsistent with the 25 mrem/year

value in 10 CFR 20.1402 and the 10 mrem/year constraint imposed by 10 CFR 20.1101(d), since misuse could result in an airborne intake of radioactive material. This commenter suggested that a more consistent argument might be made for a criterion of 10 mrem/year TEDE for all scenarios.

Response: The safety criteria for a class exemption such as the new industrial product exemption are design criteria. Demonstrating that a product meets these criteria depends on projections of future events. There is no monitoring of actual user exposures. As products used under exemption are used without any further regulatory control, the agency cannot ensure that users will not be exposed to a number of different products. They may also be exposed to other sources of radiation. Given the uncertainty in the ultimate exposures and the fact that individuals may be exposed to multiple sources, using the public dose limit of 1 mSv (100 mrem)/year is not adequate or appropriate.

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

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

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

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

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

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

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

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

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

Comment: One commenter specifically supported making such changes to the safety criteria for the two class exemptions established in 1969 provided they are also changed to reflect the Federal Radiation Council (FRC)/ Environmental Protection Agency (EPA) guidance

on use of ICRP-26 in the setting of radiation safety regulations. Another commenter indicated that manufacturers in any industry cannot typically be held responsible for the intentional misuse of any product, but gave examples of safety features that can be incorporated in the products to help prevent improper use.

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

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

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

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

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

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

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

Response: Detectors for maintaining ultra clean nano fabrication facilities would appear to be a type of product with a reasonable benefit to society. The NRC considers it reasonable to allow such a product to be used under exemption, if it is adequately shown to meet the safety criteria in Part 32 for evaluation of such products. As the change in scope of the class of products covered by this exemption is relatively limited, the NRC does not expect to see the development of a large number of new products as a result of this change and most are likely to be products used in moderate numbers.

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

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

Response: If detectors were developed that could be approved for use under this exemption for use in nano technology, they would not be exclusively used for the production of frivolous products, but might also be used for more important applications. Overall some reasonable societal benefit would be expected to balance the limited impact from exempting the

detectors. Similarly, the detection of drugs is generally accepted as presenting an overall benefit to society, but NRC recognizes that there could be situations in which the determination of societal benefit is a matter of judgment. Under the final regulations, the NRC will look to see whether the product provides a benefit in protecting health, safety, or property, and if it does, the NRC will find there is a societal benefit.

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

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

Response: With regard to the suggestion to allow complete exemption of products with activities below IAEA exemption “clearance” levels, this comment is not specifically responsive to the question posed. However, the NRC does not agree that there should be a “complete exemption” such as the commenter suggested. The NRC notes that, related to this issue, the NRC’s regulations in §§ 30.14 and 30.70 exempt materials based on the concentration of the byproduct material contained within it. Although this is not considered a “clearance” provision, distribution licenses are only required by § 32.11 for products and materials into which

byproduct material is introduced by an intentional action. The regulations in §§ 30.18 and 30.71 exempt materials based on the quantity of the byproduct material. In this case, distribution licenses are required in the case of commercial distribution. These are the circumstances for which the NRC considers it appropriate to exercise oversight of the processes to ensure that the materials transferred for use under these general material exemptions in fact meet the constraints of the exemption.

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

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

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

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

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

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

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

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

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

E. Other Issues.

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

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

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

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

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

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

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

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

Response: These concerns were presented in a petition for rulemaking (PRM-31-5), which has been handled separately from this action. [Additional info, such as reference to a notice of disposition of the petition, may be added here based on the status of this action at the time this notice is being sent to the *Federal Register* for publication.]

IV. Summary of Final Amendments by Section.

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

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

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

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

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

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

10 CFR 30.32(g) – Restructured for clarity.

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

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

10 CFR 30.32(g)(4) – Adds a provision to allow for constraints on the number and type of sealed sources and devices to be used and the conditions under which they are to be used rather than requiring complete identification of all sealed sources and devices to be licensed in certain cases.

10 CFR 30.38 - Adds an explicit provision for amendment of registration certificates and removes reference to Form 313.

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

10 CFR 30.61 – Adds registration certificates to provisions for modification and revocation of licenses and updates reference to Parts under which licenses are issued.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 CFR 32.110 - Specific acceptance sampling procedures are removed.

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

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

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

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

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

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

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

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

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

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

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

V. Criminal Penalties.

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

VI. Agreement State Compatibility.

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

NRC program elements (including regulations) are placed into four compatibility categories (See the Compatibility Table in this section). In addition, the NRC program elements can also be identified as having particular health and safety significance or as being reserved

solely to the NRC. Compatibility Category A are those program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Category A program elements in an essentially identical manner to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B are those program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. Compatibility Category C are those program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. An Agreement State should adopt the essential objectives of the Category C program elements. Compatibility Category D are those program elements that do not meet any of the criteria of Category A, B, or C, and, thus, do not need to be adopted by Agreement States for purposes of compatibility.

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

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

Compatibility Table for Final Rule

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

Section/Paragraph	Change	Subject	Compatibility	
			Existing	New
32.32	New	Conditions of licenses issued under § 32.30: Quality control, labeling, and reports of transfer	……..	NRC
32.51(a)(6)	Add	Byproduct material contained in devices for use under § 31.5; requirements for license to manufacture, or initially transfer	……..	B
32.53(b)(5) & (d)(4)	Amend	Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer	B	B
32.53(e) & (f)	Add	Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer	B	B
32.55	Amend	Same: Quality assurance, prohibition of transfer	B	B
32.56	Amend	Same: Material transfer reports	B	B
32.57(d)(2)	Amend	Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer	B	B
32.57(e)	Add	Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer	B	B
32.59	Amend	Same: Leak testing of each source	B	B
32.61(e)(4)	Amend	Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer	B	B
32.61(f) & (g)	Add	Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer	……..	B
32.62(c), (d), & (e)	Amend	Same: Quality assurance; prohibition of transfer	B	B
32.74(a)(4)	Add	Manufacture and distribution of sources or devices containing byproduct material for medical use	……..	B
32.101	Remove	[Existing title - Schedule B--prototype tests for luminous safety devices for use in aircraft]	B	★
32.102	Remove	[Existing title - Schedule C—prototype tests for calibration or reference sources containing americium-241 or radium-226]	B	★
32.103	Remove	[Existing title - Schedule D--prototype tests for ice detection devices containing strontium-90]	B	★
32.110	Remove	[Existing title - Acceptance sampling procedures under certain specific licenses]	B	★
32.210(a), (b), (d), & (e)	Amend	Registration of product information	B ★★	B ★★
32.210(g)	Add	Registration of product information	……..	B ★★
32.210(h)	Add	Registration of product information	……..	C ★★
32.211	New	Inactivation of certificates of registration of sealed sources and devices	……..	B ★★
32.303(b)	Amend	Criminal penalties	D	D
40.5(b)(1)(iv)	Amend	Communications	D	D

Section/Paragraph	Change	Subject	Compatibility	
			Existing	New
70.5(b)(1)(iv)	Amend	Communications	D	D

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

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

VII. Voluntary Consensus Standards.

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC is making the requirements for distributors of byproduct material clearer, less prescriptive, and more risk-informed and up to date. The Commission is also redefining categories of devices to be used under exemptions, adding explicit provisions regarding the sealed source and device registration process, and adding flexibility to the licensing of users of sealed sources and devices. This action does not constitute the establishment of a standard that establishes generally applicable requirements. However, the regulations being amended concerning sealed source and device reviews, in particular § 32.210(d), will continue to indicate that the NRC uses accepted industry standards, if applicable, in its evaluations.

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

The Commission has determined under the National Environmental Policy Act (NEPA) of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, not to prepare an environmental impact statement for this final rule because the Commission has concluded on the basis of an environmental assessment that this final rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment. The following is a summary of the Environmental Assessment: Many of the individual actions being taken are the type of actions described in the categorical exclusions of §§ 51.22(c)(2) and 51.22(c)(3)(i) and (iii). In addition, the rule will remove prescriptive procedural provisions, add a new class exemption and a new product-specific exemption, broaden an existing class exemption, add flexibility to the basis for licensing the use of sealed sources and devices, and remove some requirements for the distributors of low risk exempt products. The Commission has concluded that none of these actions would have significant impacts to the environment or otherwise include any condition requiring consultation under section 102(2)(C) of NEPA.

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

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

IX. Paperwork Reduction Act Statement

This final rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, control numbers 3150-0017; 3150-0001; and 3150-0120.

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

Public Protection Notification.

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

X. Regulatory Analysis.

The Commission has prepared a regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The analysis is available for inspection on http://www.regulations.gov by searching on Docket ID NRC-2008-0338 and in the NRC's PDR, 11555 Rockville Pike, Rockville, MD 20852.

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 will not have a significant economic impact on a substantial number of small entities. A significant number of the licensees affected by this action would meet the definition of "small entities" set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121. However, none of the revisions to the regulatory program will result in a significant economic impact on the affected entities.

XII. Backfit Analysis.

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

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

XIII. Congressional Review Act.

In accordance with the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects

10 CFR Part 30

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

10 CFR Part 31

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

10 CFR Part 32

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

10 CFR Part 40

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

10 CFR Part 70

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

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR Parts 30, 31, 32, 40, and 70.

PART 30 - RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

1. The authority citation for Part 30 continues to read as follows:

Authority: 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); Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 549 (2005).

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 under §§ 32.11 through 32.30 of this chapter to persons exempt from licensing requirements.

* * * * *

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

§ 30.8 Information collection requirements: OMB approval.

* * * * *

(c) * * *

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

* * * * *

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

§ 30.15 Certain items containing byproduct material.

(a) * * *

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

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

(iii) Such devices authorized before **[insert 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.

* * * * *

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

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

* * * * *

(b) Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under paragraph (a) of this section, should apply for a license under § 32.22 of this chapter and for a certificate of registration in accordance with § 32.210 of this chapter.

* * * * *

6. Section 30.20 is revised to read as follows:

§ 30.20 Gas and aerosol detectors containing byproduct material.

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

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

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

§ 30.22 Certain industrial devices.

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

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

registration in accordance with § 32.210 of this chapter.

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

§ 30.32 Application for specific licenses.

* * * * *

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

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

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

(2) For sources or devices manufactured before **[insert 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 application must include:

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

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

experience, and the results of a recent leak test.

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

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

* * * * *

9. Section 30.38 is revised to read as follows:

§ 30.38 Application for amendment of licenses and registration certificates.

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

10. Section 30.39 is revised to read as follows:

§ 30.39 Commission action on applications to renew or amend.

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

11. Section 30.61 is revised to read as follows:

§ 30.61 Modification and revocation of licenses and registration certificates.

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

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

(c) Except in cases of willfulness or those in which the public health, interest, or safety requires otherwise, no license or registration certificate shall be modified, suspended, or revoked unless, before the institution of proceedings therefor, facts or conduct that may warrant such action shall have been called to the attention of the licensee or certificate holder in writing

and the licensee or certificate holder shall have been given an opportunity to demonstrate or achieve compliance with all lawful requirements.

PART 31 - GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

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

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

§ 31.3 [Removed and Reserved]

13. Section 31.3 is removed and reserved.

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

§ 31.23 Criminal penalties.

* * * * *

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

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

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

Authority: 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).

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

§ 32.1 Purpose and scope.

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

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

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

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

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

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

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

* * * * *

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

§ 32.2 Definitions.

* * * * *

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

* * * * *

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

18. In § 32.8, paragraph (b) is revised to read as follows:

§ 32.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 32.11, 32.12, 32.14, 32.15, 32.16, 32.18, 32.19, 32.20, 32.21, 32.21a, 32.22, 32.23, 32.25, 32.26, 32.27, 32.29, 32.30, 32.31, 32.32, 32.51, 32.51a, 32.52, 32.53, 32.54, 32.55, 32.56, 32.57, 32.58, 32.61, 32.62, 32.71, 32.72, 32.74, 32.201, 32.210, and 32.211.

* * * * *

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

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

* * * * *

(b) * * *

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

(5) In the case of ionizing radiation measuring instruments and timepieces containing tritium in the form of paint, quality control procedures to be followed in the fabrication of

production lots of the product and the quality control standards the product will be required to meet;

* * * * *

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

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

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

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

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

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

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

(1) Any part or product tested and found defective under the criteria and procedures specified in the license issued under § 32.14, unless the defective part or product has been

repaired or reworked, retested, and found by an independent inspector to meet the applicable acceptance criteria; or

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

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

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

(c) [Reserved]

* * * * *

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

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

(a) * * *

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

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

* * * * *

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

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

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

* * * * *

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(9) The expected useful life of the device;

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

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

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

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

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

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

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

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

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

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

(4) If a radionuclide to be used in the device is listed in Appendix E to part 20 of this chapter, the quantity of that radionuclide in the device does not exceed 10^{-4} times the value listed there as a Category 2 quantity.

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

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

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

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

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

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

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

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

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

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

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

Each person licensed under § 32.30 shall:

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

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

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

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

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

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

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

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

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

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

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

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

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

(c) Maintain records of all transfers and file a report with the Director of the Office of Federal and State Materials and Environmental Management Programs by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the devices are transferred for use under § 30.22 of this chapter or equivalent regulations of an Agreement State.

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

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

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

(iii) The number of units of each type of device transferred during the reporting period by model number.

(4)(i) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year.

(ii) Licensees who permanently discontinue activities authorized by the license issued under § 32.30 shall file a report for the current calendar year within 30 days after ceasing distribution.

(5) If no transfers of byproduct material have been made under § 32.30 during the reporting period, the report must so indicate.

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

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

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

(a) * * *

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

* * * * *

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

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

* * * * *

(b) * * *

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

* * * * *

(d) * * *

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

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

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

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

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

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

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

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

(iii) Any other evidence of physical damage.

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

28. Section 32.55 is revised to read as follows:

§ 32.55 Same: Quality assurance, prohibition of transfer.

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

(b) Each person licensed under § 32.53 shall:

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

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

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

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

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

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

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

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

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

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

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

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

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

29. Section 32.56 is revised to read as follows:

§ 32.56 Same: Material transfer reports.

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

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

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

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

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

* * * * *

(d) * * *

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

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

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

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

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

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

31. Section 32.59 is revised to read as follows:

§ 32.59 Same: Leak testing of each source.

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

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

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

* * * * *

(e) * * *

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

* * * * *

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

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

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

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

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

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

(iii) Any other evidence of physical damage.

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

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

§ 32.62 Same: Quality assurance; prohibition of transfer.

* * * * *

(c) Each person licensed under § 32.61 shall:

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

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

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

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

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

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

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

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

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

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

Subpart C - Specifically Licensed Items

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

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

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

(a) * * *

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

* * * * *

§ 32.101 [Removed]

36. Section 32.101 is removed.

§ 32.102 [Removed]

37. Section 32.102 is removed.

§ 32.103 [Removed]

38. Section 32.103 is removed.

§ 32.110 [Removed]

39. Section 32.110 is removed.

Subpart D - Sealed Source and Device Registration

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

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

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

§ 32.210 Registration of product information.

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

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

* * * * *

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

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

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

* * * * *

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 32.303 Criminal penalties.

* * * * *

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

PART 40 - DOMESTIC LICENSING OF SOURCE MATERIAL

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

Authority: 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); Energy Policy Act of 2005, Pub. L. No. 109-59, 119 Stat. 594 (2005).

Section 40.7 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 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).

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

§ 40.5 Communications.

* * * * *

(b) * * *

(1) * * *

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

* * * * *

PART 70 - DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

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

Authority: 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); Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 194 (2005).

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

Section 70.7 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 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).

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

§ 70.5 Communications.

* * * * *

(b) * * *

(1) * * *

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

* * * * *

Dated at Rockville, Maryland, this_____ day of_____, 2011.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.

Regulatory Analysis for Final 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

REGULATORY ANALYSIS
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1. STATEMENT OF THE PROBLEM

The U.S. Nuclear Regulatory Commission (NRC) conducted a systematic reevaluation of the exemptions from licensing in Title 10 of the *Code of Federal Regulations* (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 amending 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 redefining categories of devices to be used under exemption. This action is primarily intended to make licensing processes more efficient and effective. It will affect 1) manufacturers and distributors of sealed sources and devices containing byproduct material and 2) future users of some products currently used under general and specific license.

2. EXISTING REGULATORY FRAMEWORK

Part 30 of 10 CFR 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 of 10 CFR 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 of 10 CFR sets out requirements for the manufacture or initial transfer (distribution) of items containing byproduct material to 1) persons exempt from licensing requirements and 2) 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 making rule changes would be to take no action. The no-action alternative would have allowed current practices to continue. If NRC does not take action, there would be no change in costs or benefits to the public, licensees or NRC. The no-action alternative would not address identified concerns.

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

This alternative will amend 10 CFR Parts 30, 31, 32, 40, and 70 to resolve several issues related primarily to NRC's objectives of effectiveness and openness in the regulatory process, while continuing to meet NRC'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. The regulatory amendments will 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 will 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, while continuing to ensure the protection of public health and safety in the future, changes in the regulations are necessary.

4. ANALYSIS OF ALTERNATIVES

Sections 5.1 through 5.8 describe each of the amendments in the rule and provide discussion and, in some cases, quantitative estimates of the costs and benefits to the licensees, the NRC, the Agreement States, and the public related to each amendment. Section 5.9 estimates the costs to NRC and Section 5.10 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 1.5 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 requirement. Currently, this hourly labor rate for FSME is $114.

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 of $33.17 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 1.5 described earlier to obtain an hourly labor rate of $50 and an annual labor rate of $89,000.

The estimation of costs for rulemaking is based on professional staff full-time equivalent (FTE). Based on actual data from NRC's time and labor system, the number of hours in 1 year that directly relate to implementation of assigned duties is 1,451; this excludes hours on such things as leave, training, and completing administrative tasks. Therefore, an NRC professional staff FTE hour rate is based on 1,451 hours. As described in the Office of Management and Budget (OMB) Circular A-76, "Performance of Commercial Activities," the number of productive hours in 1 year is 1,776. As this actual value is likely to vary from State to State and no specific data are available, the FTE costs for the Agreement States are based on the number of hours estimated in OMB Circular A-76. Costs are determined by multiplying the number of FTEs by 1,451 hours or 1,776 hours times the hourly labor rate, for NRC or Agreement States, as appropriate.

For all licensee labor rates, $55/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";[2] 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,

[1] Department of Labor (U.S.), Bureau of Labor Statistics, Employer Costs for Employee Compensation, September 2010, Table 3 - Employer costs per hour worked for employee compensation and costs as a percent of total compensation: State and local government workers, by major occupational and industry group, September 2010.

[2] Department of Labor (U.S.), Bureau of Labor Statistics. Occupational Employment Statistics, Occupational Employment and Wages, May 2009 17-2111 Health and Safety Engineers, Except Mining Safety Engineers and Inspectors. Mean hourly wage is $36.45 x 1.5 = $55/hour.

"Regulatory Analysis Technical Evaluation Handbook." The following attributes will be affected by the rule:

- Industry Implementation and Operation –The final rule will 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 will also allow some industrial products to be used under exemption from license instead of a general or specific license, which could increase the use of some products.

- NRC Implementation and Operation –The NRC will incur costs to develop a rule and to revise existing guidance. The final rule will 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 will need to amend their regulations to maintain compatibility with NRC requirements; impacts to the Agreement State regulatory programs will be minimal.

- Environmental Considerations – The final rule will 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 final rule 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 under which many of these products are currently used or under a specific 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 final rule will improve regulatory efficiency by removing prescriptive provisions and some unnecessary provisions, and clarifying some of the regulations. Also, adding a new class exemption and broadening another will eliminate the application of unnecessary regulatory requirements to low risk devices.

- Improvements in Knowledge – For certain issues, the final rule may improve the general knowledge of potential licensees/applicants.

- Other Considerations – The final 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 5.1 through 5.8 as they pertain to the individual issues.

The final rule is *not* 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, quantification 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.

5. DESCRIPTION, DISCUSSION, AND ANALYSIS OF VALUES AND IMPACTS OF THE AMENDMENTS

5.1 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 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." 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.

5.1.1 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 review and resultant registration. However, as a matter of licensing practice, applicants/licensees obtain sealed source and device (SS & D) 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 will 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 will also 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 will 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 will be required are being evaluated and registered. The final rule will 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 final rule. The effect of the addition of a new class exemption in § 30.22 and the requirement for registration for those products (§ 32.30(c)(3)) is covered in Section 5.3.

Costs for NRC implementation for the overall rule are discussed in Section 5.9.

The relevant portions of § 32.210 will 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 will require a comparable change in some Agreement State regulations; however, each State will conduct one rulemaking following the planned revision of Parts 30, 31, 32, 40, and 70. The cost for the rulemaking is discussed in Section 5.10.

Benefits:

Not only will the regulations be more explicit and understandable, but there will 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.

5.1.2 Revise Regulations to Explicitly Allow for Amendment, Modification and Revocation, Review, and Inactivation of SS & D Registration Certificates

Other provisions will be amended so as to explicitly apply to registration certificates in addition to licenses. The final rule will 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 will be added. Inactivation means that no further distribution is authorized, but information about previously distributed products is maintained in the database. Distributors will be required to request inactivation of certificates for sources and devices that they no longer intend to distribute. The usual time limit for submitting the request will be 2 years after the last initial transfer. However, the final rule recognizes that the decision to cease distribution may occur after 2 years have passed since the last transfer and allows 90 days after the determination that no more transfers will be made to request inactivation of the certificate.

In addition, a provision for explicitly addressing review and reissuance of certificates is being added (§ 32.210(h)). The new provision in § 32.210(h) may be used to 1) update the certificate with respect to applicable industry or NRC standards or current security concerns or 2) 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 is an activity only very rarely 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 when the certificate holder requests amendments to 1) accommodate desired changes in a product or associated procedures or 2) 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 in order 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. For example, such circumstances might involve: 1) the actual design of a source or device, 2) quality assurance programs, or 3) information to be 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 1) reviewing certificates (in part or in whole) at the time of license renewal; 2) adding separate expiration dates to certificates with typically longer terms than licenses, e.g., 10 to 20 years; and 3) 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 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 newly issued registration certificates only (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 would be 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 both provide the certificate holder and the NRC with the advantage of an anticipated timeframe for reconsideration of devices/sources and the associated documentation. Either of these approaches would likely contribute to accountability on the part of manufacturers/distributors and to the application of ALARA to product designs. However, 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 chosen 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 revisions will 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 normally within 2 years after ceasing distribution of covered sources or devices. For most of these actions, including the requirement to request inactivation, the final rule will 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 will vary from year to year, is expected to be small, and for purposes of illustration is assumed to average four reviews per year, mostly dealing with certificates for devices. There are now approximately 225 active NRC certificates, of which about 132 are for devices. Many of these now cover a number of models.

The average effort involved in a review of an existing certificate will be less than that for a new certificate. The number of hours involved in any particular case will 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 will 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.

Costs to licensees:

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 will be:

4 reviews/year x 12 hr/review x $55/hour = ~$2,600

Other potential costs are more difficult to quantify. However, consideration of licensee costs will 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 uncertain and assumed for illustrative purposes to average approximately four; however, as these will selectively involve mostly certificates for devices (for which the review is more complex), the average number of hours per action will 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 will be approximately:

4 reviews and reissuances x 24 hours/reissuance x $114/staff hour = ~$11,000.

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 5.9.

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, to at least 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 will be encouraged. Paragraph (h) of § 32.210 will be Compatibility Category C, meaning that the essential objectives should be adopted by those States that conduct evaluations of sealed sources and devices. 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 will result for Agreement States that issue registration certificates if they increase efforts to review and reissue, or

inactivate certificates. Of the final amendments related to this issue, only § 32.210 (with the exception of new paragraph (h)) 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 will require a comparable change in some Agreement State regulations; however, each State will conduct one rulemaking following the planned revision of Parts 30, 31, 32, 40, and 70. The cost for the rulemaking is discussed in Section 5.10.

Benefits:

These explicit provisions concerning review and inactivation of registration certificates and the addition of registration certificates to the provisions for amendment and revocation will provide a clearer basis for these Commission actions. Thus the provisions will contribute 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 will 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 will provide an orderly approach to ensuring that the industry adjusts to a changing environment and/or standards. It will 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 some devices that had been approved for use under the general license in § 31.5 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. The process of reviewing certificates could make distributors more accountable. It will 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 will continue while the review process was ongoing.

Other possible improvements may result from review and updating of registration certificates. These could include: 1) 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 2) 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.

5.2 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: 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 final rule includes the following provisions:

§ 30.32(g)(2) - will extend the provision for providing alternative information on NARM legacy sealed sources and devices (previously in § 30.32(g)(3)) to all legacy sealed sources and devices containing byproduct material.

§ 30.32(g)(3) – will add a provision for limited information for certain smaller unregistered calibration and reference sources.

§ 30.32(g)(4) – will 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, when doing so is not feasible.

The change reflected in § 30.32(g)(2) 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 a new § 30.32(g)(3) will 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 for the exclusion are somewhat different than those in the current guidance.) Although some review of the proposed design and manufacturing methods will 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)(4) will also provide some flexibility to applicants and license reviewers in the licensing of the use of sealed sources and devices. It will 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 will incur costs associated with the rulemaking. These are discussed in Sections 5.9 and 5.10.

These changes are not expected to increase occupational doses. Paragraph 30.32(g)(2) has the same standard for approval using alternative information to support the approval. With respect to § 30.32(g)(3), calibration and reference sources meeting the criteria of exclusion from registration (in § 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)(4), adequate constraints will 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 will 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 will eliminate the need in some cases of issuing exemptions from § 30.32(g).

For licensees/applicants, it is estimated that an average of 10 hours will 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 will be saved as a result of not needing an exemption from § 30.32(g). In the Regulatory Analysis for the proposed rule, it was also estimated that an additional 10 hours per such licensing action would be saved as a result of no longer having to prepare environmental assessments for the actions. However, most, if not all, of these exemptions that would no longer be required would have fallen under a recently added categorical exclusion in § 51.22(c)(25); thus, this additional benefit is no longer applicable.

In the case of small unregistered calibration and reference sources licensed for use under § 30.32(g)(3), it is estimated that an average of 5 hours will be saved by the applicant and a similar amount for NRC.

For situations where the new § 30.32(g)(4) 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 will 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.

5.3 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, will 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 will 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 will be:

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

Under these provisions, some manufacturers and distributors of generally licensed devices will 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 will 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 will seek to change the status of their devices so that their future customers will be exempt from licensing. It is estimated that approximately 10 existing licensees will apply in the 2 to 3 years following the rule change, and an additional three new applicants for exempt distribution licenses per year will result. However, there is uncertainty in these numbers, as they are projections of future voluntary actions. The requirements will 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 will be less of a factor for small entities. The lack of complete consistency in the general license provisions among the Agreement States would tend to make a conversion to use under exemption more desirable.

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 will 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 will be evaluated for use under the exemption and a new certificate will be issued. The affect on fees will 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 will be a voluntary expenditure in order to obtain an overall benefit. This one-time expenditure combined with Benefits to Existing Licensees/Distributors will 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 $55/hour	=	~$ 4,400

Device Evaluation Required:

20 registrations x 24 hours/device x $55/hour	=	~$26,000
	Total:	~$30,000

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 $114/staff hour	=	~$ 9,100
20 evaluations x 21 hours/evaluation x $114/staff hour	=	~$48,000
	Total:	~$57,000

Costs to Agreement States:

Agreement State licensing and inspection programs will only be impacted to the extent that a few of their general license distributors might possibly change completely over to exempt distribution, which will be covered by an NRC license. Even in this case, their possession and use will 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 5.9 and 5.10.

Costs to public:

There are limited potential costs to the public from this aspect of the final rule due to devices being smelted and contaminating metals. The technology of detecting radioactive sources in the metals recycling industry has improved and includes multiple points of detection during the process. While the small quantities that may be approved for use under the exemption may be less likely to be detected, the potential for significant resulting contamination is also limited. Due to the uncertainty in the probability and extent of such incidents, an actual cost is not estimated.

Occupational Health/Public Health:

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

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

The safety criteria will ensure that future doses from disposal are unlikely to exceed 10 μSv (1 mrem)/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 will be no direct effect on current licensees general or specific. However, future users of devices approved for use under the exemption will benefit from not having the requirements of the general license or, in some cases, a specific license. Some current general licensees will 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 will 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 rule will allow certain industrial devices to become exempt from licensing; therefore, such devices will be disposed of as ordinary trash. Users will 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 will 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 Richland, Washington facility can only accept low-level radioactive waste from Rocky Mountain Low-Level Radioactive Waste Compact and Northwest Interstate Compact States, of which there are 11. Although a facility has not yet been opened, the Texas Low-Level Radioactive Waste Disposal Compact will accept waste from Texas and Vermont. Therefore, a majority of the States either use a waste broker for disposal,

or send their wastes to the facility in Clive, Utah, operated by Energy Solutions. However, the Clive, Utah facility cannot accept sealed sources.

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 it 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 chosen solution, future users (including some current general licensees) will 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 6 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 $20 - $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) = $80/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 $55/hour = $11/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 $55/hour = $11/device-year

In addition, users (currently generally licensed) will 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 $55/hour = $33/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 will 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 will 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 will no longer apply under the chosen solution. Therefore, future users, including some current general licensees, will save by not having to pay a person to perform these duties. It is recognized that this person performs other duties that will 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 $55/hour = $220/user-year

The general license in § 31.5 was Compatibility Category B for about 10 years, but the Commission recently decided to change it to Compatibility Category C. In some States, some of these devices would have required a specific license, but for those devices covered by the general license, the applicable requirements in many of the Agreement States were equivalent, because of the previous compatibility requirement. Exemptions are Compatibility Category B, so the new exemption will require equivalent provisions in Agreement State regulations. Thus, the change in status should result in similar cost savings per general licensee. For those using such devices under a specific license, cost savings will be greater, but are not estimated.

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

10,000 leak test kits x $40	=	$400,000
5,000 devices tested/year x $11	=	$ 55,000
5,000 devices tested for operation/year x $11	=	$ 55,000
10,000 transfer reports/year x $33	=	$330,000
5,000 responsible individuals x $220	=	$1,100,000
	Total	~$1,900,000

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

The 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 will no longer be required. Therefore, 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 will 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 Agreement States into which they are transferring devices. Manufacturers and distributors of

these products will be required to submit reports of transfer to the NRC annually (§ 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 will be less than for generally licensed devices.

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

The most significant benefit to manufacturers and distributors will be increased sales. Additionally, for those devices not uniformly covered by general license in all jurisdictions, the complexity of dealing with this and the effects on sales will be removed. 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 will benefit from the new provision by a reduction in paperwork (reviewing reports, tracking devices, etc.) associated with generally licensed devices (and to a limited extent, specifically 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 will be approximately 500 hours annually dealing with reports associated with potentially impacted generally licensed devices. NRC has approximately 20 percent of such general licensees. Therefore, the regulatory agencies will save approximately the following annual amount:

100 hours/year x $114/staff hour	=	$11,400/year
400 hours/year x $50/hour	=	$20,000/year

Benefits to Public:

It is likely that persons previously not obtaining and using the subject devices under general license will now purchase some of the devices for use. Examples of such persons are 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.

5.4 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 final rule will replace the wording in § 30.20, “designed to protect life or property from fires and airborne hazards,” with less restrictive wording. This will 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 will 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 will be evaluated for use under the exemption and a new certificate will be issued. The affect on fees will 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.

Costs to Licensees/Distributors:

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 will 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 $55/hour = ~$ 1,800

Device Evaluation Required:
4 registrations x 24 hours/device x $55/hour = ~$ 5,300

	Total/year:	~$ 7,100

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 $114/staff hour	=	~$ 3,600
4 evaluations x 21 hours/evaluation x $114/staff hour	=	~$ 9,600
	Total/year:	~$13,000

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 5.9 and 5.10.

Costs to Public:

There are some limited potential costs to the public from this aspect of the final 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 will likely increase the market in affected devices, some increases in the number of persons exposed are expected. The safety criteria associated with this exemption will limit routine exposures to no more than 5 mrem (50 μSv)/year and also control accident risks. Actual exposures are typically lower than those in the safety criteria. The 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 will be expected to provide a significant benefit to society, thus ensuring a reasonable cost/benefit for the individual product.

Environmental Considerations:

This provision will increase the number of devices allowed to be disposed as ordinary trash. Estimated doses from disposal at landfills or municipal incinerators for detectors previously distributed for use under this exemption have been low. The types of additional detectors anticipated are likely to be used in smaller numbers than the initial products used under this exemption; i.e., smoke detectors. This should limit increases in environmental effects of increased numbers of detectors being disposed.

Benefits:

Benefits to Licensees/Users:

There will be no direct effect on current general or specific licensees. However, future users of devices approved for use under the exemption will benefit from not having the requirements of the general license, or in some cases, a specific license. Some current general licensees will 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 5.3, there are a number of costs incurred by general licensees, which will not be incurred by future users under an exemption from licensing. The following discusses typical costs for general licensees, which will 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 5.3.

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 final rule will allow certain devices to become exempt from licensing; therefore, such devices will be disposed of as ordinary trash. Users will 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 will 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 Richland, Washington facility can only accept low-level radioactive waste from Rocky Mountain Low-Level Radioactive Waste Compact and Northwest Interstate Compact States, of which there are 11. Although a facility has not yet been opened, the Texas Low-Level Radioactive Waste Disposal Compact will accept waste from Texas and Vermont. Therefore, a majority of the States either use a waste broker for disposal, or send their wastes to the facility in Clive, Utah, operated by Energy Solutions. However, the Clive, Utah facility cannot accept sealed sources. 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 it 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 chosen solution, users exempt from regulation will no longer have to leak test the sources. It is assumed that a leak test, if required, is performed every 6 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 $20 to $40 per kit depending on the number of kits purchased.

$$\frac{\text{2 tests/year/device}}{\text{1 test/kit}} \times \$40/\text{kit} = \$80/\text{device-year}$$

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 $55/hour = $11/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 $55/hour = $11/device-year

In addition, users will 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 $55/hour = $33/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 will 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 will no longer apply under the chosen solution. It is recognized that this person normally performs other duties that will 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 will save by not having to pay a person to perform these duties.

4 hours/year x $55/ hour = $220/user-year

The general license in § 31.5 was Compatibility Category B for about 10 years, but the Commission recently decided to change it to Compatibility Category C. In some States, some of these devices would have required a specific license, but for those devices covered by the general license, the applicable requirements in many of the Agreement States were equivalent, because of the previous compatibility requirement. Exemptions are Compatibility Category B, so the new exemption will require equivalent provisions in Agreement State regulations. Thus, the change in status should result in similar cost savings per general licensee. For those using such devices under a specific license, cost savings will be greater, but are not estimated.

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

1000 leak test kits x $40	=	$ 40,000
500 devices tested/year x $11	=	$ 5,500
500 devices checked for operation/year x $11	=	$ 5,500
500 transfer reports/year x $33	=	$ 16,500
1,000 responsible individuals x $220	=	$220,000
	Total	~$288,000

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

The chosen solution will likely cause a slight change in prices for users. 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, or sometimes recouped in the price of devices replacing the ones being returned. If such devices become exempt from regulation, this disposal service will no longer be required. Therefore, 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 will 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. Additionally, for those devices not uniformly covered by general license in all jurisdictions, the complexity of dealing with the differences in regulations in various jurisdictions and the effects on sales will be removed. No attempt has been made to quantify these benefits.

A significant reporting and recordkeeping cost for distributors is labeling. However, similar labeling requirements apply to distributors of gas and aerosol detectors. Therefore, there will not be a savings associated with this aspect of the recordkeeping. Although there are a number of distributor requirements that will 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, will be similar to current costs, although somewhat reduced.

Benefits to NRC/Agreement States:

The NRC and the Agreement States will benefit from the chosen 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 it 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 will accrue to the public from the use of the devices. The products will be required to provide some protection to health, safety, or property.

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

This rule will 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 5.9, and Agreement State rulemaking discussed in Section 5.10.

However, the one NRC licensee may need to amend its license at the time of its next renewal, resulting in onetime costs to that licensee and the NRC, and with an associated change to the fees.

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.

5.6 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 will be made less prescriptive and continue to contain general requirements and in some cases provide standards by which performance may be judged rather than specifying details of procedures that must be followed. Regulatory guidance will be provided on acceptable approaches to meeting the requirements. Licensees may also be allowed 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 being made:

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 will include examples of acceptable approaches: 1) NUREG-1556, Vol. 16, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Licenses Authorizing Distribution to General Licensees" and 2) 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 percent risk of more than 5 percent defectives to 5 percent 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 equivalent provisions to these. The NRC has 49 licensees under § 32.14; some of these will no longer have NRC oversight of their quality assurance/quality control requirements as a result of changes discussed in Section 5.7.2. 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 will 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 will 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 will be more performance-based. Applicants will be free to propose alternative methods to those presented in guidance to satisfy the requirements in the regulations. The requirements will continue to provide adequate assurance that the products being distributed meet performance standards. The performance standard will be somewhat revised to reduce the risk of defective products being distributed. Any new industry standards will more easily be accommodated.

The *Code of Federal Regulations* will be reduced by several pages.

5.7 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 will 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.

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

Some current requirements are considered unnecessary given the risk associated with the particular product. In this rule, the NRC will 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 rule will revise § 32.14(b)(4) to make exceptions to prototype testing requirements.

Cost Impacts:

No costs are anticipated for applicants/licensees. There will be no costs to NRC beyond rulemaking and implementation costs discussed in Section 5.9. There will 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 10 μSv (1 mrem)/year. Overall, an insignificant risk to the public will 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 will be reduced.

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

Using those assumptions, $55/hour for applicants, and $114/staff hour for NRC, savings to applicants will be approximately $1,300/year and for NRC, approximately $2,700.

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

5.7.2 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).

<u>This rule will eliminate individual requirements considered unjustified based on risk as follows</u>:

Revise § 32.14 (b)(5) to make exceptions to requirements to submit quality control procedures for review.

Revise § 32.15, to qualify the condition of license for maintaining quality assurance practices so as to limit it to products for which such procedures are required. This accommodates the exceptions made in § 32.14(b)(5).

Cost Impacts:

No costs to applicants/licensees are anticipated. There will be no costs to NRC beyond rulemaking and implementation costs discussed in Section 5.9. However, some current licensees may choose to amend their licenses to remove conditions in the license, which will no longer be required, resulting in small administrative costs to those licensees and to NRC. There will 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 10 μSv (1 mrem)/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 will 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 will be reduced.

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

Using those assumptions, $55/hour for applicants, and $114/staff hour for NRC, savings to applicants will be approximately $1,300/year and for NRC, approximately $2,700.

There are currently 49 licensees under § 32.14, many of whom will be free to make adjustments in their quality assurance/ quality control procedures. (Any amendments to licenses will be limited to removing conditions of the license to conduct QC in the manner to which the licensee previously committed.) No attempt has been made to quantify this benefit. However, as this is an ongoing effect, the overall benefit for this change will be greater than that concerning prototype tests discussed in Section 5.7.1.

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

5.8 Minor Clarifying or Administrative Revisions

Other minor revisions are being made to better organize, clarify, or update the regulations in these parts, such as the renaming of Subparts C and D and the movement of §§ 32.72 and 32.74 from Subpart B to Subpart C. These two sections will 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 5.9 and 5.10. 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.

5.9 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 $165,400/FTE.

NRC staff will need to update existing guidance in the NUREG-1556 series related to distribution licensing to reflect the revisions to the regulations. Specifically, 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" will require minor revisions or supplementation. As the changes for this rule are being made within overall revisions of these NUREGs, the additional updating needs should be a relatively limited cost impact as a result of this final rulemaking. The staff is also preparing interim guidance for use until the completion of the updates of the relevant volumes of NUREG-1556. This effort was done in parallel with the development of relevant revisions to the NUREGs to minimize the added resources from development of the interim guidance.

5.10 Costs to Agreement States of Compatible Regulations

Costs will be incurred by the Agreement States for development and implementation of compatible regulations. The costs will vary significantly by State because of differences in internal procedures for developing regulations. Some rule changes will be required to meet Compatibility Category B for certain revisions. As these need to be essentially word-for-word compatible, the process should be relatively simple. Two provisions, §§ 30.32(g) and 32.210(h), iare Compatibility Category C; this may also result in some revision of the Agreement State regulations. For this final rule, the NRC assumes an average of 0.1 FTE at $8,900/FTE for each State. There are currently 37 Agreement States; therefore, the total cost for all Agreement States will be approximately $329,000.

6. 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 final rulemaking will be 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 and some other specific licensees, without a reduction in the protection of public health and safety in the future. 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. This rule will advance the Commission's objectives of effectiveness and openness.

The largest single cost will be implementation of the final 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.

7. IMPLEMENTATION

The NRC's schedule for implementation of this rulemaking calls for the effective date of the rule to be in 2012 for the NRC's jurisdiction and full implementation by the Agreement States by 2015. The applicable guidance documents are: 1) NUREG-1556, Vol. 3, Rev. 1, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration;" 2) NUREG-1556, Vol. 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses;" and 3) 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 are being revised as part of a broader update. There are no changes requiring entirely new guidance; i.e., nothing that necessitated having guidance available in draft for comment along with the proposed rule. Details of procedures being removed from the regulations are being added to the applicable guidance as revised to provide examples of acceptable approaches; however, these details have generally been in the regulations for many years. 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. As these will not be completed by the time the final rule is published, interim guidance is to be published concurrently with the final rule.

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.

8. IMPLICATIONS FOR OTHER FEDERAL AGENCIES

Promulgation of this final rule will have no adverse effects on other Federal agencies.

9. EFFECT ON SMALL ENTITIES

The final rule will not significantly impact small or large entities.

10. 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>.

Environmental Assessment for Final Rule – 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 or the Commission) is amending its regulations governing the use of byproduct material in Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 30, 31, 32, 40, and 70. These amendments will make the requirements for distributors of byproduct material clearer, less prescriptive, and more risk-informed and up-to-date. The Commission is also redefining the categories of devices to be used under exemptions, adding explicit provisions for the use of the sealed source and device registration process, and adding flexibility to the licensing of users of sealed sources and devices. This action is primarily intended to make licensing processes more efficient and effective. 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 of the 10 CFR, 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 within the class of 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 are 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 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 final rule is therefore best understood and discussed as a collection of autonomous small issues. If taken independently, many of the amendments being made 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 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 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 Preferred Action

Based on the NRC's review of regulations that govern the licensing, manufacture, use, and disposal requirements for byproduct material as contained in 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 required 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 will improve the effectiveness and efficiency of certain licensing actions, while continuing to ensure the protection of public health and safety in the future. Parts 40 and 70 of the Commission's regulations will contain minor conforming amendments.

3.0 Applicability of Categorical Exclusion for Certain Amendments

Many of the 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 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 revisions to §§ 30.6, 32.56, 40.5, and 70.5 fall under the categorical exclusion in § 51.22(c)(3)(iii). 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 Preferred Action and Alternatives: Generic Discussion

Under the preferred action, the NRC is amending certain sections of 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 based on the Commission's objectives of effectiveness and openness in the regulatory process while continuing to meet its 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. 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.

These issues are essentially inherent in the regulations themselves, such as overly prescriptive provisions; no non-rulemaking alternatives can realistically address these issues.

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 and the no-action alternative are discussed below, issue by issue.

5.0 The Preferred 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 rule provides 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)(2) provides for substituting some categories of information with other information to demonstrate the sealed source or device meets the same safety standard. This rule extends this provision (previously in § 30.32(g)(3)) to materials covered by Part 30 prior to the final rule published October 1, 2007 (72 FR 55863).

The provision in a new § 30.32(g)(3) 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)(4) 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, is 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 are comparable to those imposed on specifically licensed distributors of gas and aerosol detectors used under § 30.20 (and equivalent Agreement state provisions). These regulations are:

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

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

Of the various revisions in this final rule, this set of provisions 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 requirements to approve a device for use under the new

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 will 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 limit noted in item (2) above provides added assurance that quantities of byproduct material in exempt devices will 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 made with this new exemption, there are a number of other factors which contribute to the conclusion that adding this exemption will 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, and has recently proposed similar reporting requirements for source material distribution (July 26, 2010; 75 FR 43425).

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 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 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, with the additional provisions noted here, will 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 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 final rule replaces 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.

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 will not significantly increase the potential for inappropriate exposures to members of the public from the net effect of materials released from regulatory control, will not significantly increase occupational or public exposures, and is unlikely to significantly affect other environmental resources.

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

This action replaces the general license in § 31.3 with an exemption from licensing in § 30.15(a)(2). As a result, there are 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 preferred action is the licensing requirements placed on the distributor. The requirements remain essentially the same as in current practice, but are 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.

5.5 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 are 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 will be provided on acceptable approaches to meeting the requirements. Licensees may also be allowed 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 being made:

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 primarily remove details of procedures to be followed from the regulations. The standards for acceptance sampling are also 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, is 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 will be expected from taking a more performance-based approach for exercising oversight over these procedures.

5.6 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 are considered unnecessary given the risk associated with the particular product. The products for which requirements are 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 is revising 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 action revises § 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 action will eliminate individual requirements considered unjustified 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 is 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 final rule.

6.0 Conclusion

The NRC is amending 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 final 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 made belong to a category of actions that 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 amendments in this overall rulemaking will 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 was published in the *Federal Register* concurrently with the publication of the proposed rule for public comment (75 FR 36211, June 24, 2010) and will be restated concurrently with the publication of the final rule.

7.0 List of Agencies and Persons Consulted

The NRC staff has determined that the preferred Federal 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 preferred Federal 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.