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

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RESOURCES:

To complete and implement an action on 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 follow on 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.

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Executive Director
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Enclosures:
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