RULEMAKING ISSUE
NOTATION VOTE

February 26, 2009 SECY-09-0035

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

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

PURPOSE:

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

SUMMARY:

The proposed amendments would revise the regulations to make the requirements for distributors of byproduct material clearer, less prescriptive, and more risk-informed and up-to-date. The proposed rule would also improve safety criteria for approving products through licensing actions, redefine categories of devices to be used under exemptions, add explicit provisions regarding the sealed source and device registration process, and add flexibility to the licensing of users of sealed sources and devices. This rule would make licensing processes

CONTACT: Catherine R. Mattsen, FSME/DILR
(301) 415-6264

more efficient and effective, and increase assurance that appropriate quantities of radionuclides are approved for use under the general license and under exemptions from license. These changes would affect manufacturers and distributors of sources and devices containing byproduct material and future users of some products currently used under general or specific license.

BACKGROUND:

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

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

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

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

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

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

DISCUSSION:

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

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

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

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

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

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

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

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

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

Establish a New Class Exemption for Certain Industrial Products

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

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

Revise Safety Criteria for the Existing Class Exemptions

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

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

Broaden the Class Exemption for Gas and Aerosol Detectors

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

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

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

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

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

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

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

Update Regulations on Certain Static Eliminators and Ion Generating Tubes

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

Make Requirements for Distributors of Certain Products Less Prescriptive

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

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

Risk-Informing the Requirements for Distributors of Exempt Products

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

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

Minor Clarifying or Administrative Revisions

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

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

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

AGREEMENT STATE ISSUES:

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

The NRC staff has analyzed the proposed rule in accordance with the procedures established within Part III of the Handbook to Management Directive 5.9, "Categorization Process for NRC Program Elements." The proposed rule would be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements.

Revisions to Subpart A of Part 32 (§§ 32.11 through 32.32) are classified as Compatibility Category "NRC." Compatibility is not required for Category "NRC" regulations. Exemptions from licensing, including §§ 30.15, 30.19, 30.20, and the new § 30.22, are classified as Compatibility Category B, as is § 31.3. Revisions to Subpart B of Part 32 (§§ 32.51 through 32.103) are classified as Compatibility Category B, as is § 32.110. Section 32.210 is classified as Compatibility Category B for States that perform SS & D evaluations and Compatibility Category D for States that do not perform SS & D evaluations. The same would be the case for the new § 32.211. Paragraph 30.32(g) is classified as Compatibility Category C. Sections 30.6, 30.38, 30.39, 30.61, 31.23, 32.8, 32.303, 40.5, and 70.5, § 32.1(a), and the definition of *Sealed Source and Device Registry* in § 32.2 are classified as Compatibility Category D. Existing compatibility designations for these regulations would not be affected. The definition of *Dose commitment* is currently Compatibility Category A, but with the note that this term and definition are superseded by the new term and definition in 10 CFR Part 20, "committed dose equivalent," and that the Part 20 term and definition should be used for purposes of compatibility and States should adopt this terminology consistently throughout their requirements. The rule proposes that

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

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

COMMITMENTS:

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

RECOMMENDATIONS:

That the Commission:

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

2. Note:

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

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

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

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

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

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

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

RESOURCES:

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

COORDINATION:

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

/RA Martin Virgilio for/

R. W. Borchardt
Executive Director
for Operations

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

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

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

RESOURCES:

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

COORDINATION:

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

/RA Martin Virgilio for/

R. W. Borchardt
Executive Director
for Operations

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

ADAMS ACCESSSION No.: ML083120324 WITS200500130/EDATS: SECY-2008-0499

OFFICE	DILR	DILR	DILR	DMSSA (email JLuehman)
NAME	CRMattsen	KHsueh	MShaffer	RLewis
DATE	1/13/2009	1/23/2009	1/27/2009	10/23/2008
OFFICE	RES	CFO	ADM	OIS (email ATse)
NAME	BSheron	JDyer (TPulliam for)	MLesar	RNichols
DATE	10/14/2008	10/7/2008	10/20/2008	11/7/2008
OFFICE	OE (email LSreenivas)	OGC	Tech Editor	
NAME	CCarpenter	BJones	PTressler	
DATE	10/28/2008	1/13/2009	2/5/2009	
OFFICE	FSME	EDO		
NAME	CMiller (GPangburn for)	RWBorchardt (MVirgilio for)		
DATE	2/8/2009	02/26/2009		

OFFICIAL RECORD COPY