

# RULEMAKING ISSUE

(Affirmation)

July 6, 2007

SECY-07-0113

FOR: The Commissioners

FROM: Luis A. Reyes  
Executive Director for Operations /RA/

SUBJECT: FINAL 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)

PURPOSE:

To request Commission approval for the publication of a final rule. This final rule amends Parts 30, 31, 32, and 150, and affects distributors of byproduct material to exempt persons, some general licensees, and some users of exempt products. The staff has developed this final rule to improve regulatory efficiency, and ensure public health and safety and protection of the environment. This paper does not address any new commitments.

SUMMARY:

This final rule will amend several regulations governing the distribution of byproduct material. The reporting requirements for licensees distributing byproduct material to persons exempt from licensing are being changed, obsolete provisions are being deleted, certain regulatory requirements are being clarified, and smoke detector distribution regulations are being simplified. In addition, this final rule clarifies the process for transferring a generally licensed

CONTACTS: Andy Imboden, FSME/DILR  
(301) 415-2327

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

device for use under a specific license. Aspects of this rule will affect all distributors of exempt byproduct material who submit transfer reports, some general licensees, and some users of exempt products. These actions are intended to better ensure the protection of public health and safety, make the licensing of distribution to exempt persons more effective and efficient, and reduce unnecessary regulatory burden to certain general licensees. Individually and collectively these amendments have been found to have no adverse environmental impacts, and have no significant additional regulatory burden.

#### 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 related to the general licenses in Part 31. The plan also discussed the possible need to make adjustments or add issues during the rulemaking process.

In 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)," dated August 23, 2005, the staff presented a proposed rule, which included the resolution of five of the issues approved by the Commission in the staff requirements memorandum (SRM) to SECY-02-0196 (November 17, 2003; ADAMS Accession No. ML033210570), and two others that had been identified by the staff in the interim.

In an SRM dated November 3, 2005, responding to SECY-05-0151, the Commission approved publication of the subject proposed rule, with the elimination of one of the amendments. The proposed rule was published in the *Federal Register* on January 4, 2006 (71 FR 275). The comment period closed March 20, 2006, and nine comment letters were received. One comment letter was submitted by a smoke detector manufacturer, and another by a manufacturer of sources used in smoke detectors. One comment was received from the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR), representing manufacturers and distributors of exempt quantities of byproduct material. One comment was received from the Radiation Safety Officer (RSO) of a university. Officials from two States (Alabama and Texas) and staff from two others (Illinois and Georgia) also submitted comments. These comments are discussed in detail in the *Federal Register* notice (Enclosure 1). As a result of consideration of the comments, minor changes were made to what was proposed in order to eliminate unanticipated burdens on licensees and to clarify some of the regulatory text.

#### DISCUSSION:

The final rule will make a number of revisions to the regulations regarding the use of byproduct material under exemptions from licensing and under general licenses, and regarding the requirements for those who distribute products and materials for use under exemptions from licensing. These improvements are part of the overall commitment to systematically assess the Nuclear Regulatory Commission's (NRC's) regulatory program to ensure the safe use and

management of byproduct material. Implementing these final amendments to Parts 30, 31, 32, and 150 will ensure that the NRC's regulatory actions are more effective, efficient, and realistic, and enhance NRC's ability to protect public health and safety.

#### Issues Included in this Final Rule

This final rule amends the regulations in Parts 30, 31, 32, and 150. The amendments address six goals: (1) improving the reporting of exempt product/material distribution; (2) requiring NRC-only licensing of introduction of exempt concentrations; (3) explicitly prohibiting bundling of exempt quantities; (4) removing obsolete provisions; (5) simplifying the licensing of smoke detector distribution; and (6) clarifying requirements in § 31.5 for transfer of generally licensed devices for use under a specific license.

#### Improving the Reporting of Exempt Product/Material Distribution

Distributors of exempt products had previously submitted reports to the NRC on a 5-year cycle. This final rule replaces this requirement with an annual reporting requirement. The longer reporting period between reports has had detrimental effects on the quality and timeliness of data available to the NRC. In addition, minor changes to the content of reports will also be made to improve the NRC's ability to assess the full impact on public health and safety from exempt products and materials. Despite the fact that licensees will have to submit more reports, these licensees' net regulatory burden will not significantly change because each report will be shorter, and the record retention period will be shorter as well. The only concern expressed in the comments on the proposed rule regarding this revision pertained to the inclusion of chemical and physical data reported by distributors of exempt quantities. The final rule has been clarified in order to address this concern. Other comments received on this subject were supportive of the proposed rule.

#### NRC Licensing of Introduction of Exempt Concentrations

Paragraph 150.15(a)(6) reserves to the NRC the authority for licensing the transfers to persons exempt from licensing and regulatory requirements. Notwithstanding § 150.15(a)(6), § 30.14 allows Agreement States to license those who introduce byproduct material into products or materials for transfer as exempt concentrations. This exemption predates the Agreement State program. This anomaly creates a gap in the information available to assess the impact of exempt products, may introduce inconsistencies in the licensing process, and results in confusion concerning whether such activities require an NRC license. It is also more efficient for one jurisdiction to license this activity than for each State to expend resources and maintain capabilities for this exceptional authority. The final rule will provide that only the NRC may authorize such introduction and transfer.

This issue garnered comments from some States. The comment submitted by Texas was strongly worded in opposition to this change. The staff notes, however, that no previous objection had been raised by Texas or any other State during the development of either the proposed rule or the rulemaking plan. Prior to publication of the proposed rule, the Agreement States were polled as to whether they had any such licensees, and additional searches were made by the staff to identify potentially affected licensees, however, none were found. Since

publication of the proposed rule, Texas has not identified any licensee who would be affected by the rule and no current Agreement State licensees of this type have been identified.

#### Bundling of Exempt Quantities

The final rule codifies the Commission's position that multiple exempt quantities should not be combined, or "bundled." This practice circumvents the basic safety considerations relied on in issuing the exemption and is not consistent with the required label provided by the manufacturer, which must state that "exempt quantities should not be combined." This final rule amends the NRC's regulations to specifically prohibit the combination of exempt quantities for the purpose of producing an increased radiation level. Comments received on this amendment were supportive.

#### Obsolete Exemption Provisions

Obsolete exemptions will be deleted. These exemptions are no longer beneficial to the public, and address products no longer commercially distributed. Some exemptions deleted by this final rule have never been used. Comments received were unanimously supportive of the NRC deleting these exemptions.

Most of these exemptions are contained in § 30.15, "Certain items containing byproduct material." The exemptions for automobile lock illuminators and shift quadrants, thermostat dials and pointers, and spark gap irradiators containing cobalt-60 will be removed completely. The exemptions for balances of precision and marine compasses and other navigational instruments will be limited to previously distributed products, because there is the possibility that some of these products may still be functional and in use. Additionally, the relevant distributor requirements in Part 32 that reference obsolete products will be removed.

In addition to the obsolete exemptions in § 30.15, the exemption in § 30.16, "Resins containing scandium-46 and designed for sand-consolidation in oil wells," will be deleted. The exemption for resins containing scandium-46 has a potential for significant doses if used. Removing this exemption will further ensure that this obsolete product will not be used without a specific license in the future.

#### Smoke Detector Product-Specific Exemption

This final rule will simplify licensing for applicants to initially distribute smoke detectors by establishing a new product-specific exemption for ionization chamber smoke detectors containing no more than 1 µCi of americium-241 in the form of a foil. These widely distributed and greatly beneficial devices are currently being used under the class exemption for gas and aerosol detectors. Current-day smoke detectors are consistently designed and the NRC has developed extensive licensing experience.

Because the existing class exemption is not being deleted, the remaining smoke detector models that do not qualify for the new exemption may still be distributed to exempt persons, so there will be no negative impacts on any existing business. An analysis of the sealed source and device registry showed that 92 percent (97 out of 106) of existing smoke detector models will potentially qualify for the new product specific exemption. The establishment of a new

product-specific exemption for these products will also reduce fees for initial distributors of smoke detectors. The only issue raised in the comments on this revision concerned allowance for variation in the activity of sources that normally result from the manufacturing process.

#### Transfer of Generally Licensed Devices to Specifically Licensed Status

Licensing and enforcement experience indicates that a clarification is needed to § 31.5 to address the transfer of a device from the authority provided by the general license to that of a specific license. Some specific licensees possess devices that are generally licensed and, recently, an increased number of these licensees have transferred their authorization to possess and use a device held under the general license to that of a specific license. Doing so allows the specific licensee to avoid paying registration fees on some devices, and is allowed under § 31.5(c)(8). Such a transfer continues to be at the licensee's discretion. This rule clarifies the responsibilities of licensees seeking such a transfer. For example, the appropriate labeling, testing, and disposal requirements are different for general licensees than for specific licensees. Additionally, such transfer currently requires prior written approval from the NRC. The regulations will be amended to eliminate the requirement for a licensee to seek prior approval, and to state exactly what the licensee must do. This will enhance regulatory clarity and improve the ease of transfer of devices held under a general license to a specific license. This proposed revision resulted in stakeholder interest during the public comment period. Concerns came mainly from States, who raised additional issues related to this general license. Some of these issues are the subject of a petition submitted by the Organization of Agreement States (OAS). The OAS petition recommends that some currently generally licensed devices should only be possessed by specific licensees. The staff believes that the changes made in this rule are warranted, regardless of the outcome of the petition. This rule will apply to the remaining generally licensed devices. These comments have been addressed in the *Federal Register* notice.

#### Outcome of this Final Rule: Advancing the NRC's Strategic Goals

Some of the revisions improve NRC's ability to ensure the protection of public health and safety and the environment through the availability of more current and useful data on distributions of byproduct material. Additionally, these amendments will help to ensure that NRC actions are effective, efficient, realistic, and timely. Better data collection will improve the effectiveness and efficiency of NRC actions through the addition of certain new provisions and the elimination of certain requirements that are no longer necessary. Based on regulatory, licensing, and enforcement experience, the staff has also identified the need to clarify regulations in response to unanticipated interpretations of certain existing regulations. Finally, the goal of ensuring openness in our regulatory process will be advanced because the NRC will have a better basis on which to inform the public about exposures resulting from the distribution of consumer products.

#### Agreement State Issues

In addition to being represented on the working group for the final rule, the Agreement States had an early opportunity to review a copy of the draft final rule. On February 22, 2007, a copy of the draft final rule was posted on NRC's Technical Conference Forum so that the Agreement States (as well as New Jersey, Pennsylvania, and Virginia) could review it and provide

comments. Written comments were received only from the State of Washington. These comments related primarily to compatibility categories and multiple licensing jurisdictions.

The State of Washington expressed several concerns in its comments. One concern was that, since § 30.14(c) requires all manufacturers, processors, and producers to be NRC licensees, this will lead to additional Federal licensing in addition to Agreement State licensing. The staff notes that this provision, in fact, exempts manufacturers, processors, and producers from NRC licensing for the transfer of products and materials containing exempt concentrations, although this exemption is contingent on the "introducer" being an NRC licensee. The State of Washington did support NRC licensing of the introduction of exempt concentrations.

The State of Washington also suggested that all parts of the rule be categorized as Compatibility Category C, and objected to parts of the rule being Category B and Category NRC. This rule contains regulations that are classified as Category NRC, Category B, Category C, and Category D in accordance with the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997 (62 FR 46517), and for the various reasons set forth in the Statement of Considerations. Consistent with what had been proposed, this final rule will change § 32.11 from Categories C/B to Category NRC, and § 32.12 will change from Category C to Category NRC. These sections involve exempt product distribution licensing, a regulatory area that is reserved to the NRC, and therefore Category NRC is appropriate. For the rest of the amendments made in this final rule, the compatibility category is not being changed.

Another comment from the State of Washington was that specific licensees producing or distributing exempt materials will now report directly to the NRC and this could lead to "information gaps." Most distributors of byproduct material to exempt persons already must be NRC licensees who make certain reports to the NRC. One additional category of licensee ("introducers" of exempt concentrations) will now need an NRC license and will report to the NRC. This fills a gap for the NRC.

There was also a concern expressed by the State of Washington that the requirements would be relaxed to allow companies to make some physical and/or informational changes to generally licensed device labels without having to report these to NRC, and that this could adversely affect the realistic control of generally licensed materials, possibly leading to missing, lost or abandoned sources. However, labels will only be allowed to be changed by specific licensees and only on devices no longer generally licensed; the change in status will be required to be reported to the NRC.

#### RECOMMENDATIONS:

That the Commission:

1. Approve for publication in the *Federal Register* the final amendments to Parts 30, 31, 32, and 150 (Enclosure 1).
2. Certify that this rule, if adopted, will not have a significant impact on a substantial number of small entities, to satisfy the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

3. Note:

- a. The final rule will be published in the *Federal Register* and will be effective 60 days after publication.
- b. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification that this rule does not have a significant economic impact on a substantial number of small entities, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b).
- c. A final Regulatory Analysis has been prepared for this rulemaking (Enclosure 2).
- d. A final Environmental Assessment has been prepared for this rulemaking (Enclosure 3).
- e. The staff has determined that this action is not a “major rule,” as defined in the Congressional Review Act of 1996 (CRA) [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 (Enclosure 4).
- f. NUREG-1556, Volume 8, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses,” will require minor revisions for consistency with these final amendments to the regulations.
- g. Appropriate Congressional committees will be informed of this action.
- h. A press release will be issued by the Office of Public Affairs when the final rule is filed with the Office of the *Federal Register*.
- i. This final rule amends information collection requirements. However, the burden for these revisions to information collection is insignificant and OMB clearance is not required.

RESOURCES:

The resources for completing action on this final rule are estimated at 0.1 full time equivalent and are in the fiscal year 2007 budget for the Office of Federal and State Materials and Environmental Management Programs.

COORDINATION:

The Office of the General Counsel has no legal objection to the final rulemaking. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

***/RA William F. Kane Acting for/***

Luis A. Reyes  
Executive Director  
for Operations

Enclosures:

1. Draft *Federal Register* Notice
2. Regulatory Analysis
3. Environmental Assessment
4. CRA Forms



COORDINATION:

The Office of the General Counsel has no legal objection to the final rulemaking. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

***/RA William F. Kane Acting for/***

Luis A. Reyes  
Executive Director  
for Operations

## Enclosures:

1. Draft *Federal Register* Notice
2. Regulatory Analysis
3. Environmental Assessment
4. CRA Forms

**ML071760264****WITS199000208**

<b>OFC</b>	RBA/DILR	RBA/DILR	D:DMSSA	DD:DILR	D:DILR
<b>NAME</b>	Almboden	KHsueh	JSchlueter	PBubar	DRathbun
<b>DATE</b>	06/25/07	06/26/07	06/26/07	06/26/07	06/26/07
<b>OFC</b>	ADM	OIS	D:OE	CFO	RES
<b>NAME</b>	MLesar	MJanney	CCarpenter	JFunches	MCunningham
<b>DATE</b>	03/09/07	06/16/07	03/16/07	03/27/07	03/02/07
<b>OFC</b>	OGC	TechEd	FSME	EDO	
<b>NAME</b>	FCameron	CPoland	CMiller (SReynolds for)	LAReyes	
<b>DATE</b>	06/25/07	06/27/07	6/29/07	07/06/07	

**OFFICIAL RECORD COPY**