

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: 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)

PURPOSE:

To request Commission approval of the publication of a proposed rule in the *Federal Register* for public comment. This proposed rule reflects miscellaneous recommended amendments to Parts 30, 31, 32, and 150.

SUMMARY:

The proposed rule would amend the regulations governing the use of byproduct material to revise requirements for reporting transfers to persons exempt from licensing, simplify the licensing of smoke detector distribution, remove obsolete provisions, and clarify certain regulatory provisions. 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. These changes would affect users of certain generally licensed devices, persons holding certain byproduct materials under exemption, and licensees who distribute byproduct material to exempt persons.

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BACKGROUND:

The staff provided the Commission with recommendations for possible improvements to the regulations governing these 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," November 1, 2002. These recommendations primarily resulted from a systematic assessment of the exemptions from licensing in Parts 30 and 40 of NRC's regulations, which govern the use of byproduct material and source material, respectively. 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 Materials," June 2001.

The rulemaking plan included in SECY-02-0196 addressed only the regulations governing byproduct material and identified 22 issues considered by the staff. The staff concluded that regulatory changes for 16 of the identified issues would be beneficial and recommended that these 16 issues be considered in the rulemaking process. The plan also discussed the possible need to make adjustments or add issues during development of the proposed rule. Additionally, in SECY-02-0196, the staff 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. Additionally, the Commission directed the staff to address certain related issues specified in the SRM. The staff subsequently responded on these issues in SECY-04-0055, "Plan for Evaluating Scientific Information and Radiation Protection Recommendations," April 7, 2004, and SECY-04-0217, "Distribution of Exempt Material - Database, Dose Limits/Criteria, and Security Issues Related to Risk-Informing 10 CFR Parts 30, 31, and 32," November 18, 2004.

DISCUSSION:

The attached Federal Register notice (Attachment 1) presents a proposed rule that addresses approximately half of the original issues the Commission directed the staff to pursue in the SRM on SECY-02-0196. During the initial development of the 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, which would significantly delay the overall rule; (3) Specific immediate benefits could be gained from addressing many of the issues for which the technical basis was more straight-forward; and (4) A single rule could be overly complex, making it difficult to understand all the issues involved. Issues resolved by this initial rulemaking would not be impacted by a later resolution of remaining items.

The subject proposed rule would resolve five of the issues approved by the Commission (listed below). These issues include all of the approved issues from Option 1 and two from Option 2 of the rulemaking plan (Attachment 7 to SECY-02-0196). Proposed changes would be made to

the reporting requirements of exempt product distributors so that the information received by the NRC is more timely, the reporting process is more efficient, and the impact of these products on the general public can be better assessed. Additionally, licensing and enforcement experience has identified certain issues that should be specified or clarified by rule. These improvements are part of the overall commitment to systematically assess the NRC's regulatory program to ensure the safe use and management of byproduct material.

In the section on Agreement State Implementation Issues in the rulemaking plan, the staff also indicated that consideration should be given to changing the provisions in §§ 32.11 and 32.12 (requirements for persons introducing exempt concentrations into products and materials) to make them Compatibility Category NRC. This change would make those sections consistent with § 150.15(a)(6), which reserves to NRC the licensing of transfers to persons exempt from licensing requirements. As this contemplated change would not alter the way these activities are currently regulated, and only impacts who would regulate these activities in the future, this action was not listed as a separate issue in the rulemaking plan. However, this change would also require revisions to the regulations. The proposed rule includes the amendments necessary to make this change to NRC-only licensing. One additional issue, which arose after development of the rulemaking plan, involves clarification of a narrow aspect of § 31.5, which is explained in more detail below. This is also included in the subject proposed rule.

Implementing these proposed amendments to Parts 30, 31, 32, and 150 would improve the NRC's regulatory effectiveness, efficiency, and realism, and enhance its ability to protect public health and safety.

Issues included in this proposed rule:

(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, (6) Exempting most general licensees from immediate notification of losses and thefts, and (7) Clarifying requirements in § 31.5 for transfer of generally licensed devices to specifically licensed status.

Improving the reporting of exempt product/material distribution

This proposed rule would revise the reporting requirements of exempt product distributors from every 5 years to annually. Before 1983, these licensees were required to report annually; the requirement was changed to every 5 years in an attempt to reduce regulatory burden. However, experience has demonstrated that no significant burden reduction was achieved with the longer reporting period, because a longer record retention time was needed and compliance difficulties occurred. More significantly, the longer period has had detrimental impacts on the use and evaluation of the data available to the NRC, which has impacted the NRC's ability to assess the full impact on public health and safety. Minor changes to the content of reports would also be made. The proposed revisions to these reporting requirements would lead to improved effectiveness, efficiency, realism, and timeliness.

NRC licensing of introduction of exempt concentrations

Paragraph 150.15(a)(6) reserves for NRC the authority for licensing transfers to exempt persons. In a clarifying revision to that paragraph published April 16, 1969 (34 FR 6517), the reasons for NRC's retaining this authority were summarized as follows: "[T]he Commission was seeking to maintain surveillance over the safety of products containing radioactive materials, without the imposition of regulatory controls, and to be able to assess the effect of the attendant uncontrolled addition of these radioactive materials to the environment." This general intent, as well as the more specific related goals of the Consumer Product Policy (Attachment 2; discussed in SECY-02-0196), could not be well attained with multiple entities regulating such distribution. Thus, from a policy standpoint, all exempt product distributors should be licensed by the NRC, so that the national impact of products used under exemption would be known. From a regulatory standpoint, almost all distribution of byproduct material to exempt persons is required to be licensed by the NRC. However, in spite of § 150.15(a)(6), other provisions in NRC regulations allow Agreement States to license those who introduce byproduct material into products or materials for transfer as exempt concentrations (§ 30.14). Having this exception to NRC-only licensing of transfers to exempt persons 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. The proposed amendment would dictate that only NRC may authorize such introduction and transfer.

No Agreement State licensees of this type have yet been identified. The Agreement States were polled as to whether they had any such licensees; none were found. To supplement the license searches, members of the working group performed searches of the Thomas Register of businesses, and general online searches, and could not identify Agreement State businesses of this type.

Bundling of exempt quantities

The proposed rule would codify the Commission's position that multiple exempt quantities should not be combined. This practice circumvents the basic safety properties relied on in issuing the exemption, and is not consistent with the required label provided by the manufacturer, which states "... exempt quantities should not be combined." This proposed rule would amend NRC's regulations to specifically prohibit the combination of exempt quantities for the purpose of producing an increased radiation level.

Obsolete exemption provisions

Some exemptions from licensing are for obsolete products and would be discontinued. Such an exemption is no longer beneficial to the public. If the products were useful, they would still be marketed to the public because there is no regulatory burden on the end-user.

For the exemptions considered obsolete, no licensees were found who were authorized to distribute the products. Most of these exemptions are contained in § 30.15, "Certain items containing byproduct material." They are for automobile lock illuminators and shift quadrants, thermostat dials and pointers, balances of precision, marine compasses and other navigational instruments, and spark gap irradiators containing cobalt-60. In addition, certain materials tagged with scandium-46 are allowed to be used under § 30.16, "Resins containing

scandium-46 and designed for sand-consolidation in oil wells.” The proposed rule would remove these exemptions, except in the case of balances of precision and marine navigational aids, where the exemption would be limited to those products already distributed, as some of these products may still be functional. Relevant distributor requirements would also be removed for these products.

Only in the case of the exemption for resins containing scandium-46 is there the potential for significant doses if used. However, resins are no longer used as the primary cementing media in oil wells. Other products used under specific license have replaced these resins in sand consolidation operations. Removing this exemption would further ensure that this product will not be used without a license in the future.

Smoke detector product-specific exemption

This proposed rule would simplify licensing for new applicants to initially distribute smoke detectors by establishing a new product-specific exemption for ionization chamber smoke detectors containing no more than 1 μCi (37 kBq) 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 very consistently designed and the NRC has developed extensive licensing experience. The establishment of a new exemption for these products would also reduce fees for initial distributors of smoke detectors.

General licensee reporting requirements

The general licenses in §§ 31.5 and 31.7 require licensees to comply with § 20.2201, which contains criteria for the reporting of lost or stolen licensed material. Some generally licensed devices contain certain radionuclides in enough quantity to meet the criteria for immediate notification. The regulations would be amended to exempt most general licensees from the immediate notification of NRC when a device is lost or stolen. However, for devices subject to registration under § 31.5(c)(13), immediate notification of losses or thefts would continue to be required. For any other lost or stolen device to which these provisions currently apply, general licensees would still be required to provide 30-day notification under §§ 20.2201(a)(ii) and 20.2201(b). This change would apply a more realistic reporting framework, commensurate with general licensing and registration.

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. An increased number of specific licensees have transferred their authorization to possess and use a device held under the general license to their specific licenses. Doing so allows the specific licensee to avoid paying registration fees on some devices, and is allowed under § 31.5(c)(8). However, 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 NRC. The regulations would be amended to enhance regulatory clarity and to improve the ease of transfer of devices held under a general license to a specific license.

Outcome of this proposed rule: advancing NRC's strategic goals

These amendments would help to ensure that NRC actions are effective, efficient, realistic, and timely. Better data collection would improve the effectiveness and efficiency of NRC actions through the addition of certain new requirements and the elimination of certain requirements found to be no longer necessary. Based on regulatory, licensing, and enforcement experience, the staff has also identified the need to clarify regulations in response to unexpected interpretations of certain existing regulations. Additionally, some of the revisions would 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. Finally, the goal of ensuring openness in our regulatory process would be advanced because the NRC would 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 having representation on the working group, the Agreement States had an early opportunity to review a copy of the draft proposed rule posted on NRC's Technical Conference Forum.

Agreement States may be concerned with removing State authority to authorize the introduction of exempt concentrations for use under § 30.14 or equivalent. However, the working group has concluded that there are few, if any, Agreement State licensees authorizing distribution for use under § 30.14 or equivalent regulations. The total number of licensees authorized to distribute any product or material containing byproduct material for use under the various exemptions from licensing is slightly more than 100 nationally. It is expected that most Agreement States each have only one or no licensee in this category, although some have similar requirements governing the distribution of NARM (Naturally Occurring and Accelerator-Produced Radioactive Material), which does not come under the authority of the NRC. It would also be more effective and efficient to have one regulatory body license the distribution of byproduct material to exempt persons. **[To be updated after Agreement State review.]**

NRC staff has analyzed the proposed rule in accordance with the procedures established within Part III of Handbook 5.9 to Management Directive 5.9, "Categorization Process for NRC Program Elements." As the exemptions and the affected general licenses are Compatibility Category B, the Agreement States would have to amend their regulations for consistency. Regulations equivalent to §§ 32.11, 32.12, and 32.17 would be removed. Other revisions to Part 32 would not require changes to Agreement State regulations as they are Compatibility Category NRC. None of these revisions would impact the conduct of Agreement State regulatory programs.

STATUS OF FOLLOW-ON ACTIVITIES

During the development of this proposed rule, the staff continued to evaluate and develop those issues from the SRM to SECY-02-0196 that are not addressed in this proposed rule with a goal to issue a second rule as soon as the issues are resolved. The status of these issues is summarized as follows:

1. The staff is completing the risk assessment aspect of reviewing the quality control and prototype testing requirements and developing the best approaches to making the regulations less prescriptive in these areas.
2. The staff is developing additional technical bases to support the possible revision of the safety criteria for approving products to be used under general license or under exemption from license, as well as to establish safety criteria for the planned class exemption for industrial products. The staff is primarily concerned that higher quantities of byproduct material than currently used under these provisions could “pass” the existing criteria and believes that there may be reasons to limit quantities of materials used under exemptions and general licenses beyond just the expected resultant doses. Any action concerning the larger-quantity generally licensed devices previously approved is expected to be handled separately from the follow-on rulemaking arising from the subject rulemaking plan.
3. The contemplated change to § 30.20 (Issue 3 of Option 2 in the rulemaking plan) was deferred to the second rulemaking in order to first consider whether changes to the safety criteria for this exemption are warranted.
4. The staff will expand the considerations concerning making the Sealed Source and Device Registration requirements explicit in the regulations beyond those originally contemplated in developing the rulemaking plan. Additional considerations include whether or not registration certificates should have expiration dates and other 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.

One issue, originally recommended by the staff in the rulemaking plan and approved in the SRM to SECY-02-0196, has subsequently been identified as unfounded, and will not be further pursued. This issue involved the possibility of reducing radionuclide quantities allowed under the exemption for electron tubes to be closer to the lower quantities actually used because it was seen as a possible application of the as low as is reasonably achievable (ALARA) principle. However, recent and more complete information negates this premise. There are products in the marketplace with quantities up to the existing limits. Therefore, the issue is considered to be closed out, and no revision will be made to the exemption.

Finally, the staff is looking at other minor issues which might be included in the follow-on rulemaking, resulting from the ongoing work during development of the proposed rules.

RESOURCES:

The total cost to develop this rulemaking is estimated at 1.3 full-time equivalent positions and approximately \$50,000 in contractor support costs. The resources to complete the action are within the approved budget for FY 2005 and FY 2006. The final rule is projected to be provided to the Commission 10 months after the SRM on this paper, if the schedule is not impacted by shifting priorities or unforeseen circumstances.

COMMITMENTS:

No new actions or activities committed to by the staff in this paper. Tracking for a follow-on rulemaking has been established.

RECOMMENDATIONS:

That the Commission:

1. Approve for publication in the *Federal Register* the proposed amendments to Parts 30, 31, 32, and 150 (Attachment 1).
2. Note:
 - a. The Federal Register notice (FRN) will provide 75 days for public comment.
 - b. 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. A draft Regulatory Analysis has been prepared for this rulemaking (Attachment 3).
 - d. A draft Environmental Assessment (EA) has been prepared for this rulemaking (Attachment 4).
 - e. NUREG-1556, Volume 8, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Exempt Distribution Licenses," would require minor revisions for consistency with these proposed amendments to the regulations. Routine updating of this NUREG is due and is planned to begin following Commission action on this paper.
 - f. The appropriate Congressional committees will be informed of this action.
 - g. A draft Form XXX has been prepared for the use of distributors reporting transfers to exempt persons (Attachment 5).
 - h. A press release will be issued by the Office of Public Affairs when the proposed rule is filed with the Office of the Federal Register.
 - i. This proposed rule amends information collection requirements. However, the burden for these revisions to information collection is insignificant and Office of Management and Budget (OMB) clearance is not required.

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.

Copies of the draft FRN and EA for the proposed rule were posted on NRC's Technical Conference Forum for Agreement State review.

Luis A. Reyes
Executive Director
for Operations

Attachments:

1. Draft Federal Register Notice
2. Consumer Product Policy
3. Draft Regulatory Analysis
4. Draft Environmental Assessment
5. Draft Form XXX- "Report of Transfers to Exempt Persons"

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