

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: FINAL RULE: 10 CFR PARTS 30, 31, 32, 170, and 171 - "REQUIREMENTS FOR CERTAIN GENERALLY LICENSED INDUSTRIAL DEVICES CONTAINING BYPRODUCT MATERIAL" AND RELATED CHANGE TO THE ENFORCEMENT POLICY

PURPOSE:

To request Commission approval of: (1) a final rule that would explicitly require general licensees who possess certain devices containing byproduct material to register their devices, and add other provisions that are intended to improve the accountability of generally licensed devices, and (2) a change to the enforcement policy with respect to the loss, abandonment, or improper disposal of sources and devices.

BACKGROUND:

Individuals who possess devices under the general license in § 31.5 are not always aware of applicable requirements and thus are not necessarily complying with all of these requirements. The Commission has been most concerned about occurrences where generally licensed devices have not been handled or disposed of properly. In some cases, this has resulted in radiation exposure to the public and contamination of property. Some generally licensed devices have been accidentally melted in steel mills causing considerable contamination of the mill, the steel product, and the wastes from the process, the slag and the baghouse dust. Although known exposures have generally not exceeded the public dose limits, there is a potential for significant exposures.

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In an April 13, 1998, Staff Requirements Memorandum (SRM) (Attachment 1), responding to SECY-97-273, "Improving NRC's Control Over and Licensees' Accountability for Generally and Specifically Licensed Devices," the Commission directed the staff to terminate the 1991 rulemaking except for the provisions that would enable NRC to request information from certain general licensees to provide the regulatory basis for a registration program and to renotice those portions of the 1991 proposed rule for public comment. The final rule was published August 4, 1999 (64 FR 42269) and became effective October 4, 1999.

The April 13, 1998, SRM also directed the staff to develop, in a subsequent rulemaking, an explicit registration and follow-up program for generally licensed sources/devices identified by the NRC/Agreement State Working Group in NUREG-1551, to assess fees to these general licensees, and to incorporate requirements for the permanent labeling of sources/devices. The proposed rule notice was provided to the Commission in SECY-99-108, approved by an SRM of June 15, 1999, and published on July 26, 1999 (64 FR 40295). There were 39 comment letters received on the proposed rule. In response to these comments, some revisions have been made in the final rule (Attachment 2). Approval of the Office of Management and Budget (OMB) was requested on the proposed rule, but was not obtained. OMB deferred its decision until the final rule, so a clearance package is required for the final rule.

In the April 13, 1998, SRM (Item 6), the Commission also directed the staff to implement an enforcement program that includes a short amnesty program and increased civil penalties for both general and specific licensees for "lost" sources. The interim enforcement policy addressing the amnesty was presented to the Commission in SECY-98-303 and published March 9, 1999 (64 FR 11508). The Commission indicated that the increased civil penalties should be significantly greater than the costs of proper disposal or transfer of a source or device. The NRC/Agreement State Working Group recommended civil penalties in the range of 2 to 3 times the cost of authorized disposal. Due to the diversity of types of sources and devices, the staff is proposing the establishment of three levels of base civil penalty for lost sources: \$5,500, \$15,000, and \$45,000. The base civil penalty could be adjusted by the civil penalty adjustment factors in the current Enforcement Policy. In addition, in accordance with Section VII.A.1(g) of the current Enforcement Policy, enforcement discretion could be used to increase the civil penalty amount or to assess a civil penalty where application of the adjustment factors normally would result in zero civil penalty. Under the current Enforcement Policy, the base civil penalty at Severity Level I for a general licensee is \$5,500. The two higher tiers would be for sources that are relatively costly to dispose of and are based on 3 times the average cost of proper transfer or disposal of the sources or devices. A civil penalty of \$45,000 to a general licensee for loss or improper disposal would be approximately 8 times greater than the base civil penalty for other types of Severity Level I violations. The staff has prepared the change to the Enforcement Policy to incorporate these separate base civil penalties for loss, abandonment, or improper disposal of sources and devices (Attachment 3). It will be published in the Federal Register concurrent with this final rule and effective on publication.

DISCUSSION:

The final provisions delineating an annual registration requirement are essentially consistent with the registration process that is to be carried out under the first rule. Although OMB clearance was obtained for that rule, the staff is now seeking OMB clearance on the registration form. Once clearance is obtained, registration will begin. It is expected that the first round of registration will have begun before this final rule is published.

The criteria for determining which devices would be included in the registration program are those recommended by the working group. As part of the registration program, licensees will be asked to verify information concerning the identification and accountability of devices, the persons responsible for compliance with the regulations, and the disposition of the devices. The staff estimates that approximately 4300 general licensees will be required to provide registration information annually. As directed by the Commission, the final rule also adds a registration fee, effective after the first round of registrations is complete.

The final rule requires that general licensees under § 31.5 appoint a responsible individual through whom the general licensee will ensure day-to-day compliance with the regulations. The distributor of the generally licensed product would have to obtain the name, title, and phone number of this person from its customers, rather than simply a contact, and provide this information to the NRC or the Agreement State in quarterly transfer reports. For those registering devices, information on this responsible individual would be updated through the registration process. The serial numbers of devices would be added to the information reported in quarterly transfer reports and to reports of transfers by general licensees so that individual devices can be tracked. Additional labeling would be required to better ensure that devices can be identified as containing radioactivity and can also be traced back to the responsible party in the event of loss of control. There are some additional provisions intended to improve the accountability of devices generally licensed under § 31.5 and to clarify the regulations pertaining to all generally licensed products containing byproduct material.

The final rule is intended to better ensure that certain general licensees are aware of applicable requirements and can account for their devices. Communication with general licensees, accomplished primarily through registration, would provide NRC assurance of licensee accountability. The staff believes that if general licensees were more aware of their responsibilities, they would be more likely to comply with the requirements for proper handling and disposal of generally licensed devices. This would reduce the potential for incidents that could result in unnecessary radiation exposure to the public and contamination of property.

The final rule is also intended to better allow NRC and the Agreement States to keep track of general licensees, including tracking of specific devices. Tracking the general licensees is important so that they can be contacted and inspected as appropriate. Tracking will also allow devices to be traced back to the owner in the event that they have been found in inappropriate locations or if a generic defect is identified in a group of devices.

The draft final rule was provided to the Agreement States on the NRC Technical Conference Website. Their comments were considered in finalization of this rule package.

RESOURCES:

The resources needed to complete this action are in the current budget.

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 paper for resource implications and has no objections. The Office of the Chief Information Officer has reviewed the final rule for

information technology and information management implications and concurs in it. However, the final rule will amend information collection requirements. The package requesting approval will be forwarded to OMB following Commission approval of the final rule. Approval of the revisions to information collection requirements must be received from OMB before the rule is published in the Federal Register. This will take approximately 2 months.

RECOMMENDATIONS:

That the Commission:

1. Approve the notice of final rulemaking (Attachment 2).
2. Approve the revision to the enforcement policy (Attachment 3).
3. 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).
4. Note:
 - a. The rulemaking will be published in the Federal Register and will be effective 60 days after publication. Fee-related amendments will be effective
 - b. This rule has been reviewed by the Agreement States.
 - c. Neither an environmental impact statement nor an environmental assessment has been prepared because the provisions in this proposed rule are the types of actions described in the categorical exclusions in § 51.22(c)(1) through (3).
 - d. A regulatory analysis has been prepared and will be available in the Public Document Room (Attachment 4).
 - e. The appropriate Congressional committees will be informed.
 - f. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the reasons for it as required by the Regulatory Flexibility Act.
 - g. The final rule will amend information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.). These requirements will be forwarded to OMB for approval.
 - h. 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.
 - i. The staff has determined that this action is not a "major rule," as defined in the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 804(2)) and has confirmed this determination with OMB. The appropriate Congressional and General Accounting Office contacts will be informed (Attachment 5);

- j. An optional Form 653 will be made available for distributors' quarterly transfer reports. (Attachment 6)
- k. Final guidance for licenses for distribution to general licensees will be published within one month of the final rule. A brief appendix for use in providing guidance to § 31.5 general licensees is included.
- l. A document containing the public comments sorted by issue will be made available to the public. (Attachment 7)

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Attachments:

1. April 13, 1998, SRM
2. Draft Federal Register Notice for Final Rule
3. Draft Federal Register Notice for Enforcement Policy
4. Regulatory Analysis
5. Notification for Congressional Review "Small Business
Regulatory Enforcement Fairness Act of 1996" (SBREFA forms)
6. Draft Form 653 - "Transfers of Industrial Devices Report"
7. Public comments sorted by subject

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RECORD NOTE: A draft copy of the final rule was sent to OIG for information on.

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