

RULEMAKING ISSUE AFFIRMATION

May 15, 2000

SECY-00-0106

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: FINAL RULE: 10 CFR PARTS 30, 31, and 32 - "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 would 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 transfer or 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 may not be 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 (i.e., 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 a Staff Requirements Memorandum (SRM) dated April 13, 1998 (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, in part, to carry out three major activities:

- (1) Terminate the rulemaking on 10 CFR Part 31.5 that was initiated in 1991 except those provisions that would enable NRC to request information from certain general licensees to provide the regulatory basis for initiation of a registration program and renotice those portions of the 1991 proposed rule for public comment.
- (2) Develop a proposed rule to implement a 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.
- (3) Implement an enforcement program that includes a short amnesty program and increased civil penalties for both general and specific licensees for "lost" sources.

To accomplish the SRM directives, the staff initiated two rulemakings, one to establish the regulatory basis for a registration program and a second, more comprehensive rule that includes details of a registration and follow-up program.

Rulemaking to Provide Regulatory Basis (Rule 1)

The proposed rule complying with the Commission's direction was published on December 2, 1998. The staff published a final rule on August 4, 1999 (64 FR 42269) which became effective October 4, 1999. That rule did not require compatibility of Agreement State regulations.

Rulemaking to Implement Registration and Follow-up Program (Rule 2)

The proposed rule notice was provided to the Commission in SECY-99-108, approved by an SRM dated 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). Office of Management and Budget (OMB) approval was requested on the proposed rule, but was not obtained. OMB deferred its decision until the final rule, so that it could review the public comments received on the proposed rule. Therefore, a clearance package is required for the final rule.

Enforcement Program

The interim enforcement policy addressing the amnesty program 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. The staff has prepared the change to the Enforcement Policy to incorporate separate base civil penalties for loss, abandonment, or improper transfer or 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 provisions in this final rule (Rule 2) delineating an annual registration requirement are consistent with the regulatory basis established under Rule 1. Although OMB clearance was obtained for Rule 1, the staff is now preparing a separate OMB clearance package on the registration form. The staff originally scheduled registration to begin by June 2000, with the understanding that the OMB approval received for Rule 1 was adequate to begin registration. However, the staff was recently informed by OMB that a separate clearance is needed for the registration form, which will take about 6 months. Once that package is submitted and clearance is obtained on the registration form, registration may begin. Depending on the timing of the two OMB clearances, the first round of registration may begin before this more comprehensive 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 acting for the general licensee to ensure 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, a registration fee will be required after the first round of registration is complete. The final fee will be established as part of the FY 2001 fee rulemaking. The fee is not being finalized at this time because NMSS anticipates that the first registrations subject to the registration fee will not be filed until FY 2002. Therefore, the final fee will be established as part of the FY 2001 notice and comment fee rulemaking, based on that year's budgeted costs and FTE rates, and the number of registrants. Based on current information, we anticipate the fee would be approximately \$440 - \$450.

The final rule will require 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 will be required 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 will be updated through the registration process. The serial numbers of devices will 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 will 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 provide greater assurance 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 information on

specific devices 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.

Some changes to the proposed Agreement State Compatibility Categories have been made in the final rule. Section 31.5, with the exception of the registration provision, will be Compatibility Category B, rather than the proposed Category C, in order to address transboundary implications. A draft of the 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 3 months after Commission approval.

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.
 - 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 final 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)

- m. A copy of the final rule, other regulations that are to be distributed to recipients of a new generally licensed device, and the change to the enforcement policy will be sent to all current general licensees.

/RA/

William D. Travers
Executive Director
for Operations

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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