

RULEMAKING ISSUE
AFFIRMATION

SECY-00-0106

May 15, 2000

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:**
- **BACKGROUND:**
 - Rulemaking to Provide Regulatory Basis (Rule 1)
 - Rulemaking to Implement Registration and Follow-up Program (Rule 2)
 - Enforcement Program
- **DISCUSSION:**
- **RESOURCES:**
- **COORDINATION:**
- **RECOMMENDATIONS:**

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.

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 renote 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 **EXIT** 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.

CONTACT: Catherine Mattsen, NMSS/IMNS
(301) 415-6264

- 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](#) 

ATTACHMENT 3

[7590-01-P]

NUCLEAR REGULATORY COMMISSION [NUREG - 1600]

Base Civil Penalties for Loss, Abandonment, or Improper Transfer or Disposal of Sources; Policy Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy Statement.

SUMMARY: The Nuclear Regulatory Commission is amending its "General Statement of Policy and Procedure for NRC Enforcement Actions," (NUREG-1600) (Enforcement Policy or Policy) to establish separate base civil penalty amounts for loss, abandonment, or improper transfer or disposal of sealed sources and devices containing NRC-licensed material.

DATES: This action is effective upon publication in the *Federal Register*. Comments on this revision should be submitted by (insert date 30 days from date of publication in the *Federal Register*), and will be considered by the NRC before the next revision of the Enforcement Policy.

ADDRESSES: Submit written comments to: David L. Meyer, Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, Mail Stop: T6D59, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001. Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m., Federal workdays. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street, N.W. (Lower Level), Washington, D.C.

The NRC's Office of Enforcement maintains the current policy statement on its homepage on the Internet at </about-nrc/regulatory/enforcement.html>.

FOR FURTHER INFORMATION CONTACT: Bill Borchardt, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Telephone (301) 415-2741, e-mail rwb1@nrc.gov.

SUPPLEMENTARY INFORMATION:

- [Background](#)
- [Scope](#)
- [Paperwork Reduction Act](#)
- [Public Protection Notification](#)
- [Small Business Regulatory Enforcement Fairness Act](#)
- [GENERAL STATEMENT OF POLICY AND PROCEDURE FOR NRC ENFORCEMENT ACTIONS](#)
 - [VI. ENFORCEMENT ACTIONS](#)
 - [C. Civil Penalty](#)
 - [1. Base Civil Penalty](#)
 - [Table 1A. --Base Civil Penalties](#)
 - [VII. Exercise of Discretion](#)
 - [A. Escalation of Enforcement Sanctions](#)

- o 1. Civil Penalties

Background

In a companion final rule published in today's *Federal Register*, the NRC is amending its regulations in 10 CFR Parts 30, 31, and 32, governing certain industrial devices containing byproduct material that are licensed pursuant to the general license provisions of 10 CFR 31.5. A proposed rule was published in the *Federal Register* on July 26, 1999 (64 FR 40295), which indicated that the NRC planned to increase the civil penalty amounts specified in its Enforcement Policy for violations involving sources or devices that are lost or improperly disposed of. The stated intent was to better relate the civil penalty amount to the costs avoided by the failure to properly dispose of the source or device.

In the notice of proposed rulemaking, the Commission stated that it was considering three levels of base civil penalty for loss or improper disposal, with the higher tiers for sources that are relatively costly to dispose of. The three levels of base civil penalty would be \$5,500, \$15,000, and \$45,000. The three tiers would be based approximately on three times the average cost of proper transfer or disposal of the source or device. The intent was to better relate the civil penalty amount to the costs avoided by the failure to properly dispose of the source or device.

In this Enforcement Policy, the change to the base civil penalty structure considers both the cost of proper disposal and the relative risk to the public from sources that are lost, abandoned, or improperly transferred or disposed of. The Commission believes that a base civil penalty amount roughly equivalent to three times the cost of proper disposal will provide for sufficient deterrence and an economic incentive for licensees to expend the necessary resources to ensure compliance. If the civil penalty were less than the cost of proper disposal, the licensee would receive an economic benefit from an improper disposal, whether intentional or not. A civil penalty roughly equivalent to the cost of disposal may not provide a sufficient deterrent because the violation could go undetected, which would still allow an economic benefit. Additionally, the civil penalty amount should be sufficient to assure that the cost of proper disposal of sealed sources and devices does not cause licensees to purposefully violate applicable disposal requirements.

Sources and devices containing small amounts of radioactive material, such as gas chromatographs, and devices containing hydrogen-3 (tritium) can be disposed of for less than one third of the lowest base civil penalty amount under the current Enforcement Policy, which is \$5,500. It would be illogical to establish a *lower* base civil penalty amount specifically for loss, abandonment, or improper transfer or disposal. Therefore, this action establishes \$5,500 as the lowest base civil penalty amount for these violations.

The companion final rule to this Enforcement Policy incorporates criteria for registration of devices containing material of the types and quantities listed in 10 CFR 31.5(c)(13)(i). These are devices containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, and 37 MBq (1 mCi) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)). Annual registration is being required for these devices because they are considered to present a higher risk for potential exposure to the public and for loss of property (due to contamination) if the device is lost, abandoned, or improperly transferred or disposed of. Based on the higher risk, violations involving loss, abandonment, or improper transfer or disposal of sources and devices in this category have been assigned a base civil penalty amount of \$15,000.

With the exception of sources and devices containing hydrogen-3 (tritium), the highest activity sources and devices (i.e., those with activities greater than 3.7×10^4 MBq (1 Curie)), have an approximate average cost of disposal of \$15,000. The base civil penalty amount for loss or improper disposal of these sources and devices has been set at \$45,000, which is three times the average cost of disposal.

The Commission believes that normally a civil penalty at least in the amount of the base civil penalty is appropriate in the case of loss, abandonment, or improper transfer or disposal of a sealed source or device. This is to ensure that the associated enforcement action properly reflects the significance of such violations. This change has been implemented in Section VII.A.1(g) of the Enforcement Policy. However, NRC may mitigate or escalate a civil penalty amount, as provided in the Enforcement Policy, based on the merits of a specific case. In doing so, NRC may consider information concerning the actual expected cost of authorized disposal and the actual consequences of the loss, abandonment, or improper transfer or disposal.

Scope

The base civil penalties established in this change to the Enforcement Policy apply to violations that involve loss, abandonment, or improper transfer or disposal of a sealed source or device, regardless of the use or the type of licensee.

Paperwork Reduction Act

This final change to the NRC Enforcement Policy does not contain new or amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a "major" rule and has verified this determination with the Office of Information and Regulatory Affairs, Office of Management and Budget.

Accordingly, the NRC Enforcement Policy is amended to read as follows:

GENERAL STATEMENT OF POLICY AND PROCEDURE FOR NRC ENFORCEMENT ACTIONS

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VI. ENFORCEMENT ACTIONS

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C. Civil Penalty

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1. Base Civil Penalty

The NRC imposes different levels of penalties for different severity level violations and different classes of licensees, contractors, and other persons. Violations that involve loss, abandonment, or improper transfer or disposal of a sealed source or device are treated separately, regardless of the use or the type of licensee. Tables 1A and 1B show the base civil penalties for various reactor, fuel cycle, and materials programs, and for loss, abandonment or improper transfer or disposal of a sealed source or device. (Civil penalties issued to individuals are determined on a case-by-case basis.) The structure of these tables generally takes into account the gravity of the violation as a primary consideration and the ability to pay as a secondary consideration. Generally, operations involving greater nuclear material inventories and greater potential consequences to the public and licensee employees receive higher civil penalties. Regarding the secondary factor of ability of various classes of licensees to pay the civil penalties, it is not the NRC's intention that the economic impact of a civil penalty be so severe that it puts a licensee out of business (orders, rather than civil penalties, are used when the intent is to suspend or terminate licensed activities) or adversely affects a licensee's ability to safely conduct licensed activities. The deterrent effect of civil penalties is best served when the amounts of the penalties take into account a licensee's ability to pay. In determining the amount of civil penalties for licensees for whom the tables do not reflect the ability to pay or the gravity of the violation, the NRC will consider necessary increases or decreases on a case-by-case basis. Normally, if a licensee can demonstrate financial hardship, the NRC will consider payments over time, including interest, rather than reducing the amount of the civil penalty. However, where a licensee claims financial hardship, the licensee will normally be required to address why it has sufficient resources to safely conduct licensed activities and pay license and inspection fees.

Table 1A.--Base Civil Penalties

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f. Loss, abandonment, or improper transfer or disposal of a sealed source or device, regardless of the use or type of licensee⁽¹⁾:

- 1. Sources or devices with a total activity greater than 3.7×10^4 MBq (1 Curie), excluding hydrogen-3 (tritium) \$45,000
- 2. Other sources or devices containing the materials and quantities listed in 10 CFR 31.5(c)(13)(i) \$15,000
- 3. Sources and devices not otherwise described above \$5,500

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VII. Exercise of Discretion

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A. Escalation of Enforcement Sanctions

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1. Civil Penalties

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(g) Cases Involving the loss, abandonment, or improper transfer or disposal of a sealed source or device. Notwithstanding the outcome of the normal civil penalty assessment process, these cases normally should result in a civil penalty of at least the base amount; or

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Dated at Rockville, Maryland, this _____ day of _____, 2000.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.

1. These base civil penalty amounts have been determined to be approximately three times the average cost of disposal. For specific cases, NRC may adjust these amounts to correspond to three times the actual expected cost of authorized disposal.