

December 29, 1998

FOR: The Commissioners

FROM: William D. Travers /s/  
Executive Director for Operations

SUBJECT: INTERIM ENFORCEMENT POLICY REGARDING PROPOSED NEW REQUIREMENTS FOR THE POSSESSION OF INDUSTRIAL DEVICES CONTAINING BYPRODUCT MATERIAL (10 CFR 31.5)

**PURPOSE:**

To obtain the Commission's approval to revise the NRC Enforcement Policy to include an interim policy on the exercise of enforcement discretion for certain violations of requirements in [10 CFR Part 31](#) for generally licensed devices containing byproduct material.

**BACKGROUND:**

In [SECY-98-199](#), the staff requested Commission approval to publish a proposed rule that would explicitly require persons who have received certain devices under a general license to provide the NRC with information about their possession and use of the devices. The intent of this new provision is to institute a registration and accounting system for generally licensed devices containing certain quantities of specific radionuclides.

The proposed rule states that the Commission intends to establish an interim enforcement policy to provide that enforcement action normally will not be taken for violations of [10 CFR 31.5](#) identified by a general licensee if appropriate corrective action is taken. This interim policy would remain in effect through one complete cycle of the registration program envisioned by the proposed rule.

The Commission approved publication of the proposed rule in the enclosed Staff Requirements Memorandum (SRM) ([Encl. 1](#)) dated October 23, 1998. In the SRM, the Commission directed the staff to develop the interim enforcement policy prior to the final rule, in the event that there is a need to "grant amnesty" in a specific situation identified as a result of the initial mailing of the proposed rule to general licensees for comment.

**DISCUSSION:**

The staff proposes to amend the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, Rev. 1, by adding Appendix D to the policy ([Encl. 2](#)). Appendix D describes the interim enforcement policy that the NRC will follow to exercise enforcement discretion for violations identified as a result of the proposed new requirement that persons licensed pursuant to the general license provision in 10 CFR 31.5 provide the NRC with information about the possession and use of their generally licensed devices. It addresses violations that persons licensed pursuant to 10 CFR 31.5 discover and report now, as well as during the initial cycle of the notice and response program contemplated by the proposed new requirement. Under this interim enforcement policy, enforcement action normally will not be taken for violations of 10 CFR 31.5 if they are identified by the general licensee, and reported to NRC if reporting is required, provided that the general licensee takes appropriate corrective action to address the specific violations and prevent recurrence of similar problems.

This change from the Commission's normal enforcement policy is intended to remove the potential for the threat of enforcement action to be a disincentive for the licensee to identify deficiencies. This approach is warranted given the limited NRC inspections of general licensees. It is intended to encourage general licensees to determine if applicable requirements have been met, to search their facilities to assure that sources are located, and to develop appropriate corrective action when deficiencies are found.

Under this interim enforcement policy, enforcement action, including issuance of civil penalties and Orders, still will be considered where there is: (a) failure to take appropriate corrective action to prevent recurrence of similar violations; (b) failure to respond and provide the information required by the notice and response program (if it becomes a final rule); (c) failure to provide complete and accurate information to the NRC; or (d) a willful violation, such as willfully disposing of generally licensed material in an unauthorized manner.

**RESOURCES:**

The resources required to implement this interim enforcement policy are included in the office's currently approved budget.

**RECOMMENDATION:**

The staff recommends that the Commission approve publication of Appendix D to the Enforcement Policy as enclosed.

**COORDINATION:**

The Office of the General Counsel has no legal objection to this paper. 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 this paper and has no information technology or information management concerns.

**Notes:**

1. Appendix D to the Enforcement Policy will become effective upon publication in the *Federal Register*. Comments will be accepted for 30 days after

publication, and will be considered prior to the next revision to the Enforcement Policy.

2. This change does not contain information collection requirements that are subject to the Paperwork Reduction Act.

3. The staff has determined that this is not a "major" rule as defined in the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 804(2).

William D. Travers  
Executive Director for Operations

CONTACT: James Lieberman, OE  
415-2741

Enclosures: 1. [SRM dated October 23, 1998](#)  
2. [Federal Register notice with Appendix D to the Enforcement Policy](#)

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ENCLOSURE 2

NUCLEAR REGULATORY COMMISSION  
[NUREG - 1600, REV. 1]

Policy and Procedure for NRC Enforcement Actions; Interim Enforcement Policy  
for Generally Licensed Devices Containing Byproduct Material (10 CFR 31.5)

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy statement.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, Rev. 1, by adding Appendix D to the policy. This amendment describes the interim enforcement policy that the NRC will follow to exercise enforcement discretion for certain violations of requirements in [10 CFR Part 31](#) for generally licensed devices containing byproduct material. It addresses violations that persons licensed pursuant to [10 CFR 31.5](#) identify and correct now, as well as during the initial cycle of the notice and response program contemplated by the proposed new requirements published in the Federal Register on December 2, 1998 (63 FR 66492), entitled "Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information".

DATES: This action is effective upon publication. Comments on this interim enforcement policy should be submitted within 30 days of publication in the Federal Register and will be considered by the NRC prior to 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, DC 20555. Hand deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm, Federal workdays. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street, NW, (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001, (301) 415-2741.

SUPPLEMENTARY INFORMATION:

- [Background](#)
- [Scope](#)
- [Paperwork Reduction Act](#)
- [Public Protection Notification](#)
- [Small Business Regulatory Enforcement Fairness Act](#)
- [Appendix D: Interim Enforcement Policy for Generally Licensed Devices Containing Byproduct Material \(10 CFR 31.5\)](#)
  - [Exercise of Enforcement Discretion](#)
  - [Exceptions](#)

BACKGROUND

In a separate action published in the Federal Register on December 2, 1998 (63 FR 66492), the NRC is proposing to amend its regulations in 10 CFR Part 31 to provide for more frequent and timely contact between the NRC and users of certain industrial devices containing byproduct material that are licensed pursuant to the general license provisions of 10 CFR 31.5. The NRC is proposing this rule after concluding that there is a lack of awareness of

NRC regulatory requirements on the part of the user of the general license (general licensee). In addition, there is evidence of inadequate handling of and accounting for generally licensed devices. Under the proposed rule, if finalized, the NRC intends to send notices to certain classes of persons licensed pursuant to the general license provisions of 10 CFR 31.5. These notices would require recipients to provide information to the NRC, as requested, concerning products that they have received under the general license.

For further information regarding these proposed new requirements, the reader is referred to the Statements of Consideration that accompany the proposed rule. As noted therein, the NRC anticipates that general licensees may discover violations of NRC regulatory requirements as a result of the proposed new requirement to respond to notices and provide information as requested. For example, general licensees who have not had contact with the NRC for many years may have failed to test for leakage of radioactive material from the generally licensed device, maintain the labels affixed to the device, or comply with the instructions and precautions in the labels. Additionally, general licensees may discover violations when copies of the proposed rule are mailed to them. For example, a general licensee that has changed its address of business may have abandoned or improperly transferred a generally licensed device during the process of moving. Under the current NRC Enforcement Policy published in NUREG-1600, Rev. 1., such violations normally would result in enforcement action.

#### SCOPE

This interim enforcement policy addresses violations that persons licensed pursuant to 10 CFR 31.5 discover and report before, as well as during, the initial cycle of the notice and response program contemplated by the proposed rule described above. It will remain in effect through at least July 1, 2000, by which time it is expected that one complete cycle of the notice and response program will be completed. However, any delays in completing the first cycle of notice and response will be taken into account, and the effective time period of this interim enforcement policy will be lengthened accordingly.

Under this interim enforcement policy, enforcement action normally will not be taken for violations of 10 CFR 31.5 if they are identified by the general licensee and reported to the NRC, if reporting is required, provided that the general licensee takes appropriate corrective action to address the specific violations and prevent recurrence of similar problems. This change from the Commission's normal enforcement policy is to remove the potential for the threat of enforcement action to be a disincentive for the licensee to identify deficiencies. This approach is warranted given the limited NRC inspections of general licensees. This approach is intended to encourage general licensees to determine if applicable requirements have been met, to search their facilities to assure that sources are located, and to develop appropriate corrective action when deficiencies are found. Under this interim enforcement policy, enforcement action, including issuance of civil penalties and Orders, may be taken where there is: (a) failure to take appropriate corrective action to prevent recurrence of similar violations; (b) failure to respond and provide the information required by the notice and response program (if it becomes a final rule); (c) failure to provide complete and accurate information to the NRC; or (d) a willful violation, such as willfully disposing of generally licensed material in an unauthorized manner.

#### PAPERWORK REDUCTION ACT

This policy statement amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements have been submitted to the Office of Management and Budget (OMB) for review and approval under OMB number 3150-0016.

#### PUBLIC PROTECTION NOTIFICATION

If 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 by adding Appendix D as follows:

#### GENERAL STATEMENT OF POLICY AND PROCEDURE FOR NRC ENFORCEMENT ACTIONS

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#### Appendix D: Interim Enforcement Policy for Generally Licensed Devices Containing Byproduct Material (10 CFR 31.5)

This Appendix sets forth the interim enforcement policy that the NRC will follow to exercise enforcement discretion for certain violations of requirements in 10 CFR Part 31 for generally licensed devices containing byproduct material. It addresses violations that persons licensed pursuant to 10 CFR 31.5 identify and correct now, as well as during the initial cycle of the notice and response program contemplated by the proposed new requirements published in the Federal Register on December 2, 1998 (63 FR 66492), entitled "Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information".

#### EXERCISE OF ENFORCEMENT DISCRETION

Under this interim enforcement policy, enforcement action normally will not be taken for violations of 10 CFR 31.5 if they are identified by the general licensee, and reported to the NRC if reporting is required, provided that the general licensee takes appropriate corrective action to address the specific violations and prevent recurrence of similar problems.

#### EXCEPTIONS

Enforcement action may be taken where there is: (a) failure to take appropriate corrective action to prevent recurrence of similar violations; (b) failure to respond and provide the information required by the notice and response program (if it becomes a final rule); (c) failure to provide complete and accurate information to the NRC; or (d) a willful violation, such as willfully disposing of generally licensed material in an unauthorized manner. Enforcement sanctions in these cases may include civil penalties as well as Orders to modify or revoke the authority to possess radioactive sources under the general license.

Dated at Rockville, Maryland, this day of , 1999.

For the Nuclear Regulatory Commission.

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Annette Vietti-Cook,  
Secretary of the Commission