

December 29, 1998

SECY-98-303

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.

CONTACT:
James Lieberman, OE
415-2741

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.

CONTACT:

James Lieberman, OE
415-2741

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

Enclosures:

1. SRM dated October 23, 1998
2. *Federal Register* notice with Appendix D to the Enforcement Policy

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October 23, 1998

MEMORANDUM TO: William D. Travers
Executive Director for Operations

Anthony J. Galante
Chief Information Officer

FROM: John C. Hoyle, Secretary /s/

SUBJECT: STAFF REQUIREMENTS - SECY-98-199 - PROPOSED RULE: 10
CFR PART 31 -- "REQUIREMENT FOR THOSE WHO
POSSESS CERTAIN INDUSTRIAL DEVICES CONTAINING
BYPRODUCT MATERIALS TO PROVIDE REQUESTED
INFORMATION"

The Commission has approved publication of the proposed rulemaking for 10 CFR Part 31.5 with the changes indicated in the attachment.

(EDO) (SECY Suspense: 11/20/98)

The staff should provide the Commission with its best estimate of the schedule and milestones necessary to complete the automated registration system once the business case has been completed and reviewed by the Information Technology Business Council, and the recommended alternative has been approved by the EC (if the project cost is over \$500K) or the CIO (if the project cost is less than \$500K).

(EDO) (SECY Suspense: 1/20/99)

The staff should continue to work closely with the Office of the Chief Information Officer (OCIO) to ensure that the automated registration system is developed in a timely manner. In order to control the costs of the automated system, the staff should critically evaluate the program needs. In evaluating alternatives, the staff should explore options such as commercial-off-the-shelf registration software and registration software available from the States or other government agencies that would be sufficiently capable of meeting the basic information capture, recording, and response requirements of the device registration program. The OCIO should ensure that resources devoted to the CPIC analysis are "scaled to the size and complexity of the proposed IT investment" and do not impose "an undue burden on the NRC program staff" (as discussed in SECY-98-032).

Full implementation of the registration program should commence no later than deployment of the automated registration system. In the interim, the staff should take the following steps to address potential safety significant situations. Since the staff plans to forward the proposed rule to affected general licensees for information purposes, the staff should plan to "screen" any information received as a result of this mailing. Specifically, the staff should make available

resources to triage the incoming information based on its safety significance, establish simple criteria for determining when, and what type of, follow up action is commensurate with the potential public health and safety risk associated with the device, and perform limited scope inspections when indicated. Follow up activities could range from a simple telephone contact to a limited scope inspection to confirm source identification, location and disposition. Disposition of the information collected in such follow up activities should also be based on its safety significance. This process does not have to be an elaborate one but is intended to identify those situations that, from a public health and safety perspective, warrant action. To complete this approach, the staff should consider developing the interim enforcement policy prior to the final rule—as currently planned by the staff—in the event that there is a need to “grant amnesty” in a specific situation identified as a result of the initial mailing to general licensees discussed above. Regardless of when the interim enforcement policy is implemented, the staff’s plan should remain in effect through one complete cycle of the registration program. Also, the Federal Register should be revised accordingly.

Regarding the second more comprehensive rule -- the staff should involve the Conference of Radiation Control Program Directors and Agreement States early in the rulemaking process by sharing the draft rule language at the earliest opportunity and including Agreement State and non-Agreement State representation on the Part 31 rule-writing team. This approach will help ensure timely resolution of such key issues as additional device labeling requirements and compatibility.

Attachment:
As stated

cc: Chairman Jackson
Commissioner Diaz
Commissioner McGaffigan
OGC
CFO
OCA
OIG
OPA
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR
DCS

Editorial Changes to Attachments to SECY-98-199

Changes to the Federal Register Notice:

4. On page 1, paragraph 1, line 2, change 'use' to 'possess.'
5. On page 4, first full paragraph, line 3, insert 'exposure' after 'radiation.'
6. On page 8, after item 3, insert a new item as follows: '4. The location of the devices.'

Changes to the Regulatory Analysis:

1. In page 15, in item 4.2, line 1, add an 's' to 'result.'
2. On page 21, first full paragraph, lines 4-5, delete the remainder of the sentence after 'devices.'
3. On page 24, last paragraph, line 3, delete the 's' on 'licensees.'

Changes to the Congressional Letters:

- In paragraph 1, line 3, replace 'add an explicit requirement' with 'explicitly require.' In line 4, replace 'provide NRC with' with 'respond to NRC requests for.' In lines 5-6, delete 'as requested by NRC.' In the last line, add 'that are primarily used in commercial and industrial applications' after 'radionuclides'.
- In paragraph 2, add a new first sentence as follows: 'NRC has observed a number of instances in the past where generally-licensed devices have not been properly handled or disposed of.' In line 2, insert 'there by' after 'and.'

Changes to the Press Release:

1. On page 1, paragraph 1, line 1, insert 'in Part 31' after 'regulations.' In line 3, delete the first 'the.'
2. On page 1, paragraph 3, line 6, insert 'unnecessary' before 'radiation.'
3. On page 2, paragraph 2, line 1, insert 'certain' before 'general.' Add a new sentence to the end of the paragraph as follows: 'About 6,000 general licensees possessing about 24,000 devices will come under the registration requirement.'

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

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

* * * * *

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

