

April 17, 2000

MEMORANDUM TO: Paul H. Lohaus, Director, STP

Jesse L. Funches, CFO

Stuart Reiter, CIO

Joseph R. Gray, Associate General  
Counsel for Licensing and Regulation, OGC

William Borchardt, Director, OE

David L. Meyer, Chief, RDB, ADM

Brenda Jo Shelton, Chief, IRMB, OCIO

FROM: Donald A. Cool, Director  
Division of Industrial and  
Medical Nuclear Safety, NMSS

SUBJECT: OFFICE REVIEW AND CONCURRENCE: FINAL RULE TO AMEND 10  
CFR PARTS 30, 31, 32, 170, and 171, "REQUIREMENTS FOR  
CERTAIN GENERALLY LICENSED INDUSTRIAL DEVICES  
CONTAINING BYPRODUCT MATERIAL"

Your concurrence is requested on the attached Commission paper forwarding the Federal Register notice for the subject final rule.

1. Title: Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material, 10 CFR Parts 30, 31, 32, 170, and 171
2. Requested Action: Office concurrence.
3. NMSS Task Leader: Catherine R. Mattsen, 415-6264
4. Working Group Members on your staff:

Maria Schwartz, OGC	415-1888
Jim Myers, STP	415-2328
J. DelMedico, OE	415-2739
Diane Dandois, OCFO	415-7544

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

5. Background: In an SRM dated April 13, 1998, the Commission directed the staff to terminate the rulemaking on 10 CFR 31.5 that was initiated in 1991, except for those provisions that would enable NRC to request information from certain general licensees to provide the regulatory basis for initiation of a registration program. Also in that SRM, the Commission directed the staff to develop, in a subsequent rulemaking, a registration and followup program for generally licensed sources/devices identified by the NRC/Agreement States Working Group in NUREG-1551, apply fees to these general licensees, and incorporate requirements for permanent labeling of sources/devices. Other items in the SRM included the development of an enforcement policy with a short amnesty program followed by increased civil penalties for lost or improperly disposed sources. The Interim Enforcement Policy describing the amnesty program was published on March 9, 1999 (64 FR 11508). The revision of the Enforcement Policy to add separate base penalties for loss, abandonment, and improperly disposed sources and devices is an attachment to this Commission paper.

The first of these rules was published in final on August 4, 1999, and contained an explicit requirement for general licensees to provide information to the NRC, as requested, concerning products that they have received for use under the general license. That provision is to be used primarily to institute a registration and accounting system for devices containing certain quantities of specific radionuclides. The licensees will be asked to verify information concerning the identification and accountability of the devices, the persons responsible for compliance with the regulations, and the disposition of the devices.

This is the second, more comprehensive rule included in the SRM of April 13, 1998 and proposed on July 26, 1999. It includes provisions to allow more complete tracking of devices by NRC, additional device labeling requirements, provisions to improve licensees' awareness of the regulations, some miscellaneous provisions for general licensees, and the addition of a fee. Thirty-nine comment letters were received on the proposed rule. The public comments on the rule have been considered in the development of this final rule.

Both of these rulemakings together are intended to ensure that general licensees are aware of and understand the requirements for the possession of devices containing byproduct material and to assure accountability for devices which have been distributed for use under the general license, thus reducing the potential for incidents that could result in unnecessary radiation exposure to the public and contamination of property. Additionally, the registration fee is specifically being added in order to improve equity under the requirements for full cost recovery.

6. Requested Completion Date: To meet the Commission due date, concurrence is requested by April 26, 2000. A meeting will be scheduled on or about April 27, 2000, to discuss and resolve any remaining issues/concerns including those raised in Agreement State comments. Please plan on having an official who can concur for your office available for this meeting. If there are no outstanding issues and all concurrences are received, this meeting will be canceled.

7. Steering Group: None
8. Enhanced Public Participation: No.
9. Compatibility for Agreement States: Yes. The draft final rule was sent to the Agreement States on March 24, 2000. Comments will be addressed with any office comments received.
10. Resources and Coordination: A copy of this concurrence package has been forwarded to the IG for information. Time for review of this package should be charged to RITS No. 231CD, TAC No. L20327.

Attachment: Commission Paper w/attachments

cc w/att:

H. T. Bell, OIG

H. Miller, RI/ORA

L. Reyes, RII/ORA

J. E. Dyer, RIII/ORA

E. W. Merschoff, RIV/ORA

W. Kane, NMSS

M. Virgilio, NMSS

W. Beecher, OPA

8. Enhanced Public Participation: No.
9. Compatibility for Agreement States: Yes. The draft final rule was sent to the Agreement States on March 24, 2000. Comments will be addressed with any office comments received.
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\*See previous concurrences.

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