

From: Elise A. Heumann (EAH1)
To: SAM2
Date: Monday, June 12, 1995 9:55 am
Subject: OC concurrence: Medical Administration

NOTE TO: Steve McGuire, RES

FROM: Elise Heumann, OC/DBA

SUBJECT: OC REVIEW OF FINAL RULE - MEDICAL ADMINISTRATION OF
RADIATION AND RADIOACTIVE MATERIALS

OC has reviewed the subject rulemaking in response to D.L. Morrison's May 30, 1995 request for OC coordination.

OC reviewed the proposed rule in October 1994. No resources were needed to implement the proposed rule, amending NRC regulations to clarify that the medical administration of radiation or radioactive materials to any individual is regulated by the provisions of 10 CFR Part 35 and not by 10 CFR Part 20. This final rulemaking takes into consideration the comments received on the proposed rule. No significant changes were made from the proposed rule. OC therefore finds that there are no resource-related issues and concurs in the final rulemaking package.

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OC Action item: OC-95-131
DBA Action item: DBA-95-137
DBA File: NML-2.7

CC: djc2, jde, sls

XA - VO

9605150043 2pp

RESEARCH ACTION ITEM

May 12, 1994

MAIL CONTROL FORM

12:45 pm

FROM: J. HOYLE
TO: J. TAYLOR
ACTION NECES/APPR?: N

FOIA No.:

RES No.: **940144**
EDO No.:
WITS No.: 9400099

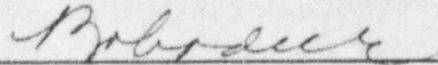
DESCRIPTION: **SECY 94027, ADMIN OF A RADIOPHARMACEUTICAL TO THE WRONG PATIENT**

SPECIAL INSTRUCTIONS:

DOCUMENT DATE: May 10, 1994
DUE TO RES: **October 18, 1994**

RECEIVED BY RES: May 12, 1994
DUE TO EDO: **October 21, 1994**

ASSIGNED TO: **B. MORRIS, DRA**
FOR SIGNATURE OF:



ROUTING:
E. BECKJORD
T. SPEIS
C.J. HELTEMES
M. FATO



OFFICE OF THE
SECRETARY

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

ACTION - Lieberman, OE,
Beckjord, RES

Cys: Taylor
Milhoan
Thompson
Blaha
Bernero
Paperiello

May 10, 1994

MEMORANDUM TO: James M. Taylor
Executive Director for Operations

FROM: John C. Hoyle, Acting Secretary

SUBJECT: SECY-94-027 - APPLICABILITY OF THE PROVISIONS
OF 10 CFR 20.1301 TO THE ADMINISTRATION OF A
RADIOPHARMACEUTICAL TO THE WRONG PATIENT -
ENFORCEMENT ACTION AGAINST THE VETERANS
ADMINISTRATION MEDICAL CENTER, LONG BEACH, CA
(EA 93-203)

The Commission (with the Chairman and Commissioners Remick and de Planque agreeing) has approved:

- 1) issuance of the proposed letter and Notice of Violation to the Veterans Administration Medical Center in Long Beach, California; and
- 2) the staff proposal to proceed with rulemaking to clarify that the medical administration of radioactivity or radioactive materials to a patient (which includes a "wrong patient") is the exclusive province of the regulations in Part 35.

Commissioner Rogers would have preferred a modification of Option 1.

The Commission is divided on the issue of whether patients should be notified concerning errors in the administration of radiopharmaceuticals where no administration was intended and where the threshold for regarding the event as a misadministration is not reached. Commissioner Remick recommends patient notification in these cases. He would not place the NRC in the position of notifying the patient, but would require the licensee to notify the patient's physician within 30 days of the error. Commissioner Rogers would require notification if the

SECY NOTE: THIS SRM AND SECY-94-027 ARE ENFORCEMENT RELATED
AND WILL BE LIMITED TO NRC UNLESS THE COMMISSION
DETERMINES OTHERWISE.

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individual had not been referred by a physician for a medical procedure involving materials or devices which the NRC regulates. In such a case, for regulatory purposes, he would consider the individual to be a member of the public rather than a patient. The Chairman and Commissioner de Planque would not require licensees to notify the individual of an unintended dose if the threshold for a misadministration (i.e., 5 rem effective dose equivalent or 50 rem dose equivalent to any individual organ) is not exceeded.

The proposed rulemaking should specifically seek public comment on the notification issue and on whether there are practical ways to apply 10 CFR Part 20 to such a situation as that described in SECY-94-027 without defeating the policies behind Part 35's definition of the term "misadministration". For example, the staff should seek comment on whether notification, if required, would implicitly impose recordkeeping and procedural requirements upon licensees beyond those explicitly set forth in 10 CFR Part 35. In the interim period until the rulemaking is completed, Part 35 requirements should be followed when the unintended dose exceeds the threshold for a misadministration.

In this particular case, the Commission (with all Commissioners agreeing) would not require the individual to be notified.

The staff should continue to exercise enforcement discretion until the rulemaking is completed. The proposed rule should be forwarded for Commission review and approval.

(EDO) (RES/OE) (SECY Suspense: 10/21/94) 9400099

cc: The Chairman
Commissioner Rogers
Commissioner Remick
Commissioner de Planque
OGC
OCA
OIG
OE