UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

JUN 13 1994

Docket: 030-03255
License: 42-00084-06

Department of Veterans Affairs
Veterans Administration Medical Center
ATTN: Robert F. Stott, Director
2202 Holcombe Boulevard
Houston, Texas 77030

SUBJECT: MISADMINISTRATION REVIEW (NRC INSPECTION REPORT 030-03255/93-01)

This refers to an incident which occurred at your facility involving a brachytherapy treatment performed in September 1993. Our initial review of this incident was performed during an inspection conducted at your facility on October 12-15, 1993 (reference subject inspection report dated December 8, 1993).

The above noted incident involved a brachytherapy treatment which was terminated due to patient intervention. Specifically, the treatment involved use of iridium-192 seeds, encased in nylon ribbon, placed in the patient's left bronchus via an intraluminal pulmonary catheter on September 24, 1993. Following implantation, the patient experienced a coughing spasm which displaced the sources into the patient's mouth. The patient removed the ribbon, effectively terminating the treatment, and placed the ribbon in a metal tray at his bedside. Although a physician was informed by the patient the following morning that the ribbon had been removed, the physician failed to place the sources in a lead container which was located in the patient's room. As a result, the unshielded sources remained near the patient until the afternoon of September 25, 1993.

At the time of the inspection, you were informed that NRC was continuing its review of this case in order to determine whether the incident should be categorized as a misadministration since the treatment was terminated due to patient intervention. The NRC's Office of General Counsel has completed its review of the circumstances associated with this incident and has determined that a misadministration did occur for reasons discussed below.

The original treatment was planned to deliver a dose of 2,400 centigray over a period of approximately 25 hours to a prescribed tissue volume. As a result of patient intervention, the sources did not remain in place over the prescribed exposure period and the final calculated treatment dose was only 1,710 centigray (29 percent less than prescribed). In addition, because the sources were displaced into the patient's mouth and then later removed and placed (unshielded) in a tray next to the patient's bed for a period of time, the patient received a dose of approximately 1 centigray to his oral cavity and a whole body dose of approximately 0.156 centigray, which constitute doses to the wrong treatment sites.

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Because patient intervention was the immediate cause of the removal of the sources, NRC does not consider the underdose to be the basis for concluding there was a misadministration. However, the whole body dose and dose to the patient's oral cavity may have been prevented or minimized if the individuals involved had been appropriately trained and had notified the authorized user and the radiation safety officer immediately. Had either of the aforementioned individuals been apprised of the situation when the referring physician was first informed by the patient that the sources had been removed, the ribbon could have been placed in a shielded container promptly to minimize the dose to the wrong treatment site. NRC has concluded that this incident does constitute a misadministration, as defined in 10 CFR 35.2, because radiation from a brachytherapy source was delivered to the wrong treatment site.

Because this incident was still under review at the time that VAMC provided its initial written report to the NRC, VAMC had elected not to notify the patient that a misadministration had occurred. However, based upon a telephone conversation between Ms. Linda Kasner of this office and Mr. Jeffrey Triebel of your staff on February 11, 1994, it is our understanding that the patient is deceased and that subsequent to our inspection, the patient's spouse was informed verbally that an error in treatment had occurred and that some notification of the incident was provided in written format. However, we wish to emphasize that given NRC's determination that the incident constitutes a misadministration, the Department of Veterans Affairs, Veterans Administration Medical Center, Houston, Texas, (VAMC) must comply with the provisions of 10 CFR 35.33 with regard to the specific information required to be reported to the patient's responsible guardian or relative.

In order to conclude our review of this matter, we are requesting that VAMC respond to this letter and confirm that the specific reporting requirements of 10 CFR 35.33 have been met. If the information provided to the patient's spouse did not meet the requirements of 10 CFR 35.33, then VAMC should provide a supplement of its initial report to the patient's spouse. Your reply to this letter should be provided to the NRC Region IV office within 15 days of the date of this letter.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter will be placed in the NRC Public Document Room.

The response directed by this letter is no subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96.511.

Should you have any questions concerning this letter, please contact Ms. Linda Kasner or Mr. Mark Shaffer at (817) 860-8100.

Sincerely,

Charles J. Cain

for Samuel J. Collins, Director
Division of Radiation Safety
and Safeguards

cc:
Texas Radiation Control Program Director

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Nuclear Medicine Service
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bcc:
DMB - Original (IE-07)
LJCallan
SJCollins
RAScarano, DRSS/RIV
WLFisher
CLCain
FAWenslawski
LLKasner
MRShaffer
Dserig, NMSS/IMAB (TWFN, 8-F-5)
NMIB
MIS System
RIV Files (2)

RIV:NMIB	AC:NMIB	DD:DRSS	D:DRSS	
LLKasner	CLCain	RAScarano	SJCollins	
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DMB - Original (IE-07)
LJCallan
SJCollins
RAScarano, DRSS/RIV
WLFisher
CLCain
FAWenslawski
LLKasner
MRShaffer
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NMIB
MIS System
RIV Files (2)

RIV:NMIB	AC:NMIB	DD:DRSS	D:DRSS	
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