

ENCLOSURE 1

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket No.: 030-30273
License No.: 40-26908-01
Report No.: 030-30273/97-01
Licensee: Nuclear Imaging, Ltd.
Facility: Sioux Falls, South Dakota
Location: Sioux Falls, South Dakota
Chamberlain, South Dakota
Oacaoma, South Dakota
Dates: April 15, 1997, through May 30, 1997
Inspector: Jeffrey Cruz
Radiation Specialist
Approved By: D. Blair Spitzberg, Ph.D., Chief
Nuclear Materials Inspection and
Fuel Cycle/Decommissioning Branch
Attachment: Supplemental Inspection Information

EXECUTIVE SUMMARY

Sioux Falls Office
NRC Inspection Report 030-30273/97-01

This routine, unannounced inspection included a review of mobile nuclear medicine activities performed by Nuclear Imaging Ltd., (NIL). The inspection included a review of the administrative aspects of the licensee's radiation safety program, selective examinations of procedures and representative records, independent measurements, and interviews with licensee personnel. This report focuses on an event reviewed during the inspection involving the loss of a package containing licensed material from a transport vehicle.

Technical Requirements that apply to the provision of mobile nuclear medicine service

- The inspector identified an apparent violation of 10 CFR 35.80(c) involving a failure to adequately secure or keep under constant surveillance and immediate control a package containing byproduct material when in transit (Section 2).

Report Details

1 Organization and Scope of the Licensee Program (87100)

NIL is licensed by the NRC to provide mobile nuclear medicine services at its main facility in Sioux Falls, South Dakota, and at any hospital located in the states of Minnesota, South Dakota, and Wyoming. NIL is also licensed to store byproduct material on company-owned vehicles at four locations in the states of South Dakota and Minnesota. Additionally, NIL maintains a number of Agreement State material licenses to perform similar activities at facilities not in NRC jurisdiction. NIL is currently utilizing fourteen vehicles to service 115 hospitals and employs approximately 19 nuclear medicine technologists. The licensee performs approximately 650 radiopharmaceutical procedures per month.

2 Technical Requirements that apply to the provision of Mobile Nuclear Medicine Service (87100, 83822, and 86740)

2.1 Inspection Scope

The inspector's review of NIL's radiation protection program included interviews with licensee personnel, observation of work activities and a review of licensee records.

2.2 Observations and Findings

A review of NIL's Radiation Safety Committee meeting minutes disclosed that on October 4, 1995, a shipping package containing approximately 300 millicuries of technetium-99m fell from the mobile nuclear medicine transport vehicle being used by NIL. This incident involved personnel employed at NIL's Mankato, Minnesota facility. The NIL internal report generated following this incident noted that the usual compartment used to store shipping packages containing licensed material during transport was not utilized due to a faulty latch. The technologists involved in this incident placed the package in another available compartment, but failed to lock the latch. The failure to lock the latch allowed the door to open and the package to fall from the vehicle while in transit. The technologists were unaware that the package had fallen from the vehicle and continued on to the scheduled appointment at an area hospital. Upon arrival at the hospital, the technologists realized that the package was missing and immediately contacted the NIL radiation safety officer to report the incident. Prior to the technologists' telephone call, NIL had been notified by Mallinckrodt Medical (MM), the supplier of the radiopharmaceuticals, that the manager of the MM pharmacy in St. Paul, Minnesota, had been contacted by a member of the public who found the package. The member of the public had identified the MM address on the package and assumed that MM owned the package. The pharmacy manager immediately traveled to Mankato to recover the package and, upon examination and survey, verified that it displayed no package

contamination or damage to the vials containing the technetium-99m. The package had originally been labeled as a Radioactive White I package and the exposure rate at the surface of the package at the time of recovery was less 0.5 millirem per hour.

10 CFR 35.80(c) requires that a licensee providing mobile nuclear medicine service shall secure or keep under constant surveillance and immediate control all byproduct material when in transit or at an address of use. Failure to secure a shipping package containing approximately 300 millicuries of technetium-99m which, on October 4, 1995, fell from the mobile nuclear medicine transport vehicle being used by NIL was identified as an apparent violation of 10 CFR 35.80(c) (030-30273/9701-01).

2.3 Conclusions

The inspector identified an apparent violation of 10 CFR 35.80(c) involving a failure to adequately secure or keep under constant surveillance and immediate control a package containing byproduct material when in transit.

Exit Meeting Summary

Region IV staff presented the inspection results to licensee management via telephone on May 30, 1997. Licensee representatives acknowledged the inspector's findings and confirmed that no proprietary information was reviewed during the inspection.

ATTACHMENT

SUPPLEMENTAL INSPECTION INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

Licensee

W. A. Boade, M.D., President

Fred C. Lovrien, M.D.

Corrine Connelly, General Manager

Mary Hawnings Frank, Nuclear Medicine Supervisor

Jennifer Kiesacker, Hot Lab Supervisor

INSPECTION PROCEDURES USED

87100	Licensed Materials Programs
83822	Radiation Protection
86740	Inspection of Transportation Activities

ITEMS, OPENED, CLOSED AND DISCUSSED

Opened

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APV Failure to secure a shipping package containing approximately 300 millicuries of technetium-99m on October 4, 1995, which fell from the mobile nuclear medicine transport vehicle being used by NIL was identified as an apparent violation of 10 CFR 35.80(c).

Closed

None

Discussed

None

LIST OF ACRONYMS USED

APV	Apparent Violation
MM	Mallinckrodt Medical
NRC	Nuclear Regulatory Commission
NIL	Nuclear Imaging, Ltd.