Bristol-Myers Squibb Company
Pharmaceutical Group Technical Operations
One Squibb Drive P.O. Box 191 New Brunswick, NJ 08903-0191
908 519-2000

August 5, 1999

Ms. E. Ullrich, CHP
US NRC Region I
475 Allendale Road
King of Prussia, PA 19406

RE: LICENSE #29-00139-02 NOTIFICATION TO THE NRC OPERATIONS CENTER

Dear Ms. Ullrich:

In accordance with 10 CFR 20.2201(a), E. R. Squibb & Sons, Inc. notified the Nuclear Regulatory Commission Operations Center on July 19, 1999, by telephone, that a package of licensed radioactive material was missing. The Operations Center notified NRC Region I personnel. The package contained 4.9 millicuries of I^{131} and was recovered intact and undamaged the following day, July 20, 1999. The attached report details this incident and is provided to Region I of the NRC in accordance with the requirements of 10 CFR 20.2201(b).

If you require any additional information or wish to discuss this matter further, please contact me at (732) 519-2987.

Sincerely,

Michael J. Vala

Michael J. Vala, CHP
Radiation Safety Officer

MJV:bl

Attachment

AUG - 6 1999

Written Report of Missing Radioactive Material
Prepared pursuant to 10 CFR 20.2201(b)

Section I - Description of Licensed Material Involved

The licensed material involved was 4.9 millicuries of I^{131}. The licensed material was contained in two therapeutic oral dosage gelatin capsules in the form of NaI^{131} with activities of 2.4 and 2.5 millicuries calibrated for July 19, 1999. Each capsule was in a plastic bottle shielded with an eighth inch lead pig. The package weighed three pounds and was a standard DOT 7A, Type A fiber shipper labeled as Radioactive Material, n.o.s., 7, UN 2982 with a Yellow-II label and a Transport Index of 0.5.

Section II - Description of the Circumstances Under Which the Loss Occurred

At 9:15 a.m. on July 19, 1999, our Customer Service department received a telephone request from North Shore University Hospital in Manhasset, Long Island, for two (2) vials of Iodotope I^{131} capsules. The hospital requested one vial to contain a 2.4 millicurie capsule and the second vial to contain a 2.5 millicurie capsule. The capsules were packaged for shipment and Del Med of South Plainfield, NJ, was contacted at 9:20 a.m. for a special pick up of this single package for delivery to the hospital that day. The pick up was scheduled for approximately 10:30 a.m.

At 9:57, a truck driver arrived at the Georges Road Security Gate of the site stating he had a pick up at Building 124 (Radiodiagnostic Manufacturing and Distribution Facility). The driver signed in at the gate and proceeded directly to Building 124. He presented himself to Distribution personnel for the special pick up, signed the bill of lading and left with the package at 10:10 a.m. He was driving a large yellow truck with "Radioactive" placards.

At approximately 11:00 a.m., a Del Med driver arrived to pick up the same package. A call was placed to Del Med, by the Distribution manager, and a copy of the signed bill of lading from the earlier pick-up was faxed to Del Med to determine if the signature was from one of their drivers. Del Med did not recognize the signature. Security was notified and a copy of the Georges Road sign in log was obtained. North Shore University Hospital was contacted at approximately 12:00 noon to determine if they had received the package; they had not. At this time, the Distribution manager notified the Radiation Safety Officer (RSO) that there was an apparent mis-shipment of 4.9 millicuries of I^{131}.

The Director of Radiodiagnostics and the RSO interviewed the Distribution Group Leader who released the package. The Distribution Group leader indicated that the first driver had been to Building 124 in the past and the driver knew there was a special pick up that morning. An additional call was placed to Del Med to verify that they had only dispatched one driver. Del Med confirmed that they had dispatched the second driver, not the first. Another call was made to North Shore University Hospital; the package still had not been received.

The Manager of New Brunswick site Security was contacted. The Security manager traced the first vehicle from its license plate. There was no telephone number associated with the registration address of the truck. The Security manager then went to the address and waited for the truck to return. A third call was placed to North Shore University Hospital; they still did not receive the package and were instructed to call the Distribution manger when they received the package. It was determined by the RSO that a package was missing and that immediate notification to the Nuclear Regulatory Commission (NRC) was required. At approximately 2:40 p.m., the RSO contacted the NRC Operations Center to report the missing package.

The E. R. Squibb Security manager succeeded in contacting the first truck driver at approximately 11:30 p.m. on July 19, 1999. The driver stated that he worked for Geologistics of Newark and was sent to pick up the package from Building 124 for shipment to Guam. After leaving Building 124, he delivered the package to the Geologistics terminal in Newark. The package was then placed in an area designated for shipments to New York. At approximately 5:30 a.m. on July 20, 1999, the package was retrieved by E. R. Squibb personnel from the Geologistics terminal and returned to Building 124 at the New Brunswick site. According to Geologistics personnel, there had been a pick up for Guam on Friday, July 16, 1999. It appears that the Geologistics dispatcher mistook the Friday, July 16th schedule for the Monday, July 19th schedule and dispatched the contract driver to E. R. Squibb, Building 124, in error for a special pick up. When the driver arrived, because there was a package for a special pick up, the package was released to the driver.

Section III - Statement of the Disposition of the Licensed Material Involved

The intact and undamaged package was returned to the licensee's possession on the morning of July 20, 1999. A survey of the package was performed by the Radiation Safety staff. Results for removable surface contamination were negative; radiation levels at the surface and at one meter from the package were as expected. The licensed material will be held for decay and disposed in an appropriate manner.

Section IV - Possible Exposures to Persons in Unrestricted Areas

As stated above, the package was prepared for shipment in accordance with DOT 7A, Type A specifications. Based upon the shipping survey information, the highest surface radiation level was 20 millirem per hour on the side of the box. The highest radiation level at one meter was 0.5 millirem per hour. The package was labeled with a Yellow-II radioactive label with a Transport Index of 0.5. When the package was returned, it was found to be sealed and free of damage. The receiving survey indicated the highest surface radiation level was approximately 15 millirem per hour and the package was free of external contamination. According to Geologistics personnel, while in their possession, the package was placed in an area of the terminal away from personnel and traffic. Since the licensed material was packaged and handled in accordance with DOT regulations for the duration of the time outside of the control of E. R. Squibb, the Total Effective Dose Equivalent (TEDE) to members of the public in unrestricted areas is assumed to be well below the limits specified in 10 CFR 20.

Section V - Actions Taken To Recover the Material

The first truck was traced through the license plate recorded on the security gate sign in sheet. The driver's name and company were difficult to ascertain accurately. From the license plate, the truck was traced to E. Elblink; this matched the company name of the security gate sign in log. An address from the truck's registration was obtained; a telephone number was not available. E. R. Squibb Security staff went to the address and waited for the truck and driver to return. When the driver returned, he was interviewed and the location of the package was identified. The intact package was recovered the following morning.

Section VI - Measures Adopted To Ensure Against A Recurrence of Loss of Licensed Material

To prevent a mis-shipment of licensed material in the future, changes to standard operating procedures were implemented immediately. These changes became effective July 21, 1999, and are as follows:

- Security is provided a list and description of the four daily routine shipments that pick up product from Building 124.
- All non-routine shipments from Building 124 will require the driver to present a purchase order number to Security to gain entry into the site. Radiodiagnostic Distribution will alert Security when a non-routine pick up is scheduled and Security will be given the associated purchase order number. If the driver does not have a purchase order number, Security will contact Radiodiagnostic Distribution for instructions.
- Radiodiagnostic Distribution modified their Standard Operating Procedure RDD-1 to incorporate the above changes. All affected personnel in Radiodiagnostic Distribution were provided training on the modified procedure.
- All affected Security personnel were trained in the modified procedure.