

UNITED STATES NUCLEAR REGULATORY COMMISSION REGION II 101 MARIETTA STREET, N.W. ATLANTA, GEORGIA 30323

OCT 2 7 1992

Report No.: 45-23645-01NA/92-04

Licensee: Department of the Navy Navy Radiation Safety Committee

Docket No.: 030-29462

License No.: 45-23645-01NA

Facility: Nation: 1 Naval Medical Center Bethesda Bethesua, Maryland

Inspection Conducted: September 23 - 24, 1992

10/27/92 Inspector: John My Pelchat, Health Physicist, Project Manager Date Signed Ann 10/27/92 Approved Ly:

Charles M. Hosey, Chief Nuclear Materials Inspection Section Nuclear Materials Safety and Safeguards Branch Division of Radiation Safety and Safeguards

Date Signed

SUMMARY

Scope:

This special, announced inspection of activities conducted under the U.S. Navy's Master Broad Materials License was limited to a review of the circumstances surrounding the loss of 3.6 millicuries of iodine-131. The inspection also included a review of the corrective actions taken by the permittee and the licensee as a result of this event.

Results:

Within the scope of this inspection, two violations were identified: (1) failure to secure licensed radioactive materials in unrestricted areas against unauthorized removal; and, (2) failure of the Radiation Safety Officer to implement procedures for the safe receipt of radioactive material packages.

REPORT DETAILS

1. Persons Contacted

Navy National Naval Medical Center (NNMC) Bethesda

*RADM D. Lichtman, Commander, National Naval Medical center (NNMC) Bethesda

*CAPT S. Larson, Acting Deputy Commande., NNMC

*CAPT R. Koehn, Director, Ancillary Services, NNMC

*CAPT E. Silverman, Chairman, NNMC Radiation Safety Committee

*CDR D. Jensen, Chairman, Radiology

*CDR R. La Fontaine, Head, Radiation Physics Division

*LCDR J. Jacobus, Radiation/Laser Safety Officer (RSO)

Hospital Corpsman 1st Class (HM1) L. Shepard, Lead Petty Officer, Radiation Safety Office

HM3 K. Pryor, Radiation Health Technician, Radiation Safecy Office

Other Licensee Personnel

*CAPT K. Mendenhall, Bureau of Medicine (BUMED)

**CDR R. Enge, Recording Secretary, NRSC

*LCDR G. Snyder, Navy Environmental Health Center (NEHC)

*Present at exit interview with permittee personnel on September 23, 1992 **Present at exit interview with licensee personnel on September 24, 1992

Organization and Scope of Licensed Activities (87100)

The U.S. Navy Radiation Safety Committee (NRSC) is authorized by License No. 45-23645-01NA to issue radioactive material permits to medical and industrial users of licensed radioactive materials. The NRSC issued Navy Radioactive Materials Permit No. 19-00168-12NP to the National Naval Medical Center Bethesda (NNMC), Bethesda, Maryland to possess and use licensed radioactive materials for the medical procedures described in 10 CFR, Parts 31.11, 35.100, 35.200, 35.300, 35.400, and 35.500. The NNMC is a 500 bed racility. The permit also authorized the possession and use of any form of radioactive materials with atomic numbers 3 - 83. inclusive, for medical research. The NNMC Radiation Safety Office issues personnel radiation dosimetry to 500 - 600 persons, about half which are involved in the clinical or research use of radioactive materials. The Raliation Safety Office is staffed by a full time Radiation Safety Officer (RSO), four enlisted Radiation Health Technicians (Pius), and one civilian RHT. Administratively, the RSO reports to the Physics and Radiation Safety Division Head who, in turn, reports to the Radiology Department Chairman. The Radiation Department Chairman reports to the Director of Ancillary Services, who in turn, reports to the NNMC Deputy Commander. The radiation safety table of organization also provides for the RSO to report directly to the NNMC Commander on radiation safety issues.

Circumstances Relative to the Loss of Licen ed Radioactive Materials (92700)

3.

The following account of the loss of licensed redioactive materials is based upon review of the licensee's records, reports and interviews with personnel. At 11:00 a.m. on the morning of August 27, 1992, 3.6 millicuries (mCi) of iodine 131 (I-131) labeled Metaiodobenzylguanidine sulfate (M-IBG), an adrenal imaging agent, was delivered to the Radiation Safety Office at the NNMC. The Radiation Safety Office is located in the basement in the same general area as the nuclear medicine and radiation therapy departments. The package was signed for by a member of the Radiation Safety Office staff.

At about noon, after the package was surveyed, an enlisted RHT took the opened package to the nuclear pharmacy, its intended destination. The nuclear pharmacy is located at the end of a hallway. A secured radiopharmaceutical storage area and Physics and Radiation Safety Division staff offices were also located along this hallway. The RHT found the nuclear pharmacy to be unattended. The RHT believing that the nuclear pharmacist was gone for a moment, "eft the package on the floor of the haïlway outside the nuclear pharmacy. However, the nuclear pharmacist was out for the day and the package remained on the hallway floor.

Upon his return on the morning of August 28, 1992, the nuclear pharmacist was asked by a staff nuclear medicine technologist if the anticipated shipment of I-131 labeled M-IBG had arrived. The nuclear pharmacist could not find the shipment. The nuclear pharmacist contacted the shipper to learn the whoreabouts of the expected shipment. The shipper advised the nuclear pharmacist that the shipment had been delivered the previous day (August 27, 1992) and had been signed for by a member of the NNMC radiation safety staff. At about 10:30 a.m., the nuclear pharmacist notified the Radiation Safety Office of the missing shipment. The Radiation Safety Office staff began a search of all areas in the nuclear medicine clinic where radioactive materials were stored or used in an unsuccessful effort to find the missing shipment.

The RSO who had been unavailable during the morning, was notified about the missing radioactive material at about 11:45 a.m. The RSO directed that the search for the missing radioactive material package be expanded. The Radiation Safety staff also began exploring the possibility that the package could have been picked up by a member of the housekeeping staff. Permittee interviews with hospital staff working near the nuclear pharmacy indicated that one nuclear medicine technologist may have recalled seeing the package on the floor outside the nuclear pharmacy later the afternoon of August 27, 1992. Permittee interviews of the housekeeping staff as they arrived for work during the evening shift revealed that two members of the housekeeping staff worked near the nuclear pharmacy. One of the housekeepers recalled picking up an open box in the hallway outside the nuclear pharmacy. The housekeeper stated that he only saw papers in the box. The housekeeper also stated that he did not recall any radioactive material markings on the box he picked up. The housekeeper disposed of the apparently empty box into the normal trash on the evening of August 27, 1992. A Radiation Safety staff survey of the trash compactor and dumpster into which the package would have been disposed of found no radiation levels above background. The housekeeping staff indicated the dumpster was most likely emptied before the survey was made. The Radiation Safety Office staff was told that the compactor was not cycled on the evening of August 27, 1992 which suggested that the radioactive materials package had not been crushed and was still intact. NNMC staff believed that the dumpster's contents were transferred to a local sanitary landfill.

Radiation Safety staff interviews of the housekeepers and their supervisors indicated that the housekeeping staff had been trained in and were familiar with the standard radioactive material symbols and signs, and with the prohibitions against housekeeping staff handling of any radioactive materials. At the end of the interviews on August 28, 1992, and upon being advised that the expanded search had not found the missing shipment, the RSO concluded that the package containing the 3.6 mCi of I-131 labeled M-IBG was lost.

The RSO reported the missing radioactive materials to the Naval Environmental Health Center (NEHC) [the Navy's medical radioactive material inspection and permitting activity] at about 5:00 p.m. on August 28, 1992. NEHC notified the NRC headquarters duty officer of the missing radioactive materials at 5:15 p.m. the same day.

At about 10:00 p.m. on August 28, 1992, a member of the NRC staff arrived on site at the NNMC. The NRC representative reviewed the event with NNMC Radiation Safety staff, including the NNMC's plans to attempt a radiological survey of the waste handling and disposal facilities where the package would have gone to if it had been disposed of in the normal trash. Upon further review, the licensee concluded that the potential hazard posed to NNMC staff from searching trash (including hospital trash) was significantly greater than the hazards to the public posed by the radiopharmaceutical shipment in a sanitary landfill. Therefore, the licensee terminated its efforts to find the radioactive materials package outside the facility. The NRC representative concurred with the license's decision.

4. Licensee Investigation (92700)

The licensee investigated the circumstances surrounding the loss of radioactive material at the NNMC on August 31 - September 1, 1992. The investigation team was made up of the BUMED representative to the NRSC and the senior inspector/permit reviewer from the NEHC. A written summary of the investigation team's findings was transmitted to the NRC by electronic facsimile (FAX) on September 10, 1992.

The investigation team reviewed the facility's isotope receipt procedures. The team found that the procedures required that radioactive material deliveries to the NNMC during normal business hours be made directly to the Radiation Safety Office. Those packages arriving after hours were to be delivered directly to the NNMC Command Duty Officer office. These packages would then be escorted to and secured in a locked storage area near the nuclear pharmacy. After incoming packages were surveyed by the Radiation Safety staff, they were to be hand delivered to the appropriate user.

The radioisotope receipt procedures further required that prior to receiving the package, the user sign for the package. Review of the receipt log record for the missing M-IBG shipment found that the user's name had been printed into the log, but the user had not signed for the shipment. The team interviewed the RHT who delivered the package. The RHT stated that when he was unable to obtain the user's signature documenting the delivery of radioactive materials, he printed the user's name to indicate the delivery had been made. The RHT indicated that he had done so on a number of occasions in accordance with instructions he received from another member of the Radiation Safety staff no longer attached to the NNMC. The RHT told the team that he had not read the facility's current radioactive material receipt procedures.

The investigation team also interviewed the two members of the NNMC housekeeping staff who cleaned near the nuclear pharmacy on August 27, 1992. The team found that one of the housekeeping staff recalled picking up an apparently empty box containing only paper outside the nuclear pharmacy and that he did not recall any radioactive materials markings on the outside of the package. The investigation team reviewed the training received by the housekeepers and found that they were familiar with the standard radioactive material symbols and signs, and with the prohibitions against the housekeeping staff handling of any radioactive materials.

After interviews with the RSO and other members of the NNMC Radiation Safety staff, the investigation team reported the following conclusions:

- The radioactive material in its original shipping box was removed from the Nuclear Medicine Clinic by the housekeeping staff and disposed on in the normal trash.
- The housekeeper was not aware of the radioactive contents of the bex.
- The RSO had not trained all of the Radiation Safety staff in the Command's (NNMC) current radioactive material receipt procedures.
- The RSO was probably not aware that the Radiation Safety staff was not following the current radioactive material receipt procedures.
- The RHT who had left the package outside the nuclear pharmacy had followed the procedures he had been trained in and he thought they were current.

The housekeeping staff had received radiation safety training and was familiar with their radiation safety procedures. The housekeeping staff apparently overlooked the shipment's markings when they disposed of the package.

"Ammo box" type packages containing unit radiopharmaceutical doses were delivered to the NNMC and placed into unsecured storage in unrestricted areas in the nuclear medicine clinic.

The investigation team identified the following violations as a result of their investigation at the NNMC:

6

Two examples of failure to secure licensed materials in unrestricted areas against unauthorized removal, in violation of 10 CFR 20.207(a). The first example, which led to the loss of 3.6 mCi of I-131 labeled M-IBG, was characterized by the NRSC as a Severity Level III violation. The second example, where unit doses stored in unrestricted areas were not secured against unauthorized removal, was characterized by the NRSC as a Severity Level IV violation.

Failure of the RSO to implement written policy and procedures for the receipt of radioactive material, in violation of 10 CFR 35.21(b)(2)(ii). This was characterized by the NRSC as a Severity Level IV violation.

The investigation team identified the following corrective actions enacted by the NNMC to prevent recurrence of the violations:

- Retraining of all Radiation Safety Office staff members in the existing radiation safety procedures including those for distributing radioactive material packages.
- Restriction of housekeeping staff access to areas in which radioactive materials were used and stored. New bilingual signs (in english and spanish) have been ordered for posting on restricted area access doors prohibiting entry by housekeeping staff.
- Discontinuing the practice of storing radiopharmaceutical deliveries in unrestricted areas. All appropriate medical center staff were trained in the facility's radioactive materials receipt procedures.

The NNMC was formally notified of the inspection findings in a letter from the NRSC dated September 29, 1992. The letter acknowledged the corrective actions enacted by the NNMC and requested that the NRSC be provided with the results of internal radiation safety program audits planned by the NNMC. In a separate action, the NRSC directed that the NEHC prepare an "information notice" type document reminding other permittees of the requirement to adequately secure licensed radioactive materials. The licensee's investigation was timely and adequately addressed the radiation safety aspects and root causes of the loss of licensed materials.

Inspection Results (92700)

The inspector reviewed the permittee's chronology of events on August 27, 1992 that led to the loss of 3.6 mCi of I-131 labeled M-IBG. Interviews with facility personnel including facility management, the RSO and the individual who left the radioactive materials in the hallway confirmed the sequence of events and the root causes identified in the licensee's investigation (see Section 4). The radioactive material package was stored in an unrestricted area and not secured or under tended surveillance. 10 CFR 20.207 requires licensed materials stored in an unrestricted area be secured or under constant surveillance so as prevent unauthorized removal. The failure to adequately secure licensed materials was an apparent violation of 10 CFR 20.207 and contributed to the loss of the material.

The inspector interviewed the RSO. The RSO stated that he had most recently revised the radioactive material receipt procedures in the early summer of 1992 as part of a general effort to update all of the Radiation Safety office's procedures. These revisions were prompted by upcoming scheduled inspections by the American College of Nuclear Medicine Physicians, the Joint Committee for Accreditation of Hospitals, and the NEHC. The RSO also stated that he directed that all members of the Radiation Safety Office staff read the updated procedures. The RSO added that he had believed that members the Radiation Safety staff were following all of the revised procedures but that he had not taken any action to verify that the Radiation Safety staff had in fact understood and implemented the revised procedures.

The RSO noted that the Radiation Safety Office had experienced a 100 percent turnover of staff since his arrival in the summer of 1991. The RSO stated that detailed training of new personnel has previously been the responsibility of the former Radiation Safety Office Leading Petty Officer (LPO). Members of the Radiation Safety Office indicated that the former LPO provided very little training to incoming personnel and frequently delegated the training of new staff to very junior Radiation Safety Office personnel.

Interviews of the individual who had delivered the radipactive materials package that was subsequently inst indicated that he had been trained in radioactive material distribution requirements by a hospital corpsman apprentice. The individual stated that before the event, he had not been required to review the written radioactive material receipt procedures. The individual added that he had previously been told that it was permissible to leave radioactive material packages outside of user areas when the authorized user was not physically present. The individual also stated that as a result of the event, the entire radiation safety staff received training in all Radiation Safety Office operating procedures including radioactive material receipt procedures. The individual also added that the current LPO was providing more supervision to the enlisted Radiation Safety Office staff and emphasized the need to work in accordance with the office's procedures. Discussions with this individual and other members of the Radiation Safety Office staff indicated that they had a good knowledge of the office's operating procedures. Review of radioactive material receipt records indicated that all incoming shipments received after the retraining had been handled in accordance with existing procedures.

10 CFR 35.21(b)(2)(ii) requires that the RSO establish and implement procedures for the ordering and safe receipt of licensed materials. The RSO's failure to implement existing radioactive material receipt procedures is an apparent violation of 10 CFR 35.21(b)(2)(ii).

The inspector reviewed the scope and status of the corrective actions that the NNMC enacted to prevent the recurrence of a similar event. These corrective actions were described in the command's Plan of Action and Milestones (POAM). This document was prepared by the Physics and Radiation Safety Division Head (the RSO's direct superior) and decreted the underlying causes and programmatic weaknesses identified as a . of the event. The POAM listed the corrective actions described in Section 4 of this report. The document also described additional management level corrective actions taken to prevent future recurrence of this type of event. The management level corrective actions listed in the POAM included:

- Increased RSO involvement in day-to-day Radiation Safety Office operations. The RSO's office was relocated to the Radiation Safety staff's spaces to facilitate closer program supervision. The RSO was also relieved of all collateral duties (except Laser Safety Officer duties) and directed to concentrate on full-time management of the Radiation Safety program and its staff.
- Increased Division Head oversight of the Radiation Safety Program. The Division Head had primary responsibility for monitoring the command's progress in implementing corrective actions. The POAM required that the Division Head be briefed by the RSO biweekly on radiation safety program issues, including identified weaknesses and recommended improvements. The POAM also required that the Division Head conduct or assign management surveillances of Radiation Safety staff work practices.

.6

The increased use of independent audits. The POAM requires that periodic independent radiation safety program audits be conducted by qualified Radiological Health Officers. Interviews of the Division Head and the RSO indicated that the initial audit frequency would be about monthly and that the frequency would be relaxed if the program showed continued improvement. Additional audits are to be performed by incoming Radiological Health Officers being assigned to the NNMC. Although new to the NNMC, these individuals would have experience in other naval radiation safety programs. Retraining for all radioact's materials users in good radiation safety work practices emphasizing the need for vigilance in looking for potential programmatic weaknesses. The training was to also emphasize the requirement to report problems to the RSO, and if users were not satisfied with the response, to report up through their chain of command.

The inspector interviewed members of the Command Duty Officer staff who would be responsible for the after hours receipt of radioactive materials. The Command Duty Officer staff demonstrated a very thorough knowledge of the facility's radioactive material receipt procedures.

Exit Interview (30703)

ė.

The scope and findings of the special inspection regarding the loss of licensed radioactive material were summarized on September 25 and 24, 1992, with those persons indicated in Section 1 above. The inspector reviewed the program areas inspected and discussed in detail the inspection findings including the apparent violations listed below. Licensee personnel acknowledged the findings and provided no dissenting comments. No proprietary material was provided to or reviewed by the inspector during the inspection.

Item Number

Description and Reference

45-23645/92-04-01 Violation - Failure to adequately secure licensed radioactive materials stored in unrestricted areas to prevent its loss or unauthorized removal (Section 5).

45/23645/92-04-02 Violation - Failure of the RSO to adequately implement procedures for the safe recript of licensed radioactive materials (Section 5).