U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report Nos.	030-01325/94-001	030-30758/94-001
EA No.	94-020	94-021
Docket Nos.	030-01325	030-30758
Licensee:	Washington Hospital Center 110 Irving Street, N.W. Washington, D.C. 20010	Medlantic Research Foundation 108 Irving Street, N.W. Washington, D.C. 20010
Facility Name:	Washington Hospital Center	Medlantic Research Foundation
Inspection At:	Washington, D.C.	Washington, D.C.
Inspection Conducted:	January 10-11, 1994	January 10-11, 1994

Inspectors: David G. Mann, Health Physicist — 1/2/94 Date

James P. Dwyer, Sr. Health Physicist — 1/3/94 Date

Approved by: Jenny M. Johansen, Chief, Medical Inspection Section — 1/3/94 Date

Inspection Summary: Special, unannounced inspection conducted on January 10-11, 1994 (Report Nos. 030-01325/94-001 and 030-30758/94-001).

Areas Inspected: Review of circumstances surrounding the apparent whole body exposures in excess of two regulatory limits that occurred during the third and fourth quarters of 1993, the licensee's investigation of the incident, and the licensee's actions to prevent similar recurrences.

Results: Several apparent violations were identified for each licensee: failure to limit the whole body radiation exposure to 1.25 rem per calendar quarter (Sections 3 & 5); failure to report an overexposure within 24 hours (Section 3); failure to conduct quarterly radiation safety committee meetings (Section 5); failure to process film badges on a monthly basis (Section 7); failure to provide appropriate personnel monitoring (Section 5); failure to provide appropriate supervisory oversight by an authorized user (Section 6); failure to follow the appropriate radioactive material ordering and receiving procedure (Section 7); failure to maintain a record of receipt of radioactive material (Section 7); and failure to survey areas where radiopharmaceuticals are prepared for use (Section 7).

DETAILS

1. Persons Contacted

Barbara V. Howard, Ph.D., MRI President & Radiation Safety Officer
Gerald S. Johnston, M.D., WHC Radiation Safety Committee Chairman
James C. Knight, MRI Vice President Operation & Finance
Mark H. Merrill, M.S.P.H., WHC Vice President Operations & Administrative Services
Michael C. Paidi, Ph.D., MRI Laboratory Manager
*Arvil Stephens, Research Associate
*Paul Sugarbaker, M.D., Researcher
Kenneth D. Williams, M.S., WHC Radiation Safety Officer
John L. Zurita, M.S., R.T.N., Manager WHC Nuclear Medicine Department

* indicates those not present at the exit interview.

2. Scope

The Washington Hospital Center (WHC) performs activities authorized under a medical broadscope license including the diagnostic, therapeutic, and clinical research administration of byproduct material to patients. The Medlantic Research Foundation (MRF) performs research and development using byproduct materials and human studies which have been approved by a Food and Drug Administration (FDA) approved Radioactive Drug Research Committee (RDRC) or for which the FDA has accepted a "Notice of Claimed Investigational Exemption For a New Drug" (IND).

3. Notification of Whole Body Exposure in Excess of Regulatory Limits

On December 10, 1993, MRF received notification from their film badge vendor indicating an exposure to the whole body of 5.390 rem for a research associate (RA). The film badge was the record of exposure for the month of September 1993. The vendor notified MRF on December 18, 1993 that the October film badge for the same research associate indicated an exposure to the whole body of 2.700 rem.

10 CFR 20.101(a) requires the licensee to limit the whole body radiation exposure to 1.25 rem per calendar quarter.

Failure to limit the whole body radiation dose of an individual in a restricted area to 1.25 rems per calendar quarter, except as provided by 10 CFR 20.101(b) is an apparent violation of 10 CFR 20.101(a) (030-30758/94-001/01).

The radiation safety officer (RSO) for the Washington Hospital Center, acting for the MRF radiation safety officer, notified the NRC of these exposure reports by telephone on January 6, 1994.

10 CFR 20.403(b)(2) requires the licensee to report, within 24 hours of discovery, any

event involving licensed material that may have caused an exposure to the whole body of 5 rems or more.

Failure to report, within 24 hours of discovery, the event which caused exposure to the whole body of an individual to 5 rems or more of radiation is an apparent violation of 10 CFR 20.403(b)(1) (030-30758/94-001/02).

4. Review of Possible Event(s) Leading to the Overexposure

On January 10, 1994, an inspection was initiated. The inspection focused on activities surrounding the reported exposures to a research associate for the third and fourth calendar quarters of 1993 and possible causes relating to the failure to report the exposures within 24 hours of their discovery. The inspectors conducted several interviews with the staff of both WHC and MRF and the research associate involved, who is not employed by either the WHC or MRF. Although the film badge used by the RA was provided by MRF, the radiation safety officers (RSO) for both WHC and MRF attributed the film badge reading to activities performed by the RA at an "old" radiopharmacy located at the WHC facility.

The RA was involved in two diagnostic research studies utilizing radiolabelled monoclonal antibodies. One involved tagging monoclonal antibodies with iodine 125 (^{125}I) and the other involved tagging the monoclonal antibodies with technetium 99m (^{99m}Tc). The RSOs indicated that studies involving ^{125}I-tagged monoclonal antibodies were performed at the MRF facility; while ^{99m}Tc-tagged monoclonal antibodies were performed at the WHC facility. The RSOs attributed the measured doses to two ^{99m}Tc tagging procedures; one performed in September 1993 and the second performed in October 1993.

5. Radiation Safety Committee Review

The inspectors reviewed the WHC radiation safety committee meeting minutes and noted that the RSC approved the ^{99m}Tc-tagged monoclonal antibody study at the November 18, 1992 meeting. The inspectors noted that neither the current WHC RSO nor the RSC chairman held these positions at that time. The inspectors reviewed a memorandum to the principle investigator from the former RSO dated November 18, 1992 indicating that the project had been approved by the RSC. The inspectors also reviewed the research study protocol and noted that the current RSC chairman replaced the previous RSC chairman as a co-investigator. In addition, the inspectors noted that the application and authorization for clinical use of radioactive materials which was submitted for renewal on October 11, 1993, was approved by both the current WHC RSO and RSC chairman.

The WHC RSO and the RSC chairman stated that neither was aware that the RA was tagging monoclonal antibodies in the "old" WHC radiopharmacy. The RSC chairman was aware, as a co-investigator, that the study was being performed; but, he believed that

monoclonal antibodies were already tagged with the ^{99m}Tc at the time of purchase. Both stated that they were unaware that the RA was ordering ^{99m}Tc under the WHC license in order to perform the tagging procedure at the WHC facility. Because the RSO did not know that the RA was tagging monoclonal antibodies at the WHC facility; he did not provide the required dosimetry or provide the required control to limit the individuals exposure.

10 CFR 20.202(a)(1) requires that appropriate dosimetry be provided to and used by individuals who may receive a radiation dose greater that 25 percent of the applicable limit.

Failure to provide appropriate personnel monitoring equipment to, and require the use of such equipment by, each individual who enters a restricted area under such circumstances that he/she is likely to receive a dose in any calendar quarter in excess of 25 percent of the applicable limit is an apparent violation of 10 CFR 20.202(a)(1) (030-01325/94-001/01).

10 CFR 20.101(a) requires that the licensee limit the whole body radiation dose to 1.25 rems per calendar quarter.

Failure to limit the whole body radiation dose of an individual in a restricted area to 1.25 rems per calendar quarter is an apparent violation of 10 CFR 20.101(a) (030-01325/94-001/02).

The MRF RSO, who is also the MRF radiation safety committee (RSC) chairman and president of the Institute, stated that MRF RSC meetings had not been held on a quarterly basis. The inspectors reviewed the MRF RSC meeting minutes and noted that the last RSC meeting was held in September 1992.

Condition 15 of License No. 08-28270-01 requires the licensee to abide by the procedures submitted in their license application and approved by the NRC. The licensee's procedures require the RSC to meet as often as necessary by not less than quarterly.

Failure of the MRF RSC to meet as often as necessary to conduct its business but not less than once in each calendar quarter is an apparent violation of License No. 08-28270-01 Condition 15 (030-30758/94-001/03).

6. Supervisory Oversight

The inspectors questioned the RA regarding how he obtained the ^{99m}Tc to perform the tagging procedure. The RA stated that he called the radiopharmacy and personally placed the order under the Nuclear Medicine Department Chairman's authorization. The inspectors noted that the WHC Nuclear Medicine Department Chairman is also the WHC

RSC chairman. As noted above, the RSC chairman had stated that he was unaware that the RA was ordering ^{99m}Tc under the WHC license in order to perform the tagging procedure. The inspectors reviewed the RA's radioactive material ordering and receipt logs to determine that 110.0 mCi and 81.6 mCi of ^{99m}Tc was ordered by the RA and delivered; on September 6, 1993 and October 31, 1993, respectively, to the WHC under the Nuclear Medicine Department Chairman's authorization. The receipt of radioactive material under the authorization of an authorized user (the Nuclear Medicine Department Chairman) indicates that the RA was working under the supervision of that authorized user.

10 CFR 35.25(a)(1) requires that an authorized user providing supervision to an individual must instruct the individual, require them to follow appropriate procedures, review the supervised individual's work, and keep records of these reviews.

Failure of the authorized user providing supervision to the RA during receipt, possession, use or transfer of byproduct material to: instruct the supervised individual; require the supervised individual to follow the established and written radiation safety procedures; and periodically review the supervised individual's use of byproduct material and keep records of these reviews is an apparent violation of 10 CFR 35.25(a)(1) (030-01325/94-001/03).

7. Radiation Safety Program

The MRF RSO stated that she and her staff identified some problems in the MRF radiation safety program. She noted that sending the film badges to the vendor for processing on a monthly basis is a condition of the NRC license. She stated that the film badges for September, October and November 1993 were collected and together sent to the vendor for procession at the end of November 1993.

Condition 15 of License No. 08-28270-01 requires the licensee to abide by the procedures submitted in their license application and approved by the NRC. The licensee's procedures for supplying film badges to radiation workers requires the film badges to be processed by a contract service on a monthly basis.

Failure to have the film badges processed by a contract service on a monthly basis is an apparent violation of License No. 08-28270-01 Condition 15 (030-30758/94-001/04).

The inspectors reviewed the WHC radioactive material ordering and receipt procedures and determined that the supervising nuclear medicine technologist or his/her designee will place all orders for radioactive material. The nuclear medicine supervisor stated that individuals designated by him to order radioactive material are named on a list provided to the radiopharmacy. The inspectors reviewed a copy of this list and noted that the RA was not included on it. As noted above, the RA was personally placing telephone orders directly to the radiopharmacy.

10 CFR 35.21(a) requires the RSO to ensure that radiation safety activities are being performed in accordance with approved procedures. The WHC procedure for ordering radioactive material requires that the supervising nuclear medicine technologist or his designee place all orders for radioactive material.

Failure of the RSO to ensure that radiation safety activities are being performed in accordance with approved procedures, specifically the radioactive material ordering and receiving procedure, is an apparent violation of 10 CFR 35.21(a) (030-01325/94-001/04).

The inspectors reviewed the WHC radioactive material ordering and receipt log, as well as the patient log. WHC had no record of the materials received by the RA.

10 CFR 30.51(a)(1) requires that a record of the receipt of radioactive material be kept showing the receipt of the material for as long as the material is possessed and for three years following the disposal of the material.

Failure of the RSO to maintain records of the receipt of the radioactive material is an apparent violation of 10 CFR 30.51(a)(1) (030-01325/94-001/05).

As stated above, both the WHC and MRF RSOs attributed the exposures to the RA reported for September and October 1993 to the tagging procedures performed by him using the two vials of ^{99m}Tc in the "old" radiopharmacy. The RA stated that the Nuclear Medicine Department Manager granted him permission to perform these tagging procedures in the "old" radiopharmacy. This was confirmed by the Nuclear Medicine Department Manager. Because the RSO was unaware of the activities being performed in the "old" radiopharmacy; this area was not included in the radiation and contamination survey program.

10 CFR 35.70(a) requires that a survey be performed in all areas where radiopharmaceuticals are prepared for use.

Failure to survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are prepared for use is an apparent violation of 10 CFR 35.70(a) (030-01325/94-001/06).

8. Corrective and Preventive Actions

At the time of the inspection neither licensee had performed an investigation beyond correlating each exposure to the months when the two tagging procedures were performed. The inspectors suggested to the WHC RSO that it should be difficult for the quantity of activity present in either of the two ^{99m}Tc filled vials to result in a 5.390 rem exposure to the film badge. A subsequent calculation performed by the WHC RSO demonstrated that it was very unlikely that the exposure resulted from the tagging

procedures alone. Following the inspection, the licensees concurred that the tagging procedures alone were an unlikely cause of the overexposure; however neither had an alternative explanation.

9. Exit Interview

The inspectors met with representatives of both the Washington Hospital Center and the Medlantic Research Institute as indicated in Section 1. The inspectors summarized the scope and purpose of the inspection, as well as the apparent findings.