U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-02745/88001(DRSS)

Docket No. 030-02745

License No. 34-05469-01 Category G1 Priority 2

Licensee: University Hospitals of Cleveland
2074 Abington Road
Cleveland, OH 44106

Inspection Conducted: February 17 and 19, 1988

Inspector: James R. Mullauer, M.H.S.
Radiation Specialist — Date 3/22/88

Reviewed By: D. G. Wiedeman, Chief
Nuclear Materials Safety
Section 1 — Date 3/22/88

Approved By: Bruce S. Mallett, Ph.D., Chief
Nuclear Materials Safety
and Safeguards Branch — Date 3/22/88

Inspection Summary

Inspection on February 17 and 19, 1988 (Report No. 030-02745/88001(DRSS))
Areas Inspected: Special announced safety inspection to followup on a telephone report of lost licensed material reported to the NRC on January 20, 1988, and described in a draft letter from the licensee dated February 12, 1988 (Attachment A). The inspector reviewed the circumstances surrounding the loss of a package containing 0.5 millicuries of phosphorus-32 which was left unattended in an unrestricted building corridor and subsequently removed by unauthorized personnel. The inspection also included a review of the licensee's ordering procedures for radioactive material.
Results: Of the areas inspected, two violations of NRC requirements were identified: (1) 10 CFR 20.207(b) - failure to tend radioactive material, under the constant surveillance and immediate control of the licensee, while stored in a unrestricted area (Section 5). (2) License Condition No. 18 - ordering radioactive material for an individual who was not on a list of current authorized users (Section 5).

DETAILS

1. Persons Contacted

University Hospital (UH)
Case Western Reserve University (CWRU)

*Robert Dubicki, Senior Vice President of Operations University Hospitals (UH)

*P. Sridhar Rao, Ph.D., Radiation Safety Officer, UH and Part-time Radiation Safety Officer for Case Western Reserve University (CWRU)

Robert Adams, Radiation Safety Committee member for UH and Part-time Radiation Safety Officer as well as Chairman of the Radiation Safety Committee for CWRU

Lois Goldstein, Purchasing Department, UH

Vernon Hall, Supervisor, Receiving Department, UH

Yung T. Huang, Assistant Professor, Lab 519 CWRU

Jim Stark, M.D., Research Fellow, Lab 519 CWRU

*Arthur Leary, Administrative Vice President, CWRU

*Ken Basch, Director of Administrative Services, CWRU

Allen Brodsky, Ph.D., Primary Radiation Safety Officer, CWRU

Kathy Uveges, Secretary, Radiation Safety Office, CWRU

Francisco Trejo, Manager, Nuclear Energy Services (NES)

*Denotes preliminary exit interview attendees on February 19, 1988.

2. Purpose of Inspection

This announced, special inspection was conducted February 17 and 19, 1988. The licensee reported a loss of licensed material by telephone on January 20, 1988, and a followup draft report was submitted to the NRC and dated February 12, 1988, (Attachment A). The inspector reviewed the circumstances surrounding the loss of a package containing 0.5 millicuries of phosphorus-32 which was left unattended in an unrestricted building corridor and removed by unauthorized personnel.

3. Organization

Leroy J. Call, Executive Vice President
Robert Dubicki, Senior Vice President of Operations
P. Sridhar Rao, Ph.D., Radiation Safety Officer
Robert Adams, Physicist

4. Licensed Program and Enforcement History

NRC Byproduct Material License No. 34-05469-01 was originally issued to University Hospitals of Cleveland on September 8, 1959, and was last renewed in its entirety via Amendment No. 22 on December 29, 1987. The license consists of a group medical program (Groups I through VI) and Type A broad scope program for medical research.

Over the last six years, the licensee has been inspected three times and had one special inspection. The last routine inspection was on November 3 and 4, 1987, and the findings included two violations regarding failure to maintain survey meter calibration records and failure to use syringe shields during patient injection.

Routine Safety Inspection: January 23 and 24, 1985

Four violations were noted:

a. License Condition No. 20; failure to perform area surveys as required and failure to record wipe test results in proper units.

b. License Condition No. 19; failure to perform dose calibrator constancy checks on every day of use.

c. License Condition No. 20; failure to maintain package receiving and opening reports on packages delivered to nuclear medicine and failure to perform package surveys.

d. 49 CFR 173.475(i); failure to perform wipe tests on generator packages sent back to the supplier.

Special Safety Inspection: June 30, July 1, 1983 and July 12-14, 1983

Reported loss of a nominal 50 millicurie cesium-137 brachytherapy source. Eight violations were noted. Violations a, b, c, and d, were assessed a $2000 Civil Penalty.

a. License Condition No. 20; failure to secure brachytherapy sources stored in a patient's room prior to use.

b. Licensed Condition No. 20; failure to secure brachytherapy sources removed from the patient on a weekend.

c. License Condition No. 20; failure of hospital personnel working on the patient's floor to accept responsibility for sources left in a patient's room after explant.

d. License Condition No. 20; failure to inventory brachytherapy sources when placed in the storage room after use.

e. 10 CFR 20.105(b)(1) and (2); radiation levels in unrestricted areas exceeded 2 mR/hr or 100 mR in any seven consecutive days.

f. License Condition No. 20; failure to wear a ring badge while handling brachytherapy sources.

g. License Condition No. 20; failure to perform an area survey after implant of brachytherapy sources.

h. License Condition No. 20; failure to maintain required documents showing the times, dates and names of personnel handling brachytherapy sources.

Routine Safety Inspection: August 9 and 10, 1982

Five violations were noted:

a. License Condition No. 20; failure to perform surveys.

b. 10 CFR 20.301; disposal of licensed material above regulatory limits.

c. License Condition No. 20; failure to wear a finger badge while handling radiopharmaceuticals.

d. License Condition No. 14.B; failure to perform a leak test on an americium-241 sealed source.

e. License Condition No. 20; air flow rates not measured as required.

5. Chronology Review of Lost Licensed Material

December 30, 1987: Dr. John Huang, a Case Western Reserve University (CWRU) researcher in the virology Laboratory Room No. 519 of the pathology building placed an order for radioactive material through the University Hospitals (UH) purchasing department. The order was for two 25 microliter vials, each to contain 250 microcuries of phosphorus-32 DCTP (deoxycytidine Triphosphate). The material is used to label compounds for subsequent autoradiography. Upon receipt of the order, the UH purchasing agent checked their list of currently authorized users and found that Dr. Huang was not an authorized user under University Hospitals license. The agent then called the CWRU radiation safety office to verify that Dr. Huang was authorized for phosphorus-32 at CWRU. (This inspector learned that ordering radioactive material through UH was common practice when CWRU researchers obtain research grants from UH.) When the purchasing agent at UH learned that Dr. Huang was authorized at CWRU, the order was processed. Ordering radioactive material for an individual not authorized at UH to receive or use radioactive material is a violation of License Condition No. 18 which references Item 12 of letter dated February 1, 1985. Item 12 of the above referenced letter states that the purchasing department of the hospital will place an order for radioactive material only if the name of the person requesting it is on a list of currently authorized users.

January 15, 1988 (Friday): The package was delivered to the receiving department of UH where it sat on a shelf until the following Monday. The package was marked at each end with a 1.5 inch by 4 inch label stating Limited Quantity and a statement that "this package conforms with 49 CFR 173.421, excepted Radioactive Material". The package was also labeled "Dry Ice" and the receipt papers stated "Refrigerate". The package, however, was not kept refrigerated.

January 18, 1988 (Monday): At 9:30 a.m., the package was delivered to the ordering Laboratory Room No. 519, of the pathology building. Dr. Stark, a fellow researcher in Laboratory No. 519 inspected the package and found that the dry ice sublimed and the materials were thawed. At 9:45 a.m., Dr. Stark decided that the materials had chemically spoiled and called UH receiving to retrieve the package. Vernon Hall, a supervisor in the receiving department spoke with Dr. Stark and stated he would personally pick up the package. Mr. Hall and stated that he does not remember being told that the package contained radioactive material. At 10:00 a.m., Dr. Stark notified the purchasing agent, Lois Goldstein, to make arrangements to have the package returned to the vendor. While Dr. Stark was on the phone, Mr. Hall arrived at the laboratory. The purchasing agent advised Dr. Stark to release the package to Mr. Hall and then call Tim Morton of the Material Management Division to advise him of the situation. Mr. Hall took the package away. On the way back to the receiving department, Mr. Hall noticed a pile of empty boxes on the fifth floor corridor of Rainbow Babies and Childrens Hospital. Mr. Hall stated that since he thought the package was going to be trashed away, he placed the package inside the empty boxes and then left. This constitutes a violation of 10 CFR 20.207(b) which requires that licensed materials in an unrestricted area and not in storage be tended under the constant surveillance and immediate control of the licensee.

When Mr. Hall arrived back in the receiving department at 11:00 a.m., Mr. Morton asked where the package was. When Mr. Hall told him what he did with the package, Mr. Morton advised Mr. Hall that the package contained radioactive material and told Mr. Hall to immediately go back to the fifth floor and retrieve the package. When Mr. Hall arrived at the fifth floor, the package and empty boxes were gone. In the meantime, 12:00 p.m., the purchasing agent Ms. Goldstein contacted Dr. Rao, Radiation Safety Officer (RSO) at U.H. about the procedure for returning radioactive material. After some discussion, it was decided that the pu hasing agent would notify Mr. Morton to have the package brought to the radiation safety office for safe keeping until the administrative details for proper disposal could be worked out.

January 19, 1988 (Tuesday): At approximately 1:30 p.m., since the package was not returned to the safety office, Dr. Rao contacted the receiving department. When Mr. Hall explained what had happened, the licensee initiated a search for the package.

January 20, 1988 (Wednesday): After multiple interviews with hospital personnel, lab personnel and housekeeping, a walk through search of areas where the package may have been placed and surveys of these areas, the licensee concluded the package was lost and notified the NRC at approximately 2:40 p.m. (CST).

Two violations of NRC requirements were identified.

6. Notifications and Reports

10 CFR 20.402(a) requires, in part, that licensees report to the Commission, by telephone, immediately after a determination that a loss or theft of licensed material has occurred in such quantities and under such circumstances that it appears to the licensee that a substantial hazard may result to persons in unrestricted areas. A written report, containing the information described in 10 CFR 20.402(b), is required to be sent to the Commission within 30 days after learning of the loss or theft of Licensed Material.

On January 20, 1988 at 2:40 p.m. (CST), Mr. Dubicki, Senior Vice President notified Region III by telephone that the package of phosphorus-32 was lost. In a draft letter dated February 12, 1988, (Attachment A) Dr. Rao reported to the Commission the information required by 10 CFR 20.402(b).

No violations were identified.

7. Exit Interview

On February 19, 1988, an exit interview was held with those denoted in Section 1 of this report. The apparent violations were discussed as well as NRC policy regarding normal enforcement procedures.

Attachments:
1. Attachment A, Ltr dtd 2/12/88
   Dubicki to Mullauer
2. Attachment B, Copy of Receipt Record
3. Attachment C, Nuclear Energy Service
   Report on Search Effort