

September 23, 1996

Fred Kolb, Vice President
 Clinical Operations
 Bethesda Hospital
 619 Oak Street
 Cincinnati, OH 45206

SUBJECT: NOTICE OF VIOLATION DATED AUGUST 21, 1996

Dear Mr. Kolb:

This acknowledges receipt of your letter dated September 17, 1996, in response to our letter dated August 21, 1996, transmitting a Notice of Violation.

We have reviewed your corrective actions, which appear to be adequate, and have no further questions at this time. These corrective actions will be examined during a future inspection.

Sincerely,

Original Signed by Roy J. Caniano

for Cynthia D. Pederson, Director
 Division of Nuclear Material Safety

License No.: 34-10921-03
 Docket No.: 030-02809

bcc w/ltr dtd 09/17/96: PUBLIC

DOCUMENT NAME: G:\LTRS 2LIC\MTLS\030\96302809.LO³

To receive a copy of this document, indicate in the box: "C" = Copy without enclosures "E" = Copy with enclosures "N" = No copy

OFFICE	DNMS/R/II	DNMS/R/III	DNMS/R/III						
NAME	DPISKURA/jaw <i>DP</i>	3JHOLT <i>3JH</i>	CDPEDERSON <i>CDP</i>						
DATE	09/20/96	09/20/96	09/23/96						

OFFICIAL RECORD COPY

270033

9609270328 960923
 PDR ADDOCK 03002809
 C PDR

TE07



TriHealth

United States Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D.C. 20555

RE: REPLY TO A NOTICE OF VIOLATION

Dear Sir/Ma'am:

*A community
partnership of
Bethesda and
Good Samaritan Hospital*

This is in response to your letter of August 21, 1996, Subject: NRC Inspection and Notice of Violation (June 21, 1996 NRC Inspection of License No. 34-10921-03, Docket No. 030-02809)

Item designations correspond to those in your enclosure.

Item 1:

10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in unrestricted areas. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in an unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, **unrestricted** area means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, on or about April 7, 1996, the licensee did not secure from unauthorized removal or limit access to approximately 290 microcuries of iodine-131 contaminated trash and bed linens located in Room 197 of Bethesda Oak Hospital, an unrestricted area, nor did the licensee control and maintain constant surveillance of this licensed material.

This is a Severity Level IV violation (Supplement IV).

This is a repeat problem identified in 1994.

(1) Reason for the Violation

During inpatient therapy procedures, the patient is considered to be a controlled area instead of an unrestricted area. From the time the patient is released until the time the room is decontaminated and released, the room has been considered to be controlled by the licensee by virtue of required postings (radioactive materials signs) and training of individuals on the nursing and housekeeping staff. This is the same control that is currently exercised during the patient stay in the room. The housekeeper who had been

Bethesda Hospital, Inc.
10500 Montgomery Road
Cincinnati, Ohio 45242-9508
513.745.1111

SEP 17 1996

9609190156 7AP

trained in radiation safety and in the proper clean up of a therapy room had retired the week prior to this incident. Due to lapse in annual refresher training for certain personnel in housekeeping, due to the fact that they did not previously perform this job function for several years, and the delay in clean up after the patient was discharged (4 days), the signs posted on the door to the room were ignored by the person from housekeeping.

(2) Corrective Steps Taken and Results Achieved

We have 2 locked therapy rooms, which were in use at this time. A third room was required to accommodate this patient, which was an unlocked patient room. Immediately after discovery of the lost material, the maintenance department was contacted to place a key lock on the door of a third inpatient therapy room. This lock can only be activated with a key to prevent a patient from being locked inside the room. Keys for the locks are possessed only by Nuclear Medicine personnel and security personnel.

A training program was provided for housekeeping personnel on 7/23/96 and 7/29/96 to make them aware of locations of storage and use of radioactive materials, and requirements for cleaning these areas. An outline of the inservice material and question and answer time were provided during the training. Emphasis has been and will continue to be placed on signage so the employee recognizes this warning even if unable to read.

Since these steps have been taken, no further problems have occurred.

(3) Corrective Steps to Avoid Further Violations

For all future inpatient radiopharmaceutical therapy procedures, the door to the room will be locked after the patient is released. The door will remain locked until Nuclear Medicine personnel are able to decontaminate and release the room for unrestricted use.

Refresher training of all housekeeping personnel involved with cleaning a former therapy room will be reviewed for content and provided on an annual basis.

Refresher Training will be audited by the Manager of Nuclear Medicine and reviewed during the third quarter Radiation Safety Committee, Health Physics Audit. Only staff who have had the appropriate annual radiation safety training will be involved in the room clean up.

(4) Date for Achieving Full Compliance

Full compliance will be achieved after the inservice has been successfully completed. Inservice completed on 7/23/96 and 7/29/96. Inservice included video presentation, outline of information to be covered, summary at the end of the presentation, with a question and answer period.

Item 2:

10 CFR 20.2001 requires that the licensee dispose of licensed material only by certain specified procedures.

Contrary to the above, on or about April 7, 1996, the licensee disposed of approximately 290 microcuries of iodine-131 in the form of contaminated trash and bed linens by release to the normal, non-radioactive trash, a method not authorized by Section 20.2001.

This is a Severity Level IV violation (Supplement IV).

(1) Reason for the Violation

Due to the lapse in training and the delay in final documentation of the patient room as discussed in Item 1, a member of the housekeeping staff removed the possibly contaminated trash and linen from the room.

(2) Corrective Steps Taken and Results Achieved

We have 2 locked therapy rooms, which were in use at this time. A third room was required to accommodate this patient, which was an unlocked patient room. Immediately after discovery of the lost material, the maintenance department was contacted to place a key lock of a third inpatient therapy room. This lock can only be activated with a key to prevent a patient from being locked inside the room. Keys for the locks are possessed only by Nuclear Medicine personnel and security personnel.

A training program was provided for housekeeping personnel on 7/23/96 and 7/29/96 to make them aware of locations of storage and use of radioactive materials, and requirements for cleaning these areas. The inservice included what to look for when dealing with radioactive materials, different types of signs, i.e. Radioactive Material vs. Radiation Area, this emphasis has been and will continue to be placed on signage, so that employees recognize this warning even if unable to read.

Since these corrective steps have been taken, no further problems have occurred.

(3) Corrective Steps to Avoid Further Violations

For all future inpatient radiopharmaceutical therapy procedures, the door to the room will be locked after the patient is released. The door will remain locked until Nuclear Medicine personnel are able to decontaminate and release the room for unrestricted use.

Refresher training of all housekeeping personnel involved with cleaning a former therapy room will be reviewed for content and provided on an annual basis.

Refresher Training will be audited by the Manager of Nuclear Medicine and reviewed during the third quarter Radiation Safety Committee, Health Physics Audit. Only staff who have had the appropriate annual radiation safety training will be involved in the room clean up.

There will be follow up with all managers of Nursing Units, Housekeeping, Nuclear Medicine, Security, and receiving regarding these violations, with the understanding that the Radiation Safety Program is a shared responsibility. The managers of Housekeeping, Security, and Receiving will be made aware of the results of the 3rd quarter audit for compliance with the Refresher Training Program.

(4) Date for Achieving Full Compliance

Full compliance will be achieved after the inservice has been successfully completed. Full compliance has been achieved as of the completion of the Radiation Safety Training on 7/23/96 and 7/29/96.

Item 3:

10 CFR 35.315(a)(5) requires, in part, that the licensee monitor material and items removed from the patient's room to determine that their radioactivity cannot be distinguished from the natural background or handle them as radioactive waste.

Contrary to the above, on or about April 7, 1996, the licensee removed a bag of contaminated trash and bed linens from a patient's room without monitoring these items for radioactivity.

This is a Severity Level IV violation (Supplement VI).

(1) Reason for the Violation

Due to the lapse in training and the delay in final documentation of the patient room as discussed in Item 1, a member of the housekeeping staff removed the possibly contaminated trash and linen from the room. Since the only persons trained to monitor trash prior to removal are in Nuclear Medicine Service, the trash was removed before anyone from Nuclear Medicine had an opportunity to monitor it.

(2) Corrective Steps Taken and Results Achieved

We have 2 locked therapy rooms, which were in use at this time. A third room was required to accommodate the patient, which was an unlocked patient room. Immediately after discovery of the lost material, the maintenance department was contacted to place a key lock on the door of a third inpatient therapy room. These locks can only be activated with a key to prevent a patient from being locked inside the room. Keys for the locks are possessed only by Nuclear Medicine personnel and security personnel.

A training program was provided for housekeeping personnel on 7/23/96 and 7/29/96 to make them aware of locations of storage and use of radioactive materials, and requirements for cleaning these areas. An outline of the inservice material and question and answer time were provided during the training. Emphasis has been and will continue to be placed on signage so the employee recognizes this warning even if unable to read.

Since these corrective steps have been taken, no further problems have occurred.

(3) Corrective Steps to Avoid Further Violations

For all future inpatient radiopharmaceutical therapy procedures, the door to the room will be locked after the patient is released. The door will remain locked until Nuclear Medicine personnel are able to decontaminate and release the room for unrestricted use.

Refresher training of all housekeeping personnel involved with cleaning a former therapy room will be reviewed for content and provided on an annual basis.

Refresher Training will be audited by the Manager of Nuclear Medicine and reviewed during the third quarter Radiation Safety Committee, Health Physics Audit. Only staff who have had the appropriate annual radiation safety training will be involved in the room clean up.

There will be follow up with all managers of Nursing Units, Housekeeping, Nuclear Medicine, Security, and Receiving regarding these violations, with the understanding that the Radiation Safety Program is a shared responsibility. The managers of Housekeeping, Security, and Receiving will be made aware of the results of the 3rd quarter audit for compliance with the Refresher Training Program.

(4) Date for Achieving Full Compliance

Full compliance will be achieved after the inservice has been successfully completed. Full compliance has been achieved as of the completion of the Radiation Safety Training on 7/23/96 and 7/29/96.

Item 4:

Condition 22. of License No. 34-10921-03 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in application dated March 25, 1991, and letters dated July 1, 1991, September 19, 1991, January 7, 1993, September 30, 1994 and May 15, 1995.

Item 8 of application dated March 25, 1991 entitled, "Training for individuals working in or frequenting restricted areas," requires the licensee to establish and implement its training program in accordance with Appendix A to Regulatory Guide 10.8, Revision 2. Appendix A specifies personnel receive instruction during annual refresher training.

Contrary to the above, as of September 7, 1994, the licensee has not provided its housekeeping staff with annual refresher training.

This is a Severity Level IV violation (Supplement VI).

(1) Reason for the Violation

In the past the training was requested via a letter sent to the Director of each ancillary department, requesting training be provided, followed by written documentation for themselves and the Manager of the Nuclear Medicine Department.

(2) Corrective Steps Taken and Results Achieved

A training program was provided for housekeeping personnel on 7/23/96 and 7/29/96 to make them aware of locations of storage and use of radioactive materials, and requirements for cleaning these areas. The inservice included what to look for when dealing with radioactive materials, different types of signs, i.e. Radioactive Material vs. Radiation Area, this emphasis has been and will continue to be placed on signage, so that employees recognize this warning even if unable to read.

Since these corrective steps have been taken, no further problems have occurred.

(3) Corrective Steps to Avoid Further Violations

Refresher training of all housekeeping personnel involved with cleaning a former therapy room will be reviewed for content and provided on an annual basis.

Refresher Training will be audited by the Manager of Nuclear Medicine and reviewed during the third quarter Radiation Safety Committee, Health Physics Audit. Only staff who have had the appropriate annual radiation safety training will be involved in the room clean up.

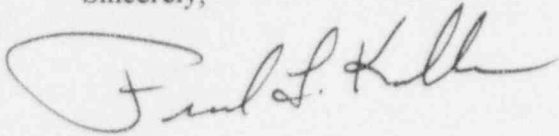
There will be follow up with all managers of Nursing Units, Housekeeping, Nuclear Medicine, Security, and Receiving regarding these violations, with the understanding that the Radiation Safety Program is a shared responsibility. The managers of Housekeeping, Security, and Receiving will be made aware of the results of the 3rd quarter audit for compliance with the Refresher Training Program.

(4) Date for Achieving Full Compliance

Full compliance will be achieved after the inservice has been successfully completed. Full compliance has been achieved as of the completion of the Radiation Safety Training on 7/23/96 and 7/29/96.

If there are any questions, please contact Fred Kolb, Vice-President, Clinical Operations, Bethesda Hospital, 10500 Montgomery Rd., Cincinnati, OH 45242.

Sincerely,



Fred Kolb
Vice-President, Clinical Operations

cc: Regional Administrator
United States Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351