

HOWARD UNIVERSITY

WASHINGTON, D.C. 20059

OFFICE OF THE VICE PRESIDENT
FOR HEALTH AFFAIRS
RADIATION SAFETY COMMITTEE

April 8, 1994

Ms. Jenny M. Johansen, Chief
Medical Inspection Section
Division of Radiation Safety and
Safeguards
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

RE: Docket No. 030-01321
License No. 08-03075-07

Dear Ms. Johansen:

I am writing to respond to your letter of March 14, 1994 which contains a report of findings during an inspection conducted on February 16 and 17, 1994 of activities at Howard University Hospital which are authorized by NRC License Number 08-03075-07. The following addresses the corrective measures which became effective immediately for the violations which were noted during that inspection:

ITEM A:

VIOLATION:

Failure to label a syringe containing a technetium-99m labeled radiopharmaceutical to show the radiopharmaceutical name or its abbreviation, or the clinical procedure to be performed, or the patient's name.

CORRECTIVE ACTION:

1. In addition to the regular training which has been conducted on an annual basis, additional training has been instituted. The Radiation Safety Officer will conduct monthly training sessions for the Nuclear Medicine staff. The training will address topics from 10CFR Part 35. Any deficiencies identified in the Nuclear Medicine radiation safety program during the previous month, will be discussed in detail. The Radiation Safety Officer will

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also cover the Model Procedures found in **Appendix I of Regulatory Guide 10.8** which will include emphasizing that labels are to be attached to the syringes to show the radiopharmaceutical, clinical procedure and the patient's name. Following each training session, the technologists will be required to sign a document stating that he/she understood what was covered during the training session. The Radiation Safety Officer will conduct spot checks and if he notes deficiencies during these checks a written report will be forwarded to the Chief of the Nuclear Medicine Division. These deficiencies will be discussed in the next training session. Disciplinary action will be administered depending on the nature of the deficiencies. The disciplinary action will be in accordance with the University policies and procedures as outlined in the Howard University Handbook. An additional Medical Physicist has been hired, who will also instruct the technologists in topics from 10CFR Part 35.

2. Disciplinary action (three [3] day suspension without pay) has been recommended by the Department of Radiology/Nuclear Medicine Division management for the technologists who violated the labeling procedure.
3. A supervisory technologist position has been requested in the FY 1995 budget request for the Nuclear Medicine Division to assume the on-site supervision of the technologists.

ITEM B:

VIOLATION:

The membership of the Howard University Hospital Radiation Safety Committee did not include an authorized user of materials identified in 10CFR 35.400.

CORRECTIVE ACTION:

1. Based on a request to the Chairman of the Department of Radiotherapy to recommend an authorized user of materials in 10 CFR Part 35.400 for membership on the Committee, Ebrahim

Ashayeri, M.D. was recommended. Once he is officially appointed to the Committee we will notify the U.S. Nuclear Regulatory Commission. The Howard University Hospital Radiation Safety Committee was merged with the Howard University Radiation Safety Committee on January 1, 1994.

ITEM C:

VIOLATION:

On December 12, 1992, the Howard University Hospital Radiation Safety Committee met and conducted business and a quorum was not established because the representative of management did not attend the meeting.

CORRECTIVE ACTION:

1. The problem of management not being present at this meeting had been identified and steps had been in place to correct the problem. The former Chairman of the Howard University Hospital Radiation Safety Committee and management had been made aware of the requirements for conducting a meeting.
2. Effective January 1, 1994, the Howard University Hospital Radiation Safety Committee was merged into the Howard University Radiation Safety Committee. This is one of the mechanisms of ensuring that the required guidelines are maintained. Official meetings will not be held unless the membership requirements as stated in 10 CFR Part 35.22 are met.

ITEM D:

VIOLATION:

Through the Radiation Safety Officer, (1) failure to ensure that radiation safety activities were being performed in accordance with the Model Spill Procedures of Appendix J to Regulatory Guide 10.8, Revision 2; (2) failure to dispose of radioactive waste in designated, labeled and properly shielded receptacles.

CORRECTIVE ACTION:

1. The re-training process for handling radioactive spills in accordance with the Model Procedures of Appendix J to Regulatory Guide 10.8, Revision 2 began immediately after the site visit and will be conducted on an on-going basis.

2. The Radiation Safety Officer and the Medical Physicist will review with the technologists the proper procedures for the disposal of radioactive waste and will conduct more frequent spot checks of the Nuclear Medicine Division.
3. Howard University Hospital is purchasing a Honeywell Security System for the Nuclear Medicine Division. The installation date is scheduled for April 30, 1994. The system will require the use of personnel I.D. and security codes for entry. Access will be limited to authorized personnel; thereby, allowing a record of who enters the hot lab, and the date and time of entry.

ITEM E:

VIOLATION:

Nuclear Medicine Technologists, working under the supervision of an authorized user, used sealed source to check the survey instruments and the records of this use, which contained several discrepancies were not reviewed periodically by the licensee.

CORRECTIVE ACTION:

1. On February 18, 1994, the Radiation Safety Officer met with the technologists and reviewed 1) the proper operation of the survey instruments, 2) use of the appropriate check source and 3) proper recording of data. At this session the technologists had to demonstrate that they understood and could conduct these activities properly and independently. Additional training sessions were conducted on February 25 and March 1, 1994. As a part of the monthly training program identified in item A1 this topic was discussed again on March 18, 1994 by the Radiation Safety Officer. The topic will continue to be covered in additional sessions.
2. The Radiation Safety personnel are now checking the readings obtained by the technologists daily and will maintain a record of the results. If it is found that the checks are not performed properly, a written notification will be sent to the Nuclear Medicine Division and reprimands will be enforced by the Radiology/Nuclear Medicine management.

ITEM F:

VIOLATION:

The Nuclear Medicine technologists were not instructed in the procedures of measuring molybdenum concentration and in the proper procedures of checking survey instruments for proper operation.

CORRECTIVE ACTION:

1. The Nuclear Medicine technologists were instructed in past training sessions, the most recent session was held in November 1993. Effective immediately additional monthly training sessions have been instituted. In particular this item will be re-emphasized with an examination at the end of the session.

The Administrator of the Department of Radiology met with the Nuclear Medicine technologists on March 24, 1994 to inform them of the seriousness of these violations and steps to be taken to reprimand individuals who do not adhere to the regulations and policies and procedures.

ITEM G:

VIOLATION:

The record of the quarterly linearity tests of the dose calibrator performed between August 31, 1992 and December 13, 1993 did not include the signature of the Radiation Safety Officer.

CORRECTIVE ACTION:

Please note as temporary Radiation Safety Officer during 1992 and 1993, Dr. Marlene McKetty signed the quarterly linearity tests of the dose calibrator in the Nuclear Medicine Division. Effective immediately Mr. Talley, the current Radiation Safety Officer, will sign the quarterly dose calibration linearity tests.

ITEM H:

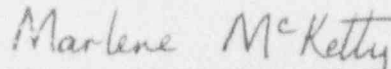
VIOLATION:

Records of physical inventory of sealed sources did not contain the signature of the Radiation Safety Officer.

CORRECTIVE ACTION:

Effective immediately the Radiation Safety Officer will sign the records of physical inventories of sealed sources. An example of the current form is attached.

Sincerely yours,



Marlene H. McKetty, Ph.D., Chairperson
Howard University Radiation Safety
Committee

cc: Dr. Walter F. Leavell
Dr. Angella D. Ferguson
Dr. Thomas Gaiter
Ms. Marie Cameron
Dr. James S. Teal
Dr. Willie McDaniel

HOWARD UNIVERSITY
WASHINGTON, D.C. 20058

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OFFICE OF THE VICE PRESIDENT
FOR HEALTH AFFAIRS
Radiation Safety Committee

September 4, 1992

Ms. Sherie Arredondo
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

RE: License No. 08-00386-19
SUD-584
SNM-563

Dear Ms. Arrendondo:

I have enclosed documentation of my training and experiences as requested by you in a telephone conversation with Diana Roach on August 18, 1992. I will serve as the Radiation Safety Officer for Howard University for a temporary period not to exceed December 31, 1992. If you need additional information, please call the Radiation Safety Office on 202/806-7216.

Sincerely yours,

Marlene McKetty
Marlene H. McKetty, Ph.D., Chairperson
Howard University Radiation Safety
Committee

cc: Dr. Russell L. Miller, Vice President
for Health Affairs
Howard University