Georgetown University
Office of Environmental Health and Safety

Room LM12 Preclinical Science
3900 Reservoir Road N.W.
Washington D.C. 20007

Radiation Safety
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25 September 1996

Dr. Mohamed M. Shanbaky
Chief, Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Docket Number: 030-01315
License Number: 08-01709-04

REPLY TO NOTICE OF VIOLATION

Dear Mr. Shanbaky:

We are responding on behalf of Georgetown University to your letter dated August 26, 1996 and the NOTICE OF VIOLATION accompanying it. These communications were the result of ROUTINE INSPECTION NUMBER 030-0135/96-001 on July 23, 24, 25, 1996.

A. *10 CFR 35.415(a)(4) requires, in part, that a licensee, promptly after implanting brachytherapy sources, survey the dose rates in contiguous unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 10 CFR Part 20.*

Contrary to the above, as of June 1996, the licensee did not survey the dose rates in unrestricted contiguous areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 10 CFR Part 20. Specifically, as of June 1996, the licensee implanted cesium-137 brachytherapy sources and did not measure the dose rate in contiguous patient rooms and unrestricted areas, to demonstrate that the dose rates were below limits described in 10 CFR 20 and license conditions.

Reason for the violation: Dose rate measurements were taken within a brachytherapy patient's room. A dose rate of 5 mR/hr at an adjoining patient wall was considered to be 2 mR/hr at the other side of the wall. Credit was taken for the shielding provided by the wall and the location of the adjacent patient's position within the room. This was done so as not to cause undue anxiety to the non-implant patients in the adjacent rooms.

Corrective steps that have been taken and the results achieved: Dose rate measurements are now made in adjoining patient rooms when the dose rate at the wall inside the brachy patient's room exceeds 2 mR/hr. The survey form used to document the dose rates has been modified to instruct the surveyor to go into the adjacent patient room if the meter reading inside the implant patient room exceeds 2 mR/hr. Compliance has been achieved.

Corrective steps that will be taken to avoid further violations: Surveys will be performed as required. A request for an exemption to monitor only the implant patient room will be submitted in the future. The request will demonstrate that when a dose rate of some maximum value is achieved, the dose rate on the other side of the wall will not exceed 2 mR/hr.

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Date when full compliance will be achieved: 26 July 1996, revised forms completed 19 September 1996.

B. *10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for training individuals working in or frequenting restricted areas are described in the application dated August 21, 1995, and were approved by License Condition No. 2.6.*

Item 8 of application dated August 21, 1995 states, in part, that the training provided to persons working with radioactive materials includes appropriate radiation safety procedures.

Contrary to the above, as of July 23, 1996, the licensee, through its Radiation Safety Officer, did not ensure that radiation safety activities were being performed in accordance with the above procedures. Training provided to nuclear medicine technologists was inadequate. Specifically, the Nuclear Medicine Technologist working in the hot lab (a restricted area) was inadequately trained in radiation safety procedures for receipt of radioactive material surveys, and the proper use of survey meter operability check. In that, the hot lab technologist taped the survey meter check source to the front of the survey meter and proceeded to survey the radioactive material packages. When performing the survey at one meter, the technologist did not notice that the results could have been artificially elevated, due to the close proximity of other packages containing radioactive material. Another technologist was inadequately trained in the proper use of personnel dosimetry. In that, she wore her finger TLD dosimeter on the left finger where the right hand received the highest dose; thereby, giving an inadequate dose assessment to the right hand.

Reason for the violation: The individual using the survey meter and monitoring the package was stressed by the NRC inspection and could not adequately respond to questions regarding her actions. From May to the date of the inspection she called the RSO nearly once each week expressing her concern about how to interface with the inspectors. She is generally the first person in the Nuclear Medicine suite.

After initial training in the use of a dedicated check source with the survey meter (nearly one year ago) all of the Nuclear Medicine Technologists adequately provided verbal responses with regard to the use of the source with the meter. The act of taping the source to the meter is recent and when questioned the technologist could not explain when, why or how it came about.

Monitoring all packages at once is an expedient and practical method. If the sum of all the packages is less than 200 mR/hr on contact or 10 mR/hr at one meter, then no one package exceeds these values. If the values are exceeded then each package must be surveyed.

The technologist was temporarily wearing the ring dosimeter on the left hand until she had the opportunity to wrap tape on the ring to make it fit better. The ring was too large for the right hand without the tape. The inspection interrupted the daily routine and caused delays in normal activities.

Corrective steps that have been taken and the results achieved: Retraining in the use of the portable survey meter, package receipt and wearing dosimetry was performed by Radiation

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Safety Office Staff (RSOS) on 25 July, 12 and 19 September 1996. The training on 19 September by the RSO included hands-on demonstration by the Technologists of each of the items cited in the NOV. There appears to be full understanding of the issues and proper procedures.

A smaller size ring was ordered to solve the dosimetry problem.

Corrective steps that will be taken to avoid further violations: RSOS is to periodically spot check the performance of the Nuclear Medicine Technologists until 30 November 1996 to ensure understanding and compliance. Future training will include hands-on demonstrations and/or verbal responses by the trainees to ensure understanding.

Date when full compliance will be achieved: 25 July 1996 for the concerns cited. Smaller ring dosimeter received 1 September 1996.

C. *Condition 26 of License No. 08-01709-04 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in application dated August 21, 1995.*

Item 2(c)(1) of Appendix C of application dated August 21, 1995, states, in part, that monitoring for radioactive contamination is required for labeled packages.

Contrary to the above, the licensee did not conduct its program in accordance with the statements, representations, and procedures contained in application dated August 21, 1995. Monitoring for radioactive contamination was not performed for labeled packages. Specifically, during the month of April 1996, several labeled packages were received in Nuclear Medicine, and the packages were not surveyed for removable surface contamination.

Reason for the violation: A review of the number of packages received and processed from 1 January 1996 through 31 July 1996 was made by the RSO. The same technologist usually begins and completes the startup procedures. Most packages arrive during this time.

Number of days packages were received received by same tech	147 109		
Number of days when documentation of wipe test was not recorded - all the same tech	April -3 ea May -3 ea	% of days wipe tests not recorded by same tech	5.5 %
Number of packages received received by same tech	505 386		
Number of packages missing wipe test results	24	% of package wipe test results not recorded by same tech	6.2 %

On the days when the package wipe tests were not recorded the background wipe test was recorded. As can be seen by the above table the packages are normally processed as required. Most likely the wipe survey was performed, the wipes counted but not recorded.

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Corrective steps that have been taken and the results achieved: The Chief Technologist has been reviewing the package receipt records and the package receipt requirements were addressed in the retraining mentioned in NOV B. Compliance has been achieved.

Corrective steps that will be taken to avoid further violations: The Chief Technologist has posted a list of tasks in order of priority for the Nuclear Medicine startup routine. The Chief Technologist is to review the daily package receipt records until 31 October 1996 to ensure compliance. The Nuclear Medicine Technologists will rotate each week or month to review the records of the startup activities from 23 September through 15 December 1996.

Date when full compliance will be achieved: 25 July 1996

With regard to the dose calibrator constancy check, this was covered in the training mentioned above and is the first item to be performed in the startup routine.

Thank you for your report on Mrs. Darden and Mr. Manning's recent inspection. We appreciate the opportunity to further improve our Radiation Safety Program.

Sincerely,

James F. Burris, M.D.
Associate Dean for Research Operations
Management Representative

Sim R. Shanks
Radiation Safety Officer