U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-02649/96002(DNMS)

Docket No. 030-02649

License No. 34-00466-01

Licensee: Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195

Inspection Conducted: September 4, 1996

Inspectors: Darrel Wiedeman, Senior Radiation Specialist

John Jones, Senior Radiation Specialist

Robert Gattone, Radiation Specialist

Approved By: B. J. Holt, Chief, Nuclear Materials Inspection Branch 1

Inspection Summary:

Inspection conducted on September 4, 1996, (Report No. 030-02649/96002(DNMS))
Areas Inspected: This was an announced, special inspection to review the events relating to an August 27, 1996 contamination incident following the administration of a therapeutic dosage of iodine-131 resulting in both onsite and offsite contamination. The NRC Region III staff conducted both onsite and offsite radiation measurements and personnel interviews on September 4, 1996. This inspection also included an independent assessment of both internal and external radiation exposures to the individuals directly involved in the incident.
Results: Three apparent violations were identified: (1) failure to survey (monitor) hands after a therapy procedure (License Condition 39(B)); (2) failure to conduct appropriate radiation surveys to determine the extent of external contamination (10 CFR 20.1501); and (3) failure to follow the instructions of the authorized user for administration of liquid iodine-131 therapy doses (10 CFR 35.25(a)(2)).

DETAILS

1. Persons Contacted

* Judy McKenna, M.S., Director of Radiation Safety/Radiation Safety Officer
* Melinda Estes, M.D., Associate Chief of Staff
John Manchook, Radiation Safety Technician
Nancy McMillen, Nuclear Medicine Technologist
Lenny Borelli, Nuclear Medicine Technologist
Shashi Khandekar, Chief Nuclear Medicine Technologist
Sabastian Cook, M.D., Authorized User, Nuclear Medicine
Julie Laveglia, R.N., Nurse

* Denotes those individuals present during the exit summary discussions conducted by telephone on September 6 and 12, 1996.

Off-Site Locations Inspected
BW3 Tavern
David Ticherich, Owner/Operator
1313 Old River Road
Cleveland, Ohio

Three private residences occupied by Cleveland Clinic employees.

2. Program Summary and Inspection History

The Cleveland Clinic Foundation (Licensee) is authorized under NRC broad scope License No. 34-00466-01 to possess and use byproduct material for medical use as described in 10 CFR 35.100, 35.200, 35.300, 35.400 and 35.500, and sealed sources of iridium-192 for use in a High Dose Rate (HDR) remote afterloading brachytherapy device for the treatment of cancer in humans. The license also authorizes use of byproduct material with Atomic Numbers between 1 and 83 including increased possession activity for a limited number of specifically listed radionuclides and sealed sources for research and development as defined in 10 CFR 30.4, instrument calibration, animal studies, and sealed sources in irradiator devices for non-human irradiator studies.

On July 19, 1991, the NRC issued a Notice of Violation and $7,500 Civil Penalty for a phosphorus-32 spill resulting in radiation exposures to individua s and off-site contamination. The incident was indicative of a programmatic breakdown, in that the NRC found 14 violations related to ineffective control, assessment, and oversight of the radiation safety program by the management of Cleveland Clinic Foundation, members of the Radioisotope Committee and the Radiation Safety Officer.

In January 1992, a special inspection was conducted concerning a brachytherapy misadministration. No violations were identified but several areas of concern were noted.

In August 1992, a routine safety inspection identified four violations: (1) failure to use absorbent pads when working with radioactive materials (repeat violation), (2) failure to provide training to individuals who used the J. L. Shepherd and Associates Mark I series irradiator (repeat violation), (3) failure to perform bioassays of individuals who used I-125 in excess of 1 millicurie (repeat violation), and (4) failure to determine the annual average concentration of radioactive material in air discharged to unrestricted areas. Additionally, the licensee made a commitment to revise the laboratory radiation safety procedures manual to delineate appropriate requirements for surveys, bioassays and other good health physics practices.

In January 1993, a special safety inspection identified two violations: (1) failure to properly implement the licensee's Quality Management Program and (2) failure to include written policies and procedures for identifying, evaluating, and correcting unintended deviations from the written directive.

In September 1993, a routine safety inspection identified two violations: (1) failure to fully implement the Quality Management Program and (2) failure to calculate the amount of time needed after a spill of radioactive gas to reduce concentration levels in the room to acceptable levels.

In January 1995, a routine safety inspection identified one violation: failure to evaluate an extremity dose to a worker to demonstrate compliance with regulatory dose limits. In addition, an area of concern was identified regarding the completion and distribution of a Radiation Safety Manual for the licensee's research laboratories.

In August 1995, a special inspection was conducted to review a brachytherapy incident. No violations were identified.

On March 19-22, 1996, a routine safety inspection and investigation by the NRC Office of Investigations (OI) identified six apparent violations in which three of the apparent violations were considered for escalated enforcement. The results of this action are currently in deliberation pending a predecisional enforcement conference scheduled for October 8, 1996.

3. Organization and Management Controls

Research and development activities are reviewed and approved by the Radioisotope and Radiation Safety Committee (RRSC). The Director of Radiation Safety (hereafter known as the Radiation Safety Officer (RSO)) reports to the Director of Quality Management and the RRSC. The RSO and Director of Quality Management meet at least monthly to review policy and procedures and evaluate the status of the radiation safety program.

The RSO's staff consists of 10 full time staff members. The radiation safety office performs several services for the research laboratories including approval, receipt and distribution of radioactive materials, and quarterly lab audits.

The RRSC is also responsible for oversight of the nuclear medicine and radiation oncology programs at the Cleveland Clinic Foundation and is supported by the radiation safety office.

4. Contamination Incident Review

On September 3, 1996, the licensee confirmed with the NRC Region III office that an iodine-131 contamination incident occurred on August 27, 1996, during the administration of approximately 196 millicuries (7.25 gigabecquerel) of iodine-131 to a patient. A nuclear medicine technologist opened a vial of iodine-131 in the patient's room, poured the liquid into a cup and gave the dosage to the patient. In addition to the administering nuclear medicine technologist, a radiation safety technician and another nuclear medicine technologist were present in the patient's room. Following the administration, surveys of the patient were performed as required, however, no immediate surveys were conducted of the licensee employees who were present in the patient's room.

On the following morning of August 28, 1996, in preparation for a laboratory survey, the radiation safety technician detected iodine-131 contamination on the tops of his shoes and on his lab coat. These same pieces of clothing were worn the previous day during the iodine-131 administration. The other two individuals who were involved in the iodine-131 administration on August 27, 1996 were contacted and low levels of contamination were also detected on the nuclear medicine technologist who administered the dosage to the patient. Bioassays and external surveys of the three licensee employees were conducted by the licensee immediately upon discovery of the iodine-131 contamination on the morning of August 28, 1996.

5. External Exposures

The licensee identified external contamination on the forehead and hair of the radiation safety technician and on the forearm, tops of her shoes, hair and face of the administering nuclear medicine technologist. The other nuclear medicine technologist showed only minor fixed contamination. The maximum beta/gamma radiation level measured was 1.5 millirem/hour (15 Sv/hr).

The licensee also performed radiation surveys offsite of the employees' cars and homes. Iodine-131 contamination was found on the arm rest and steering wheel of the radiation safety technician's vehicle and on a pillow in his residence. Low level contamination was also detected on portions of the other nuclear medicine technologist's vehicle. The highest removable contamination level identified by the licensee was 2,744 disintegrations per minute (dpm). The two employees' vehicles were decontaminated to levels below the NRC release criteria of 200 dpm/100 cm^2 and the pillow was placed in storage for decay.

The NRC evaluated the licensee's direct radiation measurements and concluded that no worker (employee) received an external occupational radiation dose in excess of the limits stated in 10 CFR 20.1201.

The NRC inspectors conducted independent surveys of the licensee employees' residences and vehicles. Additionally, the inspectors surveyed locations where the licensee employees had been prior to the licensee's identification of the contamination event. No additional contamination was found by the NRC inspectors.

6. Internal Exposures

Air Samples

In accordance with the licensee's procedures, a lapel air sampler was worn by the nuclear medicine technologist who administered the iodine-131 dosage on August 27, 1996. The sampler was started prior to the administration and was shut off at the end of the procedure which took approximately 10 minutes. The charcoal sample media was processed within one hour after the procedure. The results of the air sample indicated 22,745 counts/10 minutes which equates to 7,400 disintegrations per minute (dpm) with an air volume of 2,967 milliliters (ml). The licensee calculated that the air sample equates to $1.1X10^{-6}$ microcuries/ml (.04 Bq/ml) which equals 56 Derived Air Concentration hours (DAC-hours).

The NRC evaluated the licensee's air sample data and concluded that the airborne concentration during the therapy procedure equates to approximately 57.1 DAC-hours and is 2.8% of the 2,000 DAC-hours/year limit specified in 10 CFR 20.1204; however, the nuclear medicine technologist was actually exposed to airborne iodine-131 for approximately 10 minutes which equates to approximately 9 DAC-hours of exposure. Therefore, the licensee's estimate of 56 DAC-hours appears to be an overestimate.

Bioassays

In accordance with its emergency procedures, the licensee performed thyroid and urine bioassays on the morning of August 28, 1996, on all three individuals involved in the incident. The thyroid bioassay results ranged from 26 to 150 nanocuries (96 to 5,500 Bq), indicating a maximum dose of approximately 51 mrem (0.51 mSv) committed effective dose equivalent (CEDE) to the wholebody. The licensee estimated that the maximum thyroid exposure for the three individuals is 1.6 rem (15 mSv) committed dose equivalent (CDE).

The NRC evaluated the licensee's bioassay data and compared it with the tables (inhalation and ingestion) listed in NUREG/GR4884 "Interpretation of Bioassay Measurements" and concluded the licensee's estimate of approximately 51 mrem (0.51 mSv) CEDE was a reasonable estimate. The NRC evaluated the licensee's estimate of 1.6 rem CDE (maximum exposure to the thyroid) and concluded that it was a reasonable estimate, based on the thyroid bioassay data. The NRC staff confirmed these assumptions with the Oak Ridge National Laboratories Internal Dosimetry Center.

The licensee also conducted additional thyroid bioassays on four nurses who provided care to the patient on August 27, 28 and 29, 1996. On September 11,

1996, the licensee reported to the NRC that all four nurses' thyroid bioassays were negative.

7. Licensee Investigation

The licensee believes that the contamination resulted when the iodine-131 volatilized from the opened vial. Prior to the administration, the top of the vial had been vented in a fume hood to release any volatile iodine vapors. However, additional volatilization may have accumulated as a result of the additional motion caused by moving the vial and pouring the iodine-131 into a cup of water. At the time of this inspection the licensee was in the process of continuing its radiological dose assessment and evaluating the root cause of the contamination incident. It will provide NRC Region III with a written report of the incident within 30 days.

8. NRC Identified Root Causes and Contributing Factors

The root cause of the contamination event appears to be a failure of the nuclear medicine technologist to follow the instructions of the authorized user (physician). Specifically, the technologist removed the metal seal and rubber septum from the vial of iodine-131 prior to administering the therapy dose. This action was contrary to the licensee's standard operating procedures (procedures manual). The procedures manual specifically states: "Administer the liquid ^{131}-NaI dose using the special straw provided for this purpose."

The administering nuclear medicine technologist stated that she forgot to bring the special straw to the patient's room on the day of the dose administration. However, because of her past practices prior to the development of the current procedure manual, the technologist assumed she had verbal approval to administer the dosage without using the straw. Therefore, she opened the vial and administered the dosage in a disposable paper cup.

A contributing factor that led to the contamination incident was the failure of the licensee's staff to conduct adequate and thorough radiation surveys of their clothes and shoes prior to leaving the dosage administration area.

Condition No. 39(B) of License No. 34-00466-01 states that the licensee shall conduct its program in accordance with statements, representations and procedures contained in letter and attachments dated May 12, 1992.

One of the procedures attached to the letter dated May 12, 1992 titled "Summary of Modifications to Renewal Application", Item 10 states: "We will adopt the model safety rules in Appendix I, Regulatory Guide 10.8, Revision 2." Appendix I states either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area.

On August 27, 1996, the radiation safety technician failed to monitor his hands for contamination in a low-background area following the iodine-131 therapy treatment or before leaving the area where the treatment was performed. The technologist indicated that his failure to survey his hands before leaving the area where the

treatment was performed was overlooked. The radiation safety technician's failure to monitor his hands after the procedure or before leaving the area is an apparent violation of License Condition No. 39(B).

10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

Pursuant to 10 CFR 20.1003, *survey* means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

On the afternoon of August 27, 1996, two nuclear medicine technologists did not make adequate surveys to assure compliance with 10 CFR 20.1201, which limits radiation exposure to occupational workers. Specifically, at the conclusion of an iodine-131 therapy treatment, the technologists surveyed their hands and the bottom of their shoes; however, they failed to monitor the tops of their shoes or other areas of their bodies to determine if contamination was present. The nuclear medicine technologists' failure to perform an adequate radiation survey is an apparent violation of 10 CFR 20.1501.

10 CFR 35.25(a)(2) requires, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall require the supervised individual to follow the instructions of the supervising authorized user.

The instructions of the supervising authorized user, titled "^{131}I-NaI TREATMENT PROTOCOL," dated 1993, requires, in part, that administration of liquid iodine-131 be done only by way of a special straw which is provided for this purpose.

On August 27, 1996, a nuclear medicine technologist, an individual under the supervision of the licensee's authorized user, failed to follow the authorized user's instructions when she removed the metal retainer and rubber septum from a vial of liquid sodium iodide (iodine-131) and administered the dosage in a disposable paper cup. The nuclear medicine technologist's failure to follow the instructions of the supervising authorized user for administering liquid iodine-131 is an apparent violation of 10 CFR 35.25(a)(2).

9. Licensee Corrective Actions

The licensee took the following corrective actions in response to the apparent violations listed above:

A. Survey Procedures

As of September 3, 1996, the licensee implemented a procedure that requires nuclear medicine technologists to survey their entire

body for possible contamination after each therapy procedure. Procedures have been also implemented that require the radiation safety technician to also survey each person who participates in an iodine-131 therapy procedure prior to leaving the area.

B. Training

The licensee provided an in-service training session to its nuclear medicine technologists to emphasize the importance of following the instructions for administering iodine therapy doses as outlined in the department's procedures manual. The radiation safety staff was informed of the new requirements for conducting radiation surveys after an iodine therapy procedure. The radiation safety office modified its standard survey form to include the results of the personnel surveys.

10. NRC Evaluation of Corrective Actions

The licensee implemented the above corrective actions prior to the inspection. The corrective actions appear to be adequate and, if properly implemented, should identify and prevent future incidents of this nature.

11. Exit Summary

At the conclusion of the on-site inspection, the inspectors held exit summary discussions with those individuals denoted in Section 1 of this report. The discussions included a review of the preliminary findings of the inspection. The licensee did not identify any information reviewed during the inspection as proprietary.