U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-02649/96001(DNMS) Program Code 02110

Docket No. 030-02649

EA No. 96-296

License No. 34-00466-01 Priority 1 Category G1

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

Inspection Conducted: March 19-22, 1996, with continuing NRC review through August 6, 1996.

Inspectors: B. J. Holt for
Michael LaFranzo
Radiation Specialist
Date 9/16/96

B. J. Holt for
Wayne Slawinski
Senior Radiation Specialist
Date 9/16/96

Approved By: B. J. Holt
B. J. Holt, Chief
Nuclear Materials Inspection
Branch 1
Date 9/16/96

Inspection Summary:

Inspection during the period March 19-22, 1996, with continuing NRC review through August 6, 1996 (Report No. 030-02649/96001(DNMS))
Areas Inspected: This was an unannounced routine inspection of the licensee's radiation safety program with primary focus on research related activities. The inspection included a review of the following: organizational and management controls, radiation safety training, management audits, security, receipt, distribution and inventory of radioactive materials, radioactive effluent and waste disposal program, internal and external radiation monitoring program, storage facilities, and the laboratory audit program. The inspection also included a limited review of the radiopharmaceutical therapy Quality Management Program (QMP) and the licensee's use of two cesium-137 irradiators.

Results: Six apparent violations of NRC requirements were identified and consist of: (1) failure to conduct annual refresher training for laboratory radiation workers from July 1993 through March 1996 (License Condition 37); (2) failure to conduct an annual senior management audit in 1995 (License Condition 37); (3) failure to secure radioactive material from unauthorized removal or access (10 CFR 20.1801); (4) failure to fully establish and implement a system for ordering and receiving radioactive material (License Condition 37); (5) failure to limit authorized user possession of radioactive material to quantities authorized by the Radioisotope and Radiation Safety Committee (License Condition 37); and (6) failure to evaluate the solubility of radioactive material prior to discharge to the sanitary sewerage system (10 CFR 20.1501).

NOTE: License Condition 37 referred to in this report is referenced in Amendment No. 62 of License No. 34-00466-01. This was the license Condition in effect at the time of the on site inspection.

DETAILS

1. Persons Contacted

* Penelope Ott, Administrator, Office of Quality Management
*+ Thomas Keys, M.D., Director of Quality Management
*+ Donald Neuman, M.D., Ph.D., Chairman of the Radiation Safety Committee
*+ Judy McKenna, Director of Radiation Safety/Radiation Safety Officer
* Mark Mettler, Radiation Safety Coordinator
* David Burkett, Medical Health Physicist
* Jill Stanley, Research Administrative Coordinator
* Guy Chisolm, Ph.D., Staff, Department of Cell Biology/Radiation Safety Committee Member
* Gopal Saha, Director of Nuclear Chemistry and Pharmacy
* Jim Shores, Supervisor, Police
* Doug Koman, Police/Security, Protective Services

* Denotes those individuals present during the site exit meeting conducted on March 22, 1996.
\+ Denotes those individuals contacted by telephone for additional inspection related information between March 22 and May 14, 1996.

In addition, NRC inspectors interviewed numerous Cleveland Clinic Foundation staff which included radiation safety staff, authorized users, supervisors of various departments, laboratory technicians and other radiation workers, nuclear medicine technicians, engineers, and maintenance personnel.

2. Program Summary and Inspection History

The Cleveland Clinic Foundation (licensee) is authorized by NRC 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 iridium-192 sealed sources 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 1 through 83, including increased possession limits for several specifically listed radionuclides for research and development as defined in 10 CFR 30.4, instrument calibration, and animal studies. The license also authorizes use of cesium-137 sealed sources in irradiator devices for non-human irradiator studies.

On July 19, 1991, the NRC issued a Notice of Violation and a $7,500 civil penalty to the licensee for violations involving a phosphorus-32 spill that resulted in radiation exposures to individuals 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 to review a licensee's reported brachytherapy misadministration. No violations were identified; however, 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. In addition, 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. This revision was to have been completed by the end of 1992.

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 written directives.

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 for 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 as committed by the licensee to the NRC in August 1992. The licensee committed to completing and distributing the Radiation Safety Manual by June 1995.

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

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 9 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. Training Program

The licensee is required to perform initial and annual refresher training for all research laboratory workers. Specifically, Condition 37 of License No. 34-00466-01 (Amendment 62) requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in a letter dated May 12, 1992. Item 8 of the letter dated May 12, 1992, states that training for individuals who handle radioactive material other than Part 35 material, will be performed as outlined in Appendix A, Regulatory Guide 10.8, Revision 2, commensurate with their responsibilities. In addition, Item 8 also states that laboratory workers will receive training at least annually which will include lecture, discussion and demonstration.

The licensee has implemented an initial training program for all new laboratory workers that consists of a 2-3 hour lecture and discussion provided by the radiation safety office. The inspectors independently verified during laboratory audits that laboratory workers had an adequate working knowledge of practices and procedures regarding the safe use and handling of radioactive material. However, at the time of the inspection in March 1996, the licensee had not implemented a refresher training program as required by License Condition No. 37 which references letter dated May 12, 1992. The RSO confirmed the retraining program had not been implemented since July 1992, and indicated the reasons were due to inadequate staff resources and other more pressing safety needs. According to the RSO, the RRSC was informed in December 1994 that the annual refresher training had not been implemented. Although no timetable was provided to the RRSC at that time, the licensee planned to implement the retraining program in 1995. In December 1995, the RSO informed the RRSC that implementation of the annual refresher training was postponed until 1996. According to the licensee, the first refresher training session was to take place in March 1996; however, scheduling problems further delayed the implementation of the program.

Failure to provide annual refresher training to laboratory workers is an apparent violation of License Condition 37.

In April 1996, the radiation safety office provided retraining to authorized users and their designees as described in Appendix A of Regulatory Guide 10.8. Authorized users and their designees were requested to retrain those laboratory workers whom they supervise. The licensee stated that starting in 1997, all laboratory radiation workers will receive annual refresher training by the radiation safety office. As of May 9, 1996, approximately 85% of the authorized users and their designees had been trained by the radiation safety office.

One apparent violation of NRC regulatory requirements was identified.

5. Management Audits

Three of the licensee's senior management representatives are required to perform an audit of the radiation safety program annually. Specifically, Condition 37 of License No. 34-00466-01 (Amendment 62) requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in a letter dated May 12, 1992. Item 7.1 of the letter dated May 12, 1992 states that the Director of Quality Management, Director of Radiation Safety and Administrator of Quality Management will, at least annually, conduct a facility tour/audit with a summary of all findings and recommendations presented to the RRSC for review, discussion, and appropriate actions.

Programs required to be audited by senior management include the nuclear medicine department, radiation oncology department, research laboratories and the radiation safety department. During each program audit, senior management is required to review various records, postings, implementation of radiation safety practices by radiation workers and compliance with reporting requirements. Audits were performed by senior management annually in 1992 through 1994; however, no audit was performed in 1995.

According to the RSO, senior management audits have historically been scheduled for the end of the calendar year. Although an audit was scheduled for December 1995, the RSO and Director of Quality Management determined there was insufficient time to conduct the audit as planned. Additionally, the RSO and Director of Quality Management determined that the senior management audit, in its current form, was not significantly contributing to the radiation safety program. Therefore, the licensee decided not to conduct the audit in 1995 but rather to amend its NRC license to remove or modify the senior management audit requirement. At the time of the inspection in March 1996, an audit by senior management had not been conducted since 1994, nor had the licensee requested an amendment to its NRC license to revise the audit requirement.

Failure of the Director of Quality Management, Director of Radiation Safety and Administrator of Quality Management to perform an audit of the radiation safety program in 1995 is an apparent violation of License Condition 37.

In July 1996, the licensee hired an independent contractor to perform the audit, as authorized by License Condition No. 37 and letter dated May 12, 1992.

The licensee plans to remove or modify the requirement for the annual senior management audits in a future amendment request to the NRC.

One apparent violation of NRC regulatory requirements was identified.

6. Security

The licensee is required to secure licensed material from unauthorized use. Specifically, 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in unrestricted areas. As defined in 10 CFR 20.1003, unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

The NRC inspectors performed a security tour of research building (FF) at Cleveland Clinic Foundation between 5:30 and 6:20 p.m. on Tuesday, March 19, 1996. A licensee representative accompanied the inspectors during the security tour. The tour included walking through hallways to determine if rooms were properly posted for radioactive material and radioactive material was secure or otherwise attended by authorized personnel. If the laboratories were posted, unlocked and a laboratory worker could not be located by the inspectors, the inspectors attempted to determine if locks or securing devices were evident on containers (refrigerators, cabinets, etc.) to prevent access to radioactive material. The inspectors noted several unattended, unlocked or open laboratories posted as radioactive material use areas, containing unknown quantities of radioactive material housed in unlocked refrigerators and freezers.

At approximately 6:20 p.m., the inspectors and licensee representative exited the building through the west ground floor door. Upon exiting, the inspectors noticed the door's electronic key card security system, which was to have locked the door after 6:00 p.m. with key card access only, was not functioning. As a result, a key card was not necessary to enter the building.

On March 20, 1996, the inspectors requested from the radiation safety office a listing of radioactive material in each laboratory which was found posted, unlocked and unattended by laboratory workers. According to the radiation safety office, five laboratories contained unsecured radioactive material in refrigerators or freezers which were accessible to the inspectors as listed below:

Building/Room	Licensed Material	Activity
FF5-12	Chromium-51	5.00 millicuries
FF4-62	Phosphorus-32	1.36 millicuries
	Calcium-45	0.87 millicuries
FF3-01	Hydrogen-3	10.37 millicuries
	Iodine-125	0.28 millicuries
	Phosphorus-32	1.00 millicuries
	Sulfur-35	0.61 millicuries
FF2-19	Iodine-125	2.65 millicuries
FF2-51	Iodine-125	0.78 millicuries
	Chromium-51	1.36 millicuries

Failure to secure from unauthorized removal or limit access to licensed materials in storage is an apparent violation of 10 CFR 20.1801.

During NRC audits of approximately 30 research laboratories, authorized users and technicians indicated after normal working hours, the last person leaving the lab is responsible for locking the laboratory doors. However, many of these individuals also stated that they have relied on the electronic key card security system, which controls access to the building, as the security mechanism to comply with licensee and NRC security requirements.

During the licensee's routine quarterly laboratory audits, the radiation safety staff reviews security procedures and practices with laboratory radiation workers and determines if radioactive material is attended and/or secured. However, these audits are performed during normal working hours when labs are normally attended by authorized personnel.

The radiation safety office's policy on security is outlined in the licensee's radiation safety manual. The manual indicates that laboratory radiation workers may leave radioactive material unattended and unsecured for up to 10 minutes. If laboratory radiation workers believe they will be out of the laboratory for longer than 15 minutes, the radioactive material must be secured. The licensee was informed by the inspectors that NRC requirements require that licensed material to be controlled at all times and that a "10 minute rule" is not adequate to comply with NRC requirements.

The RSO contacted each authorized user in the laboratories where radioactive material was found to be unsecured and informed them of the security violations. The remaining users have been or will be informed during annual retraining sessions which are being held this year.

During the site inspection in March 1996, the radiation safety office had contacted Cleveland Clinic Foundation's security division and informed them of the malfunctioning key card system. According to the licensee, the key card security system was repaired for building FF in April 1996.

Following the site inspection, the RSO indicated that the radiation safety office was in the process of developing procedures to perform security spot checks throughout the licensee's facilities where radioactive material is used to verify compliance with NRC security requirements. In addition, the licensee is considering other security mechanisms, e.g. locks on refrigerators and freezers containing radioactive material.

One apparent violation of NRC regulatory requirements was identified.

7. Receipt of Radioactive Material

The licensee is required to establish and maintain a system for the ordering and receiving of radioactive material which shall include the authorized user or department, isotope, chemical form, and activity. Specifically, Condition 37 of License No. 34-00466-01 (Amendment 62) requires that licensed material be possessed and used in accordance with

statements, representations and procedures contained in a letter dated May 12, 1992. Item 10.6 of the letter dated May 12, 1992, states that the licensee will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix K to Regulatory Guide 10.8, Revision 2. Item 2 of Appendix K states that the radiation safety office will establish and maintain a system for ordering and receiving radioactive material and that system will include written records that identify the chemical form and activity for each authorized user.

The licensee has a computer database in place which identifies the authorized user, isotope and maximum activity per package that the authorized user is permitted to order. However, the database does not include the chemical form and maximum possession limits which are limited by an authorized users Radioactive Material Authorization form, approved by the RRSC. The radiation safety staff, which approves each order for radioactive material and receives and distributes packages to the various authorized users, does not check to ensure the chemical form of the licensed material ordered is as authorized by the RRSC and that authorized users do not exceed maximum possession limits per nuclide.

Failure to fully establish and maintain a system for ordering and receiving radioactive material is an apparent violation of License Condition 37.

The license plans to purchase and install a software package that will track licensed material, orders, use and disposal throughout the licensee's facility and improve radioactive material accountability practices.

One apparent violation of NRC regulatory requirements was identified.

8. Inventory

The licensee is required to limit the quantities of radioactive material possessed by authorized users to those authorized and approved by the RRSC. Specifically, Condition 37 of License No. 34-00466-01 (Amendment 62) requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in a letter dated May 12, 1992. Item 10, Section 16.5, titled "Amendment Request to Radioactive Material Authorization," requires the licensee to limit an authorized users radioactive material possession to specific quantities as approved by the Radioisotope and Radiation Safety Committee (RRSC).

Inspector review of laboratory records and quarterly inventory reports for 1994, 1995 and 1996, identified several cases where authorized users possessed quantities of licensed material greater than that authorized by the RRSC. Examples are provided below:

Authorized User	Isotope	Maximum Inventory Limit(RRSC)	Actual Inventory	Date of Actual Inventory
Dr. Philip Howe	Sulfur-35	25 mCi	79 mCi	12/94
Dr. Ahsan Husain	Sulfur-35	0.5 mCi	1.1 mCi	9/95
Dr. Henry Hoff	Hydrogen-3	20 mCi	31 mCi	3/95
Dr. Alan Wolfman	Phosphorus-32	30 mCi	40 mCi	2/96
Dr. Edward Plow	Chromium-51	12 mCi	20 mCi	1/96

Failure to limit authorized users total possession of radioactive material to quantities approved by the Radioisotope and Radiation Safety Committee is an apparent violation of License Condition 37.

Quarterly inventory reports are received by the radiation safety office from each authorized user which includes the amount of radioactive material for each nuclide possessed by the authorized user as of the date of the inventory. As a self initiated action in January 1996, a radiation safety office staff member reviewed all quarterly inventory reports from all authorized users from the fourth quarter of 1995 and compared possession limits against the radionuclide limits requested by the authorized user and approved by the RRSC. The licensee's review identified that thirteen authorized users were in excess of their possession limits. These findings were summarized in a report dated January 24, 1996; however, the report was not provided to the RSO until a few days prior to the NRC inspection. The RSO did not review the report until the first day of the inspection.

The RSO stated that the licensee will inform the authorized users in excess of authorized possession limits to either dispose of the excess licensed material or request amended possession limits authorized through the RRSC. No timetable was provided to the NRC regarding the above licensee corrective actions.

The licensee plans to purchase the necessary equipment and develop a computerized database that will allow the radiation safety office to track radioisotopes ordered, received, possessed and disposed of throughout the licensee's facility. According to the RSO, the computer program will have the capability to track the amount of licensed material possessed at any one time by an authorized user. However, funding was not approved for this software package as of March 1996.

One apparent violation of NRC regulatory requirements was identified.

9. Radioactive Effluent and Waste Disposal Program

The licensee is required to insure liquid effluent is soluble or biologically dispersible when disposed of in the sanitary sewerage system. Specifically, 10 CFR 20.2003 states, in part, that a licensee may discharge licensed material into a sanitary sewerage if the material is readily soluble or dispersible biological material in water. 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. As defined by 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.

During the inspection, the NRC determined the licensee was not supplying authorized users with the appropriate information regarding the disposal of licensed material into the sanitary sewerage system. Specifically, the licensee did not evaluate the solubility of chemicals tagged with licensed material that were disposed into the sanitary sewerage system. The licensee distributed a radiation safety newsletter where the authorized users were informed that non-soluble licensed material was not to be disposed of in the sanitary sewerage system. However, the licensee did not make a proper evaluation regarding the solubility of licensed material using the guidance equivalent to that in Information Notice 94-07 or other appropriate methodology.

Failure to evaluate the solubility of liquids containing licensed material discharged into the sanitary sewerage system is an apparent violation of 10 CFR 20.1501.

Between January 1994 and December 1995, the licensee has disposed of approximately 371.9 millicuries (13.7 GBq) of various NRC licensed nuclides into the sanitary sewerage system. The inspectors verified five of the most commonly used chemicals which are attached to the nuclides disposed of in the sanitary sewerage system are soluble or biologically dispersible. The licensee plans to add a section in the radiation safety manual regarding solubility of radioactive material disposed of in the sanitary sewerage system at an undisclosed date. The licensee did not indicate what type of information would be included in the revised radiation safety manual. However, as of May 1996, the licensee had not made a full evaluation regarding the solubility or the biological dispersibility of NRC licensed material disposed of via the sanitary sewerage system.

One apparent violation of NRC regulatory requirements was identified.

10. Other Areas Inspected

The inspection included review of other areas of the licensee's radiation safety program including, internal and external radiation monitoring program, storage facilities, cesium-137 irradiators, laboratory audit program, and a limited Quality Management Program (QMP) review.

No apparent violations of NRC regulatory requirements were identified.

11. Exit Summary

At the conclusion of the on-site inspection, the lead inspector conducted a site exit meeting with those individuals denoted in Section 1 of this report. The summary included a discussion of the preliminary findings of the inspection. On May 10 and 14, 1996, the lead inspector individually contacted those individuals denoted in Section 1 of this report regarding NRC findings at the licensee's facility after further NRC review. The licensee did not identify any information reviewed during the inspection as proprietary in nature.