U.S. NUCLEAR REGULATORY COMMISSION REGION I

Report No.	030-12779/89-0	1		
Docket No.	030-12779			
License No.	37-17452-01	Priority <u>III</u>	Category <u>V</u>	
Licensee:	University City Philadelphia Pe	Science Center ennsylvania		
Facility Na	me: University	City Science Center		
Inspection	At: Philadelph	nia, Pennsylvania		
Inspection	Conducted: Sep	tember 13, 1989		
Inspectors:	John J. Mille	Millin Senior Health Physic	cist 10-16-8, date	9
		M. Gotelle stello, Senior Health 1	Physicist 10-16-89 date	
Approved by	John R. Whit	e, Chief prials Safety Section C	/0/10/8 date	2

Inspection Summary: Inspection conducted on September 13, 1989 (Report No. 030-12779/89-01

Areas Inspected: Routine unannounced inspection of a research and development program, including licensee action on previous inspection findings; scope of licensed activities; organization; management control program; training and instruction to employees; receipt and transfer of material; and radiation and contamination surveys.

<u>Results</u>: Eight apparent violations were identified: 1) failure of RSO to review authorized purchase orders; 2) failure to maintain an inventory; 3) failure to maintain records of surveys by RSO; 4) use of licensed material by an unauthorized individual, 5) failure of RSO to monitor incoming packages; 6) failure to maintain a record of licensed material transferred to another licensee; 7) failure to maintain records of area surveys; and 8) failure to calibrate survey instruments annually.

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DETAILS

1. Persons Contacted

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*Robert Krutsick, Senior Vice President *Robert Alper, Radiation Safety Officer Bernadine Hawes, Director, Office and Research Management S. Tsuyoshi Ohnishi, Director, Membrane Research Institute Jeanne Myers, Principal Investigator Edward J. Macarak, Authorized User Jean Corby, Research Assistant Andrea Sessa, Research Assistant

*Individuals present at exit interview.

2. Licensee Action on Previous Inspection Findings

(Closed) Inspection 86-01: failure to post rooms where licensed material are used or stored with "Caution Radioactive Material" signs in accordance with 10 CFR 20.203(e). The inspectors toured the laboratory areas and all were appropriately posted to warn of the presence of radioactive material.

(Closed) Inspection 86-01: use of licensed material at a location not authorized by the license. License No. 37-17452-01 was amended to include the laboratory located at 3508 Market Street, Philadelphia, Pennsylvania. The inspectors did not identify any additional places of use or storage that were not authorized on the license.

(Open) Inspection 86-01: use of licensed material by an unauthorized individual. License No. 37-17452-01 was amended to include the researcher identified during Inspection 86-01 as an unauthorized user. During this inspection, another individual who used and was not supervised in the use of licensed material was identified.

3. Scope of Licensed Activities

Scientists at the University City Science Center order millicurie quantities and use microcurie quantities of hydrogen-3, carbon-14, phosphorus-32, sulfur-35, calcium-45, and iodine-125 in various research and development applications. Iodine-125 used by the licensee is received as a bound compound (non-volatile). No iodinations are performed on site. Similarly, the other isotopes are received as labeled compounds and no organic synthesis is performed.

Licensed material is actively used in approximately eight laboratories. Most of these laboratories are part of the Connective Tissue Research Institute located at 3624 Market Street. One laboratory actively using licensed material is in the Metabolic Research Institute located at 3508 Market Street. Although the license authorizes the use of byproduct material at the Membrane Research Institute, located at 3401 Market Street, both the RSO and the Director of the Institute informed the inspectors that radioactive materials had never been used at this location. The RSO stated that he never saw licensed material at the Membrane Research Institute. He also stated that he will request removal of the Membrane Research Institute from the license after he performs a survey to assure no contamination is present.

The Director of Metabolic Research Institute stated that he ordered and received 1 millicurie of calcium-45 and 10 microcuries of carbon-14 from NEN/Dupont during June of 1988. He added that he never opened the package and transferred it to his laboratory at Hahnemann University where he is also an authorized user. The Director stated that the licensed material was ultimately disposed of at Hahnemann University. The inspectors noticed that the Director's laboratory was posted with a "Caution Radioactive Materials" sign and the safe handling procedures for calcium-45 was posted on the wall. The RSO checked later with the purchasing department and determined that the Director of the Metabolic Research Institute ordered 1 millicurie each of calcium-45 and carbon-14 on July 7, 1988 and he also ordered 1 millicurie of carbon-14 on August 30, 1988.

No violations were identified.

4. Organization

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Robert Alper, Ph.D., is listed as an authorized user and Radiation Safety Officer (RSO) on University City Science Center's license. He is engaged in research and serves as Radiation Safety Officer as a collateral duty. He stated that he spends less than 10% of his time administering the radiation safety program. Dr. Alper reports directly to Dr. Dale Evans, Vice President, Research and Development and Mr. Robert Krutsick, Senior Vice President, Financial Affairs. Dr. Evans and Mr. Krutsick report directly to the President of the company. All the various institute directors also report directly to Dr. Evans. 1

No violations were identified.

5. Management Control Program

The inspectors reviewed the licensee's ordering and receipt procedures. The RSO stated that many of the orders for licensed material are placed by telephone by the researchers and upon arrival the radioactive material is routinely delivered directly to the researcher's laboratory. The RSO also stated that by the time he receives the purchase order, often the radioactive material has already been ordered, received, and is being used by the researcher. The RSO added that he does not routinely review all orders for radioactive material. Condition 18 of License No. 37-17452-01 requires that the RSO authorize the purchase of all licensed material to ensure that the University City Science Center's inventory of radioactive material does not exceed the amounts specified in its license.

The failure of the RSO to review and authorize the purchase orders for adioactive material to ensure that licensed possession limits are not exceeded is an apparent violation of License Condition 18.

The RSO informed the inspectors that he does not maintain an inventory record of all licensed material at the University City Science Center. He stated that each researcher maintains an inventory in their laboratories, but he does not maintain a central inventory record to ensure that licensed possession limits are not exceeded. Despite the lack of a central inventory record, the inspectors determined, by interviewing personnel, that the isotopes in possession limits. Condition 18 of License No. 37-17452-01 requires that an inventory record be maintained on file in the Radiation Safety Office under the supervision of the RSO.

The failure of the RSO to maintain an inventory record is an apparent violation of License Condition 18.

When the RSO was asked about auditing laboratories, he stated that he visits each laboratory quarterly to ensure the researchers are in compliance and also to make an independent survey for contamination. The RSO stated that no records of his audits/surveys are maintained. Condition 18 of License No. 37-17452-01 requires that records of surveys be maintained on file in the Radiation Safety Officer under the supervision of the RSO.

The failure of the RSO to maintain records of laboratory surveys is an apparent violation of License Condition 18.

6. Training and Instructions to Employees

The inspectors toured the laboratories and interviewed personnel. Jeanne Myers, Ph.D., stated that she had worked at the University City Science Center for approximately six years and she presently was a principal investigator. She was currently working with microcuries of phosphorus-32 and she routinely ordered one millicurie of phosphorus-32 at a time. When the inspectors identified to the RSO, that Dr. Myers was not an authorized user on the license, he was surprised and stated that it was an oversight during the renewal process. Dr. Myers reports directly to Dr. Kefalides, but the RSO stated that Dr. Kefalides never enters the laboratory. Condition 11 of License No. 37-17452-01 requires that licensed material be used by or under the supervision of individuals specifically named.

The use of licensed material by Dr. Myers and not by or under the supervision of an individual specifically named on the license is an apparent violation of License Condition 11.

The inspectors interviewed two laboratory assistants who worked under Dr. Myers for approximately six weeks. Both individuals exhibited a knowledge of radiation safety precaution and procedures commensurate with their duties. The laboratory assistants stated that they had received instruction from Dr. Myer concerning the safe use of radioactive materials and they were scheduled to attend formal training addressing radiation safety in the spring. Dr. Alper stated that the formal radiation safety course is presented annually in a videotape format. The inspectors recommended to Dr. Alper that although the license requires that radiation safety training be provided only annually, Dr. Myers' laboratory assistants should not wait until the spring of 1990 to review the radiation safety videotape.

7. Receipt and Transfer of Materials

The inspectors asked the RSO to review the records of monitoring performed on incoming packages containing radioactive material. The RSO stated that incoming packages are routinely delivered directly to the researcher's laboratory and the researcher performs the required monitoring and maintains the records. The RSO was unable to locate package monitoring records for his own research laboratory. Condition 18 of License No. 37-17452-01 requires that all packages containing quantities of radioactivity material are received by the RSO and externally wipe tested. Condition 18 also requires that the RSO retain records of package receipts which include the date of receipt and the results of the package survey.

The failure of the RSO to monitor all incoming packages and maintain records of those surveys is an apparent violation of License Condition 18.

The Director of Metabolic Research Institute stated he had ordered and received radioactive material but that he never opened the package and transferred it to his laboratory at Hahnemann University. He and the RSO stated that they had not maintained a record of the transfer. 10 CFR 30.51 requires that a licensee keep records showing the transfer of licensed material.

The failure of the licensee to keep a record of the licensed material transferred to Hahnemann University is an apparent violation.

8. Radiation and Contamination Surveys

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Dr. Myers informed the inspectors that her laboratory is monitored weekly, but records of the monitoring are not faithfully maintained. Survey records indicated that her laboratory was last monitored on December 12, 1986 and on September 20, 1985.

The RSD stated that he routinely monitors his laboratory, but he could not produce records of survey results. Condition 18 of License No. 37-17452-01 requires that records of weekly surveys be maintained.

The failure to maintain records of weekly area surveys is an apparent violation of License Condition 18.

Two Technical Associates Model Pug 1AB Geiger-Mueller survey meters, serial numbers 043144 and 12544, used to monitor for contamination, in a laboratory actively using phosphorus-32, were last calibrated on April 30, 1987 and May 1, 1987 respectively. Condition 18 of License No. 37-17452-01 requires that the G-M meters be calibrated annually.

The feilure to calibrate the G-M survey meter annually is an apparent violation of License Condition 18.

9. Independent Measurements

The inspectors took smears in the sinks and on the floors and animal cages in the Metabollic Research Institute. No removable contamination in excess of background was detected.

No violations were identified.

10. Exit Interview

The inspectors discussed the results of the inspection with the individuals identified in Section 1.

The inspectors expressed their concern over the apparent lack of central control over the Radiation Safety Program.

CASE No. 1-89-015

United States Nuclear Regulatory Commission



Report of Investigation

Membrane Research Institute/University City Science Center:

Improper Research of Radioative Materials

Office of Investigations

Reported by OI: RI

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SYNOPSIS

On August 30, 31, and September 1, 1989, a Confidential Source (CS) alleged to NRC Region 1 personnel that violations of NRC regulations had occurred at the University City Science Center's (UCSC) Membrane Seearch Institute (MRI) between January and February 1988. The MRI facility is located at 3401 Market Street, Philadelphia, PA. The CS alleged that the Director of MRI directed a MRI scientist to synthesize and smuggle Carbon 14 (a radioisotope) into the United States, and that the radioisotope was used at MRI for experiments without the required NRC license. The CS also alleged that the waste produced from these experiments was improperly stored and disposed of.

During the time of these alleged experiments, the Director of MRI was not authorized under UCSC's NRC license for the possession and/or use of radioisotopes. However, the Director of MRI received NRC authorized user status via a license amendment dated March 30, 1988.

On September 12, 1989, the NRC Regional Administrator, Region I, requested that an investigation be initiated to determine the veracity of these allegations. It was further requested that the Office of Investigations (OI) determine if others in the UCSC organization were aware of the alleged illicit possession and/or use of radioisotopes at the MRI facility.

A review of documents provided by the CS, and witness interviews, corroborated the allegations.

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On October 10, 1989, the Director of MRI, accompanied by his attorney, was interviewed by the reporting Investigator. He admitted to directing an MRI scientist to synthesize and transport five microcuries of Carbon 14 from Japan into the United States. He also admitted to directing experiments with Carbon 14 prior to the receipt of his NRC authorized user status. The Director of MRI denied that he had unsafely disposed of wastes produced from these experiments but admitted he had disposed of this waste in secret to limit knowledge of its existence. He also denied that the management of UCSC had knowledge of these activities prior to his informing them on October 5, 1989.

The Director of MRI admitted to arranging for a second transport of ten microcuries of Carbon 14 from Japan, but said he had directed an MRI scientist to obtain the proper United States and Japanese government clearances for this shipment, which occurred during the summer of 1988. The MRI scientist identified as having possession of the clearances denied knowledge of their existence.

Subsequent interviews revealed that UCSC management was not aware of the Director of MRI's illicit activities prior to October 5, 1989. These interviews also indicated that the total quantity of Carbon 14 the Director of MRI caused to be brought into the United States was between ten and twenty

Based on testimonial and documentary evidence, it is concluded that the Director of MRI deliberately caused a radioisotope to be synthesized, brought into the country, and experimented with without the required NRC license. Based on the testimony, it is also concluded that the Director of MRI safely

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disposed of the waste generated by these experiments, after receiving NRC authorized user status on March 30, 1988. It is further concluded that there is insufficient evidence to suggest that other UCSC officials were aware of this activity until the Director of MRI informed them on October 5, 1989.

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