UNIVERSITY of PENNSYLVANIA

PHILADELPHIA 19104

Office of the General Counsel
110 College Hall CO
(215) 898-7660

March 3, 1986

Mr. John D. Kinneman, Chief
Nuclear Materials Safety
Section A,
Division of Radiation Safety
and Safeguards
United States Nuclear
Regulatory Commission
Region I
631 Park Avenue
King of Prussia, PA 19406

Re: Inspection No. 85-01; October 16-18, 21 and 25, 1985
Docket Nos. 030-02939, 070-00123, 030-07056
License Nos. 37-00118-07, SNM-114, 37-00118-11

Dear Mr. Kinneman:

I am writing on behalf of the University of Pennsylvania (the "University") in response to the Notice of Violation contained in your December 20, 1985 letter addressed to Dr. Barry Cooperman, Vice Provost for Research. Although your letter alleged a number of technical violations, the University understands from the inspectors' comments at the conclusion of the on-site review, that the NRC is pleased with the recent improvements made by the University to its Radiation Safety Program. The University looks forward to continuing its amicable relationship with the NRC and provides the following in response to the NRC's request for information:

From the discussion of our findings at the conclusion of the inspection, we understand that you will develop safety recommendations for the use of phosphorus-32 which includes guidelines for issuing personnel dosimeters for phosphorus-32 users. Further, we understand that you will continue to provide the resources necessary to maintain continuous iodine-125 hood

exhaust monitoring during all iodinations and that you will implement a centralized Radiation Safety training program by January 1, 1986 such that the majority of personnel who use radioactive material will receive this training by June 30, 1986. We also understand that, by December 31, 1985, you will implement the audit program described in your October 24, 1984 letter. You are advised that this audit program should include assuring the proper security of licensed material. In your reply to this letter, please confirm our understandings and describe those actions taken or planned to improve the effectiveness of your phosphorus-32 safety and dosimetry program.

The University confirms that it will continue to provide the resources necessary to maintain continuous hood exhaust monitoring of I-125 during the performance of all iodinations. Further, the University is in the process of recruiting and hiring a second employee to help with iodination surveillance.

The University also confirms that it has begun its centralized basic training program in Radiation Safety and in December, 1985, made its first presentations to users. To date, the University has trained approximately ten percent of its research laboratory personnel. A majority of research laboratory personnel who use radioactive material under the University's licenses are expected to receive training by June 30, 1986.

In December, 1985, the University engaged a certified health physicist, George Holeman, who is not affiliated with the University and has extensive experience with institutional programs under broad license, including Yale University's program, to conduct a comprehensive management audit.

With respect to monitoring of persons working with P-32, the University shall provide ring and trunk monitoring devices to persons handling millicurie quantities of P-32. The University will monitor the results regularly unless at least three months of monitoring results demonstrate that a user's exposure is less than ten percent of the applicable exposure limit, and the Radiation Safety Office has reviewed the user's procedures and is satisfied that it is extremely unlikely that exposure limits will be approached. Thereafter, the University will resume regular monitoring of the user if he or she increases the quantity of P-32 or changes his or her methodologies. The University's survey team also monitors purchases of P-32 and, to the extent possible, observes the handling of newer and larger quantity uses of P-32. This latter practice provides on-the-spot instruction of appropriate safety procedures to users.

A. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that materials not in storage be under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, as of October 21, 1985, several radioisotope research laboratories, which contained quantities of licensed material were unlocked and not under constant surveillance and immediate control. These laboratories were accessible to visitors and employees.

This is a Severity Level IV violation. (Supplement IV).

The University has emphasized to its University users by memorandum of the fundamental importance of maintaining the security of licensed materials and is emphasizing security procedures in its Quarterly Survey Program. The University has also solicited users' comments on the improvement of security measures.

B. 10 CFR 19.12 requires that all individuals working in or frequenting any portion of a restricted area be instructed in the precautions and procedures to minimize exposure to radiation and radioactive materials, and in the applicable provisions of the Commission's regulations and licenses.

Contrary to the above, as of October 18 and 21, 1985, individuals working in restricted areas had not been instructed in the applicable provisions of the regulations concerning personnel dosimetry (CHOP), in the requirements for shipping packages of radioactive materials (Graduate and HUP), in the procedures for determining the constancy of the dose calibrator (CHOP), in the requirements for personnel and area monitoring (Graduate, CHOP, HUP, Research) and in the provisions of the "University of Pennsylvania Radiation Safety Guide" (Research).

This is a Severity Level IV violation. (Supplement VI)

Since the inspection, the University's Radiation Safety Office has presented in-service training programs to personnel at the Children's Hospital of Philadelphia and

Graduate Hospital (Nuclear Medicine Operations) concerning the regulations discussed by the Commission. In addition, the University has discussed with the departmental radiation safety officer at the Hospital of the University of Pennsylvania the applicable provisions of the regulations. CHOP, Graduate Hospital and HUP will also receive a written summary of the applicable safety regulations.

The Radiation Safety Office has instituted an instructional program for all research laboratory personnel as discussed above and is sending a memorandum to all users reminding them of monitoring and recordkeeping requirements contained in 10 CFR Part 20 and the Radiation Safety Guide. These areas will receive special attention in the Quarterly Survey Program.

C. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with all sections of Part 20. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, as of October 16, 1985, surveys (evaluations) were not made to assure compliance with 10 CFR 20.101 which limits radiation dose to individuals in restricted areas. Specifically, no evaluation of the dose to the whole body and extremities of Nuclear Medicine technologists (CHOP) whose dosimeters were only sporadically returned from January to July, 1985 had been made.

This is a Severity Level IV violation. (Supplement IV)

The problem discussed by the Commission results from the failure of users to return their dosimeter(s) on time or at all. In the past, the University has attempted to address this problem by utilizing local badge collectors and following up on missing dosimeters with regular surveys. The University is currently in the process of implementing a computer program to keep track of film badge records on group and individual bases. This program is on last trial status and is expected to expedite the routine follow-up of late badge returns. The computer printout will enable the Radiation Safety Office to determine which individuals are not cooperating with the personnel monitoring program. The Radiation Safety Office will then contact quickly the supervisors of these individuals to ensure compliance.

The second issue raised by the Commission is how the University will treat late or non-returned badges in an individual exposure record. The commercial personnel monitoring company used by the University will not process film badges more than six months old. Therefore, when the computer program discussed above is implemented, if efforts to retrieve the badge are unsuccessful after six months after issue of the dosimeter, the computer will automatically estimate exposure based upon an arithmetical average of past results for the individual concerned. The University believes that the six month waiting period is reasonable in light of its experience that typical exposures to personnel covered by the University's license fall substantially below twenty-five percent of applicable limits.

The combination of computer generated reports of late badge returns and exposure estimates will greatly assist the Universty in indentifying and responding to the difficult practical problem created by late or lost badges.

D. 10 CFR 71.5(a) requires that no licensee deliver any licensed material to a carrier for transport without complying with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation in 49 CFR Parts 170 through 189.

49 CFR 173.475(i) requires that prior to each shipment of any package, the shipper ensure by examination or appropriate test that the external radiation and contamination levels are within allowable limits.

Contrary to the above, as of October 16, 1985, packages of radioactive materials have been routinely shipped from Graduate Hospital without an examination or appropriate test to determine that external radiation and contamination levels are within allowable limits. In particular, the Mo-99 generators are shipped to the manufacturer without the appropriate surveys.

This is a Severity Level IV violation. (Supplement V)

The University has discussed with Graduate Hospital the requirement that shipments of radioactive materials, including Mo-99 generators, be appropriately surveyed. The University will periodically review Graduate Hospital's procedures to ensure that these regulations are being followed. By way of further answer, see the University's response to paragraph B above.

E. Condition 26 of License No. 37-00118-07 requires that surveys at the licensee's Radiopharmacy located at HUP, and the Nuclear Medicine facilities at HUP, CHOP and the Graduate Hospital be performed in accordance with procedures in Appendix I of Regulatory guide 10.8.

1. Item 1 of Appendix I requires that all elution, preparation and injection areas be surveyed daily.

   Contrary to the above, as of October 16, 1985, there have been no daily or weekly surveys at the Children's Hospital of Philadelphia since June 7, 1985.

   Furthermore, as of October 17, 1985, preparation and injection areas in the Nuclear Cardiology section of the Hospital of the University of Pennsylvania were not surveyed on a daily basis.

   This is a Severity Level IV violation. (Supplement VI)

   The problems discussed above have been reviewed with the concerned staff members and have been corrected.

2. Item 4.b of Appendix I requires that weekly surveys include wipe tests. The method for performing wipe tests should be sufficiently sensitive to detect 200 dpm per 100 $cm.^2$ Item 6 of this appendix requires that areas be cleaned if the contamination level exceeds 200 dpm/100$cm.^2$

   Contrary to the above, as of October 17, 1985, the method for performing the weekly wipe tests at the Radiopharmacy and the three hospitals did not have the required sensitivity nor were areas cleaned on several occasions when the contamination level exceeded 200 dpm/100 $cm.^2$

   This is a Severity Level IV violation. (Supplement VI)

   Weekly wipe tests in the Nuclear Medicine groups are now counted in a manner to detect the presence of 200 dpm/100 square centimeters. Appropriate decontamination procedures will be enforced when observed contamination levels exceed 200 dpm/100 square centimeters.

F. Condition 27 of License No. 37-00118-07 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in

application dated February 25, 1980, and letters dated March 18, 1983, April 22, 1983, May 9, 1983, including ALARA program and July 14, 1983.

1. Page 21 of the "University of Pennsylvania Radiation Safety Guide" lists general rules for radioisotope users. Rule No. 1 prohibits eating, smoking or drinking in radioisotope use areas.

   Contrary to the above, as of October 21, 1985, eating, drinking and the storage of food and drink were observed in many of the radioisotope research laboratories.

   This is a Severity Level IV violation. (Supplement VI)

   The Radiation Safety Office has again emphasized by memorandum to all approved users that the rules against eating, drinking, smoking or applying cosmetics in radioisotope use areas must be obeyed. In addition, the Radiation Safety Office, in cooperation with the Environmental Health and Safety Office, is in the process of posting revised signs for restricted areas explicitly warning users not to eat, drink, smoke or apply cosmetics therein. I am enclosing a copy of a new sign. All Radiation Safety Office surveyors have been instructed to report to the Radiation Safety Office any violation of these rules.

2. Item 14 of the letter dated May 9, 1983, requires that personnel preparing patient doses, injecting patients or frequenting preparation or dispensing areas monitor their hands with a station monitor with log records required for times consistent with luncheon breaks and end-of-work shifts.

   Contrary to the above, as of October 16, 1985, the required monitoring had not been performed at the required frequency at CHOP and records of the monitoring were not maintained at the Graduate Hospital and CHOP.

   This is a Severity Level IV violation. (Supplement VI)

   In its in-service training program, which is discussed further in the University's response to paragraph B. above, the University is impressing Nuclear Medicine users with the requirement of monitoring hands and recording this data.

Pursuant to the provisions of 10 CFR 2.201, the University of Pennsylvania, is hereby required to submit to this office within thirty days of the date of the letter which transmitted this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending this response time.

See discussion above.

I trust that the above information satisfies the concerns of the Commission. If you require any additional information, please contact me.

Very truly yours,

Neil J. Hamburger

NJH:smr
Enclosure
cc: Barry Cooperman
John Hale
John Thomas

CAUTION

RADIOACTIVE MATERIALS

EATING, DRINKING, SMOKING AND APPLYING COSMETICS ARE PROHIBITED IN THIS AREA

ADMITTANCE TO AUTHORIZED PERSONNEL ONLY

SPECIAL PROCEDURES OR PRECAUTIONS: _____

_____

_____

VISITORS AND PERSONNEL NOT ASSIGNED TO THIS AREA

CONTACT	NAME	LOCATION	PHONE	HOME PHONE
FOR ENTRY OR ADVICE				
IN EMERGENCY				
IN EMERGENCY				

DATE POSTED: _____

ENVIRONMENTAL HEALTH & SAFETY OFFICE
898-4453

RADIATION SAFETY OFFICE
898-7187