

APPENDIX A  
NOTICE OF VIOLATION

University of Pennsylvania  
Philadelphia, Pennsylvania 19104

Dockets Nos. 030-02939  
070-00123  
030-07056  
License Nos. 37-00118-07  
SNM-114  
37-00118-11

As a result of the inspection conducted on October 16, 17, 18, 21 and 25, 1985, which included the University's research facilities (Research), the Hospital of the University of Pennsylvania (HUP), Children's Hospital of Philadelphia (CHOP), Graduate Hospital (Graduate), the Wistar Institute and the New Bolton Center, and in accordance with the NRC Enforcement Policy (10 CFR 2, Appendix C), the following violations were identified:

- 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)

- 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)

- 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)

- 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)

- 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)

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<sup>2</sup>. Item 6 of this appendix requires that areas be cleaned if the contamination level exceeds 200 dpm/100cm<sup>2</sup>.

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/100cm.

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

- 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)

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)

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.