December 21, 2004

EA 04-219

Mr. Philip P. Gerbino, Pharm. D.
President
University of the Sciences
600 South 43rd Street
Philadelphia, PA 19104-4495

SUBJECT: NOTICE OF VIOLATION (NRC Inspection Report No. 030-00953/2004-001)

Dear Dr. Gerbino:

This letter refers to the unannounced, routine NRC inspection conducted on September 9, 2004, at your facility located in Philadelphia, PA, as well as the subsequent in-office review of additional information received from your staff dated September 10, 2004. The enclosed inspection report documents the findings of the inspection, which were discussed with Mr. Mark Blum and Ms. Renee Siegel of your staff on October 4, 2004. You subsequently provided information regarding your corrective and preventive actions in a letter dated October 25, 2004.

Based on the findings from this inspection, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. On December 2, 2004, James Dwyer of my staff informed Ms. Renee Siegel, your Director of Environmental Health and Radiation Safety, that this violation was being considered for escalated enforcement action, and the NRC did not need any additional information to make an enforcement decision. However, Mr. Dwyer provided Ms. Siegel an opportunity for your organization to attend a predecisional enforcement conference or to provide a written response, prior to the NRC determining appropriate enforcement action. During this conversation, Ms. Siegel declined the opportunity to attend a conference or to provide a written response.

During our inspection, NRC inspectors toured laboratories, cold rooms, and radioactive waste rooms where licensed material was utilized and stored. The inspectors identified three laboratories that were unoccupied and in which licensed material was present and unsecured. The failure to secure, control or maintain constant surveillance of the licensed material is a violation of NRC requirements. In addition, the NRC is concerned that unsecured radioactive materials were found in the same laboratories during previous audits performed by your Radiation Safety Office staff and actions taken to correct and prevent recurrence following these audits were apparently ineffective.

Although the material remained in the three laboratories the entire time, and it was unlikely that unauthorized persons came into direct contact with the material, this violation is of concern to the NRC because (1) the failure to control radioactive material could result in the loss of the

material; and (2) unintended radiation doses to members of the public could occur since classes were in session and students were seen entering and exiting the building. Therefore, this violation is categorized at Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $3,000 is considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement action within the last two years or two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. Credit for corrective actions is warranted because your corrective actions were considered prompt and comprehensive. These corrective actions included, but were not limited to: (1) immediately securing the laboratories; (2) discussing this incident with the authorized users responsible for the laboratories; (3) posting signs on laboratory doors to remind your staff of the security requirements; (4) double locking licensed material; (5) increasing the authority of your Radiation Safety Officer over the storage and security of licensed material; and (6) performing periodic inspections to gauge the effectiveness of your corrective actions.

Therefore, to encourage prompt and comprehensive correction of violations, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation without a civil penalty for this Severity Level III violation. However, you should be aware that significant violations in the future could result in a civil penalty. In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reasons for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in this letter and inspection report. Therefore, you are not required to respond to this violation unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room). (Note:Public access to ADAMS has been temporarily suspended so that security reviews of publicly available documents may be performed and potentially sensitive information removed. Please check the

NRC website for updates on the resumption of ADAMS access.) To the extent possible, your response should not include any personal privacy, proprietary or safeguards information so that it can be made available to the public without redaction. The NRC also includes significant enforcement actions on its web site at http://www.nrc.gov; select **What We Do, Enforcement,** then **Significant Enforcement Actions.**

Sincerely,

/RA/ James T. Wiggins Acting For

Samuel J. Collins
Regional Administrator

Docket No. 030-00953
License No. 37-00582-02

Enclosures:
1. Notice of Violation
2. NRC Region I Inspection Report 030-00953/2004-001

cc w/encls:
Commonwealth of Pennsylvania

Dr. Gerbino

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NAME	JWray		DHolody		JDwyer		GPangburn		KFarrar	
DATE	12/16/04		12/20/04		12/16/04		12/17/04		12/20/04	

OFFICE	RI/RA									
NAME	Scollins (JTW for)									
DATE	12/21/04									

OFFICIAL RECORD COPY

ENCLOSURE 1

NOTICE OF VIOLATION

University of the Sciences
Philadelphia, PA

Docket No. 030-000953
License No. 37-00582-02
EA 04-219

During an NRC inspection conducted on September 9, 2004, as well as an in-office review of additional information received from your staff dated September 10, 2004, a violation of NRC requirements was identified. The violation was discussed with the licensee during an exit meeting on October 4, 2004. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600, the violation is set forth below:

10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, controlled area means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason; and unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, on September 9, 2004, the licensee did not secure from unauthorized removal or access, licensed material in laboratories, which are controlled areas, nor did the licensee control and maintain constant surveillance of this licensed material. Specifically on that date, the inspectors found:

1. 384 microcuries of hydrogen-3 (H-3), 41 microcuries of carbon-14 (C-14) and 190 microcuries of iodine-125 (I-125) unsecured in a research room;

2. 0.1 microcuries of H-3, 1.9 microcuries of C-14 and 0.3 microcuries of I-125 unsecured in another research room; and

3. 979 microcuries of H-3 and 176 microcuries of C-14 unsecured in another research room.

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

The NRC has concluded that information regarding the reasons for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in this letter and NRC Inspection Report No. 030-00953/2004-001. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA 04-219" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest the violation, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 21st day of December 2004

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

EA No.	04-219
Inspection No.	03000953/2004001
Docket No.	03000953
License No.	37-00582-02
Licensee:	University of the Sciences in Philadelphia
Location:	600 South 43rd Street Philadelphia, PA 19104-4495
Inspection Dates:	September 9 - October 4, 2004
Documentation Provided:	Laboratory safety inspection reports and radioactive material inventories were provided on September 10, 2004. The licensee's corrective and preventive action plan was provided on October 25, 2004.

Inspectors:

James W. Dwyer for _____ ***December 16, 2004***
Kathy Dolce Modes — date
Health Physicist

John Nicholson _____ ***December 16, 2004***
John Nicholson — date
Health Physicist

Approved By:

James W. Dwyer _____ ***December 16, 2004***
James Dwyer, Chief — date
Commercial and R&D Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

University of the Sciences in Philadelphia
NRC Inspection Report No. 03000953/2004001

During a routine inspection of the University of the Sciences in Philadelphia (USP) on September 9, 2004, NRC inspectors toured laboratories, cold rooms and radioactive waste rooms where licensed material was actively utilized and stored. These laboratories/rooms were located in buildings that also contained classrooms, offices and common areas. The University was in session at the time of the inspection and students were observed entering and exiting all of the buildings. The inspectors identified three laboratories where licensed materials were present and unsecured and the laboratories were not occupied. The first laboratory contained 384 microcuries of hydrogen-3, 41 microcuries of carbon-14, and 190 microcuries of iodine-125. This amounts to approximately 191 times the Appendix C value in 10 CFR Part 20. The second laboratory contained 0.1 microcuries of hydrogen-3, 1.9 microcuries of carbon-14, and 0.3 microcuries of iodine-125. This amounts to less than the Appendix C value. The third laboratory contained 979 microcuries of hydrogen-3 and 176 microcuries of carbon-14. This amounts to approximately 3 times the Appendix C value. The licensee's records indicated that security problems had been identified in these same laboratories during audits performed between 2001 and 2004. The inspectors noted that corrective and preventive actions for these previously identified problems were not documented and, based on the findings of the inspection, the actions were not effective.

Within the scope of this inspection, one violation was identified for the failure to secure from unauthorized removal or access licensed materials that are stored in controlled or restricted areas in accordance with 10 CFR 20.1801.

REPORT DETAILS

I. Organization and Scope of the Program

a. Inspection Scope

The organization and scope of the program were reviewed.

b. Observations and Findings

The University of the Sciences in Philadelphia (USP) has a limited scope academic research and development license authorizing the use of hydrogen-3 (H-3), carbon-14 (C-14), phosphorus-32 (P-32), phosphorus-33 (P-33), sulfur-35 (S-35), calcium-45 (Ca-45), chromium-51 (Cr-51), iron-59 (Fe-59), and iodine-125 (I-125). Generally, no more than microcurie quantities of these materials are used at any one time. Licensed materials are used for teaching and training of students and for biomedical research. While both in vitro and in vivo research use of radioactive materials occurs at USP, in vivo use is much less common. There are 13 authorized users (a.k.a. supervisors), approximately 15 radioactive material workers and 23 authorized use locations at USP.

The Director of the Environmental, Health and Radiation Safety Office serves as the Radiation Safety Officer (RSO) for the license. The RSO reports to the Assistant Vice President of Facilities Services & Real Estate. The RSO is assisted by an administrative assistant, a stock room manager and several work study students. The students have been trained to assist with radioactive material package delivery, waste pick-up, inventory tracking and laboratory surveys.

USP maintains a Safety Committee that meets every other month while school is in session. The RSO reports to the Safety Committee on the results of the annual program reviews and other radiation safety related issues or incidents. The results of the annual laboratory safety inspections conducted by the RSO are also reported to the Safety Committee.

c. Conclusions

No violations or safety concerns were identified.

II. Management Oversight of the Program

a. Inspection Scope

The oversight of the radiation safety program by management was reviewed.

b. Observations and Findings

The RSO conducts an annual laboratory safety audit and an annual review of the radiation safety program.

The annual laboratory safety audit is a comprehensive review looking at the environmental, biological, chemical and radiation safety issues associated with each laboratory. Issues for improvement and recommendations for corrective action are noted on a separate report for each laboratory. The results of the laboratory safety audits are reviewed with the Safety Committee. Laboratory safety audit records include a section to address and record corrective actions. Inspectors noted that while conducting laboratory safety audits in 2001, 2002, 2003 and 2004, the RSO identified several laboratories containing radioactive materials that were not secured (unlocked) and/or were not attended. Some laboratories were found to be unsecured on more than one occasion. The inspectors noted there was no follow up information in these records to indicate that the recommended corrective/preventive actions were implemented.

The annual review of the radiation safety program for 2004 was reviewed with the Safety Committee and the results and topics covered were recorded in the meeting minutes. No problems were identified. Annual program reviews were conducted by the RSO in 2002 and 2003 but were not documented.

c. Conclusions

The fact that some laboratories were found to be unsecured on more than one occasion raises concerns about the adequacy of the implementation of the licensee's corrective and preventive actions. See Section IV of this report for additional information related to the security of radioactive materials. No violations were identified.

III. Facilities and Equipment

a. Inspection Scope

The facilities and equipment of the licensee associated with licensed material were reviewed.

b. Observations and Findings

The inspectors visited laboratories where licensed material is used or stored, including the areas where licensed material is received and radioactive waste is stored and disposed of. Laboratories had clearly designated work areas and equipment for using radioactive material. Absorbent paper and/or spill trays were in place to control minor spills. Survey instruments were available that were appropriate for the radionuclides being used. Storage areas and waste containers in laboratories were properly labeled. Lucite or lead shielding was utilized to reduce the potential for exposure to personnel.

c. Conclusions

No violations or safety concerns were identified.

IV. Material Receipt, Use, Transfer, and Control

a. Inspection Scope

The receipt, use transfer and control of licensed material were reviewed.

b. Observations and Findings

There are a number of areas at USP where licensed material is used and/or stored including laboratories, cold rooms, waste storage, darkroom and class rooms. With the help of the RSO, the inspectors reviewed the list of laboratories, identified the inactive facilities, and identified locations to inspect. During the course of visiting these areas, the inspectors discovered 3 laboratories where licensed material was present and unsecured and the laboratories were not occupied. At least 2 of these laboratories had been identified with this problem on more than one occasion by the licensee's RSO while conducting annual safety inspections during 2001, 2002, 2003 and 2004. Prior to exiting these laboratories, the RSO locked the laboratory doors.

After the on-site inspection, the licensee was given time to prepare a complete and accurate inventory of licensed material in these 3 unsecured and unattended rooms. In the licensee's report dated September 10, 2004, they reported that the following radionuclides and cumulative activities were present in each location. The first laboratory contained 384 microcuries of H-3, 41 microcuries of C-14, and 190 microcuries of I-125. This amounts to approximately 191 times the Appendix C value in 10 CFR Part 20. The second laboratory contained 0.1 microcuries of H-3, 1.9 microcuries of C-14, and 0.3 microcuries of I-125. This amounts to less than the Appendix C value. The third laboratory contained 979 microcuries of H-3 and 176 microcuries of C-14. This amounts to approximately 3 times the Appendix C value.

10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, controlled area means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason; and unrestricted area means an area, access to which is neither limited nor controlled by the licensee. Failure of the licensee, on September 9, 2004, to secure from unauthorized removal or limit access to licensed material in laboratories which are controlled areas, is a violation of 10 CFR 20.1801.

c. Conclusions

Within the scope of this inspection, one violation was identified for the failure to secure from unauthorized removal or access licensed materials that are stored in controlled or restricted areas in accordance with 10 CFR 20.1801.

V. Training of Workers

a. Inspection Scope

The radiation safety training program was reviewed.

b. Observations and Findings

A refresher and new orientation radiation safety training course was being conducted at the time of the on-site inspection. A consultant was providing initial and refresher training for personnel who plan to work with radioactive material or in a laboratory where radioactive materials may be present. This training opportunity is usually provided twice each year. The RSO also provides general awareness radiation safety training to all new employees as part of the new employee orientation training conducted every other month.

The inspectors spoke with several people regarding their radiation safety training. These included authorized users and radioactive material workers in laboratories as well as support personnel who deliver packages and handle radioactive waste. All of these individuals appeared to be aware of what to do in the case of an emergency and they knew to go to the RSO for assistance with a problem. Laboratory personnel were aware of the requirements for securing, tracking and working safely with radioactive material. All personnel displayed an adequate understanding of their responsibilities working with licensed material; however, when laboratory personnel who did not work with radioactive material were told a laboratory containing material was unlocked and unattended, they did not take action to secure the laboratory. It appeared that these individuals, while aware of the requirements for securing radioactive materials, may not have considered it their responsibility since they themselves were not working with radioactive materials.

c. Conclusions

Individuals who do not use radioactive material, but who work in a laboratory that uses radioactive material, will need to accept responsibility for securing the laboratory.

No violations or safety concerns were identified.

VI. Radioactive Waste Management

a. Inspection Scope

The handling of radioactive waste was reviewed.

b. Observations and Findings

Radioactive waste is collected from the laboratories by a trained student worker and brought to the radioactive waste storage room. The licensee holds short-lived (P-32, P-33, I-125) dry waste for decay-in-storage in this room. The dry waste is consolidated in separate containers for each radionuclide. It is held for at least ten half-lives, surveyed and then picked up by a vendor to be incinerated. Long-lived dry radioactive waste is also consolidated in the waste storage room. It is packaged and picked-up by a contract waste broker, Philotechnics, Ltd. The licensee's radiation safety staff disposes of aqueous liquid waste via the sanitary sewer by means of a sink in the waste storage room. There is no drain disposal permitted in the individual laboratories. There is a secured waste shed that is also used for radioactive waste storage but was empty at the time of the on-site inspection.

c. Conclusions

No violations or safety concerns were identified.

VII. Exit Meeting

An exit meeting was conducted by telephone on October 4, 2004, with the individuals identified at the end of this report. By letter dated October 25, 2004, the licensee provided information on corrective and preventive actions they are taking to improve the security of licensed material. These actions included: (1) the recommended purchase and use of smaller locked refrigerators, locked cabinets or lock boxes secured inside refrigerators; (2) the requested transfer of radioactive material from inactive laboratories to the Radiation Safety Department for storage or disposal; (3) the posting of security reminder signs on laboratory doors where licensed material is used or stored; and (4) the performance of periodic inspection by the RSO to monitor the effectiveness of the corrective and preventive actions. In addition, USP management provided the RSO with the authority to suspend an authorized user’s authorization to use licensed materials if the materials are found unsecured. USP management also stated that individual departments will be held fiscally responsible for any financial penalties that are incurred.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

*Renee Siegel, Radiation Safety Officer and Director, Environmental, Health and Radiation Safety Department
Pardeep Gupta, Authorized User
Diane Morell, Authorized User
Vinette Achtert, Stockroom Manager
Ann Montgomery, Administrative Assistant
Diana Stockdale, Training Consultant
*Mark Blum, Assistant Vice President of Facilities Services & Real Estate