



TEMPLE UNIVERSITY
A Commonwealth University

Health Sciences Center

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Senior Vice President
for the Health Sciences Center

DCS
PDR

January 29, 1997

BY FEDERAL EXPRESS

Mr. James Lieberman
Director, Office of Enforcement
U.S. Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike
Rockville, MD 20852-2738

Subject: REPLY TO NOTICE OF VIOLATION
(NRC Inspection Report Nos. 030-02963/96-002 and 030-00458/96-002)

Dear Mr. Lieberman:

This letter responds to the Notice of Violation and Proposed Imposition of Civil Penalties issued to Temple University ("Temple") by the U.S. Nuclear Regulatory Commission ("NRC") on December 31, 1996. First, I want to assure you that at no time was the safety of our personnel or the public compromised, nor was our commitment to provide quality patient care minimized. Moreover, Temple's management joins me in recognizing the need for significant improvement both in our radiation safety program and in our ability to identify problems and implement effective corrective action. It is for this reason that we have taken corrective actions, described below and in the attached document, which represent a broad-based effort to thoroughly evaluate the strengths and weaknesses of our radiation safety program and to begin to develop prompt and lasting improvements.

In addition to the specific corrective actions discussed in response to each violation, we have taken several important steps intended both to thoroughly evaluate our radiation safety program and to ensure that our corrective actions are responsive to the underlying causes of the violations. First, as you know, we have hired a permanent Radiation Safety Officer (RSO), Dr. Lily Lodhi. Dr. Lodhi is a very experienced and competent RSO who will contribute significantly to long term and sustained improvements in our radiation safety program. She has unrestricted access to and support from Temple's senior management. Second, I have directed Dr. Lodhi to conduct a comprehensive review of our radiation safety program to identify areas of weakness in the program. Third, we have retained an outside

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auditor, Dr. John Glenn, formerly of the NRC, to review our management structure, oversight and operations. That review is underway and we are confident that Dr. Glenn's insights will be helpful in identifying any needed changes in our management structure and control functions. Fourth, we have retained independent medical physicists to review the quality control of our license related activity. The results of these audits will be shared with the Temple University Radiation Protection Committee (TURPC).

Dr. Lodhi also has begun reviewing the activities in our Nuclear Medicine Department and has provided training to its staff. Based upon her findings and recommendations, we have appointed a new technologist to supervise the activities of all the technologists within the department (including the former supervising technologists), temporarily suspended the use of generators, and installed key pad combination locks at the entrances to the hot lab. In addition, the activities in the Nuclear Medicine department are currently being audited daily by the Radiation Safety Office to evaluate the adequacy of radiation safety procedures.

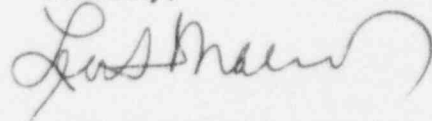
Also, periodic audits by the Assistant to the Senior Vice President are being conducted to review the security of licensed materials.

Our specific responses to the violations noted and a check for the civil penalty in the amount of \$10,000.00 are enclosed.

The management of Temple University, in conjunction with TURPC, will continue to closely monitor our radiation safety program and will take appropriate action to ensure that we meet all regulatory requirements.

Thank you for your consideration.

Sincerely,



Leon S. Malmud, M.D.
Senior Vice President

Mr. James Lieberman

January 29, 1997

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cc: Hubert J. Miller
Regional Administrator, Region 1
U.S. Nuclear Regulatory Commission
Paul H. Boehringer
Linda C. Knight, Ph.D.
Lily Lodhi, Ph.D.
Donald N. Redmond
Susan B. Smith, Esq.

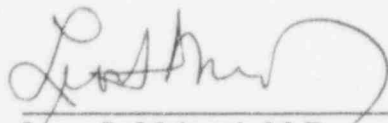
Encs: Reply to Violations
Check No. 123492

AFFIDAVIT

I, Leon S. Malmud, M.D., Senior Vice President, Temple University Health Sciences Center ("Temple"), do hereby affirm and state:

1. I am an officer of Temple and am authorized to execute this affidavit on behalf of Temple.
2. The facts set forth in the attached Reply to Notice of Violation, dated January 29, 1997, are true and accurate to the best of my knowledge, information and belief.

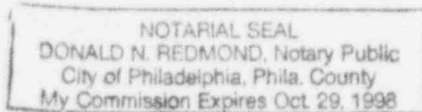
TEMPLE UNIVERSITY
HEALTH SCIENCES CENTER

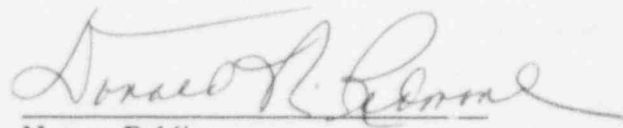


Leon S. Malmud, M.D.

Subscribed and sworn to before me, a Notary Public in and for the Commonwealth of Pennsylvania, this 29th day of January, 1997.

My Commission expires:





Notary Public

TEMPLE UNIVERSITY'S REPLY TO NOTICE OF VIOLATION

The following specific responses correspond to each of the violations identified in the Notice of Violation of December 31, 1996.

Violation I.A.

Summary of the Violation: In violation of 10 C.F.R. §§ 20.1801 and 20.1802, on October 1, 1996, Temple failed to secure from unauthorized removal or limit access to licensed material stored in the Nuclear Medicine Department Hot Lab.

Response to Violation: Temple admits the violation.

Reasons for the Violation: The Hot Lab was secured by an inadequate physical control system. Specifically, the same key that permitted general access to the Nuclear Medicine Department also permitted access to a seldom used door to the Hot Lab. In addition, insufficient attention to detail contributed to this violation in that Nuclear Medicine Department personnel failed to prevent unauthorized access. Finally, the housekeeping staff disregarded training instructions that they could not enter the Hot Lab without being accompanied by an authorized person.

Corrective Actions Taken: All Hot Lab doors have been fitted with combination key-pad locking devices. Only those personnel authorized access to the Hot Lab have been provided the entry code. Additionally, Temple has instituted appropriate physical controls over the master keys for the key-pad locking devices. Finally, Nuclear Medicine Department technical staff have received training on Temple's nuclear materials security procedures, and the housekeeping staff has been re-instructed not to enter the Hot Lab except when accompanied by an authorized person.

Corrective Actions to be Taken: There are no pending corrective actions specific to this violation.

Date of Full Compliance: Temple currently is in full compliance.

Violation I.B.

Summary of the Violation: In violation of 10 C.F.R. §§ 20.1801 and 1802, on September 30, and October 24, 1996, Temple failed to adequately secure from unauthorized removal or limit access to licensed materials stored in refrigerators in various research facilities. Also, Temple personnel failed to maintain constant surveillance of this unlocked material.

Response to Violation: Temple admits this violation.

Reasons for the Violation: Failure of authorized users to comply with Temple policies caused this violation. Inadequate emphasis on security issues in training and weaknesses in Temple's audit practices also contributed to this violation.

Corrective Actions Taken: On December 10, 1996, the Acting RSO issued a written reminder to all authorized users of nuclear materials, highlighting Temple's security requirements and requiring a signed acknowledgment from each user. The individuals involved in the specific instances described in the inspection report have been counseled. The Radiation Safety Department completed its first round of unannounced audits by January 16, 1996.

Corrective Actions to be Taken:

- Temple is providing additional training for all authorized users of nuclear materials. This training addresses the security of licensed material as well as specific instruction for authorized users to challenge the presence of all unauthorized persons.
- On an ongoing basis, the RSO or her designee and/or senior management will continue to conduct unannounced audits and spot check the security of nuclear materials maintained in research labs during off-working hours.
- TURPC will consider appropriate disciplinary and/or administrative sanctions upon review of the specific circumstance of any future infractions.

Date of Full Compliance: Temple expects to achieve full compliance by January 31, 1997.

Violation II.

Summary of the Violation: In violation of 10 C.F.R. § 35.21(a), Temple failed to ensure that Radiation Oncology Department personnel performed monthly calibrations of the high dose rate remote afterloader (HDR), as required by Temple procedures.

Response to Violation: Temple admits this violation.

Reasons for the Violation: Personnel errors, inadequate procedural controls and lack of sufficient management controls over calibration testing contributed to this violation. The medical physicist involved in this violation lacked sufficient appreciation for the need for strict adherence to all applicable license conditions. In addition, the pre-treatment checklist did not include verification of the monthly calibration.

Corrective Actions Taken:

- The medical physicist involved in the specific incident described in the inspection report has been suspended temporarily from all licensed activities until the outside physics audit and the NRC's investigation of these issues have been completed to the satisfaction of TURPC.
- The TURPC conducted a thorough review of this event, including an interview with the medical physicist involved in order to identify appropriate corrective actions.

- The pretreatment checklist has been modified to include verification of completion of the monthly calibration.
- All technical staff (Physicist, Dosimetrist and Technologist) in the Radiation Oncology Department have received training on the requirement for monthly calibration of the (HDR) and the pretreatment checklist has been changed as indicated.
- Monthly calibrations by qualified staff and monthly reviews by the Director of Radiation Oncology and the RSO or her designee have been fixed to specific monthly dates.

Corrective Actions to be Taken:

- The Radiation Oncology and Nuclear Medicine Departments have identified all applicable test calibrations, surveys, checks and other recurring actions, and compiled them into departmental scheduling tools. The RSO or her designee will complete a validation review of the scheduling tools developed by both the Nuclear Medicine and Radioactive Oncology Departments.
- Each month, the Directors of the Department of Nuclear Medicine and Radiation Oncology will report the completion of all scheduled actions required by Temple's procedures, license or regulations. This report will also be provided to the RSO, TURPC and the Director of Environmental Health and Safety. These reports will continue for at least six months and until the Senior Vice President is satisfied that such reporting is no longer necessary.
- Each month, the RSO or her designee will perform an audit of a sufficient sample of the actions reported as completed by the two departments to provide reasonable assurance that activities have been adequately performed. The results of these audits will be presented at the next TURPC meeting.
- Outside medical physicists have been contracted to review Radiation Oncology policies, procedures and records.

Date of Full Compliance: Temple currently is in full compliance.

Violation III.A.

Summary of the Violation: In violation of 10 C.F.R. § 35.21(a), Temple failed to comply with its procedure for ensuring that all personnel involved in licensed activity receive prior authorization by the full Radiation Protection Committee. Specifically, researchers were permitted to possess and use radioactive materials after review by TURPC's Research Subcommittee but prior to approval by the full TURPC.

Response to Violation: Temple admits the violation.

Reasons for the Violation: Insufficient understanding of the license condition and inadequate control of license correspondence resulted in this violation. Temple assumed that the Research Subcommittee, delegated authority by the Radiation Protection Committee to review research proposals, could also act on its behalf to approve temporary authorization for use of licensed materials pending approval by the full TURPC. In addition, although NRC correspondence subsequent to a prior, similar violation advised Temple of the need for a license amendment to authorize use of the Research Subcommittee to approve research protocols, that correspondence was either lost or not properly tracked to assure it was acted upon.

Corrective Actions Taken:

- TURPC suspended all interim authorizations for use of radioactive materials not previously approved by the full committee.
- The full TURPC now meets on a bimonthly basis rather than quarterly.
- Temple has instituted a system of correspondence controls to ensure that individuals responsible for licensed activities are aware of communications between Temple and the NRC.

Corrective Actions to be Taken: No additional corrective actions specific to this violation are pending.

Date of Full Compliance: Temple currently is in compliance.

Violation III.B.

Summary of the Violation: In violation of 10 C.F.R. § 35.632(a)(3), Temple failed to perform a required annual full calibration of its teletherapy unit between June 1994 and August 1995.

Response to Violation: Temple admits this violation.

Reasons for the Violation: Inattention to detail by the medical physicist to properly perform the annual calibration. The lack of effective tools to assist management in oversight of scheduled activities also contributed to this violation.

Corrective Actions Taken: Full calibration of the teletherapy unit was performed in December 1996, and included all elements stated in 10 C.F.R. § 35.632(b).

Corrective Actions to be Taken: The RSO or her designee will review appropriate records to ensure that full calibration in accordance with the regulatory requirements is performed in a timely fashion.

Date of Full Compliance: Temple currently is in compliance.

Violation III.C.

Summary of the Violation: In violation of 10 C.F.R. 35.50(b)(3), Temple failed to perform quarterly linearity tests of each dose calibrator during two periods each in excess of one calendar quarter.

Response to Violation: Temple admits the violation.

Reasons for the Violation: The individual responsible for performing quarterly linearity checks did not strictly adhere to calibration schedules.

Corrective Actions Taken:

- The linearity checks have been performed in a timely fashion in each of the quarters subsequent to the periods noted in the NOV.
- The RSO or her designee has reviewed and will continue to review appropriate records during the periodic audits of the Nuclear Medicine Department to ensure that these tests are performed in a timely fashion.

Corrective Actions to be Taken: There are no outstanding corrective actions specific to this violation.

Date of Full Compliance: Temple currently is in full compliance.

Violation III.D.

Summary of the Violation: In violation of 10 C.F.R. § 20.2101, Temple failed to record the results of external contamination surveys in appropriate units.

Response to Violation: Temple admits the violation.

Reasons for the Violation: Lack of understanding by the Nuclear Medicine technologists of the regulations contributed to this violation.

Corrective Actions Taken:

- The procedure governing the performance and recording of swipe survey results has been modified to clearly reflect the requirement to report in appropriate units.
- All nuclear medicine technologists who routinely perform external contamination surveys have received training on the updated procedure and the regulatory requirement to report surveys in particular units.

Corrective Actions to be Taken: In conjunction with the RSO's periodic audits of the Nuclear Medicine Department, the RSO will spot check compliance with the revised procedure and regulatory requirements for recording contamination survey results.

Date of Full Compliance: Temple currently is in full compliance.