SHADYSIDE HOSPITAL
5230 Centre Avenue
Pittsburgh, PA 15232
412-623-2078

DEPARTMENT OF
RADIOLOGICAL SCIENCES
AND
DIAGNOSTIC IMAGING

January 12, 1994

Regional Administrator
U.S. Nuclear Regulatory Commission
Region I 475 Allendale Road
King of Prussia, PA 19406-1415

ATTENTION: DOCUMENT CONTROL DESK
U.S. NUCLEAR REGULATORY COMMISSION
Washington, D.C. 20555

RE: REPLY TO NOTICE OF VIOLATION
Docket No. 030-03001
License No. 37-02523-01

Dear Sirs:

In response to the "Notice of Violation" of December 31, 1993, and in accordance with 10 CFR 2.201, Shadyside Hospital, 5230 Centre Avenue, Pittsburgh, PA, submits the following response to the violations and apparent weaknesses in the radiation safety program cited as a result of the inspection of December 9 and 10, 1993. In accordance with the instructions in Appendix A of the "Notice of Violation" the responses will be outlined as follows:

1) Reason for violation.
2) Corrective steps that have been taken and the results achieved.
3) The corrective steps that will be taken to avoid further violations.
4) The date when full compliance has or will be achieved.

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Appendix A, Notice of Violation, Item A:

(1) 10 CFR 35.14: Failure to notify NRC when an authorized user permanently discontinued performance of duties under our License occurred as a result of a failure to communicate the notification to the Radiation Safety Committee.

(2) The required notification to NRC was made on December 13, 1993.

(3) A communique will be submitted to all authorized users indicating the requirement to notify the Radiation Safety Committee in the event of a permanent discontinuation of their duties under the License at Shadyside Hospital. Shadyside Hospital will notify the NRC within 30 days of such an event.

(4) Full compliance will be achieved as of January 31, 1994.

Appendix A, Notice of Violation, Item B

(1) 10CFR35.50(e): Failure to document the required model and serial numbers of the dose calibrator used on the daily constancy form occurred as a result of form transcription errors and an inadvertent oversight during audits of the required records.

(2) New forms have been developed that include documentation of all items required by regulation.

(3) Audits of required records will assure that the forms that are used and the records that are documented include the model and serial number of the dose calibrator as required by regulation.

(4) Full compliance will be achieved as of January 31, 1994.

Should you have any questions or further requirements, please contact me.

Sincerely,

Edward Klaman

Edward Klaman
Executive Vice President
Shadyside Hospital

Apparent Weakness in the radiation safety program:

Item 1, Therapeutic radiopharmaceutical administration records:

(1) Full compliance to the documentation requirements of Quality Management (QMP) was not achieved due to incomplete training of the personnel involved in the maintenance of QMP records.

(2) All personnel in Nuclear Medicine have been trained in the requirements of the QMP including procedures and documentation requirements. All authorized users and physicians working under the supervision of authorized users performing procedures under the QMP have been trained in the requirements of the QMP including procedures and documentation requirements.

(3) Refresher training in the requirements of the QMP will be provided to all personnel on an annual basis, and as needed, to assure that they are properly trained.

(4) Full compliance will be achieved as of January 31, 1994.

Item 2, Ventilation rate measurements in scanning rooms using Xe-133:

(1) Full compliance to requirements for measuring ventilation rates in all rooms using Xe-133 was not achieved as a result of procedural changes in Nuclear Medicine that were not communicated to the Radiation Safety Committee.

(2) The shortcoming was discovered in routine audits of the radiation safety program, and the required measurement procedure was initiated at that time.

(3) Nuclear Medicine personnel have been trained in the requirement regarding the areas of permissible use of Xe-133. Ventilation rate measurements will be conducted in all areas using X3-133 in accordance with our License condition.

(4) Full compliance was achieved as of May 13, 1993.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

DEC 31 1993

Docket No. 030-03021

License No. 37-02523-01

Shadyside Hospital
ATTN: Edward Klaman
Executive Vice President
5230 Center Avenue
Pittsburgh, Pennsylvania 15232

Dear Mr. Klaman:

Subject: Inspection No. 030-03021/93-001

On December 9 and 10, 1993, Dr. Sattar Lodhi of this office conducted a routine safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records.

The findings of the inspection were discussed with you and members of your staff at the conclusion of the inspection. The NRC is concerned about an apparent lack of supervision by the Radiation Safety Officer of your activities in the nuclear medicine area. For example, several records of therapeutic radiopharmaceutical administrations contained errors, including the respective written directives not containing the necessary information. That your periodic program audits failed to identify these errors or nonconformity with your established procedures is indicative of an inadequacy of your audit program. Similarly, xenon-133 was being administered to patients in two of your scanning rooms in the nuclear medicine department but for a period the ventilation rate in one of these rooms was not checked. Please include in your response the specific steps you have taken and/or are planning to take to address these apparent weaknesses in your radiation safety program.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed as Appendix A and categorizes each violation by severity level in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy). You are required to respond to this letter and in preparing your response, you should follow the instructions in Appendix A.

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Please use the enclosed self-addressed green envelope when you respond to this letter to assist us in the timely processing of your response.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and your reply will be placed in the Public Document Room. The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

Your cooperation with us is appreciated.

Sincerely,

Jenny M. Johansen, Chief
Medical Inspection Section
Division of Radiation Safety
and Safeguards

Enclosure:

Appendix A, Notice of Violation

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Pennsylvania

APPENDIX A

NOTICE OF VIOLATION

Shadyside Hospital
Pittsburgh, Pennsylvania 15232

Docket No. 030-03021
License No. 37-02523

During an NRC inspection conducted on December 9 and 10, 1993 violation of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

A. 10 CFR 35.14 requires that a licensee notify the NRC by letter within thirty days when an authorized user, Radiation Safety Officer, or Teletherapy Physicist permanently discontinues performance of duties under the license or has a name change, or when the licensee's mailing address changes.

Contrary to the above, on October 31, 1993, the licensee's one of the authorized users permanently discontinued performance of duties under the license and as of December 10, 1993, a period in excess of 30 days had elapsed and the licensee did not notify NRC.

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

B. 10 CFR 35.50(e) and 35.50(e)(1) require, in part, that a licensee retain records of daily constancy checks of the dose calibrator for three years unless directed otherwise, and that the records include the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the check, the activity measured, and the initials of the individual who performed the check.

Contrary to the above, as of December 9, 1993, the licensee's records of daily constancy checks of its dose calibrator performed between October 1, 1993 and December 9, 1993 did not include the model and serial number of the dose calibrator.

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

Pursuant to the provisions of 10 CFR 2.201, Shadyside Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional

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Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.