MAY 18 1994

Docket Nos. 030-00472
030-03018

License Nos. 37-02385-01
37-02385-02

Carlisle Hospital
ATTN: Charles Young, Vice President
for Administration
246 Parker Street
Carlisle, Pennsylvania 17013-1212

Dear Mr. Young:

Subject: Routine Inspection Nos. 030-00472/94-001 and 030-03018/94-001

This refers to your letter dated March 29, 1994, in response to our letter dated February 28, 1994. Thank you for informing us of the actions documented in your letter. However, your response to our above mentioned letter is inadequate because it does not include: (1) the reasons for the violations; (2) the actions you have taken to prevent a recurrence of similar violations; and (3) your response to the NRC's concern regarding the oversight of the licensed activities by the management, the Radiation Safety Committee and the Radiation Safety Officer.

A copy of our February 28, 1994 letter with enclosures is enclosed for your reference. Please follow the instructions given in the Notice of Violation in preparing your response. You are required to respond to this letter within 15 days from the date of this letter.

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.

OFFICIAL RECORD COPY - S:\PENDING\CARLISLE.REP - 05/05/94

Your cooperation with us is appreciated.

Sincerely,

Original Signed By:
Jenny M. Johansen

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

Enclosures:
Letter dated February 28, 1994
Appendix A, Notice of Violation

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

bcc:
Region I Docket Room (w/concurrences)

RI:DRSS	RI:DRSS
Lodhi	Johansen
5/5/94	5/5/94

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

FEB 28 1994

Docket Nos. 030-00472
030-03018

License Nos. 37-02385-01
37-02385-02

Carlisle Hospital
ATTN: Charles Young
Vice President, Administration
246 Parker Street
Carlisle, Pennsylvania 17013

Dear Mr. Young:

Subject: Combined Inspection Nos. 030-00472/94-001 and 030-03018/94-001

On February 2 and 3, 1994, Dr. Sattar Lodhi of this office conducted a routine safety inspection at the above address of activities authorized by the above listed NRC licenses. 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 at the conclusion of the inspection. These discussion included the use of your cobalt-60 teletherapy unit during the period from December 3, 1992 to April 7, 1993, and the inspector's observations that your senior management, the Radiation Safety Committee, and the Radiation Safety Officer did not appear to be actively involved in the implementation of your radiation safety program. The NRC views these observations as a weakness in your radiation safety program and are a cause of concern to NRC. Please include in your response to this letter steps you have taken to improve the communications between the senior management, the Radiation Safety Committee, the Radiation Safety Officer and personnel and departments of the hospital involved in the use of radioactive materials. The issue related to the use of your cobalt 60 teletherapy unit during the above mentioned period is under review by the NRC and you will be notified of any enforcement action upon completion of this review.

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

Carlisle Hospital
Carlisle, Pennsylvania 17013

Docket Nos. 030-00472
030-03018
License Nos. 37-02385-01
37-02385-02

During an NRC inspection conducted on February 2 and 3, 1994, violations 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 35.22(b)(2) requires that, to oversee the use of licensed material, the Radiation Safety Committee must review, on the basis of safety and with regard to the training and experience standards in Subpart J of 10 CFR Part 35, and approve or disapprove any individual who is to be listed as an authorized user, the Radiation Safety Officer, or a Teletherapy Physicist before submitting a license application or request for amendment or renewal.

Contrary to the above, on multiple occasions, the licensee submitted requests for a license amendment and as of those dates, the licensee's Radiation Safety Committee had not reviewed and approved, on the basis of safety and with regard to the training and experience standards in Subpart J of 10 CFR Part 35, an individual who was named in the requests as the licensee's authorized user. Specifically, on May 12, 1992, the licensee submitted a request for license amendment to include an individual as authorized user on its license, and again on July 14, 1992, the licensee submitted a request for license amendment to include another individual as authorized user on its license and as of those dates the Radiation Safety Committee had not reviewed and had not approved the respective individual to be listed as authorized user. Similarly, on November 24, 1993, the licensee submitted a request for a license amendment to reflect the change of its Radiation Safety Officer, and the new Radiation Safety Officer was not approved by the Radiation Safety Committee.

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

B. 10 CFR 35.22(a)(2) requires that the Radiation Safety Committee meet at least quarterly.

Contrary to the above, the licensee's Radiation Safety Committee did not meet

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between June 12, 1992 and November 19, 1992, a period in excess of one calendar quarter.

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

C. 10 CFR 35.32(b) requires, in part, that the licensee develop procedures for and conduct a review to verify compliance with all aspects of the quality management program at intervals no greater than 12 months.

Contrary to the above, as of February 2, 1994, the licensee had neither conducted a review nor developed procedures for conducting a review to verify compliance with the licensee's quality management program.

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

D. 10 CFR 35.634(a)(1) requires that a licensee authorized to use teletherapy units for medical use perform monthly output spot-checks on each teletherapy unit that include determination of timer constancy and timer linearity over the range of use.

Contrary to the above, the licensee's monthly output spot-checks performed on March 11, 1993, on its teletherapy unit did not include a determination of timer constancy and timer linearity over the licensee's full range of use of up to 7.79 minutes.

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

E. 10 CFR 19.12 requires, in part, that all individuals working in a restricted area be instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses.

Contrary to the above, as of February 2, 1994, individuals who were working in the Nuclear Medicine Suite, a restricted area, had not been instructed in the applicable provisions of the regulations and the conditions of the license. Specifically, the nuclear medicine technologists were not instructed how to check the survey instruments for proper operation with the dedicated check source.

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

F. 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 February 2, 1994, the licensee's records of daily constancy checks of its dose calibrator performed between January 2, 1994 and February 2, 1994 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, Carlisle 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 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.