

**BRADLEY
MEMORIAL
HOSPITAL
And Health Center**

81 Meriden Avenue
Southington
Connecticut
06489
203/276-5000

October 9, 1989



John F. Mullett
President
Albert J. Duzik, Jr.
Chairman of the Board

Director, Office of Enforcement
U.S. Nuclear Regulatory Commission
Attn.: Document Control Desk
Washington, D.C. 20555

Re: Reply to a Notice of Violation
Docket #: 030-12270
License # 06-17145-01
EA 89-134
NRC Inspection No. 89-001

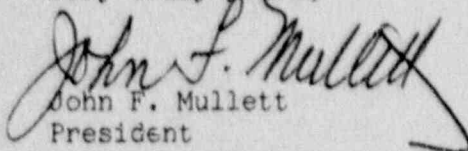
Dear Sir:

In accordance with your letter of September 18, 1989 regarding the Notice of Violation and the proposed imposition of Civil Penalty, Bradley Memorial Hospital and Health Center has enclosed a check for \$625.-- (the proposed civil penalty); and has provided responses to the items requested.

In your letter of September 18, 1989 you requested responses to Enclosure 2. Attached you will find the hospital's responses to these items.

The Radiation Safety Officer, the Radiation Safety Committee and the hospital's physicists will be taking an active role in monitoring the department's activities. The functions and roles of each party are detailed in the hospital's responses. If you require further information or clarification, please feel free to contact me.

Very truly yours,


John F. Mullett
President

cc: Regional Administrator
US Nuclear Regulatory Commission, Region I
475 Allendale Rd.
King of Prussia, PA 19406

Encl.
JFM/g

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NMSS LIC30
06-17145-01 PDC

Quality Health Care for the Southington Community

JE14
w/check \$625
16628

HOSPITAL RESPONSES TO ENCLOSURE 2

- A. The licensee states that the new Chief Nuclear Medicine Technologist has been assigned to review and update all policies and procedures and communicate them to the staff. The licensee should describe the role of the Radiation Safety Committee and the Radiation Safety Officer in reviewing and approving these changes and in ensuring the continuing implementation of the training program.

Response:

The hospital hired a trained and certified nuclear medicine technologist two weeks prior to the NRC inspection in March of this year. The individual the hospital hired began work in April and her first task was to review and update all the policies and procedures of the department under the direction of the RSO. In June of this year all of the policies and procedures within the nuclear medicine department were reviewed and updated.

The procedure followed within the institution for review and approval of the policies and procedures is for the Chief Nuclear Medicine Technologist to submit proposed changes to the RSO. The RSO reviews the proposed changes and updates the policies and procedures, and submits his recommendations to the Radiation Safety Committee for approval. Once the policies and procedures are approved, the Chief Nuclear Medicine Technologist reviews them with the staff. Each staff member is required to initial any policy changes once he/she has reviewed and understands the change.

The department also has a training program which is for all individuals who work in or are frequenting the restricted area. This training program is reviewed and approved at the Radiation Safety Committee on a yearly basis. All employees who work in the restricted area are required to review the program on a yearly basis. The items included in the training program are the following:

1. The technologist will be kept informed of storage, transfer or use of radioactive materials or of radiation.
2. The technologist will be instructed in the following:
 - a. Health protection and problems associated with exposure to radioactive materials or radiation.
 - b. Precautions or procedures to minimize exposure.
 - c. The purpose and function of protective devices.
 - d. The applicable NRC regulations and licenses for the protection of personnel from exposure and observance of such.
 - e. Their responsibility to promptly report to the licensee any condition which may lead to or cause a violation of NRC regulations and licenses or an unnecessary exposure.
 - f. Appropriate response to warnings in the event of any unusual occurrence or malfunction that may involve exposure.

The training program has been reviewed by the RSO and approved by the Radiation Safety Committee. Copies of the Radiation Safety Committee minutes are attached for your review.

- B. The licensee described adequate corrective action, except that the sample chart for dose calibrator constancy does not include acceptable limits of variance. Provide information regarding how the limit of variance will be determined and how the personnel performing the test will be or have been informed of the method.

Response:

The sample chart for the dose calibrator constancy is set up according to the accuracy of the dose calibrator. The limits of variance are $\pm 5\%$. The hospital's physicist has determined the value of the standards and the chart includes the value of the standard with the $+5\%$ and -5% range identified. The technologist now obtains the value with the dose calibrator and compares it to the standard range. If the value is over the $+5\%$ limit or under the -5% limit, the technologist will immediately notify the RSO and the Chief Nuclear Technologist. No patient studies will be performed until the problem is rectified. All nuclear medicine technologists have been inserviced on this procedure.

C., D., E., F.: No further information requested.

- G. 1. The licensee should describe the instrument which will be used for evaluating contamination on personnel.

Response:

The instrument that will be used to evaluate contamination on personnel will be the G-M survey meter.

G. 2. No further information required.

- H. The licensee submitted confusing information concerning this violation. The licensee should make explicit statements regarding when physical checks of the ventilation rates were and will be made and who will make the checks.

Response:

The Chief of Nuclear Medicine will do the collecting systems checks of the radioactive aerosols and gases on the last Friday of every month. The hospital's physicists will measure the ventilation rates of radioactive aerosols and gases in the imaging room and surrounding areas, which was done on July 1, 1989 and will be done again on January 1, 1990; continuing as such every six months.

These changes will be documented and checked by the Radiation Safety Officer and presented to the Radiation Safety Committee on a bi-annual basis.

I. No further information required.

- J. The licensee should state and ensure that all instruments are now equipped with dedicated check sources.

Response:

At the time of the inspection conducted on March 30, 1989, the hospital was using instruments loaned to us by our physicist while the hospital's instruments were out being calibrated.

The hospital's survey instruments were and continue to be equipped with dedicated check sources and are checked daily with results being logged and initialed.

The date and time of calibration is noted on our survey instruments.

- K. The licensee should describe the procedure for ensuring that the instrument is calibrated at this required interval.

Response:

The policy of the Nuclear Medicine Department is that the "cutie-pie" ionization chamber will be calibrated annually by the hospital's physicist. The last calibration was done in May 1989 and will continue to be done annually every May.

This will be documented and checked by the RSO and presented annually to the Radiation Safety Committee.

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203/621 3661

John F. Melton
Albert J. D'Amico, Jr.

August 4, 1989

A meeting of the Radiation Safety Committee was held on Friday, August 4, 1989 at 12:00 noon in conference Room B. The meeting was called to order by chairperson, Dr. Alan Melton.

In attendance were: Dr. Melton, Patricia Cozzolino, R.N., Clarence Silvia, Vice President, Michele Rispoli, NMT Chief Nuclear Medicine Technologist.

Minutes were read and old business discussed:

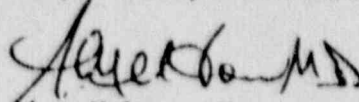
1. The technologists have corrected all violations from the NRC.
2. Doreen Fazo, R.T.(R) returned from her leave on June 19, 1989.
3. The hospital has not yet received an answer from the NRC regarding Michele Rispoli as the Radiation Safety Officer.

New Business:

1. Dr. Melton, Michele Rispoli, and Clarence Silvia, Vice President attended an Enforcement Conference to discuss the violations and corrections that were made. The NRC will review the corrections and contact the hospital upon completion of this review.
2. The department has purchased a new dose calibrator reference source, a new spot marker source, new syringe shields, and new safety glasses.
3. The department ordered lead lined cabinets, plastic sharps containers, a lead lined refrigerator, and a Xenogard air/trap monitor.

The meeting was adjourned at 1:15 P.M.

Respectfully submitted,


Alan Melton, M.D.

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Chairman of the Board

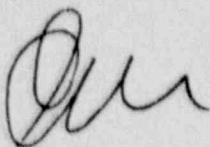
June 26, 1989

A meeting of the Radiation Safety Committee was held on Monday, June 26, 1989 at 12:00 noon in Conference Room B. The meeting was called to order by the RSO, Dr. Alan Melton.

In attendance were: Dr. Alan Melton, RSO, Patricia Cozzolino, R.N., Clarence Silvia, Vice President Management Representative, Michele Rispoli, NMT, Chief Nuclear Medicine Technologist and Doreen Fazo, R.T.(R).

1. Minutes from May 1, 1989 were read and approved. No corrections or charges were made.
2. Old Business:
 1. Corrections of NRC violations were discussed and reviewed.
3. New Business:
 1. The Nuclear Medicine Technologist Training Program was discussed.
 2. The RSC and RSO agreed that Nuclear Medicine Technologist will be trained and know all radiation safety procedures.
 3. Part 19 and Part 20 of the Reg. Guide were reviewed.
4. Conclusion
The Radiation Safety Committee approved the Nuclear Medicine Training Program and all questions on Part 19 and Part 20 of the Reg. Guide were answered.

The meeting was adjourned at 2:00 P.M.



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John F. Melton
Albert J. Duffek, Jr.
Chairman of the Board

May 1, 1989

A meeting of the Radiation Safety Committee was held on Monday, May 1, 1989 at 12:00 noon in Conference Room B. The meeting was called to order by chairperson, Dr. Alan Melton.

In attendance were: Dr. Melton, Patricia Cozzolino, R.N., Clarence Silvia, Vice President, Michele Rispoli NMF Chief Nuclear Technologist.

Minutes were read and old business was discussed:

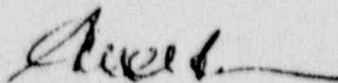
1. Loreen Fazo was granted an extended leave of absence. She will be returning to the department on June 19, 1989.
2. The Radiology Department Heads have continued to interview for a full-time Nuclear Medicine Technologist.

New Business:

1. On March 30, 1989, the department was inspected by the Nuclear Regulatory Commission. Several violations were brought forth by the Commission. Dr. Melton read the violations to the Committee.
2. Dr. Melton announced that, as of today, Michele Rispoli, has been hired as the full-time Nuclear Medicine Technologist. Also, a letter has been sent to the NRC requesting an amendment to the license, making Michele the Radiation Safety Officer.

The meeting was adjourned at 1:00 P.M.

Respectfully submitted,



Alan Melton, M.D.

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Edward F. Mullett
Albert J. Chodak, Jr.
President of the Board

February 15, 1989

A meeting of the Radiation Safety Committee was held on Wednesday, February 15, 1989 at 12:00 noon in Conference Room B. The meeting was called to order by chairperson, Dr. Alan Melton.

In attendance were: Dr. Melton, Patricia Cozzolino, R.N., Clarence Silvia, Vice President, and Mike Pikora, R.T.(R).

Minutes were read and old business was discussed:

1. It is felt that the letter that was sent to all referring physicians concerning exam times and explanations had a positive impact. No further problems have occurred.

New Business:

1. Mike Pikora, R.T.(R) has accepted a position elsewhere. As of February 20, 1989, he will no longer be with us. Also, Judy Joyce, R.T.(R) has accepted a position elsewhere. Judy continued to oversee the Nuclear Medicine Department ever after she became the Radiology Supervisor. Unfortunately, Doreen Fazo, R.T.(R) is on a maternity leave until May. The department has begun advertising for a full-time Nuclear Medicine Technologist.

2. The NRC Information Notice No. 89-02 was discussed to remind licensees and their employees of the penalties that could result from the intentional violation of regulatory requirements.

3. The NRC Information Notice No. 89-12 was discussed to alert recipients to a frequent problem concerning dose calibrator quality control tests, identified by NRC inspectors during inspections of medical programs, and also to emphasize the importance of quality control procedures for equipment used to assay patient doses.

The meeting was adjourned at 1:30 P.M.

Respectfully submitted,

Alan Melton
Alan Melton, M.D.