FEB 10 1997

EA 96-396

Laurence A. Tanner, President and Chief
Executive Officer
New Britain General Hospital
100 Grand Street
New Britain, Connecticut 06050

SUBJECT: NOTICE OF VIOLATION
(NRC Investigation Report No. 1-96-013)

Dear Mr. Tanner:

This letter refers to your January 14, 1997 correspondence, in response to our December 20, 1996 letter.

Thank you for informing us of the corrective and preventive actions documented in your letter. These actions will be examined during a future inspection of your licensed program.

Your cooperation with us is appreciated.

Sincerely,

Original Signed by: F. Costello for

Charles W. Hehl, Director
Division of Nuclear Materials Safety

Docket No. 030-01250
License No. 06-02388-01

cc:
Peter J. Mas, M.S., Radiation Safety Officer
State of Connecticut

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New Britain General

New Britain
General Hospital

100 Grand Street
New Britain
Connecticut 06050
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Laurence A. Tanner
President

"REPLY TO A NOTICE OF VIOLATION"

Docket No. 030-01250
License No. 06-02388-01
EA 96-396

Prepared for:

U.S. Nuclear Regulatory Commission
Attention: Document Control Desk
Washington D.C. 20555

1. Reason for Violation or, if Contested, the Basis for Disputing the Violation

   Reply: New Britain General Hospital (Licensee) does not contest the violation of 10 CFR 30.9. The violation was a result of a false entry made by the former Chief Nuclear Medicine Technologist. This false entry was a result of a former employee not following departmental procedures. This action was identified by the Licensee and corrective action was taken.

2. Corrective Steps That Have Been Taken and the Results Achieved

   Reply: The employee who made the false entry was removed from performing NRC licensed activities and was subsequently terminated from employment by the hospital. The Radiology Safety Officer has continued to perform audits of the records and has not found any further questionable entries. The individual responsible for the falsification is no longer employed by the hospital which has corrected the problem.

3. Corrective Steps That Will be Taken to Avoid Further Violations

   Reply: The employees in the department were interviewed and the importance and seriousness of the NRC regulations and requirements were reviewed with them. A meeting was held with all of the staff subsequent to the violation regarding the need to comply with all NRC requirements and that falsification of records will not be tolerated. The new Chief Nuclear Medicine Technologist reviews the NRC regulations with all new hires and stresses that compliance is required. The seriousness of any falsification of records is also reviewed with employees on their date of hire. They are informed that any falsification of documents could result in termination. This same material is reviewed with

"REPLY TO A NOTICE OF VIOLATION"

Docket No. 030-01250
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3. Corrective Steps that will be Taken to Avoid Further Violations - Contd.

all staff members on an annual basis to ensure that they are aware of the need to comply with all NRC regulations. In addition, the RSO will continue to perform audits of the documents.

4. The Date When Full Compliance will be Achieved

Reply: The violation occurred on November 29, 1995 and corrective action was immediately taken to correct the situation. Full compliance has already been achieved.

Submitted by:

Laurence A. Tanner
President and CEO
New Britain General Hospital

cc: Mr. Hubert J. Miller
Regional Administrator
United States Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

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

December 20, 1996

EA 96-396

Mr. Lawrence A. Tanner, President
New Britain General Hospital
100 Grand Street
New Britain, Connecticut 06050

SUBJECT: NOTICE OF VIOLATION
(NRC Office of Investigations Report No. 1-96-013)

Dear Mr. Tanner:

This refers to the investigation conducted by the NRC Office of Investigations (OI) on April 12, 1996, at the New Britain General Hospital in New Britain, Connecticut. The OI Synopsis was sent to you with our letter, dated November 5, 1996. On November 18, 1996, a Predecisional Enforcement Conference was conducted with you to discuss the apparent violation, its cause, and your corrective actions to prevent recurrence. A copy of the Predecisional Enforcement Conference Report will be sent to you by separate correspondence.

Based on the information developed during the investigation, and the information provided during the conference, the NRC has determined that a violation of NRC requirements occurred. This violation is cited in the enclosed Notice of Violation (Notice). The violation involves your failure to comply with 10 CFR 30.9 in that your former Chief Nuclear Medicine Technologist (CNMT) made false entries into the New Britain General Hospital dose calibrator constancy record.

The dose calibrator constancy record was inaccurate in that the indicated readings recorded by the CNMT for the barium and cesium settings for November 29, 1995, were approximately 5% lower than they should have been. These recorded readings on that day were essentially the same as those recorded on the day prior to that date; however, based on a dose calibrator accuracy test performed by the Radiation Safety Officer (RSO) on November 28, 1995, the settings had been increased by 5% on that date. Therefore, the test results recorded by the former CNMT on November 29, 1995, should have been approximately 5% higher than the test results on the day before. Based on the OI investigation, the NRC concluded that the constancy test was not conducted on November 29, 1995, and the record was falsified. This discrepancy was identified by the RSO on November 30, 1995, and brought to the attention of hospital management and subsequently the NRC.

Falsifying records required to be maintained by the Commission's requirements is of significant regulatory concern because the conduct of licensed activities in accordance with the Commission's requirements depends in large part on the integrity of individuals conducting licensed activities. Since this violation was caused by a first line supervisor, the violation is classified 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 $2,500 is considered for a Severity Level III violation or problem. The NRC considered whether credit was warranted for identification and corrective action in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Credit for identification is warranted because you identified the violation. Your corrective actions, which were described at the enforcement conference, included: (1) initially removing the CNMT from some NRC-licensed activities and requiring supervision for some NRC-licensed activities; (2) subsequently terminating the employment of the CNMT; and (3) conducting one-on-one meetings with members of the Nuclear Medicine Department, during March 1996, in order to obtain an understanding of their view of this falsification event. Thus, credit for your corrective action is warranted.

Therefore, to encourage identification and prompt and comprehensive correction of violations, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. Please note that a Notice of Violation is also being issued on this date to the Former CNMT (copy enclosed).

At the conference, the RSO indicated that he has not been able to locate copies of documents which have been incorporated into, and are therefore part of, your NRC license. Additionally, the RSO stated that his reviews of the licensed program were based on his general understanding of NRC requirements and guidance, not the site-specific NRC license for your facility. This is of concern to the NRC as it raises questions regarding the adequacy of these reviews. Copies of these documents were sent to you and your RSO by separate correspondence. Upon receipt of this material, you should immediately review the documents to ensure that your program is conducted in accordance with the license conditions and Commission's regulations. These documents contain required procedures which are to be followed by the hospital and are required to be maintained by the hospital in accordance with 10 CFR Part 35.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. As noted above, the NRC recognizes your efforts in taking corrective action with respect to the CNMT and informing the NRC. Nonetheless, you should further emphasize to all Nuclear Medicine Department staff at your facility the importance of complying with all applicable Commission regulations and required procedures and that deliberately violating the Commission's regulations and required procedures will not be tolerated. Therefore, in your response, please describe the actions you have taken or plan to take to emphasize to your staff the importance of maintaining complete and accurate records and the unacceptability of deliberate misconduct. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and any response will be placed in the NRC Public Document Room.

Sincerely,

Hubert J. Miller
Regional Administrator

Docket No. 030-01250
License No. 06-02388-01

Enclosure: Notice of Violation

cc w/encl:
State of Connecticut

ENCLOSURE

NOTICE OF VIOLATION

New Britain General Hospital
New Britain, Connecticut

Docket No. 030-01250
License No. 06-02388-01
EA 96-396

During an NRC investigation by the NRC Office of Investigations (OI), for which the synopsis of the report was sent to the licensee on November 5, 1996, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violation is listed below:

10 CFR 30.9(a) states, in part, that information required by the Commission's regulations to be maintained by the licensee shall be complete and accurate in all material respects.

10 CFR 35.50 requires, in part, that each licensee shall check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use and that the licensee retain a record of each check required by 10 CFR 35.50 for three years unless directed otherwise.

Contrary to the above, on November 29, 1995, information required by the Commission's regulations to be maintained by the licensee, was not complete and accurate in all material respects. Specifically, the then Chief Nuclear Medicine Technologist, a first line supervisor, made inaccurate entries into the licensee's dose calibrator constancy record on that date. The readings reported for the barium and cesium settings on November 29, 1996, by the then CNMT were approximately 5% lower than they should have been. This conclusion is based on the results obtained on November 28, 1995, by the Radiation Safety Officer (RSO) when he performed an accuracy test of the dose calibrator and the fact that the RSO adjusted the dose calibrator settings on November 28, 1995, to increase the readings for the barium and cesium settings by 5%. This record was material since it was required to be maintained by NRC regulations. (01013)

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

Pursuant to the provisions of 10 CFR 2.201, New Britain General Hospital (Licensee) 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 alleged 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. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an Order or a Demand for Information may be issued as to why the license should not be