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December 28, 1993

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

Re: Boston City Hospital
Docket No. 030-01807
License No. 20-00275-08
EA No. 93-256

Dear Sir/Madam:

Enclosed are the licensee, Boston City Hospital's, Reply to a Notice of Violation and Answer to a Notice of Violation in the above case.

If there is any additional information which would be helpful in your determination, please do not hesitate to call me.

Yours truly,

Lynn M. Worley
Special Assistant Corporation Counsel

LMW/jr
cc: Thomas T. Martin, Regional Administrator
(Region 1, 475 Allendale Road,
King of Prussia, PA 19406-1415)

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Boston City Hospital
Docket No. 030-01807
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REPLY TO NOTICE OF VIOLATIONS

This serves as a Reply to the Notice of Violation issued by the United States Nuclear Regulatory Commission (NRC) to Boston City Hospital (BCH) on December 2, 1993. This reply is being submitted jointly with an Answer to the Notice of Violation attached hereto addressing certain sections of the Notice of Violation.

I. Violation of a Security Requirement

1. Licensee admits that the door to the hot lab was open and not within constant surveillance on October 6, 1993.

2. Licensee was involved in construction of a new hot lab at the time of the inspection. The licensee was actually attempting to correct a problem, identified by licensee relating to certain defects in the physical plant of the hot lab. Specifically, licensee was in the process of responding to the fact that deterioration in the hot lab floor made it difficult to close the door. A temporary partition related to this construction blocked the normal view of the hot lab door.

3. On October 28, 1993, the hot lab was relocated. This is a secure room with a self closing door and a self locking combination lock. There are no defects in the physical plant of the hot lab which would prevent the door from closing securely after personnel exit.

4. See #3--Additionally, the necessity of not propping the hot lab door open has been stressed.

5. This was completed October 28, 1993.

II. Quality Management Program Requirements

A. 10 CFR 35.25(a)(1)

1. Licensee admits that supervised individuals had not been adequately trained in the written quality management program (QMP).

2. While licensee had conducted inservice training in the QMP, these had not been interactive requiring personnel to state their understanding.

3. On November 1, 1993, the Radiation Safety Officer conducted a special, interactive training session. Copies of the QMP were provided to each person in the Nuclear Medicine Department. Personnel were questioned as to their understanding of the QMP.

4. These training sessions will be ongoing with at least an annual inservice on the QMP.

5. As of November 1, 1993 personnel of the Nuclear Medicine Department demonstrated an understanding of licensee's QMP, including those sections relating to the requirement that authorized users review written directives and sign them prior to administration of by-product.

B. 10 CFR 35.32(a)(1)(iv) and (4)

1. Licensee admits that on four occasions between April 9 and September 3, 1993 the written directive was not signed by the authorized user prior to administration of by-product.

2. All by-product administration was at the direct order of an authorized user, prior to administration. However, the authorized user believed that dictating this information to a computer program which only he could access met this requirement.

3. All Nuclear Medicine Department personnel, including authorized users, participated in an interactive inservice on the QMP, including written directives on November 1, 1993. Additionally, the written directive form has been changed to clearly require the authorized user's signature.

4. Compliance with this regulation is being monitored by the Radiation Safety Officer. Additional inservice training, at least annually, is planned relating to the QMP.

5. Full compliance has continued from November 1, 1993.

C. 10 CFR 35.32(b)

1. Licensee admits that as of October 6, 1993, it had not developed procedures for monitoring compliance with its QMP.

2. While procedures for monitoring compliance with licensee's QMP had been discussed at Radiation Safety Committee meetings, these discussions had not been committed to writing. A review of the entire Nuclear Medicine Department was conducted July, 1993. This data had not been evaluated by October, 1993.

3. A Quality Management Program Audit form has been developed. At least two patients' care has been audited for compliance with the QMP. This audit is ongoing and results will be evaluated by the Radiation Safety Committee at least annually.

Additionally, all reviews of the Nuclear Medicine Program will be evaluated in a timely manner--no more than 30 days--after the receipt of the review for compliance with the QMP.

4. See #3.

5. Full compliance was achieved by November 1, 1993.

III. Other Violations

A. 10 CFR 19.12

1. Licensee admits that two nuclear medicine technologists told the investigator that they had not been instructed in the procedure to check the survey meter.

2. It is uncertain why the technologists stated that they had not been trained. They have mandatory annual retraining which includes information on checking survey meters.

3. On November 1, 1993 the Radiation Safety Officer conducted a special training session for all members of the Nuclear Medicine Department to make certain that each employee could demonstrate familiarity with all aspects of survey meter calibration, particularly the ability to check the survey meter for proper operation with a check source.

4. All future annual retraining will include demonstrating affirmatively that personnel are familiar with all aspects of their job functions. Arrangements have been made to have Radiation Safety Officers from other hospitals conduct mock "inspections" to gage licensee's continuing compliance with this and other regulations.

5. Licensee complied with this requirement on November 1, 1993. Retraining will continue annually.

B. 10 CFR 35.14

1. Licensee admits that on two occasions it failed to notify the NRC within thirty days after an authorized user permanently ceased performing under the license.

2. This was an oversight on the licensee's part.

3. The Radiation Safety Officer will check regularly with the Radiation Safety Committee for authorized users who have permanently left licensee's facility.

4. See #3.

5. Licensee began compliance as of October 28, 1993 and continues to comply.

C. 10 CFR 35.50(b)(3)

1. Licensee admits that the dose calibrator was not tested to 10 microcuries.

2. This was an oversight on licensee's part.

3. The dose calibrator was tested for linearity over the range of its use between 110 mCi and 9.31 uCi on November 4, 1993.

4. The dose calibrator will be tested down to 10uCi quarterly.

5. Licensee complied by November 4, 1993.

Subscribed and sworn to this 30th day of December 1993.

Haro Der Hagopian RSO.

Haro Der Hagopian

BOSTON CITY HOSPITAL
Docket No. 030-01807
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ANSWER TO A NOTICE OF VIOLATION

This answer is filed pursuant to 10 CFR 2.205. Specifically, this answer addresses extenuating circumstances involved and reasons why a penalty should not be imposed. Licensee vigorously contests the conclusion that results of the October 6, 1993 inspection constitute a decline in performance.

1. Violation of a Security Requirement

Rather than indicating a decline in performance, the brief lack of constant surveillance of the hot lab represents a unique and temporary situation. As pointed out in licensee's reply, licensee had identified a problem with the physical plant of the hot lab, i.e., that the deterioration of the floor made opening and closing the door very difficult. Licensee identified this as a potential security problem and took steps to correct the problem. The correction of this potential problem was to build a completely new hot lab with new floors and a self-closing and combination locked door.

The root cause of the violation of 10 CFR 20.207(a) was a direct result of licensees attempts to maintain the security of the hot lab. Construction within the confined nuclear medicine area caused significantly more disruption and confusion than anticipated. This was a solitary situation. Even though construction was proceeding, the hot lab door was within the line of sight of licensee's personnel until a temporary partition was erected during the final stage of construction.

Among the steps that licensee took to maintain security during construction was to inform construction supervisors to keep their personnel away from the hot lab. Licensee also located a secretary near the door to the hot lab. Unfortunately the secretary had stepped away from her desk without informing anyone when the inspector arrived.

Licensee had identified a potential problem relating to the security of the hot lab prior to the October 6, 1993 inspection and took immediate corrective action in attempts to eliminate this potential problem. Licensee also took actions to maintain the security of the hot lab during construction. Since licensee

had not previously dealt with construction in the immediate area of the hot lab, these precautions were thought to be adequate. Unfortunately, that was not the case. However, this being a new and unique experience it was difficult to anticipate every possible problem.

The issue here is not licensee's deteriorating compliance. Rather, it's that a mistake was made during a unique and time-limited situation. The door being open without the direct line of sight of licensee's personnel is certainly a violation, should not have occurred and would not have occurred but for construction. However, this violation should be viewed in the larger context of licensee identifying a potential permanent problem and taking lasting and comprehensive action to prevent a breach of hot lab security. This anticipatory correction of potential problems is more consistent with licensee's prior good performance. The door being open is an isolated failure that is inconsistent with licensee's prior performance.

2. Violations relating to Quality Management Program (QMP)

The QMP is an entirely new regulatory scheme. Licensee is making efforts to fully implement the QMP. Learning an entirely new scheme is rarely accomplished immediately. Licensee has conducted training on the QMP with its employees and attempted to implement forms that make compliance with the QMP automatic. That personnel failed in one specific area to completely follow the QMP does not indicate a "failure to implement the QMP."

Licensee had held mandatory training on the QMP. However, the QMP program is new and evolving. There are difficulties, not exclusively at licensee's facility, in introducing any completely new program. In dealing with this new program, licensee had made efforts to assure compliance. The inspection of October 6, 1993 did draw licensee's attention to the fact that mandatory training sessions do not mandate learning. Consequently, licensee is developing more inter-active training with testing.

3. Dose Calibrator 10 CFR 35.50(b)(3)

While the regulation mandates calibration of the dose calibrator down to 10uCi, licensee was informed by various personnel of the NRC that this level is being evaluated for change. This is undoubtedly because, as licensee is sure that the NRC recognizes, testing of technetium-99 on the dose calibrator down to 10uCi leads to a greater margin of error rather than a reduction. While licensee has tested the dose calibrator to the required limit, its failure to do so was based on a desire to reduce the margin of error related to the administration of by-product. This goal is clearly in keeping with the purpose of the NRC regulations.

Consequently for all of the forgoing reasons, licensee requests that remission or further mitigation of the penalty is consistent with 10 CFR Part 2, Appendix C.

Respectfully submitted,
BOSTON CITY HOSPITAL
By its attorney
Albert W. Wallis

Dated DECEMBER 30, 1993

Lynn Worley

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