UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 030-01807
BOSTON CITY HOSPITAL	)	License No. 20-00275-08
Boston, Massachusetts	)	EA 93-256

ORDER IMPOSING CIVIL MONETARY PENALTY

I

Boston City Hospital (Licensee), Boston, Massachusetts, is the holder of Byproduct/Source Material License No. 20-00275-08 (License), issued by the U. S. Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 35. The License authorizes the Licensee to use byproduct material for medical diagnosis and therapy; in prepackaged kits for in-vitro studies; as specifically identified radionuclides for research and development and animal studies; as a strontium-90 sealed source for instrument calibration; and as a strontium-90 sealed source for the treatment of superficial eye conditions. The license most recently was renewed on September 17, 1992, and is due to expire on August 31, 1997.

II

An NRC inspection of the Licensee's activities was conducted on October 6, 1993. During the inspection, seven violations of NRC requirements were identified, one of which involved the failure to maintain control of access to licensed material. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated

December 2, 1993. The Notice states the nature of the violations, the provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violations. The Licensee responded to the Notice on December 28, 1993. In its response, the Licensee admitted all of the violations, but requested remission or mitigation of the proposed civil penalty.

III

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation or remission contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the violations occurred as stated and that the penalty proposed for the violation designated in Section I of the Notice should be mitigated by 50 percent for the Licensee's good prior performance consistent with the NRC Enforcement Policy.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The Licensee pay a civil penalty in the amount of $1,250 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission Washington, D.C. 20555, with a copy to the Commission's Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for

collection.

In the event the Licensee requests a hearing as provided above, the issue to be considered at such hearing shall be whether, on the basis of the violation set forth in Section I of the Notice that the Licensee admitted, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

Dated at Rockville, Maryland
this 24th day of March 1994

APPENDIX

EVALUATIONS AND CONCLUSION

On December 2, 1993, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations identified during an NRC inspection conducted on October 6, 1993. A proposed civil penalty was issued for the violation in Section I of the Notice. Boston City Hospital (Licensee) responded to the Notice by a letter dated December 28, 1993. In its response, the Licensee admits all of the violations, but requests remission or mitigation of the proposed civil penalty. The NRC's evaluation and conclusion regarding the Licensee's requests are as follows:

Restatement of Violations

I. Violation of the Security Requirement

10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be tended under the constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on October 6, 1993, licensed material consisting of at least 200 millicuries of technetium-99m and 40 microcuries of iodine-131 located in the hot lab of the nuclear medicine department, an unrestricted area, was not secured against unauthorized removal, and was not under the constant surveillance and immediate control of the licensee.

This is a Severity Level III violation (Supplements IV and VI). Civil Penalty - $2,500

II. Violations of the Quality Management Program Requirements

A. 10 CFR 35.25(a)(1) requires, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall instruct the supervised individual in the licensee's written quality management program.

Contrary to the above, the licensee established a written quality management program, and as of October 6, 1993, had not instructed the supervised individuals in the licensee's written quality management program. Specifically, the nuclear medicine technologists, who also administer I-131 dosages, were not trained in the

licensee's written quality management program requirement regarding the authorized users' review of the written directive and the signature requirement.

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

B. 10 CFR 35.32(a)(1)(iv) and (4) requires, in part, that: the licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user; and the quality management program must include written policies and procedures to meet the objectives that, prior to administration, a written directive is prepared for any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, and that each administration is in accordance with the written directive.

10 CFR 35.2 defines a written directive as an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of quantities greater than 30 microcuries of sodium iodide I-125 or I-131, and containing the dosage.

Contrary to the above, the licensee's written policies and procedures for the quality management program did not ensure the objective that a written directive be prepared prior to administering greater than 30 microcuries of sodium iodide I-131, and that each administration is in accordance with the written directive. On multiple occasions, prior to administration of a radiopharmaceutical containing I-131, the licensee did not prepare a written directive containing the required information. Specifically, on at least four different occasions between April 9, 1993, and September 3, 1993, the licensee administered dosages of iodine-131 in quantities greater than 30 microcuries to patients, without the written directives for these administrations, in that the instructions specifying the dosage to be administered on these occasions were not signed by an authorized user.

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, and evaluate each of these reviews to determine the effectiveness of the quality management program and, if

required, make modifications to meet the objectives of 10 CFR 35.32(a).

Contrary to the above, as of October 6, 1993, the licensee had not developed procedures for conducting a review to verify compliance with all aspects of the licensee's quality management program. Specifically, the RSO stated that there were no written policies or procedures to conduct the required review; that a review of the nuclear medicine program was conducted in July 1993; and the July 1993 review has not yet been evaluated to determine the effectiveness of the quality management program or the needed changes.

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

III. Other Violations of NRC Requirements

A. 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 to the extent within the worker's control, in the applicable provisions of the Commission's regulations and licenses.

Contrary to the above, as of October 6, 1993, individuals who were working in the nuclear medicine department, a restricted area, had not been instructed in the applicable provisions of the regulations and the conditions of the license. Specifically, at least two nuclear medicine technologists stated that they were not instructed in the procedure to check the survey meter for proper operation, a matter within their control.

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

B. 10 CFR 35.14 requires, in part, that a licensee notify the NRC by letter within 30 days when an authorized user permanently discontinues performance of duties under the license.

Contrary to the above, in July 1993, at least two authorized users permanently discontinued performance of duties under the license, and the licensee did not notify the NRC as of October 6, 1993, a period in excess of 30 days.

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

C. 10 CFR 35.50(b)(3) requires, in part, that a licensee test each dose calibrator at least quarterly for linearity over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries.

Contrary to the above, the licensee's dose calibrator linearity tests performed on February 9, 1993, and April 21, 1993, did not include activities below 18 microcuries. Similarly, the linearity test performed on July 27, 1993, did not include activities below 17.8 microcuries, and there are no other linearity tests during the quarters when the identified tests were performed.

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

Summary of Licensee's Request for Mitigation

In its December 28, 1993 written response to the Notice, the Licensee admits the violations but requests remission or mitigation of the civil penalty. In support of its request, the Licensee vigorously contests the NRC's conclusion that the results of the October 6, 1993 inspection constitute a decline in performance. Rather than indicating a decline in performance, the Licensee maintains that the brief lack of constant surveillance of the hot lab represents a unique and temporary situation. The Licensee adds that it had identified a potential security problem with the existing hot lab (i.e., deterioration of the floor made opening and closing the door very difficult) and that it took steps to correct the problem, including the building of a completely new hot lab with new floors and a self-closing, combination locked, door.

The Licensee indicates that it took actions to maintain security of the existing hot lab during the construction of the new lab, such as instructing the construction supervisors to keep their personnel away from the hot lab and locating a secretary near the door to the hot lab. However, the Licensee acknowledges that the secretary had stepped away from her desk without informing anyone prior to the NRC inspector's arrival.

The Licensee further contends that the lack of security of the hot lab is not indicative of the Licensee's deteriorating compliance; rather, this security violation was the result of a mistake made during a unique and time-limited situation. The Licensee acknowledges that having the door open without the direct line of sight of the Licensee's personnel is certainly a violation that should not have occurred, and would not have occurred but for construction. However, the Licensee maintains that this violation should be viewed in the larger context of the

Licensee identifying a potential permanent problem and taking lasting and comprehensive action to prevent a breach of hot lab security. The Licensee states that this anticipatory correction of potential problems is more consistent with its prior good performance, and the door being open is an isolated failure that is inconsistent with the Licensee's prior performance.

Additionally, in supporting its request for mitigation, the Licensee addressed circumstances for the violations relating to its Quality Management Program (QMP) and its dose calibrator. The Licensee states that learning an entirely new regulatory scheme such as the QMP is rarely accomplished immediately, and that Licensee personnel's failure in one specific area to completely follow the QMP does not indicate a failure to implement the QMP. With regard to the dose calibrator, the Licensee states that while 10 CFR 35.50(b)(3) mandates calibration of dose calibrators down to 10 microcuries, the Licensee was informed by various personnel of the NRC that this level is being evaluated for change because measurement of technetium-99m in the dose calibrator at this quantity leads to a greater margin of error. The Licensee maintains that its failure to test the dose calibrator down to this level was based on its desire to reduce the margin of error.

NRC Evaluation of Licensee's Request for Mitigation

The NRC determined that the failure to secure licensed material against unauthorized removal was a significant violation which was classified at Severity Level III in accordance with Supplement VI.C.1 of the Enforcement Policy (10 CFR Part 2, Appendix C). In determining the amount of the civil penalty, the NRC considered the escalation and mitigation factors set forth in the NRC Enforcement Policy.

The NRC recognizes that the Licensee had identified, even prior to the NRC inspection, a potential problem concerning the security of the hot lab and initiated long term action to correct it. Although the Licensee did not assure that appropriate security was maintained during the interim period, the NRC agrees that the Licensee's initiative in making the long-term changes to the hot lab is indicative of extensive corrective actions. However, the failure to secure licensed material against unauthorized removal from the hot lab is a significant regulatory concern.

With regard to the Licensee's understanding and implementation of its QMP and circumstances related to its dose calibrator, the NRC views the Licensee's failure to prepare a written directive, as defined in 10 CFR 35.2, prior to administering greater than 30 microcuries of sodium iodide, as a failure to implement the QMP in accordance with 10 CFR 35.32(a)(1)(iv) and (4). Concerning

the dose calibrator, the staff expects licensees to fully comply with NRC regulations. Licensees are not excused from compliance with NRC requirements because revisions to those requirements may be under consideration.

With respect to the Licensee's prior performance, Section VI.B(c) of the Enforcement Policy states, in part, that "the base civil penalty may be mitigated by as much as 100% if the current violation is an isolated failure that is inconsistent with the licensee's outstandingly good prior performance. The base civil penalty may also be escalated by as much as 100% if the current violation is reflective of the licensee's poor or declining prior performance."

The NRC acknowledges that the Licensee had generally good performance during the last two NRC inspections. However, the staff notes that in addition to the four violations identified during the last two NRC inspections conducted in 1992 and 1989, six violations occurred over a period of nine months since the 1992 NRC inspection. These violations, in addition to the security violation, are not reflective of outstandingly good performance. Therefore, on balance, after reconsidering the matter, the staff has concluded that while full mitigation (i.e., 100 percent) is not appropriate, 50 percent mitigation of the base civil penalty based on the Licensee prior performance is warranted.

NRC Conclusion

The NRC concludes that the violations occurred as stated, and that the Licensee has not provided an adequate basis for full remission of the proposed civil penalty; however, mitigation of 50 percent is warranted based on the Licensee's prior performance. Accordingly, the NRC has determined that a civil penalty in the amount of $1,250 should be imposed.

Boston City Hospital

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