UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	
	)	
Baystate Medical Center, Inc.	)	Docket No. 030-09946
Springfield, Massachusetts 01107	)	License No. 20-01412-05
	)	EA 92-114
	)	

ORDER IMPOSING CIVIL MONETARY PENALTY

I

Baystate Medical Center, Inc. (Licensee) is the holder of Byproduct Material License No. 20-01412-05 (license) issued by the Nuclear Regulatory Commission (NRC or Commission). The license authorize the Licensee to use byproduct materials for diagnostic and therapeutic procedures involving radiopharmaceuticals and brachytherapy devices in accordance with the conditions specified therein.

II

An inspection of the Licensee's activities was conducted during May 27-28, 1992. The results of the inspection indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated August 21, 1992. The Notice stated the nature of the violations, the provision 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 in two letters, dated September 10 and 14, 1992, respectively. In its response, the Licensee stated that one of the two violations (Violation A) is incorrect. In addition, the Licensee requested mitigation of the civil penalty.

III

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that: (1) the violations did occur as stated in the Notice, and (2) the penalty proposed for the violations designated in the Notice should be imposed.

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 $2,000 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, ATTN: 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 final and 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 issues to be considered at such hearing shall be:

(a) whether Violation A occurred as set forth in the Notice referenced in Section II above, and,

(b) whether, on the basis of such violation, and Violation B as set forth in the Notice and admitted by the Licensee, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

James Lieberman, Director
Office of Enforcement

Dated at Rockville, Maryland
this 6th day of January 1993

APPENDIX

EVALUATIONS AND CONCLUSION

On August 21, 1992, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for two violations identified during an NRC inspection on May 27-28, 1992, at Baystate Medical Center, Inc. (licensee). The licensee responded to the Notice on September 10, 1992. The licensee indicated that one of the two violations (Violation A), as stated, was incorrect. The licensee also requested mitigation of the civil penalty. The NRC's evaluations and conclusions regarding the licensee's requests are as follows:

1. Restatement of Violation A

   10 CFR 35.32 requires, in part, that the licensee establish and maintain a quality management program which must include written policies and procedures to meet the objective that a written directive be prepared for any administration of quantities greater than 30 microcuries of iodine-131. 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 administration of a radiopharmaceutical and containing certain information including, for iodine-131, the dosage.

   Contrary to the above, as of May 18, 1992, the licensee's quality management program did not include a written procedure to meet the objective that a written directive signed by an authorized user be prepared for administration of quantities greater than 30 microcuries of iodine-131; and, on May 18, 1992, a licensee technologist administered 4.1 millicuries of iodine-131 to a patient without a written directive being reviewed or signed by an authorized user prior to the administration.

2. Summary of Licensee Response to Violation A

   In its responses, the licensee states that Violation A is incorrect. The licensee contends that its QM program as submitted does contain the requirement that a written directive be signed by an authorized user for administration of iodine-131 for activities of 30 microcuries to 250 millicuries. The licensee provided a copy of the QM program procedure with its response. In addition, the licensee contends that the only clear violation that occurred is that the technologist did not obtain the authorized user's signature before administration of 4.1 millicuries of iodine-131.

3. NRC Evaluation of Licensee Response

The licensee's QM program, Paragraph C1.1, does require a "written directive;" however, Paragraph C1.1 allows this "directive" to be signed by the authorized user *or designated Nuclear Medicine Technologist* prior to the administration of the dosage. As stated in Violation A, 10 CFR 35.2 defines a written directive as an order *signed by an authorized user*. The so-called "written directive" in the licensee's QM Program does not meet the requirement because the directive does not have to be signed by an authorized user and may instead be signed by a nuclear medicine technologist. This distinction is significant because the requirement is intended to ensure that the authorized user becomes involved *before* the radiopharmaceutical is administered to the patient. Therefore, the violation did occur as stated in the Notice.

4. Summary of Licensee Response Requesting Mitigation of the Civil Penalty

The licensee requests mitigation of the penalty on the basis that (1) the new QM rule went into effect as of January 27, 1992, and the licensee has made every effort to implement an effective program to maintain full NRC compliance; (2) the licensee's original procedures (Management Audit and In-Service Program) have been a part of the NRC's Regulatory Guide NUREG 0267 on ALARA; (3) the licensee has voluntarily participated and actively contributed to the development of the NRC new regulations (NRC QM rule); (4) the licensee has an excellent record of 24 years of full compliance with NRC regulation; (5) when violations occur, the licensee has self-identified them, reported, and corrected them immediately; (6) the issue of an overexposure as described by the NRC is overstated and is done without any consideration of the clinical outcome to the patient; and (7) when the entire incident is put in proper perspective, the classification as an aggregate violation related to safety is improper.

5. NRC Evaluation of Licensee Response

As previously stated in the Notice of Violation and Proposed Imposition of Civil Penalty, the application of the civil penalty adjustment factors in the NRC Enforcement Policy would normally warrant complete mitigation of the civil penalty because of the licensee's identification of the misadministration and related violations, the prompt and comprehensive corrective actions once the violations were identified, and the licensee's prior good enforcement

history. The NRC further acknowledges the licensee's efforts to implement the QM program, its excellent record, and its identification and correction of problems.

In this case, however, the violations resulted in a misadministration and involved a radiation exposure to the thyroid gland that was more than 50% greater than the intended radiation exposure for the thyroid uptake procedure that was being conducted at the time. Therefore, in accordance with the NRC Enforcement Policy, Supplement VI.B.3, these violations constitute a Severity Level II problem. Consistent with the guidance set forth in Section VI.B.2 of the Enforcement Policy, notwithstanding the normal application of the civil penalty adjustment factors, a civil penalty of at least 50% of the base amount is warranted for Severity Level I and II violations involving overexposures.

The licensee argues that the issue of an overexposure should be considered in the context of the clinical outcome to the patient. In this case, the radiopharmaceutical dosage (and, concomitantly, the radiation dose) administered to the patient for the thyroid uptake procedure was approximately 250 times the intended dosage for that procedure. A thyroid uptake procedure is done to determine the disease status of the thyroid gland and to determine, among other things, if a much larger, therapeutic dosage of the radiopharmaceutical should be administered and if so, how much. The fact that the patient was subsequently shown to need the much larger, therapeutic dosage did not enter into NRC's deliberations on the civil penalty, nor should it, as that circumstance was purely fortuitous.

6. NRC Conclusion

The NRC staff concludes that the violations did occur as stated and that the licensee has not provided an adequate basis for further mitigation or reduction of the civil penalty. Accordingly, the proposed civil monetary penalty in the amount of $2,000 should be imposed.

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