

Commission on November 7, 1960. The License was most recently renewed by the Nuclear Regulatory Commission (NRC or Commission) on April 24, 1990, and is currently under timely renewal. The License authorizes the Licensee to possess and use certain byproduct materials in accordance with the conditions specified therein at the Licensee's facility in Brookline, Massachusetts.

II

An inspection of the Licensee's activities was conducted on February 8, and March 1, 1995, at the Licensee's facility located in Brookline, Massachusetts. The results of this 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 April 20, 1995. 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 one of the violations.

The Licensee responded to the Notice in two letters, both dated April 28, 1995. In its responses, the Licensee denies the violation assessed a civil penalty (Violation I), and requests that the penalty be withdrawn.

III

After consideration of the Licensee's response and the statements of fact, explanation, and argument contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, the Violation I occurred as stated in the Notice. The staff also has determined that an adequate basis was not provided for mitigation of the penalty and that a penalty of \$750 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 \$750 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 James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852-2738.

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, PA 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 issues to be considered at such hearing shall be:

(a) Whether the Licensee was in violation of the Commission's requirements as set forth in Section I of the Notice referenced in Section II above, and

(b) Whether on the basis of such violation, this Order should be sustained.

Dated at Rockville, Maryland this 16th day of June 1995.

For the Nuclear Regulatory Commission.

James Lieberman,

Director, Office of Enforcement.

Appendix

Evaluations and Conclusion

On April 20, 1995, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations identified during a NRC inspection conducted at the Licensee's facility located in Brookline, Massachusetts. The penalty was issued for one violation. The Licensee responded to the Notice in two letters, both dated April 28, 1995. In its responses, the Licensee denies the violation assessed a penalty (Violation I), and requests that the civil penalty be withdrawn. The NRC's evaluation and conclusion regarding the Licensee's requests are as follows:

Restatement of Violation I

10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, unrestricted area means an

area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, as of February 8, 1995, the licensee did not secure from unauthorized removal or limit access to licensed materials stored in an unrestricted area. Specifically, on numerous occasions, the licensee did not secure diagnostic capsules (each containing between 14 and 129 microcuries of iodine-131(I-131)) located in patients' homes, an unrestricted area, nor did the licensee control and maintain constant surveillance of this licensed material.

Summary of Licensee's Response to Violation I

In its responses, the Licensee denies the violation and requests that the civil penalty be withdrawn.

The Licensee states that the NMSS Licensee Newsletter 95-1 issued in March/April 1995, and the **Federal Register** dated January 25, 1995, both state that the medical administration of any radiation or radioactive material to any individual, including an individual who is not supposed to receive a medical administration, is regulated by the Commission's provisions governing the medical use of byproduct material (10 CFR Part 35) rather than the dose limits in NRC's regulation concerning standards for protection against radiation (10 CFR Part 20). The Licensee states that Part 35 takes precedence over Part 20 because the Licensee's use of I-131 in this instance is a medical use. The Licensee states that the regulation for unrestricted areas does not apply, and asserts that this is stated in 10 CFR 20.1002. The Licensee states that it appears that there should not have been a citation, since the I-131 was used for medical use.

The Licensee also states that the dispensing of I-131 capsules for diagnostic use has never resulted in any harm, and there is no way that capsules containing between 14 and 129 microcuries could have caused unnecessary exposure to members of the public anymore than if the patient had ingested the same capsule prior to leaving the premises. The Licensee further states that there have never been any reports in medical literature of instances of I-131 causing any harm to anyone at this dosage. The Licensee states that it is purely speculative and misleading to state that this could cause any unnecessary exposure to members of the public.

The Licensee further states that a patient who ingests 25 millicuries of I-131 for therapeutic purposes is permitted to go home, be with family, and mingle with the public without restriction. In addition, the licensee states that it seems paradoxical and illogical that the possession of a 100 microcurie capsule, either in the patient's possession or ingested internally, would constitute any public health hazard.

NRC Evaluation of Licensee's Response to Violation I

Notwithstanding the Licensee's contention, the NRC maintains that a violation of 10 CFR Part 20 occurred, and that 10 CFR 20.1801 and 20.1802 required that the I-131 be