

exceptions of Examples A.3 and G of the violation, the violation occurred as stated in the Notice; the Examples A.3 and G of the violation will be withdrawn; and the penalty proposed for the violation designated in the Notice should be imposed.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 \$80,000 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 James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852-2738.

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 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 the violation in the Notice referenced in Section II above, and the following specific examples given with the violation: Examples A.1, A.2, A.4, B.1, B.2, C., and D.; and

(b) whether, on the basis of the violation set forth in the Notice of Violation, this Order should be sustained.

Dated at Rockville, Maryland this 24th day of April 1995.

For the Nuclear Regulatory Commission.

Hugh L. Thompson, Jr.,

Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support.

Appendix—Evaluations and Conclusion

On May 31, 1994, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for a violation identified during an NRC inspection of Radiation Oncology Center at Marlton (ROCM) (Licensee). The licensee responded to the Notice on August 31, 1994, October 4, 1994, and December 1, 1994. The Licensee denies Examples A.3, A.4, B.1, B.2, D., and G. of the violation, denies in part and admits in part Examples A.1, A.2, and C. of the violation, and admits Examples A.5, E., and F. of the violation. In addition, the Licensee protests the amount of the civil penalty proposed and requests mitigation of the civil penalty as appropriate. The NRC's evaluation and conclusion regarding the Licensee's requests are as follows:

Restatement of Violation

10 CFR 35.21(a) requires, in part, that the licensee, through the Radiation Safety Officer (RSO), shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program.

Contrary to the above, the Licensee, through the RSO, did not ensure that radiation safety activities were performed in accordance with approved procedures and regulatory requirements in the daily operation of the Licensee's byproduct material program. Specifically, the RSO named on the Radiation Oncology Center at Marlton (ROCM) license stated at the enforcement conference that, although she had signed the license submittal, she believed that her responsibilities and authorities were primarily a medical function and not a regulatory function. She said that she was aware that she was named as the RSO on the license and added, "I was told that being—I was the fixed fixture there, that was the easiest thing to do, and that is all I was told. I had no concept of what that entailed." The following are specific examples of the failure of the Licensee, through the RSO, to ensure that radiation safety activities were performed in accordance with approved procedures and regulatory requirements in the daily operation of the Licensee's byproduct material program:

A. Condition 14 of License No. 29-28685-01 requires that the Licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated July 11, 1991, letter received December 18, 1991, and letter dated January 15, 1992.

1. Item 8.B of the Licensee's application, dated July 11, 1991, requires that all source exchanges be carried out by Omnitron Factory Personnel under the observation of the RSO.

Contrary to this requirement, source exchanges carried out by Omnitron Factory Personnel were not always under the observation of the RSO. Specifically, the RSO stated that although she observed the first source exchange at the facility on March 5, 1992, she did not observe the three subsequent source exchanges on June 4, September 16, and December 9, 1992.

2. Item 10.12 of the Licensee's application, dated July 11, 1991, requires that surveys of radiation levels in all adjacent areas and controlled areas be performed at initial installation and then quarterly thereafter at source exchanges and that results of the surveys be maintained.

Contrary to this requirement, surveys of radiation levels in all adjacent areas and controlled areas were not performed during the source exchanges which occurred on March 5, June 4, and September 16, 1992. In addition, the Licensee was unable to supply the inspectors with documentation demonstrating that surveys were performed in any adjacent areas following the December 9, 1992 source change.

3. Item 10.15.A.4 of the Licensee's application, dated July 11, 1991, requires, in part, that a daily check of all interlocks, safety systems and alarms be performed and documented in log books, that daily operational system checks be recorded, and that source position indicators (visual and radiation detection) be checked before each use and recorded.

Contrary to this requirement, as of February 4, 1993, daily checks of all interlocks, safety systems and alarms were not performed and documented in log books. Specifically, Licensee personnel believed that the performance of these checks was the responsibility of the physics consultant even though the physics consultant was only present for approximately one half of the total patient treatments, and the ROCM staff did not perform these daily checks when the physics consultant was not present. In addition, the Licensee was unable to provide any documentation indicating that daily checks of all the inter-locks, safety systems and alarms; daily operational system checks; and daily checks of source position indicators (visual and radiation detection) were performed on the occasions when the physicist was present.

4. Item 8.E.5 of the Licensee's application, dated July 11, 1991, requires, in part, that each operator/user of the HDR individually demonstrate competence in the emergency procedures during "dry run" emergencies using several failure modes for each operator.

Contrary to this requirement, as of February 4, 1993, each operator/user of the HDR did not individually demonstrate competence in the emergency procedures during "dry run" emergencies using several failure modes for each operator.

5. Item 9.1.C.4 of the Licensee's application, dated July 11, 1991, requires, in part, that the radiation monitor (PrimAlert) have a battery backup.

Contrary to this requirement, as of February 4, 1993, the Licensee did not have a battery back-up to operate the radiation monitor (PrimAlert).

B. 10 CFR 19.12 requires, in part, that all individuals working in or frequenting any