UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	Docket No. 030-02643
Miami Valley Hospital	)	License No. 34-00341-06
Dayton, Ohio	)	EA 93-288

ORDER IMPOSING CIVIL MONETARY PENALTY

I

Miami Valley Hospital (licensee) is the holder of Byproduct Material License No. 34-00341-06 issued by the Nuclear Regulatory Commission (NRC or Commission) on June 24, 1958. The license authorizes the licensee to use and possess licensed material for the purposes described in 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.400, 10 CFR 35.500, 10 CFR 31.11, and in accordance with the license conditions specified therein.

II

An inspection of the licensee's activities was conducted from October 25 to October 27, 1993. 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 Propcsed Imposition of Civil Penalty (Notice) was served upon the licensee by letter dated March 1, 1994. The Notice stated 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 Violation I.A.

The licensee responded to the Notice by letter dated March 28, 1994. In its response, the licensee admitted the violations but requested that the civil penalty assessed for Violation I.A. be mitigated.

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 Violation I.A. occurred as stated and that the penalty proposed for Violation I.A. 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 $2,500 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 III, 801 Warrenville Road, Lisle, Illinois 60532-4351.

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 Violation I.A. designated in the Notice, 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 23rd day of May 1994

APPENDIX

EVALUATION AND CONCLUSION

On March 1, 1994, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations identified during an NRC inspection. Miami Valley Hospital (licensee) responded to the Notice on March 28, 1994. The licensee admitted the violations but requested that the civil monetary penalty proposed for Violation I.A. be mitigated. The NRC's evaluation and conclusion regarding the licensee's request follows:

Restatement of Violation I.A.

Condition 24. of License No. 34-00341-06 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application received on September 25, 1988.

Item 10.4 of the section of the referenced application entitled, "Safe Use of Radiopharmaceuticals," requires that the licensee follow Appendix I to Regulatory Guide 10.8, Revision 2. Item 2 of Appendix I requires individuals to wear gloves at all times while handling radioactive materials.

Contrary to the above, on September 10, 1993, an individual handled radioactive material, strontium-89, without wearing gloves.

Summary of Licensee's Request for Mitigation

The licensee admitted the violation and requested that the civil penalty be mitigated because, according to the licensee: (1) the apparent willful nature of the violation was not deliberate or capricious and the authorized user is not a deliberate violator of NRC regulations but rather acted out of conflicting needs dictated by concern for the safety of the technologist, the patient's condition, the authorized user's schedule, and the small risk of a spill; (2) the authorized user was completely candid; (3) the authorized user was fully cooperative; (4) the authorized user has an excellent record of performance with NRC license requirements and this is the first violation in which he has been involved; (5) the violation is the isolated action of the authorized user and did not result from lack of management oversight; and (6) substantial corrective action has already been taken and documented concerning this violation.

NRC Evaluation of Licensee's Request for Mitigation

On September 10, 1993, an authorized user physician administered 3.5 millicuries of strontium-89 to a bedridden patient at the patient's home. The physician was not wearing gloves during this palliative treatment, although he had been reminded by the Manager of Nuclear Medicine that he needed gloves for the procedure. As the physician attempted to expel air from the syringe, a small amount of strontium-89 was also expelled from the syringe, which contaminated the physician's right index finger, resulting in an overexposure. The overexposure would have been avoided had the physician worn gloves.

The NRC agrees that the nature of the violation was not deliberate (*i.e.*, the authorized user was not a deliberate violator of NRC regulations). If that had been the case, more stringent enforcement sanctions would have been considered, including enforcement action directly against the authorized user under the Deliberate Misconduct Rule (56 FR 40664). NRC did find that the violation was *willful*. 10 CFR Part 2, Appendix C, "Policy and Procedure for Enforcement Actions; Policy Statement" (Enforcement Policy) provides in Section IV.C. that the term "willfulness" embraces a spectrum of violations ranging from deliberate intent to violate or falsify *to and including careless disregard for requirements* (emphasis added). In reviewing the incident, the NRC concluded that, based on the reminder from the Manager of Nuclear Medicine and based on the licensee's contention that the physician was not ignorant of NRC license requirements, the physician either knew or should have known that he was required to use gloves during the procedure. While the physician may have believed that other factors, such as convenience or scheduling, outweighed the need to wear gloves, this does not excuse his disregard of the requirements once the issue of the gloves was specifically brought to his attention. If there was any confusion concerning the issue, the authorized user clearly should have sought a clarification, for example by contacting the RSO. Therefore, the matter of not wearing gloves constitutes a willful violation involving careless disregard as those terms are used in the Enforcement Policy. The licensee's argument that the violation is not deliberate provides no basis for mitigation of the civil penalty amount.

Regarding the licensee's characterization of the authorized user (*i.e.*, candid, cooperative, and excellent record of NRC performance), the character attributes of a person are not relevant to whether a civil penalty will be mitigated. Rather, the NRC Enforcement Policy identifies six specific factors to be considered for escalation or mitigation of a civil penalty. (See Section VI.B.2, Enforcement Policy). Furthermore, the NRC expects and requires that licensee personnel be candid and cooperative and comply with all NRC requirements.

The NRC recognizes that this was an isolated event; however, that does not change the fact that the violation occurred. The violation was willful and was appropriately categorized at Severity Level III. Had there been multiple examples of the violation, the base civil penalty would have been increased by as much as 100% based on the escalating factor in the Enforcement Policy for multiple occurrences.

Regarding the licensee's argument that the violation did not result from a lack of management oversight, the NRC acknowledges that management above the level of the authorized user was not involved in the violation. However, the NRC Enforcement Policy, Section IV.C, Footnote 7, defines a "licensee official" as including an authorized user of licensed material whether or not listed on a license. In this case, the authorized user, acting as a "licensee official", did not exercise

sufficient oversight over his own actions to ensure that NRC requirements were followed.

Finally, the licensee argues that the civil penalty should be mitigated because of the actions taken to correct the violation. The NRC recognized the licensee's corrective actions and considered whether to allow mitigation for those actions in determining the amount of the civil penalty. The staff fully mitigated the base civil penalty for corrective actions for the violations in Section II, however, the staff exercised discretion as permitted in Section VII of the Enforcement Policy and did not mitigate the base civil penalty for the willful violation in Section I.A. as stated in the NRC's letter of March 1, 1994. NRC did not mitigate the civil penalty for Violation I.A. to emphasize that willful violations cannot be tolerated by either the Commission or the licensee.

NRC Conclusion

The NRC has concluded that this violation occurred as stated and that neither an adequate basis for a reduction of the severity level nor for mitigation of the civil penalty was provided by the licensee. Consequently, the proposed civil penalty in the amount of $2,500 should be imposed.

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