



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

March 25, 1994

Docket No. 030-02764
License No. 34-06903-05
EA 94-039

University of Cincinnati
ATTN: Donald C. Harrison, M.D.
Senior Vice President and
Provost for Health Affairs
141 Health Professions Building
Cincinnati, OH 45267-0063

Dear Dr. Harrison:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$5,000
(NRC INSPECTION REPORT NO. 030-02764/94001)

This refers to safety inspections conducted from January 16 through 17, 1994, and February 7 through 11, 1994 at the University of Cincinnati. The report documenting these inspections was mailed to you by letter dated March 10, 1994. On March 16, 1994, a telephone enforcement conference was held to discuss one of the identified violations regarding your failure to maintain control over licensed materials. A copy of the enforcement conference report is enclosed.

During this inspection, we identified several issues that cause us significant concern: (1) poor communications among the radiation safety, oncology and facility management offices; (2) failure of a housekeeping supervisor to heed radiation warnings signs; (3) poor housekeeping practices in a radioactive material use laboratory that could contribute to radioactive contamination and/or lost licensed material; and (4) inadequate implementation of quality management program requirements regarding identification of patients undergoing NRC regulated therapy.

The first two concerns were principal causes for a significant violation of the requirements to control access to NRC licensed material for radiation purposes as described in Section I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). That violation resulted in hazardous radioactive materials leaving the university and potentially being accessible to members of the general public. Therefore, in accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, that violation has been categorized as a Severity Level III violation.

The NRC recognizes that corrective actions were taken following the October 6, 1993, declaration that the strontium-90 source was missing. Those corrective actions included: (1) centralizing storage of all NRC licensed material used by the radiation oncology department; (2) taking disciplinary action against the housekeeping supervisor involved; and (3) retraining housekeeping personnel regarding their responsibilities under your radiation safety program.

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However, to emphasize the need to secure NRC licensed material against unauthorized removal, I have decided to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$5,000 for the Severity Level III violation. The base value of a civil penalty for a Severity Level III violation is \$2,500. The civil penalty adjustment factors in the Enforcement Policy were considered. The civil penalty was initially mitigated 50 percent because you identified the violation and mitigated an additional 50 percent for the corrective actions described below. However, the civil penalty was escalated 100 percent because of the University of Cincinnati's poor performance in maintaining adequate controls over NRC licensed material. As an example, the NRC issued a Severity Level III violation without a civil penalty for the loss on July 21, 1991, of three iridium-192 brachytherapy seeds. The civil penalty was escalated an additional 100 percent, because, as described in the March 10, 1994 inspection report, the University failed to take advantage of opportunities to identify that the source was missing on June 23, 1993, and August 3, 1993. The remaining factors in the enforcement policy were also considered and no further adjustment to the base civil penalty is considered appropriate. Therefore, on balance, the civil penalty was escalated 100 percent.

The remaining violations in Section II of the Notice pertain to other findings identified during the inspection. Each of those violations is separately categorized at Severity Level IV and a civil penalty is not assessed for those violations.

You are required to document your response to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In addition to your specific response to the violations, please also address the actions you have implemented or plan to take to address each of our concerns previously described. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.


In addition to the violations described in the enclosed Notice of Violation, the inspection identified one apparent violation for which we are not issuing a Notice of Violation pursuant to Section VII.B of the Enforcement Policy. The violation concerns the University's failure to post the radiation room of the panoramic irradiator located in room E357 of the Medical Science Building as a very high radiation area, in accordance with 10 CFR 20.1902(c). We also have decided to withdraw the apparent violation concerning the University's opening of a sealed source containing licensed material. We have determined that the inadvertent opening of the iodine-125 sealed source described in Section 7 of our March 10, 1994 inspection report does not constitute a violation of Condition 20 of License No. 34-06903-05. We have no further questions regarding these two matters.

Finally, during the enforcement conference, you requested a copy of Information Notice No. 89-60, "Maintenance of Teletherapy Units." Although that Notice was intended to alert licensees of the importance of performing the required five-year teletherapy unit maintenance, it also discusses the maintenance and

replacement of manufacturer-designated critical components. Please include in your response to this letter your planned improvements in irradiator maintenance.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your responses will be placed in the NRC Public Document Room. The response directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,



John B. Martin
Regional Administrator

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalty
2. Information Notice 89-60
3. Enforcement Conference Report
Report No. 030-02764/94002

See Attached Distribution

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