

ENCLOSURE

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Washington Hospital Center
Washington, D. C.

Docket No. 030-01325
License No. 08-03604-03
EA No. 96-385

During an NRC inspection conducted on September 17-26, 1996, and subsequent investigation by the NRC Office of Investigations, the report of which was issued on December 9, 1996, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600, the NRC proposes to impose civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

I. VIOLATIONS ASSOCIATED WITH FAILURE TO PERFORM BIOASSAYS

- A. 10 CFR 35.315(a)(8) requires, in part, that a licensee measure the thyroid burden of each individual who helped prepare or administer dosages of iodine-131 in amounts that required the patient to be hospitalized for compliance with 10 CFR 35.75, and that the measurements be performed within three days after the administration of the dosage.

Contrary to the above, on numerous occasions during 1995 and 1996, the licensee administered doses to patients ranging from 126 to 280 millicuries of iodine-131, dosages that require hospitalization for compliance with 10 CFR 35.75, and in multiple instances, such as February 20 and 27, and June 10, 1996, the licensee did not measure the thyroid burdens of personnel who helped prepare and/or administer these dosages. (01013)

- B. Condition 28 of License No. 08-03604-03 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated August 26, 1994. The application dated August 26, 1994, requires, in part, that the Model Training Program in Regulatory Guide 10.8, Appendix A be followed. The Model Training Program, in part, requires that personnel be instructed whenever there is a change in duties, regulations or the terms of the license and that instructions include appropriate radiation safety procedures.

Contrary to the above, as of September 26, 1996, personnel were not instructed when there was a change in radiation safety procedures. Specifically, two physicians who were required to have their thyroid burdens measured after assisting with the preparation and/or administration of therapeutic doses of iodine-131, were not trained in the operation of a new thyroid probe required to perform bioassays. (01023)

These violations represent a Severity Level III problem (Supplement VI).
Civil Penalty - \$2,500

II. VIOLETIONS ASSOCIATED WITH LOSS OF CONTROL OF LICENSED MATERIAL

- A. 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, on February 22, 1996, the licensee did not control or maintain constant surveillance of licensed material that was in an unrestricted area and not in storage. Specifically, a 280 microcurie iodine-125 seed was lost while it was located in the operating room, an unrestricted area. (02013)

- B. 10 CFR 20.1501 requires, in part, that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in 10 CFR Part 20, and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

Pursuant to 10 CFR 20.1003, *survey* means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

Contrary to the above, on February 22, 1996, the licensee did not make surveys to assure compliance with 10 CFR 20.1802, to evaluate quantities of radioactive material that could be present. Specifically, an adequate survey was not performed to determine the location of a missing 280 microcurie iodine-125 seed, in that a survey was not performed of all individuals prior to their egress from the operating room, in an attempt to locate and recover the iodine-125 seed. (02023)

- C. 10 CFR 20.2201 requires, in part, that each licensee report by telephone, within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, all licensed material in a quantity greater than 10 times the quantity specified in Appendix C to Part 20 that is still missing at this time; also, within 30 days after the telephone report, a written report must be submitted. Appendix C to Part 20 specifies 1.0 microcurie of iodine-125 as the quantity of licensed material requiring labeling.

Contrary to the above, as of January 31, 1997, no report had been made to the NRC with respect to a 280 microcurie iodine-125 seed that was lost on February 22, 1996. (02013)

These violations represent a Severity Level III problem (Supplement IV).
Civil Penalty - \$2,500

Pursuant to the provisions of 10 CFR 2.201, Washington Hospital Center (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalties (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an Order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalties by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalties proposed above, or may protest imposition of the civil penalties, in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalties will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalties, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalties should not be imposed. In addition to protesting the civil penalties, in whole or in part, such answer may request remission or mitigation of the penalties.

In requesting mitigation of the proposed penalties, the factors addressed in Section VI.B.2 of the Enforcement Policy should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing civil penalties.

Upon failure to pay any civil penalties due that subsequently have been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalties, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234(c) of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalties, and Answer to a Notice of Violation) should be addressed to: James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I.

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Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide legal basis to support your request for withholding the information from the public.

Dated at King of Prussia, Pennsylvania
this 10th day of April 1997