



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V

1450 MARIA LANE, SUITE 210
WALNUT CREEK, CALIFORNIA 94596-5368

OCT 22 1990

Docket No. 030-03537
License No. 53-00458-04
EA 90-132

Department of the Army
Commander, Tripler Army Medical Center
Tripler AMC, Hawaii 96859

Attention: Major General Girard Seitter III
Commanding Officer

Dear Sir:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$5,000
(NRC INSPECTION REPORT NO. 030-03537/90-01)

This refers to the special inspection conducted by the Nuclear Regulatory Commission from June 29 to July 2, 1990 at the Tripler Army Medical Center to review the events surrounding the ingestion of radioactive milk by the nursing infant of a lactating patient who had received radioactive iodine as part of her diagnostic examination at your facility. The inspection resulted from your report of the event to NRC by telephone on June 27, which was followed by a written report dated July 20, 1990. The inspection was documented in Inspection Report 030-03537/90-01, forwarded to you on August 3, 1990. During the inspection the inspectors identified one apparent violation. The results of the inspection were discussed during an Enforcement Conference on August 16, 1990.

The violation described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) involves failure to comply with your procedure requiring licensee personnel to ensure, prior to the administration of radioactive substances to any female patient between the ages of 12 and 60, that the patient is not breast-feeding an infant. Due to this failure, your patient breast-fed her three-week old infant after the patient had received a dose of iodine-131 on June 19, 1990, leading to an NRC-calculated 30,000 rad thyroid dose to the infant, destruction of its thyroid function, and an NRC-calculated 17 rad whole body dose. (We recognize that your calculations showed 45,000 rad to the thyroid and 2 rad whole body based on a less sophisticated model.) The immediate cause of the event was a technologist's failure to ask the patient whether she was lactating. This event could have been avoided if there had been adequate checks to ensure that the appropriate questions were asked prior to the administration of radioactive materials. Also on the day of the administration, the technologist was fulfilling his responsibility as well as that of a radiopharmacist who was absent.

Because of the injury to the infant, this violation is considered one of very significant regulatory concern. It has been classified at Severity Level I in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1990) (Enforcement Policy).

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

A/B

OCT 22 1990

Department of the Army

- 2 -

The staff recognizes that you took prompt corrective action including modifying your quality assurance procedures to provide for a redundant system to verify pregnancy and nursing status and posting new signs in patient waiting areas to make clear that pregnant or nursing patients notify the receptionist. In addition, you established a plan for followup medical care for the infant. However, to emphasize the importance of strict compliance with NRC requirements to protect the public health and safety, I have been authorized, after consultation with the Director, Office of Enforcement, the Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support, and the Commission, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$5,000 for the Severity Level I violation.

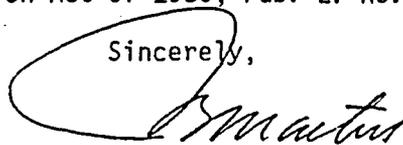
The base value of a civil penalty for a Severity Level I violation is \$5,000. The NRC recognizes your identification and reporting of the event, and your prompt, aggressive corrective actions. Nonetheless, while those actions were commendable, a civil penalty is warranted to emphasize that you and other medical licensees must assure that management controls are adequate so that the necessary resources, oversight, and attention to detail prevent similar violations from occurring in the future. But for your reporting and corrective actions, additional enforcement action would have been considered.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice in preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. 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 accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, the enclosure, and your response will be placed in the NRC Public Document Room.

The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,



John B. Martin
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Department of the Army
Tripler Army Medical Center
Hawaii 96859

Docket No. 030-03537
License No. 53-00458-04
EA 90-132

During an NRC inspection conducted from June 29 to July 2, 1990, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1990), the Nuclear Regulatory Commission proposes to impose a civil penalty 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 violation and associated civil penalty are set forth below:

- A. 10 CFR 35.25(a)(2) provides, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall require the supervised individual to follow the instructions of the supervising authorized user.

The instructions of the supervising authorized user, entitled "Management of Pregnant Patients", dated May 25, 1989, require, in part, that all female patients between the ages of 12 and 60 fill out a pregnancy statement. The statement asks if the patient is pregnant or nursing (breast feeding). The instructions further require, with exceptions not applicable here, that no patient who indicates that she is pregnant or lactating be given a radioactive substance.

Contrary to the above, on June 19, 1990, a nuclear medicine technologist, an individual under the supervision of the licensee's authorized user, administered 4.89 millicuries of iodine-131 to a patient without having the patient complete the required "pregnancy statement", specifically, the portion that asks if the patient is nursing (breast feeding); and the patient was lactating at the time.

This is a Severity Level I violation
Civil Penalty - \$5,000

Pursuant to the provisions of 10 CFR 2.201, Tripler Army Medical 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 this date of this Notice. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) admission or denial of the 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 may be issued to show cause 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.

Notice of Violation

- 2 -

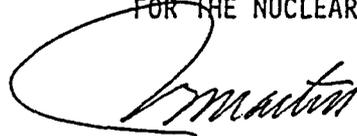
Within the same time as provided for the response required above under 10 CFR 2.201, the licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, with a check, draft, money order or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty 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 penalty will be issued. Should the licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, 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 penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C (1990), 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 a civil penalty.

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

The response noted above (Reply to a Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region V, 1450 Maria Lane, Suite 210, Walnut Creek, CA 94596.

FOR THE NUCLEAR REGULATORY COMMISSION



John B. Martin
Regional Administrator

Dated at Walnut Creek, California
this 22 day of October 1990