

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Dennis I. Maehara, M.D., Inc.
Honolulu, Hawaii

Docket No. 030-30919
License No. 53-23290-01
EA 89-160

During an NRC inspection conducted on July 10 and 14, 1989, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1989), 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 violations and associated civil penalty are listed below:

I. Violations Assessed a Civil Penalty

- A. 10 CFR 20.101(a) limits the extremity radiation dose of an individual in a restricted area to 18.75 rems per calendar quarter.

Contrary to the above, during the second quarter of 1989, a physician, working in a restricted area with a medical applicator containing a strontium-90 sealed source, received an estimated extremity dose to the fingertip of one hand of 51 rem.

- B. License Condition 14 requires compliance with licensee's statements and representations in an application dated November 25, 1988.

Item 10-2, "Radiation Safety Program", of the licensee's application dated November 25, 1988 states in part:

- "3. After removing the Sr-90 eye applicator from its secured storage location:
- a. Do not touch the treatment end of the applicator with your hands or any other portion of your body.
 - b. Always hold the applicator by its handle...
4. If the applicator is to be sterilized, place on a flat surface, use a cotton swab, sponge, or gauze dampened with a sterilizing agent, then wipe the treatment end of the applicator across the swab, sponge, or gauze. Do not sterilize by holding the swab or gauze in your hand. "

Contrary to the above requirements, on May 10, 1989, a physician sterilized the treatment end of a strontium-90 eye applicator on six separate occasions by touching its surface with alcohol swabs which were held by the hand.

These violations have been categorized in the aggregate as a Severity Level III problem (Supplements IV and VI).

Cumulative Civil Penalty - \$250 (assessed equally between the two violations).

II. Violations Not Assessed A Civil Penalty

- A. 10 CFR 35.59(h) requires that, with certain limited exceptions, the ambient dose rates be measured quarterly in all areas where possessed sealed sources or brachytherapy sources are stored. 10 CFR 35.400(e) defines brachytherapy sources to include strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions.

Contrary to the above requirement, as of the date of the inspection, the licensee had not measured the ambient dose rates in the area of the licensee's facility that was used on May 10, 1989 for the storage of a Tracerlab Model RA-1 Medical Applicator containing a 43 millicurie strontium-90 sealed source, and the exceptions in 10 CFR 35.59(h) did not apply.

This is a Severity Level IV Violation (Supplement VI).

- B. 10 CFR 35.59(d) requires that a licensee using sealed sources shall maintain for five years records of leak tests performed on the sources.

Contrary to the above requirement, at the time of the inspection, the licensee had not maintained a record of the leak test that was performed on the strontium-90 source in the eye applicator on December 9, 1988.

This is a Severity Level V Violation (Supplement VI).

- C. License Condition 14 requires compliance with the licensee's statements and representations dated November 25, 1988. Item 10-1, of the application dated November 25, 1988, requires the licensee to comply with Department of Transportation (DOT) regulations in 49 CFR Parts 170-189 when transporting a strontium-90 eye applicator.

49 CFR 172.200(a) provides that each person who offers a hazardous material for transportation shall describe the hazardous material on a shipping paper in a manner prescribed by Subpart C of 49 CFR Part 172. 49 CFR 172.101 classifies radioactive material as a hazardous material for the purpose of transportation.

Contrary to the above requirement, on May 10, 1989, a sealed source containing 43 millicuries of strontium-90 was transported by private carrier between the licensee's medical office facility and another physician's office at 641 Keeaumoku Street, Honolulu, Hawaii, without any shipping papers describing the hazardous material.

This is a Severity Level V Violation (Supplement V).

- D. 10 CFR 19.11(a) and (c) require that current copies of the following documents be posted: (1) 10 CFR Parts 19 and 20; (2) the license, license conditions, or documents incorporated into a license by reference, and amendments thereto; (3) the operating procedures applicable to the licensed activities; and (4) Form NRC-3. 10 CFR 19.11(b) states that if posting of a document specified in Section 19.11 (a)(1), (2) or (3) is not practicable, the licensee may post a notice which describes the document and states where it may be examined.

Contrary to the above requirements, at the time of the inspection, the above documents were neither posted in the licensee's office facility, nor was there a notice which described the documents and stated where they may be examined.

This is a Severity Level V Violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Dennis I. Maehara, M.D., Inc., (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. 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, (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.

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 to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, or money order payable to the Treasurer of the United States in the amount of the civil penalty proposed above, 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 the 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, such answer may request remission or mitigation of the penalty.

Notice of Violation

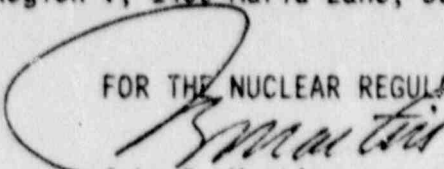
- 4 -

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B. of 10 CFR Part 2, Appendix C, 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 234(c) of the Act, 42 U.S.C. 2282(c).

The responses to the Director, Office of Enforcement, 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, DC 20555, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region V, 1450 Maria Lane, Suite 210, Walnut Creek, California 94596.

FOR THE NUCLEAR REGULATORY COMMISSION


John B. Martin
Regional Administrator

Dated at Walnut Creek, California
on this 2 day of November 1989