

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

José L. Fernández, M.D.
San Juan, Puerto Rico

Docket No. 030-31873
License No. 52-25114-01
EA 97-137

During an NRC inspection conducted on October 18, 1995, April 8-10, 1996, and August 7 and 9, 1996, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions," NUREG-1600, the NRC 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 set forth below:

- A. 10 CFR 35.32(a) requires, in part, that the licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

Contrary to the above, between July 1, 1994, and October 18, 1995, the licensee failed to establish a written quality management program to govern its use of eye applicators containing strontium-90 (Sr-90) for the administration of brachytherapy radiation doses at its Mayagüez and San Juan, Puerto Rico offices. Consequently, numerous patients were administered radiation doses which were not as directed by the authorized user. (01012)

- B. 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

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, the licensee failed to comply with the requirements of 10 CFR 20.1801 and 20.1802 as evidenced by the following:

1. Between January 1994 and October 1994, the licensee failed to secure from unauthorized removal or access an eye applicator containing approximately 83 millicuries (mCi) of Sr-90, located in a materials storage room, an unrestricted area, nor did the licensee control or maintain constant surveillance of this licensed material. Specifically, the licensee amended its license to include a new place of use at an office in Mayagüez, Puerto

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Rico, took possession of the source, and left it unattended at the new place of use until the purchase of the practice and source from the previous licensee was finalized in October 1994.

2. Between October 1994 and October 18, 1995, following initiation of licensed activities at the Mayagüez office, the licensee failed to secure from unauthorized removal or access an eye applicator containing approximately 83 mCi of Sr-90, located in a materials storage room, an unrestricted area, nor did the licensee control or maintain constant surveillance of this licensed material. (01022)

- C. License Condition No. 12 of NRC License No. 52-25114-01 requires that licensed material be used only by José L. Fernández, M.D., the licensee.

Contrary to the above, as of August 4, 1995, the licensee permitted an individual, other than José L. Fernández, M.D., to use licensed material on at least two occasions on human beings. (01032)

- D. 10 CFR 35.33(a)(3) requires, in part, for a misadministration, that the licensee notify the patient, within 24 hours after discovery of the misadministration.

10 CFR 35.2 defines, in part, "misadministration," to mean an administered brachytherapy radiation dose that differs from the prescribed dose by more than 20 percent of the prescribed dose.

Contrary to the above, on March 1, 1996, the licensee became aware that 71 misadministrations occurred, but did not notify three of the 71 patients about the misadministrations until April 8, 1996, a period greater than 24-hours after discovery of the misadministrations. (01042)

- E. 10 CFR 35.33(a)(4) requires, in part, for a misadministration, that the licensee furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either: (1) a copy of the report that was submitted to the NRC; or (2) a brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the NRC can be obtained from the Licensee.

Contrary to the above, on March 1, 1996, the licensee became aware that 71 misadministrations occurred, and the licensee notified the NRC on March 1, 1996, but did not notify three of the 71 patients about the misadministration until April 8, 1996, a period greater than 15 days after the discovery of the misadministrations. (01052)

- F. 10 CFR 35.59(b)(2) requires, in part, that the licensee in possession of a sealed source test the source for leakage at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State.

Contrary to the above, as of October 18, 1995, the licensee had not tested a sealed source containing approximately 83 mCi of Sr-90 for leakage since January 1994, an interval in excess of six months, and no other interval had been approved by the Commission. (01062)

- G. 10 CFR 35.59(g) requires, in part, that a licensee in possession of a sealed source or brachytherapy source conduct a quarterly physical inventory of all such sources in its possession.

Contrary to the above, the licensee did not conduct a physical inventory of its brachytherapy sources during the period January through October 1994, a period in excess of a calendar quarter. (01072)

- H. 10 CFR 30.41(a) and (b)(5) require, in part, that no licensee transfer byproduct material except to a person authorized to receive such byproduct material under the terms of a specific or general license or their equivalents issued by the Commission or an Agreement State.

10 CFR 30.41(c) requires that, prior to transferring byproduct material, the licensee verify that the transferee's license authorizes the receipt of the type, form, and quantity of byproduct material to be transferred. 10 CFR 30.41(d) specifies acceptable methods for this verification.

Contrary to the above, on February 20 and 26, 1997 the licensee transferred two sources containing approximately 83 mCi and 20 mCi of Sr-90, respectively, to Rafael Cavero, M.D., a person who was not authorized to receive such byproduct material under the terms of a specific license issued by the City of New York, Bureau of Radiological Health. None of the acceptable methods of verification specified in 10 CFR 30.41(d) were utilized by the licensee. (01082)

- I. 10 CFR 30.34 states, in part, that each license issued or granted under Parts 31 through 36 and 39 of 10 CFR is subject to all valid rules, regulations, and Orders of the Commission.

Item IV.E of the "Order Modifying NRC Materials License No. 52-25114-01," issued on October 21, 1996, required that the licensee, within 90 days of the date of the Order (October 21, 1996), transfer all Sr-90 sources in its possession to an authorized recipient and provide to the Regional Administrator, Region II, Atlanta, Georgia, a completed NRC Form-314.

Contrary to the above, the licensee shipped the Sr-90 source located at the Mayagüez office on February 20, 1997, and the source located at the

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office in San Juan, Puerto Rico on February 26, 1997, to a physician in the city of New York; however, the transfers were not executed within 90 days of October 21, 1996, as specified in the Order. (01092)

This is a Severity Level II problem (Supplements IV and VI).
Civil Penalty - \$8,000

The NRC has concluded that information regarding the reason for the violations, the circumstances surrounding the violations and the actions taken in response to them have already been adequately addressed on the docket in your letters to the Commission dated March 31 and May 9, 1997. However, Dr. José L. Fernández (Licensee) is required to submit a written statement or explanation pursuant to 10 CFR 2.201 within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty if the description therein does not accurately reflect the corrective actions taken or his position. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response shall be submitted under oath or affirmation.

Within the same time as provided for the response noted above, Dr. Fernández 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 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 2.206 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.

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 U. S. 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 responses noted above (letter with payment of civil penalty 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

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North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region II.

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 the legal basis to support your request for withholding the information from the public.

Dated at Atlanta, Georgia
this 11th day of June 1997