NOTICE OF VIOLATION

Felix E. Schletter, M.D.
& Jerrold M. Stock, M.D.
Morristown, New Jersey 07960

Docket No. 30-12431
License No. 29-17252-01
EA 86-149

As a result of an inspection conducted on January 31 and March 13, 1985, and a subsequent investigation conducted by the NRC Office of Investigations, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR 2, Appendix C (Enforcement Policy) (1986), the violations are set forth below:

A. Condition 14 of License No. 29-17252-01 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in the application dated December 28, 1981.

1. Item No. 13 of this application requires that therapeutic doses of iodine-131 be assayed with a dose calibrator before being administered to patients.

Contrary to the above, on multiple occasions between November 1983 and January 31, 1985, therapeutic doses of iodine-131 were administered to patients without being assayed with a dose calibrator. Specifically, after the dose calibrator became inoperable sometime between July and November, 1983, assays were performed with a survey meter, a method neither in accordance with the license nor as accurate as assaying with a dose calibrator.

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

2. Item No. 10 of this application requires that the dose calibrator be calibrated in accordance with procedures contained in Section 2., Appendix D, Regulatory Guide 10.8 (Revision 1). Subitem G.5 of Section 2 requires that records be kept of dose calibrator accuracy tests.

Contrary to the above, no records were maintained of dose calibrator accuracy tests performed prior to January 31, 1985, and the licensee was not able to demonstrate that the tests were performed.

This is a Severity IV violation. (Supplement VI)

B. 10 CFR 19.11(a) and (b) require that current copies of Part 19, Part 20, the license, license conditions, documents incorporated into the license, license amendments and operating procedures be posted, or that a notice describing these documents and where they may be examined, be posted. 10 CFR 19.11(c) requires that Form NRC-3, "Notice to Employees," be posted.

Contrary to the above, on January 31, 1985, the documents specified in CFR 19.11(a) (b) & (c) were not posted, nor was a notice posted which described these documents and where they may be examined.

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

Pursuant to the provisions of 10 CFR 2.201, Felix E. Schletter, M.D. and Jerrold M. Stock, M.D., are hereby required to submit to this office, within thirty days of the date of the letter which transmitted this Notice, a written statement or explanation in reply, including: (1) the reasons for the violations, if admitted; (2) the corrective steps which have been taken and the results achieved; (3) corrective steps which will be taken to avoid further violations; and (4) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending this response time.

SYNOPSIS

This investigation was opened following the receipt of a written request, dated June 14, 1985, from the Regional Administrator, Region I. The Office of Investigations (OI) was asked to determine if two physicians, holders of NRC Materials License No. 29-17252-01, made material false statements on their License Application of December 28, 1981, and in a March 30, 1982, letter to NRC in support of that Application. Their License, issued by NRC on April 4, 1982, permits them to use Iodine-131 (I-131) pre-packaged capsules for the treatment of thyroid conditions.

Item No. 10 of the physicians' 1981 Application and their March 1982 letter indicates that their dose calibrator will be calibrated annually. Additionally, Item No. 13 of their Application states that they will assay all pre-calibrated I-131 capsules in their dose calibrator before administering them to patients. According to the NRC staff, this assay by the physicians is a necessary corroboration of the manufacturer's assay because the physicians have the primary responsibility for ensuring that the prescribed I-131 dose is delivered to their patients.

In their NRC License, the physicians are committed to NRC Regulatory Guide 10.8 of October 1980 entitled, "Guide for the Preparation of Applications for Medical Programs." Appendix D, Section 2 of Regulatory Guide 10.8 states, "All radiopharmaceuticals must be assayed for activity to an accuracy of 10%. The most common instrument for accomplishing this is an ionization-type dose calibrator. The instrument must be checked for accurate operation at the time of installation and periodically thereafter." It also states that the physicians must "Keep a log of these calibration checks." Further, Condition No. 14 of the physicians' renewed NRC License states, "Except as specifically provided otherwise by this License, the Licensee shall possess and use licensed material described in Items 6, 7, and 8 of this License in accordance with statements, representations, and procedures contained in Application dated December 28, 1981, and letter dated March 30, 1982. The NRC's regulations shall govern the Licensee's statements on applications or letters, unless the statements are more restrictive than the regulations."

On January 31, 1985, a surprise inspection of the physicians' facility in Morristown, New Jersey, was conducted by an NRC inspector from Region I, who was accompanied by an inspector from the Bureau of Radiation Protection, State of New Jersey. The NRC inspector found some violations of NRC regulations, including two breaches involving the suspected making of material false statements by the physicians. The NRC inspector discovered that the physicians did not, on occasions, assay their pre-packaged I-131 capsules prior to administering them to patients. According to one physician's own statement, uttered during the NRC inspection, the physicians did not assay these capsules because their Picker Dose Calibrator (PDC) had been inoperative since "January 4, 1980." These findings by the NRC inspector, if correct, violated Condition No. 14 of the physicians' NRC License and contradicted the representations they made in Item No. 10 and Item No. 13 of their 1981 Application and in their March 1982 letter in support of that Application. In effect, the representations made by the physicians to NRC in their December 1981 Application and March 1982 letter would be material false statements if their PDC had been inoperative since "January 4, 1980," a date which was 11 months prior to the date of their Application to NRC.

The physicians were interviewed separately on January 9, 1986, and each stated that their Application and supporting documents were true and correct when they were submitted to NRC. The Radiation Safety Officer (RSO) is the physician who was present during the NRC inspection in January 1985. The RSO stated that he was surprised by the inspectors' questions about their PDC and, without thoroughly examining his available records, provided incorrect information about the date the unit broke. He produced invoices from his former and present Consultant-Physicists (C-Ps) indicating that their PDC was calibrated in March 1982 and that an operating problem with that instrument did not occur until July or November 1983. The C-Ps were interviewed and verified the validity of the invoices that had been relinquished by the RSO. These invoices provide documentary evidence that the physicians' PDC was operational at the time they submitted their Application to NRC.

The physicians admitted that after their PDC broke, approximately July 1983, they administered an I-131 capsule to five different patients between March 1984 and November 1984 without first assaying the capsules in their PDC. However, the physicians stated that after the PDC broke, they did take a "rough reading" of each capsule with an operable survey meter before giving the capsule to a patient. The physicians did not retain the records of any calibrations performed on their old PDC by their former C-P. The RSO could only state that these records were "missing or lost." Following the surprise NRC Inspection, the physicians purchased a new CAL/RAD II dose calibrator approximately February 1985.

The evidence gathered during this investigation indicates that the physicians did not utter any material false statements when applying for their current NRC Materials License. However, it appears that they may have violated some NRC requirements after their License was granted in April 1982.