NOTICE OF VIOLATION

Syncor Corporation
Allentown, Pennsylvania

Docket No. 030-19768
License No. 37-21092-01MD
EA 88-53

During an NRC inspection conducted on February 8, 1988, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1988), the violations are listed below:

I. VIOLATION ASSOCIATED WITH LABELING ERRORS

Condition 23 of License No. 37-21092-01MD (superseded amendment) required that licensed material be possessed and used in accordance with statements, representations and procedures in application dated May 28, 1982 and certain specific letters.

Item 23 of this application described the required customer container labeling which specifies the name of the radiopharmecutical.

Condition 24 of License No. 37-21092-01MD (current amendment) requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated August 15, 1987.

Item 10.13 of this application describes the required customer container labeling, which includes specification of the name of the radiopharmaceutical.

Contrary to the above, between September 1986 and February 8, 1988, syringes, vial shields and/or unit dose container shields containing radioactive material were labeled with the wrong radiopharmaceutical name on six separate occasions, which resulted in fourteen misadministrations by hospitals.

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

II. VIOLATIONS ASSOCIATED WITH MANAGEMENT CONTROL

A. 10 CFR 20.101(a) requires that no licensee possess, use, or transfer licensed material in such a manner as to cause any individual in a restricted area to receive in any period of one calendar quarter a total occupational dose to the hands and forearms in excess of 18.75 rems.

Contrary to the above, during the fourth calendar quarter of 1987, a radiopharmacist working in the radiopharmaceutical dispensing area, a restricted area, received a total occupational dose in excess of 18.75 rems.

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B. 10 CFR 19.12 requires, in part, that all individuals working in, or frequenting any portion of, a restricted area be instructed in precautions or procedures to minimize exposure to radioactive materials.

Contrary to the above, as of February 8, 1988, a radiopharmacist working in the dispensing area, a restricted area, had not been adequately instructed in precautions or procedures to minimize exposure to radioactive materials in that, although the individual had been shown the kit preparation and dose drawing techniques, the individual was not observed to verify his ability to independently use these techniques, a necessary aspect of the instruction process.

C. Condition 24 of License No. 37-21092-01MD requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated August 15, 1987.

1. Item 10.10 of this application describes the precautionary measures for handling millicurie quantities of liquid radioiodine and requires that weekly bioassays be performed for individuals who compound iodine-131 capsules.

Contrary to the above, between September 1, 1987 and December 14, 1987, radiopharmacists compounded iodine-131 capsules approximately three or four times per week, but during this time, weekly bioassays of the individuals who prepared the capsules were not performed.

2. Item 10.4 of this application requires adherence to the "Procedures for Calibration of Dose Calibrators" contained in Appendix E of the "Guide for the Preparation of Applications for Nuclear Pharmacy Licenses" dated August, 1985. Item 4 of Appendix E requires the assay of at least one reference source to verify the constancy of the dose calibrator before each day the dose calibrator is used.

Contrary to the above, on at least ten days between September 1987 and February 8, 1988 when the dose calibrator was used for iodine-131 compounding, a reference source was not assayed in the dose calibrator to verify constancy.

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

Pursuant to the provisions of 10 CFR 2.201, Syncor Corporation (Licensee) is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice. This reply should be clearly marked as a

"Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation if admitted, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) 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 give to extending the response time for good cause shown.

FOR THE NUCLEAR REGULATORY COMMISSION

Original Signed By
WILLIAM T. RUSSELL

William T. Russell
Regional Administrator

Dated at King of Prussia, Pennsylvania
this 22 day of June 1988.