

Enclosure

NOTICE OF VIOLATION

Syncor International Corporation  
Chatsworth, California

Docket No. 030-33224  
License No. 04-26507-01MD

During an NRC inspection conducted on August 26 through September 17, 1996, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG 1600, the violation is listed below:

10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present. Pursuant to 10 CFR 20.1003, *survey* means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

Condition 21 of License 04-26507-01MD requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in an application dated May 31, 1993. Item 9, "Sodium Iodide I-131 Capsule Preparation," of the application specifies, in part, that prior to and following capsule preparation, an area survey of the I-131 glove box and other immediate work areas be performed to assure that they are contamination free. Item 10.7, "General Rules for Safe Use of Radioactive Materials," of the application specifies, in part, that hands and clothing be monitored after each procedure or before leaving an area where radioactive materials are used.

Contrary to the above, on August 12, 1996, the licensee did not make surveys to assure compliance with 10 CFR 20.1301, which limits radiation levels in unrestricted areas. Also, a survey of the I-131 glove box and immediate work area was not performed prior to and following preparation of sodium iodide I-131 capsules on August 12, 1996, and an individual failed to perform adequate monitoring of clothing (shoes) after a sodium iodide I-131 compounding procedure and prior to leaving the area where iodine-131 had been used. As a result, a pharmacist failed to identify I-131 contamination in the glove box area and on his shoe, and contamination was subsequently tracked into the unrestricted area of the facility. Contamination in the unrestricted area of the facility was not immediately identified because surveys performed in this area were not adequate.

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

Pursuant to the provisions of 10 CFR 2.201, Syncor International Corporation is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington,

Texas 76011, and the Walnut Creek Field Office, 1450 Maria Lane, Walnut Creek, California 94596, within 30 days of the date of the letter transmitting this Notice of Violation (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, or, if contested, the basis for disputing the violation, (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. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

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 Arlington, Texas  
this 7th day of October 1996