

November 6, 1996

EA 96-323

Diagnostic Photon Corporation
ATTN: Dr. Justo Caamaño
President
G.P.O. Box 4408
Carolina, Puerto Rico 00994

SUBJECT: NOTICE OF VIOLATION AND PREDECISIONAL ENFORCEMENT CONFERENCE
SUMMARY [NRC INSPECTION REPORT
NO. 52-16345-02MD/96-01]

Dear Dr. Caamaño:

This refers to the inspection conducted on July 26 and 29, 1996, and subsequent telephone conversations and reviews of records performed through September 18, 1996. The inspection included a review of activities authorized for your Carolina, Puerto Rico facility. At the conclusion of the onsite inspection, the preliminary findings were discussed with you. The preliminary inspection results were also documented in an inspection report dated September 20, 1996.

The inspection consisted of an examination of activities conducted under your license with respect to radiation safety and compliance with NRC regulations and the conditions of your license. It included selective examinations of procedures and representative records, interviews with personnel, and direct observations by the inspector.

Based on the results of this inspection, certain of your activities appeared to be in violation of NRC requirements, as specified in the enclosed Notice of Violation (Notice). A predecisional enforcement conference was held in San Juan, Puerto Rico on September 26, 1996. A list of individuals who attended the conference is provided in Enclosure 2. During the conference, the NRC expressed concern that an apparent transfer of control of licensed activities had taken place without prior NRC consent. The report which documented this finding, Inspection Report 96-01, also described: (1) two other apparent violations, involving the apparent failure of Syncor International Corp (SIC) and Syncor Overseas Limited (SOL) to obtain a valid NRC license prior to possessing and distributing byproduct material in Puerto Rico, and (2) apparent violations regarding failures to follow procedures and notify the NRC of changes in nuclear pharmacists.

During the conference, you, your representatives and representatives of SIC and SOL described the circumstances surrounding the apparent violations. The involved parties provided sufficient information for us to determine that a violation for an apparent failure to obtain prior NRC approval of the transfer of control over licensed activities did not occur. Consequently, the other two apparent violations involving SIC and SOL did not occur. However, we have

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concluded that a citation for your failure to provide the NRC the credentials of authorized nuclear pharmacists within 30 days is warranted. We also concluded that a violation for failing to use approved labeling also occurred. The labeling violation will not be cited because its low safety significance meets the criteria for enforcement discretion specified in Section VII.B.1.(a)-(d) of the Enforcement Policy. Based on the above, we believe that escalated enforcement action is not warranted at this time. In addition, please note that we have revised page 4 of our inspection report as you requested. (See Enclosure 3.)

The NRC has concluded that information regarding the reason for the cited violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be achieved is already adequately documented in the transcripts of the conference. In addition, your license was amended on October 25, 1996, to reflect transfer to Syncor de Puerto Rico. Therefore, you are not required to respond to this letter unless the information provided at the conference by all involved parties does not accurately reflect your corrective actions or your position.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and any reply will be placed in the NRC Public Document Room. A copy of this letter is also being sent to an officer of SIC and SOL to inform them of our decision to not take enforcement action against either SIC or SOL.

Should you have any questions concerning this letter, please contact us.

Sincerely,



Bruce S. Mallett, Director
Division of Nuclear Materials Safety

Docket No. 030-19134
License No. 52-16345-02MD

Enclosures: 1. Notice of Violation
2. List of Attendees
3. Revised Page 4 of Inspection
Report 96-01

cc w/encls:
Syncor International Corporation; and
Syncor Overseas, Ltd.
ATTN: Mr. Haig S. Bagerdjian
Vice President
20001 Prairie Street
Chatsworth, California 91311

Commonwealth of Puerto Rico

Distribution w/encls: (See Page 3)

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J. Lieberman, OE

OE:EA (B. Summers)(2)

(*) See next page for previous concurrences

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cc w/encls:

Syncor International Corporation &

Syncor Overseas, Ltd.

ATTN: Mr. Haig S. Bagerdjian

Vice President

20001 Prairie Street

Chatsworth, California 91311

Commonwealth of Puerto Rico

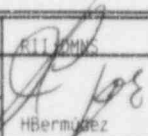


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