

September 20, 1996

EA 96-324

Syncor International Corporation  
ATTN: Mr. Haig Bagerdjian  
Vice President  
20001 Prairie Street  
Chatsworth, CA 91311

SUBJECT: NRC INSPECTION REPORT NOS. 52-16345-02MD/96-01, 999-90002/96-03  
AND 999-90002/96-04, AND NOTICE OF PREDECISIONAL ENFORCEMENT  
CONFERENCE.

Dear Mr. Bagerdjian:

This refers to the NRC's inspection of the use of radioactive materials at the Diagnostic Photon nuclear pharmacy in Carolina, Puerto Rico. The inspection included: (1) the NRC's review of the Syncor International Corporation (SIC) Management Agreement with Diagnostic Photon Corporation (DPC), Carolina, Puerto Rico, dated February 6, 1996, submitted by SIC on June 28, 1996, (2) the NRC's review of the Assignment made by SIC in favor of Syncor Overseas, Ltd. (SOL) dated July 16, 1996, (3) the onsite inspection conducted on July 26 and 29, 1996, at the DPC Carolina, PR facility, (4) subsequent telephone conversations between NRC staff, and you and SIC/SOL representatives, and (5) subsequent reviews of correspondence generated by SIC/SOL representatives through September 18, 1996. The enclosed report presents the results of the onsite inspection and subsequent conversations and reviews.

Based on the results of this inspection, two apparent violations involving SIC and SOL were identified and are being considered for escalated enforcement action, in accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600. The apparent violation involving SIC relates to the receipt, possession, use and distribution of byproduct material without a valid NRC license, nor under the supervision of an NRC licensee during the period March 1 - July 16, 1996 [10 CFR 30.3]. Specifically, control of licensed activities and the license was transferred from DPC to SIC without NRC consent.

Since escalated enforcement is being considered, no Notice of Violation is presently being issued. Please be advised that the number and characterization of the apparent violations described in the enclosed inspection report may change as a result of further NRC review.

Additionally, four apparent violations involving the DPC NRC license were identified and are also being considered for escalated enforcement action. The apparent violations regarding the DPC NRC license involve the transfer of control [10 CFR 30.34(b)] of NRC-licensed activities without prior NRC approval, the failure to provide to the NRC, within 30 days, the credentials of individuals who were allowed to work under the DPC NRC license as authorized nuclear pharmacists [10 CFR 32.72 (b)(5)], the use of unauthorized

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procedures [Condition 20 of License No. 52-16345-02MD], and failure to train a pharmacist on the operating and emergency procedures incorporated into License No. 52-16345-02MD [10 CFR 19.12].

A predecisional enforcement conference to discuss the apparent violations involving all three parties in this case has been scheduled for September 26, 1996, at 1:00 p.m., at the Sands Hotel in Isla Verde, Carolina, Puerto Rico. The decision to hold a predecisional enforcement conference does not mean that the NRC has determined that violations have occurred or that enforcement action will be taken. This conference is being held to obtain information to enable the NRC to make an enforcement decision, such as a common understanding of the facts, root causes, missed opportunities to identify the apparent violations sooner, corrective actions, significance of the issues and the need for lasting and effective corrective action.

In addition, this is an opportunity for you to point out any errors in our inspection report and for you to provide any information concerning your perspectives on 1) the severity of the violations, 2) the application of the factors that the NRC considers when it determines the amount of a civil penalty that may be assessed in accordance with Section VI.B.2 of the Enforcement Policy, and 3) any other application of the Enforcement Policy to this case, including the exercise of discretion in accordance with Section VII.

In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation. The guidance in the enclosed NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful.

The enclosures listed below are being sent to all three parties involved in this case under separate cover letter. You will be advised by separate correspondence of the results of our deliberations on this matter.

No response regarding the apparent violation is required at this time. In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

Sincerely,

Original signed by  
Bruce S. Mallett

Bruce S. Mallett, Director  
Division of Nuclear Materials Safety

Docket Nos. 030-31302;999-90002/96-04  
License No. 52-25066-01

Enclosures: (See page 3)

Enclosures:

1. Inspection Report
2. NRC Information Notice 96-28
3. Enforcement Policy: Section V. "Predecisional Enforcement Conferences"

cc w/encls: Commonwealth of Puerto Rico

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J. Lieberman, OE

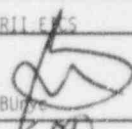

D. Cool, NMSS

R. Scarano, RIV

OE: EA File (B. Summers) (2)

N. Mamish, OE

D. Flack, NMSS

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DOCUMENT NAME: G:\DNMS\MLIB2\SIC.RPT

\* see previous correspondence

## Enclosures:

1. Inspection Report
2. NRC Information Notice 96-28
3. Enforcement Policy: Section V. "Predecisional Enforcement Conferences"

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DATE	09 / 16 / 96	09 / 17 / 96	09 / / 96	09 / / 96	09 / / 96	09 / / 96
COPY?	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

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