

September 20, 1996

EA 96-323

Diagnostic Photon Corporation
ATTN: Dr. Justo Caamaño
President
P.O. Box 4408
Carolina, Puerto Rico 00984

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 Dr. Caamaño:

This refers to the NRC's inspection of the operation of your Puerto Rico nuclear pharmacy, which is authorized to use radioactive materials pursuant to NRC License No. 52-16345-02MD. The enclosed report presents the results of the onsite inspection and subsequent conversations and reviews. In summary, the report covers: (1) your telephone conversations with Mr. H. Bermúdez of my staff on June 28 and July 3, 1996, (2) the NRC's review of your Management Agreement with Syncor International Corporation (SIC) dated February 6, 1996, submitted by SIC on June 28, 1996, (3) the NRC's review of the Assignment made by SIC in favor of Syncor Overseas, Ltd. (SOL) dated July 16, 1996, (4) the onsite inspection conducted on July 26 and 29, 1996, at your Carolina, Puerto Rico facility, (5) subsequent telephone conversations between NRC staff and you and your representatives, and with representatives of SOL, and (6) subsequent reviews of correspondence generated by your representatives and representatives of SOL through September 18, 1996.

Based on the results of this inspection, the NRC identified apparent violations regarding control and oversight of your licensed activities. Four apparent violations of NRC requirements regarding your license 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. Two additional apparent violations involving Syncor International Corporation and Syncor Overseas, Ltd. were also identified and are also being considered for escalated enforcement action. Accordingly, no Notice of Violation is presently being issued for these inspection findings. The four apparent violations regarding your license involve (1) the transfer of control of NRC-licensed activities without prior NRC approval, (2) the failure to train an incoming pharmacist on your operating and emergency procedures and your license, (3) the failure to provide to the NRC, within 30 days, the credentials of individuals after allowing them to work as authorized nuclear pharmacists, and (4) the use of unauthorized operating procedures. 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.

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

Enclosures:

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

cc w/encls: Commonwealth of Puerto Rico

Distribution w/o encls 2 and 3: (See page 3)

Distribution w/o encls 2 and 3:

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J. Lieberman, OE

D. Cool, NMSS

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N. Mamish, OE

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* See previous comments

Diagnostic Photon Corp.

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


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