

November 6, 1996

EA 96-324

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

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

Dear Mr. Bagerdjian:

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 Diagnostic Photon Corporation (DPC) at their Carolina, Puerto Rico facility. At the conclusion of the onsite inspection, the preliminary findings were discussed with Mr. Jay Simon of your staff. 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 DPC's license with respect to radiation safety and compliance with NRC regulations and the conditions of DPC's 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. 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 1. During the conference, the NRC expressed concern that an apparent transfer of control of licensed activities had taken place without prior NRC consent and, as a result, Syncor International Corporation (SIC) and Syncor Overseas, Ltd. (SOL) had operated in Puerto Rico without a valid NRC license. In response, you, your representatives and representatives from DPC described the circumstances surrounding the apparent violations. The involved parties provided sufficient information for the NRC to determine that a violation for an apparent failure to obtain prior NRC consent for the transfer of control over licensed activities did not occur. Consequently, the other two apparent violations involving SIC and SOL regarding their conduct of licensed activities without a valid NRC license did not occur. Based on the above, we believe that escalated enforcement action against DPC, SIC and SOL is not warranted. In addition, please note that we have revised page 4 of our inspection report as requested by DPC (see Enclosure 2). Finally, we note that License No. 52-16345-02MD was amended on October 25, 1996, to reflect transfer to Syncor de Puerto Rico.

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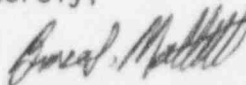
Syncor

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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 DPC to inform them of our decision not to take escalated enforcement action against DPC.

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. List of Attendees
2. Revised Page 4 of Inspection Report

cc w/encls:

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

Commonwealth of Puerto Rico

Distribution w/encls:

PUBLIC
RII Docket File, DNMS
J. Lieberman, OE
OE:EA (B. Summers)(2)
R. Scarano, R-IV

(*) See Next Page for Previous Concurrences

OFFICE	RII DNMS	RII DNMS	RII EICS	RII ORA		
SIGNATURE						
NAME	HBermudez *	JPotter *	BUryc *	CEvans *		
DATE	11 / / 96	11 / / 96	11 / / 96	11 / / 96	11 / / 96	11 / / 96
COPY?	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

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DOCUMENT NAME:g:\dnms\m11b2\syncor.rpt

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Docket No. 030-19134
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
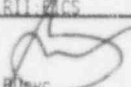

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RII Docket File, DNMS
J. Lieberman, OE
OE:EA (B. Summers)(2)
R. Scarano, R-IV

OFFICE	RII-DNMS	RII-DNMS	RII-RCS	RII-ORA		
SIGNATURE				NLD 		
NAME	J. Lieberman	J. Potter	B. Summers	C. Evans		
DATE	11 / 5 / 96	11 / 5 / 96	11 / 05 / 96	11 / 06 / 96	11 / / 96	11 / / 96
COPY?	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

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DOCUMENT NAME: g:\dnms\m11b2\syncor.rpt

LIST OF ATTENDEES

Predecisional Enforcement Conference
Diagnostic Photon Corporation, Syncor International Corporation,
Syncor Overseas, Limited
September 26, 1996
San Juan, Puerto Rico

Diagnostic Photon Corporation

J. Caamaño, M.D., President and Radiation Safety Officer
N. Oldham, Alternate Radiation Safety Officer
A. González Géigel, Esq., Legal Counsel

Syncor Overseas, Ltd. and Syncor International Corporation

H. Bagerdjian, Esq., Vice President and General Counsel
J. Coffey, Vice President, Quality and Regulatory
J. Simon, R.Ph., Director of Expansion
F. Peña, Pharmacy Manager

Nuclear Regulatory Commission

B. Mallett, PhD., Director, Division of Nuclear Materials Safety (DNMS)
B. Uryc, Director, Enforcement and Investigation Coordination Staff (EICS)
C. Evans, Esq., Regional Counsel
H. Bermúdez, Senior Radiation Specialist, Materials Licensing/Inspection Branch 2, DNMS
A. Boland, Enforcement Specialist, EICS (*)
L. Howell, Chief, Materials Licensing and Inspection Branch, DNMS, NRC Region IV (*)
J. Montgomery, Project Manager, Syncor Master Materials License, NRC Region IV (*)
T. Taylor, Health Physicist, NRC Office of Nuclear Materials Safety and Safeguards (*)
J. Longo, Esq., Attorney, NRC Office of the General Counsel (*)

(*) By telephone

This authority was transferred to SOL by SIC on July 16, 1996 without DPC consent. Neither of these assignments of control were consented by the NRC.

- d. The DPC RSO and Alternate RSO were restricted from access to the pharmacy. Through discussions with the DPC RSO, Alternate RSO and SOL representatives, the inspector determined that the Alternate RSO was escorted from the facility on July 22 by SOL staff. An SOL representative indicated that, if and when DPC's President/RSO wishes to access the facility to supervise licensed activities as required by his function as RSO, he must be allowed in by SOL personnel without restriction but SOL personnel must be onsite whenever the RSO is present. Through discussions with SOL representatives, the inspector further learned that, during June and July 1996, DPC's RSO seldom frequented the facility to supervise licensed activities. DPC's President stated to the inspector that his lack of attendance was due to his intention to avoid conflicts.
- e. As described further in Section 2, the SIC lead representative at the pharmacy, indicated, on June 28, 1996, that the Agreement allowed him to control the pharmacy. The representative indicated this included implementation of NRC-licensed activities.

Based on: (1) the language contained in the Agreement which addresses the transfer of control of the operation of the pharmacy and SIC's use of DPC's licenses, as summarized in Section 1 of this report, (2) the President of DPC's statements during the June 28, and July 3 and 26, 1996 conversations regarding loss of control over licensed activities and his inability to ascertain the credentials of dispensing pharmacists at his facility, (3) the fact that SIC and SOL dictated who the Authorized Nuclear Pharmacists (ANPs) would be, without any input from DPC management, (4) the fact that, at least during the weeks of July 15 and 22, 1996, it was SIC's operating and emergency procedures that were being implemented, not DPC's, (5) the fact that the pharmacist who worked during the weeks of July 15 and 22, 1996 did not receive training on DPC's operating and emergency procedures or the license because it was his understanding that he was to operate under SIC's Operations Manual, (6) the fact that SIC and SOL representatives implemented changes to the licensed program without DPC or NRC approval by changing the labels and transport containers to conform with SIC's standard operating practices, (7) the SIC representative's understanding that the Agreement allowed him to control NRC licensed activities at the pharmacy, (8) the fact that the Alternate RSO was prohibited by SOL from entering the pharmacy (9) the fact that DPC's President and RSO has been denied the keys the pharmacy, and (10) the lack of presence of the RSO during June and July 1996 to supervise licensed activities and his