

NOTICE OF VIOLATION

Diagnostic Photon Corporation
Carolina, Puerto Rico

Docket No. 030-19134
License No. 52-16345-02MD
EA 96-323

During an NRC inspection conducted on July 26 and 29, 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 32.72(b)(5) requires, in part, that the licensee provide to the Commission a copy of each individual's certification by the Board of Pharmaceutical Specialties, the Commission or Agreement State license, or the permit issued by a licensee of broad scope, and a copy of the state pharmacy licensure or registration, no later than 30 days after the licensee allows the individual to work as an authorized nuclear pharmacist.

Contrary to the above, as of September 26, 1996, the licensee had not provided the NRC the credentials specified in 10 CFR 32.72(b)(5) for individuals the licensee has allowed to work as authorized nuclear pharmacists since March 1, 1996.

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

The NRC has concluded that information regarding the reason for the 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 addressed on the transcripts of the predecisional enforcement conference held on September 26, 1996. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the information provided at the conference by all involved parties does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20055, with a copy to the Regional Administrator, Region II, within 30 days of the date of the letter transmitting this Notice of Violation.

Dated at Atlanta, Georgia
This 6th day of November, 1996

Enclosure 1

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