DCD/DCB (RIDS)

August 24, 1990

Docket No. 030-14827
License No. 34-18309-01MD
EA 90-053

Syncor International
ATTN: Mr. Gene McGrevin
President
20001 Prairie Street
Post Office Box 2185
Chatsworth, California 91313-2185

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - $20,000
(NRC OFFICE OF INVESTIGATIONS REPORT NO. 3-88-009)

This refers to the NRC routine safety inspection conducted July 6-8 and September 12-15, 1988 of activities authorized by NRC License No. 34-18309-01MD at Syncor International's facility, Blue Ash, Ohio. The report of inspection was forwarded to you on October 25, 1988. This also refers to the subsequent investigation conducted between August 19, 1988 and January 18, 1990 by the NRC Office of Investigations (OI). A copy of the investigation report synopsis was mailed to you on March 23, 1990. During the inspection and investigation, violations of NRC requirements were identified. An Enforcement Conference, attended by you and members of your staff, was held with Dr. Carl J. Paperiello, Deputy Regional Administrator, and other members of the NRC staff in the NRC Region III office on April 27, 1990, at which time the violations, their causes, and your corrective actions were discussed.

The violations described in Section I of the enclosed Notice of Violation (Notice) involve failure to follow the manufacturer's instructions in the package insert for the preparation of Tc-99m labeled radiopharmaceuticals and failure to perform alumina breakthrough tests following each elution of the Mo-99/Tc-99m generators. As a related issue, falsification of alumina breakthrough test records also occurred. Both violations are especially significant in that the failure to follow the manufacturer's instructions contributed in substantial part to an incident in which the final product of the formulation process was the wrong radiopharmaceutical. As a result, 17 patient doses containing Tc-99m sodium pertechnetate, instead of the intended Tc-99m methylene diphosphonate (MDP), were distributed to area hospitals, which resulted in 14 diagnostic misadministrations. An additional concern is that neither Syncor International nor the NRC is able to determine if quality control tests were actually performed on the final product to ensure that the Tc-99m was properly chemically bonded ("tagged") to the radiopharmaceuticals. Both the failure to follow manufacturer's instructions and the presence of alumina can affect the tagging process. Quality control tests are also

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

IE14

important because they can prevent patient misadministrations by assuring that the correct radiopharmaceutical is specified on the container label. Moreover, the failure to follow required instructions and perform required tests and the fabrication of related records raises significant questions about the integrity of the individuals involved. Syncor International contended at the enforcement conference that these failures were not willful acts on the part of the staff at the Blue Ash, Ohio, facility, because the former manager allowed these actions to occur. Nonetheless, these failures clearly involve elements of willfulness on the part of the licensee because of the acknowledged complicity of the pharmacy manager.

The failure to follow the manufacturer's instructions was identified through internal audits prepared by a pharmacy technologist and the pharmacy manager, and through a Syncor corporate audit; however, corrective action was not implemented. In addition, concerning the alumina tests: (1) a staff pharmacist knew of the requirement to perform the test, (2) the pharmacist repeatedly failed to perform the test, and (3) the pharmacist falsified the test records which made it appear that the tests had been done. Further, the fact that alumina breakthrough tests were not performed following each generator elution was identified through internal audits performed by your staff at the facility in Blue Ash, Ohio, and effective corrective action was not implemented. These facts further demonstrate the willful failure to follow the manufacturer's instructions and willful failure to perform required tests, as well as the willful falsification of records.

We recognize that, at the time of the Enforcement Conference, you were told that NRC did not then intend to issue a citation for the violation involving failure to follow the manufacturer's instructions. We have reconsidered that position and have decided that a citation should be issued in view of the willfulness of the violation.

The Violation in Section II of the Notice involves falsification of an NRC-required record of a daily radiation survey. This violation covers but one of many records falsification problems documented in the OI report, all of which are cause for concern about the integrity of the employees involved. However, based on our review of the records that NRC required to be kept at that time, we are issuing the citation only for the falsified record of the daily radiation survey since that record was required to be maintained by your license. Further, this particular falsification is of increased significance because it was performed at the specific direction of the manager of the Syncor Blue Ash facility.

These problems demonstrate the need for increased management attention to assure that identified deficiencies are immediately pursued and effectively resolved and that licensee employees are forthright and candid in the conduct of licensed activities, in their dealings with NRC, and in the maintenance of NRC-required records.

To emphasize the significance that the NRC places on the willful failure to follow NRC requirements and on the falsification of required documents, I have

been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Director of Nuclear Materials Safety, Safeguards and Operations Support to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) in the amount of $20,000 for the violations described in Sections I and II of the Notice. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1988) (Enforcement Policy), the violations described in Section I of the enclosed Notice have been categorized collectively as a Severity Level III problem.

The base civil penalty for a Severity Level III violation or problem is $5,000. The escalation and mitigation factors in the Enforcement Policy were considered and the base civil penalty was increased a total of 200 percent. The base civil penalty was increased by 100 percent due to the prior notice the licensee received in the form of audits, which indicated that the licensee knew, or should have known, that the manufacturers' instructions were not always being followed in the preparation of Tc-99m radiopharmaceuticals and that alumina breakthrough tests were not always performed following each elution of the Mo-99/Tc-99m generators. The base civil penalty was increased an additional 100 percent for the duration of the violations each of which continued for at least a year or more during the 1987-1988 time frame. The adjustment factor for corrective action was considered not applicable to this enforcement action since the effective corrective actions were taken and the root cause determination was made as a direct result of the Order Modifying License (Effective Immediately) issued on October 12, 1988 (Enforcement Action No. 88-194). The remaining factors in the Policy were considered and no further adjustment was considered appropriate.

The violation in Section II has been classified at Severity Level III in accordance with the Enforcement Policy. The escalation and mitigation factors were considered and no adjustment to the base civil penalty has been deemed appropriate.

The violations in Section III involve three incidents that occurred between October 1987 and June 1988 in which mislabeled Technetium-99m radiopharmaceuticals were distributed from the radiopharmacy. On each occasion, the label placed on the vial of material indicated the correct radionuclide and activity, but the chemical form of the material as stated on the label was incorrect; thus it was not possible for your client medical facilities to detect the error. In each incident, the mislabeling resulted in diagnostic misadministrations. As explained in NRC's October 17, 1988 letter to Mr. Monty Fu of Syncor, NRC now classifies such a series of events as a Severity Level III problem. However, no penalty is proposed in this case because, at the time that the events occurred, the classification of such incidents at Severity Level III, while in accordance with the Enforcement Policy, was a departure from past practice. Similar violations in the future may result in civil penalties.

Section IV of the enclosed Notice pertains to other violations identified during the course of the NRC inspection. Each of these violations has been classified at Severity Level IV respectively. A civil penalty is not assessed for these violations.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. As you are aware, following the NRC inspections conducted on July 6-8 and September 12-15, 1988, an Order was issued to Syncor International on October 12, 1988, which was prior to the completion of the OI investigation. The Order required Syncor International to address the issues known to NRC at that time, including the qualifications, training, and commitment of Syncor's employees to perform licensed activities and the adequacy of the corporate oversight of the licensed programs at Syncor facilities. While we are satisfied with Syncor's response to that Order, in light of the findings of the OI investigation, your response to this letter and Notice should address:

1. Actions (for example, orientation, training, and periodic refresher training) taken or planned to assure that, in the future, all individuals associated with NRC-licensed activities at Syncor facilities fulfill their responsibility to Syncor and to the NRC to conduct those activities, deal with NRC, and maintain NRC records, in a forthright and candid manner and in accordance with the requirements of 10 CFR 30.9.

2. Your basis for having confidence in the integrity of those employees involved in the violations in Sections I and II of the Notice and your basis for having assurance that those individuals will not, in the future, willfully commit violations of NRC requirements.

After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Action of 1980, Pub. L. No. 96-511.

Sincerely,

Carl J. Paperiello for

A. Bert Davis
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalties

RIII	RIII	RIII	RIII
Grobe/db	Norelius	Paperiello	Davis
08/ /90	08/23/90	08/23/90	08/23/90

DISTRIBUTION:
PDR
SECY
CA
J. Taylor, EDO
H. Thompson, DEDS
J. Sniezek, DEDR
J. Lieberman, OE
J. Goldberg, OGC
R. Bernero, NMSS
R. Cunningham, NMSS
Enforcement Coordinators
RI, RII, RIV, RV
F. Ingram, GPA/PA
B. Hayes, OI
V. Miller, SPA/SP
E. Jordan, AEOD
D. Williams, OIG
OE:J. DelMedico
OE:D. Burrier (P File)
OE:Chron
OE:EA
DCS
State of Ohio
RAO:RIII
PAO:RIII
SLO:RIII
R. Adams, RIII