Syncor
"The Service Difference"

Syncor International Corporation

November 5, 1996

U.S. Nuclear Regulatory Commission
Attn.: Document Control Desk
Washington, DC 20555

RE: Reply to a Notice of Violation, Syncor International Corporation, Chatsworth, CA (Glastonbury, CT) License No. 04-26507-01MD

To Whom It May Concern:

This letter is in response to the NRC's letter of October 7, 1996 regarding the inspection of Syncor's Glastonbury, CT, pharmacy, which was completed on September 17, 1996. Following is Syncor's response to the Notice of Violation:

1. This violation occurred because a staff member did not completely follow Syncor's procedures regarding iodine-131 capsule compounding, and did not perform adequate foot monitoring prior to exiting the restricted area. Syncor's procedures specify that post compounding surveys of the compounding area are to be made. Also, Syncor's procedures state that hand and foot monitoring is to take place each time a staff member exits the restricted area. A contributing factor to the inadequate surveys was that the staff member felt rushed to fill the prescriptions for the iodine-131 capsules.

   Following the identification of the iodine-131 contamination, the pharmacy staff performed surveys of the restricted area and of portions of the unrestricted area of the facility. Because only portions of the unrestricted area were surveyed, some iodine-131 contamination was missed. The pharmacy staff believed that the surveys they performed were representative of where the contamination would have been spread by the compounding pharmacist, and on that basis did not survey the entire unrestricted area of the pharmacy. Surveys were performed in the hallway leading away from the restricted area exit used by the pharmacist, and contamination was identified on a mat immediately outside the restricted area door, but not anywhere in the hallway leading away. Since contamination was not found anywhere else in the hallway, the pharmacy staff believed that they had identified all of the contaminated areas.

2. The following corrective steps have been taken at Syncor's Glastonbury pharmacy, with results achieved as noted:

   A. Retraining of the pharmacist involved was conducted. This consisted of a review of the iodine-131 compounding procedures, and a reiteration of the importance of careful hand and foot monitoring.

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B. Disciplinary action has been taken against the involved pharmacist for violating Syncor's procedures.

C. As an additional safeguard against the spread of iodine-131 contamination, the staff at this pharmacy are now surveying their feet prior to leaving the iodine-131 compounding room into the rest of the restricted area. A pancake type GM probe is being used for the survey.

D. To address the issue of the pharmacist feeling rushed, Syncor's customers have been given a more reasonable time frame for same day delivery of iodine-131 capsules that they order. If a pharmacist is unable to compound the capsule prior to the end of his/her shift, the order will be passed on to the next shift's pharmacist.

E. To minimize the opportunity for contamination to be spread outside of the radioiodine hood, gloves, absorbent paper, plastic wrap and other non-sharps waste generated while compounding iodine-131 capsules will now be bagged within the radioiodine hood. Sharps waste will continue to be stored for decay in the main fume hood as described in Syncor's capsule compounding procedures.

F. The foot monitor in place at the rear restricted area exit of the Glastonbury pharmacy has been upgraded to a model that utilizes more pancake type GM detectors (Ludlum Model 44-26, Pancake GM Foot Monitor). This improved foot monitor utilizes three pancake type GM detectors, whereas the monitor in place at the time of the event only used one pancake type GM detector.

G. Signs have been put up at each restricted area exit which read, "STOP - MONITOR HANDS AND FEET".

H. A reenactment of the event was performed with the involved pharmacist, supervised by the pharmacy Radiation Safety Officer. This was used as a training tool to identify weaknesses in the pharmacist's technique, and to investigate potential causes of the contamination.

To date, the above corrective actions have prevented recurrence of this type of event in this pharmacy.

3. To ensure that in all of Syncor's pharmacies required surveys are of sufficient detail and scope to identify contamination in pharmacy areas and on personnel, and that individuals are aware of the importance of conducting thorough surveys after handling materials, the following additional steps have been taken:

A. An in-depth evaluation of this event was provided to Syncor's NRC pharmacy staff. This evaluation described the details of the event, probable causes of the event, and methods to prevent occurrence of events of this nature. A reiteration of Syncor's expectation that all radiation safety procedures will be followed at all times was included, i.e., being rushed is no excuse for not following the procedures. A goal of this evaluation is to increase the level of awareness regarding this type of event, especially if unrestricted area contamination is involved or suspected.

B. To assist with reminding pharmacy staff to perform hand/foot surveys prior to exiting the restricted area, and expanding on the corrective action currently in place at the Glastonbury pharmacy, a new sign is being created to place on restricted area exits, with wording such as, "MONITOR HANDS & FEET BEFORE EXITING."

Syncor's Quality and Regulatory Department is informing all pharmacy managers that they should retrain all staff regarding proper iodine-131 compounding techniques, as well as proper exit monitoring. This retraining should be followed up by observations of the pharmacy RSO to assure proper performance.

C. A recommendation has been sent to all NRC pharmacy managers to evaluate their restricted area exit monitors to ensure that the monitors will adequately identify contamination. This included a recommendation for the Ludlum Model 44-26 Foot Monitor.

D. Syncor's Quality and Regulatory Department is reviewing the capsule compounding procedures for weaknesses which could possibly lead to the spread of contamination. Modifications to the procedures will be made as appropriate.

E. Syncor's audit staff have been briefed regarding this event, and will monitor for future compliance with the regulations, and Syncor's policies and procedures. Syncor's auditors directly engage pharmacy staff to determine their level of knowledge, and to assess if the pharmacy staff are properly carrying out their duties.

This typically consists of interviews of pharmacy personnel, and observations of the pharmacy staff performing their duties. While record keeping and other audit areas remain important items, increased significance is being given to the execution of duties by the pharmacy staff. Syncor's audit staff is currently evaluating methods by which they

can increase the depth to which they are able to evaluate a pharmacy's performance.

Syncor will continue to monitor the effectiveness of the corrective actions implemented, and make adjustments as necessary to prevent recurrence.

4. Full compliance with 10 CFR 20.1501 and License Condition 21 was achieved following the completion of all surveys after the discovery of the unrestricted area contamination on August 15, 1996.

Sincerely,

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