DCD

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

November 19, 1997

David W. Pellicciarini, C.H.P.
Program Manager, Health Physics
Syncor International Corporation
6464 Canoga Avenue
Woodland Hills, California 91367

SUBJECT: RADIOPHARMACEUTICAL PACKAGE CONTAMINATION

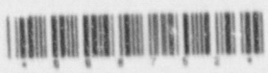
Dear Mr. Pellicciarini:

On May 6, 1997, you reported to the NRC Operations Center a personal contamination event that involved a Syncor-St. Louis Customer Service Assistant (CSA) and the Washington University Medical School, Barnes Hospital radiopharmacy. Your written report dated June 5, 1997, was submitted to the NRC as per 10 CFR 20.2203 and concluded that a contaminated needle that was dropped at the Barnes Hospital radiopharmacy was the most probable cause of the event.

On July 2, 1997, your staff provided to the NRC Region III office additional written information regarding the personal contamination levels and the dose assessment for the CSA that included values that showed greater contamination on the CSA's trousers than on the CSA's hands. Subsequently, you completed a re-enactment of the radiation surveys and estimated the contamination level on the CSA's trousers was substantially less than on the CSA's hands.

The Washington University Medical School Radiation Safety Officer (RSO), in a letter to the NRC dated September 24, 1997, estimated the contamination levels on the CSA and asserted that the Barnes Hospital radiopharmacy was not the source of the contamination and that the individual was contaminated before arrival at Barnes Hospital. According to the RSO, the highest levels of contamination were on the CSA's trousers. The RSO subsequently concluded that a one square centimeter spot on the back of the CSA's trousers was the most probable source of contamination of the CSA's hands, vehicle and the cases that were removed from Barnes Hospital. Also, the RSO completed reenactments of the dropped needle and estimated the maximum amount of radioactivity lost from the contaminated needle was less than his estimate of the activity on the CSA's trousers.

The NRC has concluded, after reviewing all the information provided by both licensees, that there is a lack of clear evidence that the contamination discovered at the Syncor St. Louis pharmacy came from the contaminated needle that was dropped on the floor of the Barnes Hospital radiopharmacy on May 6, 1997. We recognize that there were uncertainties associated with the contamination levels estimated by both licensees resulting in neither being able to determine the exact cause.



1/0

030006

IE07

Various errors and inconsistencies occurred in some of your data collected relative to this incident. In particular, it was noted that confidence in your reported values was lacking because: (1) there were errors in the initial values and survey techniques, (2) the values were not expressed in a standardized manner to allow for comparison, and (3) measurements were not performed at standardized distances from surfaces.

This incident was one of several package contamination events that has occurred in 1997 involving radiopharmaceutical shipments between Syncor and its customers. When contamination events of this type occur, it is essential that both Syncor and its customers implement well planned and consistent contingency procedures to accurately quantify the contamination parameters, adequately decontaminate equipment and personnel, and complete a timely root cause analysis that will aid in preventing recurrences

No reply to this letter is required; however, we did want to express our concerns regarding the above incident to emphasize the importance of implementing comprehensive and technically sound procedures that are consistently applied by the Quality and Regulatory staff and your pharmacy personnel.

Sincerely,

Linda Howell

for Ross A. Scarano, Director
Division of Materials Safety

Docket No. 030-33224
License No. 04-26507-01MD

E-Mail report to Document Control Desk (DOCDESK)

bcc to DCD (IE07)

bcc distrib. by RIV:
RIV Regional Administrator
RAScarano
LLHowell
MRShaffer
CLCain
DBSpitzberg
FAWenslawski
JLMontgomery
BPrange
RCaniano, RIII
NMI&FC\DB
RIV Materials Docket File - 5th Floor
WCFO Materials Docket File
RIII Materials Docket File

DOCUMENT NAME: G:\ST-LOUIS.WPD

To receive copy of document, indicate in box: "C" = Copy without enclosures "E" = Copy with enclosures "N" = No copy

RIV:DNMS:MB	C:MB	DD:DNMS	D:DNMS		
JLMontgomery	FAWenslawski	LLHowell	RAScarano		
11/14 /97	11/19 /97	11/17/97	11/ /97		

OFFICIAL RECORD COPY