DEC 17 1990

Docket No. 30-18918/90-01
License No. 35-19583-01MD

Syncor Corporation
Medical Services Group Center
ATTN: Brian Maxey, R.Ph.
Radiation Protection Officer
7212 East 38th Street
Tulsa, Oklahoma 74145

Gentlemen:

Thank you for your letter of November 13, 1990, in response to our request for further information dated November 7, 1990. We have reviewed your reply and find it responsive to the concerns raised in the Notice of Violation issued to Syncor on September 24, 1990 and to the questions raised during the exit briefing conducted on September 13, 1990.

Your corrective actions will be reviewed during future inspections to determine whether full compliance has been achieved and will be maintained. Should you have any questions regarding this matter, we will be pleased to discuss them with you.

Sincerely,
Original Signed By:
A. B. BEACH

A. Bill Beach, Director
Division of Radiation Safety
and Safeguards

cc:
Oklahoma Radiation Control Program Director

Frank Comer
Manager, Regulatory Compliance
Syncor International Corporation
20001 Prairie Street
Chatsworth, CA 91311

bcc w/copy of licensee letter:
DMB - Original (IE-07)
RDMartin
ABBeach
LAYandell
MRodriguez, OC/LFDCB (MS 4503)
CLCain
WLFisher
LLKasner
NMSIS
MIS System
RIV Files (2)
RSIS Operator

RIV:NMSIS	C:NMSIS	D:DRSS
LLKasner:ch	CLCain	ABBeach
12/13/90	12/13/90	12/19/90

IE-07

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REG4 LIC30
35-19583-01MD PDR

syncor®

November 13, 1990

A. Bill Beach, Director
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission-Region IV
611 Ryan Plaza Drive, Suite 1000
Arlington, Texas 78011

RE: Docket #30-18918/90-01
License 35-19583-01MD

Dear Mr. Beach:

With respect to your questions concerning similar training violations having occurred. They have not. At the conclusion of our corporate exit interview, and after reviewing the letter that Linda Kasner referenced, we found that Mr. Stinchcomb was the only pharmacist who had failed to have training by Mr. Brower before capsule compounding began at this location..

The letter that was referenced, stated only that the manager or RSO at a specific location would receive training from Mr. Brower prior to initiating the procedures for compounding I-131 capsules. Also the two Region IV license applications were unique in there content relative to I-131 capsule compounding because of a commitment made as a result of a question by the gentleman reviewing the amendment request, Mr. Whiten.

Both Linda Kasner and Dr. John Glen were called the day of the "corporate exit interview" and were informed of our findings relative to your concern in this matter.

Violation A.1. The reason for this violation was stated in Mr. Stinchcomb's reply. Actually the individual who set up the equipment i.e, glove box, shielding and initiated the procedure at this location had been trained by Mr. Brower in Allentown. This individual after setting up and initiating the procedure worked at this location for a period of four months. While Mr. Foti (the pharmacist who had been trained) was not designated as manager or RSO, he had been a manager and RSO at another Syncor location which had been closed, and had previously set up this procedure at that location.

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In Mr. Stinchcomb's reply, he indicated that he would be trained prior to November 30, 1990. Because Mr. Brower is leaving, Syncor's employee scheduling problems may require the training to be done in December. We therefore wish to indicated that compliance will be achieved by 12/31/90.

Violation A.2. To reason for this violation was failure of the customer services assistant to comply with the provisions of the license application and his training.

To prevent further violations the case covers will be modified as stated in Mr. Stinchcomb's letter and monitoring of compliance will be performed by the radiation safety officer. This requirement will also be addressed in on going training programs.

Violation B: The reason for this violation is that a customer service assistant failed to comply with the provisions of 49 CFR 177.8 17 (e) (2) (i).

To prevent further violations compliance with this DOT regu'ation will be stressed in future training programs and the RSO will monitor to see that shipping papers are located as required.

Sincerely,

Frank M Comer

Frank M. Comer
Manager, Regulatory Compliance

FC:dlo

cc: B. Maxey, Tulsa, OK
R. Stinchcomb, Kansas City, MO
License File

SEP 24 1990

In Reply Refer To:
License: 35-19583-01MD
Docket: 30-18918/90-01

Syncor Corporation
Medical Services Group Center
ATTN: R. Stinchcomb, R.Ph.
Radiation Protection Officer
7212 East 38th Street
Tulsa, Oklahoma 74145

Gentlemen:

This refers to the routine, unannounced radiation safety inspection conducted by Ms. L. L. Kasner and Mr. R. A. Leonardi of this office on August 27-28, 1990, of the activities authorized by NRC Byproduct Material License No. 35-19583-01MD. The findings of the inspection were reviewed with the radiation protection officer (RPO) at the conclusion of the inspection. These findings were also reviewed during a telephonic exit briefing conducted by Ms. Linda Kasner, Dr. Donna-Beth Howe, and Dr. John Glenn with Messrs. Frank Comer, Richard Kesee, and Gene McGrevin on September 13, 1990.

The inspection was an examination of the activities conducted under the license as they relate to radiation safety and to compliance with the Commission's rules and regulations and the conditions of the license. The inspection consisted of selective examinations of procedures and representative records, interviews of personnel, independent measurements, and observations by the inspector.

The inspector observed that the facility was well organized and that consideration had been given to appropriate placement of areas where high activity sources were stored and used in order to provide adequate shielding for personnel. Additionally, work areas were organized to reduce potential cross-contamination with respect to established traffic patterns within the lab. She noted that licensed materials had been properly received and stored, and no violations were identified regarding the use of byproduct material and subsequent dispensing and distribution of radiopharmaceutical products.

During this inspection, the inspector also reviewed the effectiveness of the Health Physics Group internal audits and the roles that the RPO and management serve in directing licensed activities. She noted that this facility had received good ratings for those internal audits conducted during this inspection period, and she generally concurred with the auditors' evaluations. Although some minor items requiring correction were noted in the audit reports, these had either been corrected or were currently under review. She further observed that the RPO had focused sufficient attention to the radiation safety program and that although many tasks were delegated to other individuals, the results of these surveys, tests, and evaluations were given adequate review by the RPO to ensure that they had been properly completed.

RIV:NMSIS	NMSIS	C:NMSIS	D:DRSS
LLKasner:nh	RLeonardi	CLCain	ABBeach
9/19/90	9/19/90	9/19/90	9/23/90

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During this inspection, certain activities were found not to be conducted in full compliance with NRC requirements. Consequently, you are required to respond to this matter in writing, in accordance with the provisions of Section 2.201 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations. Your response should be based on the specifics contained in the Notice of Violation enclosed with this letter. In preparing your response, please refer to the instructions provided in the enclosed Notice.

As reviewed with Syncor officials during the telephonic exit briefing, NRC believes that the violation regarding training provided to pharmacy managers for compounding iodine-131 capsules (noted as Violation A.1 in the enclosed Notice) may represent a licensing issue which needs to be promptly addressed. As reviewed during the aforementioned teleconference, NRC does not believe this problem to represent a significant safety issue at this time; however, it does represent a violation of the conditions of possibly more than one license and deserves further review by Syncor. Based on your review and evaluation, corrective actions should include other NRC licensed Syncor facilities with similar circumstances and license conditions.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter, the enclosures, and your response to this letter will be placed in the NRC Public Document Room.

The response directed by this letter and the accompanying Notice is not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

Should you have any questions concerning this letter, we will be pleased to discuss them with you.

Sincerely,
Original Signed By:
A. B. BEACH

A. Bill Beach, Director
Division of Radiation Safety
and Safeguards

Enclosure:
Appendix - Notice of Violation

cc:
Frank Comer
Chief Health Physicist, Licensing
Syncor Corporation
Chatsworth, California
Oklahoma Radiation Control Program Director

bcc:
DMB - Original (IE-07)
RDMartin
ABBeach
LAYandell
MRodriguez, OC/LFDCB (4503)
*CLCain
*WLFisher
*LLKasner
*RALeonardi
*NMSIS
*MIS System
*RIV Files (2)
*RSTS Operator
*REHall, URFO
J. E. Glenn, NMSS
D. B. Howe, NMSS

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APPENDIX

NOTICE OF VIOLATION

Syncor Corporation
Tulsa, Oklahoma

Docket: 30-18918/90-01
License: 35-19583-01MD

During an NRC inspection conducted on August 27-28, 1990, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1990) (Enforcement Policy), the violations are listed below:

A. License Condition 25 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in letters dated May 12, and August 17, 1987.

1. Item 9, of the letter dated May 12, 1987, references an attached training program outline and a letter from licensee management, dated December 12, 1986, concerning the training for personnel expected to compound iodine-131 capsules.

   The December 1986 letter specifies that each Syncor pharmacy manager or the radiation protection officer (RPO) at the specific location, will receive 1 week of training under the direct supervision of a specific individual in the Allentown, Pennsylvania lab before the compounding of iodine-131 therapy capsules may begin at a NRC licensed pharmacy.

   Contrary to the above, between August 1987 and September 1990, iodine-131 therapy capsules had been compounded at the Tulsa, Oklahoma, facility although the pharmacy manager (also the RPO) present during this period had not received 1 week's training under the supervision of the individual named in the license, but had instead received 1-2 days training from another pharmacist.

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

2. Item 9 of the letter dated August 17, 1987, specifies that provisions for entirely covering the packages being returned from customers, in accordance with the (licensee's) waste return policy, would be implemented. Specifically, Item 9 states that additional material would be added to the bottom and handle area of the slip over cover, or that an equivalent slip over cover which entirely covers the package would be used.

   Contrary to the above, as of August 28, 1990, the Tulsa, Oklahoma, facility had not provided for entirely covering packages returned from the licensee's customers in accordance with the licensee's waste return policy. Additionally, on August 27-28, 1990, the inspector observed packages returned from customers to the licensee's facility without the use of any slip over cover. (These packages contained technetium-99m products returned for disposal by the licensee.)

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

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B. 10 CFR 71.5(a) requires that licensees who transport licensed material outside the confines of their plants or deliver licensed material to a carrier for transport comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170-189.

49 CFR 177.817(e)(2)(i) requires, in part, that when the driver is at the vehicle's controls, the shipping paper shall be within his immediate reach and either readily visible to a person entering the driver's compartment or in a holder mounted to the inside of the door on the driver's side of the vehicle.

Contrary to the above, on August 27, 1990, the inspector determined that while transporting licensed materials, one of the licensee's drivers did not routinely carry shipping papers within his immediate reach, nor were they readily visible to a person entering the driver's compartment or in a holder mounted on the driver's door. These papers had instead been placed in the trunk or rear of the vehicle, as admitted by the driver.

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

Pursuant to the provisions of 10 CFR 2.201, Syncor Corporation is hereby required to submit to this office, within 30 days of the date of the letter transmitting this Notice, a written statement or explanation in reply, including for each violation: (1) the reason for the violation if admitted, (2) the corrective steps which have been taken and the results achieved, (3) the corrective steps which will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending the response time.

Dated at Arlington, Texas,
this 24th day of September 1990