

FEB - 4 1991

In Reply Refer to:
License: 35-23359-01MD
Docket: 30-20964/91-01

Syncor Corporation
ATTN: Karen Barker, R.Ph.
Pharmacy Manager
7801 North Robinson
Oklahoma City, Oklahoma 73116

Gentlemen:

This refers to the routine, unannounced radiation safety inspection conducted by Ms. L. L. Kasner of this office on January 14-15, 1991, of the activities authorized by NRC Byproduct Material License 35-23359-01MD, and to the discussion of our findings held by the inspector with the pharmacy manager at the conclusion of the inspection. These findings were later discussed during a telephonic exit briefing conducted by the inspector with Mr. Frank Comer on January 22, 1991.

The inspection was an examination of the activities conducted under the license as they relate to radiation safety and 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, and observation of individuals completing tasks associated with certain procedures reviewed during this inspection.

The inspector observed that the placement of work stations, waste storage areas, and those areas designated for the use and storage of molybdenum-99/technetium-99m generators and volatile radioiodine had been optimized to reduce unnecessary personnel exposure and maximize work efficiency. The facility, records, and work activities were generally noted to be well organized and workers were observed to be thorough in conducting transportation and facility radiation and contamination surveys. The inspector also observed that the pharmacy manager and staff were successful in ensuring that radiopharmaceutical and instrument quality control testing were conducted according to procedure and in a timely fashion.

Although this inspection revealed that the majority of activities had been conducted in accordance with NRC requirements, the inspector observed that certain of your activities were not conducted in accordance with specific license conditions. Consequently, you are required to respond to this matter in writing, in accordance with the provisions of Section 2.201 of NRC's "Rules of Practice," Part 2, Title 10, code of Federal Regulations. In preparing your response, please refer to the instructions provided in the enclosed Notice of Violation.

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The inspector also reviewed the actions you had taken with respect to the two violations observed during our previous inspection conducted on February 27, 1989. She noted that the violation regarding records for the pharmacy manager's training for procedures related to compounding therapeutic iodine-131 capsules had been corrected as required. The reason for the violation had previously been discussed during a conversation between Ms. Kasner and Mr. Comer regarding a similar violation observed at Syncor's Tulsa, Oklahoma, facility.

A second violation, involving the documentation of dose calibrator constancy test results, had not been corrected. This item is noted as Violation A.1 in the enclosed Notice. Although the inspector determined that the method used to conduct the test and evaluation of test results had been adequate during this inspection period, the test results had not been documented in accordance with the specifications provided in the license application. The inspector reviewed this matter with the pharmacy manager who acknowledged that the violation had been discussed with Syncor management and that as a result of this discussion, Syncor had determined that the violation had not occurred. However, this discrepancy was not discussed with NRC and no further corrective action was considered. This issue was discussed during the telephonic exit briefing conducted with Mr. Comer.

While NRC agrees that this specific license requirement is restrictive, nonetheless, we believe that the previous interpretation was correct and that the violation occurred as stated. We emphasize that as noted in our previous correspondence, by signing an NRC Form-591 you agree that the violation did occur and confirm that you will correct the violation within 30 days. Any discrepancy in interpretation should be brought to NRC's attention and discussed prior to making a unilateral decision regarding the validity of a citation.

A violation was also observed during this inspection concerning the distribution of radiopharmaceutical reagent kits. While this violation does not represent a significant safety risk, it is notable inasmuch as this issue had recently been identified at Syncor's Tulsa, Oklahoma, facility.

We wish to emphasize that NRC's Enforcement Policy encourages licensees to take the initiative to identify and correct violations of regulatory requirements or specific license conditions. In accordance with certain provisions of the policy, a licensee's review of similar facilities for the purpose of identifying and correcting further occurrences of previously cited violations is a requisite in order for NRC to exercise the discretion granted by the policy for self-identified violations. We encourage that you fully utilize this provision in the Enforcement Policy with regard to future inspection findings.

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.

Syncor Corporation

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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 w/enclosure:
Oklahoma Radiation Control Program Director

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

bcc:
DMB - Original (IE-07)
RDMartin
ABBeach
LAYandell
MRodriguez, OC/LFOCB (4503)
*WLFisher
*CLCain
*LLKasner
*NMSIS
*MIS System
*RIV Files (2)
*RSTS Operator
*REHall, URFO

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