

APPENDIX A
RADIOPHARMACY INSPECTION RECORD
Region I

Inspection record No. 2000-013

License No. 04-26507-01MD

Licensee (Name & Address):

Docket No. 030-33224

Syncor International Corporation
6464 Canoga Avenue
Woodland Hills, California 91367

Licensee Contact: Mary Ellen Giordano
Priority: 1 Program Code: _____

Telephone No. 215-781-2980

Date of Last Inspection: 3/30/99

Date of This Inspection: 12/20/2000 Site inspected 12/20/2000 is located at 200 Rittenhouse Circle, Bristol, PA

Type of Inspection: ☐ Announced ☒ Unannounced
 ☒ Routine ☐ Special
 ☐ Initial

Next Inspection Date _____ ☐ Normal ☐ Reduced ☐ Extended

Justification for change in normal inspection frequency:

Summary of Findings and Actions:

- ☐ No violations cited, clear NRC Form 591 or regional letter issued
- ☐ Non-cited violations
- ☐ Violation(s), Form 591 issued
- ☐ Violation(s), regional letter issued
- ☐ Followup on previous violations

Inspector(s) /RA/

Date 1/24/2001

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(Sign Name)

Teresa Hall Darden
(Print Name)

Approved /RA/

(Sign Name)

Date 2/27/2001

M. Shanbaky
(Print Name)

Issue Date: 05/07/98

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PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:
(License amendments issued since last inspection, or program changes noted in the license.)

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
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See Master License

2. INSPECTION AND ENFORCEMENT HISTORY:
(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders.)

1999 Inspection at this site was clear

3. INCIDENT/EVENT HISTORY:
(List any incidents, or events, reported to U.S. Nuclear Regulatory Commission since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)

None at this facility

PART II - INSPECTION DOCUMENTATION

- * References that correspond to each inspection documentation topic are in IP 87117, Appendix B, Radiopharmacy Inspection References.

The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that not all areas indicated in this part are required to be addressed during each inspection. However, for those areas not covered during the inspection, a notation ("Not Reviewed" or "Not Applicable") should be made in each section, where applicable.

All areas covered during the inspection should be documented in sufficient detail to describe what activities and procedures were observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the licensee demonstrated any practices at your request, describe those demonstrations. The observations and demonstrations you describe in this report, along with measurements and some records review, should substantiate your inspection findings. Attach copies of all licensee documents and records needed to support violations.

1. ORGANIZATION AND SCOPE OF PROGRAM:
(Management organizational structure; Radiation Safety Officer (RSO); type, quantity, and frequency of byproduct material use; staff size; number of facilities served; distribution and redistribution of materials; oversight by Food and Drug Administration/State)

This Syncor facility site operates under the Corporate Organizational structure in accord with its policies and directives. The Bristol Pa site is open from 1:00 a.m.

to 6:00 p.m. daily and distributes approximately 1632 doses a year. Iodine-131 is also compounded and distributed from this site. Six trucks and one small car operate from this facility. A certified nuclear pharmacist is scheduled to be on site during hours of pharmacy operation. This facility will be redistributing Iodine-125 brachytherapy seeds without opening packages received from the manufacturer. The staff received training for this function on 12/19/2000.

2. MANAGEMENT OVERSIGHT:

(Management support to radiation safety; RSO; authorized nuclear pharmacists and change notifications; supervision of drug preparation by the ANP; program audits or inspections; as low as reasonably achievable (ALARA) reviews; staff coverage)

Corporate program management oversight is provided from the California headquarters. Local management oversight is provided through the site RSO, who is a certified nuclear pharmacist and senior staff member. There is a regional manager who regularly visits the site and reviews activities. Compliance surveys/Audits are performed both by on site management and corporate management. During 2000 from January through October 23, 2000, at least eleven compliance surveys/Audits were conducted of activities at this site. When violations were identified, corrective actions were implemented and verified during the next compliance survey/Audit by the Auditor.

3. FACILITIES:

(Facilities as described; uses; control of access; fire protection; engineering controls; shielding; ventilation systems; maintenance program)

Facilities were as described in license. All engineering controls were operational and maintained as required.

4. EQUIPMENT AND INSTRUMENTATION:

(Operable and calibrated survey instruments and dosimetry; area and process monitors; maintenance; shielding; generators; procedures; 10 CFR Part 21 procedures; calibration records; fixed radiation monitors)

Equipment was operable and calibrated as required; No violations identified.

5. MATERIAL USE, CONTROL, AND TRANSFER:

(Materials and uses authorized; security and control of licensed materials; and procedures for receipt and transfer of licensed material; iodine handling)

Licensed materials were used, controlled and secured as required. No violations were identified.

6. OPERATING AND EMERGENCY PROCEDURES:

(Procedure development and availability; manufacturer's instruction; emergency preparedness; assistance arrangement with outside agencies)

Operating and Emergency procedures were available. Interviewed Staff were knowledgeable of all procedures. No violations were identified.

7. AREA RADIATION SURVEYS:

(Radiological survey locations and frequencies; leak tests; inventories; handling of radioactive materials; protective clothing; personnel monitors; safety precautions in preparation and use of drugs; records and reports; public doses)

Records review indicated that radiological surveys, leak tests and inventories were performed as required. The inspector observed that protective clothing and dosimetry were worn as required and material was handled in accord with safe rules for handling RAM. During this inspection, response to a spill was observed. Cleanup and surveys were handled safely and in accord with appropriate decontamination procedures.

8. TRAINING AND INSTRUCTIONS TO WORKERS:

(Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities; 10 CFR Parts 19 and 20 requirements; emergency response)

Interviewed staff were knowledgeable about routine activities, regulatory requirements, and emergency procedures. Observed appropriate response to spill during this inspection.

9. RADIATION PROTECTION:

(Radiation protection program with ALARA provisions; access control; dosimetry; exposure evaluations; dose and survey records and reports; annual notifications to workers; bulletins and other generic communications)

Observation of workers indicated that all wore film badges as required. Review of records revealed that, except for the following discussion, no staff exceeded the regulatory dose limits, and ALARA provisions were observed. However, review of the July 2000 Landauer Radiation Dosimetry Report revealed that 29.6 rem had been added to the Lifetime Equivalent Deep and Shallow Dose of one nuclear pharmacist. Further investigation indicated that the nuclear pharmacist had, on two occasions during 1999, while compounding I-131 capsules, contaminations had occurred which caused the work area as well as herself to become contaminated with iodine-131. Upon discovery of the self contaminations, which was within three hours of the contaminating event, the nuclear pharmacist decontaminated herself and then reported the incident to Corporate Health Physics (CHP) who performed dose assessments. In both instances, CHP advised the nuclear pharmacist to immediately take Thyro-block to block thyroid uptake. Bioassay results were negligible (approximately 3 nanocuries 9/99 & 1 nanocurie 12/99). The first incident occurred on 9/23/99 and was calculated to have added 0.587 rem to the shallow dose equivalent (SDE) or skin dose. The second incident occurred on 12/22/99 and was calculated to have added 28.473 rem to the SDE. Upon questioning of the dose received by the nuclear pharmacist, CHP stated that they had submitted the dose to Landauer, to be added to the nuclear pharmacist's SDE dosimetry record, but Landauer had misunderstood and added the dose to deep as well as to SDE. CHP said that they would call Landauer and straighten out the clerical error. Landauer reported to the inspector that when a licensee reports a dose to be added to a worker's record, unless otherwise specified by the licensee, the entire dose is added to all three areas; DDE (deep), SDE, and Eye (LDE). Landauer also stated that it is up to the licensee to request that the dose record be changed. On January 12, 2001,

Region I received a fax from Syncor Corporate which stated that the results on the Landauer Dosimetry Record was due to a clerical error and Landauer had been contacted during the first week of January 2001 to fix the error. With Syncor's revision of the dose assignment as indicated in the Landauer Record, the inspector concluded that there were no doses that exceeded the regulatory limits.

10. DECOMMISSIONING:
(Records relevant to decommissioning; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; Timeliness Rule requirements; changes in radiological conditions since decommissioning plan was submitted)

No decommissioning was in progress and none is planned at this time.

11. TRANSPORTATION:
(Quantities and types of licensed material shipped; packaging design requirements; shipping papers; hazardous materials (HAZMAT) communication procedures; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports.)

Review of transportation procedures and records revealed no violations or safety concerns.

12. NOTIFICATIONS AND REPORTS:
(Overexposure and misadministration reports; administrative changes in RSO, authorized users, and physicist; reports to individuals)

No violations or safety concerns were identified.

13. POSTING AND LABELING:
(Notices; license documents; regulations; bulletins and generic information; area postings; and labeling of containers of licensed material)

No violations or safety concerns were identified.

14. MISADMINISTRATION:
(Review misadministration cases, if any, and ensure appropriate corrective actions were taken.)

No violations or safety concerns were identified.

15. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:
(Areas, both restricted and unrestricted, surveyed and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date)

NRC 019613 Ludlum 14 C survey meter was used to perform surveys at the licensee's facility. NRC measurements were comparable with the licensee's. No violations or safety concerns were identified.

Debriefed with Branch Chief and Region IV Project manager

3. YEAR-2000 ISSUES:
(Convey, to the NMSS Year-2000 Coordinator, all year-2000 licensee-identified problems and corrective actions taken.)

None identified

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