U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT

REGION III

Report No. 03011339/81-01

Docket No. 030-11339

License No. 24-16617-01MD Priority I Category B

Licensee: Pharmaco Nuclear, Inc.
1734 E. 63rd Street, Suite 214
Kansas City, MO 64110

Inspection At: Pharmaco Nuclear, Inc., Kansas City, MO

Inspection Conducted: April 28, 1981

Inspectors: D. Wiedeman FOR R. E. Burgin 5-14-81

D. Wiedeman FOR W. J. Adam, Ph.D. 5-14-81

Approved By: D. G. Wiedeman, Acting Chief 5-14-81
Materials Radiation Protection
Section 1

Inspection Summary

Inspection on April 28, 1981 (Report No. 03011339/81-01)
Areas Inspected: RoutinE, unannounced inspection of licensee action on previous inspection findings; Organization; Use of Material; Facilities and Equipment; Exposure Controls - External, Dosimetry and Surveys; Exposure Controls - Internal; Receipt/Transfer of BPM; Rad-waste Disposal; Confirmatory Measurements; Leak Tests and Source Inventory; Training; Fire Protection and Audits. The inspection involved seven inspector-hours onsite by two NRC inspectors.
Results: Of the 14 areas inspected, no items of noncompliance were identified.

DETAILS

1. Persons Contacted

*Mr. Terrance O'Hara, Radiopharmacy Manager
*Mr. Frank Comer, Consulting Physicist

*Denotes attendance at exit interview on April 28, 1981.

2. Licensee Action on Previous Inspection Items

(Closed) Noncompliance 03011339/79-01: License Condition 16, calibration of survey instruments, corrected as described in letter to Region III dated January 7, 1980.

3. Organization

Amendment No. 10, dated January 24, 1980, lists Terry O'Hara, Richard E. Keesee, David A. Hurwitz, Ph.D., Frank M. Comer, Gary R. Redmore and Curtis R. Blaum as authorized users. Mr. Keesee is the president and no longer handles byproduct material. Mr. Comer serves as consulting physicist. The other named users are radiopharmacists (one still in training). The Kansas City facility also employs two technicians, seven drivers and a secretary/receptionist.

4. Use of Materials

The licensee is currently authorized to possess a maximum of 15 curies of molybdenum-99 in the form of Mo-99/Tc-99m generators. A review of receipt records indicated a weekly receipt of one 9.9 curie generator from Union Carbide, a 2.7 curie and a 2.2 curie generator from New England Nuclear. Xenon-133 is received in 10-20 mCi vials for redistribution only. The current possession limit for Xe-133 is 3 curies. The licensee reached this limit on February 27, 1981, and stated that if it appeared that the xenon possession limit was being approached, uncommitted doses of xenon would be given to authorized customers in order to avoid overpossession.

The maximum amount of Xe-133 possessed during 1980 (December 5, 1980) was 2848 mCi.

Other material received includes I-131 (as rose bengal and sodium iodide), Tl-201, Ga-67, I-125, I-123, Cr-51, Co-57, Yb-169, Se-75, P-32 and Fe-59.

No items of noncompliance were identified.

5. Facilities and Equipment

Facilities and equipment are as described in license amendment applications.

The facility consists of a large suite on the second floor of a professional building, housing several offices, reception area, employee lounge, lab, hot lab area and cold storage.

The licensee's radiation detection instruments consist of a Victoreen 740-F geiger counter, Victoreen 491 (Cutie-Pie) high range meter, a continuous area monitor and three dose calibrators (one Capintec and two Pickers). Survey meters and the area monitor are calibrated in-house on a quarterly basis. The inspectors reviewed instrument calibration records for 1980 through April 1981.

The license back-up material contains no specific reference to dose calibrator quality control tests; however, the methods are essentially those described in Regulatory Guide 10.8, Appendix D. Constancy checks are performed daily with both Co-57 and Cs-137 calibration sources. Accuracy tests are performed annually, and linearity checks are performed approximately quarterly by the Tc-99m decay method. Accuracy and linearity tests were being conducted on the day of and the day following this inspection.

Posting and labelling were examined during a tour of the facility. Restricted areas were clearly delineated. "Radiation Areas" were properly marked and the labeling of containers, including shipping containers, appeared adequate.

No items of noncompliance were identified.

6. Exposure Controls - External

The licensee controls external exposure through exposure rate measurements and whole body and extremity (finger) TLD and film badge monitors.

a. Dosimetry

All radiopharmacists, technicians, physicists and drivers are issued both whole body and extremity (ring) badges on a monthly basis. Badges are supplied and processed by Landauer Company. The licensee maintains complete NRC-Form 5 equivalents. The inspectors reviewed monthly exposure records for all personnel for the period January 1979, through March 1981. The single highest total annual exposure for whole body and extermity reports for the calendar years 1977, through 1980, are summarized below.

	1977*	1978*	1979	1980
Maximum Annual Whole Body Exposure (mR)	1210	560	530	320
Maximum Annual Extremity Exposure (mR)	21870	22780	8160	9620

*1977 and 1978 exposure data from IE Inspection Report No. 03011339/7901.

From a review of the above exposure table, there appears to be a general downward trend for both whole body and extremity exposures over the referenced period.

b. Surveys

The licensee is required to perform daily area surveys of all elution and preparation areas as well as weekly wipes for removable contamination. A log is maintained of the wipe test results.

Samples taken for removable contamination are counted in a well-type sodium iodide scintillation detector with a single-channel analyzer. Background counts ranged from 175 to 308 cpm. Two cases of contamination were noted. These areas were decontaminated and resurveyed. The locations of the wipes appear to be logically placed within the hot lab.

No items of noncompliance were identified.

7. Exposure Controls - Internal

Bioassays

The licensee is required to perform evaluations of I-131 concentrations to assure compliance with 10 CFR 20.103.

Currently this requirement is being met through monthly urine and thyroid bioassays. Thyroid uptake is evaluated using a three inch Picker Magnascanner with scaler, calibrated with an I-131 capsule of a nominal ten microcuries in a lucite thyroid phantom. A constancy check is performed before use with a Cs-137 calibration source. A review of bioassay results showed no I-131 uptakes which were significantly above background. While the data was recorded in cpm only, and efficiency valve for the counting system with respect to I-131 was available.

No items of noncompliance were identified.

8. Receipt and Transfer of Material

The licensee maintains an authorized user listing as required by 10 CFR 30.41. Packages on hand appear to be appropriately labelled and conform with DOT specifications. Contamination surveys (GM surveys and wipes) of both incoming and outgoing packages are performed; however, no record of the results of these surveys is maintained other than the transport index on the outgoing packages. No reportable shipping events were noted.

No items of noncompliance were identified.

9. Rad-Waste Disposals

All wastes are divided into either "Technetium Waste" or other "Short-lived Materials" (I-131, Xe-133, Ga-67, etc.). A separate log is maintained for both groups. Waste syringes, vials, containers, etc., are stored for decay for several years prior to disposal. Records reviewed indicated two waste disposals had been made; one on January 25, 1979 (1975, 1976 and 1977 wastes), the other on October 11, 1980 (1978 and 1979 wastes). Surveys of the waste were made prior to disposal, and the results documented. The licensee makes no disposals via release to the atmosphere or sanitary sewerage.

No items of noncompliance were identified.

10. Independant Measurements

During this inspection, an area survey of the hot lab and waste storage room was performed using a Xetex 305B (NRC Serial No. 007854, calibrated March 9, 1981). A waste container holding spent syringes for decay, measured 5.0 mR/hr on the surface. Ambient levels in the waste storage room were 1.2 to 2.0 mR/hr at approximately three feet above the floor. The newest shielded generator measured 2.4 mR/hr at approximately six inches from the surface. Levels within the hot lab, including dose preparation areas, hoods and the dose calibrator were at or near background.

No items of noncompliance were identified.

11. Leak Tests and Source Inventory

The licensee is required by license condition to perform leak tests every six months on all sealed sources of 100 microcuries or greater containing material, other than hydrogen-3, of a half life greater than thirty days. Leak test results were reviewed for 1979 and 1980. No results above 0.005 microcuries of removable contamination were noted.

The most recent source inventory, conducted January 12, 1981, included: one 265 microcurie Ba-133 source, two Co-60 sources of less than 100 microcuries each, one 217 microcurie Cs-137 source and one 96.1 millicurie Cs-137 source. A number of these sources are used as check or calibration sources and the inventory information required by 10 CFR 35.14(f)(2) is recorded when the source is used (at least quarterly).

No items of noncompliance were identified.

12. Training

Training requirements of 10 CFR 19.12 are fulfilled with a two-hour training tape which covers Parts 19 and 20, radiation units, purposes and function of dosimeters and radiation protection procedures. The

training is provided to all individuals who enter the restricted area, including drivers.

No items of noncompliance were identified.

13. Fire Protection

The licensee has provided tours of their facility to members of the local fire department on several occasions. In addition to this, a letter is submitted to the Fire and Police Department annually, advising them of the fact that radioactive materials are kept on the premises. There is also an annual inspection of the facility by the Fire Marshall.

No items of noncompliance were identified.

14. Audits

A quarterly audit of licensed activities is conducted by the consulting health physicist and includes a review of posting, personnel monitoring, surveys, disposal records, inventories, leak tests and instrument calibrations. A record of these audits is maintained.

No items of noncompliance were identified.

15. Exit Interview

An exit interview was held at the conclusion of the inspection on April 28, 1981, with licensee representatives denoted in Paragraph 1. Items discussed included corrective actions on previous items of noncompliance; personnel radiation exposure trends; and the possible re-prioritization of the license.