U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 82-01(DETP)

License No. 34-19089-01

Docket No. 30-16055 Priority I Category B

Licensee: Advanced Medical Systems, Inc.
1020 London Road
Cleveland, OH 44110

Inspection Conducted: January 6, 1982

Inspector: R. E. Burgin R.E. Burgin 2/19/82

Approved By: D. J. Sreniawski, Chief D.J. Sreniawski 2/19/82
Materials Radiation Protection
Section No. 2

Inspection Summary

Inspection on January 6, 1982 (Report No. 82-01)
Routine unannounced inspection - Areas Inspected: Organization and administrative control; health physics practices and procedures; facility air sampling; personnel monitoring; air and liquid effluents; waste shipments and disposals; area surveys; instrumentation; use of material and license conditions. The inspection involved six inspector hours onsite by one NRC inspector.
Results: No items of noncompliance or deviations were identified.

DETAILS

1. Persons Contacted

Information for this routine safety re-inspection was provided by the following licensee representatives:

Mr. Darwin Murray, Service and Source Fabrication Manager
Mr. Robert J. Skritch, Sales Support Manager
Mr. Peter Holman, Sales Coordinator
Mr. Glen Sibert, Service Engineer

The Ohio State Health Department was notified of this inspection, however, no representative of that agency was present during the inspection.

2. Use of Material

Under License No. 34-19089-01 the licensee uses byproduct material, primarily cobalt-60, for the fabrication and distribution of teletherapy sources to authorized recipients, research and development of sealed sources, and removal and replacement of sealed sources in Picker, Advanced Medical Systems and Keleket-Barnes Teletherapy Equipment. During the calendar year 1981, approximately 40 sources were distributed, including 14 newly fabricated sources.

3. Personnel Radiation Protection - External

External radiation exposure is monitored by film badges supplied by Radiation Detection Company. Whole body badges are processed on a weekly basis and wrist badges are processed once a month. In addition, all personnel involved in the fabrication, exchange or loading of sources wear pocket dosimeters.

Past exposure histories (Form NRC-4) have been prepared for all personnel involved in the source fabrication, exchange and loading program. Therefore, personnel are permitted to receive whole body exposures of up to three (3) rem per quarter. The film badge records were reviewed for November 1, 1979 through September 21, 1981. During this period the maximum quarterly whole body exposure was 2.615 rem and the maximum quarterly extremity exposure was 3.030 rem. All personnel exposures for this period were within the limits specified in 10 CFR 20.101(b). Dosimeter readings agreed with exposures shown on the film badge processor's report.

The maximum quarterly and annual exposures are summarized below for calendar years 1979, 1980 and 1981 (through September 21, 1981).

	EXTREMITY (mrem)		WHOLE BODY (mrem)	
	High Quarter	Annual	High Quarter	Annual
1979	125	125	45	45
1980	3030	3030	3615	3690
1981*	1240	2970	1775	3450

*Through September 21, 1981.

No items of noncompliance were identified.

4. Personnel Radiation Protection - Internal

Internal radiation exposure is monitored by whole body counting at Toronto General Hospital, Whole Body Counting Center, Toronto, Canada. Personnel engaged in the source fabrication program are given whole body counts twice each year under the supervision of K. G. McNeill, Ph.D. of Toronto General Hospital.

The range of results since 1980 were:

April 7, 1980	0-21 nanocuries (Co-60)
October 23, 1980	0-16 nanocuries
April 27, 1981	0-10 nanocuries
November 23, 1981	3-7 nanocuries

All results were less than the 10 microcurie whole body MPBB* for cobalt-60.

No items of noncompliance were identified.

*ICRP Handbook, page 206.

5. Surveys

a. Restricted Areas

Direct reading radiation (GM) surveys and contamination (smear) surveys are performed in the restricted areas every 31 days or less. The survey records were reviewed for 1980 through December 21, 1981. During this period, the highest levels of removable contamination were found in the decon-room of the restricted lab and certain basement locations. High levels ranged from 2.215×10^5 dpm/ft^2 (filter room) to 1.408×10^6 dpm/ft^2 (restricted area of basement). The highest radiation levels (also in the restricted basement and decon room) were 200-300 mR/hr.

b. Unrestricted Areas

Direct reading and smear type surveys are performed of unrestricted areas every 14 days. The records were reviewed for 1980 through

December 14, 1981. During this period, the removable contamination ranged from 0 dpm to 238 dpm per square foot. The licensee has an action level of 200 dpm* at which point the area is decontaminated until the level is below the 200 dpm. The records of direct radiation surveys show all radiation levels in unrestricted areas were less than 1.3 mR/hr.

*(well counter efficiency = .085).

No items of noncompliance were identified.

6. Air Sampling

a. In-Plant

Continuous fourteen-day air samples are collected in the hot laboratory at two locations. Both sampling heads are permanently mounted; they are calibrated for flow rate every three months. Filter papers are exchanged every fourteen days and evaluated.

Although the air samples are run continuously, the licensee uses a dilution time of 72 to 112 hours per two weeks to determine concentrations of activity released to restricted areas. Use of the smaller volume of air results in concentration estimates that are conservative. In-plant air concentrations were reviewed for the period 1980 through December 1981.

During this period, the maximum concentration noted in restricted areas was 2.25×10^{-9} µCi/ml in 1980 and 5.11×10^{-10} µCi/ml in 1981. The MPC for insoluble cobalt-60 is 9×10^{-9} µCi/ml.

The hot cell air sampling consists of a 10 minute air sample taken before each entry into the hot cell. This sample is obtained using a filter holder which is mounted on the end of a length of tubing which is passed down an access port in the hot cell wall and then connected to a vacuum pump which has a flow meter in line. Pre-entry samples are taken to determine "stay time" in the hot cell. In addition, samples are taken during actual occupancy of the hot cell. Records reviewed from 1980 through December 1981, showed the maximum concentration for pre-entry was 1.24×10^{-6} Ci/ml. Calculations showed the maximum allowable "stay time" was five minutes, however, no entry was made. The maximum calculated stay time (for Co-60 concentration of 6.41×10^{-8} µCi/ml) was 360 minutes; maximum actual stay time was only 170 minutes.

Mine safety appliance half face masks with Type H cannister filters are worn each time an individual enters the hot cell. Although respirators are worn during all cell entries, no allowance is made for the use of respirators.

b. Stack

The stack effluent is determined by continuously monitoring a filter paper sampler with a MD-1, 1.4 mg/cm^2 end window GM tube connected to a Picker Model 600049 Labmeter (data recorded by a Picker Model 2990 strip chart recorder). The air flow through the stack sampler averages 7.5 CFM. Stack monitoring records were reviewed from 1980 through December 1981. The 1980 maximum and average concentrations were 1.09×10^{-14} µCi/ml (4/25/80) and 9.79×10^{-15} µCi/ml, respectively. The 1981 maximum and average concentrations were 1.52×10^{-14} µCi/ml (9/17/81) and 5.22×10^{-15} µCi/ml, respectively. All stack effluents were well below the maximum permissible concentration of 3×10^{-10} µCi/ml for unrestricted areas.

No items of noncompliance were identified.

7. Waste Disposal

a. Liquid

Liquid radioactive waste is disposed to the sewer in 50 gallon batches. Waste is dumped from the top of the holding tank into a 55 gallon drum. If sampling shows the concentration in the drum is within permissible limits the 50 gallons of liquid is discharged into the sanitary sewer. The total cobalt-60 release to the sewerage system in 1980 was 10.605 millicuries. The 1981 total was 15.616 millicuries. Records showed all releases were below Part 20 limits.

b. Solid

The licensee plans to dispose of solid radioactive waste by transferring it to a licensed waste disposal agency; however, there have been no shipments of radioactive waste since the issuance of this license November 2, 1979.

No items of noncompliance were identified.

8. Independent Measurements

Direct reading radiation (GM) measurements were made at various locations throughout the licensee's facility with a Xetex-305B, NRC No. 008997, last calibrated October 15, 1981. All general areas were <0.1 mr/hr; the hot cell window was <0.2 mr/hr; and the source/head storage room ranged from 0.1 to 55.0 mr/hr (restricted area). All radiation levels in restricted and unrestricted areas were within regulatory limits. All areas were posted with appropriate radiation warning signs.

No items of noncompliance were identified.

9. Quality Assurance

a. Leaks Tests

All sealed sources are leak tested by the licensee prior to transfer to a customer to assure that removable contamination does not exceed 0.005μCi.

b. Survey Meter Calibrations

The licensee calibrates their survey instruments every six months. There are approximately a dozen G-M meters maintained in a "ready state." A calibrated survey meter accompanies each source installation kit. The shipping records include the survey meter serial number and the calibration date. Any instrument that has not been calibrated within a six-month period is not used until it is recalibrated.

No items of noncompliance were identified.

10. License Conditions

All license conditions were reviewed during the inspection and no problems were noted.

No items of noncompliance were identified.

11. Management Interview

At the conclusion of the inspection, an interview was held with Mr. Darwin Murray, Service and Source Fabrication Manager, and Mr. Robert Skritch, Sales Support Manager. They were informed that no items of noncompliance were identified during this inspection.