

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

REGION III

Report No. 03004306/81-01

Docket No. 030-04306

License No. 12-13813-01

Priority 1

Category B

Licensee: Medi-Physics
3350 North Ridge
Arlington Heights, IL 60004

Inspection At: Medi-Physics, Arlington Heights, IL

Inspection Conducted: April 8 and 9, 1981.

Inspectors:

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4/23/81

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4/27/81

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Section 1

4/27/81

Inspection Summary

Inspection on April 8 and 9, 1981 (Report No. 03004306/81-01)

Areas Inspected: Routine, unannounced inspection of licensee action on previous inspection findings; Organization; Use of Material; Facilities and Equipment; Exposure Controls - External, Dosimetry, Surveys and Environmental Monitoring; Exposure Controls - Internal, Air Monitoring; Receipt/Transfer of BPM, Distribution; Rad-Waste Disposal and Effluents; Confirmatory Measurements; Internal Audits/Radiation Safety Committee; Leak Test; Training; and Emergency Planning/Fire Protection. The inspection involved 14 inspector-hours onsite by two NRC inspectors.

Results: Of the 13 areas inspected, no items of noncompliance were identified.

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DETAILS

1. Persons Contacted

- *David Gallagher, Plant Manager
- *Richard A. Allen, Health Physics Technician II, RSO
- *Mark Doruff, Health Physics Technician

*Denotes those present at exit interview on April 9, 1981.

2. Licensee Action on Previous Inspection Items

(Closed) Noncompliance 03004306/79-01: 10 CFR 20.407, Annual Exposure Report submitted June 8, 1979.

(Closed) Noncompliance 03004306/79-02: 10 CFR 20.101(a), Extremity over-exposure, see letter to Region III dated July 20, 1979.

(Closed) Noncompliance 03004306/79-02: License Condition 12, unauthorized users, found to have been corrected as described in letter to Region III dated September 6, 1979.

(Closed) Noncompliance 03004306/79-02: 10 CFR 20.203(c), CHS posting, found to have been corrected as described in letter to Region III dated September 6, 1979.

3. Organization

David Gallagher - Plant Manager
Richard Allen - Health Physics Technician, RSO
Charles Anderson - Alternate, RSO
Tom Springer - Operations Manager
Mary Papantos - Production Supervisor
Ted Larason - Production Supervisor
Mark Doruff - Health Physics Technician
Kiron Trivedi - Production Technician III
Mike Dickerson - Production Lead Technician
Gerry Wilgus - Production Chemist II

4. Use of Material

The licensee is authorized to possess and use approximately 25 byproduct material isotopes of various forms for testing and production of radiopharmaceuticals, for use as reference standards and for distribution to authorized individuals. Material actually possessed at the time of this inspection, aside from trace contaminants received as part of the Mo-99 metal, included: Xe-133 as a gas in prepackaged units, Mo-99 as 250 Ci metallic bars, Cs-137 as a 3 Ci sealed source, an Eu-152 calibration source and three nominal 10 microcurie Am-241 calibration/check sources. The Mo-99 is received

twice weekly. The running total for Mo-99 on hand ranged from 179 Ci to 454 Ci for January 1981. Current trends indicate reduced use of byproduct materials in favor of cyclotron produced materials.

The maximum amount on hand of Xe-133 for January 1981, was approximately 16 Ci. The Xe-133 is only being repackaged for distribution to authorized individuals. Approximately 18-20 individuals are involved with the use of byproduct materials.

No items of noncompliance were identified.

5. Storage

All byproduct materials are secured within the restricted area, including waste and prepackaged materials. The 3.0 curie Cs-137 calibration source is stored in the waste pharmaceutical decay storage room which is locked and posted. No material was observed in an unrestricted area.

No items of noncompliance were identified.

6. Facilities and Equipment

Facilities and equipment are as described in license amendment applications. The licensee is currently constructing a second cyclotron unit at the facility.

a. Survey Instruments

A list of the licensee's radiation detection instruments is included as Attachment I. The number and kind of instruments appeared appropriate for this program.

The licensee is required by license condition to calibrate survey instruments and area monitors on a semiannual basis. The inspectors reviewed calibration records for 1979 and 1980 and determined that the instruments were being calibrated in a timely manner. Survey instruments were being calibrated in-house at two points on each scale using the 3.0 curie Cs-137 source. Area monitors and count rate meters are being calibrated electronically. A monthly electronics check on these instruments is also being performed.

b. Posting and Labeling

Posting and labeling were examined during a tour of the facility. Restricted areas were clearly delineated with both "Caution - Radioactive Material" signs and yellow and magenta boundary markers. "Radiation Areas" and "High Radiation Areas" were properly marked including the radioactive waste storage room. Labeling of containers, including shipping containers, appeared appropriate.

No items of noncompliance were identified.

7. Exposure Controls - External

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

a. Dosimetry

All Production, Health Physics and Quality Control personnel are issued whole body, right hand and left hand extremity (ring) badges on a monthly basis. Badges are supplied and processed by Radiation Detection Company (California). The licensee maintains complete NRC Form 4 and NRC Form 5 equivalents. The inspectors reviewed the quarterly exposure records for all Production, Health Physics and Quality Control personnel for the period April 1979, through December 1980. The quarterly averages and highest single exposure are summarized by department in Attachment II. From a review of these exposure records, there appears to be a general downward trend for both averaged and single high exposures for all groups since third quarter 1979.

One overexposure occurred during second quarter 1979. This was a 24.14 rem extremity exposure to the left hand of a production worker. The details are covered in licensee's letter to Region III dated July 20, 1979, and in Inspection Report No. 03004306/79-02.

Annual exposure summaries are enclosed as Attachments III and IV for calendar years 1979 and 1980, respectively. The 1979 high exposure was in the 6.0 - 7.0 rem range, while the 1980 high exposures had dropped to the 4.0 - 5.0 rem range.

Self-reading pocket dosimeters are read and recorded daily. Exposures are tabulated semi-monthly by the RSO, and are compared with whole body badge results. The RSO also maintains a separate log for all persons recording greater than 50 millirem in one day.

It should be noted that the licensee's use of byproduct material (primarily molybdenum-99/technetium-99m and xenon-133) has been reduced and cyclotron product use has increased. Further increases in the use of cyclotron products are anticipated upon the completion of the facility's second cyclotron unit.

b. Surveys

A condensed survey schedule is included as Attachment V. Surveys for removable contamination are performed by taking 100 cm² wipes and counting with a NaI single channel analyzer. Various sites within the restricted and unrestricted areas are sampled. Survey results of restricted areas reviewed for 1980 and 1981 ranged from 0 dpm to 378,530 dpm/100 cm². The area requiring decontamination most frequently was the thallium-processing hot cell. Common contamination in the restricted area

were Pb-201, Tl-202, Tl-201 and Mo-99. The licensee maintains an action level of 5000 dpm/100 cm² for decontamination of restricted areas. Decontamination efforts are documented in the survey results form. Occasionally, decontamination of the hot cell and target processing lab is deferred. This is only the case when: (1) it would cause a major interruption in processing or, (2) personnel exposure could be reduced by allowing the contaminant to decay to acceptable levels in lieu of decontamination, as in the case of Tc-99m.

Wipe surveys of most unrestricted areas are performed on a weekly basis. Survey results ranged from 0 dpm/100 cm² to 71,190 dpm/100 cm². Contaminants routinely include Tl-201 and Tc-99m. The action level for decontamination of unrestricted areas is 1000 dpm/100 cm². Decontamination efforts were documented in the survey result forms.

Area surveys are also performed in the restricted area. These surveys are performed with an Eberline E-120 using the HP-270 energy-compensated probe. Survey results ranged from 0.02 mr/hr to 24 mr/hr. The waste storage area yielded the highest readings.

Results of contamination surveys performed during this inspection are reported in Attachment VII.

No items of noncompliance were identified.

c. Environmental Monitoring

The licensee maintains TLD and film dosimeters on the exterior walls and roof of the hot lab and cyclotron vault. Monthly doses ranged from "minimal" to 403mr for the period August 1979 to the date of this inspection.

No items of noncompliance were identified.

8. Exposure Controls - Internal

The licensee is required by license condition to perform continuous air sampling of the restricted area with collection and analysis to occur five times weekly. This satisfies the 10 CFR 20.103 requirement to evaluate airborne concentrations. Air samples are drawn from each of the restricted areas at a known flow rate through charcoal filter cartridges of known efficiency. Air sampling results for 1980 and 1981 were reviewed by the inspectors. For the month of December 1980, cumulative totals for Tc-99m and Mo-99 were 2.25 E-10 microcuries/milliliter and 1.26 E-10 microcuries/milliliter, respectively. These totals appeared to be representative of monthly cumulative concentrations for 1980 and the first quarter of 1981.

Bioassays are being performed to evaluate uptake of airborne, accelerator produced materials.

No items of noncompliance were identified.

9. Receipt and Transfer of Material

The licensee maintains an authorized user listing to comply with 10 CFR 30.41. Packages on hand appeared to be appropriately labelled and conform with DOT specifications. A record of surveys of incoming packages is maintained. No abnormal contamination levels were noted with respect to either removable contamination or surface dose rates from the molybdenum shipments. No reportable shipping events were noted.

No items of noncompliance were identified.

10. Rad-Waste Disposals and Effluents

The licensee utilizes three means of radioactive waste disposal; release to the sanitary sewerage system, atmospheric releases and commercial waste vendors.

a. Vendors

The licensee employs Nuclear Engineering Company (NECO) for commercial disposals. Records reviewed indicated waste transfers were made in January, April and December 1980, and February 1981. All paperwork associated with the transfers appeared to be in order. The inspectors also examined 55-gallon waste drums awaiting pick-up by NECO. No free-standing liquids were observed. The licensee maintains current copies of the applicable NRC and DOT regulations for waste shipments. A copy of the licensee's "Radioactive Waste Release Check List" is enclosed as Attachment VI.

b. Releases to the Atmosphere

Air from various process hoods and rooms is exhausted through a HEPA/charcoal filter system to a stack on the roof. Sampling of the exhaust occurs via the same system that is used to monitor airborne concentrations in the restricted and unrestricted areas. Sampling results for November 1980, showed cumulative totals of 2.38 E-11 microcuries/milliliter and 4.13 E-12 microcuries/milliliter for Tc-99m and Mo-99, respectively. These results appeared to be representative of other monthly cumulative totals for 1980 and 1981.

c. Releases to the Sanitary Sewer System

Waste water from laboratory areas where there is a possibility of contamination, drains into one of two 1000-gallon retention tanks where the material is allowed to decay to acceptable

levels before discharge. The tanks are allowed to fill to a 95% full level, sampled for radionuclide concentration and discharged to the sanitary sewer system. Discharge occurs approximately once daily.

Quarterly cumulative totals for 1980 (including accelerator produced materials) were: 70.27mCi, 118.31mCi, 150.83mCi and 200.39mCi. The licensee and NRC sample results of April 8, 1981, holding tank samples are reported in Attachment VIII.

No items of noncompliance were identified.

11. Audits/Radiation Safety Committee

No formal audit function is specified by license condition. However, licensed activities are reviewed by the Radiation Safety Committee monthly. The committee is composed of authorized users, specifically, those department heads responsible for all activities involving the use of radioactive materials, and is chaired by the Radiation Safety Officer. The inspectors reviewed Radiation Safety Committee minutes for 1980, which documented areas discussed such as: trends in personnel dosimetry results, air sampling results, proposed and completed training sessions and changes in regulations or operating procedures. Committee meeting minutes are submitted to corporate management.

Additional responsibilities of the committee include review of unusual occurrences or incidents and evaluations of employee qualifications for expanded use of materials.

No items of noncompliance were identified.

12. Leak Tests

The licensee is required to perform leak tests of sealed sources in accordance with 10 CFR 35.14(e)(1)(i) and License Condition 13, at intervals not to exceed six months.

Sealed calibration sources in the licensee's possession consist of three americium-241 check sources (nominal ten microcuries each). All were leak tested in May and November of both 1979 and 1980.

The licensee also possesses one cesium-137 source (3.0 curies on July 24, 1979) for in-house survey instrument calibrations. This source has been leak tested semi-annually. The last leak test was conducted on February 24, 1981.

No items of noncompliance were identified.

13. Training

A training program is not specified by license condition or application. However, a three part training program is being conducted. The first segment of the program is a health physics orientation course taught by the Radiation Safety Officer and covers such areas as: posting, regulatory agencies, radiation units, basic nuclear physics, contamination, use of survey meters and dosimeters, and the contents of Regulatory Guide 8.13. This is followed by a period of supervised training under an authorized user (production supervisor). Finally, an employee may attend an advanced training series. The most recent four week session from this series dealt with detection of an unknown sample using a Ge(Li) detector.

Interdisciplinary general safety training is also conducted at weekly intervals and has included use of full-face respirators and contamination control.

Records of each individuals in-house training history are maintained and were reviewed by the inspectors. Parts 19 and 20 are issued to workers and a signed receipt statement is maintained.

No items of noncompliance were identified.

14. Emergency Planning/Fire Protection

The licensee has posted safety and emergency procedures and conducts workshops for major spills of byproduct material. The facility is equipped with automatic alarm sprinkler systems, in addition to smoke detectors, heat detectors and portable fire extinguishers. Security is maintained with motion detectors and door alarms.

The licensee provided tours of the Medi-Physics facility to 50-60 members of the Arlington Heights Fire Department and Rescue Squad, who have drafted a proposed Fire-Fighting Plan. Arrangements have also been made with Northwest Community Hospital in Arlington Heights in the event of incidents resulting in the overexposure or contamination of Medi-Physics personnel.

No items of noncompliance were identified.

15. Exit Interview

An exit interview was held at the conclusion of the inspection, on April 9, 1981, with licensee representatives denoted in Paragraph 1. Items discussed included corrective actions taken for previous items of noncompliance; personnel radiation exposure trends; the reduction of byproduct material use and the increased use of cyclotron products; the results of independent surveys of specific processing/production areas and holding tank samples; and the possible re-prioritization of the license.

Attachments: As Stated

NRC 313-I - Item 10 - Radiation Detection Instruments

<u>Type of Instrument</u>	<u>Manufacturers Name</u>	<u>Model Number</u>	<u>Number Available</u>	<u>Radiation Detected</u>	<u>Sensitivity Range</u>
Count Rate Meter	Eberline	E520/HP270G	2	γ	0-2000 mR/hr
Count Rate Meter	Eberline	E120/HP270	2	β-γ	0-50 mR/hr
Ion Chamber	Eberline	RO-2	1	β-γ	0-5 R/hr
Ion Chamber	Eberline	RO-2A	1	β-γ	0-50 R/hr
Count Rate Meter	Eberline	PAC4G-3/AC21B	1	α-β-γ	0-500,000 cpm
SCA/NaI	Ludlum/Eberline	2200/SPA-3	1	γ	0-999,999 counts
HFM	Ludlum	40	1	β-γ	0-50,000 cpm
Ion Chamber	Eberline	RO 5-C	1	β-γ	0-199.9 R/hr
Neutron Rem Counter	Eberline	PRS-1/NRD	1	n	0-99,999.9 rem/hr
Area Monitor	Xetex	501A	1	γ	0-99.9 mR/hr
Count Rate Meter	Ludlum/Eberline	177/PP210	4	β-γ	0-500,000 cpm
Count Rate Meter	Eberline	RM 15/HP210	2	β-γ	0-500,000 cpm
Count Rate Meter	Eberline	RM-14/HP100	2	β-γ	0-50,000 cpm
Ion Chamber	Eberline	PIC-6A	2	γ	0-1000 R/hr
Teletector	Eberline	6112	1	β-γ	0-1000 R/hr
Count Rate Meter	Ludlum/Eberline	14A/HP270G	2	γ	0-200 mR/hr
Area Monitor	Eberline	RMS II	2 channels	γ	0-100 mR/hr
MCA/Ge(Li)	Canberra	8100e/7000	2	γ	0-999,999 counts

QUARTERLY WHOLE BODY AND EXTREMITY (RING) EXPOSURES (IN REMS)

Exposures averaged by department. Number in parentheses is highest single exposure.

Year-Quarter	PRODUCTION			HEALTH PHYSICS			QC		
	Whole Body	Rt. Hand	Lt. Hand	Whole Body	Rt. Hand	Lt. Hand	Whole Body	Rt. Hand	Lt. Hand
1979 - 2	1.034 (1.945)	9.626 (18.71)	9.863 (24.14)*	(Not Reviewed)			0.107 (0.207)	4.083 (10.55)	3.425 (5.45)
- 3	1.174 (2.005)	9.477 (13.52)	10.378 (14.32)	0.445 (0.765)	0.995 (1.93)	0.760 (1.46)	0.147 (0.37)	1.496 (5.05)	2.195 (6.10)
- 4	0.964 (1.250)	9.751 (13.77)	11.957 (16.70)	0.780 (1.18)	4.905 (8.91)	2.460 (4.39)	0.282 (0.755)	2.668 (7.08)	3.125 (5.97)
1980 - 1	1.067 (1.685)	11.655 (16.47)	9.185 (11.88)	0.895 (1.15)	7.69 (12.58)	6.155 (10.45)	0.167 (0.290)	1.772 (4.20)	1.485 (2.35)
- 2	0.888 (1.280)	9.564 (13.16)	8.206 (12.87)	0.56 (0.72)	2.83 (2.91)	2.36 (3.99)	0.135 (0.295)	1.006 (2.15)	1.56 (2.70)
- 3	0.763 (1.125)	10.271 (13.41)	9.593 (13.64)	0.393 (0.475)	2.66 (4.64)	2.78 (5.09)	0.194 (0.395)	1.214 (2.56)	1.725 (3.10)
- 4	0.750 (1.170)	8.146 (14.59)	7.533 (15.60)	0.508 (0.625)	1.44 (1.98)	1.33 (1.93)	0.212 (0.330)	1.686 (2.69)	2.173 (2.64)

* See report for overexposure details