

U. S. NUCLEAR REGULATORY COMMISSION
REGION I

Report Nos. 030-04659/90-001
030-11391/90-001

Docket Nos. 030-04659
030-11391

| | Priority | Category |
|---------------------------------|----------|------------|
| License Nos. <u>20-06799-02</u> | <u>2</u> | <u>E1A</u> |
| <u>20-06799-04G</u> | <u>4</u> | <u>E</u> |

Licensee: Cambridge Medical Technology Corporation
575 Middlesex Turnpike
Billerica, Massachusetts 01865

Facility Name: Cambridge Medical Technology Corporation

Inspection At: Billerica, Massachusetts

Inspection Conducted: May 24, 1990

Inspectors: Betsy Ullrich
Elizabeth Ullrich, Health Physicist

8/7/90
date

Mark C. Roberts
Mark C. Roberts, Health Physicist

8-7-90
date

Approved by: John D. Kinneman
John D. Kinneman, Chief
Nuclear Materials Safety Section B

8/7/90
date

Inspection Summary: Special, Announced Safety Inspection Conducted May 24, 1990, (Combined Report Nos. 030-04659/90-001 and 030-11391/90-001).

Areas Inspected: Organization and Scope of licensed activities; use of materials; licensee internal reports; effluent control and measurements. Additional information was obtained from the licensee's consultant by facsimile copy on July 2, 1990.

Results: No violations were identified.

DETAILS

1. Persons Contacted

*James McLeaman, Maintenance
K. A. Ajit-Simh, Consultant (by telephone)

*denotes those present at exit interview

2. Organization and Scope of Licensed Activities

The following information was determined by a review of the license and from statements by the licensee's representative, and was verified by observation. Licensed activities are conducted at a facility at 575 Middlesex Turnpike, Billerica, Massachusetts.

The licensee has been authorized to possess and use up to five curies of iodine-131 and seven curies of iodine-125 for research and development and for manufacturing and distribution of radioimmunoassay kits containing iodine-125 labelled compounds. The licensee is also authorized to use and possess one millicurie of hydrogen-3 for research and development and one millicurie of iodine-129 for calibration of instruments.

On November 1, 1989, the licensee terminated licensed operations and transferred the remaining I-125 to Ventrex Laboratories, an NRC licensee in Portland, Maine. The licensee contracted with Chem-Nuclear Systems Incorporated to perform the initial phase of a decontamination, stabilization and survey program at the facility. This work was conducted over the time period January 15-22, 1990. The licensee transmitted a copy of the resulting survey report to USNRC Region I in February, 1990. Also, in February of 1990, the licensee shipped approximately 200 drums containing radioactive wastes to an authorized waste disposal contractor. Areas known to have radioactive contamination remaining include the waste compactor room and the hoods in the iodination laboratory (and their associated ductwork).

No violations were identified.

3. Use of Materials

The inspector toured the licensee's laboratory shipping/receiving, refrigerators, freezers and waste storage areas. Direct radiation measurements were made by the inspectors utilizing a thin NaI crystal and rate meter. Radiation levels in excess of background were measured at the sealed door of the waste compactor room and at the face of the hoods in the iodination lab. Each of these areas is posted with a unique yellow and magenta radiation caution sign indicating that the area is not to be opened without NRC approval and there is internal radioactive contamination

present. A tamper seal and wire have been placed on each hood to provide evidence of opening. All seals were in place. No other areas inside the building indicated radiation levels in excess of the background count rate.

The inspectors also performed measurements in the waste storage area at the rear of the parking lot behind the building. An area on the floor of a locked shed in this area indicated detectable activity up to 10,000 cpm on the radiation survey meter.

No violations were identified.

4. Licensee Internal Reports

Prior to arrival at the facility, the inspectors had reviewed a copy of the Chem-Nuclear Systems decontamination and radiological survey report concerning the clean-up of the iodination laboratory. The conditions found by the inspectors are accurately described in this report.

Upon arrival at the facility, the inspectors were provided with a copy of a May 1, 1990 Preliminary Radiological Site Survey (Letter Report) by Goldberg, Zoino and Associates, Inc., performed for Shawmut Bank. This report is included as Attachment 1.

No violations were identified.

5. Effluent Control and Measurements

The licensee samples the effluent from the chemical fume hoods in the radioiodination laboratory by pumping air through a charcoal sample cartridge. Previously, the pump was located in the compacting room, but has since been removed to the facility's roof due to concerns that the samples may become contaminated due to activity in this room and thus provide higher calculated effluent results. The inspectors measured contamination up to 1400 cpm on the tygon tubing associated with the pump.

Effluent results previously transmitted to Region I were reviewed by the inspectors. Recalculation of selected sample results confirmed the licensee's calculations. For three of the sampling periods, the effluent exceeded the 10 CFR 20, Appendix B, Table II, Column 1 concentration of $8 \text{ E-}10 \text{ } \mu\text{Ci/cc}$. However, since the termination of operations, the average concentration is below this concentration. Data from December 15, 1989 through June 22, 1990 was requested from Mr. K. A. Ajit-Simh, a consultant performing the periodic effluent measurements for the licensee. Mr. Ajit-Simh provided the information and informed one of the inspectors during a phone call that no sampling was performed in January or February 1990 since the pump was disabled. A summary of the data provided is included in Attachment 2. Effluent measurements were continued following pump replacement.

No violations were identified.

6. Exit Interview

The results of the direct measurements were discussed with Mr. McLeman upon completion.

ATTACHMENT 1

Report No. 30-4659/90-001
30-11391/90-001

May 1, 1990
Project No. 60607

Shawmut Bank, N.A.
515 Massachusetts Avenue
Cambridge, Massachusetts 02139

Subject: Letter Report
Preliminary Radiological Site Survey
Cambridge Medical Technology Corporation
Billerica, Massachusetts

Attention: Jeffrey Law

Gentlemen:

In accordance with our proposal dated April 17, 1990, File No. 60607, Goldberg, Zoino & Associates, Inc. (GZA) completed a preliminary radiological survey at the above referenced site. The scope of work consisted of the following: review of available records; a site visit; evaluation of the iodination ventilation system relative to potential radiological hazards; certain radiological measurements; and preparation of this letter report.

The following is a summary of our findings:

1. Site perimeter exposure measurements were within expected background values (i.e., approximately 10-12 uR/hr).
2. Ambient exposure measurements made within the facility in areas removed from the iodination hoods and compactor room were within expected background values;
3. The iodination hoods and compactor room were sealed to isolate them from the surrounding area;
4. There were no measurements of ambient exposure above background within the facility at ground level associated with the radionuclides present in the iodination hood systems, exhaust vents and compactor room;
5. Records demonstrating the total radionuclide activity in the hood systems prior to sealing were not available;
6. Measurements documenting decay of radionuclides in the hood systems following sealing were not available;

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Project No. 60607 - Page Two

7. Exposure rate measurements taken at each of the hood windows ranged from 15 to 250 uR/hr, compared to background readings of 10-12 uR/hr;
8. Documented procedures to be employed in the event of a breach in the isolation of the hood systems were not available;
9. Records of the radioactivity levels prior to facility decontamination efforts by Chem-Nuclear Systems, Inc. were not available; and
10. Stack effluent monitoring results were not available for the time period when decontamination and sealing of the hood systems occurred (i.e., January, 1990).
11. There was no direct evidence of the presence of radioactive material in the form of Hydrogen -3 (i.e., Tritium);

Based on the above-cited findings, subject to the attached limitations, GZA recommends the following:

1. Bi-weekly monitoring of the hood systems for two months and then monthly measurements for an additional two months, to document the decay of radionuclide contamination;
2. Consolidation of license material documents to create a clear actuarial record of facility usage, decontamination and close-out; and
3. Preparation of procedures to be followed in the event that the sealed integrity of the hood systems is breached.

We are hopeful this information is suitable for your purposes and should you have need for any additional information, please feel free to contact the undersigned.

Very truly yours,

GOLDBERG-ZOINO & ASSOCIATES, INC.

Joe
Linda A. Payne
Richard T. Smokowski, C.H.P.
Consultant

Rick P. Harding
Rick P. Harding, Ph.D.
Associate & Project Reviewer

Attachment
/lp

Report Nos. 30-04659/90-001
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Attachment 2

I-125 Effluent Concentrations

| <u>Time Period</u> | <u>Licensee Measured Concentration ($\mu\text{Ci}/\text{cc}$)</u> |
|---------------------------------------|--|
| November 9, 1989 - November 20, 1989 | 1.45 E-10 |
| November 20, 1989 - November 22, 1989 | 6.95 E-11 |
| November 22, 1989 - November 24, 1989 | 5.71 E-11 |
| November 24, 1989 - November 27, 1989 | 5.55 E-11 |
| November 27, 1989 - November 28, 1989 | 8.94 E-11 |
| November 28, 1989 - November 28, 1989 | 1.15 E-10 |
| November 28, 1989 - November 29, 1989 | 3.69 E-11 |
| November 29, 1989 - November 30, 1989 | 4.66 E-11 |
| November 30, 1989 - December 1, 1989 | 3.36 E-11 |
| December 1, 1989 - December 4, 1989 | 2.67 E-11 |
| December 4, 1989 - December 5, 1989 | 3.00 E-11 |
| December 5, 1989 - December 6, 1989 | 2.54 E-11 |
| December 6, 1989 - December 7, 1989 | 2.44 E-11 |
| December 7, 1989 - December 8, 1989 | 2.23 E-11 |
| December 8, 1989 - December 13, 1989 | 1.74 E-11 |
| December 15, 1989* | 1.97 E-11 |
| December 20, 1989* | 1.58 E-11 |
| December 29, 1989* | 1.30 E-11 |
| March 8, 1990* | 7.30 E-12 |
| March 29, 1990* | 5.85 E-12 |
| May 1, 1990* | 6.32 E-12 |
| June 1, 1990* | 4.16 E-12 |
| June 19, 1990* | 5.99 E-12 |
| June 22, 1990* | 3.33 E-12 |

*Sampling period approximately 24 hours