U. S. ATOMIC ENERGY COMMISSION
DIRECTORATE OF REGULATORY OPERATIONS

REGION III

RO Inspection Report No. 74-01

Licensee: Isomedix, Incorporated
25 Eastmans Road
P. O. Box 177
Parsippany, New Jersey
07054

License No. 29-15354-02
Priority: III
Category: E

Type of Licensee: Irradiator

Type of Inspection: Announced - Initial

Date of Inspection: June 14 and 21, 1974

Princpal Inspector: C.E. Norelius for W. H. Schultz 8/14/74 (Date)

Accompanying Inspectors: None

Other Accompanying Personnel: None

Reviewed By: C. E. Norelius, Senior Health Physicist 8/14/74 (Date)
Materials Radiological Protection Section

## SUMMARY OF FINDINGS

### Enforcement Action

During this inspection four items of noncompliance were noted.

1. Contrary to 10 CFR 19.11, the licensee did not post notices to workers. (Paragraph 9)

2. Contrary to License Item No. 7 and 10 CFR 30.3, the licensee possessed 8,000 Ci of cobalt 60 as sealed sources which were received from Gamma Process Company. These sealed sources are not authorized by this license. (Paragraph 13)

3. Contrary to license Condition 13.A, the licensee put cobalt 60 sealed sources into use without being leak tested and without a certificate from the transferor indicating that a test had been made within six months prior to the transfer. (Paragraph 33)

4. Contrary to License Condition No. 14 which states the AECL instruction manual for the IR68 Cobalt 60 Irradiation Unit shall be followed, the licensee did not post the emergency procedures as required. (Paragraph 11)

### Licensee Action on Previously Identified Enforcement Items

There were no previously identified enforcement items.

### Unusual Occurrences

No unusual occurrences were reported or identified.

### Other Significant Findings

A. Current Findings

1. During the inspection the AEC representative discussed the possibility of unauthorized personnel removing the shielding plugs from outside the South wall of the irradiation facility. The licensee representative agreed to have the steel jacketed plugs welded to the steel liners to prevent removal of the plugs. (Paragraph 20)

2. During the inspection the AEC representative discussed the need for a radiation monitoring system which would function at all times and not only when the cobalt 60 source assembly is in a stored position. The licensee representative agreed to review this matter. (Paragraph 23)

B. Unresolved Items: None.

Management Interview

At the conclusion of the inspection the AEC representative discussed the inspection findings with Mr. Wolford. He was informed that four items of noncompliance were noted. He was also informed these items of noncompliance would be forwarded to the licensee in writing.

## REPORT DETAILS

### Persons Contacted

1. Mr. Otto C. Wolford, General Manager, was contacted by telephone on June 14, 1974 and on that date a partial inspection was made to review the adequacy of interlocks and safety equipment at the licensee's facility.

2. Mr. Wolford was contacted by telephone on June 20, 1974 and the initial inspection was completed on June 21, 1974.

3. The Illinois State Health Department was contacted by telephone, however, no representative from that agency was present during the inspection.

### General

4. This was an announced initial inspection of the licensee's byproduct material program. Areas of review included organization and administrative control, design and construction of the facility, byproduct material inventory, personnel monitoring, radiation surveys, leak tests, source loading, emergency and operating procedures, instrumentation, radiation safety practices, and records.

### Management Control

5. The president of Isomedix, Inc. is Mr. George R. Dietz. His office is located at Parsippany, New Jersey. The licensee's facility is located at 6401 Oakton Street, Morton Grove, Illinois. This facility has only two employees. Mr. Wolford is General Manager and Radiation Safety Officer. He is assisted by Mr. Zikar M. Khanani. Mr. Wolford reports directly to Mr. Dietz.

6. Licensee personnel at the Morton Grove facility have available written instructions and operating procedures," Instruction Manual IR68 Cobalt 60 Irradiation Unit", Edition No. 1, March 1973. These procedures are as submitted with the license application dated July 18, 1973.

7. Licensee personnel have available copies of the AEC license and appropriate AEC regulations.

8. Form AEC-3, "Notice to Employees" was posted in the office area.

9. It was noted the licensee had not posted copies of 10 CFR Parts 19 and 20, the license, and related documents and procedures referenced in the license nor was a notice posted which described the documents and stated where they may be examined. This constitutes noncompliance with 10 CFR 19.11, "Posting of notices to workers."

10. During the two inspection visits the licensee representative described and demonstrated the operation of the irradiation facility. Based on his statements and observations by the AEC representative it appears the operation of the unit is in conformance with the licensee's written procedures.

11. License Condition No. 14 states, in part, the procedures contained in AECL's instruction manual for the "IR68 Cobalt 60 Irradiation Unit" shall be followed. The instruction manual contains emergency instructions which, according to the manual, should be posted in a prominent position close to the control station. During the inspection it was noted the emergency instruction were not posted at the control station. This constitutes noncompliance with License Condition No. 14.

Uses of Materials, Physical Facilities and Equipment

12. The licensee uses byproduct material procured under this license for commercial irradiation of products and calibration of radiation detection instruments. At the time of the inspection the licensee had the following byproduct material on hand:

    (a) 137,510 Ci (2-12-74) of cobalt 60 as sealed sources received on 3-1-74. The sources are AECL Model C-188, Type 3. The activity is comprised of 26 individual source elements.

    (b) Two cobalt 60 sealed sources (1.3 uCi each).

    (c) One cobalt 60 sealed source (1.3 mCi).

    (d) One cobalt 60 sealed source (about 40 Ci) contained in a BNL self-shielded irradiator. This unit will be disposed in the near future.

    (e) Approximately 8,000 Ci of cobalt 60 contained in a large shipping cask. This material was received from Gamma Process Company, the former occupants of the building. This material is presently in storage and awaiting disposal.

    (f) One 4 uCi strontium 90 sealed source contained in a Jordan Radector survey meter.

    (g) One 3 uCi strontium 90 sealed source contained in a Jordan RAMS II monitor. This device is not being used.

13. This license does not authorize the possession and storage of the 8000 Ci of cobalt 60 which formerly was licensed by Gamma Process Company. This constitutes noncompliance with License Item 7 and 10 CFR 30.3.

14. The shielded facility contains and AECL IR68 Cobalt 60 Irradiation Unit. The unit arrived August 22, 1973 and was assembled and tested by AECL personnel. The Cobalt 60 sealed sources were loaded into the unit on March 4, 1974. The system was tested under actual operating conditions on March 6, 1974 and on the same day commercial operation of the unit was started.

15. The irradiation facility has been licensed continuously since March 20, 1957, however, it was not put into use by Isomedix, Inc. until March 6, 1974. During the period March 20, 1957 through May 3, 1967 the program was covered by a license issued to Cook Electric Company. During the period May 4, 1967 through January 28, 1974 the program was covered by a license issued to Gamma Process Company. Since January 29, 1974 the program has been covered by a license issued to Isomedix, Inc.

16. Details of the building, hot cell, cell door, water conditioning equipment, water level controls, source storage pool, and ventillation systems have not been altered since installation in 1957.

17. The facility is intended to be a service irradiator, wherein products of other companies will be received and irradiated to specified doses, either on a test or production basis. A secondary use is for radiation sterilization of medical supplies.

18. A drawing of the radiation room and adjacent areas is attached to this report as Exhibit A.

19. The building is one story, rectangular is shape, approximately 58' X 53' enclosed by standard cement block walls. The irradiator is set in the souteast corner of the building. The irradiation room is a cube sixteen feet on each side. The two side walls (east and west) and the back wall (south) are 68 inches thick of poured-in-place reinforced standard concrete. The ceiling is 48 inches of poured-in-place steel reinforced standard concrete. The front (north) wall and cell door are 48 inches of magnetite concrete poured in steel shells. In addition to the access door, the front wall of the cell contains a leaded glass viewing window, a pair of master-slave manipulators, and several cylinderical access ports. The rear wall (south) contains five cylinderical access ports. The cell access door and all other penetrations of the biological shield are stepped to reduce radiation leakage. During the inspection it was noted the five access ports in the south wall have a steel liner which is plugged with a stepped steel pipe filled with concrete. The plugs are designed to be removed from the outside but the handles have been partially removed leaving only two stubs about an inch long on each plug. Also, each plug is secured with a padlock.

20. During the inspection the licensee representative agreed to remove the padlocks, remove the remaining stubs and weld the plugs into the steel liners which pass through the biological shield.

21. During the inspection it was noted the licensee's facilities and the AECL irradiator are as described in the license application.

22. During the inspection the licensee's facilities were reviewed. This included the water conditioning equipment, water level controls and ventillation systems. It was noted these are as described in this license application, dated July 18, 1973, and as described in license applications submitted by former users of the shielded facility.

23. The AECL Irradiator is provided with a geiger type radiation monitor which is operational only when the cobalt 60 sources are in the storage position. In the source exposed position the facility has no operational radiation monitor. This matter was reviewed with the licensee representative and he stated he would consider the possibility of installing a radiation monitoring system which would be operational at all times.

24. A Berthold RATO/F survey meter is used by operating personnel to check radiation levels before entering the hot cell. This instrument has five ranges with full scale readings of 1, 10, and 100 mR/hr and 1 and 10 R/hr. The instrument was calibrated by Wolford on June 20, 1974. Only the first three ranges of the instrument are calibrated because of the limited strength of the calibration source.

Personnel Radiation Protection

25. Licensee personnel wear film badges which are sent to R. S. Landauer on a bi-weekly basis. Victoreen indirect reading (0-200 mr) dosimeters are available but are not routinely used. Licensee personnel use dosimeters only when changing sources. Film badge records were reviewed and it was noted the maximum total exposure for the year 1974 was 30 mrem. Form AEC-4 has been completed for both licensee personnel and Form AEC-5 is being maintained.

26. Posting and labeling is in accordance with the applicable sections of 10 CFR 20.203. The door to the hot cell is posted Caution-Radioactive Material and Caution-High Radiation Area. A Caution-High Radiation Area sign is mounted above the cell entrance door. This sign is illuminated whenever the cobalt 60 source assembly is not in a completely down position. The sign is energized with a mechanical switch and not by the presence of radiation.

27. The AECL Irradiator is provided with a series of interlock devices which will prevent a person from entering a High Radiation Area. When the source is in an exposed position the entrance door to the cell cannot be opened. The door to the cell can be opened only by a large electrical drive motor which is interlocked with various safety circuits. However, if someone should be inside the exposure room when the source is raised to an exposed position a manual switch can be operated which by-passes all safety circuits and permits the person inside the room to

open the door to the cell. This cannot occur from outside the exposure room. There are no provisions for by-passing the safety circuits from outside the exposure room.

28. A complete survey of the shielded facility was made by AECL personnel during the period October 29-31, 1973 prior to the installation of the AECL IR68 Irradiator. The survey results were submitted to AEC on November 15, 1973. No significant contamination was detected.

29. AECL personnel made a direct reading survey on March 7, 1974 after installation of the cobalt 60 sources. The radiation level in unrestricted areas outside the building walls was less than 0.1 mr/hr. The maximum radiation level on the roof (where the source cable passes through the shield) was 1.5 mr/hr. Radiation levels inside the building were also measured. The maximum level detected was 50 mr/hr at the manipulator port opening. The maximum radiation level at the cell door was 1.8 mr/hr.

Waste Disposal

30. The licensee's inventory includes a number of sealed sources which will be disposed of in the near future. These sources will be shipped either to a supplier or a licensed waste disposal agency. The licensee has made no disposals or radioactive waste since the issuance of this license.

Leak Tests

31. The 26 cobalt 60 sealed sources were put into commercial use on March 6, 1974. However, the licensee did not receive a leak test certificate from AECL prior to using the sealed sources. At the time of the source loading AECL personnel made a gross leak test by pouring water into the source cavity of the shipping cask then collecting the water and checking it with a survey meter. Nothing above background was noted. AECL personnel informed the licensee the water would be returned to AECL for analysis and a report of the test results would be issued. The licensee did not receive this report.

32. On May 10, 1974 the licensee representative made a leak test by wiping the 26 sealed cobalt 60 sources with a single paper towel. The towel was analyzed with a gas flow proportional counter and showed less than 0.001 uCi of removable contamination.

33. Although the cobalt 60 sealed sources were put into use on March 6, 1974 no leak test results were available until May 10, 1974. This constitutes noncompliance with License Condition No. 13.A, in that, the licensee put 26 cobalt 60 sealed sources into use without making a leak test and without a certificate from AECL indicating a test had been made within 6 months prior to transfer to the licensee.

34. A review of the leak test records during this inspection showed all sealed sources in the licensee's inventory were leak tested on May 10, 1974 and all showed less than 0.001 uCi of removable contamination.

Independent Measurements

35. During the inspection the AEC representative made direct reading radiation surveys with an Eberline Model E-500 B survey meter. The maximum radiation level at 12 inches from the surface of the shipping cask containing 8000 Ci of cobalt 60 was 7 mr/hr. The maximum radiation level at 12 inches from the surface of the BNL irradiator was 4 mr/hr. Additional measurements were made at various other locations throughout the licensee's facilities and all agreed closely with the survey made by AECL personnel on March 7, 1974.

Attachment:
Exhibit A

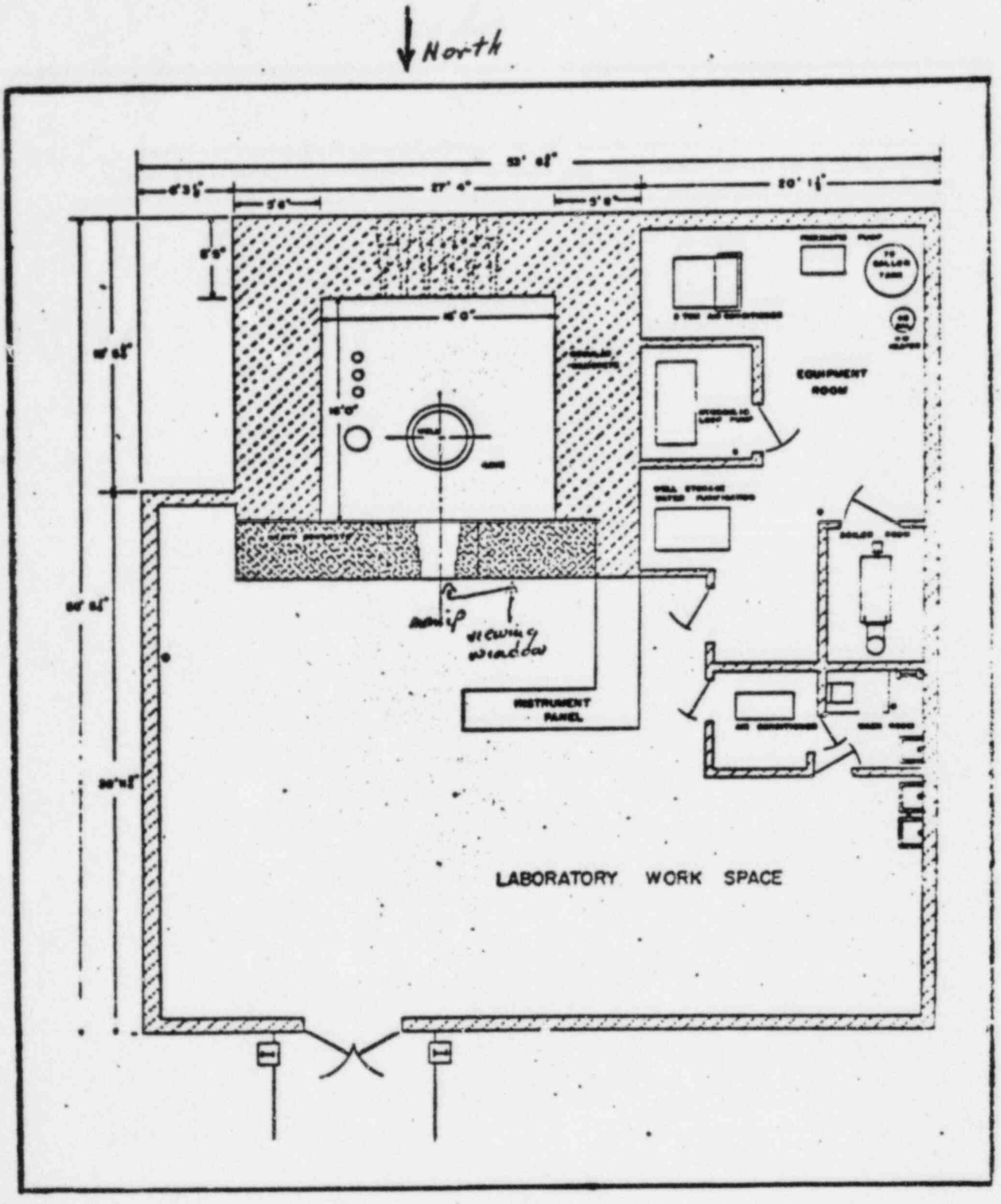
North
EQUIPMENT ROOM
INSTRUMENT PANEL
LABORATORY WORK SPACE

EXHIBIT A