

DEC 9 1975

Isomedix, Inc.
Attention: Mr. George Dietz, President
P. O. Box 177
Parsippany, New Jersey 07054

License No. 79-15364-01
Inspection No. 75-01

Reference: Your letter dated November 17, 1975
In response to our letter dated November 4, 1975

Comments:

Thank you for informing us of the corrective and preventive actions you documented in response to our correspondence. These actions will be examined during a subsequent inspection of your licensed program.

With respect to your November 17 letter, Mr. Slobodien of this office discussed your response by telephone with you on December 1, 1975. From this conversation it is our understanding that:

1. You will report the results of your March 19, 1975 leak test of your cesium-137 sources as required by Condition 13e of your license to the NRC's Division of Materials and Fuel Cycle Facility Licensing.
2. You will leak test the cesium-137 sources individually and report the results to Licensing by December 31, 1975.

If our understandings are incorrect, please inform us in writing within seven (7) days of your receipt of this letter.

Your cooperation with us is appreciated.

Sincerely,

Paul R. Nelson, Chief
Fuel Facility and
Materials Safety Branch

bcc: (w/encs)
IE Mail & Files (For Appropriate Distribution)
PDR
Local PDR
NSIC
REG: I Reading Room
State of New Jersey

W.P. Epstein:ny
12/8/75

McClintock
12/8/75

Nelson
12/9/75

DATA SHEET

Attached N/A

Appendix A ☒ ☒
Appendix B ☐ ☒
Appendix C ☐ ☒

DOCKET NO. 03008985FACILITY ISOMEDIX IncINSPECTION NO. 7501CITY, STATE Parsippany N.J.DATE/S 10/22/75

SUBJECT - RADIATION SAFETY

LICENSE NO/S. 29-15364-0

PHONE # FTS

LOCAL 201-287-4700INSPECTOR E. EmleyREVIEWER RO McVintch

TYPE OF INSPECTION:

☐ INITIAL
☒ REINSPECTION

☐ SPECIAL
☐ ROUTINE

☐ ANNOUNCED
☒ UNANNOUNCED

DATE OF LAST INSPECTION: _____

RECOMMENDED DATE, NEXT INSPECTION: 10/76

☐ SPECIAL
☐ ROUTINE

TYPE OPERATION: Manufacture + Distributor + Irradiation service

SCOPE OF OPERATION

☐ SMALL
☐ MEDIUM

☒ LARGEPRESENTLY CLASSIFIED CAT/PRI E; AS OF AMENDMENT NO. III☒ NO CHANGE REQUIRED☐ CHANGES TO CAT/PRI☐ PER ATTACHED MEMO DATED _____SUMMARY OF FINDINGS

☐ NO NONCOMPLIANCE NOTED
☐ 591 ☐ ROL ☐ OTHER
☐ NO SPECIAL PROBLEMS

☒ SEE APPENDIX A FOR NONCOMPLIANCE ITEMS

☐ SEE APPENDIX B FOR PROBLEM AREAS
RELATIVE TO _____

PERSONS CONTACTED*

NAME	TITLE	ORG	NAME	TITLE	ORG
1. G. R. Dietz	Pres		6.		
2. G. W. Karl	Manager		7.		
3. W. McKinn	Not airt Mgt.		8.		
4.			9.		
5.			10.		

* MANAGEMENT MEETING ATTENDEES

	INSPECTION ITEM	SOURCE OF INFORMATION	ACCEPTANCE CRITERIA	FINDINGS
P/I 7410	Management Controls	OCTZ	actively concerned with program reviews all reports	good
.01 .06	Responsibilities; Qualifications Users---RSO---Management	Duty Per.	L/C <u>12</u> which references document dated <u>9/7/72</u>	gr
.02	Internal Audits	Duty	L/C as above; 10 CFR 19, 20, 31, 35	good
.04	Inventory Controls; Related Records	Duty	L/C 6, 7, 8; 30.41, 30.53	good records
	<u>Training</u>			
.07	Qualification, Competence of Instructors		Inspector Judgement	good
	Technican Instruction/Training	Employee Interviews	Document dated <u>9/7/72</u> L/C <u>16</u> 19.12	gr
	Posting of Notices, Lic., AEC-3, etc.		19.11	/
	Special Work Permits		19.12	/
	Cleaning & Bldg. Maint. Pers.		19.12	/
7415	<u>Inspection History</u>			
.01	Corrective action; Previously noted noncompliance	none	Pertinent regulations Licensee Letter dated _____	last suspect clear

	INSPECTION ITEM	SOURCE OF INFORMATION	ACCEPTANCE CRITERIA	FINDINGS
.02	Incidents, accidents, unusual occurrences since last inspection including equipment malfunctions	<i>city + memo</i>	20.402; 20.403; 20.405 Inspector Judgement	<i>none</i>
.02	Unresolved Items, per list, Problem areas, per previous inspection, evaluation memo.	<i>city</i>	Pertinent regulations Inspector Judgement	<i>none</i>
P/I 7420	<u>Uses of Material</u>			
.01	License limitations, re: purpose, personnel, location, etc.	<i>yes</i>	L/C 9, 10 et. seq. ✓	<i>good</i> ✓ 50000 Ci @ 137. 50000 in immediate units per sal. 140000 Ci @ 137 110000 Ci @ 137 New Laboratory Installation 500000 Ci @ 137
.01	Scope of program		Not applicable	
7430	<u>Surveys</u>			
.01	Restricted Areas Unrestricted Areas Extremities Airborne Activity, Contamination Trash, Wastes, Burials Liquid and Gaseous Effluents Leak Tests ✓ Incoming Packages		20.101 20.105 20.103 20.301; 20.304 20.106; 20.303 L/C 230 (NC) 20.205	✓ ✓ ✓ N/A all sealed sources no burn N/A no liquid eff. →
.02	Personnel Monitoring Equip. Records Personnel Exposures - ALAP Bioassay Results		20.202 20.401(a); 20.401(b) 20.1 20.103-40 MPC HRS/WEEK	✓ ✓ ✓ <i>none</i>

INSPECTION ITEM	SOURCE OF INFORMATION	ACCEPTANCE CRITERIA	FINDINGS
7420 <u>Equipment</u>			
.03 Adequacy of instrumentation; fixed & portable meters and systems alarms; warning devices, Calibrations of Instruments	<i>seen by Insp</i>	Inspector Judgement 20.203 Qtrly; Inspector Judgement	<i>Good excellent attitudes close opening, could source & return to storage pools</i>
<u>Observations/Measurements</u>			○
.01 Posting of notices, warning signs, alarms, warning devices	<i>seen</i>	19.11(b), (c), (d); 20.203	<i>grr</i>
Physical security; housekeeping		20.207; Insp. Judgement	<i>grr</i>
Radiation levels		20.105	
Wearing of required P.M. devices		20.202	<i>WA</i>
Breathing Zone Air sampling sys.		20.201(b)	<i>WA</i>
Isokinetics, Effluent sampling systems		20.106, 20.301, 20.303	<i>Good exhaust from all filters</i> ○
AP; Contamination controls via ventilation, Hood face velocities, gloveboxes		20.103; 20.106	<i>✓ good</i>
Protective clothing; disposable equipment		20.103	<i>Good</i>

NONCOMPLIANCE BACKUP

Facility 151 Medent Insp. No. 7501License No. ~~200~~ 29-15364-01

BASIS FOR CITATION

Item # 1
 10 CFR _____
 L/C 13(C) -
 *Class _____

146 sources 400ci each Cs 137
 were placed in well #3 in Artall #1
 for storage. A couple of the top of the well
 on 2/74 it revealed only 350 cpm. but a
 updated on 3/19/75 revealed 8836 cpm on
 top of the well and 6690 cpm on sides. A count 9/18/75
 revealed 7637 cpm on top and 6586 on sides.

Item # _____
 10 CFR _____
 L/C _____
 *Class _____

inside the well 7364 the surface.
 of 3/19/75 was equivalent to 0.05 uci
 This was not reported to the NRC.
 Nor was anything done to determine
 the source of the leakage from the
 146 sources in Well #3.

Item # _____
 10 CFR _____
 L/C _____
 *Class _____

Item # _____
 10 CFR _____
 L/C _____
 *Class _____

Item # _____
 10 CFR _____
 L/C _____
 *Class _____

Item # _____
 10 CFR _____
 L/C _____
 *Class _____

APPENDIX B

- ☐ Inspector Comments
- ☐ Unresolved Items
- ☐ Uncorrected or Repeated n/c
- ☐ Unusual Occurrences, Etc.

Facility _____ Inspection No. _____

License No. _____

The next inspector should be aware of the following:

APPENDIX C - SPECIAL CONSIDERATIONS

Licensee _____ Lic. No. _____ Insp. No. _____

<u>Inspection Item</u>	<u>Source Of Information</u>	<u>Acceptance Criteria</u>	<u>Findings</u>
MEDICAL PROGRAMS A) DOSE CONSIDERATIONS: LENSES OF EYES OF FLUOROSCOPISTS EXTREMITY DOSE TO THOSE WHO LOAD, HANDLE, WOUND, CLEAN BRACHYTHERAPY APPLICATORS, THERAPEUTIC DEVICES, GENERATORS FROM CONTRIBUTION FROM X-RAYS, RADIUM, ETC. NURSE, AUTOPSY, MORTICIAN PERSONNEL B) VERIFY ADEQUACY OF MILK BREAKTHROUGH TESTS		INSPECTOR JUDGMENT 20.20.(f) ref 20.101 L/C —	
Teletherapy Programs Posting, Accessibility of Roof, Beam Direction Interlocks 5 year maintenance check (Mechanical) Malfunctions (Electrical) (Radiological)		20.101; 20.105 L/C — INSPECTOR JUDGMENT	
Heart Pacemakers Patient Location/ Death procedures		SUPPLIER LICENSE; L/C —	
Distributors - { GEN-LIC. } ITEM. { LIC.EXCHNG }		PERFORMANCE VS. B.I.V., X-CAT, X-D-19, etc.	

ISOMEDIX

DEC 23 1975

Memo to Files

PERIODIC AUDIT OF LICENSEE ENFORCEMENT HISTORY - JUNE 1974-NOVEMBER 1975

This audit is made pursuant to Regional Office Instruction No. 2705, "Periodic Audit of Licensee Enforcement History" dated November 18, 1975.

<u>Licensee</u>	<u>Docket No.</u>	<u>License No.</u>	<u>Comments</u>
University of Connecticut	03000589	06-1450	Items cited in the first inspection in 1974 - 8 infractions. No items of noncompliance were found during an inspection in February 1975. Scheduled for reinspection first quarter 1976.
Cooper Hospital	03002512	29-08285-01	Items cited in the first inspection in 1974 - 14 infractions. As a result of the first inspection in 1975, 2 infractions were indicated. No items of noncompliance were found during a second inspection in November 1975.
CIS Radiopharmaceuticals, Inc.	03004758	20-13695-01	Items cited in the second inspection in 1974 - 2 violations, 5 infractions. Management meeting held at Office of Inspection and Enforcement, Region I in March 1974. The third inspection in 1974 revealed same items uncorrected. Civil Penalties assessed. No items of noncompliance were found during an inspection in July, 1975.

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<u>Licensee</u>	<u>Docket No.</u>	<u>License No.</u>	<u>Comments</u>
Walworth Company	03006071	37-02445-02	Notification of over-exposure of employee in October 1974 resulted in investigation and inspection in October 1974 and April 1975 respectively. Civil penalties imposed. No items of noncompliance were found during the second inspection in December 1975.
Sun Shipbuilding & Dry Dock Company	03006073	37-02500-01	Items cited in the first inspection in 1974 - 1 violation, 7 infractions. Items cited in the second inspection in 1974 - 6 infractions. Items cited in the first inspection in October 1975 - 2 deficiencies. Re-inspection scheduled for third quarter 1976.
Howard Hospital Supply Co. (RAD/IRID, Inc.)	03007603	08-14043-01	Items cited in the first inspection in 1975 - 10 infractions. No items of noncompliance were indicated during a second inspection in October 1975.
Gamma Diagnostics, Inc.	03008748	20-15215-01	Items cited in the first inspection in 1975 - 4 infractions. Items cited in the second inspection in 1975 - 5 infractions, no recurrent items. As a result of a third inspection in December, 1975, 2 infractions properly reported and reinspection scheduled for first or second quarter 1976.

<u>Licensee</u>	<u>Docket No.</u>	<u>License No.</u>	<u>Comments</u>
Isomedix	03008985	✓ 29-15364-01	Items cited in the first inspection in 1974 - 3 violations, 1 infraction. Civil penalty assessed. No items of noncompliance were found during an inspection in October, 1975. Reinspection scheduled for third or fourth quarter 1977.
St. Mary's Hospital	03009047	37-15400-01	Items cited in the first inspection in October 1975 - 9 infractions. Reinspection scheduled for January 1976.

Eugene Epstein
for

R. O. McClintock
Section Leader
Materials Radiological Protection
Section

cc: Gary Snyder,
Assistant to the Director