



June 6, 1975

Mr. Bernard Singer
Director
Materials Branch
Directorate of Licensing
U.S. Nuclear Regulatory Commission
Washington, D. C. 20555

RE: License
29-15364-01

Dear Mr. Singer:

This is to request that:

- (a) Additional personnel be added as qualified operators for our cobalt-60 irradiator, licensed under amendment 04. A summary of experience and training, for each is enclosed.

Personnel for which operator status is requested are:



- (b) Item 6(b), AEC Form 313, be amended to include:

Neutron Products, Inc. (Dickerson, Maryland)
Cobalt-60 sources as follows:

Model 12CC5 and 24CC5 (clad wire coils)
with and/or without fillers. Fillers are
designated as 12S3, 10S3, 12C3 and 10C3.

Maximum curie content per 12CC5: 5,000 ci
Maximum curie content per 24CC5: 10,000 ci

N.P.I. has informed us that these source designs have
previously been filed with and reviewed by AEC, and
have been found to be acceptable for licensing.

8507200329 850510
PDR FOIA
GLOWACK85-111 PDR

**COPIES SENT TO
REGULATORY OPERATIONS**

Isomedix Inc. • 25 Eastmans Road, Parsippany, New Jersey (201) 887-4700
Mailing Address: Post Office Box 177, Parsippany, New Jersey 07054

CHICAGO DIVISION • 7828 Nagle Ave., Morton Grove, Illinois 60053 (312) 966-1160

56526

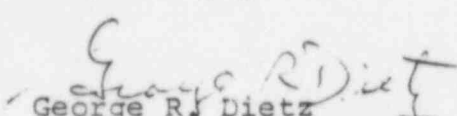
- 2 -

- (c) [redacted] and also a licensed operator of the -04 unit, as well as the hot cell units, be designated as Assistant Radiation Safety Officer for Isomedix. [redacted] has routinely assisted the undersigned in all phases of our own routine safety inspections, record keeping, and Region I inspections, for well over six months.

Finally, I would like to request that review of this request be accelerated if possible. Additional cobalt-60 for the -04 unit is on order, with delivery expected on/about June 9. The services of the additional operators for the irradiator, as requested herein, will be needed to meet the full production schedule for the proposed processing.

Thank you for your consideration.

Very truly yours,


George R. Dietz
Radiation Safety Officer

Enclosures

GRD:km

Supplemental Information to
Isomedix Letter, June 6, 1975

Item 4 (AEC - 313): Amend to add

Item 8:

<u>Type of Training</u>	<u>Where Trained</u>	<u>Duration of Training</u>	<u>On the Job</u>	<u>Formal Course</u>
a. Principles and Practices of radiation protection.	Isomedix	3 months	Yes	Yes
b. Radioactive measurement standardization and monitoring techniques, and instrumentation.	Isomedix	3 months	Yes	Yes
c. Math and calculations basic to the use and measurement of radio-activity	Isomedix	3 months	Yes	Yes
d. Biological effects of radiation	Isomedix	3 months	Yes	Yes

Item 9:

<u>Isotope</u>	<u>Max.Amount</u>	<u>Where Experience was gained</u>	<u>Duration</u>	<u>Type of Use</u>
Co-60	190,000 curies	Isomedix	3 months	General processing, e.g., sterilization

through [redacted] and [redacted] has received on-the-job training in the use of shielding and time-distance relations in reducing radiation exposure; the use, maintenance and limitations of monitoring and surveying instruments; and protective, routine, and emergency procedures in effect at the New Jersey facility. The on-the-job training was correlated with a formal course given by [redacted]. Contents of this training program, and minimum hours per subject, follow.

Formal Education - [redacted]

High School graduate
Rets Electronic School - 1 year.

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CONTENTS OF TRAINING PROGRAM

HOURS

1. The Hazards of Radiation

1/2

Unavoidable low level exposure

hazard evaluation.

2. The Effects of External Radiation

1

a. Effects on the body

b. Units of measurement

c. Levels of injury

d. Long term exposures

e. The banking concept

3. Protection from External Radiation

1

a. Time

b. Distance

c. Shielding materials

1

d. Define curies and half value layers,

dose rate curves in the Isomedix irradiator.

4. Radiation Physics

1

The Nucleus-isotopes-radioactive decay

5. Internal Radiation Problems

1

a. How radioactive material enters the
body.

b. Effects on the body.

6. Contamination 1

- a. Hazards associated with contamination
- b. Prevention of spread.
- c. Decontamination procedures

7. Instruments and Dosimetry 1

- a. Geiger counters
- b. Ionization chambers.
- c. Scintillation counter.
- d. Film Badges
- e. Pocket Electroscopes.

8. Review of Isomerix Facilities and Procedures 1

- a. Source interlock systems.
- b. Operating procedures for routine irradiations.
- c. Operating procedures for hot cell operations.

9. Verbal Discussion on the Above Course 1

Questions to determine understanding of all the topics.

Total Hours

9 1/2 Hours

The AEC publication, "Living with Radiation" was used as a basis for this training.

Item 8:

<u>Type of Training</u>	<u>Where Trained</u>	<u>Duration of Training</u>	<u>On the Job</u>	<u>Formal Course</u>
a. Principles and Practices of radiation protection.	AECL	7 years	Yes	Yes
	Radiation Int'l.	2 years	Yes	No
	Isomedix Ltd.	4 years	Yes	No
	Isomedix Inc.	3 years	Yes	Yes
b. Radioactive measurement standardization and monitoring techniques, and instrumentation.	SAME AS ABOVE			
c. Math and calculations basic to the use and measurement of radio-activity.	SAME AS ABOVE			
d. Biological effects of radiation.	SAME AS ABOVE			

Item 9:

<u>Isotope</u>	<u>Max.Amount</u>	<u>Where Experience was gained</u>	<u>Duration</u>	<u>Type of Use</u>
Co-60	1,000,000 ci	AECL	7 years	General processing, self-contained irradiators
Co-60	300,000 ci	Radiation Int'l.	2 years	General processing.
Co-60	300,000 ci	Isomedix Ltd.	4 years	General processing.
Co-60	500,000 ci	Isomedix Inc.	3 years	General processing.
Co-60	100,000 ci	Newfield Prods.Ltd.	2 years	General processing.
Cs-137	250,000 ci	Isomedix Inc.	2 years	Assly into self-contained irradiators.

[redacted] (cont'd.)

During his seven years with AECL, Mr. Masefield was Head of Irradiator Design. In addition to supervising design and construction of self-contained irradiators, he supervised design and commissioning of large production irradiators, including the Ethicon units in Somerville, New Jersey and San Angelo, Texas, as well as a production facility in Peterborough, Canada.

He was a licensed operator and RSO of the Newfield Product, Ltd. irradiator in Canada for two years.

He is thoroughly familiar with the contents of our standard operator training program, attached, and as such, participated in an accelerated review of the contents with the Isomedix RSO.

[redacted] participated in the design and installation of mechanical and safety systems on the subject irradiator and is thoroughly familiar with its details.

Formal Education:

Higher National Certificate in Mechanical Engineering, Wolverhampton University of Technology, England.

Graduate of Institute of Mechanical Engineers

Other

Member, American Nuclear Society.

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CONTENTS OF TRAINING PROGRAM

HOURS

1. The Hazards of Radiation 1/2
 - Unavoidable low level exposure
 - hazard evaluation.
 2. The Effects of External Radiation 1
 - a. Effects on the body
 - b. Units of measurement
 - c. Levels of injury
 - d. Long term exposures
 - e. The banking concept
 3. Protection from External Radiation 1
 - a. Time
 - b. Distance
 - c. Shielding materials 1
 - d. Define curies and half value layers,
dose rate curves in the Isomedix irradiator.
 4. Radiation Physics 1

The Nucleus-isotopes-radioactive decay
 5. Internal Radiation Problems 1
 - a. How radioactive material enters the
body.
 - b. Effects on the body.
-

- 6. Contamination 1
 - a. Hazards associated with contamination
 - b. Prevention of spread.
 - c. Decontamination procedures
- 7. Instruments and Dosimetry 1
 - a. Geiger counters
 - b. Ionization chambers.
 - c. Scintillation counter.
 - d. Film Badges
 - e. Pocket Electroscopes.
- 8. Review of Isomerix Facilities and Procedures 1
 - a. Source interlock systems.
 - b. Operating procedures for routine irradiations.
 - c. Operating procedures for hot cell operations.
- 9. Verbal Discussion on the Above Course 1
 - Questions to determine understanding of all the topics.

Total Hours

9 1/2 Hours

The AEC publication, "Living with Radiation" was used as a basis for this training.

Item 8: [REDACTED]

<u>Type of Training</u>	<u>Where Trained</u>	<u>Duration of Training</u>	<u>On the Job</u>	<u>Formal Course</u>
a. Principles and Practices of radiation protection.	Isomedix	1 year	Yes	Yes
b. Radioactive measurement standardization and monitoring techniques, and instrumentation.	Isomedix	1 year	Yes	Yes
c. Math and calculations basic to the use and measurement of radio-activity.	Isomedix	1 year	Yes	Yes
d. Biological effects of radiation.	Isomedix	1 year	Yes	Yes

Item 9: [REDACTED]

<u>Isotope</u>	<u>Max.Amount</u>	<u>Where Experience was gained</u>	<u>Duration</u>	<u>Type of Use</u>
Co-60	300,000 ci	Isomedix	8 months	General Process- ing.
Cs-137	240,000 ci	Isomedix	8 months	Assly into self-contained irradiators

Formal Education: Georgia Institute of Technology; 2 years, engineering studies toward BS in Mechanical Engineering.

[REDACTED] through [REDACTED] and [REDACTED] has received on-the-job training in the use of shielding and time-distance relations in reducing radiation exposure; the use, maintenance and limitations of monitoring and surveying instruments; and protective, routine, and emergency procedures in effect at the New Jersey facility. The on-the-job training was correlated with a formal course given by [REDACTED]. Contents of this training program, and minimum hours per subject, follow.

[REDACTED] also designed and supervised installation of the total mechanical and safety system of the irradiator in question. He is thoroughly familiar with its functioning.

CONTENTS OF TRAINING PROGRAM

HOURS

1. The Hazards of Radiation 1 1/2
 - Unavoidable low level exposure
 - hazard evaluation.
 2. The Effects of External Radiation 1
 - a. Effects on the body
 - b. Units of measurement
 - c. Levels of injury
 - d. Long term exposures
 - e. The banking concept
 3. Protection from External Radiation 1
 - a. Time
 - b. Distance
 - c. Shielding materials 1
 - d. Dose curves and half value layers,
dose rate curves in the Isomedix irradiator.
 4. Radiation Physics 1

The Nucleus-isotopes-radioactive decay
 5. Internal Radiation Problems 1
 - a. How radioactive material enters the
body.
 - b. Effects on the body.
-

6. Contamination 1
 - a. Hazards associated with contamination
 - b. Prevention of spread.
 - c. Decontamination procedures
7. Instruments and Dosimetry 1
 - a. Geiger counters
 - b. Ionization chambers.
 - c. Scintillation counter.
 - d. Film Badger
 - e. Pocket Electroscopes.
8. Review of Isomex Facilities and Procedures 1
 - a. Source interlock systems.
 - b. Operating procedures for routine irradiations.
 - c. Operating procedures for hot cell operations.
9. Verbal Discussion on the Above Course 1
 - Questions to determine understanding of all the topics.

Total Hours

9 1/2 Hours

The AEC publication, "Living with Radiation" was used as a basis for this training.

Memorandum to File Isomedia, Inc.

Next inspector should review overexposure
reported for 2nd Quarter 1979.

Appears to be paper problem
rather than failure to evaluate
(Albert not in accord with ALARA)

J. E. Glen
11/1/79

✓ Docket No. 30-8985

DEC 10 1979

Isomedix, Incorporated
ATTN: Mr. G. Dietz
President
80 South Jefferson Road
Whippany, New Jersey 07931

Gentlemen:

Subject: Inspection 79-03

This refers to the inspection conducted by Mr. F. Costello of this office on November 6, 1979 at your irradiation facility in Parsippany, New Jersey of activities authorized by NRC License No. 29-15364-01 and to the discussions of our findings held by Mr. Costello with yourself at the conclusion of the inspection.

The area examined during this inspection was limited to a review of your program in decontaminating a portion of your Parsippany facility for release for unrestricted use. Within this area, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, measurements made by the inspector, and observations by the inspector.

Our inspector also verified the steps you have taken to correct the item of noncompliance brought to your attention in a letter dated September 4, 1979. We have no further questions regarding your action at this time.

In addition, our inspector examined those activities conducted under your license relating to the subjects covered in your letters dated September 20, 1979 and October 11, 1979. With regard to the subject covered in your September 20, 1979 letter, we have no further questions regarding this matter. With respect to the subject covered in your October 11, 1979 letter, we will review the whole body counting data for the individual involved during the next inspection of your licensed program.

Based on the results of this inspection, it appears that one of your activities was not conducted in full compliance with NRC requirements, as set forth in the Notice of Violation, enclosed herewith as Appendix A. This item of noncompliance has been categorized into the levels as described in our correspondence to you dated December 31, 1974. This notice is sent to you pursuant to the provisions of Section 2.201 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations. Although Section 2.201 requires you to submit to this office, within 20 days of your receipt of this notice, a written statement of explanation, we note that this item of noncompliance was reported to this office in your letter dated September 20, 1979, and your corrective actions were reviewed during our November 6, 1979 inspection. Therefore, no response with respect to this matter is

required.

8001310105
OFFICE

DATE

FFMS

FFMS

FFMS

Costello, CGC

Glenn

McClintock

12/7/79

12/10/79

12/10/79

DEC 10 1979

From discussions at the conclusion of the inspection, it is our understanding that you are modifying your waste handling procedures to assure that proper surveys are performed and recorded prior to shipment. We will review this matter during our next inspection of your licensed program.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter will be placed in the Public Document Room.

No reply to this letter is required; however, should you have any questions concerning this inspection, we will be pleased to discuss them with you.

Sincerely,

Robert O. McClintock, Chief
Materials Radiological Protection
Section

Enclosure: Appendix A Notice of Violation

bcc:
IE Mail & Files (For Appropriate Distribution)
Central Files
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
REG:I Reading Room
State of New Jersey

OFFICE ►					
SURNAME ►					
DATE ►					

APPENDIX A

NOTICE OF VIOLATION

Isomedix, Incorporated
Whippany, New Jersey 07981
License No. 29-15364-01

Docket No. 30-8985

Based on the results of an NRC inspection conducted on November 6, 1979 it appears that one of your activities was not conducted in full compliance with NRC regulations as indicated below:

10 CFR 20.101(a) limits the whole body exposure of an individual in a restricted area to one and one quarter rems per calendar quarter, except as provided by 10 CFR 20.101(b). Paragraph (b) allows a whole body exposure of three rems per calendar quarter provided certain specified conditions are met.

Contrary to this requirement, one individual working in your restricted area received a radiation dose of 3.140 rem to the whole body during the second quarter of 1979.

This is an infraction.

~~80013100~~
~~80013100~~ IP

OFFICE ►

SURNAME ►

DATE ►

Page 1 of Attached☐ Appendix A☐ Appendix B☒ Appendix C☐ MemoINSPECTION REPORT NO. 79-03ISOMEDIX, INCWhispering, NJLicensee contact: B. DietzTelephone no. 201-887-4706License no. 29-15364-01 Last amendment and date: Category: E, and Priority: IV, as of last amendment.Inspection date(s): 11/6/79 Type of inspection: Special, Unannounced

SUMMARY OF FINDINGS AND ACTION

☐ No noncompliance, clear SSI issued☐ Noncompliance, SSI issued☒ Noncompliance, Appendix A☐ Regional action Hq action☐ Action on previous noncompliance, Appendix B☐ Supplemental info, Appendix C

RECOMMENDATIONS

See basis in Appendix C or attached memo.

☐ Change Category to: ☐ Change Priority to: ☐ Next inspection date:

PERSONS CONTACTED

B. Dietz, PresidentInspector: D. CostelloApproved: R. McEntee11/21/7911/26/798547134381

Plan approved: _____ Date: _____

Licensee: _____

License no: _____

Inspection Items	Scheduled for inspection	Post-inspection status	Module no.	766 Time Info
Management meeting - Entrance and Exit Interviews [REQUIRED]	/	/	307038	1
Initial Management Meeting				
Program requirements, MC 23 [REQUIRED]	<i>Limited Inspection</i>		777108	2
Licensee Event Followup			927008	
Followup on Inspector-identified problems			927018	
Followup on Noncompliance and Deviations			927028	
IE Bulletin/Immediate Action Letter Followup			927038	
Followup on Headquarters Requests	-	-	927048	
Followup on Regional Requests			927058	
Independent Inspection Effort [REQUIRED]	/	/	927068	1
Inspector Dispatched to Site			937008	
Followup on Significant Event Occurring During Inspection			937018	

The inspection was limited to a review of a reported overexposure, urinalysis results, and the progress of the decontamination effort.

The overexposure resulted from confusion on the part of the sub-contractor, Chem-Nuclear, as to the period of time constituting the second calendar quarter. The licensee has identified the cause of the problem and corrected it. The inspector reviewed the dosimeter logs and interviewed the individual involved and determined that the licensee had control over the accumulation of dose. The overexposure resulted from an administrative problem. The highest exposure for the third quarter was 2190 mrem as of 9/24/79 film badge units. The doses being received currently are much less than previously because of the greatly reduced dose rates in the work areas. MPC-4's were reviewed and noted as proper.

The licensee had reported to Region I in a letter dated October 11, 1979 the results of ~~the~~ employee urinalyses. One result was greater than the minimum detectable levels and this indicated 1.5×10^{-4} mCi/liter. The inspector reviewed the licensee's air sampling results and respiratory protection program. A No air sample ~~was~~ indicated concentration in excess of MPC_a for CO-60. The inspector reviewed the calibration of the equipment used to evaluate the air samples and determined that an HP-210 ~~or~~ GM was used with a PS-2 scaler. This equipment was calibrated with a Co-60 standard ~~of~~ (.005 μ Ci on 9/68). Because of the

limited sensitivity of ~~usual~~ urinalysis for determining ^{60}Co uptake, the licensee agreed to have a whole body count performed on the individual whose urinalysis indicated a positive result.

The decontamination is still incomplete. There are still several hot spots in the pool, and ~~there~~ there are 4 holes in the pit all with low levels of contamination in the bottom. The ventilation system still contains activity and will be removed. The licensee is taking daily smear surveys in the unrestricted area to ensure ~~that~~ against the spread of contamination during the cleanup. The liquid waste is being solidified using Cuscomite. Chem Nuclear drums the waste, loads it onto a truck or coast, and ships it to Barnwell, South Carolina. Water is solidified with cement. The inspector ~~agreed~~ ~~was~~ observed one drum which was opened in his presence and noted that the waste was in solid form with no free-standing liquid. The licensee has not been recording the number of outgoing waste trucks and coasts and has agreed to modify procedures to ensure that this is done.