

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		3. License number
1. Isomedix Operations, Inc.		20-28791-01
2. 435 Whitney Street Northborough, Massachusetts 01532		4. Expiration date
		December 31, 1992
		5. Docket or Reference No
		030-32931/29-19769-02
6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Cobalt 60	A. Sealed sources (AECL Model C-188, Type 1, 2, 3, or 4)	A. Not to exceed 14,250 curies per source and 4,000,000 curies total
B. Cesium 137	B. Sealed sources	B. Not to exceed 10 microcuries per source and 100 microcuries total
9. Authorized use		
A. For use in AECL Model Ir-126 irradiator for irradiation materials, including food, other than explosives, corrosives, or highly flammable products.		
B. For use in instrument check sources.		

CONDITIONS

10. Licensed material may be used only at the licensee's facilities at 435 Whitney Street, Northborough, Massachusetts.
11. A. Licensed material shall be used by, or under the supervision and in the physical presence of, George Dietz, George Baker, Stanley Yap, John Masefield, William M. Owens, or other individuals designated by the Radiation Protection Officer.
B. The Radiation Safety Officer for this license is George Dietz.
12. Each individual user under this license shall be designated in accordance with the "Operator Designation and Training" procedures described in Section 9 and 10 of the application for license dated May 24, 1982 and letter dated June 15, 1987.
13. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiator shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such

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(Continued)

CONDITIONS

14. The irradiation of foods and the distribution of food for human consumption shall be in accordance with the rules and regulations of the U.S. Department of Health and Human Services, Food and Drug Administration.
15. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed 3 years.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- E. Sealed sources and detector cells need not be leak tested if:
- (i) they contain only hydrogen 3; or
 - (ii) they contain only a gas; or
 - (iii) the half-life of the isotope is 30 days or less; or
 - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
 - (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

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CONDITIONS

- F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source involved, the test results, and corrective action taken.
- G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.
16. Written instructions contained in Section 8 - 1 of the application for license dated May 24, 1982 shall be followed and a copy of these instructions shall be made available to each individual using or having responsibility for use of licensed material. Any changes in these instructions shall have the prior approval of the Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.
17. This license does not authorize repairs or alterations of the irradiator involving removal of shielding or access to the licensed material except as provided otherwise by specific condition of this license. Removal, replacement and disposal of sealed sources shall be performed only by "AECL" or by other persons specifically authorized by the Commission or an Agreement State to perform such activities.
18. Before initiation of irradiator operations or after reloading of sources in the irradiator and before restart of the irradiator, a radiation survey shall be conducted to determine radiation levels around, above and below the irradiator with the sources in the shielded position and in the exposed position. The results of the survey shall be sent to the U.S. Nuclear Regulatory Commission, Region Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406, not more than 30 days after the survey is conducted.

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(Continued)

CONDITIONS

19. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated May 24, 1982
- B. Letter dated August 9, 1982
- C. Letter dated August 18, 1982
- D. Letter dated June 15, 1987
- E. Letter dated February 29, 1988
- F. Letter dated April 13, 1989
- G. Letter dated May 16, 1989
- H. Letter dated May 19, 1989
- I. Letter dated April 12, 1991

For the U.S. Nuclear Regulatory Commission

Original Signed By:
Judith A. Joustra

By

Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

Date SEP 24 1992

SEP 24 1992

License No. 20-28791-01
Docket No. 030-32931
Control No. 117170

Isomedix Operations, Inc.
ATTN: George R. Dietz
Vice President
435 Whitney Street
Northborough, Massachusetts 01532

Dear Mr. Dietz:

Please find enclosed your NRC material license.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the Region I Material Licensing Section, (215) 337-5093, so that we can provide appropriate corrections and answers.

Please be advised that you must conduct your program involving licensed radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, please note the items in the enclosed, "Requirements for Materials Licensees."

We have issued a new license in response to your letter dated April 12, 1991 because the address in Condition No. 2 of your license determines the license number. Since you requested that Condition 2 of your license be changed from Whippany, New Jersey to Northborough, Massachusetts, a new license number was required.

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, the NRC expects licensees to pay meticulous attention to detail and to achieve the high standard of compliance which the NRC expects of its licensees.

You will be periodically inspected by NRC. A fee may be charged for inspections in accordance with 10 CFR Part 170. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in prompt and

Reviewer -

9-18-92

Cover letter for new license should include a statement explaining the New license issue. The Company ^{changed or} moved to another state and it should not have been a straight Amendment but a New license and Term.

RJB

REVIEWER -

ADMINISTRATIVE CHANGE
OF LICENSE NUMBER REQUIRED
DUE TO OVERSIGHT IN
ADMINISTRATIVE PROCESSING
OF LICENSE 29-19769-02 AMENDMENT
(11 PAGES)
IN 1991.

ISSUE NEW MASS. LICENSE
THEN TERMINATE NEW JERSEY
LIC. 29-19769-02 (117171).
EXP. DATE FOR MASS. LICENSE
REMAINS DEC. 31, 1992. ^{7/88}

vigorous enforcement action against you. This could include issuance of a notice of violation, or in case of serious violations, an imposition of a civil penalty or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

We wish you success in operating a safe and effective licensed program.

Sincerely,

Original Signed By:
Judith A. Joustra

Francis M. Costello, Chief
Industrial Applications Section
Division of Radiation Safety
and Safeguards

Enclosures:

1. License No. 20-28791-01
2. Requirements for Materials Licensees
3. NRC Form 313
4. 10 CFR 2, 19, 20, 30, 71, and 170 and 171

DRSS:RI
White/gcb

9/23/92

DRSS:RI
Costello

9/23/92



April 12, 1991

L&L 28791
030-32931
03521

Mr. Anthony Kirkwood
U.S. Nuclear Regulatory Commission
Region I
Nuclear Material Section B
475 Allendale Road
King of Prussia, Pennsylvania 19406

RE: License #29-19769-02

Dear Mr. Kirkwood:

Enclosed is our Application for Material License Amendment requesting the following:

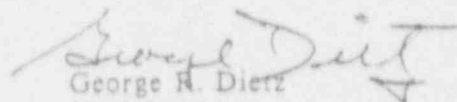
Items 1 and 2 of the license (NRC Form 374) should be changed to:

1. Isomedix Operations Inc.
2. 435 Whitney Street
Northborough, Massachusetts 01532

Mrs. Sandra Kimberly confirmed the fee schedule cited in paragraph 12 of the Form 313.

Very truly yours,

ISOMEDIX INC.


George R. Dietz
Vice President

GRD:kl
Enclosure

OFFICIAL RECORD COPY

ML 10

117170

ISOMEDIX INC.

SEP 17 1992

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF MATERIAL SAFETY, NMSS
WASHINGTON, D.C.

ALL OTHER PERSONS LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30333

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
795 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
511 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

L & L 28791

030-
03521

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR (Check appropriate item):

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code):

- ☐ A. NEW LICENSE
☒ B. AMENDMENT TO LICENSE NUMBER 29-19769-02
☐ C. RENEWAL OF LICENSE NUMBER _____

Isomedix Inc.
11 Apollo Drive
Whippany, New Jersey 07981

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED:

Same as license condition #10

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION:

George R. Dietz

TELEPHONE NUMBER

(201) 887-4700

SUBMIT ITEMS 5 THROUGH 11 ON 8 1/2 X 11 PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREA.
9. FACILITIES AND EQUIPMENT	10. RADIATION SAFETY PROGRAM
11. WASTE MANAGEMENT	12. LICENSES FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY <u>3C</u> AMOUNT ENCLOSED \$ <u>370.00</u>

13. CERTIFICATION: Must be completed by applicant. THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS PARTS 20, 22, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE - CERTIFYING OFFICER: George R. Dietz TYPED/PRINTED NAME: George R. DIETZ TITLE: Vice President DATE: 4-12-91

1. ANNUAL RECEIPTS	2. NUMBER OF EMPLOYEES (Full-time entire facility excluding outside contractors)	3. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (Labor and/or shift pay) IN THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? (NRC regulations permit it to protect confidential commercial or financial—proprietary—information furnished to the agency in confidence)
<\$250K \$250K-\$500K \$500K-\$750K \$750K-\$1M	\$1M-\$3.5M \$3.5M-\$7M \$7M-\$10M >\$10M	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO

FOR NRC USE ONLY		APPROVED BY
TYPE OF FEE	FEE LOG	DATE
AMOUNT RECEIVED	CHECK NUMBER	

BETWEEN:

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PROGRAM CODE: 03521
STATUS CODE: 3
FEE CATEGORY: -----
EXP. DATE: 0
FEE COMMENTS: -----
DECOM FIN ASSUR REQD:

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A. REGION

1. APPLICATION ATTACHED

2. FEE ATTACHED

AMOUNT: \$ 00.00
CHECK NO.: 0000000000

3. COMMENTS

Administrative Change of a
incorrectly issued license
Amendment that had a state
change. RES. 117171

SIGNED
DATE

Rebecca J. Brown
9/18/92

B. LICENSE AND MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /_/)

1. FEE CATEGORY AND AMOUNT:

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:

AMENDMENT
RENEWAL
LICENSE

3. OTHER

SIGNED
DATE

MS 63407
entered for
9-18-92