

APPLICATION FOR MATERIAL LICENSE

030-30145

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 FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNELYVANIA, 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 30323

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
799 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
611 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

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)

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

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

Diagnostic Imaging Center of New Jersey
772 Northfield Avenue
West Orange, New Jersey 07052

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

SAME AS #2.

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

William G. Maniscalco, M.S.

TELEPHONE NUMBER

201-795-8252

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 AREAS.

9. FA 8801280171 870915
REG1 LIC30
29-28077-01 PDR

10. RADIATION SAFETY PROGRAM.

11. WA.

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY office Nuclear Med Dept AMOUNT ENCLOSED \$ 580.00

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 30, 32, 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

TYPED/PRINTED NAME

TITLE

DATE

Irwin Singer

M.D.

7/21/87

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS

< \$250K
\$250K-\$500K
\$500K-\$750K
\$750K-\$1M

\$1M-\$3.5M
\$3.5M-\$7M
\$7M-\$10M
> \$10M

b. NUMBER OF EMPLOYEES (Total for entire facility excluding outside contractors)

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (Total and/or staff hours) ON 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)

YES

NO

FOR NRC USE ONLY

TYPE OF FEE

FEE LOG

FEE CATEGORY

COMMENTS

APPROVED BY

AMOUNT RECEIVED

CHECK NUMBER

DATE

29 JUL 1987

ITEM 5+6

RADIOACTIVE MATERIALS

BYPRODUCT, NUCLEAR MATERIAL	REAGENT, AND/OR SPECIAL FORM	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM AMOUNT THAT LICENSEE MAY POSSESS AT ANY ONE TIME UNDER THIS LICENSE
Any byproduct material listed in groups I and II of schedule A, section 35.100 of 10 CFR 35.	Any radiopharmaceutical listed in groups I and II of Schedule A, section 35.100 of 10 CFR 35.	Any radiopharmaceutical listed in groups I and II of Schedule A, section 35.100 of 10 CFR 35.	AS necessary for any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100, Title 10 Code of Federal Regulations
Any reagent kit listed in group III of schedule A, section 35.100 of 10 CFR 35.	Any form except generators, listed in Group III of Schedule A, Section 35.100 of 10 CFR 35.	Any form except generators, listed in Group III of Schedule A, Section 35.100 of 10 CFR 35.	As necessary for preparation and use of pharmaceuticals for any diagno- stic procedures listed in Group III, of Schedule A, sec. 35.100, 10 CFR 35.
Iodine 131 as listed in group IV of schedule A, section 35.100 of 10 CFR 35.	Iodide as listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35.	Iodide as listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35.	30 mCi for any therapeutic procedure listed for 131 Iodine in Group IV of Schedule A, Sec. 35.100, 10 CFR 35.

ITEM 7

INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

Irwin Singer, M.D. : training and experience on file with
New York City License # 2618-1 (enclosed).

(7-A thru C)

ITEM 7-1

Same as Item 7.

ITEM 7-2

Same as Item 7.

ITEM 7-3

Same as Item 7.

ITEM 8

TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

We will establish and impliment the model training program that was published in Appendix A, Revision 2, Regulatory Guide 10.8.

CITY OF NEW YORK
RADIOACTIVE MATERIALS LICENSE
AMENDMENT NUMBER 5

Pursuant to the New York City Charter and Article 175 of the New York City Health Code, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to transfer, receive, possess and use the radioactive material(s) designated below; and to use such radioactive materials for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders now or hereafter in effect of all appropriate regulatory agencies and to any conditions specified below.

In accordance with application received in office of New York City Bureau of Radiation Control on August 11, 1986, from Stuart Sheinbrot, M.D.

- | | |
|---|--|
| 1. Name: Stuart Sheinbrot, M.D.
Irwin Singer, M.D. | 3. License Number:
2618-1 is hereby amended in its entirety to read as follows: |
| 2. Address: 2626 East 14 Street
Brooklyn, New York 11235 | 4. Expiration Date:
August 31, 1991 |
| | 5. Reference Number: |

6. Radioactive materials (element and mass #)	7. Chemical and/or physical form	8. Maximum quantity licensee may possess at any one time
(A) Any radioactive materials listed in Groups I & II of Table (6), Section 175.117 Article 175 of the NYC Health Code.	(A) Any radiopharmaceutical listed in Groups I & II of Table (6) Section 175.117 Article 175 of the NYC Health Code.	(A) As necessary for uses authorized in subitem 9(a)
(B) Cobalt 57	(B) Sealed Source (Type-E vial: Model#NES 206 or NES-352)	(B) 5 Millicuries
(C) Rubidium 81	(C) Contained in a dispensing column within a Krypton-81m gas generator and eluted by passage of humidified oxygen or air through the column, (Supplied by Medi-Physics)	(C) 5 Millicuries
(D) Krypton 81m	(D) Gas (Supplied by Medi-Physics NDA#18-088)	(D) 5 Millicuries
(E) Thallium 201	(E) Thallous Chloride (Supplied by N.E.N. N.D.A. #17-896; Mallinckrodt N.D.A. #18-110; or Squibb N.D.A. #18-548)	(E) 20 Millicuries
(F) Iodine 131	(F) Sodium Iodide (Oral solution or capsules, Supplied by Isorex N.D.A. #8-200; Squibb N.D.A. #10-929; Mallinckrodt N.D.A. #'s 16-515 & 16-517 or Syncor N.D.A. #'s 17-300 & 17-315)	(F) 20 Millicuries

FOR THE NEW YORK CITY DEPARTMENT OF HEALTH

Date

by
Richard P. Borri, Acting Chief

item 7-B

CITY OF NEW YORK
RADIOACTIVE MATERIALS LICENSE
AMENDMENT NUMBER 5 LICENSE NUMBER 2618-1

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CONDITIONS

9. Authorized use:

- (A) Any diagnostic procedure listed in Groups I & II of Table Six(6), Section 175.117, Article 175 of the New York City Health Code.
- (B) To be used as calibration standard.
- (C) The radioisotope from which the Krypton 81m is produced.
- (D) Pulmonary ventilation studies.
- (E) Myocardial imaging.
- (F) Diagnosis of thyroid function and treatment of hyperthyroidism.

10. (A) The licensee shall comply with the provisions of Article 175 of the New York City Health Code, entitled "Radiation Control".

(B) Failure to pay the fee for inspection of a radioactive material site, and notification from the Department will result in termination of this license.

11. Radioactive material shall be used only by Stuart Sheinbrot, M.D. or Irwin Singer, M.D.

12. The radioactive material shall be used only at 2626 East 14 Street, Brooklyn, New York 11235.

13. (A) Radioactive material authorized in the groups specified in Subitems 6 and 7 shall be used in accordance with the provisions of Section 175.103(o)(p)(q)(r) and (s) of Article 175 of the New York City Health Code and also in accordance with the information contained in the label affixed to the package or leaflet or brochure accompanying the package.

(B) Radiopharmaceuticals being distributed with the investigational use labeling and a "Notice of Claimed Investigational Exemption for a New Drug"(IND) number assigned by the Food and Drug Administration(FDA) are not authorized in the groups specified in Subitems 6 and 7.

(C) The possession limit, when specified in Subitem 8, includes all radioactive material possessed by the licensee under this license whether in storage, implanted in hospitalized patients or otherwise in use.

14. Radioactive gases as free gas or in solution, to be administered to humans, shall be procured from a supplier who distributes the product indicated for human use in accordance with the Federal Food, Drug and Cosmetic Act.

15. Radioactive material to be administered to humans shall be procured from a supplier licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to distribute the product to Group Licensees.

16. (A) The licensee may use the Calichek device for doing linearity tests of his dose calibrator provided he follows the procedures in the Calcorp, Inc., Manual dated March 2, 1982.

(B) The Licensee may use the Lineator device for doing linearity tests of his dose calibrator provided he follows the procedures in the Atomic Products Corporation Lineator Instructions Manual dated June 20, 1983.

FOR THE NEW YORK CITY DEPARTMENT OF HEALTH

Date

by

Richard P. Borri, Acting Chief

item 7-C

CITY OF NEW YORK
RADIOACTIVE MATERIALS LICENSE
AMENDMENT NUMBER 5 LICENSE NUMBER 2618-1

Page 3 of 3 Pages

17. The license is authorized to hold radioactive material with a physical half-life of less than 45 days for decay-in-storage before disposal in ordinary trash provided:

(A) Radioactive waste to be disposed of in this manner shall be held for decay for a minimum of ten(10) half-lives.

(B) Prior to disposal as normal waste, radioactive waste shall be monitored to determine that its radioactivity cannot be distinguished from background with typical low-level laboratory survey instruments. All radiation labels will be removed or obliterated.

(C) Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

18. (A) 1. Each sealed source containing radioactive material, other than hydrogen 3, with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six(6) months. In the absence of a certificate from a transferor indicating that a test has been made within six(6) months prior to the transfer, the sealed source shall not be used until tested.

2. Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

(B) The test shall be capable of detecting the presence of 0.005 microcurie of removable contamination on the source. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored, on which one might expect contamination to accumulate.

(C) Records of leak test results shall be kept in units of microcuries, and maintained for inspection by the Bureau for Radiation Control.

(D) If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use, and shall cause it to be decontaminated and repaired, or to be disposed of in accordance with Department Regulations. A report shall be filed within five(5) days of the test with the Radioactive Materials Division, Bureau for Radiation Control, 111 Livingston Street, Brooklyn, New York 11201, 20th Floor, describing the equipment involved, the test results, and the corrective action taken.

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. Article 173 of the New York City Health Code shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations. Application and attached information received in office of New York City Bureau for Radiation Control on August 11, 1986.

FOR THE NEW YORK CITY DEPARTMENT OF HEALTH

Date

by Richard P. Borri
Richard P. Borri, Acting Chief

ITEM 9

INTRUMENTATION

CALIBRATION

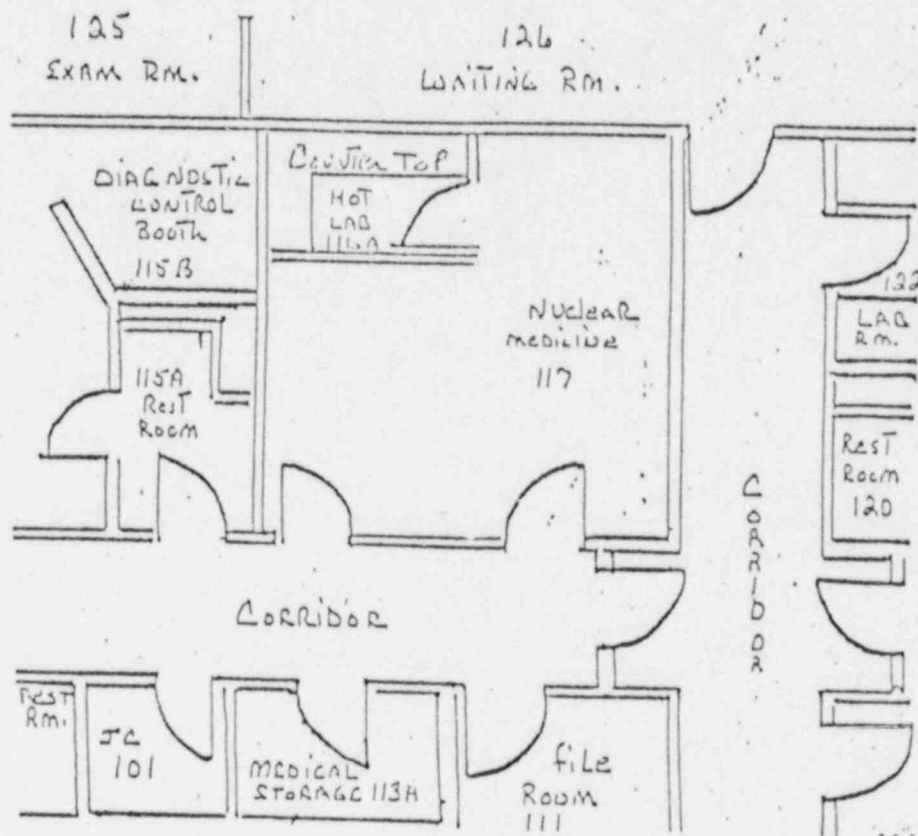
FREQUENCY

Ludlum 14-C	-----performed by:-----	-----Annually
	Teledyne Isotopes	
	50 Van Buren Ave.	
	Westwood, N.J. 07675	
Victoreen 498	-----performed by:-----	-----Annually
	same as above	
MedX LF-61	-----Field Uniformity-----	-----Daily
	Field Resolution using a bar phantom-----	-----Weekly
Capintec CRC-7	-----Consistency: using Co57, Cs137, Ba133 reference-----	-----Daily
	sealed sources and following the procedures	
	in NRC Regulatory Guide 10.8, Appendix D,	
	Section 2C.	
	Linearity: following procedures as above-----	-----Quarterly and after
	Section 2E.	repair
	Accuracy: following procedures as above-----	-----Annually and after
	Section 2G.	repair
	Geometric Variation: following procedures as-----	-----At Installation and
	above Section 2F.	after repair

PERSONNEL EXTERNAL MONITORING PROGRAM: Monthly Total body badges and TLD rings supplied by R.S. Landaur, Inc. in accordance with Appendix D, revision 2, Regulatory Guide 10.8.

9A

DIAGRAM: NUCLEAR MEDICINE FACILITY
Diagnostic Imaging Center WEST ORANGE, N.J.
of New Jersey



ALL SOURCES AND ISOTOPES WILL BE, FOR MOST OF THE DAY, SHIELDED INSIDE EITHER A LEAD VAULT, BEHIND LEAD BRICKS OR IN THE MANUFACTURERS SHIPMENT SHIELDING INSIDE THE HOT LAB.

THE SHIELDING OF THE WALL ADJACENT TO ROOM 126, THE WAITING ROOM, WILL BE 2.0mmPb.

THE SHIELDING OF THE WALL ADJACENT TO THE CONTROL BOOTH, ROOM 115B, REQUIRED NO ADDITIONAL SHIELDING AS IT IS SHIELDED ON THE CONTROL BOOTH SIDE WITH 2.0mmPb.

THE REMAINING WALLS, ADJACENT TO ULTRA SOUND, ROOM 116 AND NUCLEAR MEDICINE, ROOM 117, REQUIRE A MINIMUM OF 1.54mmPb.

THE DOOR MUST BE SHIELDED AS PER THE SPECIFICATION FOR THE NUCLEAR MEDICINE WALL AT LEAST 1.54mmPb.

THE SHIELDING SHOULD BE EXTENDED TO A HEIGHT OF 7.0 ft. ON EACH WALL

THE CEILING IS NOT A CONSIDERATION AT THIS TIME AS THERE IS NO SECOND FLOOR.

ITEM 10

RADIATION SAFETY PROGRAM

The ALARA Program will be followed as per Appendix G, Revision 2,
of Regulatory Guide 10.8.

Leak Testing as per Appendix H, Revision 2 regulatory Guide 10.8.

~~Safe~~ use of Radiopharmaceuticals as per Appendix I.

Spill Procedures as per Appendix J.

Ordering and Receiving as per Appendix K.

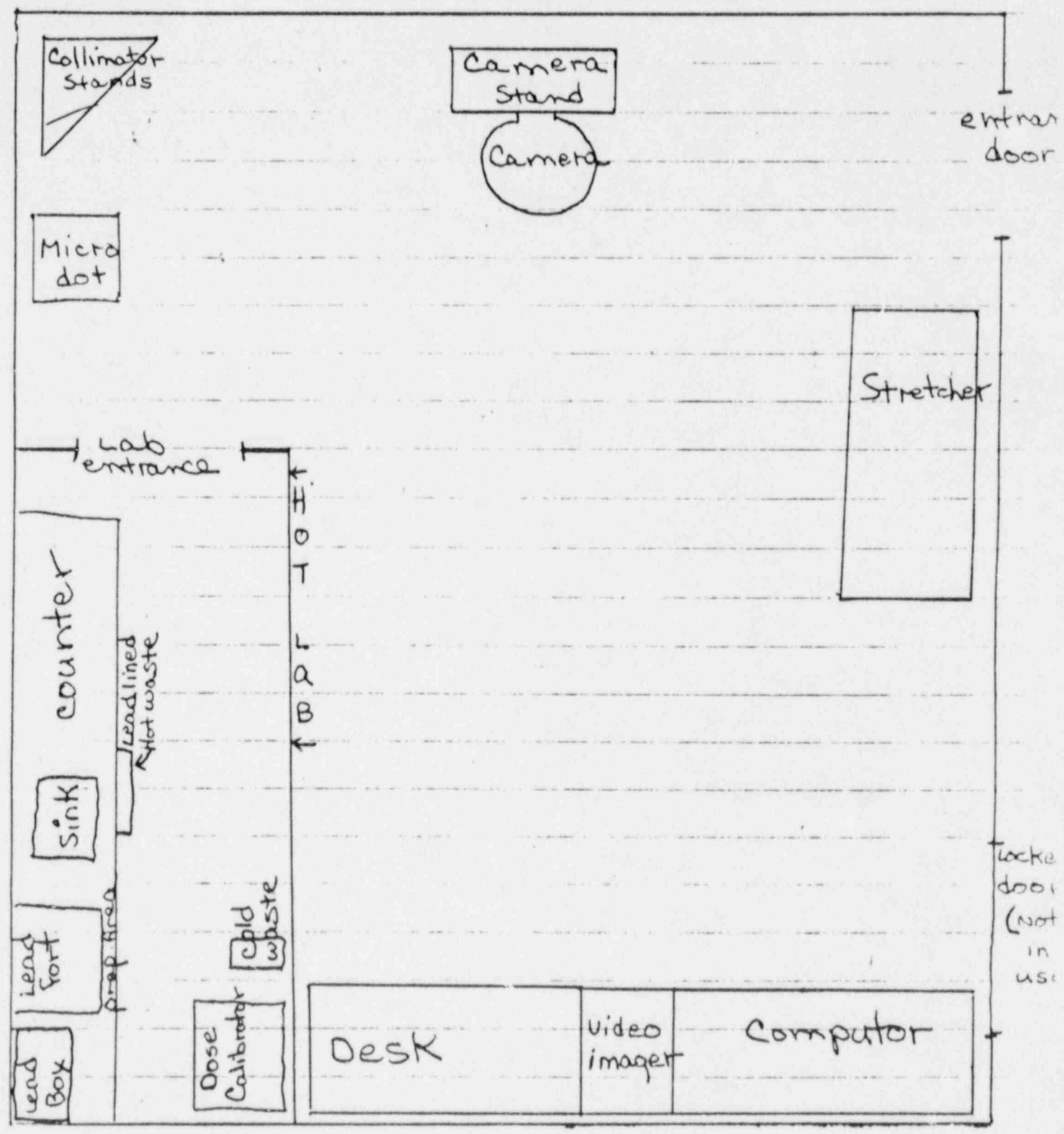
Opening packages as per Appendix L.

Records of Byproduct Material used as per Appendix M.1 and M.2.

Area Survey Procedures as per Appendix N.

29 JUL 1987

Diagnostic Imaging Center of N.J. Nuclear Medicine Department Area Survey Map



item 10 E

DIAGNOSTIC IMAGING CENTER OF NEW JERSEY

DAILY SURVEY-WEEKLY WIPE TEST

BKG- _____ mr/hr
BKG- _____ cpm

LOCATION	monday	tuesday	wednesday	thursday	friday	friday
	mr/hr	mr/hr	mr/hr	mr/hr	mr/hr	cpm
STRETCHER						
ENTRANCE						
CAMERA						
FLOOR						
Micro-dot CONSOLE						
computer CONSOLE						
LAB-FLOOR						
PREP AREA						
SINK						
Dose CALIBRATOR						
LEAD FORT						
DESK						
SURVEYOR						

SURVEY INSTRUMENT- Ludlum G-M Meter

WIPE TEST INSTRUMENT- gamma camera in uptake mode

COMMENTS OR ACTION TAKEN: _____

Radiological Physicist

As per attachment 10A

All sealed sources and hot waste are stored in the lead box. All doses and their preparations are handled behind a lead glass shield, in the lead fort. Syringe shields are used when handling syringes. gloves are worn at all times in the lab. All radioactive vials are handles in their lead shield or with 10 inch tongs.

ITEM 11

Waste management.

All unit doses and needles are returned to and by the manufacturer (Mallinckrodt or Syncor).

Any additional supplies used (needles, syringes, vials) are dated and stored in a lead box (see item 10-A) for 10 half-lives and survey readings are background level.

All contaminated gloves and swabs used are stored in lead-lined waste container for at least 10 half lives and survey readings are background level.

storage and disposal records are maintained in the department (see item 10-B).

All radioactive labels will be defaced or removed from packages and containers prior to disposal in in-house waste.

BETWEEN: C. James Holloway, Chief
License Fee Management Branch
Office of Resource Management

John E. Glenn, Chief
Nuclear Materials Safety & Safeguards Section B
Division of Radiation Safety and Safeguards

030-30145

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee:

Diagnostic Imaging Center of NJ
7/21/87

Application Dated:

Control No.:

107624

License No.:

New

2. FEE ATTACHED

Amount:

\$580.00

Check No.:

00466

3. COMMENTS

Signed

Date

Forster
8/4/87

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount:

7C

\$580

2. Correct Fee Paid. Application may be processed for:

Amendment

Renewal

License

Signed

Date

J. Lamberly
8/10/87