L+L-28032
030-3007

NRC FORM 313M (8-86) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved by OMB 3150-0041 Expires 6-30-89

INSTRUCTIONS – *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(Institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

Life Signs/Boston, Inc.
d.b.a Boston Cardiovascular Health Center
1101 Beacon Street
Brookline MA 02146

TELEPHONE NO.: AREA CODE (617) 232 - 1990

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

Life Signs/Boston, Inc.
dba Boston Cardiovascular Health Center
One Brookline, Place Suite 305
Brookline, MA 02146 (617)734-7722

2. PERSON TO CONTACT REGARDING THIS APPLICATION

F.X. Masse

TELEPHONE NO.: AREA CODE (617) 245-6600

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

a. [X] NEW LICENSE
b. [ ] AMENDMENT TO LICENSE NO. _____
c. [ ] RENEWAL OF LICENSE NO. _____

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*

Alan H. Robbins, MD
Charles Boucher, MD

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

Alan H. Robbins, MD, with consultation from F.X. Masse Associates, Inc.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)*

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE

Log ____ May 13
Remitter ____
Check No. 257987 (35)
Amount $1,200 (refunded 6/20)
Fee Category 7C
Type of Fee Application
Date Check Rec'd 5/22/87
Date Completed 5/27/87
By: [illegible]

8801050423 870714
REG1 LIC30
20-28032-01 PDR

14 MAY 1987 107251

"OFFICIAL RECORD COPY" ML10

NRC FORM 313M (8-86)

NRC FORM 313M
(8-86)
10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE -- MEDICAL

Approved by OMB
3150-0041
Expires 6-30-89

INSTRUCTIONS - *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

Life Signs/Boston, Inc.
d.b.a Boston Cardiovascular Health Center
1101 Beacon Street
Brookline MA 02145

TELEPHONE NO. AREA CODE (617) 232 - 1990

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

same

2. PERSON TO CONTACT REGARDING THIS APPLICATION

F.X. Masse

TELEPHONE NO. AREA CODE (617) 245-6600

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

a. [X] NEW LICENSE
b. [ ] AMENDMENT TO LICENSE NO.
c. [ ] RENEWAL OF LICENSE NO.

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*

Alan H. Robbins, MD
Charles Boucher, MD

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

Alan H. Robbins, MD, with consultation from F.X. Masse Associates, Inc.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

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10 CFR 31.11 FOR IN VITRO STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
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IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)*

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. _____ Date: _____

7. MEDICAL ISOTOPES COMMITTEE N/A	15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*
Names and Specialties Attached; and	X Appendix G Rules Followed; or
Duties as in Appendix B; or *(Check One)*	Equivalent Rules Attached
Equivalent Duties Attached	16. EMERGENCY PROCEDURES *(Check One)*
8. TRAINING AND EXPERIENCE	X Appendix H Procedures Followed; or
X Supplements A & B Attached for Each Individual User; and	Equivalent Procedures Attached
Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES *(Check One)*
9. INSTRUMENTATION *(Check One)*	X Appendix I Procedures Followed; or
Appendix C Form Attached; or	Equivalent Procedures Attached
X List by Name and Model Number	18. WASTE DISPOSAL *(Check One)*
10. CALIBRATION OF INSTRUMENTS	X Appendix J Form Attached; or
Appendix D Procedures Followed for Survey Instruments; or *(Check One)*	Equivalent Information Attached
X Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS N/A *(Check One)*
Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*	Appendix K Procedures Followed; or
X Equivalent Procedures Attached	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	20. THERAPEUTIC USE OF SEALED SOURCES N/A
X Description and Diagram Attached	Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM	Appendix L Procedures Followed; or *(Check One)*
X Description of Training Attached	Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133) N/A
X Detailed Information Attached	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS N/A
	Detailed Information Attached
X Appendix F Procedures Followed; or	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b N/A
Equivalent Procedures Attached	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	XX	FILM	R.S. Landauer Jr. & Co.	monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	XX	TLD	R.S. Landauer Jr. & Co.	monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL: New England Baptist Hospital

MAILING ADDRESS: 91 Parker Hill Avenue

CITY: Boston | STATE: MA | ZIP CODE: 02120

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED
(See Section 170.31, 10 CFR 170)

(1) LICENSE FEE CATEGORY: 7B

(2) LICENSE FEE ENCLOSED: $ $1,200.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) ~~NAME~~ *(Type or Print)* RICHARD D. JACQUIN

(2) ~~TITLE~~ PRESIDENT

c. DATE: 4/29/87

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.

5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

Supporting information on application of Boston Cardiovascular Health Center:

Item 7 Since this application proposes a clinicial laboratory operation, no medical isotopes committee (radiation safety committee) is proposed. Responsibility for the safe operation of this program will rest directly with the individual users with support as necessary from F.X. Massé Associates, Inc.

Item 8 The training and experience of Dr. Alan H. Robbins was submitted in support of application for licensure at New England Baptist Hospital, Boston, Massachusetts, NRC license #20-15522-01.

The training and experience of Dr. Charles Boucher was submitted in support of the application for licensure at the Spaulding Rehabilitation Hospital, Boston, Massachusetts, NRC license #20-20615-01. Since this proposed use is similar to the use at those hospitals, with comparable medical coverage, these references should suffice for both users. As this program grows, other qualified users will join the group and license amendment will be requested.

Item 9 Enclosed is a description of the camera equipment to be purchased for this proposed use. This equipment will be supplemented by the following:

1. Capintec CRC 10 dose calibrator or equivalent

2. Ludlum model 14-C with 44-7 end window probe

Item 11 Enclosed is a diagram of the room in which the nuclear medicine operation will be conducted. The counter adjacent to the sink will be equipped with an L-shield for shielding during preparation of the individual patient doses. Spent source containers (in their original shields) and other dry solid wastes will be stored in the cabinet under the sink for decay.

Dyna Mo provides unsurpassed detector positioning capability no matter how tight the quarters. Vertical travel accommodates beds of any height as well as under-table imaging. The detector is extendible up to 16" to provide a full 42" projection. The detector yoke rotates a full 355° for complete flexibility in opposite side lateral imaging. Dyna Mo is clearly designed for convenience of the operator and comfort of the patient.

Detailed Specifications

Speed:	0 to 2.4 km/h (1.5 mph)
Power:	Batteries (4) are rechargeable
Running Time:	2 hrs. @ max load
Charging Time:	8 hrs.
Max. Incline:	10%
Overall Dimensions:	Length – 66" (168cm) Width – 32-1/2" (83cm) Height – 68-1/2" (174cm) Under Clearance – 4" (10cm)
Weight:	1200 lbs. (545 Kg.)

Detector Positioning Specifications

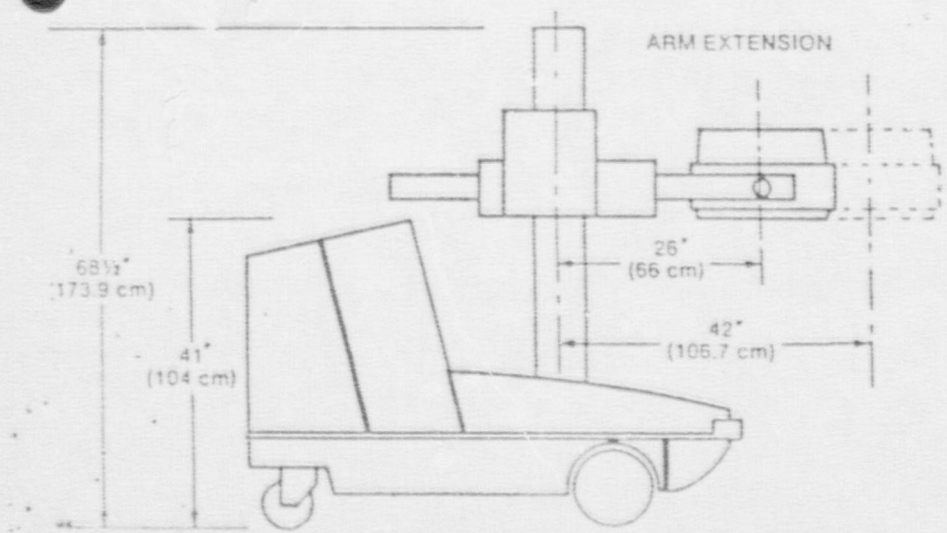
Up-Down:	Speed – 80/40 cm./min, respectively. Lowest position images patient under 29" (74cm). Highest position 52" (132cm)
Beam Motion:	16" (40cm). Reach over bed 26" (66cm). With hood under bed, reach is 38" (96cm)
Head rotation:	270°
Yoke and column rotation:	355°

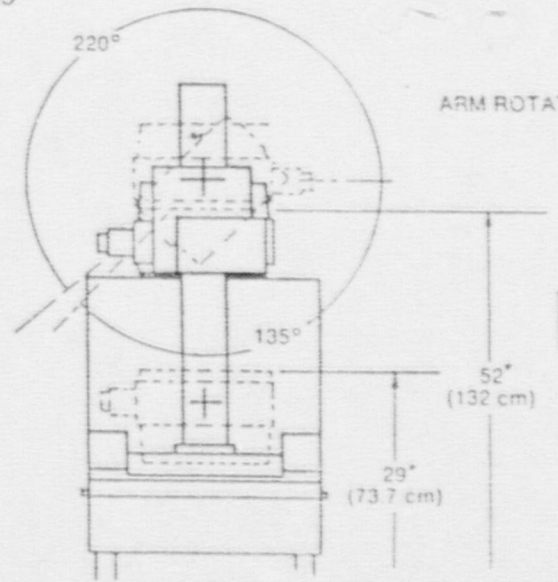
Detector Specifications

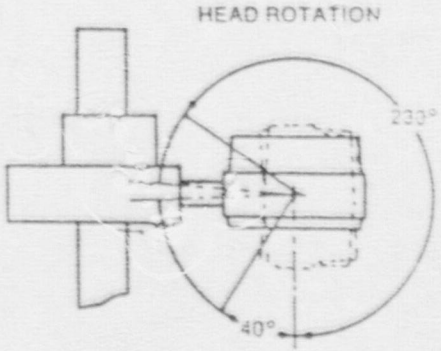
Intrinsic Resolution:	1/12" (2.1mm) Tc
Energy Resolution:	13% FWHM, Tc
Intrinsic Uniformity:	±10%
Field Size:	10.2" (26cm)
Maximum Shielded Energy:	200KeV
Linearity:	±3% over full field
Construction:	NaI (Tl) crystal 37.2" dia. PMT's with variable density light pipe

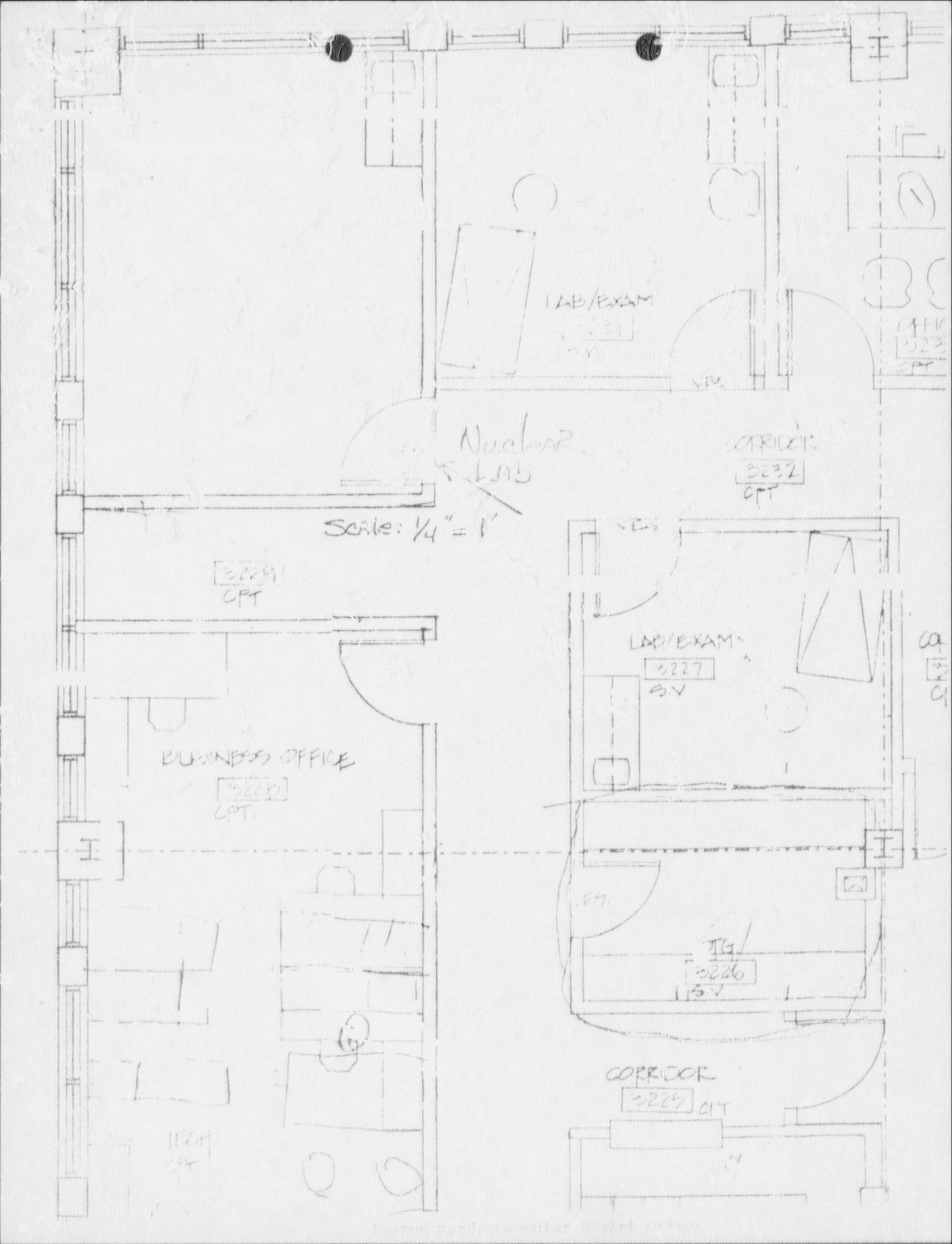
Electronics Specifications

Counting Rate:	Maximum 50% window – 160,000 CPS, point source, ^{99m}Tc, no scatter 20% window – 100,000 CPS, point source, ^{99m}Tc, no scatter
Dead Time:	1.5 μsec single pulse pair resolving time








LAB/EXAM
3231
CPT
Nuclear
3230
CORRIDOR
3232
CPT
Scale: 1/4" = 1'
3229
CPT
LAB/EXAM
3227
CPT
BUSINESS OFFICE
3228
CPT.
TIG
3226
CPT
CORRIDOR
3225
CPT

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

X 1. Survey instruments will be calibrated at least annually and following repair.

X 2. Calibration will be performed at two points on each scale used for radiation protection purposes, i.e., at least up to 1 R/hr.

The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ±10 percent of the calculated or known values for each point checked. Readings within ±20 percent are considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret readings to within ±10 percent. Also, when higher scales are not checked or calibrated, an appropriate precautionary note will be posted on the instrument.

3. Survey instruments will be calibrated

____ a. By the manufacturer

____ b. At the licensee's facility

(1) Calibration source

Radionuclide _____

Manufacturer's name _____

Model no. _____

Activity in millicuries _____

or

Exposure rate at a specified distance _____

Accuracy _____

Traceability to primary standard _____

____ (2) The calibration procedures in Section I of Appendix D will be used

or

____ (3) The step-by-step procedures, including radiation safety procedures, are attached.

X c. By a consultant or outside firm

(1) Name *F.X. Masse Associates Inc.*

(2) Location *PO Box 95, Middleton, MA 01949*

(3) Procedures and sources

_X_ have been approved by NRC and are on file in License No. *20-17148-01*

____ have been approved by an Agreement State; a copy of the Agreement State license, the procedures, and a description of the sources are attached, and the consultant's report will contain the information on

____ the attached "Certificate of Instrument Calibration."

____ the consultant's reporting form as attached.

____ are described in the attachment, and the consultant's report will contain the information on

____ the attached "Certificate of Instrument Calibration."

____ the consultant's reporting form as attached.

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

N/A First elution from new Mo-99/Tc-99m generator

or

X Other* (specify) A source of Tc-99m with activity equivalent to the maximum activity assayed to clinical situations will be used.

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Suggested Activity (mCi)	Activity (mCi)	Accuracy
Co-57	3-5	One millicurie or more	within ± 5%
Ba-133	0.1-0.5	100 microcuries or more	within ± 5%
Cs-137	0.1-0.2	100 microcuries or more	within ± 5%
Ra-226	1-2	N/A	N/A

C. _____ The procedures described in Section 2 of Appendix D will be used for calibration of the dose calibrator

or

X Equivalent procedures are attached.

*For licensees who are not authorized for Mo-99/Tc-99m generators, activity must be equivalent to the highest activity used.

ANSI Standard N42.13 1986 entitled "Calibration and Usage of Dose Calibrator Ionization Chambers of the Assay or Radionuclides" are followed rather than Appendix D.

PERSONNEL TRAINING PROGRAM

I. Individuals who work in or frequent restricted areas will be instructed in the items specified in 10 CFR 19.12 at the time of initial employment and at least annually thereafter.

This instruction will include:

a. All terms of the license pertinent to radiation safety.

b. Areas where radioactive material is used or stored.

c. Potential hazards associated with radioactive material.

d. Radiological safety procedures appropriate to their respective duties.

e. Pertinent NRC regulations.

f. Rules and regulations of the license.

g. Obligation to report unsafe conditions to the radiation safety officer.

h. Appropriate reponse to emergencies or unsafe conditions.

i. Right to be informed of their radiation exposure and bioassay results.

j. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.

II. Individuals whose duties may require them to work in the vicinity of licensed material will be informed about radiation hazards and appropriate precautions at the time of initial employment and at least annually thereafter. This information will be provided initially at hospital employee orientation sessions and annually thereafter at in-service meetings.

APPENDIX E

PROCEDURES FOR ORDERING AND ACCEPTING DELIVERY OF RADIOACTIVE MATERIAL

1. The Supervisory Nuclear Medicine Technologist will place all orders for radioactive materials and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

2. A system for ordering and receiving radioactive materials will be established and maintained. The system will consist minimally of the following:

   a. Ordering of routinely used materials

      (1) Written records that identify the isotope, compound, activity levels, and supplier, etc., will be used.

      (2) The written records will be referenced when opening or storing radioactive shipment.

   b. Ordering of specially used materials (e.g., therapeutic uses)

      (1) A written request* will be obtained from the physician who will perform the procedure.

      (2) Persons ordering the materials will reference the physician's written request when placing the order. The physician's request will indicate isotope, compound, activity level, etc.

      (3) The physician's written request will be referenced when receiving, opening, or storing the radioactive material.

   c. It is essential that written records* be maintained for all ordering and receipt procedures.

3. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.

4. During off-duty hours, security personnel or other designated individuals will accept delivery of radioactive packages in accordance with the procedures outlined in the sample memorandum below.

* In the case of special orders, the physician's written request and appropriate shipping/receipt records will be referenced and the dose assayed prior to its administration.

SAMPLE** MEMORANDUM

MEMORANDUM FOR: Security Personnel

FROM: Alan H. Robbins, MD

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

Any packages containing radioactive material that arrive between 4:30 PM and 7 AM or on Sundays shall be signed for by the Security Guard on duty and taken immediately to the Nuclear Medicine laboratory. Unlock the door, place the package on top of the counter, and relock the door.

If the package is wet or appears to be damaged immediately contact Alan H. Robbins, MD. Ask the carrier to remain until it can be determined that neither he nor the delivery vehicle is contaminated.

RADIATION SAFETY OFFICER: Alan H. Robbins, MD

OFFICE PHONE: 232-1990

HOME PHONE:

APPENDIX F

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Special requirements will be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits as specified in paragraphs 20.205(a)(1) and (c)(1) of 10 CFR Part 20 (more than 20 Ci for Mo-99 and Tc-99m). They will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). All shipments of liquids greater than exempt quantities will be tested for leakage. The NRC Regional Office will be notified in accordance with the regulations if removable contamination exceeds 0.01 μCi/100 cm^2 or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 feet (or 1 m).

2. For all packages, the following additional procedures for opening packages will be carried out:

   a. Put on gloves to prevent hand contamination.

   b. Visually inspect package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.

   c. Measure exposure rate at 3 feet (or 1 m) from package surface and record. If >10 mR/hr, stop procedure and notify Radiation Safety Officer.

   d. Measure surface exposure rate and record. If >200 mR/hr, stop procedure and notify Radiation Safety Officer.

   e. Open the package with the following precautionary steps:

      (1) Open the outer package (following manufacturer's directions, if supplied) and remove packing slip.

      (2) Open inner package and verify that contents agree with those on packing slip. Compare requisition,* packing slip, and label on bottle.

      (3) Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).

      (4) Check also that shipment does not exceed possession limits.

   f. Wipe external surface of final source container and remove wipe to low background area. Assay the wipe and record amount of removable radioactivity (e.g., μCi/100 cm^2, etc.). Check wipes with a thin-end-window G-M survey meter, and take precautions against the spread of contamination as necessary.

   g. Monitor the packing material and packages for contamination before discarding.

      (1) If contaminated, treat as radioactive waste.

      (2) If not contaminated, obliterate radiation labels before discarding in regular trash.

3. Maintain records of the results of checking each package, using "Radioactive Shipment Receipt Record" (see next page) or a form containing the same information.

---

*In the case of special orders (e.g., therapy doses), also compare with physician's written request.

APPENDIX G

GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials.

3. Monitor hands and clothing for contamination after each procedure or before leaving the area.

4. Always use syringe shields for routine preparation of patient doses and administration to patients, except in circumstances such as pediatric cases when their use would compromise the patient's well-being. In these exceptional cases, use other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).

5. a. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

   b. Do not store food, drink, or personal effects with radioactive material.

6. a. Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10 percent.

   b. For therapeutic doses, also check the patient's name, the radionuclide, the chemical form, and the activity vs. the order written by the physician who will perform the procedure.

7. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level. Personnel monitoring devices when not being worn to monitor occupational exposures should be stored in a designated low background area.

8. Wear TLD finger badges during elution of generator and preparation, assay, and injection of radiopharmaceuticals.

9. Dispose of radioactive waste only in specially designated and properly shielded receptacles.

10. Never pipette by mouth.

11. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.

12. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.

13. Always transport radioactive material in shielded containers.

APPENDIX H

EMERGENCY PROCEDURES

Minor Spills

1. NOTIFY: Notify persons in the area that a spill has occurred.

2. PREVENT THE SPREAD: Cover the spill with absorbent paper.

3. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as disposable gloves.

4. SURVEY: With a low range, thin window G-M survey meter, check the area around the spill, hands, and clothing for contamination.

5. REPORT: Report incident to the Radiation Safety Officer.

Major Spills

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.

2. PREVENT THE SPREAD: Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

3. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.

4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.

5. CALL FOR HELP: Notify the Radiation Safety Officer immediately.

6. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

*RADIATION SAFETY OFFICER: _____

*OFFICE PHONE: _____

*HOME PHONE: _____

*ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER:

_____

_____

_____

*On the actual copy that is posted in the nuclear medicine department, this informa will be filled in and updated as necessary.

APPENDIX I

AREA SURVEY PROCEDURES

1. All elution, preparation, and injection areas will be surveyed daily with an appropriately low-range survey meter and decontaminated if necessary.*

2. Laboratory areas where only small quantities of radioactive material are used (less than 200 μCi) will be surveyed monthly.

3. Waste storage areas and all other laboratory areas will be surveyed weekly.

4. The weekly and monthly surveys will consist of:

   a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.

   b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 200 dpm per 100 cm^2 for the contaminant involved. Wipes of elution and preparation areas or other "high background" areas will be removed to a low background area for measurement.

5. A permanent record will be kept of all survey results, including negative results. The record will include:

   a. Location, date, and identification of equipment used, including the serial number and pertinent counting efficiencies.

   b. Name of person conducting the survey.

   c. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.

   d. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).

   e. Detected contamination levels, keyed to locations on drawing.

   f. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

6. Area will be cleaned if the contamination level exceeds 200 dpm/100 cm^2.

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* For daily surveys where no abnormal exposures are found, only the date, the identification of the person performing the survey, and the survey results will be recorded.

APPENDIX J

WASTE DISPOSAL

Note: In view of the recent problems with shallow-land burial sites used by commercial waste disposal firms, NRC is encouraging its licensees to reduce the volume of wastes sent to these facilities. Important steps in volume reduction are to segregate radioactive from nonradioactive waste, to hold short-lived radioactive waste for decay in storage, and to release certain materials in the sanitary sewer in accordance with § 20.303 of 10 CFR Part 20.

1. Liquid waste will be disposed of (check as appropriate)

X — In the sanitary sewer system in accordance with § 20.303 of 10 CFR Part 20.

N/A — By commercial waste disposal service (see also Item 4 below).

X — Other (specify) See #3

2. Mo-99/Tc-99m generators will be (check as appropriate)

N/A — Returned to the manufacturer for disposal.

N/A — Held for decay* until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the generators will be disposed of as normal trash.**

N/A — Disposed of by commercial waste disposal service (see also Item 4 below).

N/A — Other (specify)

3. Other solid waste will be (check as appropriate)

X — Held for decay* until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the waste will be disposed of in normal trash.

N/A — Disposed of by commercial waste disposal service (see also Item 4 below).

N/A — Other (specify)

4. The commercial waste disposal service used will be

N/A
(Name) (City, State)

NRC/Agreement State License No. N/A

* Be sure that waste storage areas were described in Item 11 and that they are surveyed periodically (Item 17).

** These generators may contain long-lived radioisotopic contaminants. Therefore, the generator columns will be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

New England
Baptist
Hospital

91 Parker Hill Avenue
Boston, Mass. 02120
617 732 5800

April 22, 1987

Life Signs/Boston, Inc.
One Brookline Place
Brookline, MA 02146

Dear Sirs:

In reference to your application for materials licenses with the U. S. Nuclear Regulatory Commission, I am writing to inform you that the New England Baptist Hospital agrees to accept patients from your office containing radioactive material should such a need arise.

Sincerely yours,

Edmund A. Steimle Jr.

Edmund A. Steimle, Jr.
Vice President
Clinical Services

EAS/cjl