FORM NRC-313M (8-78) 10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE – MEDICAL

Approved: GAO R0557

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

Louis A. Weiss Memorial Hospital
4646 North Marine Drive
Chicago, Illinois 60640

TELEPHONE NO.: AREA CODE (312) 878 - 8700

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

As Above

2. PERSON TO CONTACT REGARDING THIS APPLICATION

R. Van Bokkelen

TELEPHONE NO.: AREA CODE (312) 878 - 8700 X-304

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. ☒ RENEWAL OF LICENSE NO. 12-02418-01

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

Please refer to Supplement 1.

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.)*

A.G. Kaluskar, Ph.D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
10 CFR 31.11 FOR IN VITRO STUDIES	X	10 mCi ea
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III	X	2 Ci ea
10 CFR 35.100, SCHEDULE A, GROUP IV	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI	X	1300 mCi

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.	X	200. mCi

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
1) Technetium - 99 m	Iprofenin	50 mCi	Hepatobiliary Scanning
2) Chromium - 51	Lyopolized	500 μCi	In Vitro Test
3) Cobalt - 57	Solids	15 μCi	
4) Rubedium - 86	any	3 mCi	In Vitro Studies

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: _____

NUREG-338, Rev. 1, Nov. 1, 1977

7. MEDICAL ISOTOPES COMMITTEE	
X	Names and Specialties Attached; and
X	Duties as in Appendix B; or *(Check One)*
	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE	
X	Supplements A & B Attached for Each Individual User; and
X	Supplement A Attached for RSO.
9. INSTRUMENTATION *(Check One)*	
	Appendix C Form Attached; or
X	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
X	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
	Equivalent Procedures Attached; and
X	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	
X	Description and Diagram Attached
12. PERSONNEL TRAINING PROGRAM	
X	Description of Training Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
X	Appendix F Procedures Followed; or
	Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
X	Appendix G Rules Followed; or
	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
X	Appendix H Procedures Followed; or
	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)*	
X	Appendix I Procedures Followed; or
	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
X	Appendix J Form Attached; or
	Equivalent Information Attached
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
X	Appendix K Procedures Followed; or
	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
	Detailed Information Attached; and
X	Appendix L Procedures Followed; or *(Check One)*
	Equivalent Procedures Attached
21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
X	Detailed Information Attached
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
	Detailed Information Attached
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
X	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	Landauer & Co. Illinois	1-2 per month
		TLD		
		OTHER (Specify)		
b. FINGER	X	FILM	Landauer & Co., Illinois	1-2 per month
		TLD		
		OTHER (Specify)		
c. WRIST	X	FILM	Landauer & Co. Illinois	1-2 per month
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

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

b. APPLICANT OR CERTIFYING OFFICIAL (Signature)

R. VanBokklen

(1) NAME (Type or Print)
R. VanBokklen

(1) LICENSE FEE CATEGORY
7 B

(2) TITLE
Associate Director

(2) LICENSE FEE ENCLOSED: $ 150.00

c. DATE
Feb. 26, 1979

FORM NRC-313M (8-78)

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 Form NRC-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.

Supplement 1

Item No. 4 (Form NRC 313M)

Individual Users.

1) J. Singh, M.D. - Nuclear Medicine

2) G.A. Lawrence, M.D. - Radiation Therapy

3) P. Shirazi, M.D. - Consultant, Nuclear Medicine,
Lutheran General Hosp. Park Ridge, Illinois

4) R.F. Dods, Ph.D. - Clinical Biochemistry/Microbiology.

5) J.B. Carter, M.D. - Clinical Microbiology

License # 12-02418-01

Supplement - 2

Item 7 (Form NRC 313 M)

Medical Specialty and Clinical Experience
of the Members of the Radioisotope Committee

Name	Medical Specialty	Experience
1. J. Singh, M.D.	a) Nuclear Medicine	Please refer to Supplement 3
2. Ashfaque Khan, M.D.	a) Internal Medicine b) Cardiology	a) Cook County Hosp. Chicago, Ill. b) Univ. of Ill. Hosp. Chgo., Ill. c) Weiss Mem. Hosp., Chgo., Ill.
3. B. Jacobson, M.D.	a) Internal Medicine b) Gastroenterology	a) Cook County Hosp. Chgo., Ill. b) V.A. Hosp., Long Beach, Calif.
4. L. Keer, M.D.	a) Pathology b) Internal Medicine c) Endocrinology	a) Univ. of Ill. Hosp., Chgo., Ill. b) M.D. Anderson Hosp.&Tumor Institute, Houston, Tx. c) Weiss Mem. Hosp., Chgo., Ill.
5. M. Szanto, M.D.	a) Internal Medicine	a) Mount Sinai Hosp. Chgo., Ill. b) Cook County Hosp., Chgo., Ill.
6. G.A. Lawrence, M.D.	a) Radiation Therapy	Please refer to Supplement 3.
7. A.G. Kaluskar, Ph.D.	a) Radiation Physicist	Please refer to Supplement 3.

License # 12-02418-01

Supplement 3

Item NO 8 (Form NRC 313 M)

Training and Experience

1) J. Singh, M.D.
   Please refer to our application of Feb. 26,1974

2) G. A. Lawrence, M. D.
   a) Please refer to our application of January 26, 1979.
   b) A preceptor statement is attached

3) P. Shirazi, M. D.
   Please refer to license No. 12-09567-01 (Lutheran General Hospital, Park Ridge, Illinois)

4) R. F. Dods, Ph. D.
   Please refer to our application of August 30, 1976

5) J. B. Carter, M. D.
   Please refer to our application of August 30, 1976

6) A. G. Kaluskar, Ph. D. (Radiation Safety Officer)
   Please see the sheets attached.

License # 12-02418-01

Supplement 3

Item 8

Form AEC-313a (2-73) Page 3

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—PRECEPTOR STATEMENT

This page is to be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each. Page 2 may be used for comments and additional information.

10. NAME AND ADDRESS OF APPLICANT PHYSICIAN (*Include ZIP Code.*)

Gilbert Anthony Lawrence, M.D. Director Radiation Therapy,
Louis A. Weiss Memorial Hosp. Chicago, Ill. 60640

11. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN NAMED IN ITEM 10 ABOVE

(A) ISOTOPE	(B) CONDITIONS DIAGNOSED OR TREATED	(C) No. Cases Observed (See 1 in key below)	(D) No. Cases Involving Personal Participation (See 2 in key below)
I-131 or I-125	Diagnosis of thyroid function	50	20
	Determination of blood and blood plasma volume		
	Liver function studies		
	Fat absorption studies		
	Kidney function studies		
	In vitro studies		
Cr-51	Gastrointestinal protein loss studies		
	Determination of red blood cell volume and studies of red blood cell survival		
Fe-59	Iron turn over studies	15	10
Co-58or Co-60	Intestinal absorption studies		
K-42	Potassium space determinations		
I-131	Thyroid imaging	75	30
	Brain tumor localization and cardiac imaging		
	Cisternography		
	Lung imaging		
	Liver imaging		
	Kidney imaging		
	Placenta localization		
Cr-51	Placenta localization		
	Spleen imaging		
Au-198	Liver imaging		
Hg-197	Brain imaging		
	Kidney imaging		
Hg-203	Brain imaging		
Sr-85	Bone imaging		
Tc-99m	Brain imaging		
	Thyroid imaging		
	Salivary gland imaging		
	Blood pool imaging		

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—HUMAN USE

(A) ISOTOPE	(B) CONDITIONS DIAGNOSED OR TREATED	(C) No. Cases Observed (See 1 in key below)	(D) No. Cases Involving Personal Participation (See 2 in key below)
Tc-99m	Placenta localization		
	Liver and spleen imaging		
	Lung imaging		
	Bone imaging		
Xe-133	Blood flow studies and pulmonary function studies		
Se-75	Pancreas imaging		
P-32	Treatment of polycythemia, leukemia, and Bone metastases	60	60
	Intracavitary treatment	10	10
I-131	Treatment of thyroid carcinoma	15	15
	Treatment of hyperthyroidism and cardiac condition	20	20
Au-198	Intracavitary treatment	——	——
~~Co-60 or~~ CO-137	Interstitial treatment	15	15
	Intracavitary treatment	300	300
Ir-192	Interstitial treatment		
Co-60 ~~CO-137~~	Teletherapy treatment	2000	2000
Sr-90	Treatment of eye disease	10	10

Key to Column (C) and (D) above

1. Observation should consist of observing radioisotope administration techniques and discussion with preceptor the case histories to establish most appropriate diagnostic and/or therapeutic procedure, limitation, contraindications, etc.

2. Personal participation should consist of (a) supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation on dosage to be prescribed; (b) collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurements, and plotting of data; and (c) adequate period of training to enable the physician to manage radioactive patients and to follow patients through diagnosis and/or the course of treatment.

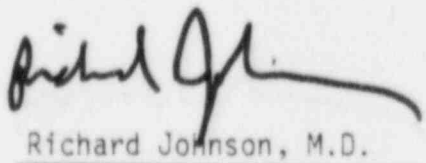
12. DATES AND TOTAL NUMBER OF HOURS OF CLINICAL RADIOISOTOPE TRAINING 1973-1978 -More than 1000 hours.

13. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF

Robert Morrison, M.D., Hammersmith Hospital, London, U.K.
Walter Shanks, M.D., The London Hospital, London U.K.
Richard Johnson, M.D. Rosewell Park Memorial Institute, Bullalo, N.Y.

AT Rosewell Park Memo. Inst. Buffalo, N.Y.
(Institution) Name and Address

New York State License #
526 - Cobalt
526-3 Ra and Cs
(Byproduct Material License Number)



Richard Johnson, M.D.
(Signature of Preceptor)

Supplement 3(b)

License # 12-02418-01

Item 8

Training and Experience of A.G. Kaluskar, Ph.D.

Type of Training	Where Trained	Duration of Training	On the Job	Formal Course
a) Principles and practices of Radiation protection	1) Illinois Institute of Technology, Chicago	1968-1969	yes	no
	2) Northwestern Univ. Chgo.	1977-1978	yes	no
	3) M.D. Anderson Hosp., Houston	2 weeks July 1978	yes	no
	4) Weiss Memorial Hosp., Chicago	May 1978-present	yes	no
b) Radioactivity Measurement Standardization and monitoring techniques and instruments	1) M.D. Anderson Hosp.	2 weeks July 1978	yes	yes
	2) Weiss Mem. Hosp.	May 1978-present	yes	no
c) Mathematics and Calculations basic to the use and measurement of Radioactivity	1) Univ of Bombay	1964-1967	yes	yes
	2) Illinois Inst. of Technology	1968-1975	yes	yes
	3) Weiss Mem. Hosp.	May 1978-present	yes	no
d) Biological Effects of Radiation	1) Illinois Inst. of Technology	1968-1975	yes	yes
	2) Weiss Mem. Hosp.	May 1978-present	yes	no
	3) M.D. Anderson Hosp.	2 weeks July 1978	no	yes

Experience with Radiation (actual use of isotopes or equivalent experience)

Isotope	Max. Amount	Where Experience was Gained	Duration	Type of Use
Co-60	400 Ci	Ill. Inst. of Technology	2 years	Expt'al Research
P-32	10 mCi	Chicago Medical School	6 months	" "
P-32	10 mCi	Northwestern University	15 months	" "
I-125	6 mCi	Northwestern University	15 months	" "
C-14	6 mCi	Northwestern University	15 months	" "
Co-60	6500 Ci	Weiss Memorial Hospital	10 months	Measurement and Calibration
Cs-137	750 mCi	Weiss Memorial Hospital	10 months	
P32	10 mCi	Weiss Memorial Hospital	10 months	

Item 9 (Form 313M)

TYPE OF INSTRUMENT	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE	WINDOW THICKNESS	USE
1) Nuclear Chicago Pho-gamma Camera-HP	1	gamma			Scanning
2) Nuclear Chicago Pho-gamma 4	1	gamma			scanning
3) Picker spectroscalar - 4R	1	gamma			Scanning
4) General Electric LOF-B	1	gamma			Scanning
5) General Electric Portable	1	gamma			Scanning
6) RADX Xenon Machine	1	gamma			Ventillation
7) Squibb CRC-6	1	gamma			Dose calibration
8) Johnson Survey Meter (GSM-5) (GP-200 Probe)	2	alpha, beta gamma	.02mR/hr (x1,x10, x100)	1.5 mg/cm^2 (mica) 0.66 Al cap	Survey
9) Victoreen "Cutie Pie" Model 740 D	1	beta, gamma	25mR/hr FS (x1 tO x1000)	0.0005" milar	Survey
10) Nuclear Chicago, Cutie Pie Model 2588	1	beta, gamma	25 mR/hr FS (x1 to x100)	1.5 mg/cm^2	Survey
11) Teledyne/manderli Intracavitary dose rate meter ENG591	1	gamma	50 R/hr	0.65 mm Al	Monitoring
12) Scintillation Well Wounter Picker Spectroscallar IIIA	1	gamma			Wipe and Contamination Test
13) Packard Gamma Counter Model 5220	1	gamma			Counting Radio-imuno Assay
14) BATEC Model 225	1	beta			CO_2 Metabolism

Supplement 4

Supplement 5 (a)

Louis A. Weiss Memorial Hospital
Chicago, Illinois 60640

License # 12-02418-01

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. 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% of the calculated or known values for each point checked. Readings within ± 20% are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

X 3. Survey instruments will be calibrated

____ a. By the manufacturer

X b. At the licensee's facility

(i) Calibration source Nuclear Products,
Manufacturer's name 3 M Company
Model no. Cs-137; 6D6C-CA
Activity in millicuries 5,10,20,25 mg. Rd. Eq. on 8/25/71
Accuracy _____
Traceability to primary standard _____ } Please refer to Supplement 5(b)

(ii) The calibration procedures in Appendix D, Section I will be used. (Yes)

or

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

____ c. By a consultant or outside firm

(i) Name _____

(ii) Location _____

(iii) Procedures and sources

____ have been approved by NRC and are on file in License No. _____

____ are attached

Item No. 10
Date: 2/26/79

Supplement 5 (a)

Louis A. Weiss Memorial Hospital
Chicago, Illinois

License # 12-02418-01

Supplement- 5 (b)

Medical Products 3M COMPANY
3M CENTER · ST. PAUL, MINNESOTA 55101

L. A. WEISS MEMORIAL HOSPITAL
Chicago, Illinois

PO 9757
PO 9756
3M 211308
3M 211307

RADIOACTIVE SOURCE CERTIFICATION

The following radioactive sources are certified by Minnesota Mining and Manufacturing Company to have been subjected to the tests described below and to have given the results listed.

Model Number	Serial Number	Nominal mg. Ra. Eq.	3M Assay* mg. Ra. Eq.	Nominal mCi Cs-137
6D6C-CA	0119	5	5.15	14
6D6C-CA	0129	5	5.15	14
6D6C-CA	0130	5	5.15	14
6D6C-CA	0131	5	5.15	14
6D6C-CA	0133	5	5.15	14
6D6C-CA	0893	10	10.4	27
6D6C-CA	0895	10	10.4	27
6D6C-CA	0902	10	10.4	27
6D5C-CA	0907	10	10.4	27
6D6C-CA	0913	10	10.4	27
6D5C-CA	0917	10	10.3	27
6D6C-CA	0920	10	10.4	27
6D6C-CA	0930	10	10.3	27
6D6C-CA	0937	10	10.3	27
6D6C-CA	1004	10	10.3	27
6D6C-CA	1018	10	10.3	27
6D6C-CA	1019	10	10.3	27
6D6C-CA	0242	20	20.6	54
6D6C-CA	0252	20	20.5	54
6D6C-CA	0258	20	20.6	54
6D6C-CA	0261	20	20.7	54
6D6C-CA	0116	25	25.8	68
6D6C-CA	0118	25	25.8	68
6D6C-CA	0133	25	25.5	68
6D6C-CA	0135	25	25.7	68

1 each 3M Model 8C9H Heavy Duty Table
1 each 3M Model 8C9F Magnifying Viewing Lamp
1 each 3M Model 8C9E Four-Drawer Cesium Safe

Wipe test, each: ≤0.0001μCi removable activity
Soak test, each: ≤0.0005μCi removable activity
Leak test, each (immersion): Negative

3M Print Number A-1921-18

OK TNL

*0.5mm Platinum Filtration
No other certification is to be implied.

Q.C. Supervisor Kenneth M. Paddock

Date August 25, 1971

Item No. 10 (Form 313M)

Calibration of Dose Calibrator

a) Sources used for calibration :

Cs-137 (250 µCi) Amersham Model R 200/001
Cs-137 (1 mCi) Amersham Model R -0001

b) The dose calibrator was calibrated by Radiation Protection Consultant, Ltd., Addison, Illinois in November 1977.

c) We receive the isotopes in precalibrated form from the supplier. We check them with our dose calibrator. In the past two years we have found that the readings of the dose calibrator are within 10 % of the precalibrated value given by the supplier.

d) However in future the procedures described in Appendix D, Section 2 will be used for the calibration of our dose calibrator.

Item 11 (Form NRC-313M): Facilities and Equipment

A. Facilities and equipment in the Radiotherapy Department (Please refer to our applications June 11, 1971, and February 26, 1974; License No. 12-02418-01, Amendment Nos. 24-25 for our Cesium 137 and P 32 program; applications of June 12, 1974 for Iridium, -192 and Iodine - 125.)

The floor plan of the Radiotherapy Department is shown in Figure 1 and the location of the Cesium storing facility.

i) Cesium 137

a. Portable 8 hole Horwitz safe, 3M nuclear products Model 8C9B.

b. Radium chemical Model No. 799 Protective well.

c. Radium chemical Model No. 462 Modern Protection block with Model No. 461 high density glass shield.

d. Radium chemical Model 50100 Ernest carrier and Heyman carrier with cart.

e. Radium chemical Model 442 CR Heyman cap remover and Model 474 lead protective vise (See attached Figrue C).

f. Assorted 10" and 12" handling forceps.

ii) Phosphorous 32

No special equipment or facility is planned for use of colloidal phosphorous, which will be obtained as a precalibrated solution, and administered by the drip method.

iii) Iridium - 192

Please refer to the attached sheets for the picture of the after loading system and description of the after loading method (Exhibits 1A & 1B). Seeds will be ordered as and when needed from Howard Hospital Supply Corp.)

iv) Iodine - 125
Please refer to the attached sheet. (Exhibit 1C) for picture of Hilaris-Mohan Gun. Precalibrated seeds will be obtained from supplier, with appropriate certificated - leak test, weld integrity, etc.

B. Facilities and Equipment in Nuclear Medicine Department. (Please refer to our applications of February 21, 1969, February 26, 1974 License # 12-02418-01 Amendment Nos. 18 through 35.)

i) The flour plan of the Nuclear Medical Department is shown in Figure 2. The description of the keyed location is given in the figure.

Item 11

ii) The diagnostic Equipment are in areas I, II and III.

iii) Radiophamaceuticals are stored in the refrigerator in lead conatiners. The doses are prepared behind the protective barrier.

iv) Decay room - In the decay room all the needles, empty vials, etc. allowed to decay in lead containers. One radiation level outside the locked door is less than 0.05 MR/hr.

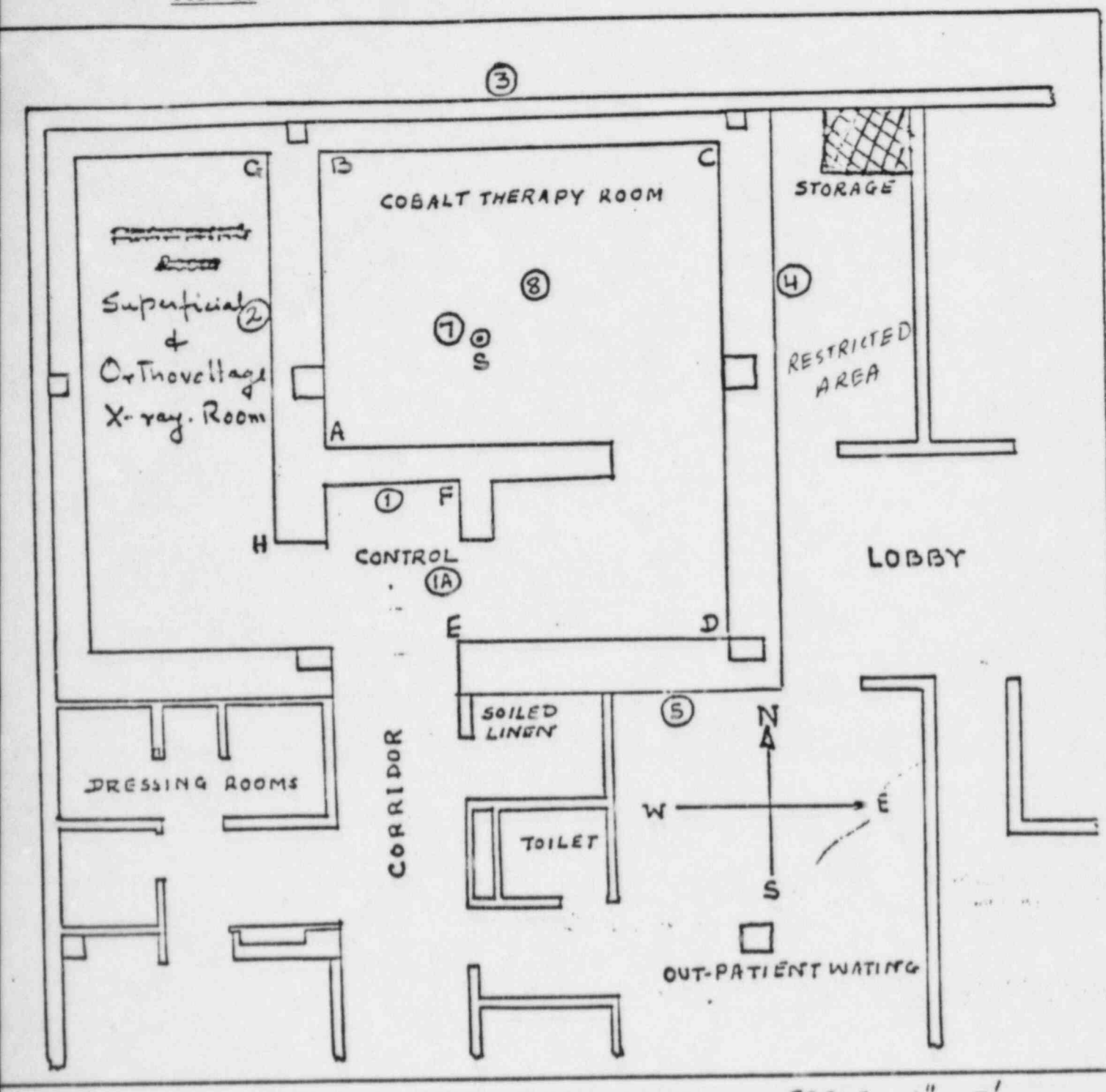
C. Clinical Microbiology and Clinical Biochemistry Laboratories. One floor plans are given in figures 3A and 3B.

i) In vitro detection A metabolic CO2 using C-14 labeled tryptic soy is done in the microbiology lab. (Fig. 3A). The labeled vials are stored in refrigerator.

ii) T-3, T-4, Schilling and other tests are done in the Radio-Immuno Assay laboratory. (Fig. 3B). Refrigerators at (1) and (2) and the storage places for all radio-active materials.

iii) The discarded needles, syringes are kept in two boxes and are allowed to decay temporarily.

Item 11



SCALE - 1" = 7'

Fig. 1 FLOOR PLAN (PART II)

Cs-137/Ra-Safe.

Behind Lead Brick Wall.

License # 12-02418-01

Supplement 6

Item 11

EXHIBIT 1 (a)

Howard Hospital Supply Corporation

2212 GEORGIA AVENUE, N.W.
WASHINGTON, D.C. 20001

Iridium 192 Seeds in Nylon Ribbons

Iridium 192 seeds in nylon ribbons have been widely used for the cure and palliation of localized unresectable cancers, since its development in 1954 by Henschke and Mahan. We have been supplying Iridium 192 seeds in nylon ribbons to a number of hospitals. In recent years there has been an increased interest due to the simplicity of techniques involved in the use of nylon ribbons in interstitial implants along with its proven clinical results and its availability.

Our entire operation is devoted to the production and supply of Iridium 192 seeds in nylon ribbons. We are, therefore, in intimate contact with our customers for the express purpose of providing the best possible service.

A standard Iridium 192 ribbon set consists of :

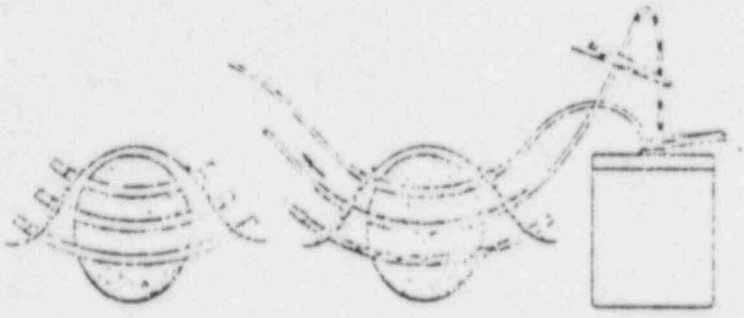
1. 14 Nylon ribbons loaded with 12 seeds each, spaced 1 cm center to center.
2. 15 Nylon afterloading tubes
3. 30 Stainless steel retaining buttons.
4. Decay chart for Iridium 192 showing calibration at time of shipment.

For further information please call or write to

KRISHNAN SUTHANTHIRAN
Vice President, Customer Service
Howard Hospital Supply Corporation
2212 Georgia Ave.NW
Washington, D.C. 20001
(202) 387-2555

License # 12-02418-01

Removable Interstitial Implant Set



The main indication for removable interstitial implants is the treatment of unresectable but localized superficial and intraoral tumors which show satisfactory response to external radiation therapy. They are also preferred over surgical excision if the latter would cause severe functional impairment. In removable implants the control of the dose and of the distribution is more accurate than in permanent implants; they are therefore preferred if cure appears possible.

With the afterloading technique which has been worked out for removable interstitial implants, the first step is the insertion of unloaded nylon tubes in and around the tumor. This is usually done in the operating room under general anesthesia. After hollow stainless steel needles are carefully positioned, empty nylon tubes are threaded through these needles and secured on each side by special buttons. Modifications of this technique are used for intraoral tumors (loop technique) and for tumors which are accessible from only one side (blind end technique).

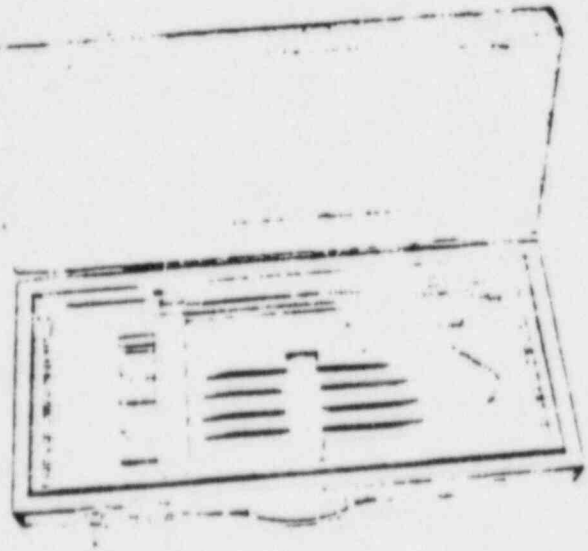
The second step is the afterloading with radioactive seeds in nylon ribbons, which is a standard and widely used procedure. Iridium 192 seeds are preferred but Gold 198, Cobalt 60 and Radon 222 can also be employed. Iridium 192 wire[22] or Tantalum 182 wire can also be used. The nylon ribbons with the Iridium 192 seeds are secured within the outer nylon tubes by a small clip. At the end of the implantation time, which usually varies from five to eight days, all inner nylon ribbons with the Iridium 192 seeds are pulled out first by means of a special instrument which cuts only the outer nylon tube.[1]

(Continued on reverse side)

Item 11

EXHIBIT 1 (c)

I^{125} Permanent Implant Gun



The instrument utilized most recently for implantation of Iodine 125 seeds is the Hilaris/Mahan Permanent Implant Gun, developed in 1969 at Memorial Hospital in New York.

While the afterloading principle is retained, the instrument has a magazine which permits the introduction of a number of seeds in succession through the same needle. A depth gauge attached to the gun permits accurate depth determination. No radiation exposure is incurred with the use of low energy seeds such as Iodine 125. In addition to the gun, the complete interstitial implantation kit includes a set of 12 hollow 17-gauge stainless steel needles, which are used during the first step of afterloading; 5 magazines, each with a capacity of 10 low energy Iodine 125 seeds. These magazines are mounted on a removable stainless steel tray, which can be taken out of the wooden container, autoclaved and kept sterile prior to implantation.

Supplement 6 License # 12-02418-01

Item 11

DEPT. OF NUCLEAR MEDICINE
LOUIS A. WEISS MEMORIAL HOSPITAL

RADIATION SURVEY RECORD

DATE OF SURVEY: Feb. 22, 1979
NAME OF SURVEYER: A. G. Kaluskar, Ph.D.

LOCATIONS	READINGS $\frac{mR}{Hr}$
1) REFRIGERATOR:	(0.05)
* 2) Pb LINED STORAGE MODULE	(< 0.1)
3) DOSE CALIBLATOR	(0.12)
4) PROTECTIVE BARRIER	(< 0.1)
5) I-131 UPTAKE MACHINE	(0.05)
6) BKG SCAN LAB	(0.1)
7) WELL COUNTER	(—)
8) OUT-SIDE DECAY ROOM	(0.05)
9) IN-SIDE DECAY ROOM	(0.15)
10) OVER THE CONTAINERS	(< 5.0)

a. Tc-99m
b. All except Se-75
c. Se-75

* There are two wells for discarded needles, syringes and vials
a. For Tc-99m
b. For all other isotopes except Se-75
The Se-75 is kept in the container in one of the module drawers.

IDENTIFICATION Map areas

I) Hot Laboratory
II) Scanning Room
III) RAPx Xenon Machine, stored
IV) Office
V) Decay Room

SIGNATURE: A. G. Kaluskar

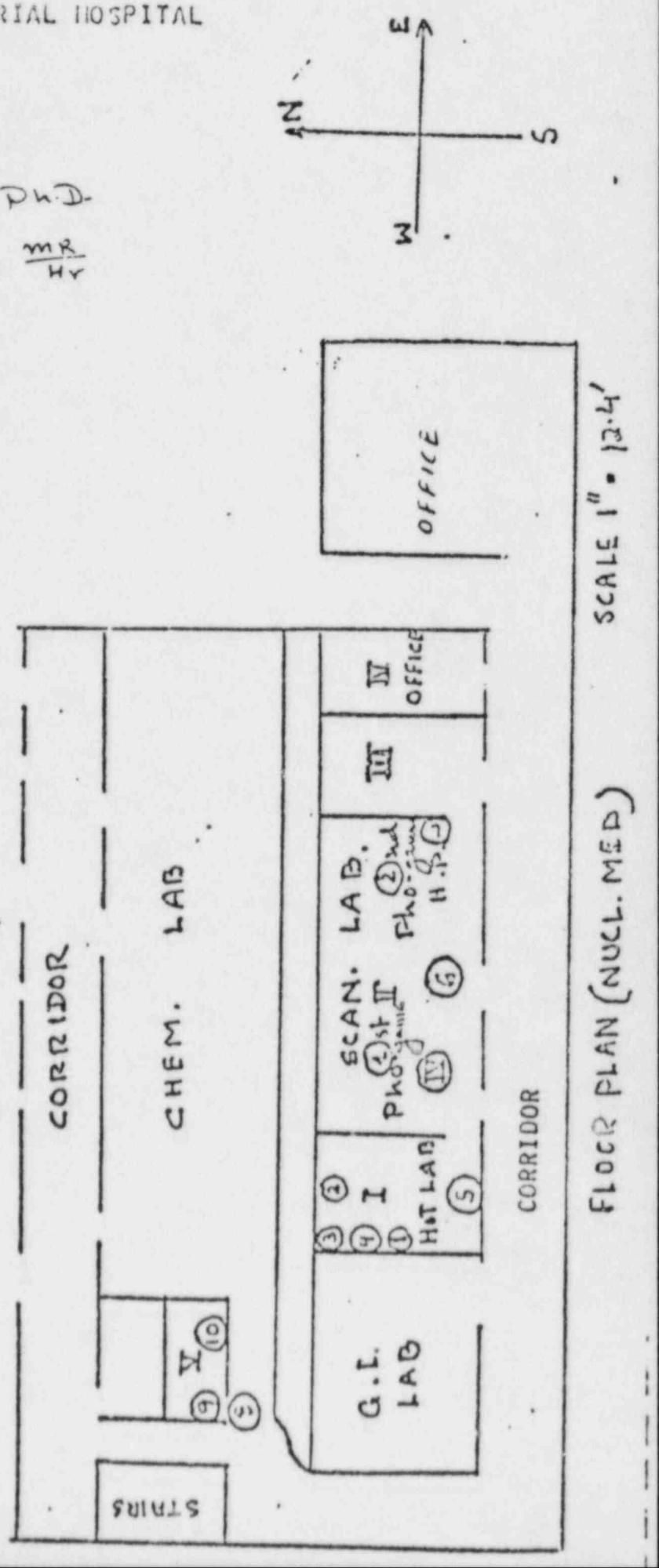
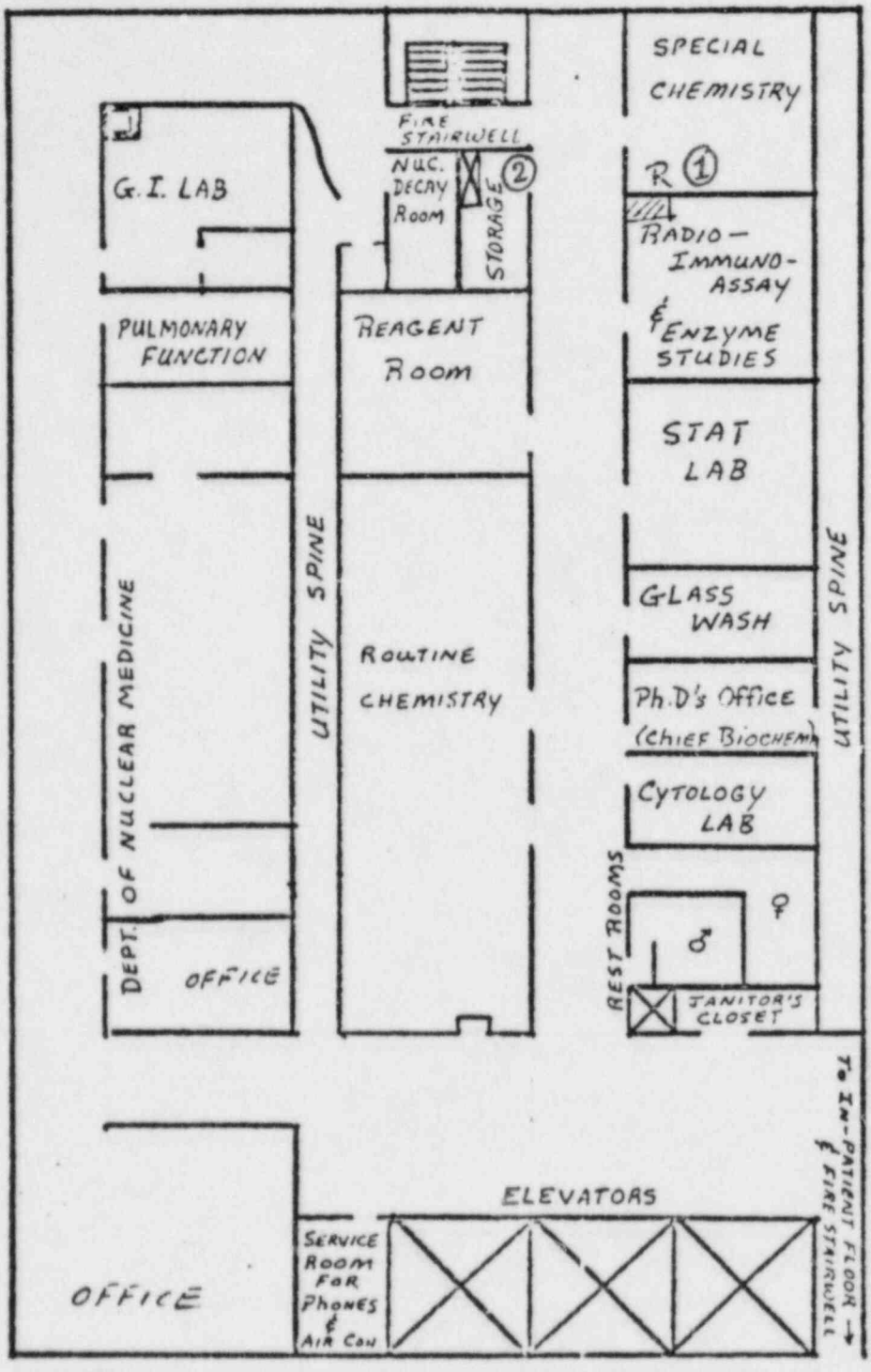


FIGURE 2

Item 11



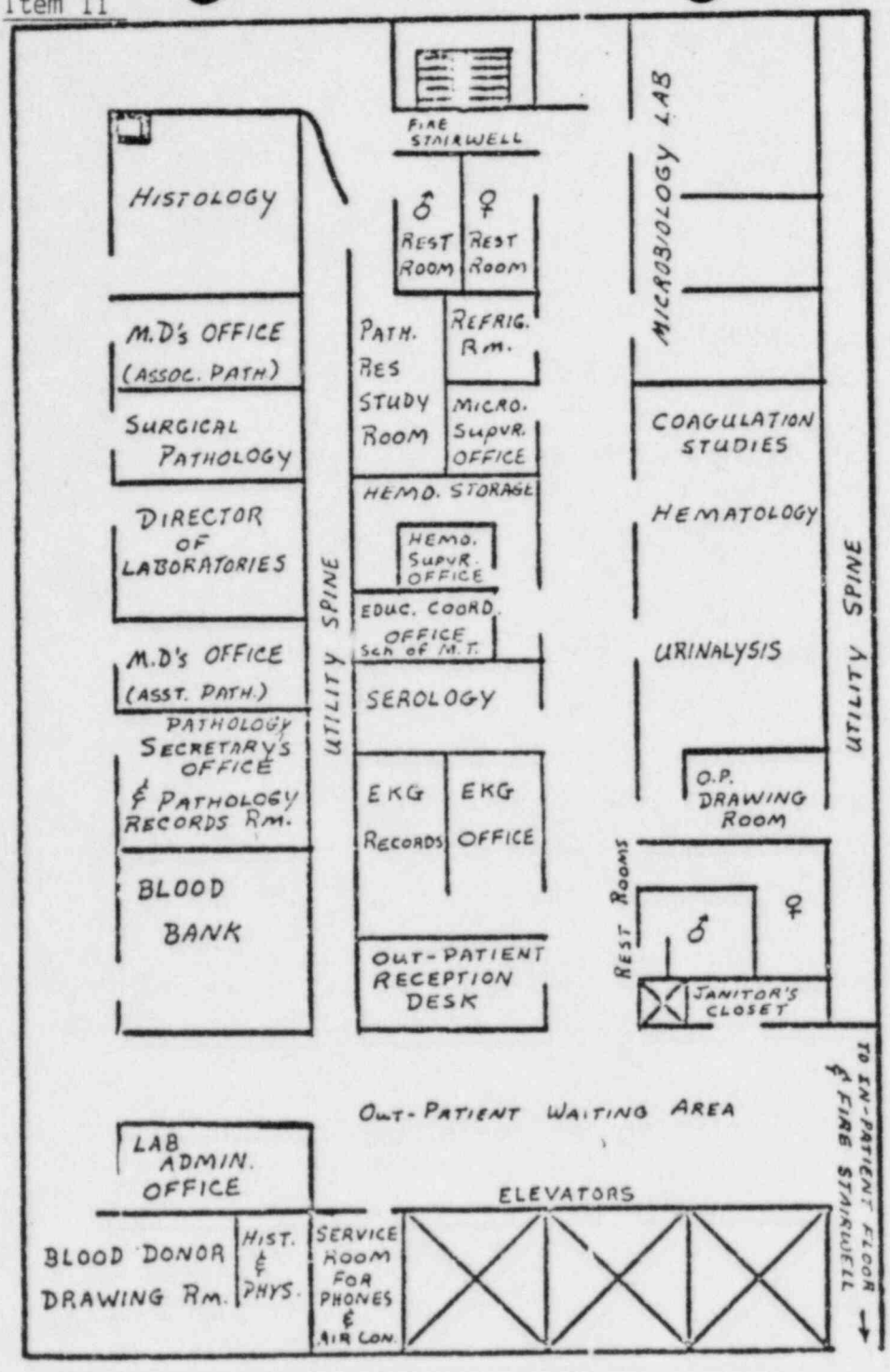
LABORATORY FLOOR PLAN (7th Floor)

—— = 5 feet

FIGURE 3 (8)

License # 12-02418-01

Item 11



: LABORATORY FLOOR PLAN (8th Floor)

= 5 feet

FIGURE 3 (A)

Item 12 (Form NRC 313 M)

Personnel Training Program

a) All the technical persons are either registered or at least registry eligible in their respective fields before they start the job.

b) All the personnel are given oral instructions by the superviser in the safe and proper use of the radio-active materials.

c) In future we will offer inservice classes at least once every year so that the personnel will receive proper instructions in the items a to z from NUREG - 0338, Rev. 1 (Nov. 1, 1977).

d) These classes will be open to all the hospital personnel but will be mandatory to all those in connection with the radioactive material. The classes will be given by RSO and/or Radiotherapist.

Supplement 8

Item No. 13 (Form 313M NRC)

Procedure for Ordering and Receiving Radioactice Material

1. The Chief Radiation Therapy Technologist/Chief Nuclear Medicine Technologist will place all orders for radioactive material and will ensure that the requested materials and quantities are authorised by the license and that possession limits are not exceeded.
2. During normal working hours carriers will be instructed to deliver radioactive packages directly to the Radiation Therapy/ Nuclear Medicine Department.
3. During off-duty hours security personnel will accept delivery of radioactive packages in accordance with the procedures outline in Mr. R. VanBokklen, Associate Director, 's memorandum (attached).

N.B. : A similar memorandum is sent to the security department for delivery to the Nuclear Medicine Department during off-duty hours.

License # 12-02418-01

Supplement 8

Item 13 (Form NRC 313M)

February 19,1979

MEMORANDUM

TO: Harold Skretny
Director, Purchasing

Michael McNutt
Chief Storekeeper

FROM: Rick Van Bekkelen
Associate Director

SUBJECT: Receipt of Packages Containing Radioactive Material For Radiation Therapy

Any packages containing radioactive material that arrive between 7:00 a.m. and 4:30 p.m. shall be brought into the hospital through the Loading Dock. The carrier will be directed to take the package to the Receiving Room where the purchase order number and item will be checked against the original order. When it is determined that the package has not been damaged, it will be delivered immediately to the department originating the order.

If the package is damaged or wet from leakage, the carrier will be asked to wait until the R.S.O. or the party originating the order can inspect the package. After an authorized person determines that neither he nor the carrier is contaminated and the package is properly sealed, the delivery be returned.

Radiation Safety Officer : Arun Kaluskar, Ph. D. X-104

RV:mas

CC: Sam Grist
Timothy Enright

License # 12-02413-01

Supplement 8

Item 13 (Form NRC 313M)

February 19, 1979

MEMORANDUM

TO: Ronald Cundiff
Director, Security & Safety

FROM: Rick Van Lokkelen
Associate Director

SUBJECT: Receipt of Packages Containing Radioactive Material For Radiation Therapy

Any packages containing radioactive material that arrives between 4:30 p.m. and 7:00 a.m. or on Saturdays or Sundays shall be signed for by the Security Guard on duty and taken immediately to the Radiation Therapy Department, Radioactive Materials Storage Room. Unlock the door, place the package on top of the counter immediately to the right of the door and relock the door upon leaving.

If the package is wet or appears to be damaged, refuse delivery. In the event that delivery is refused, notify the Radiation Safety Officer or the party ordering the isotopes.

Radiation Safety Officer - Arun Kaluskar, Ph.D.
870-8700 Ext. 104 (work)
326-0541 (home)

Radiotherapist - Gilbert Lawrence, M.D.
870-8700 Ext. 101 (work)
879-7292 (home)

RV:mas

CC: Sam Crist

License # 12-02418-01

Supplement 8

Item 13

1. MARK FOR RECEIVING AND RETURNING RADIOACTIVE MATERIAL

RECEIVING:

a) The material received from an outside supplier will be delivered directly to the Radiation Therapy Department by the Store-room security.

1) Packages received must be placed in the Radium Room behind the safe.

2) Shipping label must accompany the package.

a) Check the amount of activity and number of sources received.
b) Check the exposure rate recorded on shipping label.
c) In the event of Radium, a leak test certificate must accompany shipment.
d) Remove shipping label and place in the floder for permanent record of shipment.

3) Using the survey meter take readings on surface of the package. (Read all sides and record the maximum).

4) Using the survey meter take readings at 100 cm. (Read all sides and record the maximum).

5) Enter all data required into the log of Radioactive Materials received and returned.

RETURNING:

Arrangements must be made through the storeroom for the return of materials shipped by U.P.S. (or other shippers of this order).

1) Place the Radioactive Materials in the original shipping container. All packages must be properly sealed.

2) Using the survey meter take readings on the surface of the package. (Read all sides and record the maximum).

3) Using survey meter take readings at 100 cm. (Read all sides and record the maximum).

4) Record all data required in the log of Radioactive Materials received and returned.

5) Package must remain in the Radium Room, behind the safe until shipper arrives for pick up.

APPENDIX J

WASTE DISPOSAL PROCEDURES

1. Liquid Waste will be disposed of

Check as appropriate

X — By commercial waste disposal service (See also No. 4 below)

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

____ Other (specify): _____

2. Mo-99/Tc-99m generators will be:

(Check as appropriate)

____ Returned to the manufacturer for disposal

____ Held for decay until radiation levels as measured 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 disposed of as normal trash. (Note: this method of disposal may not be practical for generators containing long-lived radioactive contaminants)

____ Disposed of by commercial waste disposal service (See also No. 4 below)

X — Other (specify): We do not have the generator

3. Other Solid Waste will be:

(Check as appropriate)

X — Held for decay until radiation levels as measured 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.

Item No. 18
Date: 1/26/79

____ Disposed of by commerical waste disposal service (See also No. 4 below)

____ Other (Specify): _____

_____

4. The commerical waste disposal service used will be: _____

Pharmaco Nuclear Inc Chicago, Illinois
(Name) (City, State)

NRC/Agreement State License No. IL-00427-01

NRC 12-17910-01 MD

Item No. 18
Date: _____

Item 20 (Form NRC 313M).

Therapeutic Use of Sealed Sources

a) The Cs-137 Sealed Sources are stored in the Horwitz safe, 3M Nuclear Products Model 8C9B. The safe is stored behind lead brick wall as shown in figure 1.

b) The sealed sources are handled using 12" handling forceps. The loading is done behind the Radium Chemical Model No. 799 protective wall. All the care is taken to see that the time taken to load is as short as possible.

c) The procedure outlined in Appendix L is followed

d) Method for determining the radiation dose to the extremities of personnel handling sources:

A = activity of the source in mg Ra-Eq.

Γ = Specific gamma ray constant in $\frac{R.\ cm^2}{hr.\ mCi}$

d = Average distance of hands from the sealed source in cm.

t = time (in hrs.) taken for loading the radioactive sealed sources.

$$\text{Exposure} = \frac{\Gamma.\ A.\ t}{d^2} \quad R.$$

e) For transporting the sealed sources from storage site to the place of use we use Radium Chemical Model No. 50100 Ernst carrier and Heyman carrier with cart.

f) The inventory of the sealed Cs-137 sources is taken at least quarterly and is logged in the log-book.
The attached sheets (Exhibits and) decribe the method for maintaining source accountability, surveys to be performed during the course of treatment and the conclusion of treatment.

Supplement 10

Item 20 (Form NRC 313M)

EXHITIT 10 (a)

LOUIS A. WEISS MEMORIAL HOSPITAL

DEPARTMENT OF RADIATION THERAPY

RECORD OF USE OF RADIOACTIVE ISOTOPES

DATE: _____ PATIENT: _____

TIME INSERTED: _____ ROOM: _____

ISOTOPE: _____ READINGS

NUMBER: _____ AT FOOT: _____

AMOUNT: (Mg/MiC) _____ AT 1 METER: _____

NURSES INSTRUCTIONS: _____ AT 2 METER: _____

_____ AT HALLWAY: _____

SIGNATURE: _____

DATE: _____ SURVEYS AFTER REMOVAL

TIME REMOVED: _____ PATIENT ROOM: _____

ISOTOPE RETURNED: _____ STORAGE AREA: _____

NUMBER: _____

AMOUNT: (Mg/MiC) _____

REMARKS: _____

SIGNATURE: _____

DIAGRAM OF DISTRIBUTION

Supplement 10

EXHIBIT 10 (b)

Item 20 (Form NRC 313 M)

PROCEDURE FOR ROOM SURVEY

Survey the room with radioactive material inserted in patient:

1) Using the survey meter on least sensitive scale X 100 (Multiply readings X 100).

2) Record Readings at:

   a) Foot of patient
   b) 1 meter laterally from patient
   c) 2 meters laterally from patient
   d) In the hall behind the closed door.

3) Place Radiactive Materials Warning sign on patient's door

4) Place yellow caution sticker on front of patient's hospital chart. All survey readings must be recorded on sticker.

5) Record all readings in the log of use of Radioactive Isotopes.

Survey the room after the removal of the radioactive materials (or removal of the patient):

1) Using the survey meter on the most sensitive scale x 1

2) Record reading in the log of use of Radioactive Isotopes.

Supplement 11

Item 21 (Form NRC 313 M)

Use of Xe-133.

We will use RADX - Xenon machine with charcoal trap. The facilities for Xe-133 studies are being prepared. The machine will be used with a ventilater hood and mashrom cap which we already installed.

License # 12-02418-01

Supplement 12

Item 23 (Form NRC 313 M)

Procedures and precautions for use of Radioactive Material specified in item 6b.

a) The procedure and precautions for use of Technetium-99m in the form of Ipsoferin Rubedium-86 is the same as decribed in Appendix K and Appendix G.

b) The procedure outlined in Appendix G will be followed for Chromium-51 and Cobalt-57.

License # 12-02418-01