FORM NRC-313M
7-77
10 CFR 30

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE -- MEDICAL

1/31/79 TB

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. Mail two copies 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 NRC Materials License. A 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

St.Anthony's Medical Center
10010 Kennerly Road
St.Louis,Mo. 63128

TELEPHONE NO.: AREA CODE 314-842 5600

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

J.B.Weber

TELEPHONE NO.: AREA CODE 314 -

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. ☒ RENEWAL OF LICENSE NO. 24-01041-04 030-10108

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

See supplement sheet

5. RADIATION PROTECTION OFFICER *(Name of person designated as radiation protection officer if other than individual user. Attach resume of his training and experience as in Supplement A.)*

John L.Bircher,M.D.with consultation from Dielman Consultants 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	X	3
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III	X	3
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		

ITEM	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM AND CARDIAC DYSFUNCTION	X	150
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	X	25
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	50
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	300
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	X	150
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. *(Small sealed sources (up to 3m Ci) and 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
	none		

JAN 2 1979

RECEIVED BY LFMB
Date JAN 9 1979
Log Jun Pgs III
By Brown
Orig. To
Action Compl 1/31/79

Applicant 3030
Check No. #180(TB) - refund #30
Amount, Fee Category
Type of Fee Renewal
Date Check Rec'd JAN 9 1979
Received By Brown

Control No. 01151

8506070448 850524
REG3 LIC30
24-01041-04 PDR

INDIVIDUAL USERS

John L.Bircher,M.D.	Groups I-V
John Wm.Fries,M.D.	" "
Marvin Cook, D.	" "
Daniel A.Abodeely,M.D.	" "
Edward R.Habert,M.D.	" "
R.W.Smith,M.D.	" "
Thomas J.Cooper,M.D.	Groups I and Invitro studies

Item #4
Date 1-2-79

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RADIATION SAFETY COMMITTEE

The purpose of the committee is to be responsible for the safe use of radioactive materials and radiation producing apparatus in this institution.

The authority for the committee comes from Title 10, Code of Federal Regulations, Part 35.11, NRC Regulatory Guide 8.18, the JCAH Nuclear Medicine Standards and the Food and Drug Administration, Bureau of Radiological Health Recommendations. The committee is institutional management, not medical staff, sponsored. Management is defined by the NRC as those persons authorized by the charter of the institution to make its policies and direct its activities.

Committee meeting must be held quarterly and reduced to writing and available to all committee members within 60 days.

The scope of committee responsibility includes nuclear imaging, invitro studies and chemistry; diagnostic radiology, therapeutic radiology: computerized tomography; and all other areas which use radioactive materials or radiation producing apparatus.

The tasks of the committee are outlined in the attached Appendix, page 8.18-11.

The responsibilities of the committee include:

(a) Approve or deny the acquisition of, and use of radioactive materials and radiation producing apparatus.
(b) Discuss radiation safety problem.
(c) Determine if current procedures are maintaining exposures ALARA (see Guide 8.18).
(d) Audit the entire program to be sure it meets all requirements.
(e) Implement specific requirements and conditions of licensure for NRC, FDA, EPA, JCAH, and other organizations.

The committee is composed of 5 members for NRC compliance-a therapeutic radiologist, a pathologist (hematologist), internist, representative of management and a person experience in ionizing radiation; for JCAH compliance, a representative from nursing and the hospital safety committee; for FDA the radiologist and chief technologist.

Radiation Safety Committee

7. (a) (b) The responsibilities, duties and meeting frequency will be as described in appendix B of NUREG-0338.Rev.1

7. (c)	Committee Members	Specialty
	John Wm. Fries, M.D.	Radiologist
	Thomas Cooper, M.D.	Pathologist
	William Leightner, M.D.	Internal Medicine
	John Bircher, M.D.	Nuclear Medicine
	George P. Casey	Executive Vice President
	Ray Dielman	Regulatory Affairs Consultant

and, for FDA Recommendation Compliance, add:

	John Wm. Fries, M.D.	Radiologist
	Myrna Hudson	Manager, Radiology

and, for JCAH compliance add:

	Donald R. Scott	Safety Committee Representative
	Georgiana Eilerman	Nursing Representative
	Richard Milles	Nuclear Medicine Technologist

Item #7

Date 1-2-79

Control No. 01151

APPENDIX C

INSTRUMENTATION

1. Survey meters

a. Manufacturer's name: Lionel (1)-(2)-(3) EON (4)

Manufacturer's model number: 6b(77296)(51241)(76462) (1) (2) (3)

Number of instruments available: 4 (4) PSM-700

Minimum range: 0 mr/hr to 0.5 mr/hr

Maximum range: 0 mr/hr to 50 mr/hr

b. Manufacturer's name: Victoreen

Manufacturer's model number: 1 A CDV-715

Number of instruments available: 1

ranges: 4

Minimum range 0 mr/hr to .5 mr/hr R/hr

Maximum range 0 mr/hr to 500 mr/hr R/hr

Item#9
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2. Dose calibrator

Manufacturer's name: Squibb

Manufacturer's model number: CRC 6A

Number of instruments available: 1

3. Diagnostic instruments

Type of Instrument	Manufacturer's Name	Model No.
Scintillation Camera	Raytheon	Cameray II (CY127)
Scintillation Camera	Searle	Pho-Gamma H.P.
Scintillation Camera Scaler & Probe	Raytheon	210

4. Other

Scaler	Abbott Logic	7402-05
Automatic Sample Changer	Abbott Logic	7407-02

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

____ b. At the licensee's facility

(i) Calibration source
Manufacturer's name _____
Model no. _____
Activity in millicuries _____
Accuracy _____
Traceability to primary standard _____

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

or

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

X c. By a consultant or outside firm

(i) Name Dielman Consultants Inc.

(ii) Location Palos Heights, Ill. 60463

(iii) Procedures and sources

X have been approved by NRC and are on file in License No. 12-17162-01

____ are attached

Item #10
Date 1-2-79

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test:

Check as appropriate

__x__ First elution from new Mo-99/Tc-99m generator

or

__x__ other* (specify) Instant Tc-99m

B. Sources Used for Instrument Accuracy and Constancy Tests:

Radionuclide	Activity (mCi)	Accuracy
57 Co	2	±5%
133 Ba		
137 Cs	.970	±1.8%
other		

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

or

____ Equivalent procedure are attached.

*Must be equivalent to the highest activity used.

Item No. 10
Date 1-2-79

Personnel Training Program

All occupational workers will receive instruction in 19.12 and subject matter including but not limited to :

(a) New rules and regulations
(b) Conditions of licensure
(c) Radiation Safety reviews and updates
(d) New procedures
(e) Changes in duties

at commencement, whenever indicated quarterly, and at our annual refresher course. The training will consist of lectures and demonstrations(if applicable)on site, appropriate programs off-site.

Auxillary workers,i.e. nursing, housekeeping, maintenance, security, will receive instruction according to Part 19.12 with emphasis on:

(a) definitions
(b) radiation areas
(c) biological considerations
(d) radiation and pregnancy
(e) caution signs, labels, warnings
(f) therapy
(g) emergency procedures
(h) radiation safety office duties and responsibilities.

Both programs will be implemented by the Nuclear Physicians, consultants, and other qualified persons.

NCRP report #48 will be used as a source of direction and instruction.

Item # 12
date 1-2-79

APPENDIX E

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. The chief Nuclear Imaging Technologist and the Chief Nuclear Chemistry Technologist will place all orders for radioactive material and will insure that requested materials and quantities are authorized 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 Nuclear Imaging and Chemistry Sections.

3. During off-duty hours security personnel will accept delivery of radioactive packages in accordance with the procedures outlined in Mr.Casey's memorandum(attached).

Item #13
Date 1-2-79

ST. ANTHONY'S MEDICAL CENTER

Memorandum for: Security Personnel

From: George P. Casey, Executive Vice President

Subject: Receipt of Packages Containing Radioactive Material.

Any package containing radioactive materials that arrive between 11 p.m. and 7 a.m. shall be signed for by the Security Guard on duty within one (1) hour of arrival and taken immediately to the Radiopharmacy Room #2352 Nuclear Medicine Section, Department of Radiology. Unlock the door, place the package on top of the counter where indicated, receipt behind the lead shielding, and lock the door.

If the package is wet or appears to be damaged immediately contact the hospital Radiation Safety Office. Ask the carrier to remain at the hospital until it can be determined that neither he or the delivery vehicle is contaminated.

Radiation Safety Office:
Office Name: Radiology Department
Home Phone: On file in Radiology Office in Radiology Department

Item #13
Date 1-2-79

10010 KENNERLY ROAD • ST. LOUIS, MISSOURI • 63128 • (314) 842-5600

PROCEDURES FOR SAFELY OPENING PACKAGES
CONTAINING RADIOACTIVE MATERIAL

We will follow the procedures described in Appendix F except item #6

Item #14
Date 1-2-79

Control No. 01151

LABORATORY RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

We will follow the laboratory rules described in Appendix G

Item # 15
Date 1-2-79

EMERGENCY PROCEDURES

We will adhere to the emergency procedures specified in Appendix H.

Item #16
Date 1-2-79

AREA SURVEY PROCEDURES

We will adhere to the area survey procedures described in Appendix I

Item # 17
Date 1-2-79

Control No. 01151

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)

____ 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

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 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)

____ Other (specify): _____

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: 1-2-79

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

_____ Other (Specify): _____

_____

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

_____
(Name) (City, State)

NRC/Agreement State License No. _____

Item No. 18
Date: _____

THERAPEUTIC USE OF RADIOPHARMACEUTICALS

We will adhere to the procedures described in Appendix K and NCRP Report #37

Further, all doses will be in capsule form whenever available

Item # 19
Date: 1-2-79

24. PERSONNEL MONITORING DEVICES

	TYPE (Check appropriate box)	SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	[x] FILM	R.S.Landauer,Jr.,Co.	Monthy
	[ ] TLD		
	[ ] OTHER (Specify)		
b. FINGER	[ ] FILM		
	[x] TLD	R.S.Landauer,Jr.,Co.	Monthly
	[ ] OTHER (Specify)		

c. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY — Not applicable

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, Part 30, 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: 7

(2) LICENSE FEE ENCLOSED: $ 180.00

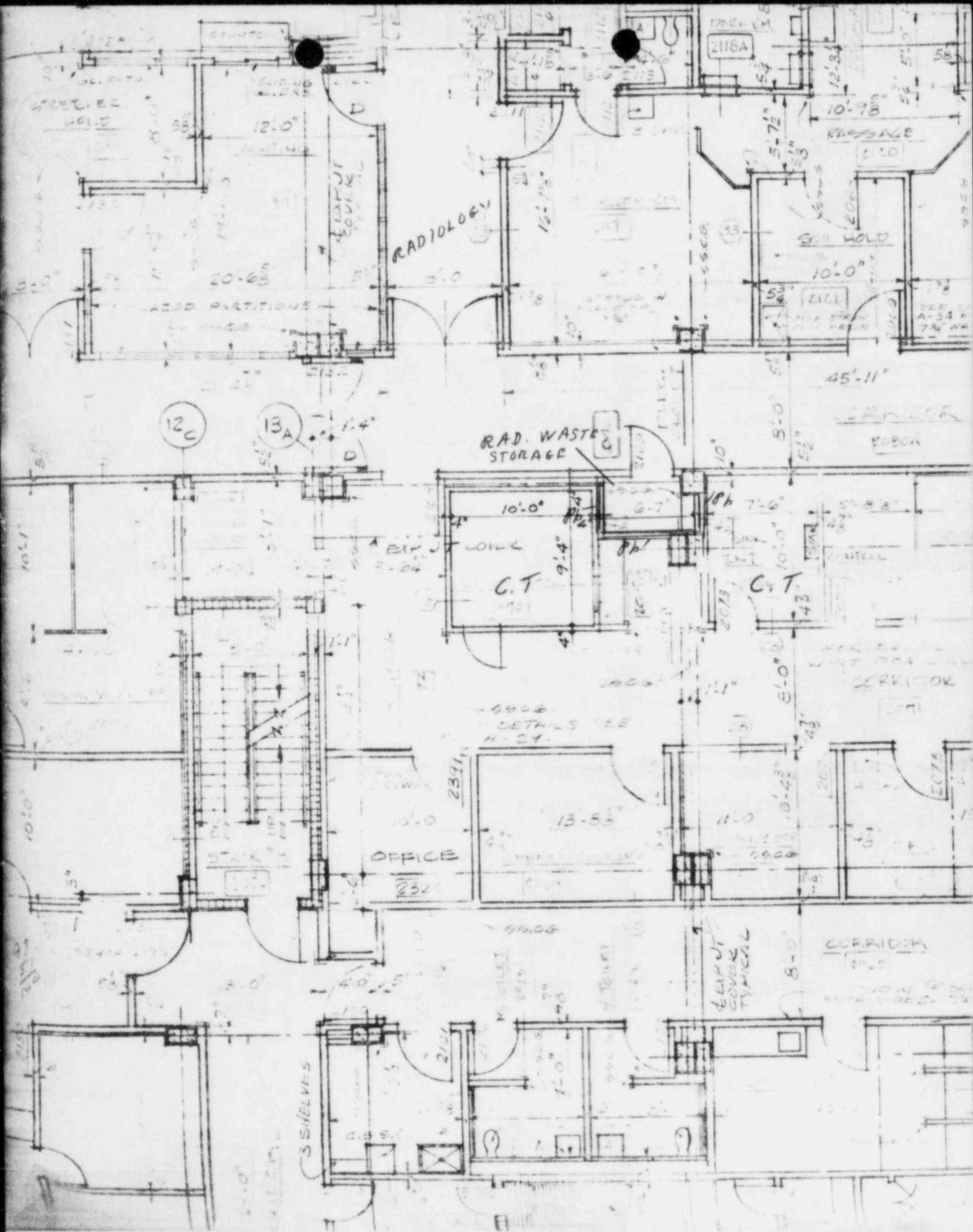
b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*: G P Casey

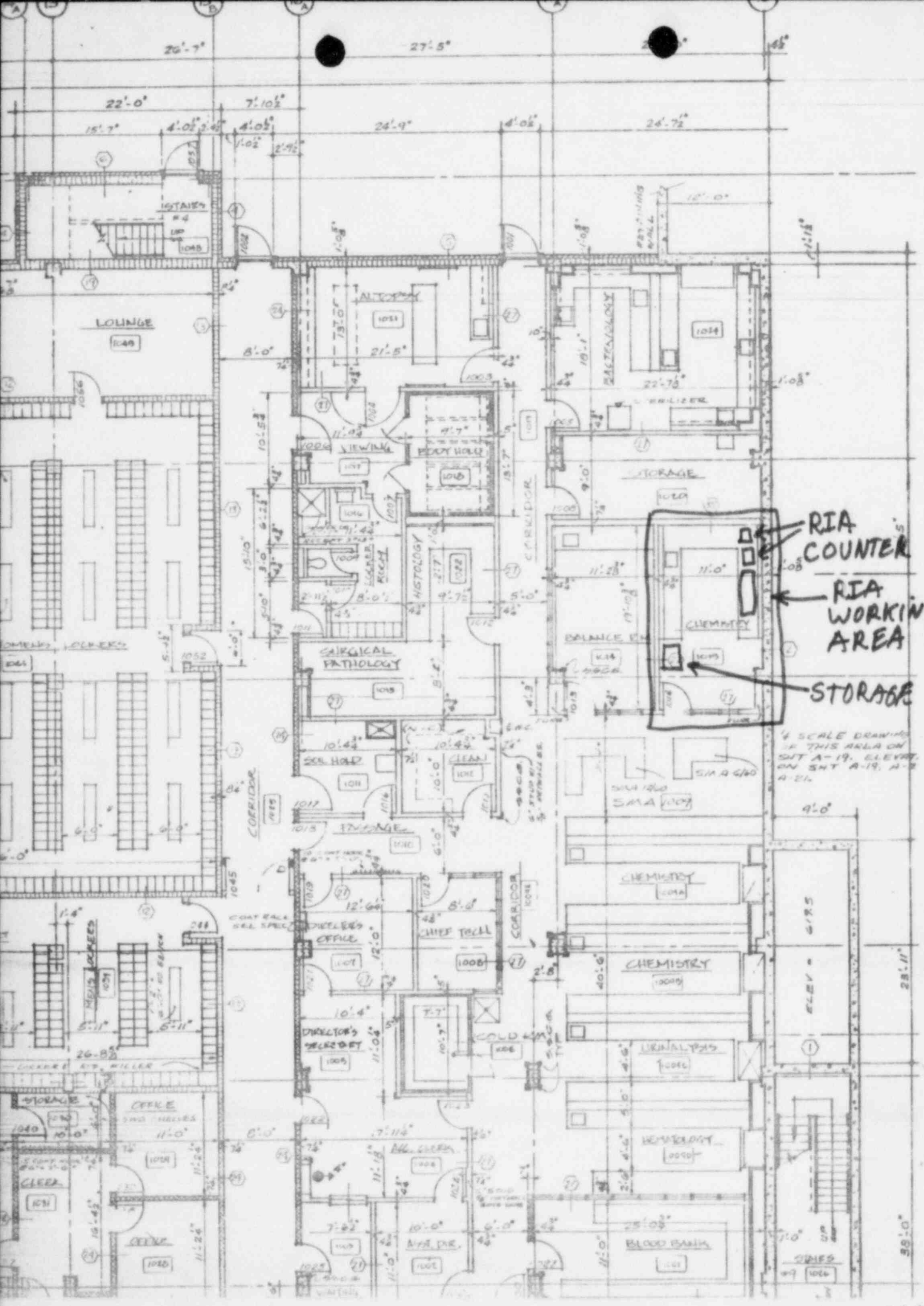
(1) NAME *(Type or Print)*: George P.Casey

(2) TITLE: Executive Vice President

c. DATE: 1-2-79

FORM NRC 313R (7-77) DRAFT


RADIOLOGY
RAD. WASTE
STORAGE
C.T
C.T
OFFICE
2118A
PASSAGE
SOIL HOLD
10'-0"
12'-0"
45'-11"
10'-0"
9'-4"
6-7"
7'-6"
13-8
10'-0
11-0
CORRIDOR
EXP JT COVER TYPICAL
3 SHELVES
12C
13A



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RIDOR
2130
ADJ. SHELVES, CF 42" X 18" X 3/4" PLYWD W/ HARDWOOD EDGE. SEE SPECS FOR BRACKETS USED
RADIOGRAPHIC RM.
2101
PLASTER CONTROL JT.
VIEW WINDOW SEE DTL
2102
2104
2105
STORAGE CABINETS
RADIOGRAPH AREA
CORRIDOR
2103
2106
WORK AREA
2108
SCRUBBING
2107
MAXITOL/AE RM.
COUNTER SEE DTL.
LLUM. NTED
SEE DTL.
PLASTER CONTROL JT.
VIEW WINDOW SEE DTL.
DISC CALORATOR