

MATERIALS LICENSE

Amendment No. 40

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

Licensee		In accordance with application dated June 29, 1983	
1. Massachusetts General Hospital		3. License number 20-03814-80 1, amended in its entirety to read as follows:	
2. Fruit Street Boston, Massachusetts 02114		4. Expiration date August 31, 1988	
		5. Docket or Reference No. 030-01867	
6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	
A. Any byproduct material listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	A. Any radiopharmaceutical listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	A. As necessary for uses authorized in Subitem 9.A.	
B. Any byproduct material listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. Any form listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. 4 curies of each byproduct material authorized in Subitem 6.B	
C. Any byproduct material listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. Any radiopharmaceutical listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. As necessary for uses authorized in Subitem 9.C	
D. Any byproduct material listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. Any radiopharmaceutical listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. As necessary for uses authorized in Subitem 9.D	
E. Any byproduct material listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35	E. Any sealed source listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35	E. 5,340 millicuries total for sources authorized in Subitem 6.E.	
F. Any byproduct material listed in Section 31.11(a) of 10 CFR 31	F. Prepackaged kits	F. 50 millicuries of each byproduct material authorized in Subitem 6.F.	

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6. Byproduct, source, and/or
special nuclear material7. Chemical and/or physical
form8. Maximum amount that
licensee may possess
at any one time
under this license

G. Xenon 133

G. Gas or gas in solution
that is the subject of
an active (i.e., not
withdrawn or terminated)
"New Drug Application"
(NDA) approved by FDA
or an active (i.e., not
withdrawn, terminated or
on "clinical hold")
"Notice of Claimed In-
vestigational Exemption
for a New Drug" (IND)
that has been accepted
by FDA

G. 2,000 millicuries

H. Uranium (depleted in
the isotope Uranium 235)

H. Cadmium plated metal

H. 150 kilograms

I. Any byproduct material
between Atomic Nos. 3
and 83, inclusive except
as below

I. Any

I. 300 millicuries each,
total: 10 curies, except
as below.

J. Hydrogen 3

J. Any

J. 60 curies

K. Carbon 14

K. Any

K. 1 curie

L. Phosphorus 32

L. Any

L. 2 curies

M. Sulfur 35

M. Any

M. 1 curie

N. Chlorine 36

N. Any

N. 0.5 curies

O. Chromium 51

O. Any

O. 0.5 curies

P. Cobalt 60

P. Any

P. 1 curie

Q. Krypton 85

Q. Any

Q. 6 curies

R. Rubidium 86

R. Any

R. 0.5 curies

S. Strontium 90

S. Any

S. 3 curies

T. Molybdenum 99

T. Any

T. 6 curies

U. Technetium 99m

U. Any

U. 6 curies

V. Iodine 125

V. Any

V. 1.5 curies

W. Iodine 131

W. Any

W. 2 curies

X. Barium 131

X. Any

X. 0.5 curies

Y. Xenon 133

Y. Any

Y. 3 curies

Z. Cesium 137

Z. Any

Z. 2.5 curies

AA. Dysprosium 165

AA. Any

AA. 25 curies

BB. Osmium 191

BB. Any

BB. 4 curies

CC. Iridium 191m

CC. Any

CC. 4 curies

DD. Iridium 192

DD. Any

DD. 2 curies

EE. Gold 198

EE. Any

EE. 2 curies

FF. Polonium 210

FF. Any

FF. 10 millicuries

GG. Americium 241

GG. Sealed sources

GG. 100 millicuries

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9. Authorized use

- A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100 Title 10, Code of Federal Regulations.
- B. Preparation and use of radiopharmaceuticals for any diagnostic procedure listed in Group III of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
- C. Any therapeutic procedure listed in Group IV of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
- D. Any therapeutic procedure listed in Group V of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
- E. Any procedure listed in Group VI of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
- F. In vitro studies.
- G. Blood flow and pulmonary function studies.
- H. For use as shielding in a linear accelerator.
- I. through FF. Medical diagnosis, therapy, research and development as defined by 10 CFR 30.4(q); including medical research with humans; animal studies.
- GG. For use as a standard for calibration purpose.

CONDITIONS

10. A. Licensed material shall be used only at the Massachusetts General Hospital, Fruit Street and the Burn Institute of the Shriners Hospital for Crippled Children, 41-45 Blossom Street, Boston, Massachusetts, and the McLean Hospital, Alcohol and Drug Abuse Research Center, 115 Mill Street, Belmont, Massachusetts.
B. Notwithstanding Condition 10.A., licensed material may be administered to patients for diagnostic and therapeutic purposes at the Massachusetts Eye and Ear Infirmary, 243 Charles Street, Boston, Massachusetts, in accordance with letter dated July 13, 1983.
11. The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 19, "Notices, Instructions, and Reports to Workers; Inspections" and Part 20, "Standards for Protection Against Radiation."
12. Licensed material in Items 6.A. through 6.E. shall be used in accordance with the provisions of Section 35.14(b)(c)(e) and (f) of Title 10, Code of Federal Regulations.
13. A. Licensed material shall be used by, or under the supervision of, individuals designated by the Massachusetts General Hospital Radiation Safety Committee, Edward W. Webster, Chairman.
B. The use of licensed material in or on humans shall be by a physician.
C. Physicians designated to use licensed material in or on humans shall meet the training and experience criteria established in Appendix A of Regulatory Guide 10.8 (Rev. 1), dated October 1980.
D. The Radiation Protection Officer for the activities authorized by this license is Frank P. Castronovo, Jr., Ph.D.

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CONDITIONS

14. A. (1) Each sealed source acquired from another person and containing licensed material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than gas shall be tested for contamination and/or leakage prior to use. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.
- (2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.
- (3) Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer.
- B. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to use or transfer as a sealed source. If the inspection or test reveals any construction defects or 0.005 microcurie or greater of contamination, the source shall not be used or transferred as a sealed source until it has been repaired, decontaminated and retested.
- C. Each sealed source containing licensed material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six months except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed three months.
- D. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.
- E. If the test required by Subsection A. or C. of this condition reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the test with the U.S. Nuclear Regulatory Commission, Region I, 631 Park Avenue, King of Prussia, Pennsylvania 19406, describing the equipment involved, the test results, and the corrective action taken.

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CONDITIONS

15. Sealed sources containing licensed material shall not be opened.
16. Patients containing Cobalt 60, Cesium 137 or Iridium 192 implants shall remain hospitalized until surveys made with an appropriate radiation detection instrument indicate that all implants have been removed. The results of these surveys shall be recorded and maintained for inspection by the Commission for five (5) years from the time the implants are removed.
17. Patients containing Iodine 131 for the treatment of thyroid carcinoma or patients containing therapeutic quantities of Gold 198 shall remain hospitalized until the residual activity is 30 millicuries or less.
18. Pursuant to Section 20.105(a) of Title 10, Chapter 1, Code of Federal Regulations, Part 20, "Standards for Protection Against Radiation," and in reliance of statements, procedures and representations made by the licensee in his letter dated July 13, 1983, the following maximum radiation levels are hereby authorized in the following unrestricted areas:

Maximum Radiation Level

3 millirem in any one hour
100 millirem in any one week
500 millirem in any one year

Unrestricted Area

Eighteen (18) inches from walls in hallways and patient rooms adjacent to rooms occupied by patients undergoing radioiodine therapy or brachytherapy

19. A. Detector cells containing titanium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 225 degrees Centigrade.
- B. Detector cells containing scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 325 degrees Centigrade.
20. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in Section 20.203(a)(1), Title 10, Code of Federal Regulations, Part 20, the licensee is hereby authorized to label detector cells and cell baths, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.
21. The licensee may transport licensed material or deliver licensed material to a carrier for transport in accordance with the provisions of Title 10, Code of Federal Regulations, Part 71, "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions."
22. The licensee shall conduct a physical inventory every six (6) months to account for all sealed sources received and possessed under the license. The records of the inventories shall be maintained for two (2) years from the date of the inventory for inspection by the Commission, and shall include the quantities and kinds of byproduct material, location of sealed sources and the date of the inventory.

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CONDITIONS

23. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
24. Experimental animals administered licensed material or their products shall not be used for human consumption.
25. Licensed material shall not be used in products distributed to the public.
26. The licensee may use the Lineator device for doing linearity tests of his dose calibrator provided he follows the procedures in the Atomic Products Corporation Lineator Instructions Manual dated June 20, 1983.
27. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:
- A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of ten (10) half-lives.
 - B. Prior to disposal as normal waste, radioactive waste shall be monitored to determine that its radioactivity cannot be distinguished from background with typical low-level laboratory survey instruments. All radiation labels will be removed or obliterated.
 - C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.
28. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated June 29, 1983, including ALARA Program, and letters dated July 1, 1983, July 7, 1983, and July 13, 1983. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

For the U.S. Nuclear Regulatory Commission

By


Nuclear Materials and Safeguards Branch
Region I
King of Prussia, Pennsylvania 19406

Date August 19, 1983

ATTACHMENT 2.
LABORATORY / FACILITIES

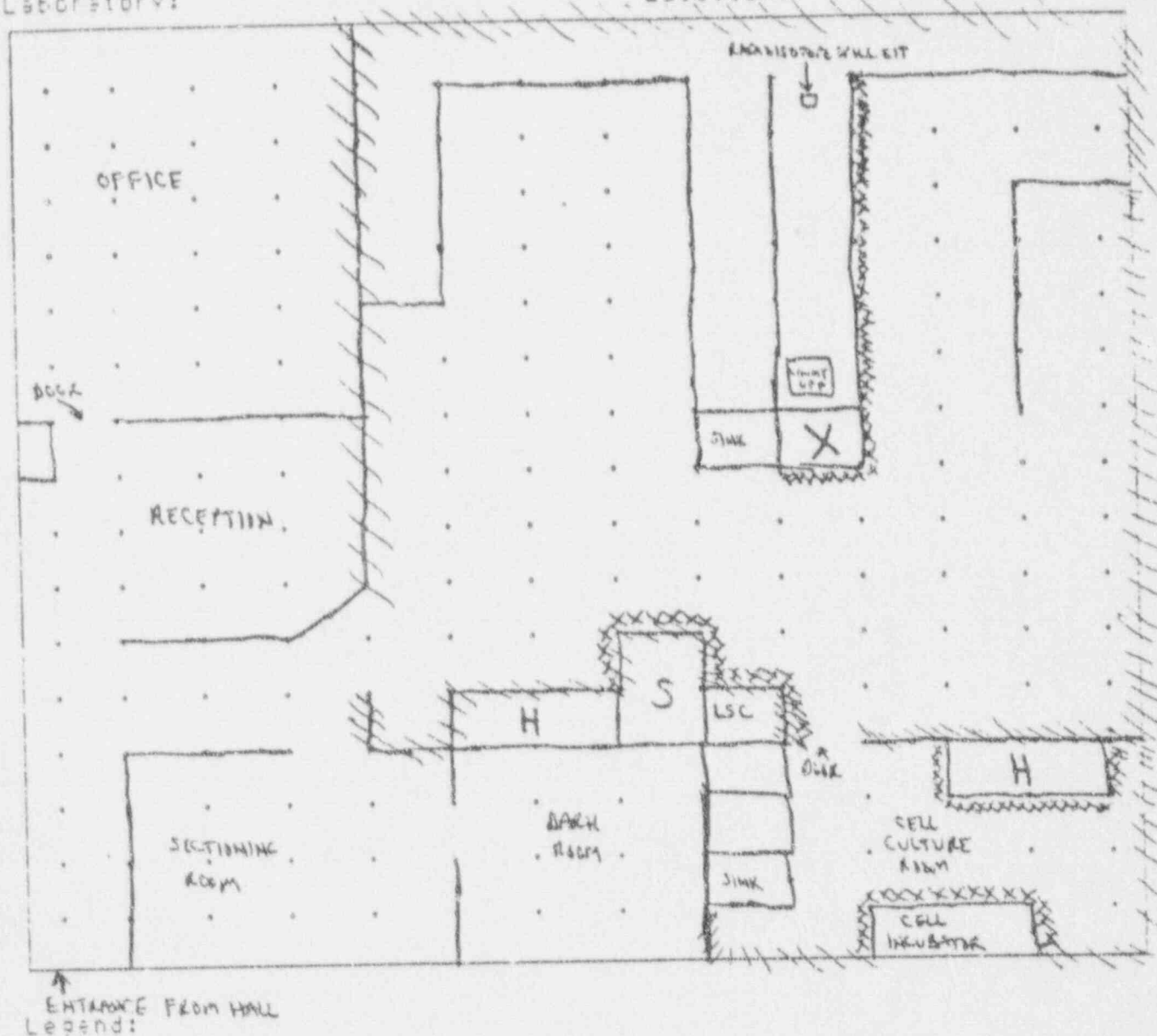
RADIOISOTOPE SAFETY

FLOOR PLAN - LABORATORY/USE AREA

The following diagram illustrates an area within the Infirmary where radioisotopes are used or stored. Key features that relate to the management of radioisotopes are labelled for survey and safety purposes. (The illustration is not meant to be a scale drawing.)

Laboratory:

Location:



//// - border of restricted area (rooms, laboratories, etc.)

xxxxx - radioisotope work area (benches, equipment, etc.)

X - "hot" sink

H - vapor hood, etc.

S - radioisotope storage

LS - locked storage

Completed by:

Date:

Revised:

Edmund L. O'Brien

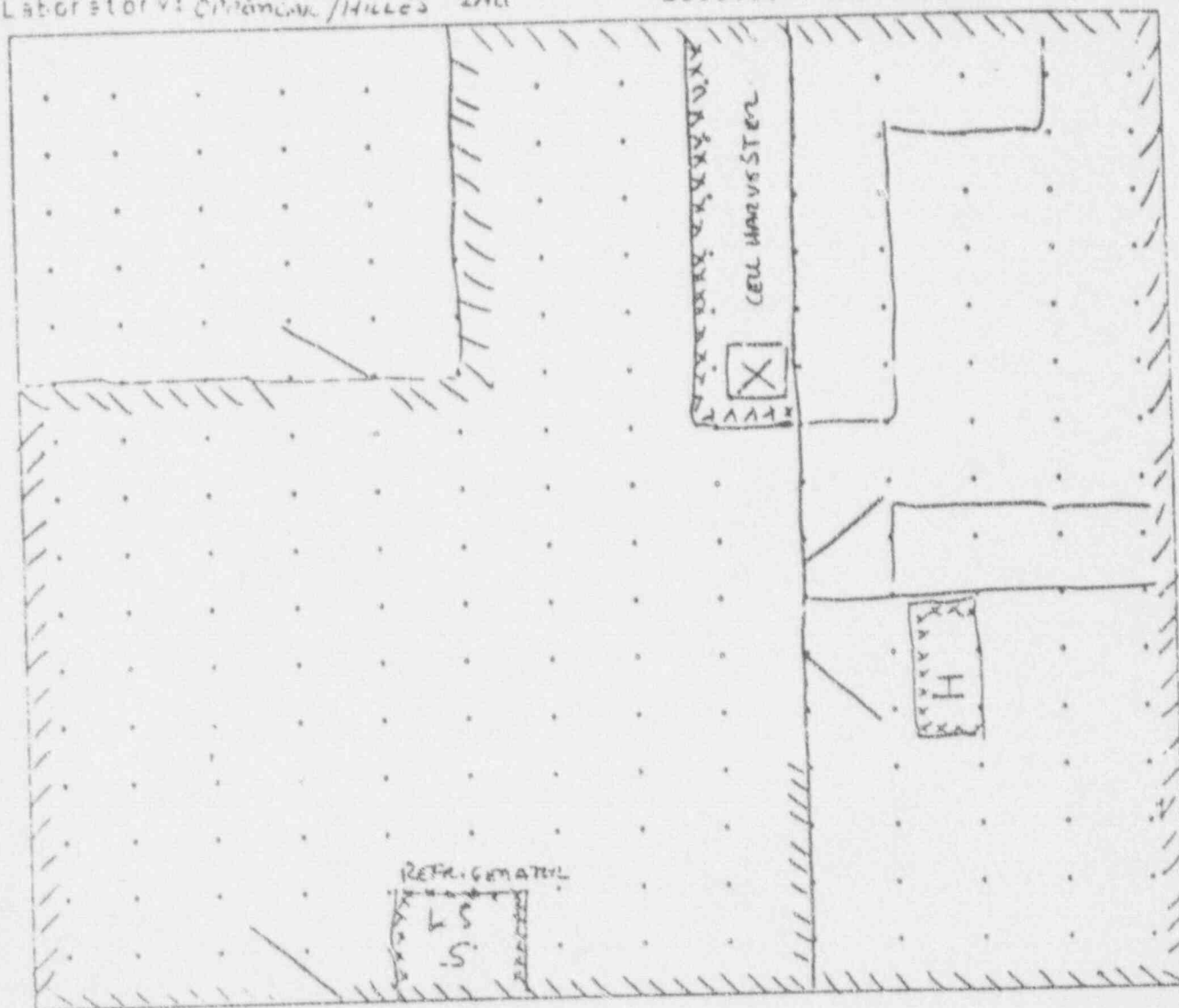
RADIOISOTOPE SAFETY

FLOOR PLAN - LABORATORY/USE AREA

The following diagram illustrates an area within the Infirmary where radioisotopes are used or stored. Key features that relate to the management of radioisotopes are labelled for review and safety purposes. (The illustration is not meant to be a scale drawing.)

Laboratory: CRONIN/HILLER LAB

Location: RM 620 CONNECTIVE



Legend:

//// - border of restricted area (rooms, laboratories, etc.)

X - "hot" sink

S - radioisotope storage

XXXXX - radioisotope work area (benches, equipment, etc.)

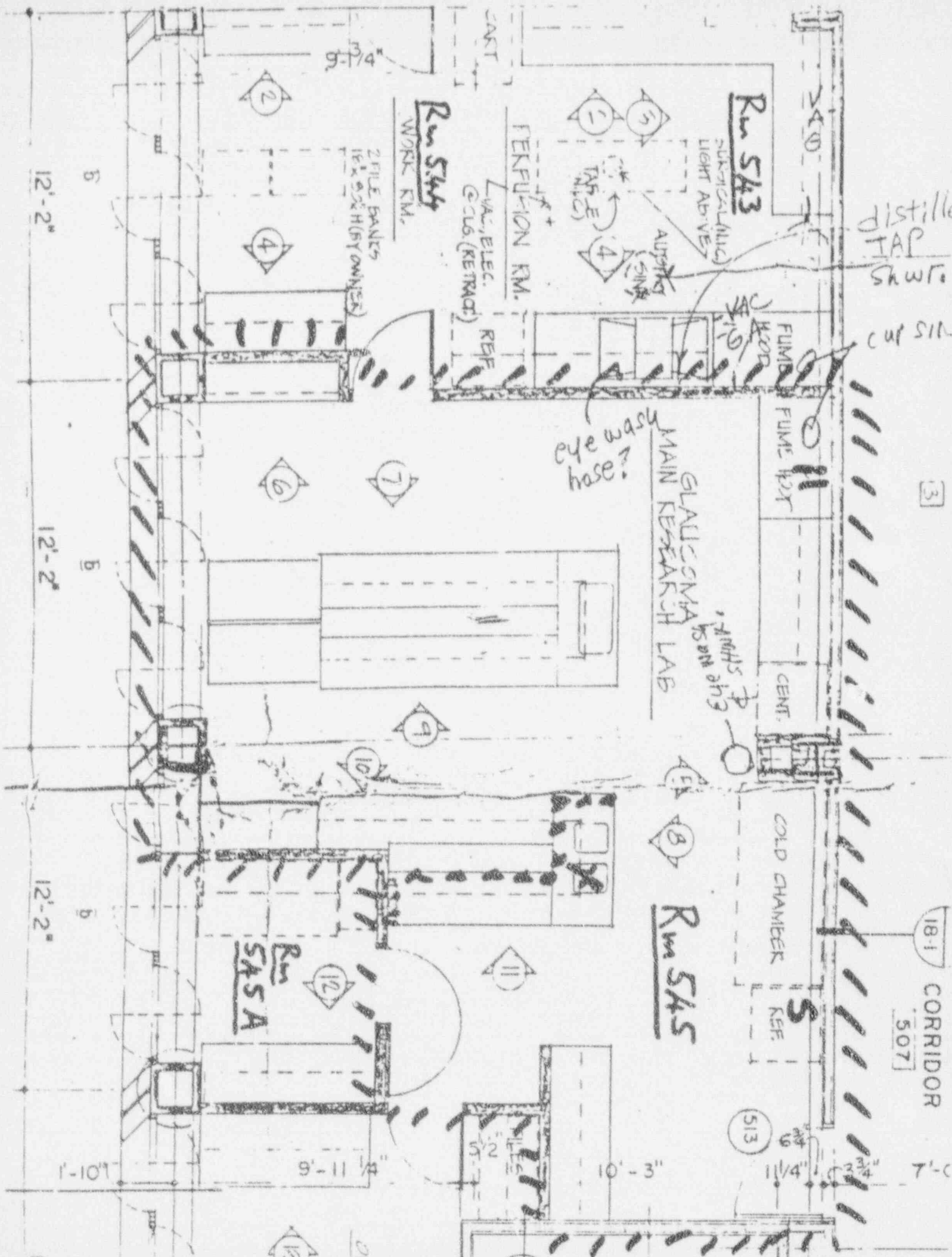
H - vapor hood, etc.

LS - locked storage

Completed by:

Date:

Signature:



DISTILL
TAP
SHWR.

VIS IN

3

18-1 CORRIDOR
507

Rm 543

SUCKING LIGHT ABOVE

GLASS/COMA LAB

7'11"15" P
K 507 213

COLD CHAMBER

Rm 545

PERFUMION RM.

VAC, ELEC.
G.C.B. (RETRACT)

Rm 544
WORK RM.

2 FILE BANKS
16 1/2 x 11 (BY OWNERS)

eye wash
base?

12'-2"

12'-2"

12'-2"

9'-11 1/4"

10'-3"

1'-10 1/4"

7'-0"

513

REF

Rm 545A

b

b

b

01

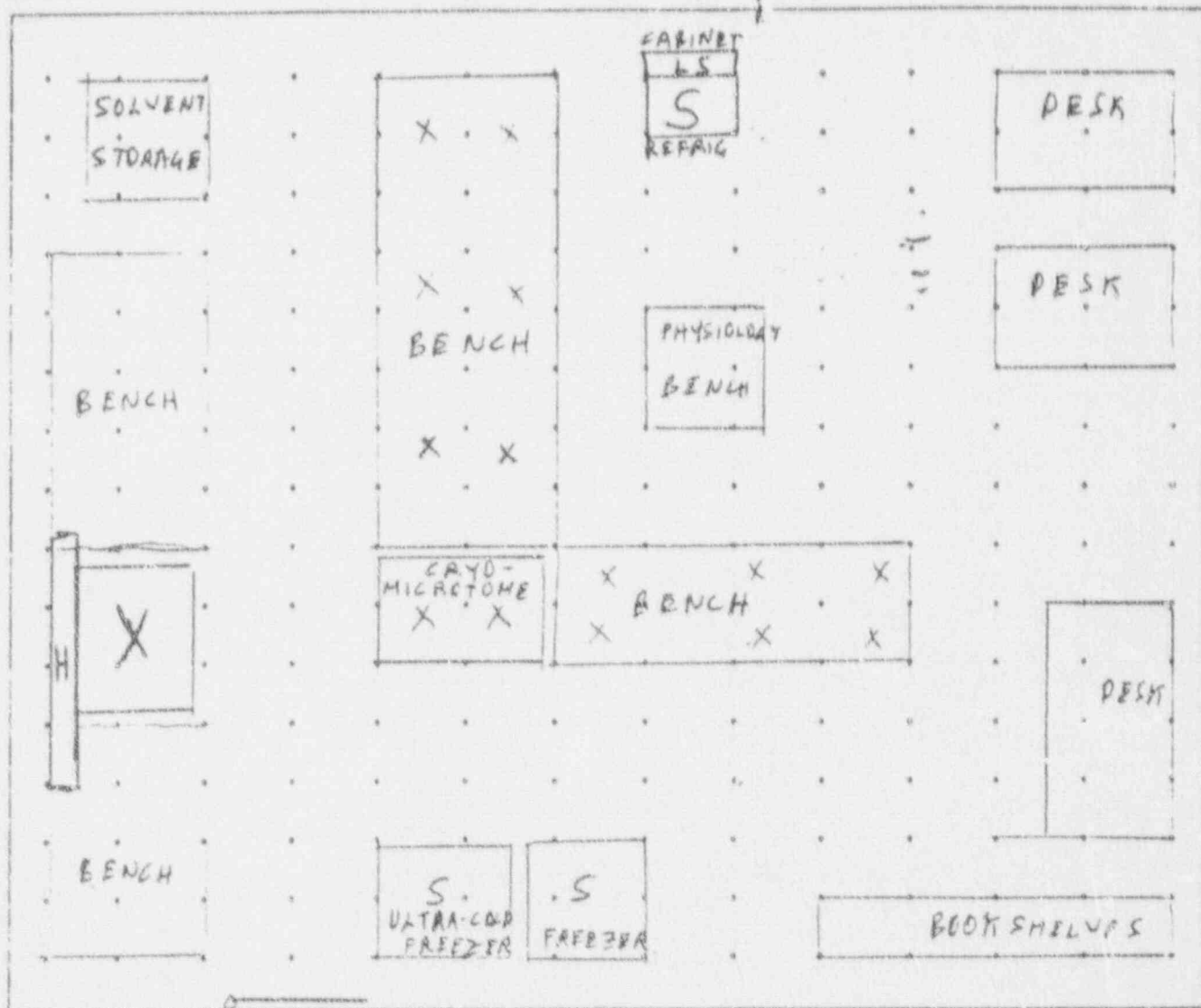
RADIOISOTOPE SAFETY

FLOOR PLAN: - LABORATORY/USE AREA

The following diagram illustrates an area within the Infirmary where radioisotopes are used or stored. Key features that relate to the management of radioisotopes are labelled for survey and safety purposes. (The illustration is not meant to be a scale drawing.)

Laboratory:

Location:



Legend:

----- - border of restricted area (rooms, laboratories, etc.)

X - "hot" sink

S - radioisotope storage

xxxxx - radioisotope work area (benches, equipment, etc.)

H - vapor hood, etc.

LS - locked storage

Completed by:

Date:

Schein

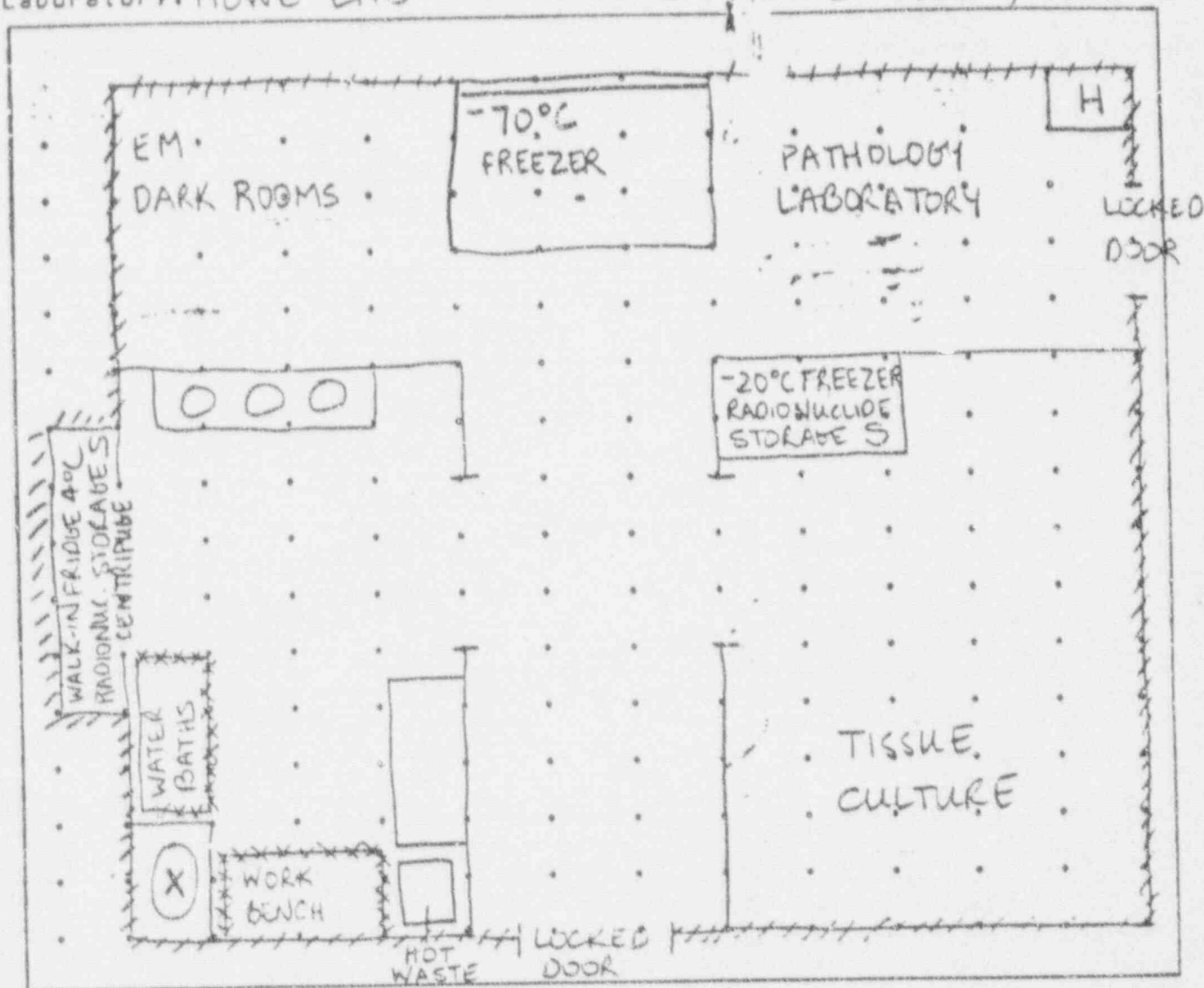
RADIOISOTOPE SAFETY

FLOOR PLAN - LABORATORY/USE AREA

The following diagram illustrates an area within the Infirmary where radioisotopes are used or stored. Key features that relate to the management of radioisotopes are labelled for survey and safety purposes. (The illustration is not meant to be a scale drawing.)

Laboratory: HOWE LAB

Location: 5th FLOOR, MEEI



Legend:

----- - border of restricted area (rooms, laboratories, etc.)

X - "hot" sink

S - radioisotope storage

xxxxxx - radioisotope work area (benches, equipment, etc.)

H - vapor hood, etc.

LS - locked storage

Completed by: V. WHITE

Date: NOV. 23, 1987

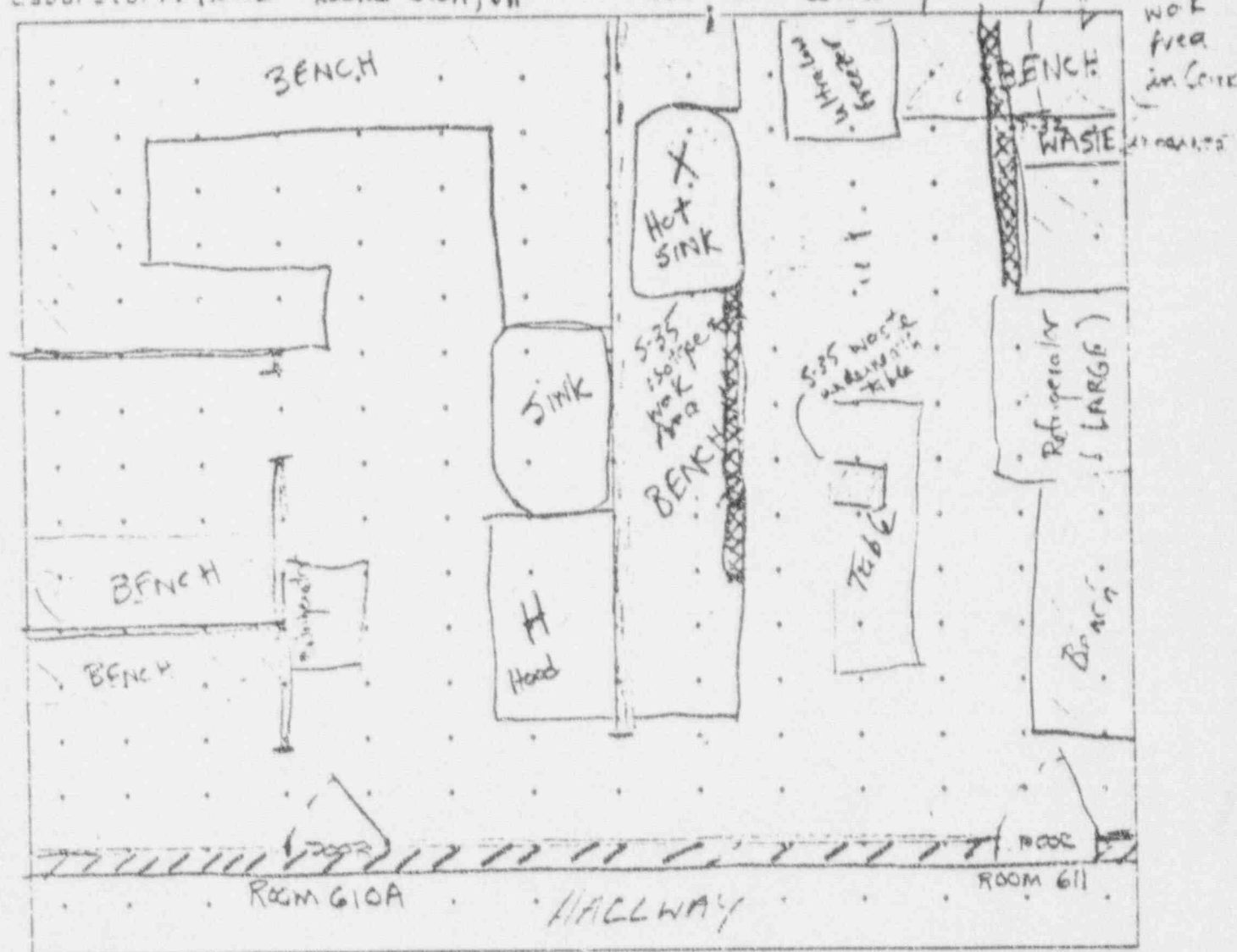
RADIOISOTOPE SAFETY

FLOOR PLAN - LABORATORY/USE AREA

The following diagram illustrates an area within the Infirmary where radioisotopes are used or stored. Key features that relate to the management of radioisotopes are labelled for survey and safety purposes. (The illustration is not meant to be a scale drawing.)

Laboratory: ^{DRYJA/YANDELL} HOWE - Rooms G10A, 611

Location: ^{MEET} Connecting Building ^{G10A} 611 ^{MAIN} work area in G10A



Legend:

//// - border of restricted area (rooms, laboratories, etc.)

X - "hot" sink

S - radioisotope storage

xxxxx - radioisotope work area (benches, equipment, etc.)

H - vapor hood, etc.

LS - locked storage

Completed by: Dr. DAVID YANDELL

Date: 11/25/67

RADIOISOTOPE SAFETY

FLOOR PLAN - LABORATORY/USE AREA

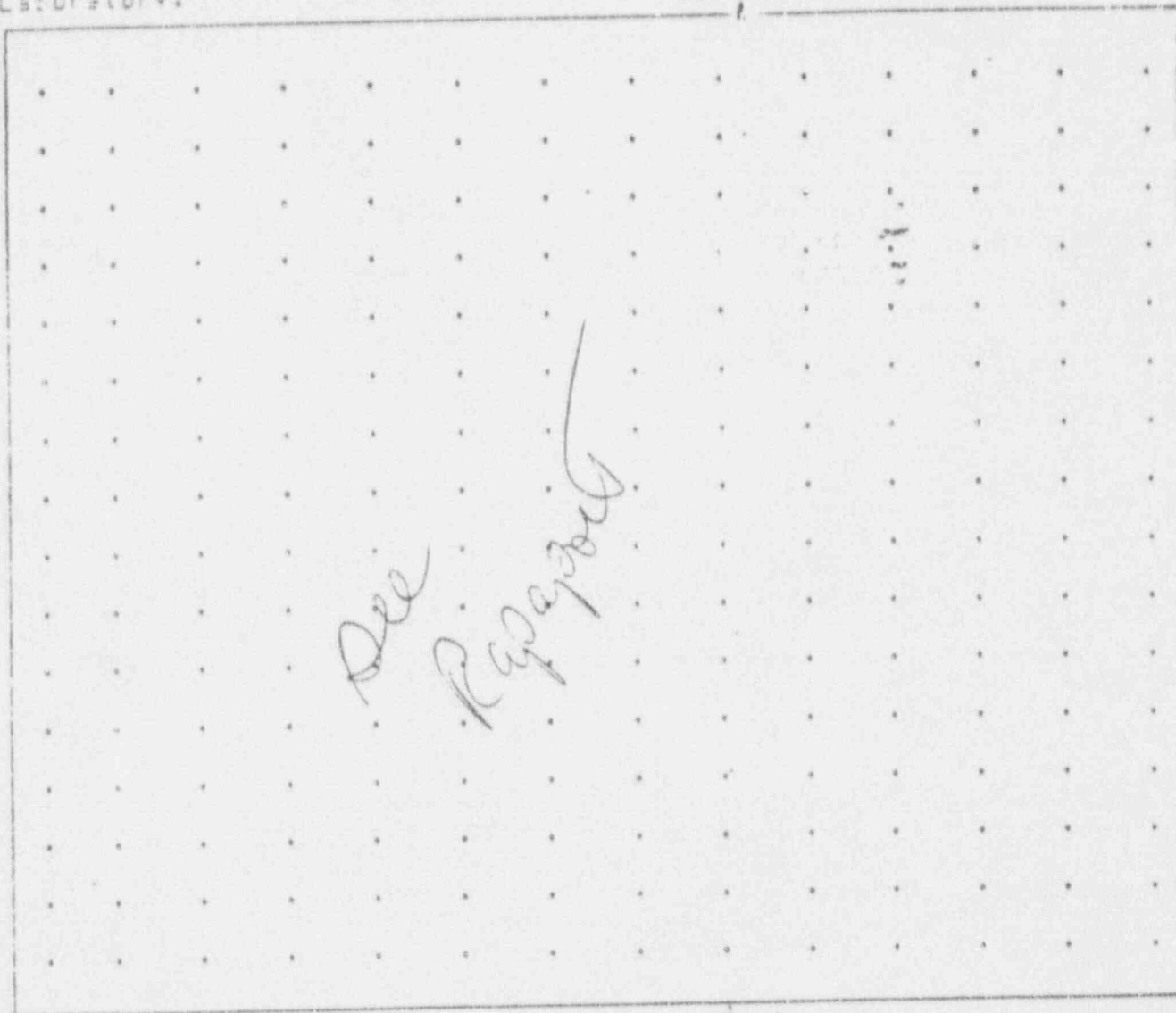
See Rapaport

The following diagram illustrates an area within the Infirmary where radioisotopes are used or stored. Key features that relate to the management of radioisotopes are labelled for survey and safety purposes. (The illustration is not meant to be a scale drawing.)

Laboratory:

Location:

621B



Legend:

//// - border of restricted area (rooms, laboratories, etc.)

X - "hot" sink

S - radioisotope storage

xxxxx - radioisotope work area (benches, equipment, etc.)

H - vapor hood, etc.

LS - locked storage

Completed by:

Date:

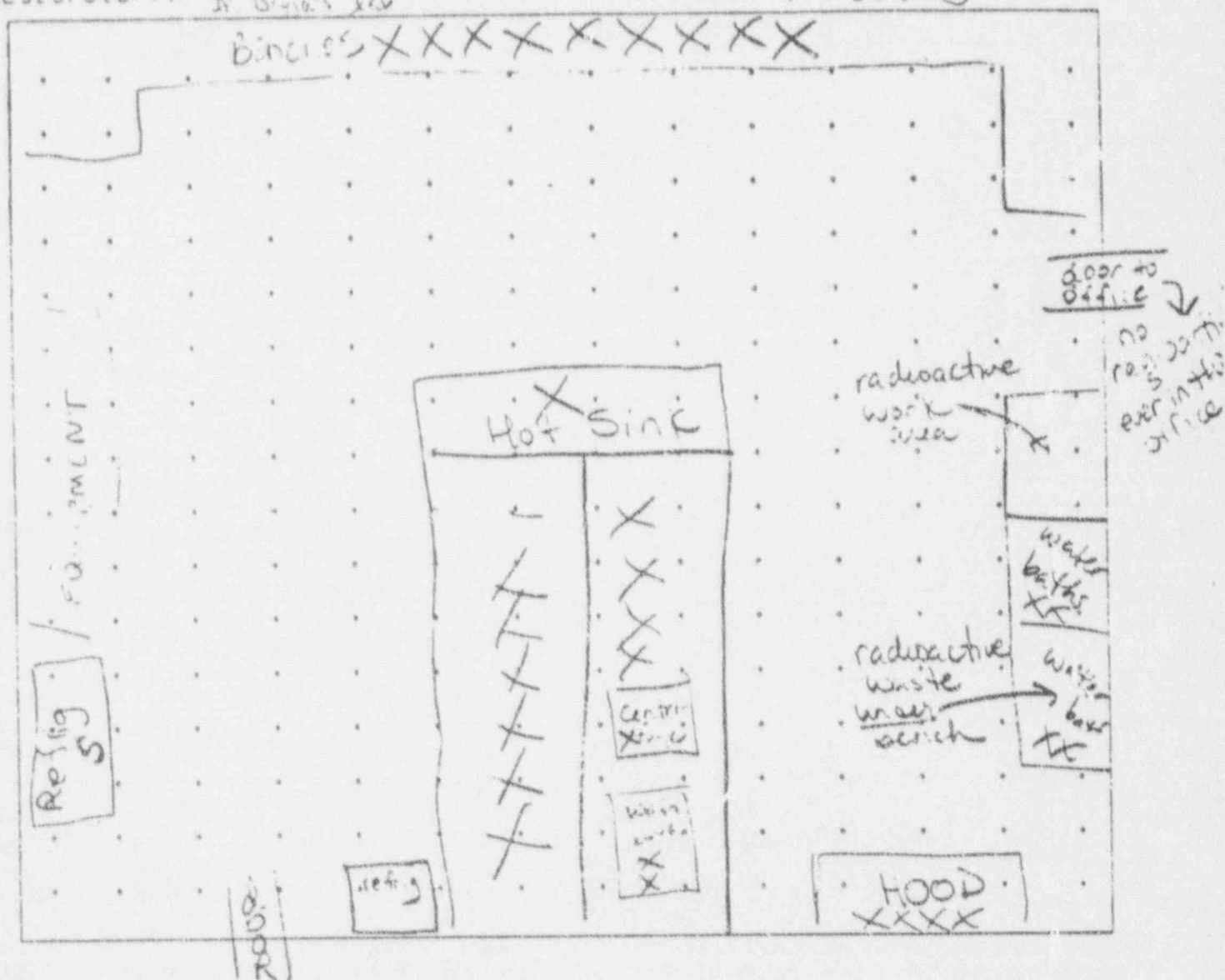
RADIOISOTOPE SAFETY

FLOOR PLAN - LABORATORY/USE AREA

The following diagram illustrates an area within the Infirmary where radioisotopes are used or stored. Key features that relate to the management of radioisotopes are labelled for survey and safety purposes. (The illustration is not meant to be a scale drawing.)

Laboratory: *Room 2 Smith Laboratory*
Dr. Deane's Lab

Location: *Rm 621 CB*



Legend:

----- - border of restricted area (rooms, laboratories, etc.)

X - "hot" sink

⊞ - radioisotope storage

xxxxx - radioisotope work area (benches, equipment, etc.)

H - vapor hood, etc.

LS - locked storage

Completed by:

Date:

10/1/77

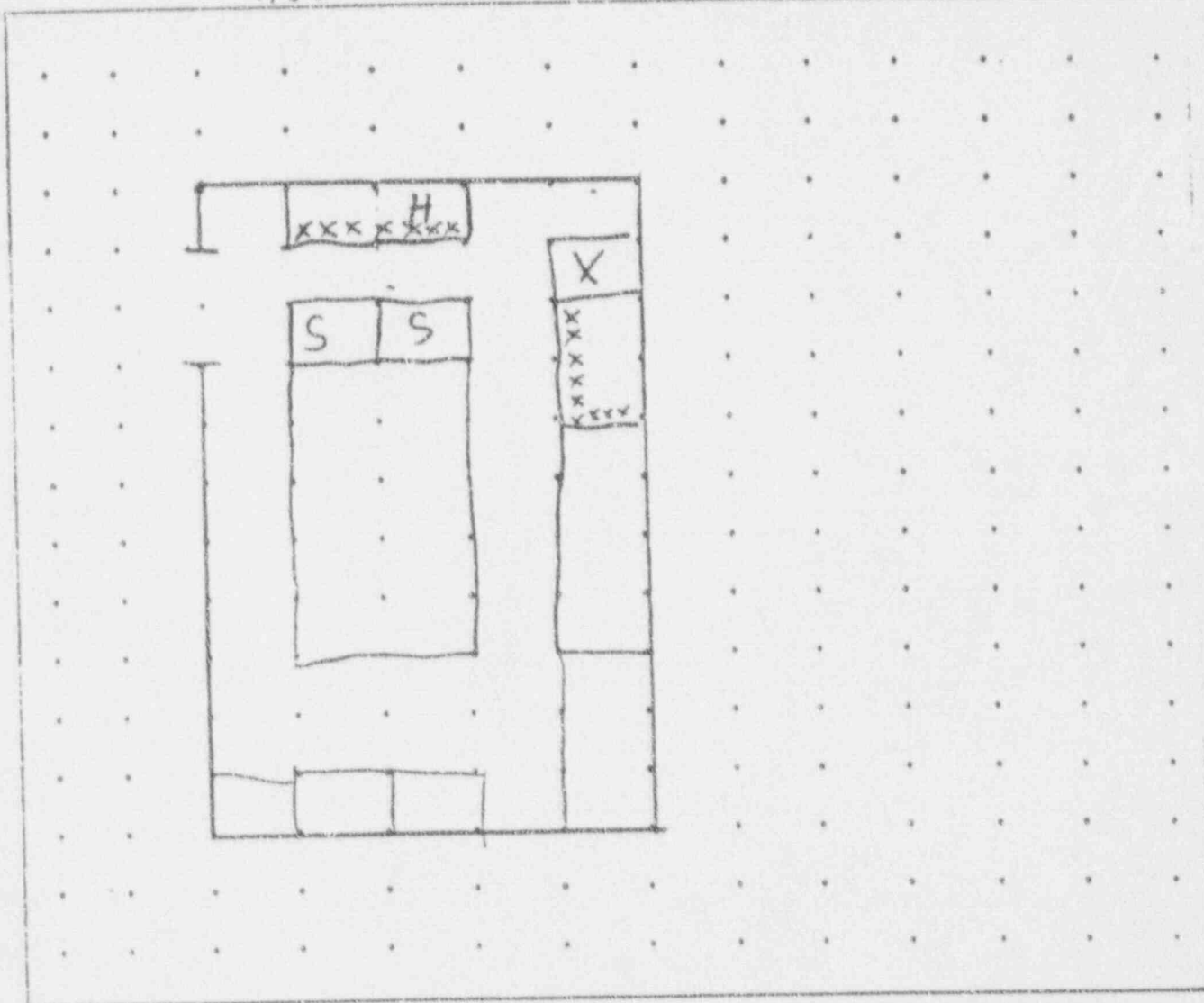
RADIOISOTOPE SAFETY

FLOOR PLAN - LABORATORY/USE AREA

The following diagram illustrates an area within the Infirmary where radioisotopes are used or stored. Key features that relate to the management of radioisotopes are labelled for survey and safety purposes. (The illustration is not meant to be a scale drawing.)

Laboratory: *Howe*

Location: *C704*



Legend:

///// - border of restricted area (rooms, laboratories, etc.)

X - "hot" sink

S - radioisotope storage

xxxxx - radioisotope work area (benches, equipment, etc.)

H - vapor hood, etc.

LS - locked storage

Completed by: *John R. Wolfe*

Date: *11/20/87*

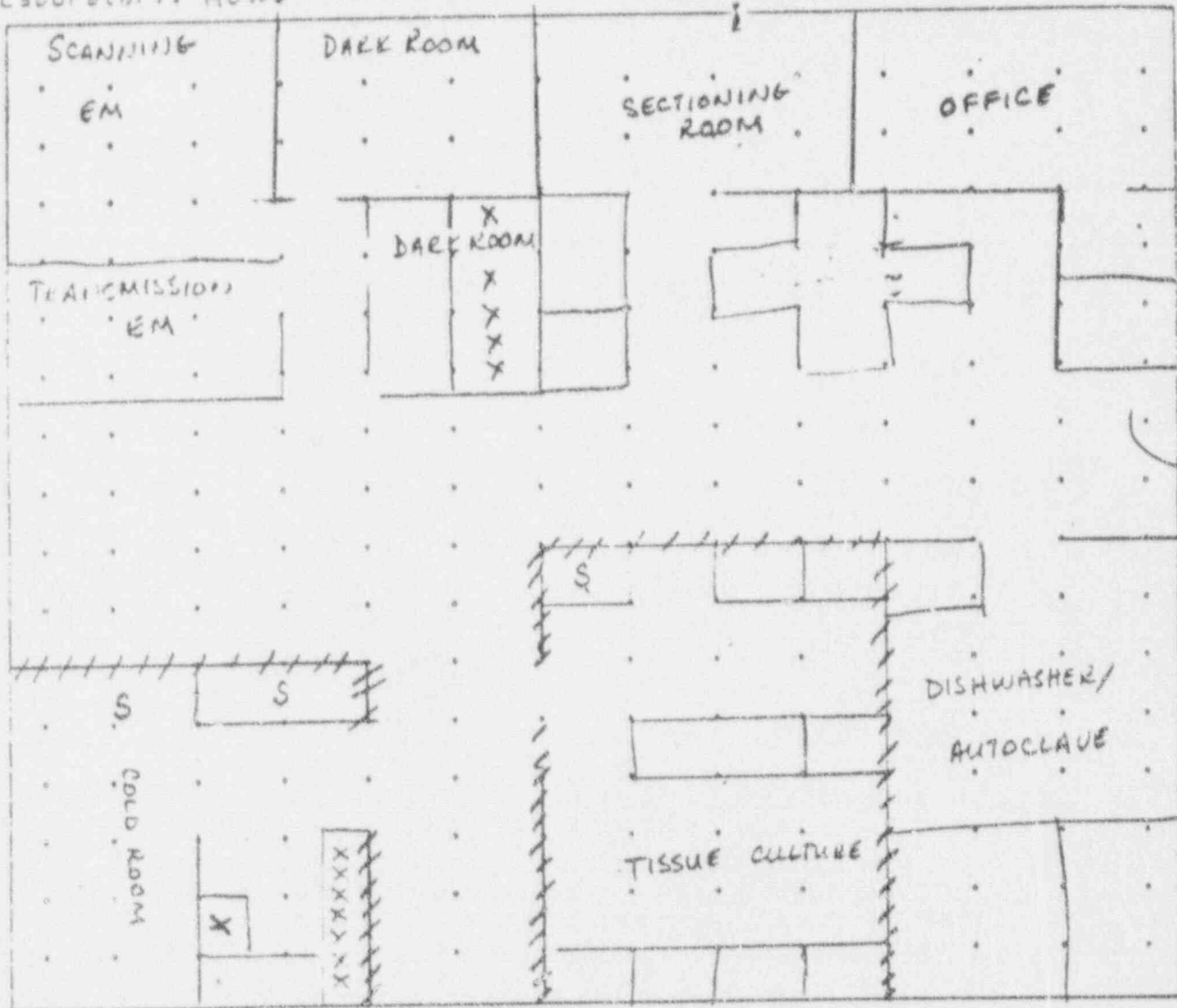
RADIOISOTOPE SAFETY

FLOOR PLAN - LABORATORY/USE AREA

The following diagram illustrates an area within the Infirmary where radioisotopes are used or stored. Key features that relate to the management of radioisotopes are labelled for survey and safety purposes. (The illustration is not meant to be a scale drawing.)

Laboratory: HOWE

Location: RM 544



Legend:

//// - border of restricted area (rooms, laboratories, etc.)

X - "hot" sink

E - radioisotope storage

XXXXX - radioisotope work area (benches, equipment, etc.)

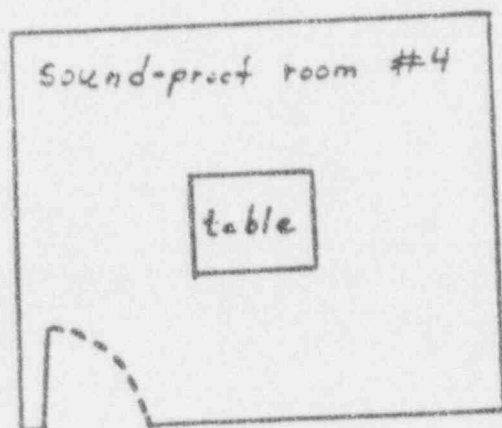
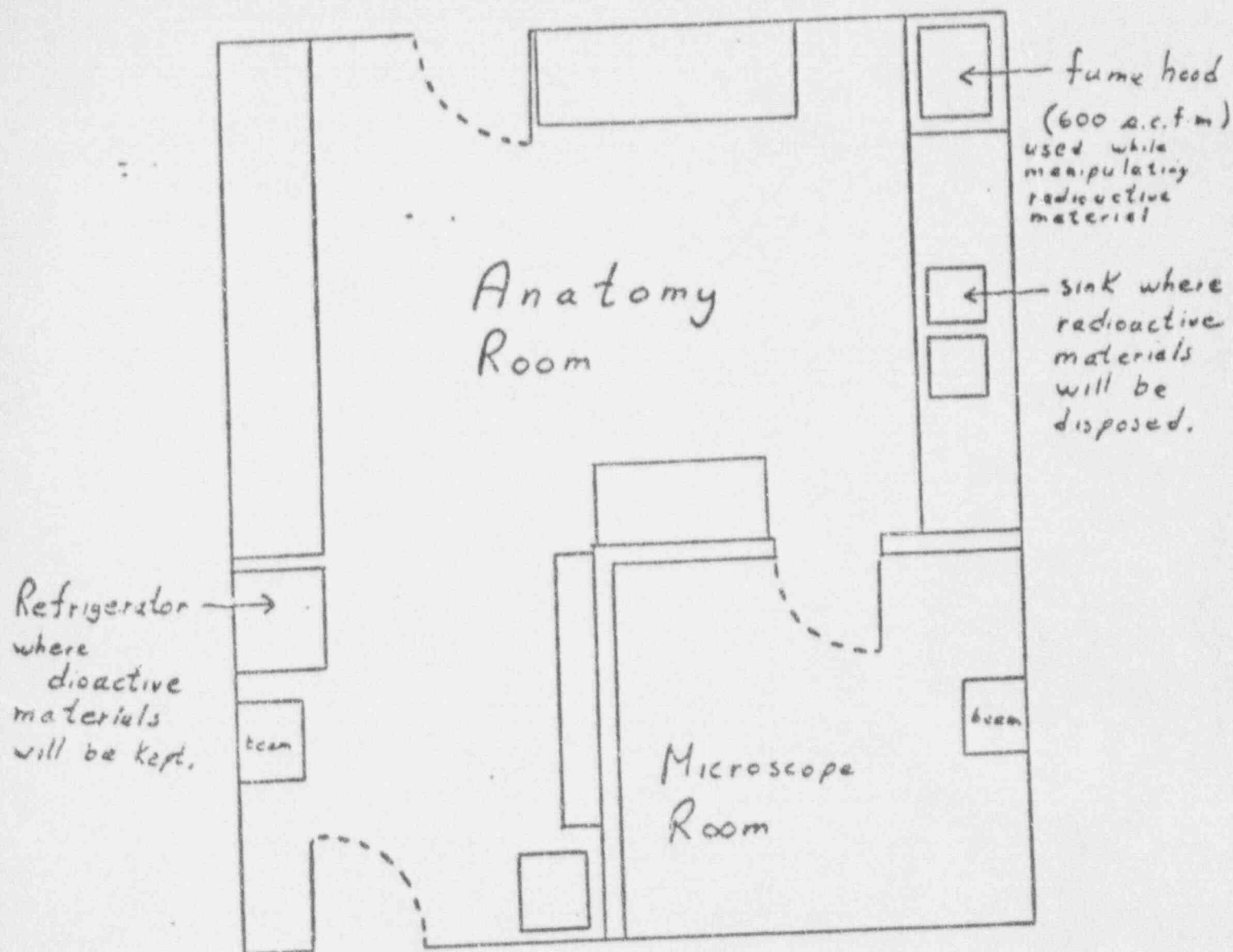
H - vapor hood, etc.

LS - locked storage

Completed by:

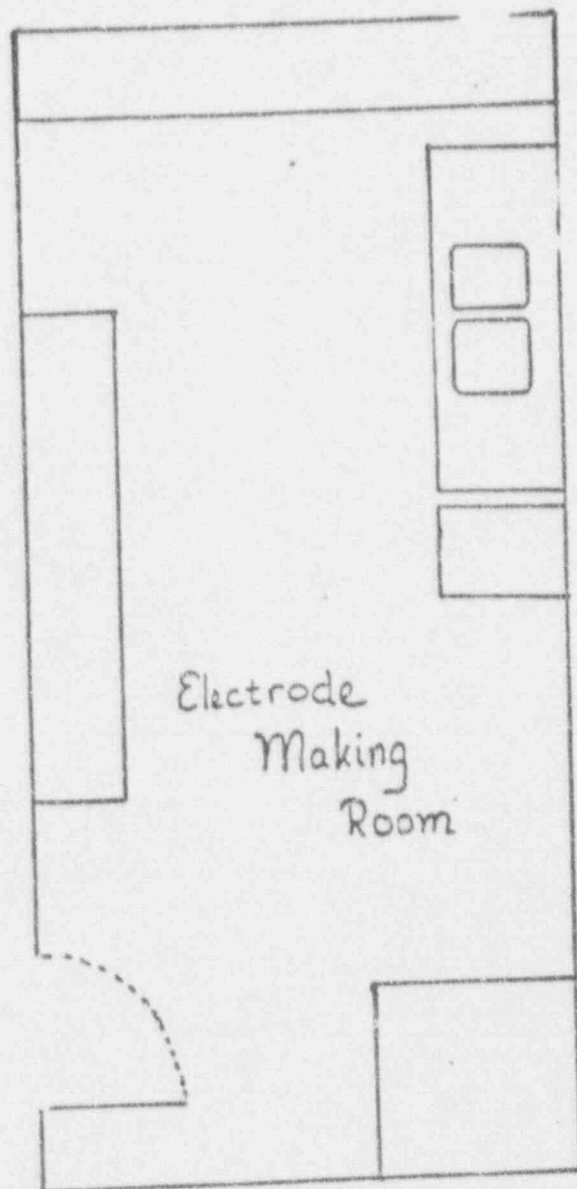
Date:

Locations in Custer-Peabody Lab (4 floor) where radioactive materials will be used.



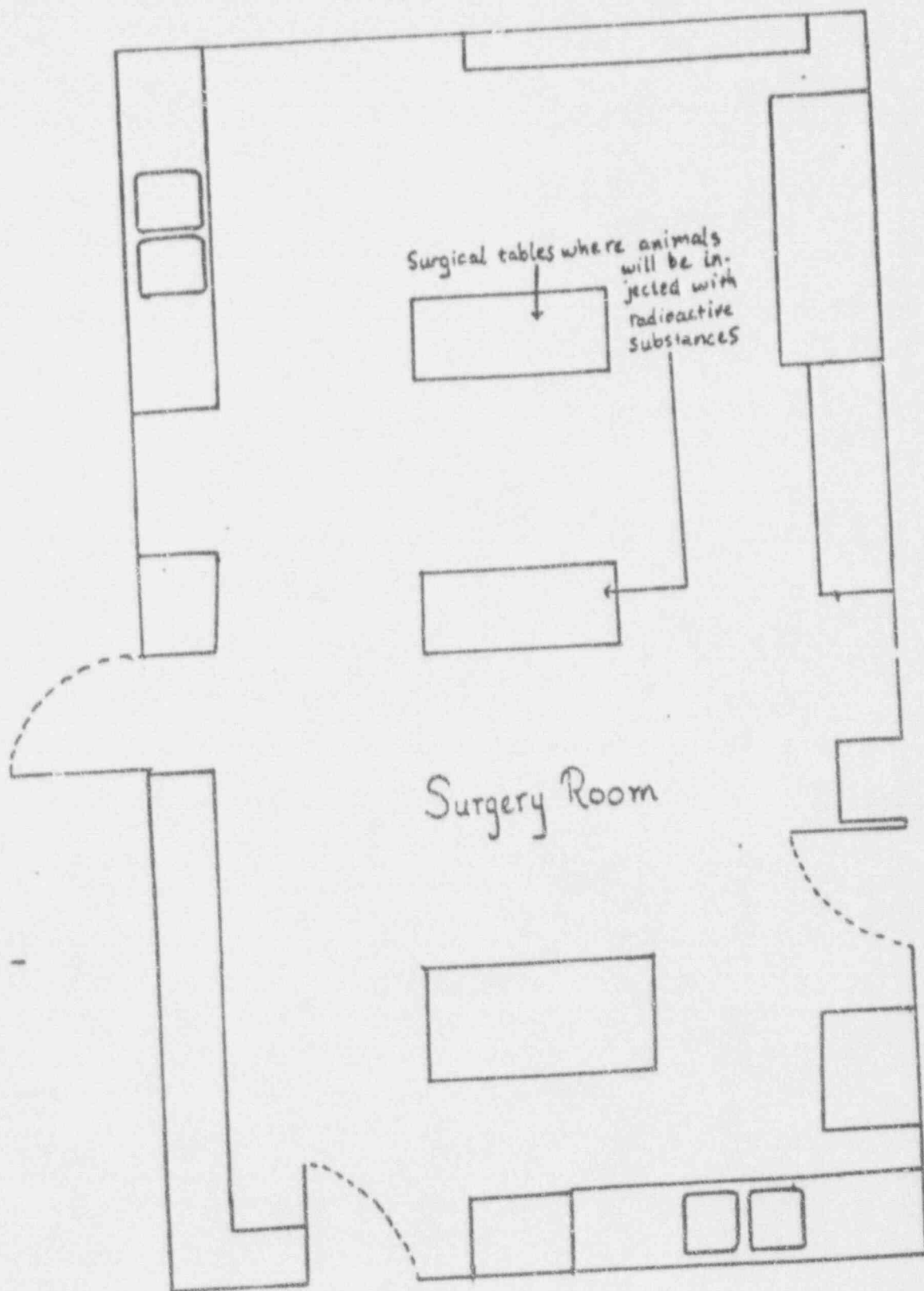
Animals will be injected in sound proof rooms.

Locations in Tucson Prabody Lab (4th fl. -) where
radioactive materials will be used.



6/11/82

Locations in 'Luton Peabody Lab (4th flr)' where radioactive materials will be used

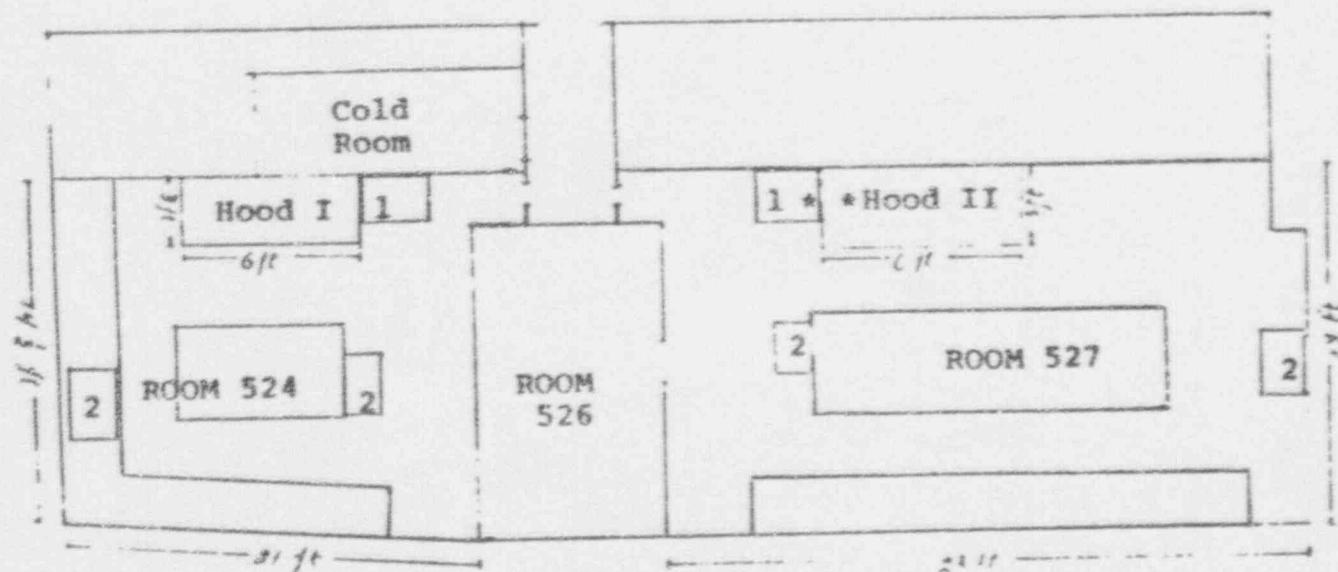


6/11/82

APPENDIX

Diagram of Room 527 and 524

Floor plan of Rooms 524 & 527, Connecting
Building, Massachusetts Eye & Ear Infirmary

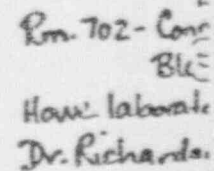


1: Refrigerator
2: Sink

*: Isotope storage area

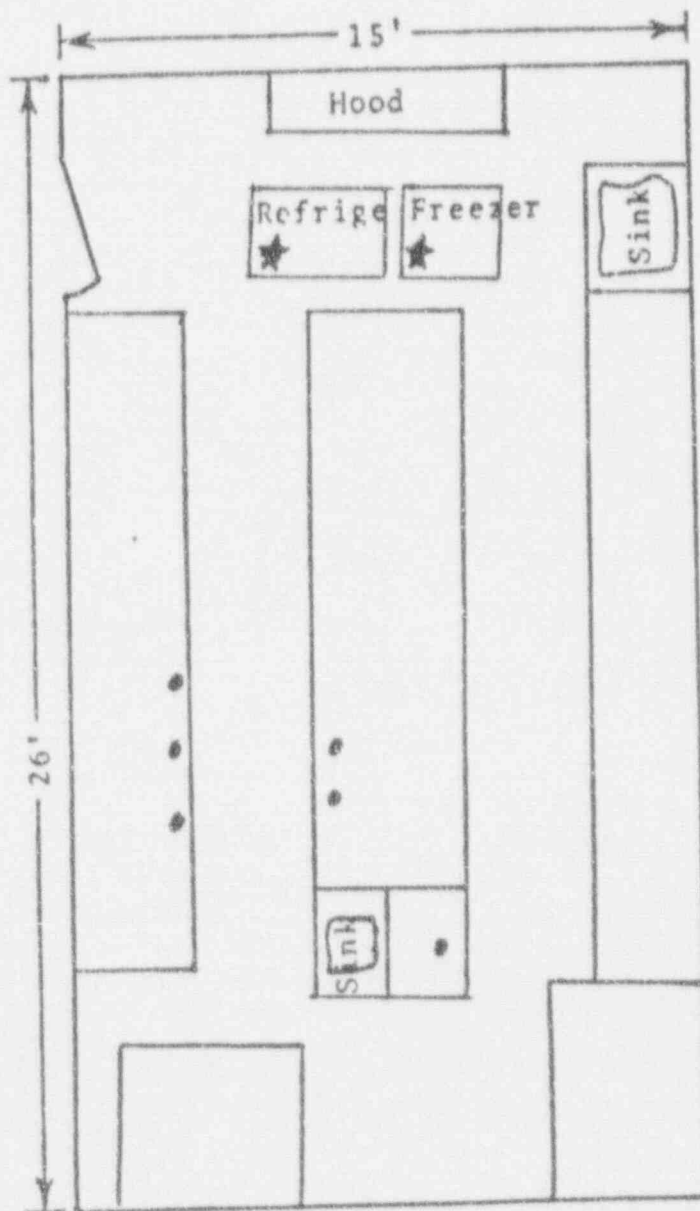
Flow rate of hood =

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Amendment Request for Reconsideration

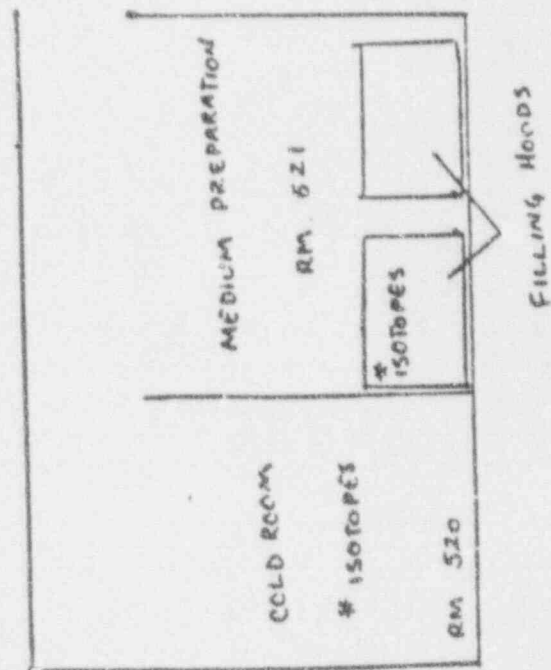
Diagram of Room 701



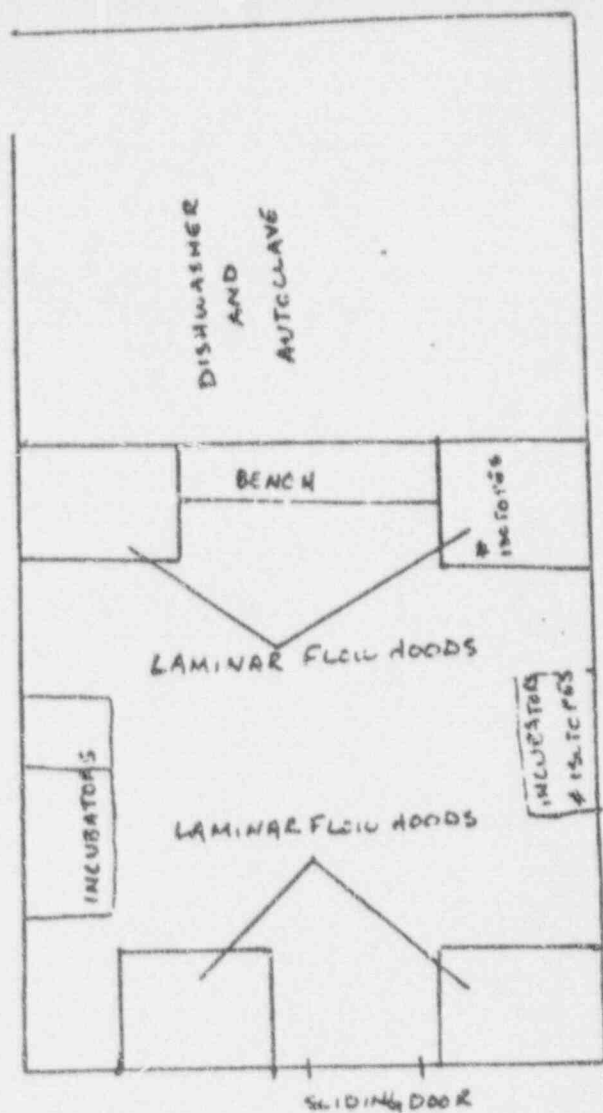
★ : Storage area
• : Work area

Flow rate of hood =

LOCATION OF RADIO ISOTOPES
USED BY DR. JAMES EPSTEIN
HOWE LABORATORY



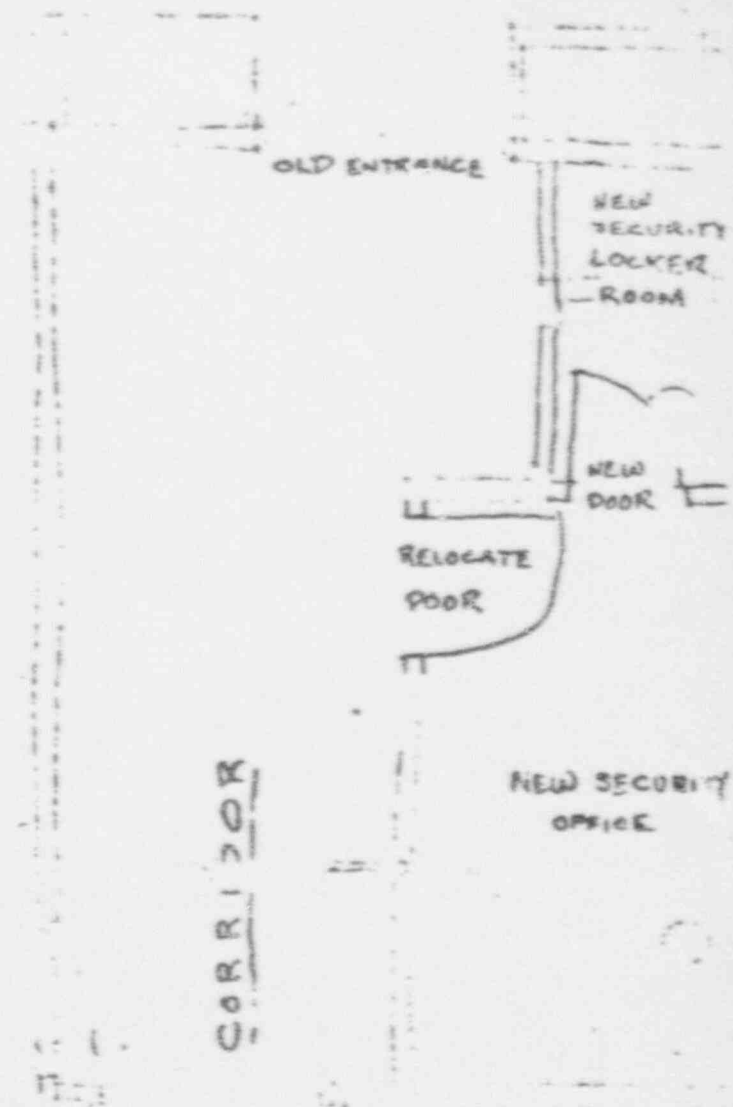
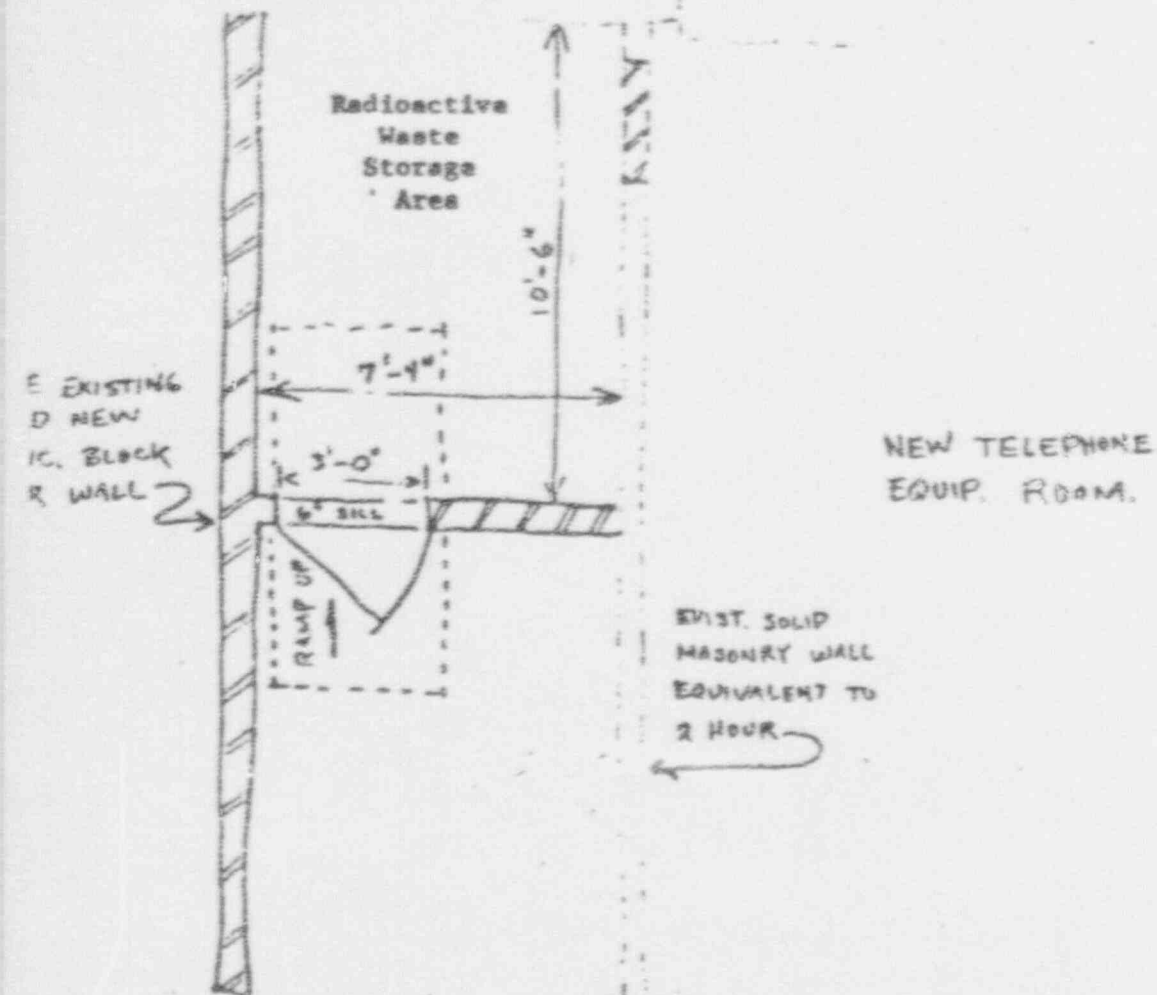
RM 511
MOSER LABORATORY



EYE PATHOLOGY LABORATORY

1 CM = 2 ft.

CHARLES STREET



CORRIDOR

GROUND FLOOR

[illegible]

10 8090