

1. APPLICATION FOR:
(Check and/or complete as appropriate)

APPLICATION FOR BYPRODUCT MATERIAL LICENSE
INDUSTRIAL

See attached instructions for details.

Completed applications are filed in duplicate with the Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety, and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 or applications may be filed in person at the Commission's office at 1717 H Street, NW, Washington, D. C. or 7915 Eastern Avenue, Silver Spring, Maryland.

a. NEW LICENSE

X b. AMENDMENT TO:
LICENSE NUMBER
20-13881-01

c. RENEWAL OF:
LICENSE NUMBER

2. APPLICANT'S NAME (Institution, firm, person, etc.)
Clinical Assays,
Division of Travenol Labs, Inc.

TELEPHONE NUMBER: AREA CODE - NUMBER EXTENSION
(617) 492-2526

3. NAME OF PERSON TO BE CONTACTED REGARDING THIS
APPLICATION

James A. Haker

TELEPHONE NUMBER: AREA CODE - NUMBER EXTENSION
(617) 492-2526 ext. 336

4. APPLICANT'S MAILING ADDRESS (Include Zip Code)

620 Memorial Drive
Cambridge, Massachusetts 02139

5. STREET ADDRESS WHERE LICENSED MATERIAL WILL BE USED
(Include Zip Code)

A. 620 Memorial Drive, Cambridge, MA 02139
B. 345 Vassar Street, Cambridge, MA 02139
C. 600 Memorial Drive, Cambridge, MA 02139

(IF MORE SPACE IS NEEDED FOR ANY ITEM, USE ADDITIONAL PROPERLY KEYED PAGES.)

6. INDIVIDUAL(S) WHO WILL USE OR DIRECTLY SUPERVISE THE USE OF LICENSED MATERIAL
(See Items 16 and 17 for required training and experience of each individual named below)

FULL NAME

TITLE

a. See Attached Sheet

b.

c.

7. RADIATION PROTECTION OFFICER

Dr. Seymour Rothchild

Attach a resume of person's training and experience as outlined in Items 16 and 17 and describe his responsibilities under Item 15.

8. LICENSED MATERIAL

LINE NO.	ELEMENT AND MASS NUMBER A	CHEMICAL AND/OR PHYSICAL FORM B	NAME OF MANUFACTURER AND MODEL NUMBER (If Sealed Source) C	MAXIMUM NUMBER OF MILLCURIES AND/OR SEALED SOURCES AND MAXIMUM ACTI- VITY PER SOURCE WHICH WILL BE POSSESSED AT ANY ONE TIME D
(1)	Iodine - 125	Any	NA	1500 millicuries*
(2)	Iodine - 131	Any	NA	2 millicuries
(3)	Hydrogen - 3	Any	NA	100 millicuries
(4)	Carbon - 14	Any	NA	2 millicuries

DESCRIBE USE OF LICENSED MATERIAL
E

(1) Manufacture, import and commercial distribution of labeled compounds and
in vitro testing.

(2)

(3)

(4)

9. STORAGE OF SEALED SOURCES

LINE NO.	CONTAINER AND/OR DEVICE IN WHICH EACH SEALED SOURCE WILL BE STORED OR USED. A.	NAME OF MANUFACTURER B.	MODEL NUMBER C.
(1)	Not Applicable		
(2)			
(3)			
(4)			

10. RADIATION DETECTION INSTRUMENTS

LINE NO.	TYPE OF INSTRUMENT A	MANUFACTURER'S NAME B	MODEL NUMBER C	NUMBER AVAILABLE D	RADIATION DETECTED (alpha, beta, gamma, neutron) E	SENSITIVITY RANGE (milliroentgens/hour or counts/minute) F
(1)	See Attached Sheet					
(2)						
(3)						
(4)						

11. CALIBRATION OF INSTRUMENTS LISTED IN ITEM 10

☐ a. CALIBRATED BY SERVICE COMPANY
NAME, ADDRESS, AND FREQUENCY

☐ b. CALIBRATED BY APPLICANT

Attach a separate sheet describing method, frequency and standards used for calibrating instruments.

See Attached Sheet

12. PERSONNEL MONITORING DEVICES

TYPE (Check and/or complete as appropriate.) A	SUPPLIER (Service Company) B	EXCHANGE FREQUENCY C
<input checked="" type="checkbox"/> (1) FILM BADGE	R.S. Landauer Jr. & Company	<input checked="" type="checkbox"/> MONTHLY
<input type="checkbox"/> (2) THERMOLUMINESCENCE DOSIMETER (TLD)	Glenwood, Illinois	<input type="checkbox"/> QUARTERLY
<input type="checkbox"/> (3) OTHER (Specify): _____ _____ _____		<input type="checkbox"/> OTHER (Specify): _____ _____ _____

13. FACILITIES AND EQUIPMENT (Check where appropriate and attach annotated sketch(es) and description(s).)

- ☒ a. LABORATORY FACILITIES, PLANT FACILITIES, FUME HOODS (Include filtration, if any), ETC.
☐ b. STORAGE FACILITIES, CONTAINERS, SPECIAL SHIELDING (fixed and/or temporary), ETC.
☐ c. REMOTE HANDLING TOOLS OR EQUIPMENT, ETC.
☐ d. RESPIRATORY PROTECTIVE EQUIPMENT, ETC.

14. WASTE DISPOSAL

a. NAME OF COMMERCIAL WASTE DISPOSAL SERVICE EMPLOYED

Interex Corporation, Natick, MA - NRC License No. 20-14082-01

b. IF COMMERCIAL WASTE DISPOSAL SERVICE IS NOT EMPLOYED, SUBMIT A DETAILED DESCRIPTION OF METHODS WHICH WILL BE USED FOR DISPOSING OF RADIOACTIVE WASTES AND ESTIMATES OF THE TYPE AND AMOUNT OF ACTIVITY INVOLVED. IF THE APPLICATION IS FOR SEALED SOURCES AND DEVICES AND THEY WILL BE RETURNED TO THE MANUFACTURER, SO STATE.

INFORMATION REQUIRED FOR ITEMS 15, 16 AND 17

Describe in detail the information required for Items 15, 16 and 17. Begin each item on a separate page and key to the application as follows:

15. **RADIATION PROTECTION PROGRAM.** Describe the radiation protection program as appropriate for the material to be used including the duties and responsibilities of the Radiation Protection Officer, control measures, bioassay procedures (if needed), day-to-day general safety instruction to be followed, etc. If the application is for sealed source's also submit leak testing procedures, or if leak testing will be performed using a leak test kit, specify manufacturer and model number of the leak test kit.
16. **FORMAL TRAINING IN RADIATION SAFETY.** Attach a resume for each individual named in Items 6 and 7. Describe individual's formal training in the following areas where applicable. Include the name of person or institution providing the training, duration of training, when training was received, etc.
 - a. Principles and practices of radiation protection.
 - b. Radioactivity measurement standardization and monitoring techniques and instruments.
 - c. Mathematics and calculations basic to the use and measurement of radioactivity.
 - d. Biological effects of radiation.
17. **EXPERIENCE.** Attach a resume for each individual named in Items 6 and 7. Describe individual's work experience with radiation, including where experience was obtained. Work experience or on-the-job training should be commensurate with the proposed use. Include list of radioisotopes and maximum activity of each used.

See Attached Sheets

18. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 2, 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.

WARNING.—18 U.S.C., Section 1001; Act of June 25, 1948, 62 Stat. 749; makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

<p>a. LICENSE FEE REQUIRED (See Section 170.31, 10 CFR 170)</p> <p>\$110.00</p>	<p>b. CERTIFYING OFFICIAL (Signature)</p> <p><i>James A. Haker</i></p> <p>c. NAME (Type or print)</p> <p>James A. Haker</p>
<p>(1) LICENSE FEE CATEGORY: 170.31 (3A)</p>	<p>d. TITLE</p> <p>Health Physicist</p>
<p>(2) LICENSE FEE ENCLOSED: \$ 110.00</p>	<p>e. DATE</p> <p>6.14.82</p>

Item 6: Individuals who will use or directly supervise the use of
licensed materials

- | | | |
|----|--------------------|---|
| a) | Dr. Francis Chen | Vice President & Director, Research & Development |
| b) | Dr. Judith Andrews | Director, Technical Support |
| c) | Philip Shapiro | Director, REgulatory Affairs |
| d) | David Krzysko | Manager, Tracer Production |
| e) | William T. Gamble | Assistant Manager, Tracer Production |
| f) | James A. Haker | Health Physicist |

Item 8: Licensed Material

	<u>Element and Mass Number</u>	<u>Chemical and/or Physical Form</u>	<u>Maximum Number of Millicuries which will be Possessed at Any Time</u>
1.)	Iodine-125	Any	1500 millicuries*
2.)	Iodine-131	Any	2 millicuries
3.)	Hydrogen-3	Any	100 millicuries
4.)	Carbon-14	Any	2 millicuries
5.)	Selenium-75	Any	1 millicurie

* Maximum possession limit at 345 Vassar Street and 600 Memorial Drive -
100 millicuries each.

Item 10: Radiation Detection Instruments

<u>Type Instrument</u>	<u>Number Available</u>	<u>Radiation Detected</u>	<u>Sensitivity Range</u>
Eberline E-120	5	Gamma	0.1 mR/hr
Ludlum 177 Ratemeter	8	Gamma	100 CPM
Elscint RA-125	5	Gamma	
Packard Auto Gamma 5110	2	Gamma	
Packard Auto Gamma 5120	1	Gamma	
Packard Auto Gamma Tandem 3320	1	Beta/Gamma	
Packard Tricarb 3330	2	Beta	
Searle 1190	2	Gamma	
Searle 1285	5	Gamma	
Packard Prias APL	1	Beta/Gamma	
Wallac LKB 1260	1	Gamma	
Gamma Trac 1190	2	Gamma	
Gamma Trac 1290	1	Gamma	

Item 11: Calibration of Instruments Listed in Item 10

a.) Calibrated by Service Company

All survey meters, including Ludlum 177 Ratemeters and Eberline E-120's, are calibrated biannually by:

Jasins and Sayles
15 Mercer Road
Natick, Massachusetts

All counting equipment is under service contract and calibrated as part of a scheduled preventive maintenance check performed twice per year.

<u>Instruments</u>	<u>Serviced By</u>
Elscint-Gamma	Elscint, Inc. 138-160 Johnson Avenue Hackensack, N.J. 07602
Packard-Gamma/Beta	Packard Instrument Company, Inc. 2200 Warrenville Road Downers Grove, Illinois 60515
Searle-Gamma	Tracer Analytic P.O. Box 369 Elk Grove, Illinois 60007

Item 13: Facilities and Equipment

At 620 Memorial Drive, the facilities and equipment include:

- A. An isolated hot lab for the preparation of ^{125}I labeled tracer to be used in radioimmunoassay kits.
- B. A room in the hot lab for packaging radioactive material. Packaging includes dispensing, closure, labeling and wipe testing.
- C. A change room for footwear and outer clothing and for monitoring clothing and skin. A Ludlum ratemeter is posted in the change room for monitoring purposes.
- D. An isolated shielded area for storing millicurie quantities of radioactive material.
- E. Six fume hoods equipped with American Air Activated Charcoal filters. Measured airflow greater than 100 FPM.
- F. Radioactive waste is disposed into appropriate containers; solid, liquid-aqueous, liquid-organic.
- G. Lab coats and protective gloves are required for working in the hot lab.
- H. A signal light alarm system which warns users of any fume hood not operating properly.

At 345 Vassar Street, the facilities include:

- A. An isolated hot lab set aside for preparation of ^{125}I labeled tracers.
- B. The hot lab contains two fume hoods with American Air Charcoal Hood filters. Measured airflow greater than 100 FPM.
- C. Purification of the iodinated tracers is performed in the hot lab on a lead shielded chromatographic column in tandem with a fraction collector.
- D. The ^{125}I (as iodide) is stored in the hood behind lead shielding and in lead containers.
- E. Radioactive waste is disposed into appropriate containers: solid, liquid-aqueous, liquid-organic.
- F. Lab coats and protective gloves are required for working in the hot lab.
- G. A Ludlum ratemeter is posted in the hot lab for monitoring purposes.

At 600 Memorial Drive, the facilities include:

- A. An isolated hot lab set aside for preparation of ^{125}I labeled tracers.
- B. The hot lab contains one fume hood with American Air Charcoal Hood filters. Measured air flow greater than 100 FPM.
- C. Purification of the iodinated tracers is performed in the hot lab on a lead shielded chromatographic column in tandem with a fraction collector.
- D. The ^{125}I (as iodide) is stored in the hood behind lead bricks and in lead containers.
- E. Radioactive waste is disposed into appropriate containers: solid, liquid-aqueous, liquid-organic.
- F. Lab coats and protective gloves are required for working in the hot lab.
- G. A Ludlum ratemeter is posted in the hot lab for monitoring purposes.

Item 15: See Enclosed Clinical Assays' Radiation Safety Manual.

Item 16: Radiation Training and Experience of each Individual Named in Items 6 and 7.

<u>Individual</u>	<u>Where Trained</u>	<u>Duration</u>	<u>On the Job</u>	<u>Formal Course</u>
Dr. Seymour Rothchild	Tracer Lab, Inc.	8 years	Yes	No
Dr. Francis Chen	Becton Dickinson Clinical Assays	5 years	Yes	Yes
Dr. Judith Andrews	University of Arizona School of Medicine	2 years	Yes	No
Philip Shapiro	New England Nuclear Corp.	6 years	Yes	Yes
	Clinical Assays	6 years	Yes	Yes
	Massachusetts General Hospital	1 month		Yes
	Emerson Hospital	2 weeks		Yes
David Krzysko	Clinical Assays	3 years	Yes	No
	Harvard School of Public Health	1 week		Yes
William T. Gamble	Clinical Assays	3 years	Yes	No
James A. Haker	New England Nuclear Corp.	1 year	Yes	No
	Northeastern University	1 year		Yes

Item 16: (Continued)

Experience with Radioactive Material

<u>Individual</u>	<u>Isotope</u>	<u>Maximum Amounts</u>
Dr. Seymour Rothchild	H ³	Curie Quantities
	I ¹²⁵	Millicurie Quantities
	S ³⁵	Hundreds of Millicuries
	P ³²	Hundreds of Millicuries
	C ¹⁴	Hundreds of Millicuries
Dr. Francis Chen	I ¹²⁵	Millicurie Quantities
Dr. Judith Andrews	I ¹²⁵	Millicuries
	Gd ¹⁵³	Millicuries
	S ³⁴	Microcuries
Philip Shapiro	Mo ⁹⁹ -Tc ^{99m}	Hundreds of Curies
	Ga ⁶⁷	Curies
	I ¹²⁵	Curies
	I ¹²⁹	Curies
	I ¹³¹	Curies
	In ¹¹¹	Curies
	In ¹¹³	Curies
David Krzysko	I ¹²⁵	Millicuries
	Co ⁵⁷	Microcuries
	H ³	Microcuries

Item 16: (Continued)

Experience with Radioactive Material

<u>Individual</u>	<u>Isotope</u>	<u>Maximum Amounts</u>
William T. Gamble	I ¹²⁵	Millicuries
	Co ⁵⁷	Microcuries
	H ³	Microcuries
	P ³²	Microcuries
	Cs ¹³⁷	Microcuries
	I ¹³¹	Microcuries
James A. Haker	Mo ⁹⁹ - Tc ^{99m}	Curies
	Ga ⁶⁷	Curies
	Tl ²⁰¹	Curies
	I ¹²⁵	Millicuries
	H ³	Millicuries

See Attached Resumes

Vice President - Seymour Rothchild

Vice President Clinical Assays	1973-Present
Staff Member International Atomic Energy Agency	1972
President and Founder New England Nuclear Corp.	1956-1970
Department Head, Labeled Chemicals Tracerlab, Inc.	1948-1956
Ph.D., Organic Chemistry University of Rochester	1948
B.A., Chemistry Brooklyn College	1942

Vice President and Director of Research and Development - Francis Chen

Director of Research and Development Clinical Assays	1981-Present
Director of Operations Clinical Assays	1980-1981
Quality Control Director Clinical Assays	1979-1980
Group Leader, Antiserum Group Clinical Assays	1978-1979
Senior Chemist Becton-Dickinson Immunodiagnostics	1977-1978
Post-doctoral Research Fellow Department of Pathology University of Pittsburgh Medical School	1976-1977
Ph.D. in Immunology Harvard University	1970-1976
M.S. and B.S. in Chemistry Tufts University	1966-1970

Director, Technical Support - Judith Andrews

Director, Technical Support Clinical Assays	1981-present
Group Leader, R&D Clinical Assays	1980-1981
Investigator Center for Blood Research	1977-1980
NIH Post doctoral Fellow Center for Blood Research	1975-1977
Assistant Investigator Center for Blood Research	1973-1975
Research Assistant-College of Medicine University of Arizona	1971-1973
Teaching Assistant-Physical Science Department Pima Community College	1971-1971
Ph.D. Chemistry Case-Western Reserve University	1966-1971
B.A. Chemistry Hanover College	1962-1966

Director, Regulatory Affairs - Philip Shapiro

Director, Regulatory Affairs Clinical Assays	1975-present
Regulatory Affairs Manager New England Nuclear Corporation	1969-1975
M.S. Biochemistry Brandeis University	1966-1969
B.S., Biology Tufts University	1962-1966

Manager, Tracer Production - David Krzysko

Manager, Tracer Production Clinical Assays	1980-present
Chemist Clinical Assays	1978-1980
Synthetic Organic Chemist Starks Associates, Inc.	1974-1978
Graduate work, Chemistry University of Wisconsin - Milwaukee	1974
B.A., Chemistry State University of New York - Buffalo	1973

Assistant Manager, Tracer Production - William T. Gamble

Assistant Manager, Tracer Production Clinical Assays	1980-present
Senior Iodination Technician Clinical Assays	1979-1980
B.S., Chemistry Boston State College	1974-1978

Health Physicist - James A. Baker

Health Physicist Clinical Assays	1982-present
Currently Enrolled, M.S. Environmental Sciences Northeastern University	1981-present
Sr. Laboratory Technologist New England Nuclear Corporation	1981-1982
B.S. Earth Sciences Salem State College	1978-1981

[illegible]

Laboratory Layout
Radiation Lab
Third Floor
620 Memorial Drive
Cambridge, Massachusetts

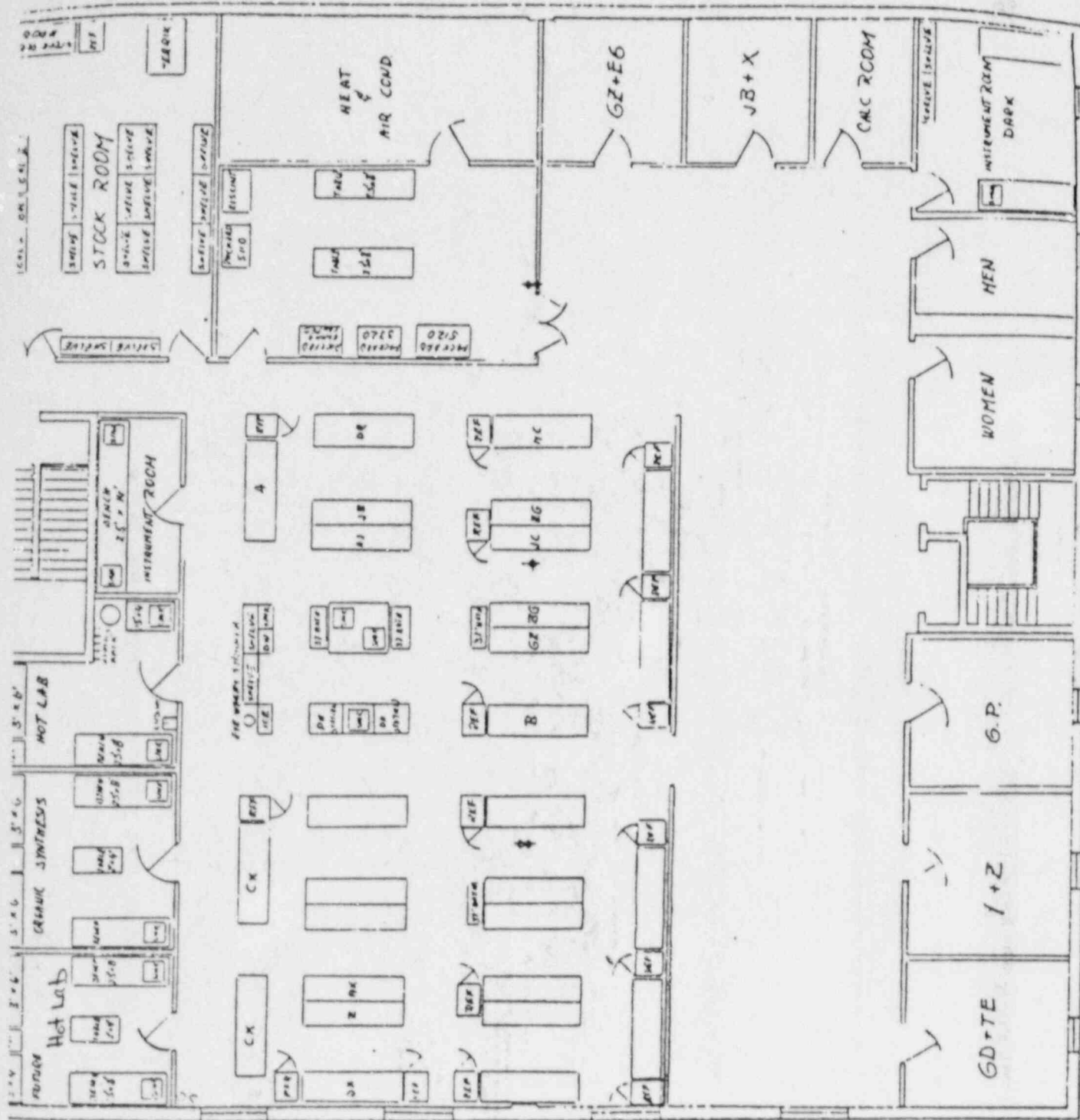
LABORATORY

LAYOUT

AT

345 VASSAR ST.

CAMBRIDGE, MA.



FORM NRC-313 I (1-79) 10 CFR 30		U.S. NUCLEAR REGULATORY COMMISSION							
APPLICATION FOR BYPRODUCT MATERIAL LICENSE INDUSTRIAL		1. APPLICATION FOR: <i>(Check and/or complete as appropriate)</i>							
<i>See attached instructions for details.</i> Completed applications are filed in duplicate with the Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety, and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 or applications may be filed in person at the Commission's office at 1717 H Street, NW, Washington, D. C. or 7915 Eastern Avenue, Silver Spring, Maryland.		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">X</td> <td style="width: 50%;"> a. NEW LICENSE </td> </tr> <tr> <td></td> <td> b. AMENDMENT TO: LICENSE NUMBER 20-13881-01 </td> </tr> <tr> <td></td> <td> c. RENEWAL OF: LICENSE NUMBER </td> </tr> </table>		X	a. NEW LICENSE		b. AMENDMENT TO: LICENSE NUMBER 20-13881-01		c. RENEWAL OF: LICENSE NUMBER
X	a. NEW LICENSE								
	b. AMENDMENT TO: LICENSE NUMBER 20-13881-01								
	c. RENEWAL OF: LICENSE NUMBER								
2. APPLICANT'S NAME <i>(Institution, firm, person, etc.)</i> Clinical Assays, Division of Travenol Labs, Inc. TELEPHONE NUMBER: AREA CODE - NUMBER EXTENSION (617) 492-2526		3. NAME OF PERSON TO BE CONTACTED REGARDING THIS APPLICATION James A. Haker TELEPHONE NUMBER: AREA CODE - NUMBER EXTENSION (617) 492-2526 ext. 336							
4. APPLICANT'S MAILING ADDRESS <i>(Include Zip Code)</i> 620 Memorial Drive Cambridge, Massachusetts 02139		5. STREET ADDRESS WHERE LICENSED MATERIAL WILL BE USED <i>(Include Zip Code)</i> A. 620 Memorial Drive, Cambridge, MA 02139 B. 345 Vassar Street, Cambridge, MA 02139 C. 600 Memorial Drive, Cambridge, MA 02139							
(IF MORE SPACE IS NEEDED FOR ANY ITEM, USE ADDITIONAL PROPERLY KEYED PAGES.)									
6. INDIVIDUAL(S) WHO WILL USE OR DIRECTLY SUPERVISE THE USE OF LICENSED MATERIAL <i>(See items 16 and 17 for required training and experience of each individual named below)</i>									
FULL NAME		TITLE							
a. See Attached Sheet									
b.									
c.									
7. RADIATION PROTECTION OFFICER Dr. Seymour Rothchild		Attach a resume of person's training and experience as outlined in Items 16 and 17 and describe his responsibilities under Item 15.							
8. LICENSED MATERIAL									
LINE NO.	ELEMENT AND MASS NUMBER A	CHEMICAL AND/OR PHYSICAL FORM B	NAME OF MANUFACTURER AND MODEL NUMBER <i>(If Sealed Source)</i> C						
			MAXIMUM NUMBER OF MILLCURIES AND/OR SEALED SOURCES AND MAXIMUM ACTI- VITY PER SOURCE WHICH WILL BE POSSESSED AT ANY ONE TIME D						
(1)	Iodine - 125	Any	NA						
(2)	Iodine - 125	Any	NA						
(3)	Hydrogen - 3	Any	NA						
(4)	Carbon - 14	Any	NA						
DESCRIBE USE OF LICENSED MATERIAL E									
(1)	Manufacture, import and commercial distribution of labeled compounds and								
(2)	<u>in vitro</u> testing.								
(3)									
(4)									

ML10

11827

9. STORAGE OF SEALED SOURCES

LINE NO.	CONTAINER AND/OR DEVICE IN WHICH EACH SEALED SOURCE WILL BE STORED OR USED. A.	NAME OF MANUFACTURER B.	MODEL NUMBER C.
(1)	Not Applicable		
(2)			
(3)			
(4)			

10. RADIATION DETECTION INSTRUMENTS

LINE NO.	TYPE OF INSTRUMENT A.	MANUFACTURER'S NAME B.	MODEL NUMBER C.	NUMBER AVAILABLE D.	RADIATION DETECTED (alpha, beta, gamma, neutron) E.	SENSITIVITY RANGE (milliroentgens/hour or counts/minute) F.
(1)	See Attached Sheet					
(2)						
(3)						
(4)						

11. CALIBRATION OF INSTRUMENTS LISTED IN ITEM 10

☐ a. CALIBRATED BY SERVICE COMPANY

NAME, ADDRESS, AND FREQUENCY

☐ b. CALIBRATED BY APPLICANT

Attach a separate sheet describing method, frequency and standards used for calibrating instruments.

See Attached Sheet

12. PERSONNEL MONITORING DEVICES

TYPE (Check and/or complete as appropriate.) A.	SUPPLIER (Service Company) B.	EXCHANGE FREQUENCY C.
<input checked="" type="checkbox"/> (1) FILM BADGE	R.S. Landauer Jr. & Company	<input checked="" type="checkbox"/> MONTHLY
<input type="checkbox"/> (2) THERMOLUMINESCENCE DOSIMETER (TLD)	Glenwood, Illinois	<input type="checkbox"/> QUARTERLY
<input type="checkbox"/> (3) OTHER (Specify): _____		<input type="checkbox"/> OTHER (Specify): _____

13. FACILITIES AND EQUIPMENT (Check where appropriate and attach annotated sketch(es) and description(s).)

- ☒ a. LABORATORY FACILITIES, PLANT FACILITIES, FUME HOODS (Include filtration, if any), ETC.
- ☐ b. STORAGE FACILITIES, CONTAINERS, SPECIAL SHIELDING (fixed and/or temporary), ETC.
- ☐ c. REMOTE HANDLING TOOLS OR EQUIPMENT, ETC.
- ☐ d. RESPIRATORY PROTECTIVE EQUIPMENT, ETC.

14. WASTE DISPOSAL

a. NAME OF COMMERCIAL WASTE DISPOSAL SERVICE EMPLOYED

Interex Corporation, Natick, MA - NRC License No. 20-14082-01

b. IF COMMERCIAL WASTE DISPOSAL SERVICE IS NOT EMPLOYED, SUBMIT A DETAILED DESCRIPTION OF METHOD WHICH WILL BE USED FOR DISPOSING OF RADIOACTIVE WASTES AND ESTIMATES OF THE TYPE AND AMOUNT OF ACTIVITY INVOLVED. IF THE APPLICATION IS FOR SEALED SOURCES AND DEVICES AND THEY WILL BE RETURNED TO THE MANUFACTURER, SO STATE

INFORMATION REQUIRED FOR ITEMS 15, 16 AND 17

Describe in detail the information required for Items 15, 16 and 17. Begin each item on a separate page and key to the application as follows:

15. **RADIATION PROTECTION PROGRAM.** Describe the radiation protection program as appropriate for the material to be used including the duties and responsibilities of the Radiation Protection Officer, control measures, bioassay procedures (if needed), day-to-day general safety instruction to be followed, etc. If the application is for sealed source's also submit leak testing procedures, or if leak testing will be performed using a leak test kit, specify manufacturer and model number of the leak test kit.
16. **FORMAL TRAINING IN RADIATION SAFETY.** Attach a resume for each individual named in Items 6 and 7. Describe individual's formal training in the following areas where applicable. Include the name of person or institution providing the training, duration of training, when training was received, etc.
 - a. Principles and practices of radiation protection.
 - b. Radioactivity measurement standardization and monitoring techniques and instruments.
 - c. Mathematics and calculations basic to the use and measurement of radioactivity.
 - d. Biological effects of radiation.
17. **EXPERIENCE.** Attach a resume for each individual named in Items 6 and 7. Describe individual's work experience with radiation, including where experience was obtained. Work experience or on-the-job training should be commensurate with the proposed use. Include list of radioisotopes and maximum activity of each used.

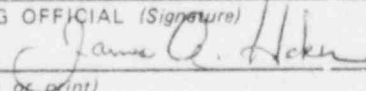
See Attached Sheets

18. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 2, 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.

WARNING.—18 U.S.C., Section 1001; Act of June 25, 1948; 62 Stat. 749; makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

a. LICENSE FEE REQUIRED (See Section 170.31, 10 CFR 170) \$110.00	b. CERTIFYING OFFICIAL (Signature)  c. NAME (Type or print) James A. Haker
(1) LICENSE FEE CATEGORY: 170.31 (3A)	d. TITLE Health Physicist
(2) LICENSE FEE ENCLOSED: \$ 110.00	e. DATE June 14, 1982

Item 6: Individuals who will use or directly supervise the use of
licensed materials

- | | | |
|----|--------------------|---|
| a) | Dr. Francis Chen | Vice President & Director, Research & Development |
| b) | Dr. Judith Andrews | Director, Technical Support |
| c) | Philip Shapiro | Director, Regulatory Affairs |
| d) | David Krzysko | Manager, Tracer Production |
| e) | William T. Gamble | Assistant Manager, Tracer Production |
| f) | James A. Haker | Health Physicist |

Item 8: Licensed Material

	<u>Element and Mass Number</u>	<u>Chemical and/or Physical Form</u>	<u>Maximum Number of Millicuries which will be Possessed at Any Time</u>
1.)	Iodine-125	Any	1500 millicuries*
2.)	Iodine-131	Any	2 millicuries
3.)	Hydrogen-3	Any	100 millicuries
4.)	Carbon-14	Any	2 millicuries
5.)	Selenium-75	Any	1 millicurie

* Maximum possession limit at 345 Vassar Street and 600 Memorial Drive -
100 millicuries each.

Item 10: Radiation Detection Instruments

<u>Type Instrument</u>	<u>Number Available</u>	<u>Radiation Detected</u>	<u>Sensitivity Range</u>
Eberline E-120	5	Gamma	0.1 mR/hr
Ludlum 177 Ratemeter	8	Gamma	100 CPM
Elscint RA-125	5	Gamma	
Packard Auto Gamma 5110	2	Gamma	
Packard Auto Gamma 5120	1	Gamma	
Packard Auto Gamma Tanden 3320	1	Beta/Gamma	
Packard Tricarb 3330	2	Beta	
Searle 1190	2	Gamma	
Searle 1285	5	Gamma	
Packard Prias APL	1	Beta/Gamma	
Wallac LKB 1260	1	Gamma	
Gamma Trac 1190	2	Gamma	
Gamma Trac 1290	1	Gamma	

Item 11: Calibration of Instruments Listed in Item 10

a.) Calibrated by Service Company

All survey meters, including Ludlum 177 Ratemeters and Eberline E-120's, are calibrated biannually by:

Jasins and Sayles
15 Mercer Road
Natick, Massachusetts

All counting equipment is under service contract and calibrated as part of a scheduled preventive maintenance check performed twice per year.

<u>Instruments</u>	<u>Serviced By</u>
Elscint-Gamma	Elscint, Inc. 138-160 Johnson Avenue Hackensack, N.J. 07602
Packard-Gamma/Beta	Packard Instrument Company, Inc. 2200 Warrenville Road Downers Grove, Illinois 60515
Searle-Gamma	Tracer Analytic P.O. Box 369 Elk Grove, Illinois 60007

Item 13: Facilities and Equipment

At 620 Memorial Drive, the facilities and equipment include:

- A. An isolated hot lab for the preparation of ^{125}I labeled tracer to be used in radioimmunoassay kits.
- B. A room in the hot lab for packaging radioactive material. Packaging includes dispensing, closure, labeling and wipe testing.
- C. A change room for footwear and outer clothing and for monitoring clothing and skin. A Ludlum ratemeter is posted in the change room for monitoring purposes.
- D. An isolated shielded area for storing millicurie quantities of radioactive material.
- E. Six fume hoods equipped with American Air Activated Charcoal filters. Measured airflow greater than 100 FPM.
- F. Radioactive waste is disposed into appropriate containers; solid, liquid-aqueous, liquid-organic.
- G. Lab coats and protective gloves are required for working in the hot lab.
- H. A signal light alarm system which warns users of any fume hood not operating properly.

At 345 Vassar Street, the facilities include:

- A. An isolated hot lab set aside for preparation of ^{125}I labeled tracers.
- B. The hot lab contains two fume hoods with American Air Charcoal Hood filters. Measured airflow greater than 100 FPM.
- C. Purification of the iodinated tracers is performed in the hot lab on a lead shielded chromatographic column in tandem with a fraction collector.
- D. The ^{125}I (as iodide) is stored in the hood behind lead shielding and in lead containers.
- E. Radioactive waste is disposed into appropriate containers: solid, liquid-aqueous, liquid-organic.
- F. Lab coats and protective gloves are required for working in the hot lab.
- G. A Ludlum ratemeter is posted in the hot lab for monitoring purposes.

"OFFICIAL RECORD COPY"

At 600 Memorial Drive, the facilities include:

- A. An isolated hot lab set aside for preparation of ^{125}I labeled tracers.
- B. The hot lab contains one fume hood with American Air Charcoal Hood filters. Measured air flow greater than 100 FPM.
- C. Purification of the iodinated tracers is performed in the hot lab on a lead shielded chromatographic column in tandem with a fraction collector.
- D. The ^{125}I (as iodide) is stored in the hood behind lead bricks and in lead containers.
- E. Radioactive waste is disposed into appropriate containers: solid, liquid-aqueous, liquid-organic.
- F. Lab coats and protective gloves are required for working in the hot lab.
- G. A Ludlum ratemeter is posted in the hot lab for monitoring purposes.

ML10

Item 15: See Enclosed Clinical Assays' Radiation Safety Manual.

"OFFICIAL RECORD COPY"

Item 16: Radiation Training and Experience of each Individual Named in Items 6 and 7.

<u>Individual</u>	<u>Where Trained</u>	<u>Duration</u>	<u>On the Job</u>	<u>Formal Course</u>
Dr. Seymour Rothchild	Tracer Lab, Inc.	8 years	Yes	No
Dr. Francis Chen	Becton Dickinson Clinical Assays	5 years	Yes	Yes
Dr. Judith Andrews	University of Arizona School of Medicine	2 years	Yes	No
Philip Shapiro	New England Nuclear Corp. Clinical Assays Massachusetts General Hospital Emerson Hospital	6 years 6 years 1 month 2 weeks	Yes Yes	Yes Yes Yes Yes
David Krzysko	Clinical Assays Harvard School of Public Health	3 years 1 week	Yes	No Yes
William T. Gamble	Clinical Assays	3 years	Yes	No
James A. Haker	New England Nuclear Corp. Northeastern University	1 year 1 year	Yes	No Yes

Item 16: (Continued)

Experience with Radioactive Material

<u>Individual</u>	<u>Isotope</u>	<u>Maximum Amounts</u>
Dr. Seymour Rothchild	H ³	Curie Quantities
	I ¹²⁵	Millicurie Quantities
	S ³⁵	Hundreds of Millicuries
	P ³²	Hundreds of Millicuries
	C ¹⁴	Hundreds of Millicuries
Dr. Francis Chen	I ¹²⁵	Millicurie Quantities
Dr. Judith Andrews	I ¹²⁵	Millicuries
	Gd ¹⁵³	Millicuries
	S ³⁴	Microcuries
Philip Shapiro	Mo ⁹⁹ -Tc ^{99m}	Hundreds of Curies
	Ga ⁶⁷	Curies
	I ¹²⁵	Curies
	I ¹²⁹	Curies
	I ¹³¹	Curies
	In ¹¹¹	Curies
	In ¹¹³	Curies
David Krzysko	I ¹²⁵	Millicuries
	Co ⁵⁷	Microcuries
	H ³	Microcuries

ML15

Item 16: (Continued)

Experience with Radioactive Material

<u>Individual</u>	<u>Isotope</u>	<u>Maximum Amounts</u>
William T. Gamble	I ¹²⁵	Millicuries
	Co ⁵⁷	Microcuries
	H ³	Microcuries
	P ³²	Microcuries
	Cs ¹³⁷	Microcuries
	I ¹³¹	Microcuries
James A. Haker	Mo ⁹⁹ - Tc ^{99m}	Curies
	Ga ⁶⁷	Curies
	Tl ²⁰¹	Curies
	I ¹²⁵	Millicuries
	H ³	Millicuries

See Attached Resumes

"OFFICIAL RECORD COPY"

Vice President - Seymour Rothchild

Vice President Clinical Assays	1973-Present
Staff Member International Atomic Energy Agency	1972
President and Founder New England Nuclear Corp.	1956-1970
Department Head, Labeled Chemicals Tracerlab, Inc.	1948-1956
Ph.D., Organic Chemistry University of Rochester	1948
B.A., Chemistry Brooklyn College	1942

Vice President and Director of Research and Development - Francis Chen

Director of Research and Development Clinical Assays	1981-Present
Director of Operations Clinical Assays	1980-1981
Quality Control Director Clinical Assays	1979-1980
Group Leader, Antiserum Group Clinical Assays	1978-1979
Senior Chemist Becton-Dickinson Immunodiagnostics	1977-1978
Post-doctoral Research Fellow Department of Pathology University of Pittsburgh Medical School	1976-1977
Ph.D. in Immunology Harvard University	1970-1976
M.S. and B.S. in Chemistry Tufts University	1966-1970

Director, Technical Support - Judith Andrews

Director, Technical Support Clinical Assays	1981-present
Group Leader, R&D Clinical Assays	1980-1981
Investigator Center for Blood Research	1977-1980
NIH Post doctoral Fellow Center for Blood Research	1975-1977
Assistant Investigator Center for Blood Research	1973-1975
Research Assistant-College of Medicine University of Arizona	1971-1973
Teaching Assistant-Physical Science Department Pima Community College	1971-1971
Ph.D. Chemistry Case-Western Reserve University	1966-1971
B.A. Chemistry Hanover College	1962-1966

"OFFICIAL RECORD COPY"

Director, Regulatory Affairs - Philip Shapiro

Director, Regulatory Affairs Clinical Assays	1975-present
Regulatory Affairs Manager New England Nuclear Corporation	1969-1975
M.S. Biochemistry Brandeis University	1966-1969
B.S., Biology Tufts University	1962-1966

ML10

Manager, Tracer Production - David Krzysko

Manager, Tracer Production Clinical Assays	1980-present
Chemist Clinical Assays	1978-1980
Synthetic Organic Chemist Starks Associates, Inc.	1974-1978
Graduate work, Chemistry University of Wisconsin - Milwaukee	1974
B.A., Chemistry State University of New York - Buffalo	1973

Assistant Manager, Tracer Production - William T. Gamble

Assistant Manager, Tracer Production Clinical Assays	1980-present
Senior Iodination Technician Clinical Assays	1979-1980
B.S., Chemistry Boston State College	1974-1978

Health Physicist - James A. Haker

Health Physicist Clinical Assays	1982-present
Currently Enrolled, M.S. Environmental Sciences Northeastern University	1981-present
Sr. Laboratory Technologist New England Nuclear Corporation	1981-1982
B.S. Earth Sciences Salem State College	1978-1981

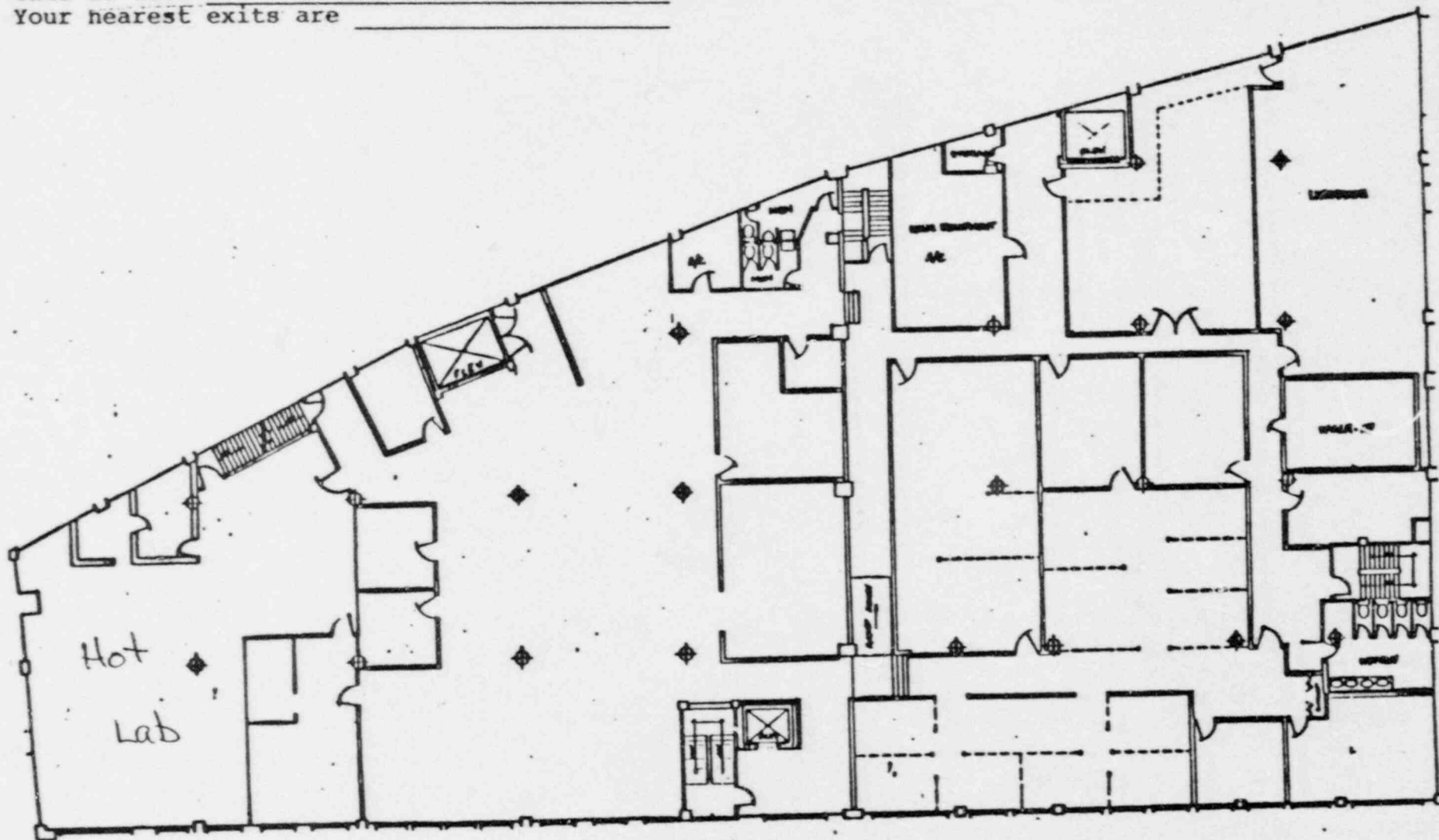
ML10

1. Aisles leading directly to an outside exit area are marked like this:

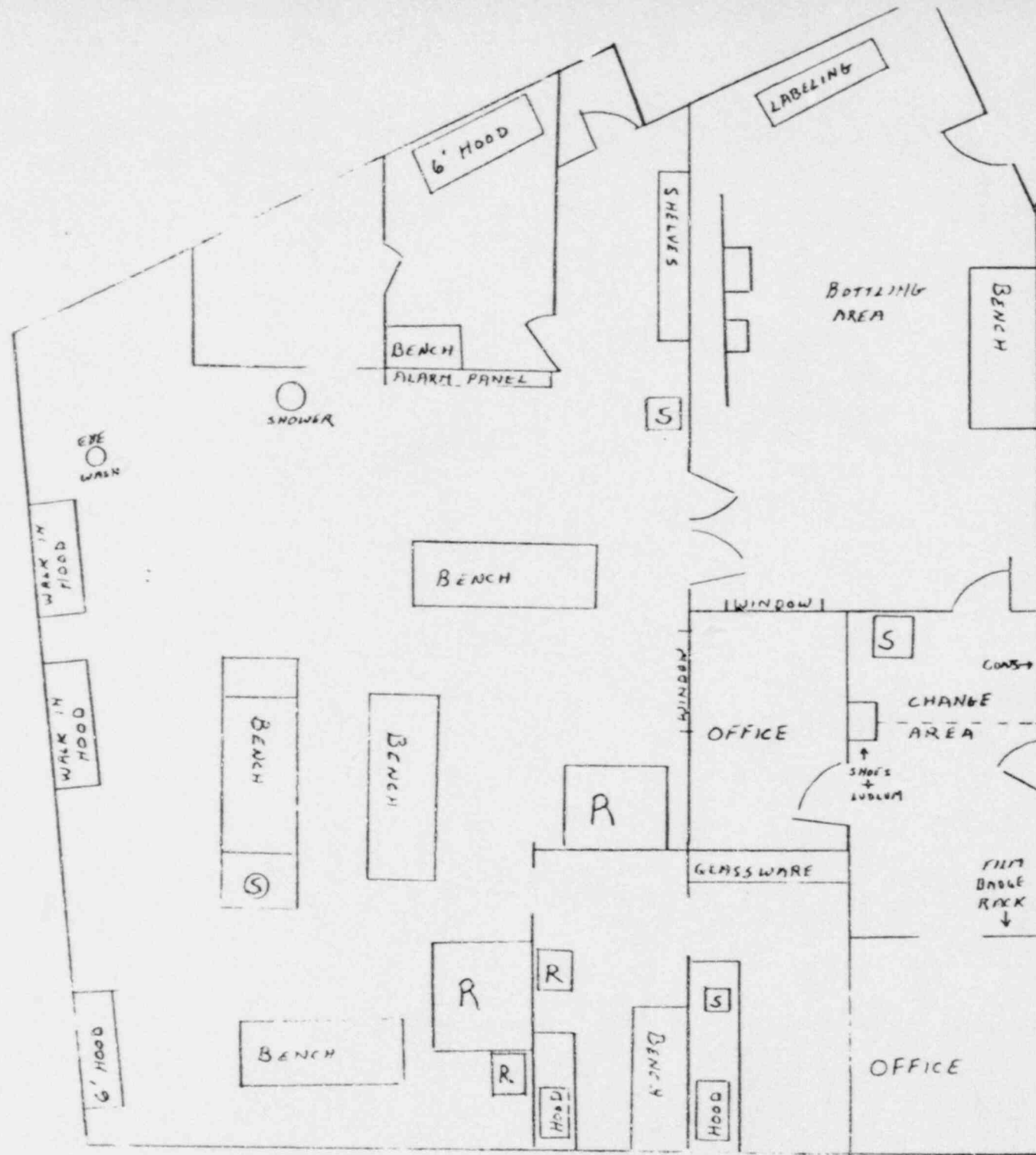
2. Know at least two evacuation routes from your work area

EMERGENCY NOTIFICATION PROCEDURE

1. For reporting fires, serious injuries, dial operator
2. Give the operator exact location and details
3. This is area _____
4. Your nearest exits are _____



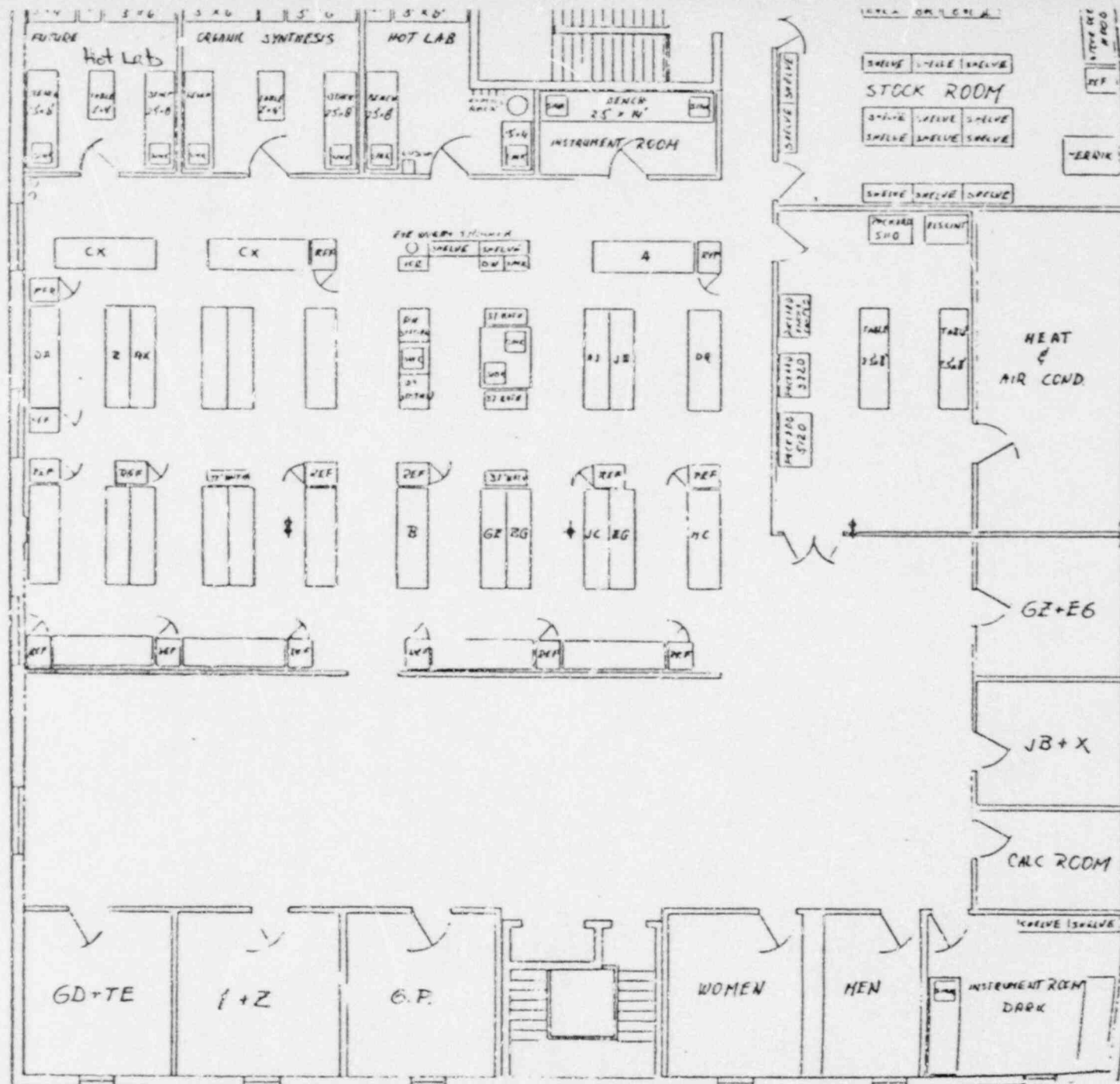
"OFFICIAL RECORD COPY"



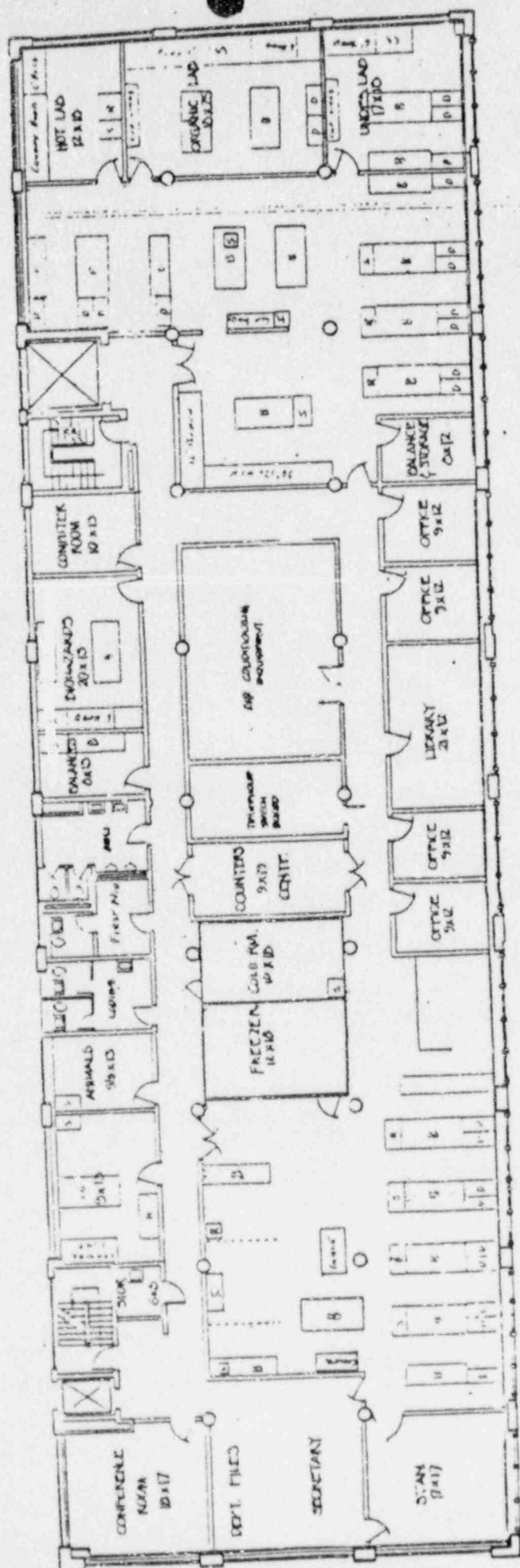
Clinical Assays
Division of Travenol Labs, Inc.

Laboratory Layout
Radiation Lab
Third Floor
620 Memorial Drive
Cambridge, Massachusetts

LABORATORY
LAYOUT
AT
345 VASSAR ST.
CAMBRIDGE, MA.



Third Floor Laboratory Layout



Scale
Approx 20' / inch

ML10

21827

600 Memorial Dr.

HOT LAB

12' x 18'

