Form approved Budget Bar =No. 38-R0027

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

INSTRUCTIONS.—Complete Items 1 through 16 if this is an initial application or an application for renewal of a license. Information contained in previous applications filed with the Commission with respect to Items 8 through 15 may be incorporated by reference provided references are clear and specific. Use supplemental sheets where necessary, Item 16 must be completed on all applications. Mail two copies to: U.S. Atomic Energy Commission, Washington, D.C., 20545, Attention: Materials Branch, Directorate of Licensing, Upon approval of this application, the applicant will receive an AEC Byproduct Material License. An AEC Byproduct Material 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, Part 20, and the license fee provisions of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 16 and the appropriate fee enclosed. (See Note in Instruction Sheet).

(a) NAME AND STREET ADDRESS OF APPLICANT (Institution, firm, hospital person, etc. Include ZIP Code and telephone number.)

Reference Laboratory Division Diamond Shamrock Health Sciences Inc. 2775 Home Road Powell, Ohio 43065

2 DEPARTMENT TO USE BYPRODUCT MATERIAL

Reference Laboratory Division

LTA 16784 b) STREET ADDRESS(ES) AT WHICH BYPRODUCT MATERIAL WILL BE USED. IN different from 1(a) Include ZIP Code)

Reference Laboratory Division Diamond Shamrock Health Sciences Inc. 2775 Home Road 030-11638 Powell, Ohio 43065

03620 ~3

3 PREVIOUS LICENSE NUMBER(S) (If this is an application for renewal of a license please indicate and give number.)

34-10463-01 Searle Diagnostics Inc. Acquired by Diamond Shamrock Health Sciences

4. INDIVIDUAL USER(S). (Name and title of individual(s) who will use ar directly Leo E. Gaudette, Ph.D

Nguyen Huu Chinh, Ph.D. C. Agnes Gaudette B.S. Carol Mount, B.S. Gary Wilkinson, B.S.

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 Items 8 and 9.)

Keith Keplinger, B.S.

Edward Harris, B.S.

6. (a) SYPRODUCT MATERIAL (Elements
and mass number of each)

Tritium - 10 Ci Carbon 14- 5 mCi Iodine 125- 200 mCi

(b) CHEMICAL AND/OR PHYSICAL FORM AND MAXIMUM NUMBER OF MILLICURIES OF EACH CHEMICAL AND/OR PHYS ICAL FORM THAT YOU WILL POSSESS AT ANY ONE TIME. (If sealed source(s), also state name of manufacturer, model number number of sourcer and maximum activity per source).

10 Ci Steroid, hormones, drugs, biometabolite in solvent/solution Steroids, biologic metabolites in solvent/ solutions

Iodide

10 mCi lodinated polypeptides, steroids, drugs, metabolites in solvent/

Iodine 131 - 10 mCi | Iodide 5 mCi

Cobalt 60 - 500 uCi

Iodinated polypeptides in solvent/solutions

B₁₂ in aqueous solutions

Sealed_Sources H⁵₁₄Packard - N1139; H³₁Isocap - 181340 C Packard - 0196; C Isocap - 181330 Ce] 37 Nuclear Chicago 18462

Sim³²⁵I Nuclear Chicago - 184681

7 DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED. (If byproduct material is for human use, supplement A (Form AEC 3/3a) must be completed in lieu of this item. If byproduct material is in the form of a sealed source, include the make and model number of the storage container and/or device in which the source will be stored and/or used.)

ALL IN VITRO STUDIES:

Radioimmunoassay of hormones and chemotherapeutic agents in clinical and research biologic samples for clinical diagnosis.

Developments of reagents and methods for lab analysis, and, application to laboratory sample analysis.

Iodination of protein hormones, non-protein hormone derivatives, small molecules entities and biologic metabolites for routine use in radioimmunoassay.

ORMAL COURS	sheets if necessary)	Use supplemental i	ED IN ITEM 4	UAL NA	ACH INDIVID	RIENCE OF E	TRAINING AND EXPE
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Yes No	Yes No						matics and calculations basic to the nd measurement of radioactivity
Yes No	Yes No						ical effects of radiation
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			ecify method of calibi	n badges, s	S USED. (For film	AY PROCEDURE	PPENDIX 4-ATTACHED Address, dosimeters, and Bio-Ass Searle Analytic Ir
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ory skatch	hoods, etc. Explana	ers, shielding, fume				Yes No	lity is attached. (Circle answer)
irvey, serv-		agements for perform	iding control measure leak tests, and arran	ogram inc	perience of person	training, and ex	TION PROTECTION PROGRAM. De procedures where applicable, name, maintenance and repair of the source
which will	description of mathod	se submit detailed	f company Otherwi	city name	is employed see	disposal service	E DISPOSAL If a commercial waste ad for disposing of radioactive wastes
The second second second second second	uisville, K	The state of the s	Control of the Contro	Charles and Street and	Salari - Toliforia-co co co an an an esca	of discount or of the control and	and the contract of the second contract of the contract of the second contract of the secon
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TRAINING AND EXP	ERIENCE OF EACH INDIVIDUAL NA	AMED IN ITEM 4	Use supplemental	sheets if necessor	Poga Ta
8. TYPE OF TRAINING			DURATION OF	-	
Leo E. Gaudette, Ph.D.			TRAINING	(Circle onswer)	FORMAL COURSE (Circle onswer)
e. Principles and practices of radiation protection		Holy Cross, Georgetown N.I.H., 1,3 W.F.E.B., New England Nuclear			(Yes) No
 Radioactivity measurement standardize tion and monitoring techniques and in struments 			Wasternoop!	Yes No	(Yes No
e. Mathematics and calculations basic to the use and measurement of radioactivity	11	7. Th.	-11	. (Yes No	Yes No
d. Biological effects of rodiation				Yes No	Yes No
9. EXPERIENCE WITH RADIATION. (Actua	d use of radioisatopes or equivalent expe	rience.)			
	HERE EXPERIENCE WAS GAINED	DURATION OF EXP	PERIENCE	TYPE C	DF USE
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protection protections aff radiation	I dedige town university.			Yes No	Yes No
 B. Redioactivity measurement standardiza- tion and monitoring techniques and in- struments 	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	100 SI #8.T r	11. 11	Yes No	(Yes No
 Mathematics and calculations basic to the use and measurement of radioactivity 	"		11 11	Yes No	Yes No
d. Biological effects of radiation	11	"	11 11	(Yes) No	Yes No
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14C Ci's + "	11	5 5		11	11
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8. TYPE OF TRAINING		To the treat of the	Without the Park Street, Stree		
	WHERE TRAINED		DURATION OF TRAINING	(Circle onswer)	(Circle onswer)
e Principles and practices of radiation protection		*		Yes No	Yes No
 Radioartivity measurement standardiza- tion and monitoring techniques and in- struments 	405 44.5 (254.54.5 (1.454.54.7		the is a result	Yes No	Yes No
 Mathematics and calculations basic to the use and measurement of radioactivity 		1	-	Yes No	Yes No
d. Biological effects of radiation				Yes No	Yes No
9. EXPERIENCE WITH RADIATION (Actual	use of radioisotopes or equivalent experie	ence.)			
BOTOPE MAXIMUM AMOUNT WH	ERE EXPENIENCE WAS GAINED	DURATION OF EXPE	RIENCE	TYPE OF	USE
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				E0051	.

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(G. Wilkinson)		WHERE TRAINE		DURATION O	ON THE JOB (Circle answer)	FORMAL COURS
e. Principles and practices of radiation		Ohio State Universit GYN; Searle Diagnos			(Circle onswer)	
 Badioactivity measurement to the and monitoring techniq struments 		Ohio State Universit Searle Diagnostic, In	У	2 yrs 1 yr	Yes No	Yes No
c. Methematics and calculations use end measurement of rad	Section 19 Total Section 19	OSU/SDI	#	2yr/1yr	Yes No	Yes No
d. Biological effects of radiation				14-	Yes No	Yes No
P. EXPERIENCE WITH RADIATIO	N. (Actual	use of radioisotopes or equivalent exp	perience.)			
SOTOPE MAXIMUM AMOUNT	WH	ERE EXPENIENCE WAS GAINED	DURATION OF EXP	ERIENCE	TYPE C	OF USE
3 _H uCi 131 _I mCi 125 _I mCi	Ohio S	State University 2 yrs State University 2 yrs e Diagnostic Inc. 1 yr			Routine A Iodination Routine A	n &Routine ssays
TRAINING .	AND EXPER	IENCE OF EACH INDIVIDUAL N	IAMED IN ITEM 4	Use supplemento	I sheets if necessary	Poge Tw
(E. Harris)		WHERE TRAINE		DURATION OF		FORMAL COURSE (Circle answer)
	******	Searle Diagnostic	Inc.	-3§1/2y	T Yes No	Yes (No
Badioactivity measurement standardization and monitoring techniques and instruments Mathematics and calculations basic to the use and measurement of radioactivity		Searle Diagnostic Inc.		3§1/2y	r Yes No	Yas No
		Searle Diagnostic Inc.		361/2y	rs Yes No	Yes No
d. Biological effects of radiation					Yes No	Yes No
P. EXPERIENCE WITH RADIATION		se of radioisotopes or equivalent expe	rience.)		-	
SOTOPE MAXIMUM AMOUNT	WHE	RE EXPERIENCE WAS GAINED	DURATION OF EXPE	RIENCE	TYPE OF	USE
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(C. Mount)	unt)			DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle onswer)
p. Principles and practices of protection		Searle Diagnostic	Inc.	4 yrs	Yes No	Yes No
Radioartivity measurement sh tion and maniforing technique struments		Searle Diagnostic Inc.		4 yrs	Yes No	Yes (No
c. Mathematics and calculations basic to the use and measurement of radioactivity		Searle Diagnostic	Inc.	4 yrs	You No	Yes No
Biological effects of radiation		Searle Diagnostic		4 yrs	Yes No	Yes (No.
SOTOPE MAXIMUM AMOUNT		e of radioisolopes or equivalent expen				
SOUTH MANIMUM AMOUNT	WHE	RE EXPENIENCE WAS GAINED	DURATION OF EXPER	HENCE	TYPE OF	USE
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I ¹²⁹ uCi	Searle	Diagnostic Inc.	1 yr	F	Radio 5 6 9 5	assay

	AND EXPER	HENCE OF EACH INDIVIDUAL N	AMED IN ITEM 4	(Use supplemental	sheets if necessor	Page 1
8. TYPE OF TRAINING (C. Mount)		- WHERE TRAINE	D	DURATION OF	ON THE JOS (Circle onswer)	FORMAL COUR
e. Principles and practices of protection			earle_Radio-	4 day	1	(Yes) No
 B. Radioactivity measurement so tion and maniforing technique struments 		11 3th filento. Sold to a solutione of	A Harothina Ayr	1"H'. N	The second liver with the second liver with the second	You No
c. Mathematics and calculations to use and measurement of radio			- U	VI 100	Yes No	(as) No
d. Biological effects of radiation			41	11	Yes No	(Yes No
P. EXPERIENCE WITH RADIATION	4. (Actual)	use of radioisotopes or equivalent exp	prience)			100
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TRAINING A	ND EXPER	ENCE OF EACH INDIVIDUAL N	AMED IN ITEM 4	(Use supplemental	sheets if necessary	Page T
(K. Keplinger)	1 ***	WHERE TRAINED		DURATION OF	ON THE JOS (Circle answer)	PORMAL COURS
e. Principles and practices of pratection	radiation	Searle Diagnostic Inc Diamond Shamrock Heal	th Sciences	7/.73-pres	Yes No	Yes No
 Radioactivity measurement section and maniforing technique struments 		17 MM - 180 102 TI	1 00 Co	, µ * , 0	Yes No	Yes No
 Mathematics and calculations be use and measurement of radio 			\- <u>''</u>	a1	(Yes) No	, Yes (No
d. Biological effects of radiation		• •	**	"	Yes No	Yes No
P. EXPERIENCE WITH RADIATION.	(Actual u	se of radioisotopes or equivalent exper	rience.)			
SOTOPE MAXIMUM AMOUNT	WHE	RE EXPENIENCE WAS GAINED	DURATION OF EXP	PERIENCE	TYPE OF	USE
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(A. Gaudette)	-	WHERE TRAINED		DURATION OF TRAINING	ON THE JOB (Circle onswer)	FORMAL COURSE (Circle onswer)
protection	radiation	New England Nuclear (Brookhaven Nat'l. Lor	Cerp, Boston ng Island, N	5 yrs Y. 1 yr	Yes No	Yes No
Radioactivity measurement state tion and manitoring technique struments	s and in-	M. Marine	1.64	Print of the second	Yes No	Yes No
. Mathematics and calculations be use and measurement of radio		at the same and the	<u> </u>		Yes No	Yes No
1. Biological effects of radiation		μ			Yes No	Yes No
EXPERIENCE WITH RADIATION.	(Actual us	e of radioisotopes or equivalent experi	ience.)		**************	
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	Brookha	aven	1 yr		D/Org. Syr	

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RADIATION PROTECTION

RULES AND REQUIRED PROCEDURES

Radiation Protection Rules and Required Procedures

1. Radiation Protection Responsibilities

A. Environment Control Director (ECD)

The Division Laboratory Director will also function as Division ECD and will be responsible for developing and maintaining a radiation protection program.

B. Radiation Protection Officer RPO

The RPO is responsible directly to the ECD for:

1. Implementing and maintaining radiation protection services.

2. Maintaining all records and correspondence necessary to insure compliance with government regulations.

3. Providing adequate information and training to personnel relating to radiation protection procedures.

4. Supervising radiation emergencies and special decomtamination operations.

5. Implementing decontamination procedures when allowable values for restricted and non-restricted areas as exceeded.

C. Laboratory Supervisor

Each Laboratory supervisor is responsible for:

1. Safe conduct of work performed within assigned laboratory.

 Posting supplementary rules pertinent to individual lab operations.

3. Training assigned personnel to the lab in safe practices and procedures related to individual lab procedures.

4. Assignment of duties to assure a secured area at close of each work period.

5. Evaluate potential hazards of new lab operations, with recommended SOP to radioisotope committee.

D. Individual Employee

Each employee is personally responsible for:

1. Learning and complying to established rules of safety and required procedures.

2. Learning and complying with all supplemental regulations within each lab.

 Performing assigned duties in a manner to always minimize radiation exposure to self, collegue and general public.

 Report immediately any real and/or suspected incident of radiation exposure.

2.

E. Radioisotope Committee (RIC)

The RIC will be responsible for:

1. Establishing a Radiation Protection Program commensurate with government regulations and personnel safety.

2. Review all recommended SOP for new lab operations

3. Review all incidents of radiation responses and non-compliance of rules and procedures.

4. Review all posted supplementary safety rules and regulations.

II. Authorization to Handle Radioactive Materials

- A. The supervisor of each laboratory will be responsible for training and clearing of individual employees to use radioactive-materials according to established lab procedures.
- B. Personnel cleared to handle radioactive materials will do so in accordance with established protocol:

General Laboratory Areas

. 1. No radioactivity in excess of 10 µc is to be employed.

2. Standard lab coats are to be worn by all personnel, buttoned and sleeves worn extended to cover arms and wrists. Individually assigned and non-transferrable coats will be routinely monitored and changed weekly.

3. Mouth pipetting is prohibited and protective gloves are compulsory whenever operations are performed that may produce hand

contamination.

4. Pregnant female employees are not to be permitted to handle any radioactive materials. It is encumbent on individual employees to advise their supervisor.

Restricted Laboratory Areas

1. Disposable lab coats, shoe covers and protective gloves are to be worn at all times in restricted areas.

2. There shall be no smoking or eating (including gum chewing) in restricted areas.

3. Mouth pipetting is absolutely prohibited.

4. Personal articles are not to be taken into restricted areas.

Restricted Areas con't.

5. Operation within a restricted area are to be carried out with all doors of entry closed.

6. All operations in restricted area are to be carried out in

isotope hoods provided.

- 7. Each restricted area hood is to be operated at "high speed" during normal work day when radioactive materials are being handled. The hoods are to be left on "low speed" at all other times.
- 8. Before the end of each work day, and/or upon completion of any specific operation, work areas and equipment shall be inspected, surveyed and cleaned as needed.

9. Work in restricted areas is permitted only during normal work day, and film badges and dosimeters are to be worn by

all personnel.

- 10. Before removal of any radioactive material from restricted area, it must be:
 - (a) Contained in shatter-proof container(b) Labeled for CAUTION RADIOACTIVE MATERIAL
 - (c) Identified as to isotope, quantity and nature

(d) Less than the following levels:

3 - 10 uCi

11. Auxiliary equipment will not be removed from restricted areas unless completely decontaminated.

Routine equipment (glassware) employed must be all disposable and discarded in appropriately labeled waste containers.

12. No protective cover is to be removed from any restricted area except as disposable waste material. Used protection cover is to be disposed in proper waste containers located in the change area, upon leaving the area.

13. On leaving a restricted area, each employee shall:

(a) Dispose of protective gloves

(b) Store lab coat in assigned area

(c) Wash and monitor hands

(d) Monitor personal clothing

14. Each person working in restricted areas shall submit upon request by the RPO

(a) a bioassay sample

(b) badges and dosimeters for evaluation

(c) specific organ scanning

III. Receipt, Transport and Storage Radioactive Materials

A. All incoming radioisotope shipments must be inspected, monitored and transported to assigned laboratories by RPO or his designated authorized representative.

B. Appropriately labeled product identified as to quantity, kind, source and lot numbers accompanied by an inventory log sheet will be stored according to level of activity.

Restricted Area - All activity in excess of 1 µc for gamma emitters and 10 µc for betas.

General Area - Quantities less than above.

Inventory will be maintained for each so as to monitor inventory of all raw materials on an on-going basis.

C. Radioactive waste disposal will observe protocol delineated herein:

1. Liquid Waste Disposal

a. No radioactive waste into sewage system.

b. Prepare for disposal as follows:

i. Aqueous liquid waste into specified containers -"Aqueous Waste"

ii. Organic liquid waste into specified containers - ''Organic Waste''

iii. Acid liquid waste into specified containers - "Acid Waste"

c. All liquid wastes solidified with solid absorbent, (monitor radiation not to exceed 5mR/hr at a distance of one foot and less than 200 mR/hr at contact).

d. Solid waste and solidified waste to be disposed of in 55 gal. sealable metal containers labeled "Solid Waste"

e. Volatile radioactive waste vented through hood ducts is to be trapped by charcoal filters which are to be routinely changed and charcoal handled as solid waste.

f. Solid waste barrels sealed for commercial disposal and monitored radioactive not to exceed 5 mR/hr at one foot and 200 mR/hr at contact.

IV. Emergency Procedure to be Observed for Radioactive Contamination
A. General Laboratory

1. Contact RPO immediately.

2. Close hoods to safety position to maximize venting of volatiles.

3. Isolate potentially contaminated area from re-entry.

 Assemble potentially contaminated personnel and monitor them for contamination.

5. Remain in area until released by RPO.

6. Under directions of the RPO, institute clean up and decontamination procedures of the area.

Monitor until background levels are achieved.

B. Restricted Area

1. Contact RPO immediately

2. Close hoods to safety position to maximize venting of volatile.

3. Isolate contaminated area.

4. Monitor related personnel for contamination.

Remain in area until released by RPO.
 Under RPO directions decontaminate.

7. Monitor until background levels are achieved.

C. Exceptions

 In the event of a contamination problem arising from volatile gases or liquids:

a. Evacuate the area to a specified location of safety.

- b. Close & lock room doors to prevent re-entry, after maximizing air flow through charcoal filtration.
- In the event of a contamination problem with associated injury:

a. Evacuate injured personnel to specified location of

b. Proceed with safety procedure as specified in A and/or B.

V. Guide for control for radiation exposure

A. Personnel

1. Exposure

- a. Dosimeter
- b. Badges

c. Bioassay

d. Specific Organ Scanning

2. Monitoring

a. Hand/Shoe Survey

b. Protective clothing

3. Medical Services

a. Emergency procedures

b. Annual physical exams

4. Operations

a. Review of procedures and facility

b. Training programs

c. Monitoring equipment

5. Records

a. Tally of internal and external exposure

b. Historical records

B. Environment

1. Exposure

- a. Environmental Monitoring
- 2. Contamination

a. Floor and general wipe surveys

b. Routine use monitoring equipment

3. Waste disposal program

4. Routine record keeping

APPENDIX I - INVENTORY RECORD EEKLY INVENTORY OF RADIOCHEMI. _S

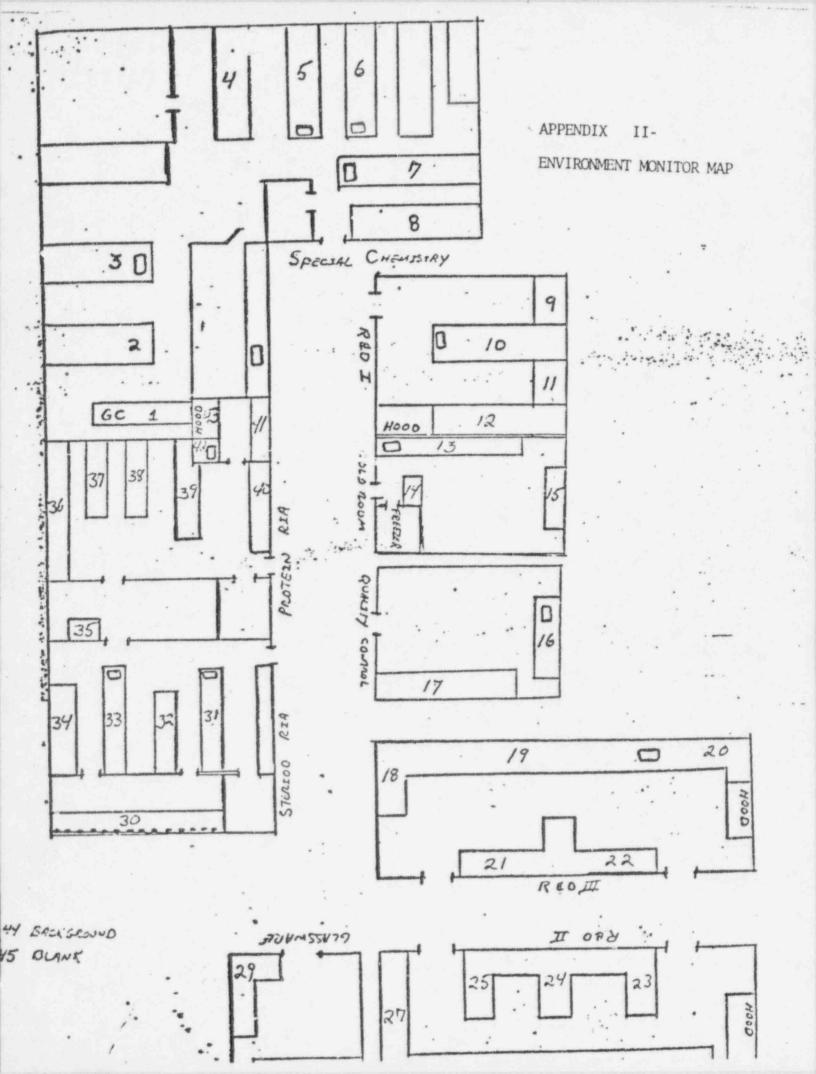
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DAILY USAGE

Date	Isotope	Compound	Amount (mCi or uCi)	Where used or disposed of
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The second secon				
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RADIOCHEMICALS RECEIVED

Date	Isotope	Compound	Amount (mCi or uCi)	Where used or disposed of
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APPENDIX LII - Environmer Monitor Record

MONTHLY MONITOR REPORT

Background C14 H3 I125 and I131	cpm cpm mr/hr	Blank Water C14H3	_cpm	Survey Meter 15.5 Sour 3.0 Source	ce mr/t
		Methanol C14_ H3			
Lab and Area	C14 cpm	H3 cpm	1125 & 1131 mr/hr	Solution	Comments
			0		
	*				

APPENDIX - IV

CALIBRATION OF GAMMA COUNTERS

Model 1185:

Count daily and record (plot) counts in the A window and in the B window the following standards:

(a) Blank for background (b) Simulated I^{125} Standard (I^{129} - 0.1 uCi- #S1567) (c) Cesium - 137 Standard (0.1 uCi - April 1971 - # 184642)

Model 1285:

Count daily and record (plot) the counts of the following standards. These standards are not removed from the machine and are always counted in the same position.

	Column #1	Column #2	Column #3
Row #1	100-184681-C	100-184681-D	100-18468-F
Row #2	100-184681-E	100-184681-Н	100-18468-G
Row #3	100-184681-B	100-184681-A	Blank for background

Weekly count junk label by pipetting 30 tubes with label and counting 10 tubes in each column. Calculate, mean, standard deviation and C.V. and record mean as well as the per cent variation between the means of the three columns.

CALIBRATION -LSC

Packard/Nuclear Chicago:

Count daily and plot counts of the following standards:

Packard- N1139 - H³ 181330-C¹⁴ Isocap-0 196 - C14 181340-H³

181350 - Blank