

INDIANA UNIVERSITY

EVANSVILLE CENTER FOR MEDICAL EDUCATION 8600 University Boulevard Evansville, Indiana 47712 (812) 464-1831

SCHOOL OF MEDICINE

April 6, 1984

Mr. James Kappler, Director
U.S. Nuclear Regulatory Commission
Region III
Radioisotopes Licensing Section
799 Roosevelt Road
Glen Ellyn, Illinois 60137

RE: By-Product Material License #13-15734-01

Dear Mr. Kappler:

We are requesting the following amendments to our By-Product Material License #13-15734-01:

 Item 6 on the license - To add as an individual user, Beat U. Raess, Ph.D. Attached are the Supplemental Sheets (pages 2 and 3) showing his Formal Training in Radiation Safety for the Individual User (item #16 on the license) and Experience for Individual User (item #17 on the license).

Dr. Raess works in Room 331 in the Health Science Bldg. which is already approved for isotopes. See diagram on page 9 of 1978 renewal application.

2. Item 8 on the license - To increase possession amounts of:

45Ca to 10 mCi 125I to 15 mCi 32P to 200 mCi

We are also requesting the following additions to license material (item 8):

42_K 86_{Rb}

KCl in solution .5M HCl solution

20 mCi 20 mCi

In order to expedite this amendment request, please do not hesitate to call us at 812-464-1831.

8610030101 860807 REG3 LIC30 13-15734-01 PDR Sincerely

George D. Guthrie, Ph.D. Associate Director Evansville Center for Medical Education Supplemental Sheet Page 3

7. RADIATION PROTECTION OFFICER

For administrative reasons, we request that the Radiation Protection Officer be changed back to Dr. George Guthrie. We want to retain Dr. Schaeffer as assistant who will function as Radiation Protection Officer on Dr. Guthrie's behalf as needed.

8. LICENSED MATERIAL

Element & Mass Number	Chemical and/or Physical Form	Name of & Model		Maximum Num Millicuries Sealed Sour Maximum Act Source Whice Possessed A Time	and/or ces & ivity Per h Will Be
		NA			
Hydrogen ³	Biochemical intermediates tritiated water.	in solution	or	500	mCi
Carbon ¹⁴	Biochemical intermediates inorganic salts.	in solution	or .	25	mCi
Iodine ¹²⁵	Iodine in NaOH solution or	iodinated	biochemicals	. 15	mCi
Phosphorus ³²	Orthophosphoric acid & biod	chemical in	termediates	200	mCi
Phosphorus ³³	Biochemical intermediates	in solution		11	mCi
Sulfur ³⁵	Biochemical intermediates	in solution		5	mCi
Chlorine ³⁶	HCl solution			2	mCi
Calcium ⁴⁵	Solution.			15	mCi*
Sodium ²⁴	Solution.			6	mCi
Potassium ⁴²	KCl in solution.			20	mCi**
Rubidium ⁸⁶	.5M HCl solution.			20	mCi**

^{*}Request an additional 5 mCi increase over amendment request. See Supplemental Sheet, Page 2.

^{**}Additions requested in amendment. See Supplemental Sheet, Page 2.

11. CALIBRATION OF INSTRUMENTS LISTED IN ITEM 10

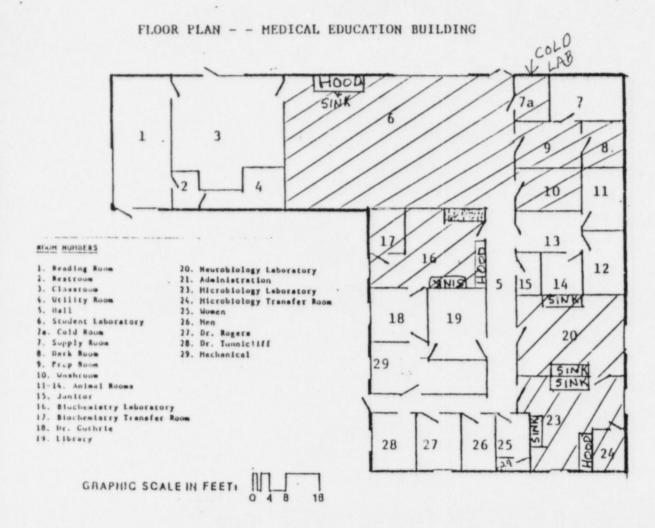
- A. Scintillation counters will be used for all quantitative determinations such as contamination measurements done with swipe tests. These will be calibrated as part of routine servicing by company representatives.
- b. Survey meters will be tested for operation using a small check source. Any contamination discovered with the survey meter will be quantitated using a swipe test counted in the calibrated instruments. We do not feel that the survey meters are instruments that can be calibrated to quanitate radioactivity accurately. One survey meter is available at each location (Medical Education Bldg. and the Health Science Bldg.) for the users.

13. FACILITIES AND EQUIPMENT

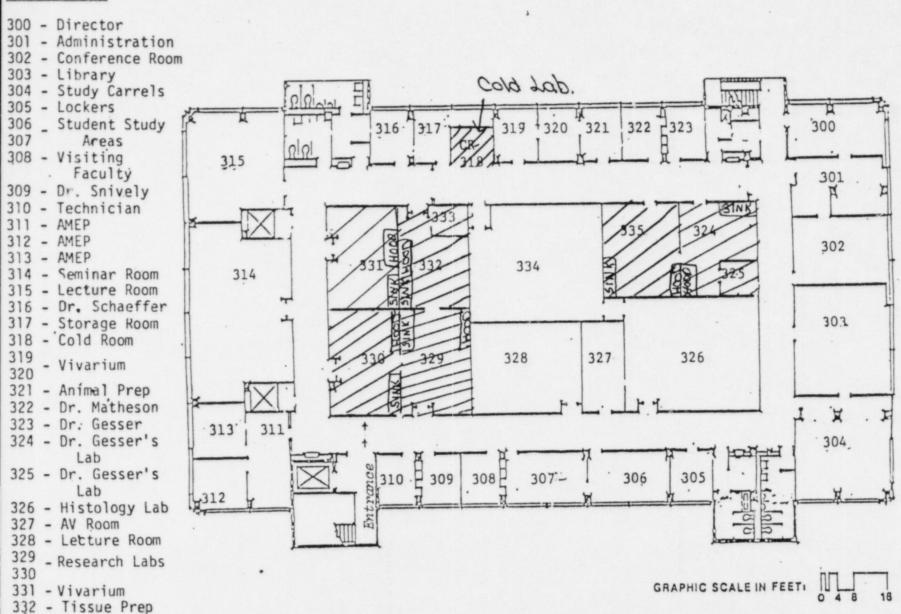
Attached are floor plans of the two facilities in which isotope usage will occur (see Supplmental Sheets, pages 7 & 8). The area where isotopes will be stored. used and disposed of are indicated on the drawings. Both facilities are restricted from the general public. In addition, the laboratory areas are restricted for use by authorized personnel only. These personnel include faculty and staff of the Center and may also include medical students by specific The number of faculty and staff at the Center is less than permission. twenty-five.

Each laboratory using isotopes has an exhaust to the outside, either through a fume hood or equivalent exhaust fan so that the total exhaust of the room can be to the outside. Dilution of isotopes from stocks to the working concentrations for an experiment are made in the hood, if necessary, to further protect against contamination of the laboratory.

Bench tops are impervious to liquids, they are standard laboratory type material (Hamlite, Hamilton Manufacturing Co., Two Rivers, Wisconsin). Shielding is employed when necessary, e.g. for stock solutions of P-32 where bremsstrahlung activity may be significant. Normally plexiglass is employed as shielding material. Initial dilutions are made behind such shielding. Unpacking of isotopes includes the inspection of packing material for contamination.



ROOM NUMBERS



3RD LEVEL FLOOR PLAN TOTAL AREA 15,325 SQ. FT. HEALTH SCIENCES BUILDING

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333 - Dark Room

334 - Gross Lab

335 - Dr. Matheson's Lab

14. WASTE DISPOSAL

b. Radioactive wastes shall be stored in an approved waste storage container. Radioactive wastes to be discarded by sanitary sewer shall utilize only one designated basin in each of rooms, 6, 16, 20, 23, 324, 329, 330, 331, 334, and 335. These basins are connected to the acid waste disposal system. The basins are of the acid-resistant type and connect to three inch diameter polyethylene pipes. The acid wastes flow through a 100 gallon neutralization tank, filled with approximately 1500 pounds of limestone, prior to being discharged into the sanitary sewer system. It has been estimated that more than 500,000 gallons of water per month or about 16,000 gallons of water per day are discharged through these portions of the sanitary sewer. Furthermore, discharge of isotopes into the sanitary sewer shall be at concentrations within the limits set in Table II of Title 10, Part 20 for each isotope used. The rules specified in Section 20.306 will be followed to establish the limits for which materials may be disposed of as non-radioactive waste.

15. RADIATION PROTECTION PROGRAM

'Duties of the Radiation Protection Officer are to monitor the use and handling of radioisotopes to:

- a. Assure that the use of radioactive material is by, or under the direct supervision of, individuals authorized in the license.
- b. Assure that personnel are appropriately instructed in the proper handling of radioisotopes and that monitoring equipment is worn or used by individuals during isotope use when this is appropriate.
- c. Assure that radioactive materials are properly secured against unauthorized use or removal.
- d. Assure that routine inspections of all laboratories using or storing radioactive materials are performed and appropriate records are kept.
- e. Assure that the terms and conditons of the license are periodically reviewed and records checked for compliance with Nuclear Regulatory Commission requirements.

· Control measures:

Isotopes are received at the receiving dock and delivered immediately to the individual user who will inspect the package and make necessary tests for contamination of packing material. Individual users will also maintain isotope inventories and disposal records.

Packages are not normally accepted by the university during off-duty hours. However, as a precaution, we have forwarded a memo to the receiving department and the security office describing the markings on isotope packages with instructions to deliver the package immediately to the appropriate building and to notify an authorized user of its receipt. (See Supplemental Sheet, Page 13.)

The responsibility for the survey of facilities rests with each authorized user. We believe this is the most effective control because isotope usage in our facility is sporadic and the authorized user is best prepared to know when and where to carry out specific swipe tests. A record sheet will include swipe check data on each experiment. These will be available for periodic inspection by the Radiation Protection Officer. The activities used in any one experiment are usually at or below exempt levels and this extent of inspecton should provide adequate control of areas where isotopes are used. We also feel that relating the frequency to the experiments performed is more effective, in our case, than to a calendar schedule. A copy of "Methods and Frequence for Conducting Surveys" will be available for each user and will be a further guide to regulate surveys by the authorized users. The toxicity classification is contained in our manual (Table 1, page 13). (See Appendix A.)

15. Cont'd. RADIATION PROTECTION PROGRAM

Bioassay procedures:

Tritium bioassays. Tritium assay by a method approved by the Radiation Protection Officer will be performed whenever the amount of tritium used in an experiment, or cumulatively over a month, exceeds those values given in Table 1 of "Guidelines for Bioassay Requirement for Tritium," Nuclear Regulatory Commission dated October 19, 1977 (see Supplemental Sheet, Page 14A). If tritium activities in any one experiment, or cumulatively over a month, exceed one-tenth of, but are not more than, the values given in Table 1, bioassays will only be performed if the design of the experiment, in the judgment of the Radiation Protection Officer, warrants a bioassay.

The bioassay normally used will be a urinalysis performed by counting an appropriate aliquote of at least 100 ml of urine.

Iodine125 bioassay: I-125 assays will be performed whenever the amount of $\overline{\text{I-125}}$ used exceeds the values given in Table 1 of the Nuclear Regulatory Guide 8.20, April 1978. (See Supplemental Sheet, Page 14). If I-125 activities in any experiment exceed one-tenth, but are not more than, the amounts given in Table 1, bioassays will only be performed if the design of the experiment, in the judgment of the Radiation Protection Officer, warrants a bioassay. The bioassay used would be a scan of the thyroid using a GSM-5 Survey Meter equipped with a DGSP-2A plutonium and I-125 probe. The equipment would be standardized against a mechanical phantom in accordance with the recommendations contained in the Handbook 87, Clinical Dosimetry, U.S. Department of Commerce, Nationl Bureau of Standards, 1963.

The DGSP-2 probe would be on hand prior to initiation of usage of I-125 in these activity ranges.

Direct Monitoring:

Personnel monitoring for individuals handling quantities greater than 1 mCi of iodine-125, sodium-24, phosphorus-32, ribidium-86 or potassium-42 will be used. The type of monitoring equipment used will be that which the Radiation Protection Officer deems appropriate for the experimental conditions being used.

Day-to-day General Safety Instructions:

Each authorized user will receive a copy of the license and the isotope user manual and will familiarize himself with the procedures and limits of isotope usage permitted by the license. He will also be informed of his own responsibilities for the instruction and monitoring of staff under his supervision. A copy of the users manual is attached. It will be reviewed and revised from time to time to assure that isotope usage meets the terms and conditions of the isotope license.

15. Cont'd. RADIATION PROTECTION PROGRAM

Laboratory personnel will receive training on the hazards of isotopes, their safe handling and the terms and conditions of our license. Training will include audio-visual tapes, individual instruction by authorized users that covers the specific use of isotopes for each laboratory worker. Spills are handled according to item VI, page 14 of the attached manual (Appendix A).

Training of students will be the responsibility of each authorized user. It will be specific to cover a given situation and may include audiovisual training tapes, lectures and on the job training as needed.

Housekeeping and security personnel will be informed that radioisotopes are being used in the areas designated. They will be shown the radioisotope warning label and informed of its use. They will be further instructed to not remove any materials from the laboratory benches or from labelled isotope waste containers. They will also be informed of how they may obtain further information on isotopes.

The general safety instructions are a part of our "Regulations for Use of Radioisotopes" manual. The manual is enclosed for reference, however, the entire manual is not being submitted as an integral part of the application because we wish to be able to edit it, as the need may arise, without the approval of the NRC. The portions relevant to safety instruction to laboratory personnel are: Item I, page 2 of the manual; Item II D, page 3, E, page 4-6, Item V page 9-12. (See Appendix A.)

15. RADIATION PROTECTION PROGRAM

INDIANA UNIVERSITY SCHOOL OF MEDICINE

EVANSVILLE CENTER

P. O. Box 3287 - Evansville, Indiana 47732

April 17, 1979

(812) 479-2061

TO:

Mailroom

Security Office

FROM: Dr. Guthyi

SUBJECT: Receipt of Radioisotopes

From time to time we will receive packages of radioisotopes as part of our normal supply shipments. These packages will be marked with an emblem similar to the one reproduced below. These packages should be delivered to the Center within three hours of receipt. One of the individuals listed below or their designated representative should receive the package.

During off-duty hours, if a package should be delivered, one of these individuals should be notified by phone of the receipt of the package. Notification should be attempted in the order listed.

Medical Education Building 8600 University Blvd.	Office Phone	Home Phone
Dr. George Guthrie	464-1831	985-2046
Dr. Howell Rogers	464-1832	464-8296
Dr. Godfrey Tunnicliff	464-1833	479-3711
Health Science Bldg.		
1901 E. Walnut St.	Office Phone	Home Phone
Dr. John Schaeffer	479-2061	477-8225
Dr. Keith Matheson	479-2061	867-6189
Dr. George Guthrie	464-1831	985-2046

Table 1

ACTIVITY LEVELS ABOVE WHICH BIOASSAY FOR I-125 OR I-131 IS NECESSARY

Activity Handled at Any One Time in Unsealed Form Making Bioassay Necessary*

Types of Operation	Volatile or Dispersible*	Bound to Nonvolatile Agent*:	
Processes in open room or bench, with possible escape of iodine from process vessels	0.1 mCi	1 mCi	
Processes with possible escape of iodine carried out within a fume hood of adequate design, face velocity, and performance reliability	1 mCi	10 mCi	
Processes carried out within gloveboxes, ordinarily closed, but with possible release of iodine from process and occasional exposure to contaminated box and box leakage	10 mCi	100 mCi	

^{*}Quantities present may be considered the amount in process by a worker at one time. Quantities in the right-hand column may be used when it can be shown that activity in process is always chemically bound and processed in such a manner that I-125 or I-131 will remain in nonvolatile form and diluted to concentrations less than 0.1 µCi/mg of nonvolatile agent. Capsules (such as gelatin capsules given to patients for diagnostic tests) may be considered to contain the radioiodine in nonfree form, and bioassay would not be necessary unless a capsule were inadvertently opened (e.g. dropped and crushed). On the other hand, certain compounds where radioiodine is normally bound are known to release radioiodine when the material is in process, and the left-hand column may then be applicable. In those laboratories working only with I-125 in radioimmunassay (RIA) kits, the quantities of I-125 are very small and in less volatile forms; thus, bioassay requirements may be judged from the right-hand column.

ACTIVITY LEVELS OR CONCENTRATIONS ABOVE WHICH BIOASSAY SHALL BE REQUIRED FOR H3

HT or To Gas

100 Ct

1.000 Ci

10,000 Ci

Nucleotide

Precursors

0.01 C1

0.01 Ci

1 Ci

in Sealed

Processed

Vessels

Table 1

HTO Form

(& forms other

than those on

0.1 C1

1 Ci

10 Ci

right-hand cols)

00

00 2

Control No

0.01 C1/Kg

HTO Mixed with More

Than 10 Kg of Inert

H₂O or Other

Substances

0.01 C1/Kg

1 Ci/Kg

release of tritium from process and occasional exposure to contaminated

reliability

Types of Operation

process vessels

Process in open room or bench, with

Processes carried out within gloveboxes,

ordinarily closed, but with possible

possible escape of tritium from

Process with possible escape of tritium, carried out within a fume

hood of adequate design, face velocity, and performance

box and box leakage

Quantities present (<10Kg) may be considered either the amount processed by an individual at any one time (when

accidental intake is more likely), or the amount of activity entered into process (throughput) during any one month

when routine handling of repeated batches is the more likely source of exposure). Concentrations in the right-hand column may be used when activity in process is always diluted in more than 10 Kg of other reagents, as in nuclear

reactor coolant systems.

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16. FORMAL TRAINING IN RADIATION SAFETY FOR INDIVIDUAL USER NAMES IN ITEM 6.

Name: George D. Guthrie, Ph.D.

			Dates	On	
			of	the	Formal
	Type of Training	Where Trained	Training	Job	Course
a.	Principles and practices of radiation protection.	Indiana University	1965-71	Yes No	Yes No
b.	Radioactivity measurement standardization and monitoring techniques and instruments.	Iowa State University Calif. Institute of Technology MIT Indiana University	1955 1957 1963 1965	Yes No Yes No Yes No Yes No	Yes No Yes No Yes No
с.	Mathematics and calculations basic to the use and measurement of radioactivity.	Same as b,		Yes No	Yes No
d.	Biological effects of radiation.	Same as b.		Yes No	Yes No
e.	Area Radiation Protection Officer - Chemistry Dept.	Indiana University	1966-71	Yes No	Yes No
f.	Chemistry Representative Radiation Control Committee	Indiana University	1966-71	Yes No	Yes No
g.	Responsible Investigator for use of radioisotopes.	Indiana University	1965-71	Yes No	Yes No
h.	Radiation Protection Officer	Evansville Center Indiana Univ, Sch, of Medicine	1973-80	Yes No	Yes No

16. FORMAL TRAINING IN RADIATION SAFETY FOR INDIVIDUAL USER NAMES IN ITEM 6.

Name: G. Keith Matheson, Ph.D.

	Type of Training	. Where	Traine	ed.		Dates of rainir	ıg ,		n ne ob	Formal Course	
a.	Principles and practices of radiation protection.	Brigham	Young	Univ.	5 m	os. 19	62	Yes	No	Yes	No
ъ.	Radioactivity measurement standardization and monitoring	"	"	"	"	,		Yes	No	Yes	No
c.	Mathematics and calculations basic to the use and measurement		"	"	"	,		Yes	No	Yes	No
d.	of radioactivity. Biological effects of radiation.		"	"	"	,		Yes	No	Yes	No
e.	Biological Warfare	U.S. A	rmy		1 mo	. 1958		Yes	No	es	No
							1				

16. FORMAL TRAINING IN RADIATION SAFETY FOR INDIVIDUAL USER NAMES IN ITEM 6, Name: Howell W. Rogers, Ph.D.

	Type of Training	. Where Trained	Dates of Training	On the Job	Formal Course
a.	Principles and practices of radiation protection.	Univ. of Mississippi Medical Center	1970-72	Yes No	Yes No
b.	Radioactivity measurement standardization and monitoring	" "		Yes No	Yes No
с.	Mathematics and calculations basic to the use and measurement	" "	in n	Yes No	Yes No
d.	of radioactivity. Biological effects of radiation.	" "	1965	Yes No	Yes No

16. FORMAL TRAINING IN RADIATION SAFETY FOR INDIVIDUAL USER NAMES IN ITEM 6.

Name: John F. Schaeffer, Ph.D.

	-		Dates	On the	Formal
	Type of Training	Where Trained	Training	Job	Course
a.	Principles and practices of radiation protection.	Syracuse Univ.	1966⊶70	Yes No	Yes No
ъ.	Radioactivity measurement standardization and monitoring techniques and instruments.	Syracuse Univ. Yale Univ.	1966 - 70 1970 - 72	Yes No	Yes (No
c.	Mathematics and calculations basic to the use and measurement of radioactivity.	Syracuse Univ. Yale Univ. Tufts Univ.	1966-70 (1970-72 1972-78	Yes No	Yes No
d.	Biological effects of radiation.	Syracuse Univ.	1966-68	Yes No	Yes No
e.	Radiation Protection Officer	Evansville Center Indiana Univ. Sch.	1981-84	Yes No	Yes No
	• •	of Medicine	-		

16. FORMAL TRAINING IN RADIATION SAFETY FOR INDIVIDUAL USER NAMES IN ITEM 6.

Name: Godfrey Tunnicliff, Ph.D.

	Type of Training	, Whe	re T	Trained	(es of ining	On the Jo	e	Formal Course	
a.	Principles and practices of radiation protection.	Univ.	of	Southhampton	1966	5 - 69	Yes	No	Yes	No
ь.	Radioactivity measurement standardization and monitoring techniques and instruments.	"		"	"	"	Yes	No	Yes	No .
c.	Mathematics and calculations basic to the use and measurement of radioactivity.	"		"	"	"	Yes	No	Yes	No
d.	Biological effects of radiation.	"		"	"	"	Yes	No	Yes	No

16. FORMAL TRAINING IN RADIATION SAFETY FOR INDIVIDUAL USER NAMES IN ITEM 6, Name: Beat U. Raess, Ph.D.

	Type of Training	, Where Trained	Dates of Training	On the Job	Formal Course
а.	Principles and practices of radiation protection.	Univ. of Rochester Univ. of Washington	1967 - 70 1970 - 82	Yes No	Yes No
ь.	Radioactivity measurement standardization and monitoring techniques and instruments.	same as above		Yes No	Yes No
с.	Mathematics and calculations basic to the use and measurement of radioactivity.	same as above		Yes No	Yes No
d.	Biological effects of radiation.	same as above		Yes No	Yes No

Name: George D. Guthrie, Ph.D.

Isotope Maximum Amount		Where Experience Occurred	Duration of Experience	Type of Use
C14	5 mCi	MIT	1962-65	Tracer Work
c ¹⁴	5 mCi	Indiana University	1965-71	и и
P32	10 mCi	" "	и и	" "
H3	10 mCi	" "	" "	" "
c14	5 mCi	Evansville Center Indiana Univ, Sch. of Medicine	1973-Pres,	" "
Н3	10 mCi	Evansville Center Indiana Univ. Sch. of Medicine	11 11	" "

Name: G. Keith Matheson, Ph.D.

Isotope	Maximum Amount	Where E	xperi	ence		uration of xperience	Туре	of Use	
R _a ²²⁶	1 mCi	Brigham Y	Zoung 1	Univ.	5	months	Formal	Training	
Fe ^{S9}	50 μC	"	"	"		"	"	"	
P32	2 mCi	"	"	"		"	"	"	
H3	1 mCi	"	"	"		"	"	"	
c14	20 mCi	"	"	"			"	- "	
s ³⁵	1 mCi	"	"	"		"	"	"	
c14	1 mCi	"	"	"	15	months		Studies/ liography	
Cr ⁵¹	2 mCi	"	"	"	6	months	InVivo γ count	Studies/	
43	1 mCi	Univ. of	Washi	ngton	6	months	InVitro Scintil	/Autoradiography lation	
14	5 mCi	"	"		3	years	InVivo/	γcounting	
13	20 mCi	Indiana 1	Univer	sity	8	yrs.		/Autoradiography immuno Assays	
14	2 mCi	"	"		8	yrs,	Radioim	muno Assays	

Name: Howell W. Rogers, Ph.D.

Isotope	Maximum Amount	Where Experience Occurred	Duration of Experience	Type of Use
c14	500 μCi.	Univ. of Mississippi	2 years	Microbiology Research
		Indiana University	12 years	"
H ³	2 Ci	Univ. of Mississippi	2 years	u u
		Indiana University	12 years	"
P32	10 mCi	Univ. of Mississippi	2 years	"
		Indiana University	12 years	"

Name: John F. Schaeffer, Ph.D.

Isotope	Maximum Amount	Where Experience Occurred	Duration of Experience Type of Use			
н3	1 mCi	Syracuse University	1966-70 Measurement of solution			
		Yale University	1970-72 Fluxes across			
		Tufts University	1972-78 biological membranes			
c14	1 mCi	ų u	" " " "			
N_a^{22}	1 mCi	" "				
N_a^{24}	5 mCi	" "	" " " "			
K ⁴²	5 mCi	Syracuse University	1966-70 " "			
C136	1 mCi	Yale University	1970-72 " "			
P ³²	1 mCi	η, τ	" " " "			
Ca ⁴⁵	1 mCi	Yale University	1970-72 " "			
		Tufts University	1972-78 " "			
Hg ²⁰³	1 mCi	Yale University	1970-72 " "			

Name: Codfrey Tunnicliff, Ph.D.

Isotope	Maximum Amount	Where Experience Occurred		ation of erience	Type of Use	
c ¹⁴	5 mCi	Univ. of Southampton Univ. of Saskatchewan		years years	Tracer	techniques
		City of Hope Medical Ctr.		months	"	"
		Clinical Research Institute of Montreal		years	"	"
		Indiana University	6	years	"	"
н3	50 mCi	Same as above				
P ³²	500 μCi	Clinical Research	1	year	"	"

Name: Beat U. Raess, Ph.D.

Isotope	Maximum Amount			Where Experience Occurred		Duration of Experience Type of		
K ⁴²	5	mCi	Univ. o	of Rochester	1967-	-70	Tracers i	
Rb ⁸⁶	5	mCi	"	"	"	"	" I'	"
P32	10	mCi	"	"	"	"	"	11
Ca ⁴⁵	5	mCi	"	"	"	"	"	"
P ³²	10	mCi -	Univ. o	of Washington	1970-	-82	"	"
I125	10	mCi	Univ. o	f Washington	1970-	-82	"	"
c^{14}	2	mCi	. "		"	"	".	"
н3	5	mCi	"	"	"	"	"	"