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#### AYERST LABORATORIES

DIVISION OF AMERICAN HOME PRODUCTS CORPORATION

685 Third Avenue / New York, N. Y. 10017 / Tel: (212) 678 5900 / Cable: ALPHAMIN, New York

November 8, 1985

Mr. Jack Davis
Nuclear Materials Safety Section A
Division of Radiation Safety and Safeguards
US Nuclear Regulatory Commission
Region 1
631 Park Avenue
King of Prussia, Pennsylvania 19406

Peference: License No. 31-21371-01

and

Amendment No. 1

Peference No. 030-20576

Ayerst Laboratories Research, Inc. Monmouth Junction, New Jersey 08540

Dear Mr. Davis:

Our July 18 1985 letter requesting an amendment to License No. 31-21371-01 and Amendment No. 01 is withdrawn.

This letter is being submitted as a revised request for an amendment to License No. 31-21371-01 and Amendment No. 01 as follows:

A. Item 8.A Increase the maximum amount of Carbon-14 which may be possessed at any one time from 250 millicuries to 500 millicuries.

Explanation: Increasing the possession limit of Carbon-14 as requested will allow (a) keeping a larger stock of C-14 labelled Ayerst experimental new drug candidates on-site and (b) conducting labelling synthesis simultaneously. It is anticipated that the amount possessed at any one time will usually be well below 500 mCi because all waste generated during a synthesis is shipped for disposal immediately after termination of the synthesis operation. However, the increase in the possession limit would be needed occassionally.

B. Item 8.H. Increase the maximum amount of Calcium 45 which may be possessed at any one time from 5 millicuries to 10 milicuries.

Explanation: Calcium 45 is now used by the Biochemistry Department.

Increase in the possession limit will permit use by the Pharmacology and Immunology Departments

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Page 2.

Mr. Jack Davis November 8, 1985

C. Item 8.F.

Increase the maximum amount of Phosphorus-32 which may be possessed at any one time from 3 mCi to 10 mCi.

Explanation:

The increase in the possession limit is needed because of the on site storage of decaying P-32 waste.

D. Condition 12

Add the following persons to Condition 12A as unlimited users of licensed materials:

Guy A. Howard, Ph.D. Joan Chapdelaine, Ph.D. Peter Grob, Ph.D.

Add the following persons to Condition 12B as limited users of licensed materials:

Paul Wooley, Ph.D. Kevin Keim, Ph.D. Joann Scatina, Ph.D. Chitra J. Punjabi, Ph.D.

Training and experience information on each of these individuals is enclosed.

E. Items 6, 7, and 8

Add the following to items 6, 7, and 8:

O Selenium 75

any

5 mCi

F. Item 14b. Delete the pertinent paragraph and substitute the following in "Application for Byproduct Material License", May 5, 1983. Attachment Item 3. Solid Waste, Par. d. very low level waste.

All radioactive solid waste will be disposed of by the contracted waste disposal company.

Sincerely,

Joseph J. Stoper Joseph J. Stapor, M.D.

Director of Industrial Hygiene

JJS:yv Enclosures (7)

cc: Ms. Sheila Gosselin Radiation Protection Officer

## A st Laboratories Research, Inc. Monmouth Junction, NJ

Guy A. Howard, Ph.D. Section Head, Bone Metabolism Biochemistry Department

August, 1985

TR	AINING AND EXPERIENC	OF EACH INDIVIDUAL NAMED IN ITE		(Use supprementa	sheets if nece	ssary)	
8 TYPE OF TRAIL	NING .	LOCATION OF TRAINING		DURATION OF		FORMAL COURSE	
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		University of Oregon, Dr. E. Herbert		8 hrs.	(VM) NO	No No	
		University of Oregon, Dr. University of Washington,	8 hrs.	(ves) No	(Ve) No		
		University of Oregon Dr. E. Herbert	0,100,	8 hrs.	€ No	( No	
d. Biological effects	of radiation	Seattle, Washington Dr. Bill Morgan		2 hrs.	Yes (No)	(Yes) No	
EXPERIENCE W	HTH RADIATION IACTUA	use of radioactive materials or equivalent ex	periencei				
MATERIALS	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED AND INSTRUCTORIS		OF EXPERIENC	E TY	PE OF USE	
	used at one time						
3 <sub>H</sub>	500 uCi (	Dr. E. Herbert		ears	in vitro, biolo- gical tracer		
14 <sub>C</sub>	500 üCi L	University of Oregon 3 Dr. E. Herbert		ears in vitro, bio gical tracer			
35 <sub>S</sub>	10 mCi	University of California 2 y Dr. R. Trout, Davis, CA		ears	in vitro, biolo- gical tracer		
32 <sub>p</sub>		University of Oregon Dr. E. Herbert, Eugene, OR		ears	in vitro, biolo- gical tracer		
125 <sub>I</sub>		University of California 2 years Dr. R. Trout, Davis, CA			tro, iodina- of protein-tra		
59 <sub>Fe</sub>	10 mCi U	University of Oregon 3 years Dr. E. Herbert, Eugene, OR			in vitro, in vivo- labeling Fe-protein		
60 <sub>Co</sub>		niverstiy of Oregon r. E. Herbert, Eugene, OR	niverstiy of Oregon 2 years		in vitro, in vivo- labeling porphyrin		
45 <sub>Ca</sub>	10 mCi U	niv. of Wash., Dr. R. Balt	zo 8 ye	ears		tro, in vivo- ing porphyrins	
14 <sub>C</sub>		и п и и	- 11		10		
35 <sub>S</sub>	н	и и и и и			"	и и	
1251		0 0 0	11		"	0 0	
125 <sub>J</sub>		. A. Medical Center acoma, WA	6 ye	ears	bone	d sources in scanner - I ed spent sourc w source	

. . .

JOAN M. CHAPDELAINE, Ph.D.

### SENIOR SCIENTIST

amino acids

	THE SAME EXP	EMIENCE	F EACH INDIVIDUAL NAMED IN	ITEMS & AND	5 (Use supplement	a sheets if nec	muni	
B TYPE UP THAIR	Principles and practices of radiation		AND INSTRUCTOR(S)		DURATION OF	ON THE JOB	FORMAL CO.	
b. Radioactivity man	ssurement standard	zation ments				Yes No	Yes (No)	
E. Mathematics and		-				(Va) No	Yes (No)	
d. Biologica effects						(Va) No	Yes No	
EXPERIENCE WI	TH RADIATION	Actus' use	of radioactive materials or equivalent			0		
MATERIALS	MUMIXAM	WHI	AND INSTRUCTORIS		N OF EXPERIENC	E TY	PE OF USE	
3 <sub>H</sub> Thymidine	10 mCi	Albei Medic	pert Eustein College of 7 years		years	Mostly in vitro assays.		
3H - 1ew	5 mCi							
and other amino acids								
1251	10 mCi	Unive Schoo	rsity of Pennsylvania	31,	years			
51 <sub>CR</sub>	5 mCi							
14 <sub>C</sub> labelled	500 uCi							

PETER GROB, Ph.D.

SENIOR SCIENTIST - IMMUNOLOGY DEPT.

B TYPE OF TRAIL	AINING AND EXP	ERIENCE	OF EACH INDIVIDUAL NAMED IN IT	EMS 4 AND	5 (Use supplement)	sheets if nece	Run)
Principles and principles     Protection			AND INSTRUCTORIS	J	DURATION OF TRAINING	ON THE ME	FORMAL COURSE
b. Radioactivity me	esurement standard		NYS Health Dept Dr. Sturman		2 years	VII) No	Yes (No)
c. Mathematics and calculations basic to the use and measurement of radioactivity  d. Biological effects of radiation.		uments ,	NYS Health Dept Dr. Sturman		2 years	(Ves) No	3-day No
		NYS Health Dept Dr. Sturman  NYS Health Dept Dr. Sturman		2 years	Va No	Ym (No)	
				2 years		Yes (No)	
RADIDACTIVE	MAXIMUM	ACTUS UI	er of radioactive materials or equivalent ex	perience)	-		0
MATERIALS	TAUCMA	+ "	MERE EXPERIENCE WAS GAINED AND INSTRUCTORIS		OF EXPERIENCE	TY	E OF USE
3 <sub>H</sub> amino acids	5 mCi	NYS I	Health DeptDr. Sturman	2 .	years	in vit	ro
14 <sub>C</sub> amino   acids	5 mCi	1				incorp	oration
14 <sub>C</sub> amino acids	2 mCi	Univ.	of Buffalo - Dr. Chadha	4 )	ears	in vit	ro oration
3 <sub>H</sub> /14 <sub>C</sub> /35 <sub>S</sub> amino acids	5 mCi	Princ	eton UnivDr. Bothwell	4 y	ears	in vit	ro oration
32 <sub>PO4</sub>	5 mCi						11 free
25 <sub>I</sub>	5 mCi						

PAUL H. WOOLEY, Ph.D.

SECTION HEAD - IMMUNOLOGY DEPT.

TYPE OF TRAIL	NING	ERIENCE OF EACH INDIVIDUAL NAMED IN I	VG	The moderner	sheets if nece	muy)	
Principles and pri	ection of radiation	AND INSTRUCTORIS	AND INSTRUCTORIS			FORMAL DOURS	
protection	* * * * * * * *	Queen Elizabeth College	Queen Elizabeth College, London			(Circle share)	
Radioactivity massurement standardization and monitoring techniques and instruments.		mens Guys Hospital Med Scho	Guys Hospital Med. School, London			No No	
Mathematics and	calculations have a	a.	or, London		Yes No	You No	
	ent of radioactivity				Yas (%)	Ya (No)	
EXPERIENCE W	TH RADIATION	Mayo Clinic, Rochester, Radiation Safety Office	MN 55905	1 hour	Yes (No)	(Vm) No	
		Actual use of rad part we materials or aquivalent a WHERE EXPERIENCE WAS GAINED	xperience)				
MATERIALS AMOUNT	AND INSTRUCTORIS	AND INSTRUCTORIS DURATION		OF EXPERIENCE TYPE OF USE			
1251	2 mCi	Guys Hospital Medical School. Dept. of Medicine G. S. Pamayo	1976	- 1980	1	belling	
125 <sub>I</sub>	2 mCi	Immunol Dept., Mayo Clinic	1980	1985	Radio Immuno-		
51 <sub>CR</sub>		C. S. David, Pn.D.			assay. Cytotox		

# Monmouth Junction, NJ

KEVIN KEIM, Ph. D.

TRA	INING AND EXP	ERIENC	OF EACH INDIVIDUAL &	ANTON				
			DE EACH INDIVIDUAL N		G AND 5	DURATION OF	ON THE ME	FORMAL COURSE
Principles and prac	mon of redistion	ď.	Fairleigh Dicki	nson Uni	V. MS PGR	Inamino	Circle shower)	(Circle answer)
Red-Dectivity mass	Lumment standard		Hoffman - L Roch	e Inc.		4 months	(Van Me	(Ven) No
and monitoring tec	nniques and inen	uments .	Hotfman - La Roch	he, Inc.		8 years	(Ver) No	- 6
Mathematics and calculations basic to the use and massurement of radioactivity		o the	Hoffman - La Roche, Inc.		8 years	(Va) No	Va No	
Biologica effects of	f radiation		Fairleigh Dickins	son Univ	. MS PGR	4 months		Yes No
ADIDACTIVE T	MAXIMUM	Actua u	se of radioactive materials or	equivalent e	*Derience		(	110
MATERIALS	TAUCMA		MERE EXPERIENCE WAS I	GAINED	1	OF EXPERIENCE	E TY	E OF USE
1125	?	Con	version and use of	f 1 <sup>125</sup>	8	years	-	search
ngiotensin		ang	iotensin. Renin k oratory use for an	cit to nimals.				
		Hof	fman La Roche, Inc					1
I 125 ACTH	?	Hoff	fman La Roche, Inc Research		8 )	ears	Re	search
H <sup>3</sup> iazepam teroids	5 mCi	Hoff	man La Roche, Inc Research		8 )	ears	Res	search
C <sup>14</sup> iazepam	2 mCi	Hoff	man La Roche, Inc Research		8 y	ears	Res	earch

Ayerst Laboratories Research, Ac.

JOANN SCATINA, Ph.D.

### SENIOR SCIENTIST

TRA	LINING AND EXPER	HENCE	OF EACH INDIVIDUAL NAMED IN	*****			المراسلانين	
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. Radicactivity mas	summent standardiza	ition	(New Jersey Medical Scho	001)	4 yrs.	(Van) No	Ves No	
and monitoring techniques and instruments.  c. Mathematics and calculations besic to the use and measurement of radioactivity.  d. Biological effects of radiation.					"	Vm No	Va No	
					n.	<b>₹ №</b>		
EXPERIENCE W	TH RADIATION (A:		se of radioactive materials or agul valent a			Va No	Ven No	
MATERIALS	TAUCMA	w	MERE EXPERIENCE WAS GAINED	1	N OF EXPERIENCE	1		
14 <sub>C</sub>						1	PE OF USE	
3 <sub>H</sub>	mCi	New	Jersey Medical School	4 3	vears	Drug u	ptake studies	
35 <sub>S</sub>							cokinetic	
abelled							tudies	
icids, nucleric							etabolism tudies	
acids and Drugs 36 <sub>CL</sub> (labelled drug)	ı					acio	acid Nucleic d incorporation udies	
urug)							7476	

CHITRA J. PUNJABI, Ph.D.

## SENIOR SCIENTIST

11	HAINING AND EXPE	PIENCE	OF EACH INDIVIDUAL NAMED IN	*****					
or ina	INING		LOCATION OF TRAINI	N.C.	DURATION OF TRAINING	ON THE MO	FORMAL COURSE		
Protection	raction of radiation		McGill University		- AMAINING	(Van) No	(Circle answer)		
Radioactivity m	assurement standardil techniques and instru	ments .	McGill University			(Van) No	Ym (No)		
Wathematics end	d calculations basic to	me	McGill University		1	_	Va (60)		
Biologica effects of radiation			McGill University			(Va) No	Va (No)		
EXPERIENCE Y	TH RADIATION I	Actual u	se of radioactive materials or aguivalent			Vas No	You (No.)		
MATERIALS	MUMIXAM		HERE EXPERIENCE WAS GAINED		OF EXPERIENCE	E TV	PE OF USE		
3 HTdR	2 mCi	McG	ill University, Canada	4 y	4 years		radioautography cellular prolifera- tion in vitro		
Cr- 125 <sub>IudR</sub>	0.5 mCi 1 mCi	Memo	orial Sloan-Kettering titute, New York	3 ye 2 ye	ears ears	In vitro	- cell ation and		
obalt-60 rradiator	Sealed source	McGi	ill University, Canada	3 ує	ears	Irradiation of s			
esium-137 rradiator	Sealed source	Inst	rial Sloan-Kettering itute for Cancer arch New York	2 y€	ears	Irradiat animals	ion of small and cells		

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