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Ayerst
AYERST LABORATORIES
DIVISION OF AMERICAN HOME PRODUCTS CORPORATION

685 Third Avenue / New York, N.Y. 10017 / Tel: (212) 878-5900 / 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Our July 18 1985 letter requesting an amendment to License No. 31-21371-01 and Amendment No. 01 is withdrawn.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.

04146

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:

0	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. Stapor

Joseph J. Stapor, M.D.
Director of Industrial Hygiene

JJS:yv Enclosures (7)

cc: Ms. Sheila Gosselin
Radiation Protection Officer

Ayerst Laboratories Research, Inc.
Monmouth Junction, NJ

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

August, 1985

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEMS 4 AND 5 (Use supplemental sheets if necessary)

8. TYPE OF TRAINING	LOCATION OF TRAINING AND INSTRUCTOR(S)	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
a. Principles and practices of radiation protection	University of Oregon, Dr. E. Herbert	8 hrs.	(Yes) No	(Yes) No
b. Radioactivity measurement standardization and monitoring techniques and instruments	University of Oregon, Dr. Herbert University of Washington, Dr. Baltzo	8 hrs. 8 hrs.	(Yes) No	(Yes) No
c. Mathematics and calculations basic to the use and measurement of radioactivity	University of Oregon Dr. E. Herbert	8 hrs.	(Yes) No	(Yes) No
d. Biological effects of radiation	Seattle, Washington Dr. Bill Morgan	2 hrs.	Yes (No)	(Yes) No

9. EXPERIENCE WITH RADIATION (Actual use of radioactive materials or equivalent experience)

RADIOACTIVE MATERIALS	MAXIMUM AMOUNT used at one time	WHERE EXPERIENCE WAS GAINED AND INSTRUCTOR(S)	DURATION OF EXPERIENCE	TYPE OF USE
^{3}H	500 uCi	University of Oregon Dr. E. Herbert	3 years	in vitro, biological tracer
^{14}C	500 uCi	University of Oregon Dr. E. Herbert	3 years	in vitro, biological tracer
^{35}S	10 mCi	University of California Dr. R. Trout, Davis, CA	2 years	in vitro, biological tracer
^{32}P	20 mCi	University of Oregon Dr. E. Herbert, Eugene, OR	3 years	in vitro, biological tracer
^{125}I	10 mCi	University of California Dr. R. Trout, Davis, CA	2 years	in vitro, iodination of protein-trace
^{59}Fe	10 mCi	University of Oregon Dr. E. Herbert, Eugene, OR	3 years	in vitro, in vivo-labeling Fe-proteins
^{60}Co	10 mCi	Universtiy of Oregon Dr. E. Herbert, Eugene, OR	2 years	in vitro, in vivo-labeling porphyrins
^{45}Ca	10 mCi	Univ. of Wash., Dr. R. Baltzo	8 years	in vitro, in vivo-labeling porphyrins
^{3}H	"	" " " "	"	" " "
^{14}C	"	" " " "	"	" " "
^{35}S	"	" " " "	"	" " "
^{125}I	"	" " " "	"	" " "
^{125}I	500 mCi	V. A. Medical Center Tacoma, WA	6 years	sealed sources in bone scanner - I changed spent source to new source

Ayerst Laboratories Research, Inc.
Monmouth Junction, NJ

JOAN M. CHAPDELAINE, Ph.D.

SENIOR SCIENTIST

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEMS 4 AND 5 (Use supplemental sheets if necessary)

8 TYPE OF TRAINING	LOCATION OF TRAINING AND INSTRUCTOR(s)	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
a. Principles and practices of radiation protection			(Yes) No	Yes (No)
b. 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)

9 EXPERIENCE WITH RADIATION (Actual use of radioactive materials or equivalent experience)

RADIOACTIVE MATERIALS	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED AND INSTRUCTOR(S)	DURATION OF EXPERIENCE	TYPE OF USE
^{3}H Thymidine	10 mCi	Albert Eustein College of Medicine	7 years	Mostly in vitro assays.
^{3}H - lew and other amino acids	5 mCi			
^{125}I	10 mCi	University of Pennsylvania School of Medicine	3½ years	
^{51}CR	5 mCi			
^{14}C labelled amino acids	500 uCi			

Ayerst Laboratories Research, Inc.
Monmouth Junction, NJ

PETER GROB, Ph.D.

SENIOR SCIENTIST - IMMUNOLOGY DEPT.

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEMS 4 AND 5 (Use supplemental sheets if necessary)

8 TYPE OF TRAINING	LOCATION OF TRAINING AND INSTRUCTOR(S)	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
a. Principles and practices of radiation protection	NYS Health Dept. - Dr. Sturman	2 years	(Yes) No	Yes (No)
b. Radioactivity measurement standardization and monitoring techniques and instruments	NYS Health Dept. - Dr. Sturman	2 years	(Yes) No	(Yes) 3-day No
c. Mathematics and calculations basic to the use and measurement of radioactivity	NYS Health Dept. - Dr. Sturman	2 years	(Yes) No	Yes (No)
d. Biological effects of radiation	NYS Health Dept. - Dr. Sturman	2 years	(Yes) No	Yes (No)

9 EXPERIENCE WITH RADIATION (Actual use of radioactive materials or equivalent experience)

RADIOACTIVE MATERIALS	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED AND INSTRUCTOR(S)	DURATION OF EXPERIENCE	TYPE OF USE
^{3}H amino acids	5 mCi	NYS Health Dept.-Dr. Sturman	2 years	in vitro incorporation
^{14}C amino acids	5 mCi			
^{14}C amino acids	2 mCi	Univ. of Buffalo - Dr. Chadha	4 years	in vitro incorporation
$^{3}H/^{14}C/^{35}S$ amino acids	5 mCi	Princeton Univ.-Dr. Bothwell	4 years	in vitro incorporation and cell free labeling
$^{32}PO_4$	5 mCi			
^{125}I	5 mCi			

Ayerst Laboratories Research, Inc.
Monmouth Junction, NJ

PAUL H. WOOLEY, Ph.D.

SECTION HEAD - IMMUNOLOGY DEPT.

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEMS 4 AND 5 (Use supplemental sheets if necessary)

8 TYPE OF TRAINING	LOCATION OF TRAINING AND INSTRUCTOR(S)	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
a. Principles and practices of radiation protection	Queen Elizabeth College, London	1 semester	Yes (No)	(Yes) No
b. Radioactivity measurement standardization and monitoring techniques and instruments	Guys Hospital Med. School, London		(Yes) No	Yes (No)
c. Mathematics and calculations basic to the use and measurement of radioactivity			Yes (No)	Yes (No)
f. Biological effects of radiation	Mayo Clinic, Rochester, MN 55905 Radiation Safety Officer	1 hour	Yes (No)	(Yes) No

EXPERIENCE WITH RADIATION (Actual use of radioactive materials or equivalent experience)

RADIOACTIVE MATERIALS	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED AND INSTRUCTOR(S)	DURATION OF EXPERIENCE	TYPE OF USE
^{125}I	2 mCi	Guys Hospital Medical School. Dept. of Medicine G. S. Pamayo	1976 - 1980	Radiolabelling Radio Immuno-assay
^{125}I ^{51}CR	2 mCi	Immunol Dept., Mayo Clinic C. S. David, Ph.D.	1980 - 1985	Radio Immuno-assay. Cytotoxicity Radio Isotope protein traces

Ayerst Laboratories Research, Inc.
Monmouth Junction, NJ

KEVIN KEIM, Ph.D.

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEMS 4 AND 5 (Use supplemental sheets if necessary)

TYPE OF TRAINING	LOCATION OF TRAINING AND INSTRUCTOR(S)	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
Principles and practices of radiation protection	Fairleigh Dickinson Univ. MS PGR Hoffman - L Roche Inc.	4 months	(Yes) No	(Yes) No
Radioactivity measurement standardization and monitoring techniques and instruments	Hoffman - La Roche, Inc.	8 years	(Yes) No	Yes (No)
Mathematics and calculations basic to the use and measurement of radioactivity	Hoffman - La Roche, Inc.	8 years	(Yes) No	Yes (No)
Biological effects of radiation	Fairleigh Dickinson Univ. MS PGR	4 months	Yes (No)	(Yes) No

EXPERIENCE WITH RADIATION (Actual use of radioactive materials or equivalent experience)

RADIOACTIVE MATERIALS	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED AND INSTRUCTOR(S)	DURATION OF EXPERIENCE	TYPE OF USE
I^{125} Angiotensin	?	Conversion and use of I^{125} angiotensin. Renin kit to laboratory use for animals. Hoffman La Roche, Inc.	8 years	Research
I^{125} ACTH	?	Hoffman La Roche, Inc. Research	8 years	Research
H^3 iazepam teroids	5 mCi	Hoffman La Roche, Inc. Research	8 years	Research
C^{14} iazepam	2 mCi	Hoffman La Roche, Inc. Research	8 years	Research

Ayerst Laboratories Research, Inc.
Monmouth Junction, NJ

JOANN SCATINA, Ph.D.

SENIOR SCIENTIST

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEMS 4 AND 5 (Use supplemental sheets if necessary)

8 TYPE OF TRAINING	LOCATION OF TRAINING AND INSTRUCTOR(S)	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
a. Principles and practices of radiation protection	Univ. of Med. & Dental of NJ (New Jersey Medical School)	4 yrs.	(Yes) No	(Yes) No
b. 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

5 EXPERIENCE WITH RADIATION (Actual use of radioactive materials or equivalent experience)

RADIOACTIVE MATERIALS	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED AND INSTRUCTOR(S)	DURATION OF EXPERIENCE	TYPE OF USE
^{14}C				
^{3}H	mCi	New Jersey Medical School	4 years	Drug uptake studies
^{35}S				Pharmacokinetic studies
(labelled amino acids, nucleric acids and Drugs ^{36}CL (labelled drug)				Drug Metabolism studies
				Amino acid Nucleic acid incorporation studies

Ayerst Laboratories Research, I
Monmouth Junction, NJ

CHITRA J. PUNJABI, Ph.D.

SENIOR SCIENTIST

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEMS 4 AND 5 (Use supplemental sheets if necessary)

TYPE OF TRAINING	LOCATION OF TRAINING AND INSTRUCTOR(S)	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
Principles and practices of radiation protection	McGill University		(Yes) No	Yes (No)
Radioactivity measurement standardization and monitoring techniques and instruments	McGill University		(Yes) No	Yes (No)
Mathematics and calculations basic to the use and measurement of radioactivity	McGill University		(Yes) No	Yes (No)
Biological effects of radiation	McGill University		(Yes) No	Yes (No)

EXPERIENCE WITH RADIATION (Actual use of radioactive materials or equivalent experience)

RADIOACTIVE MATERIALS	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED AND INSTRUCTOR(S)	DURATION OF EXPERIENCE	TYPE OF USE
^{3}HTdR	2 mCi	McGill University, Canada	4 years	radioautography cellular proliferation *in vitro*
^{51}Cr- ^{125}IudR	0.5 mCi 1 mCi	Memorial Sloan-Kettering Institute, New York	3 years 2 years	*In vitro* - cell incorporation and release assays
Cobalt-60 Irradiator	Sealed source	McGill University, Canada	3 years	Irradiation of small animals and cells
Cesium-137 Irradiator	Sealed source	Memorial Sloan-Kettering Institute for Cancer Research New York	2 years	Irradiation of small animals and cells

CONVERSATION RECORD

TIME

DATE 10/9/85

TYPE ☐ VISIT ☐ CONFERENCE ☒ TELEPHONE ☐ INCOMING ☐ OUTGOING

Location of Visit/Conference:

ROUTING	
NAME/SYMBOL	INT

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
Sheila Gosselin	Ayerst Lab	201-329 2300 X 2478

SUBJECT

Amendment dated July 18, 1985

SUMMARY

(1) Will submit additional info to

a) list individuals authorized for all materials

b) " " " " " " except those listed in L/C 12B

c) delete some of the individuals as authorized above.

d) specify method of disposal of solid waste

Will submit addendum next week.

"OFFICIAL RECORD COPY"

ACTION REQUIRED

XL1B

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Jack Davis		10/9/85

ACTION TAKEN

SIGNATURE	TITLE	DATE