Ayerst

AYERST LABORATORIES
DIVISION OF AMERICAN HOME PRODUCTS CORPORATION

Applicant ... 19332
Check ... 10/30/84
Amount ... Amendment
Type of ... 10/26/84
Date Check ... Brown
Received ...

685 Third Avenue / New York, N.Y. 10017 / Tel: (212) 878-5900 / Cable: ALPHAMIN, New York

October 18, 1984

RECEIVED BY LFMB
Date 10/26/84
Log 071
By Brown
Orig. To
Action Compl. 10/31/84

U.S. Nuclear Regulatory Commission
Region I
631 Park Avenue
King of Prussia, PA 19406

Reference: License Number 31-21371-01
Ayerst Laboratories Research, Inc.
Monmouth Junction, N.J. Facility

Dear Sir:

Ayerst Laboratories Research, Inc., is submitting an amendment to its license, number 31-21371-01. The changes are detailed below and in the attachments. (Item numbers employed are those used in NRC Form 313I.)

Item 6

Please delete Dr. Stern. Add the following personnel, Drs. AcKerman, Ferrone, Hayward, Kemper, Kimble, McCaleb, McKean, and Scatina. Their training and experience in handling radionuclides are attached.

Item 8

We are requesting possession of four additional isotopes, the cumulative total for the four is requested to be 10 milliCuries (see attached list). In addition, we are requesting increased possession limits for ^{45}Calcium, ^{51}Chromium, and ^{125}Iodine to accommodate increasing research activities and to allow for more on-site decay (^{125}I). Attached is an amended item 8 that details these requested changes.

Item 12

We are planning a monthly exchange frequency for the TLDs instead of the currently licensed bimonthly rate.

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Item 14B Waste Disposal

Change A1a (^{14}C-^{3}H-^{36}Cl-^{35}S-^{45}Ca) to:

Waste is poured down the drain at a controlled rate of 0.3 microCuries/liter water (Not to exceed N.J. regulations).

Add to A1c:

^{45}Ca contaminated urine will be collected and shipped off-site.

Add to 3a:

^{45}Ca contaminated carcasses will be shipped off-site.

Add to 3b:

All ^{45}Ca contaminated material will be shipped off-site.

Change B (^{32}P-^{125}I-^{51}Cr) to

1. Soluble:
   Waste is poured down the drain at a controlled rate of 0.04 microCuries/liter water (not to exceed N.J. regulations).

2. All other waste:
   Collected in catalogued three-gallon pails and decayed in a designated area of the building. The decay site will be adequately protected against unauthorized removal. This area will be designed in such a way as to guarantee the exposure limits prescribed in 10 CFR 20.105 are not exceeded.

If you have questions or comments about these changes, please contact Dr. R. Kaplan at 212-878-6083.

Thank you.

Sincerely,

Ellen Levine

for John Rapoza
Assistant Vice-President,
Regulatory Affairs

RECEIVED
84 OCT 26 P2:3?
LIC. FEE ... BRANCH

AYERST LABORATORIES RESEARCH, INC.
MONMOUTH JUNCTION, N.J.

Currently licensed isotope for which we are requesting increased possession limits:

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 MILLICURIES AND/OR SEALED SOURCES AND MAXIMUM ACTIVITY PER SOURCE WHICH WILL BE POSSESSED AT ANY ONE TIME D
(1)	^{45}Calcium	Any		5 milliCuries
(2)	^{51}Chromium	Any		20 milliCuries
(3)	^{125}Iodine	Any		50 millicuries
(4)				

	DESCRIBE USE OF LICENSED MATERIAL E
(1)	
(2)	
(3)	
(4)	

NRC FORM 313 I (12-81)

AYERST LABORATORIES RESEARCH INC.
MONMOUTH JUNCTION, NJ

Additional Isotopes

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 MILLICURIES AND/OR SEALED SOURCES AND MAXIMUM ACTIVITY PER SOURCE WHICH WILL BE POSSESSED AT ANY ONE TIME D
(1)	141 Cerium	Microspheres	NEN, 3M or	10 milliCuries
(2)	95 Niobium	Microspheres	equivalent	cumulative total
(3)	46 Scandium	Microspheres	for all 4	for these 4
(4)	85 Strontium	Microspheres		nuclides

	DESCRIBE USE OF LICENSED MATERIAL
(1)	Blood flow studies in laboratory animals
(2)	
(3)	
(4)	

NRC FORM 313 I (12-81)

AYERST LABORATORIES RESEARCH INC.
MONMOUTH JUNCTION, N.J.

NAME: Marilee McKean, Ph.D.

TITLE: Research Associate, Biochemistry

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	Course-Drexel Univ. Prof. Kieth P. West Graduate training- Drexel Univ.	5 yr	(Yes) No	(Yes) No
b. Radioactivity measurement standardization and monitoring techniques and instruments	Course-Drexel Univ. Prof. Kieth P. West Graduate training- Drexel Univ.	5 yr	(Yes) No	(Yes) No
c. Mathematics and calculations basic to the use and measurement of radioactivity	Course-Drexel Univ. Prof. Kieth P. West Graduate training- Drexel Univ.	5 yr	(Yes) No	(Yes) No
d. Biological effects of radiation	Course-Drexel Univ. Prof. Kieth P. West Graduate training- Drexel Univ.	5 yr	(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
^{125}I	5 mCi	Graduate School Drexel Univ.	3 yr	Iodination of proteins
^{14}C	50 mCi	Graduate School Drexel Univ.	3 yr	Tracer studies in vitro
^{3}H	0.5 mCi	Graduate School Drexel Univ. also have used ^{14}C and ^{3}H in post - graduate training and to conduct my own research	3 yr	Tracer studies in vitro

NAME: Dennis M. Ackerman, Ph.D.

TITLE: Section Head - Department of Pharmacology

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL				
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	Emory University	1.5 yrs.	Yes No	Yes No
b. Radioactivity measurement standardization and monitoring techniques and instruments	Emory University; Smith Kline & French Labs.	2.5 yrs.	Yes No	Yes No
c. Mathematics and calculations basic to the use and measurement of radioactivity	Emory University	1.5 yrs.	Yes No	Yes No
d. Biological effects of radiation	Emory University; Smith Kline & French Labs.	2.5 yrs.	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
^{14}C	250 micro-curies	Emory University Atlanta, GA Dr. A. Pruitt	1.5 yrs.	whole animal
^{3}H	5 milli-curies	Emory University Atlanta, GA Dr. A. Pruitt	1.5 yrs.	whole animal
^{141}Ce	1 milli-curie	Smith Kline & French Labs. Philadelphia, PA 19101 Dr. A. Compton	1 yr	whole animal
^{51}Cr	1 milli-curie	"	"	"
^{85}Sr	1 milli-curie	"	"	"

AYERST LABORATORIES RESEARCH, INC.
MONMOUTH JUNCTION, N.J.

NAME: Dr. Ron Ferrone

TITLE: Senior Research Investigator

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	Penn State University, PA	4 yrs	Yes No	(Yes) No
b. Radioactivity measurement standardization and monitoring techniques and instruments	Ochsner Med. Foundation	2 yrs	(Yes) No	Yes No
c. Mathematics and calculations basic to the use and measurement of radioactivity	Squibb Princeton	6 yrs	(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
^{14}C	250 microCi	Penn State University Dr. T.M. Hollis	4 yrs	in vitro; RIA
^{3}H	250 microCi			
^{125}I	10 microCi			
^{141}Ce ^{95}Nb ^{85}Sr ^{51}Cr	1 mCi	Alton Ochsner Med. Foundation New Orleans, LA Dr. G. M. Walsh	2 yrs	in vivo-- microspheres
^{141}Ce ^{95}Nb ^{85}Sr ^{51}Cr	1 mCi	Squibb	6 yrs	in vivo-- microspheres

AMERICAN LABORATORIES RESEARCH, INC.
MONMOUTH JUNCTION, N.J.

ITEMS 16 AND 17

MARSHALL A. HAYWARD - SENIOR SCIENTIST

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL

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	Univ. of Illinois - D. Shamro Michigan State Univ. J. Boezi	1 week 1 week	Yes No	Yes (No)
Radioactivity measurement standardization and monitoring techniques and instruments	"	"	(Yes) No	Yes (No)
Mathematics and calculations basic to the use and measurement of radioactivity	"	"	(Yes) No	Yes (No)
Biological effects of radiation	"	"	(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}H	1 mCi	MSUL J. Boezi	1 ½ years	Enzyme assays
^{3}H	5 mCi	Univ. of Ill. D. Shepiro	6 years	Assays, standards
^{14}C	1 mCi	Univ. of Ill. D. Shepiro	6 years	Assays, standards
^{32}P	1 mCi	Univ. of Ill. D. Shepiro	4 years	Plus probe synthesis, & nick translation
^{35}S	5 mCi	Univ. of Ill. D. Shepiro	3 years	in vitro translation
^{125}I	5 mCi	Univ. of Ill. D. Shepiro	2 years	protein labeling
^{131}I	2 mCi	Univ. of Ill. D. Shepiro	2 years	protein labeling

AYERST LABORATORIES RESEARCH, INC.
MONMOUTH JUNCTION, N.J.

ITEMS 16 AND 17

CHRISTOPHER KEMPER - SENIOR SCIENTIST

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL

TYPE OF TRAINING	LOCATION OF TRAINING AND INSTRUCTOR(S)	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURS (Circle answer)
Principles and practices of radiation protection	Sterling-Winthrop Res. Inst.	2 yrs	(Yes) No	Yes No
Radioactivity measurement standardization and monitoring techniques and instruments	" "	"	(Yes) No	Yes No
Mathematics and calculations basic to the use and measurement of radioactivity	Dr. Robert Block, RPI Troy, NY	"	(Yes) No	Yes No
Biological effects of radiation	Univ. of Louisville, Dr. H. Hurst		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
H^3 & C^{14}	1 mCi	Sterling-Winthrop Res. Dr. Clarke Davison Ms. Tanya Williams	2 years	Drug Metabolism
C^{14} Fe^{59}	1 mCi	Univ. of Louisville Dr. Donald Nerland	1 year	Drug Metabolism

NAME: E. Kimball, Ph.D.

TITLE: Section Head / Connective Tissue Section

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

B. 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	Nat'l Institute of Health Bethesda		Yes No	(Yes) No
b. Radioactivity measurement standardization and monitoring techniques and instruments	Nat'l Institute of Health		(Yes) No	Yes No
c. Mathematics and calculations basic to the use and measurement of radioactivity	Nat'l Institute of Health		(Yes) No	Yes No
d. Biological effects of radiation	Nat'l Institute of Health		Yes No	(Yes) No

C. 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}Hamino acids	50 mCi	Nat'l Institute of Health	7 years	In vitro labeling biosynthetic
^{3}H-dT	10 mCi	Nat'l Institute of Health	7 years	
^{3}H-Acetic Anh.	100 mCi	Nat'l Institute of Health	7 years	Protein labeling
^{14}C Iodo-acetamide	1 mCi	Nat'l Institute of Health	7 years	Protein labeling
^{125}I	5 mCi	Nat'l Institute of Health	7 years	Radio assays; Protein labeling; cell labeling
^{35}S-methionine	10 mCi	Nat'l Institute of Health	7 years	Biosynthetic cell labeling
^{51}Cr	5 mCi	Nat'l Institute of Health	7 years	Cell labelling-- ^{51}Cr release assays
^{32}P	10 mCi	Nat'l Institute of Health	7 years	Cell labeling
^{14}C-amino acids	5-10 mCi	Nat'l Institute of Health	7 years	Biosynthetic cell labeling

AYERST LABORATORIES RESEARCH INC.
MONMOUTH JUNCTION, N.J.

NAME: Dr. Michael L. McCaleb

TITLE: Research Associate, Dept. of Biochemistry

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	Purdue University		(Yes) No	(Yes) No
b. Radioactivity measurement standardization and monitoring techniques and instruments	Purdue University		(Yes) No	(Yes) No
c. Mathematics and calculations basic to the use and measurement of radioactivity	Purdue University		(Yes) No	(Yes) No
d. Biological effects of radiation	Purdue University		(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	1 mCi	Purdue University Sloan Kettering Inst. Univ. Roch. Med. Ctr.	4 years 2 years 2 years	in vitro and in vivo experimentation
^{14}C	1 mCi	Purdue University Sloan Kettering Inst. Univ. Roch. Med. Ctr	4 years 2 years 2 years	in vitro and in vivo experimentation