Medical Center

American Lake
Tacoma WA 98493

Veterans Administration

March 25, 1985

In Reply Refer To: 505/00

License Management Branch
U.S. Nuclear Regulatory Commission
Region V
1450 Maria Lane, Suite 210
Walnut Creek, CA 94596

THRU: Director, Nuclear Medicine Service (115)
Veterans Administration Central Office
810 Vermont Avenue, N.W.
Washington, D.C. 20420

SUBJ: Amendment to Materials License Number 46-19584-01

1. It is requested that the maximum amount of the following isotopes be increased as follows:

Byproduct, Source, and/or Special Nuclear Material	Chemical and/or Physical Form	Requested Maximum Amount We may Possess at any One Time under Our License
A. Carbon 14	A. Any	A. 20 millicuries
B. Hydrogen 3	B. Any	B. 50 millicuries
C. Iodine 125	C. Any	C. 15 millicuries
D. Phosphorus 32	D. Any	D. 15 millicuries
E. Calcium 45	E. Any	E. 20 millicuries

An increase in the amount of Hydrogen 3, Carbon 14, and Phosphorus 32 is requested for use in the procedure described in a recent license amendment request dated March 1, 1985, for an increase in the amount of Sulfur 35. To recapitulate: labeling of intact cells grown in a culture with [3H]amino acids or sugars, [14C]amino acids or sugars, [32P]phosphoric acid, and [35S] sulfuric acid. Extracts of these labeled cells are fractionated by various biochemical and immunochemical techniques to isolate specific peptides related to the research interests of the investigators. Each procedure would use 0.25 to 5 millicuries of labeled material. Label would be stored at 4°C in an appropriately labeled refrigerator following proper procedures.

The radioisotopes would be in the form of amino acids or sugars (Hydrogen 3 and Carbon 14), phosphoric acid (Phosphorus 32), and sulfuric acid (Sulfur 35).

Employees would follow safety procedures for high and low energy beta-emitters outlined in the original application.

An increase in the amount of Phosphorus 32 is also requested for use in certain types of molecular biological experiments. The isotope in the form of [alpha-32P]dexoycytidine triphosphate will be used to label DNA fragments

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in vitro with purified enzymes. The DNA fragments will be used in binding experiments with DNA or RNA extracted from cells and fractionated by gel electrophoresis. Each labeling procedure would use 50-100 microcuries of isotope. Label would be stored at either -20°C or -70°C in an appropriately labeled freezer following proper procedures.

The isotope would be in the form of [alpha-32P]deoxycitidine triphosphate.

Employees would follow safety procedures for high energy beta-emitters outlined in the regulations.

An increase in the amount of Iodine 125 is requested for use in radio-immunoassays. The procedure is essentially the same as described for the amendment request from this Medical Center, dated January 19, 1982, except that peptides rather than cell membrane proteins will be labeled.

2. Request the following individuals be named as users of the materials and uses indicated:

Roger Birnbaum, Ph.D.	Hydrogen 3, Carbon 14, Phosphorus 32, Sulfur 35, and Iodine 125
Douglas M. Burns, Ph.D.	Hydrogen 3, Carbon 14, Phosphorus 32, Sulfur 35, and Iodine 125
Peter J. Gkonos, M.D.	Hydrogen 3, Phosphorus 32, Sulfur 35, and Iodine 125
Richard Ostenson, M.D.	Hydrogen 3 and Iodine 125
Bernard A. Roos, M.D.	Hydrogen 3, Carbon 14, Phosphorus 32, Sulfur 35, and Iodine 125
Charles W. Wilkinson, Ph.D.	Hydrogen 3 and Iodine 125
Stephen M. Loop	Hydrogen 3 and Iodine 125

(Supplements A & B enclosed)

Kenneth Gross, M.D.	Groups I, II and III Iodine 125
Vernon Larson, M.D.	Groups I, II and III Iodine 125
Robert Whitney, Jr., M.D.	Groups I, II and III Iodine 125
John Flood, M.D.	Groups I, II and III Iodine 125

(Copy of Washington State Radioactive Materials License WN-M0151-1 enclosed)

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3. Request that Roger S. Birnbaum, Ph.D. be names as Assistant Radiation Safety Officer who is to function as Radiation Safety Officer in Dr. Robentt's absence.

4. Request that John R. Farley, Ph.D. be taken off our license as a user as he no longer works here.

5. Our Radiation Safety Committee (Medical Isotopes Committee) now consists of the following:

Gary B. Robnett, M.D., Chief, Radiology Service
Roger S. Birnbaum, Ph.D., Research Service
Eugene Wales, Administrative Assistant to Chief of Staff
Samuel D. Mires, R.T., Supervisory Radiology Technologist
Charlotte Brown, R.N., Nursing Service

6. Request Appendix J be changed as indicated on the one enclosed.

William E. Claypool

WILLIAM E. CLAYPOOL
Medical Center Director

Attachments 3

APR 18 1985

JAMES J. SMITH, M. D. (115)
Director, Nuclear Medicine Service
VA Central Office
Washington, D.C. 20420

NRC FORM 313M SUPPLEMENT A (9-81) — U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
BIRNBAUM, Roger S.	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	U.California, Berkeley, 1963, 1966, 1967. Brandeis Univ., 1967, 1968. U.Mass. Med. Ctr., 1971, 1972.	20 hr.	100 hr.
b. RADIATION PROTECTION	Brandeis Univ. U.Mass. Med. Ctr. Harvard Med. School, 1976, 1977.		10 hr.
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	U.California, Berkeley	5 hr.	
d. RADIATION BIOLOGY	Brandeis Univ. U.Mass. Med. Ctr.	5 hr.	5 hr.
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
^{3}H	15 mCi	U. Mass. Med. Ctr.	4 years	In vitro
		CWRU, Cleveland	1 year	"
		VAMC, Cleveland	6 years	"
^{14}C	1 mCi	U. Mass. Med. School	4 years	"
^{35}S	10 mCi	VAMC, Cleveland	6 years	"
^{32}P	5 mCi	U. Mass. Med. Ctr.	1 year	Enzyme Assays
		VAMC, Cleveland	1 year	In vitro
^{125}I	10 mCi	Harvard Med. School	2 years	RIA
		VAMC, Cleveland	6 years	"

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NRC FORM 313M SUPPLEMENT A (9-81) — U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1 NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2 STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Douglas M. Burns, Ph.D.	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Univ. of Missouri, Columbia 1971 & 1973, 1974 & 1975 Vanderbilt Univ. Med. School 1975-1980, 1977 RSO Course	15 6	15 30
b. RADIATION PROTECTION	Same as above	5 6	15 30
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Same as above	15 6	15 30
d. RADIATION BIOLOGY	Same as above	- -	15 30
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
^{32}P	2mCi	Univ. of Missouri, Columbia	16 months	In vitro
"	2mCi	Vanderbilt Univ. Med. School	12 months	In vivo
"	1mCi	Cleveland VA Medical Center	36 months	In vitro
^{35}S	5 mCi	Cleveland VA Medical Center	36 months	In vitro
^{14}C	1mCi	Univ. of Missouri, Columbia	16 months	"&enzyme assay
	1mCi	Vanderbilt Univ. Med. School	36 months	"&enzyme assay
	1mCi	Cleveland VA Medical Center	36 months	"&enzyme assay
^{125}I	1mCi	Vanderbilt Univ. Med. School	24 months	In vitro & protein labeling
^{3}H	1mCi	Univ. of Missouri, Columbia	16 months	In vitro
"	1mCi	Vanderbilt Univ. Med.School	24 months	" & In vivo

NRC FORM 313M SUPPLEMENT A (9-81) — U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
GKONOS, Peter J.	Washington

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Internal Medicine	Medicine	9/81
Endocrinology	Medicine	11/83

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	University of Michigan 1971 - 1973 (Physics & Chemistry)	4-6	
b. RADIATION PROTECTION	Yale School of Medicine	2	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	University of Michigan (Physics & Chemistry)	3-4	
d. RADIATION BIOLOGY	Thomas Jefferson University 1975 - 1976	2	
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
^{3}H	5 mCi	Yale School of Medicine	1981 - 1983	In vitro
		CWRU, Cleveland	1984	"
^{32}P	250 uCi	Yale School of Medicine	1981 - 1983	"
^{125}I	1 mCi	CWRU, Cleveland	1984	"
^{35}S	5 mCi	CWRU, Cleveland	1984	"

NRC FORM 313M SUPPLEMENT B
(9-81)

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME
GKONOS, Peter J.

STREET ADDRESS
11426 105th Ave., S.W., Apt. N-4

CITY	STATE	ZIP CODE
Tacoma	WA	98498

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION		
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING		
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER			
Tc 99m	BRAIN IMAGING		
	CARDIAC IMAGING		
	THYROID IMAGING		
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING		
	LUNG IMAGING		
	BONE IMAGING		
OTHER			

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other ^{125}I ^{35}S ^{3}H	Radioiodination of peptides with ^{125}I Labeling of cells in vitro with ^{35}S and ^{3}H amino acids		Training in these techniques for six months with Dr. Bernard Roos.

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Bernard A. Roos

b. NAME OF INSTITUTION
VA Medical Center/CWRU

c. MAILING ADDRESS
10701 East Boulevard

d. CITY
Cleveland, OH 44106

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE

7. PRECEPTOR'S NAME *(Please type or print)*
Bernard A. Roos
Bernard A Roos

8. DATE
3/26/85

NRC FORM 313M SUPPLEMENT B
(9-81)

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GPO 890-913

NRC FORM 313M SUPPLEMENT A (9-81) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
OSTENSON, RICHARD CLARENCE	WASHINGTON

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Internal Medicine		Sept. 1978
Medical Oncology		Nov. 1981

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION			
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY	University of Washington School of Medicine, 1971	10	
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
^{3}H	20 mCi/expt	Univ. of Arkansas Medical Ctr., Little Rock	1977 - 1978	In vitro
^{3}H	30 mCi/expt	Fred Hutchinson Cancer Ctr., Seattle	1978 - 1984	"
^{125}I	10 mCi/expt	VAMC, Tacoma	1978 - 1984	"
^{51}Cr	10 mCi/expt	FHCRC, Seattle	1978 - 1981	"

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
ROOS, BERNARD ALLEN	WASHINGTON

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Internal Medicine	Medicine	June 1975

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES *(Hours)* C	SUPERVISED LABORATORY EXPERIENCE *(Hours)* D
a. RADIATION PHYSICS AND INSTRUMENTATION			
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
^{3}H	30mCi/expt	UCSD, San Diego	1970 - 1977	In Vitro
"	"	CWRU, Cleveland	1977 - 1984	"
^{14}C	5mCi/expt	CWRU, Cleveland	1977 - 1984	"
^{35}S	10mCi/expt	CWRU, Cleveland	1977 - 1984	"
^{32}P	10mCi/expt	CWRU, Cleveland	1977 - 1984	"
^{125}I	10mCi/expt	CWRU, Cleveland	1977 - 1984	"

NRC FORM 313M SUPPLEMENT B
(9-81)

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

BERNARD A. ROOS

STREET ADDRESS

70 SILVER BEACH DRIVE

CITY	STATE	ZIP CODE
STEILACOOM	WA	98388

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION		$Na^{125}I$ was used to radioiodinate peptides by oxidation methods based on chloraminet or lactoperoxidase. These peptides were used for radioimmunoassay.
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES	500	
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING		
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER			
Tc-99m	BRAIN IMAGING		
	CARDIAC IMAGING		
	THYROID IMAGING		
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING		
	LUNG IMAGING		
	BONE IMAGING		
OTHER			

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other ^{125}I	Radioimmunoassay	10 years	Radioiodination of peptides and radioimmunoassay were learned from Dr. Leonard J. Deftos. (see below)

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
LEONARD J. DEFTOS, M.D.

b. NAME OF INSTITUTION
VA MEDICAL CENTER

c. MAILING ADDRESS
3350 La Jolla Village Dr.

d. CITY
SAN DIEGO, CA 92131

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE
x L J Deftos MD

7. PRECEPTOR'S NAME *(Please type or print)*
x L.J. DEFTOS

8. DATE
x 1/31/85

NRC FORM 313M SUPPLEMENT B
(9-81)

GPO 890-813

NRC FORM 313M SUPPLEMENT A (9-81) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Charles W. Wilkinson, Ph.D.	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Univ. of Michigan, Ann Arbor 1965	10	
b. RADIATION PROTECTION	Univ. of Calif., Santa Barbara 1974 Mt. Sinai Sch. Med., New York 1981		30 15
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Univ. of Calif., Santa Barbara 1974		40
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
H^3	100 µCi	U. Calif., Santa Barbara	2 years	PIA
H^3	50 µCi	U. Calif., San Francisco	1 year	RIA
H^3	100 µCi	Mt. Sinai Sch. Med., N.Y.	1 year	autoradiography & binding
I^{125}	2 mCi	Mt. Sinai Sch. Med., N.Y.	1 year	RIA & iodination
I^{125}	2 mCi	VA Med. Ctr., Seattle	2 years	RIA & iodination

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NRC FORM 313M SUPPLEMENT A (9-81) — U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
STEPHEN M. LOOP	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Washington State Univ., Pullman, WA, 1973 Fred Hutchinson CRC, 1975-80	6	100
b. RADIATION PROTECTION	Fred Hutchinson CRC, Seattle, WA, 1975-82	4	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Univ. of Wash., Seattle, 1981 Fred Hutchinson CRC, 1975-80 WSU, 1975 Univ. of Wash., Seattle, 1981	3 3 3	20
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
^{51}Cr	10 mCi	Fred Hutchinson Cancer Research Center 1124 Columbia St. Seattle, WA 98104	1975 - 1982	Release Assays
^{125}I	20 mCi			Protein Iodin.
^{131}I	10 mCi			Protein Iodin.
^{3}H	3 mCi			Isotope Incorp.
X-ray machine - Cesium Source		Roswell Park Memorial Institute 666 Elm St. Buffalo, N.Y.	1973	Animal Irradiation.

Amendment Number 2 in accordance with application and attachments dated

STATE OF WASHINGTON

RADIOACTIVE MATERIALS LICENSE

Pursuant to the Nuclear Energy and Radiation Control Act, RCW 70.98, and the Radiation Control Regulations, Part III, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to transfer, receive, possess and use the radioactive material(s) designated below; and to use such radioactive materials for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules and regulations promulgated by the State Department of Social and Health Services.

Licensee		3. License number	WN-M0151-1 is amended in its entirety to read as follows:
1. Name	ALLENMORE COMMUNITY HOSPITAL	4. Expiration date	June 30, 1985
2. Address	South 19th and Union Street Tacoma, Washington 98405	5. Reference number	Previously WN-M0080-1 (06-14-81) (10-17-81) (06-22-82)

6. Radioactive materials (element and mass number)	7. Chemical and/or physical form	8. Maximum quantity licensee may possess at any one time
A. Any radioactive material as defined in Groups I and II of Schedule A, WAC 402-22-200.	A. Any radiopharmaceutical as defined in Groups I and II of Schedule A, WAC 402-22-200.	A. As necessary for uses authorized in Subitem 9.A.
B. Any radioactive material as defined in Group III of Schedule A, WAC 402-22-200.	B. Any form as defined in Group III of Schedule A, WAC 402-22-200.	B. 2 Curies of each radioactive material authorized in Subitem 6.B.
C. Any radioactive material as defined in Group IV of Schedule A, WAC 402-22-200.	C. Any radiopharmaceutical as defined in Group IV of Schedule A, WAC 402-22-200.	C. As necessary for uses authorized in Subitem 9.C.
D. Any radioactive material as defined in Group V of Schedule A, WAC 402-22-200.	D. Any radiopharmaceutical as defined in Group V of Schedule A, WAC 402-22-200.	D. As necessary for uses authorized in Subitem 9.D.
E. Any radioactive material as defined in Group VI of Schedule A, WAC 402-22-200.	E. Any source or device as defined in Group VI of Schedule A, WAC 402-22-200.	E. As necessary for uses authorized in Subitem 9.E.
F. Radium 226.	F. Sealed sources (Platinum-iridium needles, leased from Radium Chemical Co., Inc.).	F. 100 millicuries.

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9. Authorized use. (Unless otherwise specified, the authorized place of use is the licensee's address stated in Item 2.

   A. Any diagnostic procedure as defined in Groups I and II of Schedule A, WAC 402-22-200.

   B. Preparations and use of radiopharmaceuticals for any diagnostic procedure as defined in Group III of Schedule A, WAC 402-22-200, including Molybdenum 99/Technetium 99m generators (approved models) for preparation of Tc99m.

   C. Any therapeutic procedure as defined in Group IV of Schedule A, WAC 402-22-200.

   D. Any therapeutic procedure as defined in Group V of Schedule A, WAC 402-22-200.

   E. Any therapeutic procedure as defined in Group VI of Schedule A, WAC 402-22-200.

   F. Intracavitary treatment of cancer.

10. The licensee shall comply with the provisions of Chapter 402-24 WAC, "Standards for Protection Against Radiation"; Chapter 402-10 WAC, "Statement of Philosophy"; Chapter 402-12 WAC, "General Provisions"; Chapter 402-48 WAC, "Notices, Instructions and Reports to Workers by Licensees or Registrants - Inspections"; and Chapter 402-22 WAC "Specific Licenses."

11. Radioactive material shall be used by, or under the supervision of, Kenneth Gross, M.D.; Vernon Larson, M.D.; Robert Whitney, Jr., M.D.; and John Flood, M.D.

12. The Radiation Protection Officer for this program shall be Vernon Larson, M.D.

13. Radioactive material to be administered to humans shall be the subject of an FDA-approved "New Drug Application" (NDA) or an FDA-accepted "Notice of Claimed Investigational Exemption for a New Drug" (IND).

14. A. Technetium 99m separated from molybdenum 99 either by elution of a molybdenum 99/technetium 99m generator or by an extraction process shall be tested to detect and quantify molybdenum 99 activity prior to administration to patients.

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B. The licensee shall not administer to patients technetium 99m containing more than one (1) microcurie of molybdenum 99 per millicurie of technetium 99m or more than five (5) microcuries of molybdenum 99 per dose of technetium 99m at time of administration. The limits for molybdenum 99 contamination represent maximum values and molybdenum 99 contamination should be kept as low as reasonably achievable below these limits.

C. In the absence of a certificate from a supplier for technetium 99m which specifies the quantity of molybdenum, the licensee shall establish written procedures for personnel performing tests to detect and quantify molybdenum 99 contamination. These procedures shall include all necessary calculations and steps to be taken if activities of molybdenum 99 in excess of the limits specified in subitem B above are detected.

D. Personnel performing tests to detect and quantify molybdenum 99 contamination shall be given specific training in performing these tests prior to conducting such tests.

E. 1. The licensee shall maintain for inspection by the department records of the results of each test performed to detect and quantify molybdenum 99 contamination and records of training given to personnel performing these tests.

2. Records described in subitem E.1 above shall be maintained for two (2) years following the performance of the tests and the training of personnel.

15. A. Radioactive material to be administered to humans shall be assayed for activity to determine the dose within 10% accuracy prior to being administered to patients.

B. In the absence of a certificate from a supplier which specifies the activity of each dose, the licensee shall establish written procedures for personnel to perform assays to an accuracy of 10% prior to being administered to patients.

C. 1. The licensee shall maintain for inspection by the department records of the results of each assay performed to determine the activity of each dose administered to a patient.

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2. Records described in subitem C.1 above shall be maintained for two (2) years following the performance of the assay.

16. Patients administered Iodine 131 or Gold 198 for therapeutic purposes shall remain hospitalized until the residual activity is 30 millicuries or less.

17. Patients containing Cobalt 60, Cesium 137 or Iridium 192 implants shall remain hospitalized until a source count and surveys made with an appropriate radiation detection instrument indicate that all implants have been removed. The results of these surveys shall be recorded and maintained for inspection by the department for five (5) years from the time the implants are removed.

18. A. 1. Each sealed source containing licensed material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.

2. Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the department.

C. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with department regulations. A report shall be filed within five (5) days of the test with the department describing the equipment involved, the test results, and the corrective action taken.

D. Tests for leakage and/or contamination shall be performed by persons specifically authorized by the department, the Nuclear Regulatory Commission or an Agreement State to perform such services.

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19. The transport of licensed material by the licensee, or the delivery of licensed material to a carrier for transport, shall be in accordance with the provisions of Section 71.5, Title 10, Code of Federal Regulations, Part 71, "Packaging of Radioactive Materials for Transport."

20. Sealed sources containing licensed material shall not be opened.

21. Except as specifically provided by this license, the licensee shall possess and use radioactive material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in the documents listed below. The department's "Rules and Regulations for Radiation Protection" shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

    A. Application and attachments dated May 26, 1981.

    B. Letter dated October 16, 1981.

    C. Letter dated June 11, 1982.

FOR THE STATE DEPARTMENT OF SOCIAL AND HEALTH SERVICES

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Date June 24, 1982
NPK/JPM

By Jerry C. Draper
for Nancy P. Kirner, Supervisor
Radioactive Materials Unit

APPENDIX J

WASTE DISPOSAL

Note: In view of the recent problems with shallow-land burial sites used by commercial waste disposal firms, NRC is encouraging its licensees to reduce the volume of wastes sent to these facilities. Important steps in volume reduction are to segregate radioactive from nonradioactive waste, to hold short-lived radioactive waste for decay in storage, and to release certain materials in the sanitary sewer in accordance with §20.303 of 10 CFR Part 20.

1. Liquid waste will be disposed of (check as appropriate)

__X__ In the sanitary sewer system in accordance with §20.303 of 10 CFR Part 20.

__X__ By commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

_____

2. Mo-99/Tc-99m generators will be (check as appropriate)

_____ Returned to the manufacturer for disposal.

_____ Held for decay* until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the generators will be disposed of as normal trash.**

__X__ Disposed of by commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

_____

3. Other solid waste will be (check as appropriate)

_____ Held for decay* until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the waste will be disposed of in normal trash.

__X__ Disposed of by commercial waste disposal service (see also Item 4 below).

__X__ Other (specify): _____

_____

4. The commercial waste disposal service used will be

RALPH M. BALTZO (Name) SEATTLE, WA (City, State)

NRC/Agreement State License No. WN-L041-1

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* Be sure that waste storage areas were described in Item 11 and that they are surveyed periodically (Item 17).

** These generators may contain long-lived radioisotopic contaminants. Therefore, the generator columns will be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

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