Madison General Hospital
Department of Radiology
202 S. Park Street
Madison, WI 53715
July 27, 1979

John W. Cooper, Ph.D., Chief
Regional Licensing Section
License Management Branch
Division of Fuel Cycle and
Material Safety
Nuclear Regulatory Commission
799 Roosevelt Road
Glen Ellyn, IL 60137

Dear Dr. Cooper:

Re: Control No. 01819

Enclosed please find two copies of our reply to your request for additional information regarding our renewal of Byproduct Material License No. 48-00395-02. We have addressed each item of your request individually.

To assist us in matters of radiological safety, we have retained the services of Dr. Paul DeLuca. A copy of his experience and training history is enclosed. Dr. Luca is presently employed by the University of Wisconsin, Madison, where he acts as director of the M.S. program in Radiological Sciences - Health Physics Option. Dr. DeLuca will serve on our Radionuclide Committee and advise us in all aspects of radiation safety.

I am also enclosing preceptor statements for Dr. Edward Ehrlich and Dr. Samuel Shih. Dr. Ehrlich is an internist doing research using small quantities of carbon 14 and tritium. The amounts on hand at any one time do not exceed 1 millicurie. Dr. Shih is head of the Department of Pathology and supervises in vitro radionuclide tests.

I hope the enclosed additional information will assist you in our license renewal. Thank you for your attention to this matter.

Sincerely yours,

John S. Edwards

John S. Edwards, M.D.

JSE/smw

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	R. S. Landauer, Jr. & Co.	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	R. S. Landauer, Jr. & Co.	Monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED *(See Section 170.31, 10 CFR 170)*

(1) LICENSE FEE CATEGORY:

(2) LICENSE FEE ENCLOSED: $

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)* John S. Edwards, MD

(1) NAME (Type or Print) John S. Edwards

(2) TITLE Director Nuclear Radiology

c. DATE 2-27-79

FORM NRC-313M (8-78)

FORM NRC-313M-SUPPLEMENT A (8-78) 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
John S. Edwards, M.D. Edward N. Ehrlich, M.D. - Applicant	WI

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Internal Medicine		November 1962

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	Initial experience at the Endocrine Division of the National Heart Institute regarding double isotope derivative assay for aldosterone; subsequently established isotope derivative assays for measuring urinary aldosterone, cortisol and corticosterone as a member of the Endocrine Section, University of Chicago, Department of Medicine. Later developed steroid binding methods utilizing tritiated steroids for in vitro measurements of plasma free steroid indexes. This was all under the supervision of Bernard Kliman, M.D. Currently developing assay procedures for measuring specific binding in vitro of corticoids to human lymphocytes.		
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
C14 & H3	1 mC	See above	18 years	No patient or other in vivo use.

FORM NRC-313M-SUPPLEMENT B
(8-78)

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
Edward N. Ehrlich, M.D.

STREET ADDRESS
202 South Park Street

CITY: Madison | STATE: WI | ZIP CODE: 53715

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	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME	NA	
	LIVER FUNCTION STUDIES	NA	
	FAT ABSORPTION STUDIES	NA	
	KIDNEY FUNCTION STUDIES	NA	
	IN VITRO STUDIES	NA	
OTHER			
I-125	DETECTION OF THROMBOSIS	NA	
I-131	THYROID IMAGING	NA	
P-32	EYE TUMOR LOCALIZATION	NA	
Se-75	PANCREAS IMAGING	NA	
Yb-169	CISTERNOGRAPHY	NA	
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	NA	
OTHER			
Tc-99m	BRAIN IMAGING	NA	
	CARDIAC IMAGING	NA	
	THYROID IMAGING	NA	
	SALIVARY GLAND IMAGING	NA	
	BLOOD POOL IMAGING	NA	
	PLACENTA LOCALIZATION	NA	
	LIVER AND SPLEEN IMAGING	NA	
	LUNG IMAGING	NA	
	BONE IMAGING	NA	
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	NA	These designated clinical activities were all performed in the Thyroid Clinic at the Univ. of Chicago under the supervision of Drs. Alexander Gottschalk and Leslie DeGroot.
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT	NA	
I-131	TREATMENT OF THYROID CARCINOMA	>100	
	TREATMENT OF HYPERTHYROIDISM	>500	
Au-198	INTRACAVITARY TREATMENT	NA	
Co-60 or Cs-137	INTERSTITIAL TREATMENT	NA	
	INTRACAVITARY TREATMENT	NA	
I-125 or Ir-192	INTERSTITIAL TREATMENT	NA	
Co-60 or Cs-137	TELETHERAPY TREATMENT	NA	
Sr-90	TREATMENT OF EYE DISEASE	NA	
	RADIOPHARMACEUTICAL PREPARATION	NA	
Mo-99/ Tc-99m	GENERATOR	NA	
Sn-113/ In-113m	GENERATOR	NA	
Tc-99m	REAGENT KITS	NA	
Other			

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

Approved by the Radiation Protections Committee, headed by Dr. Melvin Griem, Department of Radiology, University of Chicago for prescribing radioactive iodine clinically in treatment of hyperthyroidism and thyroid cancer, 1960-1974.

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

a. NAME OF SUPERVISOR
Melvin Griem, M.D.

b. NAME OF INSTITUTION
University of Chicago

c. MAILING ADDRESS
950 East 59th Street

d. CITY
Chicago, IL 60637

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE

Edward N. Ehrlich.

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

Edward N. Ehrlich, M.D.

8. DATE

7/27/79

FORM NRC-313M-SUPPLEMENT B
(8-78)

CURRICULUM VITAE

Edward Norman Ehrlich

Date of Birth: September 20, 1928, Detroit Michigan

Married, three children: Lisa born 1962, Joel 1966, Janet 1969

B.S. University of Michigan, 1948
M.D. University of Michigan Medical School, 1952

1952-53 Intern, Wayne County General Hospital, Eloise, Michigan
1953-54 Resident in Medicine, Wayne County General Hospital, Eloise, Michigan
1954-57 Active Duty USNR, Medical Officer in Little America V, Operation Deepfreeze I, 1955-57
1957-60 Resident in Medicine, The University of Chicago, Chicago, Illinois
1960-61 Instructor in Medicine, The University of Chicago, Chicago
1962-68 Assistant Professor of Medicine, The University of Chicago, Chicago
1968-73 Associate Professor of Medicine, The University of Chicago, Chicago
1973-74 Professor of Medicine, The University of Chicago, Chicago
1974- Professor of Medicine, University of Wisconsin, Medical School, Associate Chairman Department of Medicine and Head, Endocrinology Section. Coordinator of University of Wisconsin Medical Teaching Service, Madison General Hospital

Internal Medicine Boards, November 8, 1962

USPHS Research Career Development Award, July 1964

MEMBERSHIPS:

American Association for the Advancement of Science
American Federation for Clinical Research
American Polar Society
Central Society for Clinical Research
Central Research Club
Chicago Society for Internal Medicine
Endocrine Society
Madison Academy of Internal Medicine
Society for Gynecologic Investigation

EDWARD N. EHRLICH

Publications

1. Ehrlich, E.N. and Landau, R.L.: Diagnosis of Occult and Borderline Disorders of the Thyroid. Med. Clin. of North Amer., 44:209-223, Jan., 1960.

2. Ehrlich, E.N., Laves, M., Lugibihl, K. and Landau, R.L.: Progesterone-Aldosterone Interrelationships in Pregnancy. J. Lab. & Clin. Med., 59:588, April, 1962.

3. Landau, R.L., Ehrlich, E.N., and Huggins, C.: Estradiol Benzoate and Progesterone in Advanced Human Breast Cancer. J.A.M.A., 182:632-636, Nov., 1962.

4. Ehrlich, E.N.: Aldosteronism and Hypertension, Med. Clin.of North Amer. 47:41-52, Jan., 1963.

5. Ehrlich, E.N., Dominguez, O.V., Samuels, L.T., Lynch, D., Oberhelman, H., and Warner, N.: Aldosteronism and Precocious Puberty Due to an Ovarian Androblastoma (Sertoli Cell Tumor). J. Clin. Endocrinol. & Metab., 23:358-367, April, 1963.

6. Ehrlich, E.N., Lugibihl, K., and Landau, R.L.: The Anabolic Influence of Aminopyrine. Metabolism, 13:799-807, Sept. 1964.

7. Frenkel, M. and Ehrlich, E.N.: The Influence of Progesterone and Mineralocorticoids upon Myasthenia Gravis. Ann. of Int. Med., 60: 971-981, June, 1964.

8. Ehrlich, E.N.: A Method for Measuring Urinary Pregnanediol by a Double Isotope Derivative Dilution Technique Utilizing Thin Layer Chromatography. J. of Lab. & Clin. Med., 65:869-882, May, 1965.

9. Ehrlich, N.E.: Reciprocal Variations in Urinary Cortisol and Aldosterone in Response to Increased Salt Intake in Humans. J. Clin. Endocrinol. & Metab., 26:1160-1169, Oct., 1966.

10. Ehrlich, E.N.: Reciprocal Variations in Urinary Cortisol and Aldosterone in Response to the Sodium Depleting Influence of Hydrochlorothiazide and Ethacrynic Acid in Humans. J. Clin. Endocrinol. & Metab., 27: 836-842, June, 1967.

11. Ehrlich, E.N.: Aldosterone, the Adrenal Cortex, and Hypertension. Ann. Rev. Med., 19:373-398, 1968.

12. Ehrlich, E.N., and Crabbe, J.: The Mechanism of Action of Amipramizide. Pflugers Archiv. 302:79, 1968.

13. Crabbe, J., and Ehrlich, E.N.: Amiloride and the Mode of Action of Aldosterone on Sodium Transport Across Toad Bladder and Skin. Pflugers Archiv. 304:284, 1968.

14. Ehrlich, Edward N., Straus, Francis H., II, Hunter, Robert L., and Wiest, Walter G.: Cytomegalic Adrenocortical Hypoplasia and Increased Plasma 20α-Hydroxypregn-4-en-3-one in a Man Exhibiting the Features of Selective Mineralocorticoid Deficiency. Journal of Clinical Endocrinology and Metabolism 29:523, 1969.

15. Ehrlich, E.N.: Cortisol Responses to Diazoxide in Man and their Possible Relationship to Effective Blood Volume. Metabolism 19:469-479, 1970.

16. Konsek, J.P., Rubenstein, A.H., and Ehrlich, E.N.: The Biologic Action of Proinsulin on Ventral Toad Skin in Vitro. Endocrinology 89(3):847-851, 1971.

17. Ehrlich, E.N.: Heparinoid-Induced Inhibition of Aldosterone Secretion in Pregnant Women. The Role of Augmented Aldosterone Secretion in Sodium Conservation during Normal Pregnancy. Amer. J. Obstet. Gynec. 109:963-970, 1971.

18. Rosenfield, R.L., Ehrlich, E.N., and Cleary, R.E.: Adrenal and Ovarian Contributions to the Elevated Free Plasma Androgen Levels in Hirsute Women. J. Clin. Endocr. Metab. 34(1):92-98, 1972.

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20. Ehrlich, Edward N. and Lindheimer, M.D.: Sodium Metabolism, Aldosterone and the Hypertensive Disorders of Pregnancy. J. Reproductive Medicine 8(3):106-110, 1972.

21. Ehrlich, E.N. and Lindheimer, M.D.: Effect of Administered Mineralocorticoids or ACTH in Pregnant Women. Attenuation of Kaliuretic Influence of Mineralocorticoids during Pregnancy. J. Clin. Invest. 51(6):1301-1309, 1972.

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23. Refetoff, S., Block, M.B., Ehrlich, E.N., Friesen, H.G.: Chiari-Frommel Syndrome in a Patient with Primary Adrenocortical Insufficiency: Cure by Glucocorticoid Replacement. New England Journal of Medicine 287:1326-1328, 1972.

24. Lindheimer, M.D., del Greco, F. and Ehrlich, E.N.: Postural Effects on Na and Steroid Excretion, and Serum Renin Activity During Pregnancy. J. Applied Physiol. 35(3):343-348, 1973.

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28. Ehrlich, E.N.: Sodium Metabolism in Pregnancy: Current View. Contemporary OB/Gyn 4:17, 1974.

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Abstracts

1. Ehrlich, E.N., Laves, M., and Landau, R.L.: Progesterone-Aldosterone Interrelationships in Pregnancy. J. Lab. & Clin. Med., 56:806, Nov., 1960. (Presented to the Central Society for Clinical Research, November, 1960)

2. Ehrlich, E.N., Lugibihl, K., and Landau, R.L.: The Anabolic Influence of Aminopyrine. J. Lab. Clin. Med., 58:815, Nov., 1961.

3. Ehrlich, E.N., Samuels, L.T., Lynch, D., Oberhelman, H., and Warner, N.: Aldosteronism and Precocious Pseudopuberty Associated with an Ovarian Sertoli Cell Tumor. Presented at the Endocrine Society, June, 1962.

4. Ehrlich, E.N., Laves, M., Loggies, T., and Lugibihl, K.: Influence of Spironolactone upon Progesterone-Aldosterone Interrelationships in Pregnancy. (Presented at 35th Annual Meeting of the Central Society for Clinical Research), J. Lab. Clin. Med., 60:871, Nov., 1962.

5. Ehrlich, E.N.: The Influence of Dietary Salt upon Urinary Cortisol in Human Subjects. J. Lab. Clin. Med. 64:854, Nov., 1964.

6. Ehrlich, E.N.: The Salt Losing Effect of Adrenocorticoids in Man. In the Program of the 47th Meeting of the Endocrine Society, June 1965, p. 86.

7. Ehrlich, E.N.: Glucocorticoid Responses to Salt Depletion in Humans. In the Program of the 48th Meeting of the Endocrine Society, June, 1966.

8. Ehrlich, E.N. and Lawrence, A.M.: Adrenocortical Responses in Humans to Ethacrynic Acid, Hydrochlorothiazide and Diazoxide. J. Lab. Clin. Med. 68:871, Nov., 1966.

9. Ehrlich, E.N. and Crabbe, J.: Reversible Inhibition of Active Sodium Transport In Vitro. Clin. Res. 16:382, 1968.

10. Ehrlich, E.N., Eigler, J., and Crabbe, J.: Reversible Inhibition of Active Sodium Transport by Amphibian Epithelia Upon Espoxure to Amipramizide. Program European Society for Clin. Invest. (Presented at 2nd Annual Meeting, Scheveningen, Netherlands, April 27, 1968.)

11. Ehrlich, E.N. and Wiest, W.G.: Adrenal Hyperplasia with Unusual Steroid Pattern in an Adult Exhibiting Hypoaldosteronism. Presented at the Meeting of the Third International Cong. of Endocrinol., Mexico, D.F. July 5, 1968. To be published in Proceedings of Third International Cong. of Endocrinol.

12. Crabbe, J. and Ehrlich, E.N.: Amipramizide and Mechanism of Hormonal Stimulation of Active Sodium Transport by Toad Skin. In Proceedings of the International Union of Physiological Sciences, VII(XXIV, International Congress, Washington, D.C., 1968. (Presented at International Union of Physiological Sciences, Washington, D.C., Aug. 31, 1968)

13. Ehrlich, E.N.: Effects of Heparinoid ROI-8307 upon Urinary Aldosterone and Pregnanediol in Pregnancy. Program Fifty-First Meeting, The Endocrine Society, 1969.

14. Konsek, J.P., Rubenstein, A.H., and Ehrlich, E.N.: The Biologic Action of Proinsulin on Ventral Toad Skin in Vitro. J. Lab. Clin. Med. 74:894, 1969 (Presented at 42nd Meeting Central Society Clinical Research, October 31-November 1, 1969).

15. Rosenfield, R.L., Ehrlich, E.N., and Cleary, R.E.: Physiologic Studies in Hirsutism. Program Fifty-Second Meeting, The Endocrine Society, 1970, p. 76.

16. Ehrlich, E.N. and Lindheimer, M.D.: Effect of Mineralocorticoid and Adrenocorticotropic Hormone Administration on Electrolyte and Aldosterone Excretion in Normal Gravid Women: Absence of Kaliuresis Despite Corticoid-induced Sodium Retention. J. Lab. Clin. Med. 76:1034-1035, 1970.

17. Ehrlich, E.N. and Lindheimer, M.D.: Dissociation of Sodium-Retaining and Kaliuretic Effects of Mineralocorticoids in Pregnancy. J. Clin. Invest. 50:27a, 1971.

18. Ehrlich, E.N. and Lindheimer, M.D. (Intr. by F.P. Zuspan): The Role of Aldosterone in Pregnancy: Evidence for a Dissociation between Its Renal Tubular Effects on Sodium (Na) and Potassium (K). Presented at Soc. Gynec. Invest., April, 1971.

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20. Amarose, A.P. and Ehrlich, E.N.: Klinefelter Phenotype in an XY Male. Presented at Fourth International Congress of Human Genetics, Paris, France, September 6-11, 1971.

21. Lindheimer, M.D. and Ehrlich, E.N.: Diurnal Variations of Electrolyte, Nonelectrolyte Solute, and Steroid Excretion in Gravidas: Influence of Posture on these Rhythms. Presented at Society Gynec. Invest., March, 1972, p. 33.

22. Refetoff, S., Block, M., Ehrlich, E.N., and Friesen, H.G.: Chiari-Frommel Syndrome (C-Fs) in a Patient with Primary Adrenocortical Insufficiency (PACI): Cure by Glucocorticoid Replacement. Clin. Res. April, 1972.

23. Ehrlich, E.N., Siddiqui, F. and Rubenstein, A.H.: Biologic Action and Tissue Binding of Insulin in Ventral Toad Skin. IV International Congress of Endocrinology, June, 1972, p. 168.

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25. Lindheimer, M.D., Ehrlich, E.N., and Oparil, S.: Evidence for an Effect of Progesterone (P) on Proximal Tubular Na^+ Reabsorption in Man. Clin. Res. 20(4):763, Oct., 1972.

26. Ehrlich, E.N., Biglieri, E.G. and Lindheimer, M.D.: ACTH-Induced Na^+ Retention in Normal Gravidas: Role of Corticosterone (B) and Desoxycorticosterone (DOC). Proc. Soc. Gynec. Invest. March 1973. (Accepted for presentation)

27. Lindheimer, M.D., Ehrlich, E.N. and Oparil, S.: Effects of Progesterone (P) on Intrarenal Na^+ Handling in Man. Proc. Soc. Gynec. Invest. March 1973.

28. Lindheimer, M.D., Ehrlich, E.N. and Oparil, S.: Evidence for Non-aldosterone Dependent Saluretic Effect of Progesterone (P). Clin. Res. 21(4):895, October 1973.

29. Nolten, W.E., Lindheimer, M.D., Oparil, S., Rueckert, P.A., and Ehrlich, E.N.: Regulation of Desoxycorticosterone (DOC) in Pregnancy. Clin. Res. 23:516A, 1975. (Presented at 48th Annual Meeting, Central Society for Clinical Research, November 7, 1975).

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37. Nolten, W.E., Lindheimer, M.D., Oparil, S., Ehrlich, E.N.: Changing Patterns of Corticoid Responses to ACTH During Normal Pregnancy. Clin Res 25:606A, 1977.

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42. Nolten, W.E., Rueckert, P.A. and Ehrlich, E.N.: Regulation and Source of Increased Desoxycorticosterone Secretion in Pregnancy.

FORM NRC-313M-SUPPLEMENT A (8-78) 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
John S Edwards, M.D.	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Anatomic Pathology		May, 1971
American Board of Clinical Pathology		May, 1971
American Board of Nuclear Medicine		May, 1972

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	Mayo Clinic, 1970-1971	20	40
b. RADIATION PROTECTION	Mayo Clinic, 1970-1971	5	10
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Mayo Clinic, 1970-1971	10	20
d. RADIATION BIOLOGY	Mayo Clinic, 1970-1971	20	20
e. RADIOPHARMACEUTICAL CHEMISTRY	Mayo Clinic, 1970-1971	15	30

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
^{125}I	50 uCi	Mayo Clinic	9 years	In Vitro
^{99m}Tc	20 mCi	U. of WI Hospitals		In Vivo
^{51}Cr	10 uCi	Madison General Hospital		In Vivo
^{131}I	100 mCi			In Vivo
^{57}Co	5 uCi			In Vivo
^{59}Fe	5 uCi			In Vitro

FORM NRC-313M-SUPPLEMENT B
(8-78)

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

Samuel C. Shih, M.D.

STREET ADDRESS

36 South Brooks Street

CITY	STATE	ZIP CODE
Madison	WI	53715

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	>1000	Both In-Vitro & In-Vivo uses
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME	100	
	LIVER FUNCTION STUDIES	10	
	FAT ABSORPTION STUDIES	10	
	KIDNEY FUNCTION STUDIES	10	
	IN VITRO STUDIES	>10000	
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING	20	
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING	20	
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	20	
OTHER			
Tc-99m	BRAIN IMAGING	> 500	
	CARDIAC IMAGING	20	
	THYROID IMAGING	50	
	SALIVARY GLAND IMAGING	5	
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION	20	
	LIVER AND SPLEEN IMAGING	> 300	
	LUNG IMAGING	> 300	
	BONE IMAGING	> 300	
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	5	
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA	10	
	TREATMENT OF HYPERTHYROIDISM	10	
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	10	
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS	10	
Other			

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

June 30, 1971 2000 hours

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

a. NAME OF SUPERVISOR
W. Newlon Tauxe, M.D.

b. NAME OF INSTITUTION
Mayo Clinic

c. MAILING ADDRESS
200 First Street

d. CITY
Rochester, Minnesota 55901

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE

Samuel C. Shih

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

Samuel C. Shih, M.D.

8. DATE

July 23, 1979

FORM NRC-313M-SUPPLEMENT B
(8-78)

CURRICULUM VITAE

Samuel C. Shih, M.D.
December 13, 1938 - birthdate
Changhua, Taiwan, China - birthplace

Male
Married - 3 children
313 Shiloh Drive
Madison, Wisconsin 53705

APPOINTMENTS:

TEACHING:	Adjunct Professor of Medical Technology University of Wisconsin - LaCrosse, Oshkosh Stevens Point, Platteville, and Whitewater, WI	1976 - date
	Assistant Clinical Professor of Pathology University of Wisconsin Medical School Madison, Wisconsin	1972 - date
	Assistant Professor of Radiology and Pathology University of Wisconsin Medical School Madison, Wisconsin	1971 - 1972
HOSPITAL:	Chief Pathologist and Director of Laboratories Madison General Hospital Madison, Wisconsin	1976 - date
	Associate Pathologist Madison General Hospital Madison, Wisconsin	1972 - 1975
	Associate Director Nuclear Medicine Section Department of Radiology University Hospitals Madison, Wisconsin	1971 - 1972
COMMITTEES:	Scientific Program Committee Wisconsin Society of Pathologists	1974 - 1977
	Medical Advisor Committee of the Badger Regional Red Cross Blood Center Madison, Wisconsin	1977 - 1979
RESIDENCY:	Nuclear Medicine and Research Mayo Clinic Rochester, Minnesota	1970 - 1971

RESIDENCY (Cont.):

	Clinical Pathology Mayo Clinic Rochester, Minnesota	1968 - 1970
	Anatomic Pathology Institute of Laboratory Medicine Perth Amboy General Hospital Perth Amboy, New Jersey	1966 - 1968
INTERNSHIP:	Medical Center Jersey City, New Jersey	1965 - 1966
MILITARY SERVICE:	Medical Officer Hukou Army Hospital Taiwan, China	1964 - 1965
EDUCATION:	Kaohsiung Medical College Kaohsiung, Taiwan, China	1957 - 1964
HONORS:	Young Investigator Award, Central Chapter of the Society of Nuclear Medicine	1971

CERTIFICATIONS:

American Board of Nuclear Medicine	1972
American Board of Pathology, Anatomic and Clinical	1971
The Educational Council for Foreign Medical Graduates	1964

LICENSES: States of Washington, Wisconsin, and Indiana 1971

SOCIETIES:
Fellow, College of American Pathologists
Fellow, American Society of Clinical Pathologists
American Association of University Professors
Wisconsin Society of Pathologists
The Society of Nuclear Medicine
American Society for Microbiology
Mayo Alumni Association
Sigma Xi

PUBLICATIONS:

Gerard, A. G., Roth, A. L., Becker, S. M., and Shih, S. C.: Regression of Sarcoidhepatosplenomegaly on Corticosteroid Therapy, J. Med. Soc., New Jersey 65: 64-67, 1968.

Shih, S. C., Shuster, M., and Kline, D.: Testicular Feminization Syndrome; Report of a Case With Chromosome Studies, J. Med. Soc., New Jersey 66: 66-69, 1969.

PUBLICATIONS (Cont.):

Shih, S. C., Tauxe, W. N., and Fairbanks, V. F.: Studies of the Urinary Excretion of ^{51}Cr During Radiochromium-Tagged-Erythrocyte Survival Studies (Abstract), Amer. J. Clin. Path. 54: 269, 1970.

Shih, S. C., Tauxe, W. N., and Fairbanks, V. F.: The Kinetics of Urinary Excretion of ^{51}Cr From Labeled Erythrocytes in Hemolytic Anemia and the Anemia of Blood Loss, Amer. J. Clin. Path. 55: 431-437, 1971.

Shih, S. C., and Taswell, H. F.: Conversion of Anti-A to Anti-A_1 by Heat, Amer. J. Clin. Path. 55: 570-572, 1971.

Shih, S. C., Tauxe, W. N., Fairbanks, V. F., and Taswell, H. F.: Urinary Excretion of ^{51}Cr From Labeled Erythrocytes, An Index of Erythrocyte Survival, JAMA 220: 814-817, 1972.

Allan, C. J., Lawrence, R. D., Shih, S. C., Williamson, K. R., Sweatt, M. A., and Taswell, H. F.: Agglutination of Erythrocytes Freshly Washed with Saline Solution: Four Saline-autoagglutinating Sera, Transfusion 12: 306-311, 1972.

Shih, S. C., Sorenson, J. A., and Piper, P. G.: In Vitro Thyroid Function Studies in Blood Donors and in Patients with Normal and Abnormal Thyroid States, Laboratory Medicine 4: 20-26, 1973.

Tauxe, W. N., Dubovsky, E. V., and Shih, S. C.: A Shorter and More Highly Discriminating ^{51}Cr-Erythrocyte Survival Test, Transient Equilibrium/Squibb Nuclear Alumni Newsletter VI: No. 3, 1977.

Kim, Y. I., Rasmussen, N. G., Shih, S. C.: Large Retroperitoneal Liposarcoma Growing in Region of Renal Capsule, Journal of Abdominal Surgery, Feb. 1978, p. 37-39.

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Allan, C. J., Lawrence, R. D., Shih, S. C., Williamson, K. R., Sweatt, M. A., and Taswell, H. F.: Agglutination of Erythrocytes Freshly Washed with Saline Solution: Four Saline-autoagglutinating Sera, Transfusion 12: 306-311, 1972.

Shih, S. C., Sorenson, J. A., and Piper, P. G.: In Vitro Thyroid Function Studies in Blood Donors and in Patients with Normal and Abnormal Thyroid States, Laboratory Medicine 4: 20-26, 1973.

Tauxe, W. N., Dubovsky, E. V., and Shih, S. C.: A Shorter and More Highly Discriminating ^{51}Cr-Erythrocyte Survival Test, Transient Equilibrium/Squibb Nuclear Alumni Newsletter VI: No. 3, 1977.

Kim, Y. I., Rasmussen, N. G., Shih, S. C.: Large Retroperitoneal Liposarcoma Growing in Region of Renal Capsule, Journal of Abdominal Surgery, Feb. 1978, p. 37-39.

Item 1

A signed signature page is enclosed.

Item 2

Although not listed, we own a Model 2592 Serale Analytic "Cutie Pie" survey meter which covers the range 0-10 mR/hr, 0-100 mR/hr and 0-1000 mR/hr. A high level ion chamber, Model 2594 is also available extending the range an order of magnitude.

Item 3

The dose calibrator is checked daily with a Mallinckrodt Model 045 Cs-137 source. This source is plastic encapsalated and has a strength of 1 mCi. After the dose calibrator is given it's yearly calibration, the Cs source reading is recorded. This reading is used as a calibration mark until the dose calibrator is again sent out for yearly calibration.

Item 4

Radiation Safety Personnel Training Program

A. All persons working with or coming into contact with radionuclides will receive an in service training course before being allowed to come into contact with byproduct materials.

   Housekeeping and maintenance personnel who are required to work in a controlled area are not permitted to come into contact with by-product material. Their service will be employed only under the direct supervision of trained personnel who will ensure their safety.

B. Training Program:

   1. All users of radionuclides will receive an in service formal training course or must demonstrate equivalent prior experience.

   2. All users must have studied a copy of the Radiation Safety Manual (a copy is enclosed) and be familiar with its content.

   3. An annual refresher course is given to each user updating current regulations, procedures and practices.

4. The training course will cover the following:

   a. Radiation and Radionuclides

   b. Radiation Detectors

   c. Biological Effects of Radiation

   d. Good Radiological Safety Practices

   e. Current NRC and local Regulations

   f. Emergency Procedures

Item 5

A. As discussed in "Patient Safety Precautions" in the original application, step 5 calls for verification and recording of each patient dosage.

B. The "Radiation Safety Regulations" have been amended to include the monitoring of hands and clothing at the end of each working day.

C. The "Radiation Safety Regulations" and the "Notes on Radiation Handling Equipment" have been amended to include the wearing of disposable gloves and lab coats when handling radionuclides.

Item 6

Area Survey Procedures:

A. Large Quantity Areas: Q > 1-10 mCi

   1. These areas are surveyed daily with a thin window GM counter and weekly with a GM counter and wipe test.

   2. Personnel handling these quantities of radionuclides receive bio-assays at appropriate intervals, e.g.

      I-125: monthly thyroid
      I-131: weekly thyroid

B. Small Quantity Areas: Q < 100 uCi

   1. These areas are surveyed monthly with a thin window GM counter and wipe tests.

C. The area survey procedure and record keeping guidlines suggested in Appendix I of Regulatory Guide 10.8 of the NRC will be followed. Survey Results are posted at the same frequency surveys are done. All survey records and bio-assay results are reviewed quarterly by the Radio nuclide committee.

D. Records will include at least the following:

1. instrument readings and wipe test results
2. location of survey readings relatable to an area schematic appropriate to survey
3. time, date and personnel involved in survey
4. equipment used in survey
5. corrective action if necessary and results of a follow-up survey
6. for daily surveys where no corrective action is needed, results will be reported as background

E. Corrective action will be taken when any reading in excess of 100 DPM/100 cm^2 is observed.

Item 7

Therapeutic Use of Radionuclides

A. We intend to follow the procedure suggested in Appendix K of Regulatory Guide 10.8 of the NRC. Procedures are outlined therein for both items 7a and 7b of the NRC letter dated June 15, 1979 regarding our renewal.

Item 8

Radioactive Waste

A. All radioactive waste is handled in a similar fashion as outlined below.

1. long lived radionuclides: $T_{1/2} \geq 8$ day
   a. materials are separated into combustable and non-combustable types.
   b. materials are stored for decay either at the ^{60}Co teletharapy room (unused) or the roof of Tower 1. These are controlled areas. Radiation levels are kept below 10 mR/hr at 1 m.
   c. when the radiation levels are below 0.02 mR/hr, the materials are disposed of by incineration (combustable) or by disposal to normal waste (non-combustable).
2. short lived radionuclides:
   a. materials are separated into combustable and non-combustable.
   b. non-combustable items are removed to either ^{60}Co room or roof of Tower 1 where they are held for decay.

c. combustable items are retained at the origin and held for decay.

d. when the radiation levels are below 0.02 mR/hr, the materials are disposed of by incineration or normal solid waste disposal.

e. liquids are either held for decay or diluted until concentrations are below the levels specified in §30.71 Schedule A of Title 10, i.e.

H-3: 3xE-2 uCi/ml or 3xE-2 uCi/gm

I-125: 2xE-5 uCi/ml or 2xE-5 uCi/gm

These fluids or solids are then disposed of through normal waste.

Item 9

Calculations for Use of Xe-133 in Nuclear Medicine Suite of Madison General Hospital

A. Introduction

1. Room Volumes: (#'s refer to drawing H3/6910·F)

#386 Hot lab 576 ft^2 1.63xE7 ml

#387 Office Space 72 ft^2
#388-389 LFOV Camera 133 ft^2
#382 Probe Room 126 ft^2
#383 Pho-Gamma Camera 126 ft^2
#385 Hallway 160 ft^2
} 1.42xE8 ml

all rooms are restricted areas with controlled access.

2. Ventalation:

Room #386 vented by 500 CFM, 8x5E8 ml/hr, stack exhausting directly outside.

Rooms #382,383,385,387,388, and 389 are vented by 500 CFM, 8x5E8 ml/hr, stack exhausting directly to outside.

These rooms have a feeder supply of 490 CFM, 8.33xE8 ml/hr of discharge air.

3. Storage:

Xe-133 is stored in hot lab, #386, in selfcontained dispenser and is shielded by Pb bricks.

Beyond the details already supplied in the original renewal application, these specifics are supplied:

a. Xe-133 is administered in room #388-389 directly under exhaust intake.

b. the output breathing line is inserted directly into exhaust intake.

c. the typical dosage is 10 mCi, 1xE4 uCi, and a maximum work load of 4 patients per week is anticipated.

B. Loss of Xe-133 During Normal Usage

Fractional loss averaged over 1 week

1. accidental patient disconnect with complete loss of dosage: assume a rate of 1:50 patients:

$$f_{ax} = \frac{1}{50} \cdot \frac{1xE4\ uCi}{pt.} \cdot \frac{4\ pt.}{wk.} \Big/ \frac{40xE3\ uCi}{wk.}$$

$$\boxed{f_{ax} = 2\%}$$

2. routine loss during administration:

assume 5% loss per patient

$$f_{ad} = 5\%$$

3. total average loss

$$\boxed{f = 7\%}$$

C. Average Xe-133 Air Concentrations

1. average loss of 7%

$$\bar{C} = 40xE3\ \frac{uCi}{wk} \cdot 0.07 \Big/ 8x5E8\ \frac{ml}{hr} \cdot 40\ \frac{hr}{wk}$$

$$\bar{C} = 2.8E3\ uCi \Big/ 3x4E10\ ml/wk$$

$$\bar{C} = 8.24E\text{-}8\ uCi/ml$$

$\bar{C} <$ 1xE-5 uCi/ml which is the MPC (air) for radiation workers

$$\boxed{\bar{C} = 0.8\%\ MPC\ (air)}$$

2. Storage Loss:

1% of dosage

1% in diffusion

$$A = 0.01 \cdot 10xE3\ \frac{uCi}{pt} \cdot 4\ \frac{pt}{wk} + 0.01 \cdot 500xE3\ uCi$$

$$A = 5.4E3\ \frac{uCi}{wk}$$

$$\bar{C} = 5.4E3 \text{ uCi/wk} \Big/ 8.5E8 \frac{\text{ml}}{\text{hr}} \cdot 40 \frac{\text{hr}}{\text{wk}}$$

$$\bar{C} = 1.6E\text{-}7 \frac{\text{uCi}}{\text{ml}} < 1E\text{-}5 \frac{\text{uCi}}{\text{ml}}$$

$\bar{C}$ = 1.6% of MPC (air)

D. Concentration in Unrestricted Areas

The outlet of stack is the area of immediate concern since entire Nuclear Medicine Suite is at negative pressure.

Release: 40E3uCi/wk patient load

0.8E3uCi/wk from accidental disconnect

A = 40.8E3uCi/wk

A ≈ 41E3uCi/wk

$$\bar{C} = \frac{41E3\text{uCi/wk} \cdot 52 \text{ wk/yr}}{8.5E8 \text{ ml/hr} \cdot 24 \text{ hr/day} \cdot 365 \text{ day/yr}}$$

$$\bar{C} = \frac{2.13E6\text{uCi/yr}}{7.45E12 \text{ ml/yr}} = 2.86E\text{-}7 \frac{\text{uCi}}{\text{ml}}$$

$\bar{C}$ = 95% MPC (air) MPC (air) = 3E-7 $\frac{\text{uCi}}{\text{ml}}$

E. Emergency Procedures:

For all calculations, assume a single compartment model, i.e.

$\dot{V}/V$ = 1.42E8 ml/8.5E8 ml/hr

10 min to change air of suite exclusive of hot lab

$\dot{V}/V$ = 1.63E7 ml/8.5E8 ml/hr

1.2 min to change air of hot lab

$C/C_o = \exp(-\lambda t)$ where C, C_o = concentration at t and t_o respectively
λ = dilution constant

$\lambda = 0.07 \text{ min}^{-1}$ (suite)

$\lambda = 0.602 \text{ min}^{-1}$ (hot lab)

1. Patient disconnect

$\bar{C}_o$ = 10E3 uCi/1.42E8 ml

$\bar{C}_o$ = 7.04E-5 uCi/ml

$\boxed{t = 28 \text{ min}}$ to $C \leq$ E-5 $\frac{uCi}{ml}$

2. Release 40E3 uCi to Suite:

$C_o = 40E3 \text{ uCi} \;/\; 1.42E8 \text{ ml}$

$\boxed{t = 117 \text{ min}}$ to $C \leq$ E-5 $\frac{uCi}{ml}$

3. Release 500E3 uCi to hot lab

$C_o = 500 \text{ E3 uCi}/1.63E7 \text{ml}$

$\boxed{t = 13.3 \text{ min}}$ to $C \leq$ E-5 $\frac{uCi}{ml}$

During any of above emergencies, room is evacuated and all access restricted until 120% t~max has passed. Room is then surveyed to determine air concentrations before re-entry by staff.

F. Dynamic Indication of Air Concentration

An accidental release of Xe-133 can be deduced and monitoured by a tissue equivalent dosimeter, i.e. survey instrument.

1. Consider dispersal of 10E3 uCi into suite:

assume enough build up is available to employ "cloud" approximation:

$V_{LFOV \text{ room}} = 3.5E7 \text{ ml}$

$$E_o = \frac{10E3 \text{ uCi} \cdot 3.7E4 \text{ DPS/uCi} \cdot 0.37 \cdot 0.081 \text{ MeV/dis} \cdot 3600 \text{ sec}}{3.5E7 \text{ ml} \cdot 1.293E\text{-}3 \text{g/ml}}$$

$E_o = 8.82E5 \text{ MeV/g·hr} \quad 5.43E7 \text{ MeV/g·R}$

$E_o = 16 \text{ mR/hr}$

but only hemisphere available: $\boxed{\dot{D} = 8 \text{ mR/hr}}$

NOTE: $\dot{D} = 0.138 \frac{R \cdot cm^2}{hr \text{ mCi}} \cdot 10 \text{ mCi} \cdot \frac{1E3 mR}{R} \cdot \frac{1}{1E4 cm^2}$

$\dot{D} = 0.138 \text{ mR/hr}$ @ 1m from a 10 mCi source

2. for 500 mCi release to hot lab

$\boxed{\dot{D} = 870 \text{ mR/hr}}$ again easily detected.

Item 1

A signed signature page is enclosed.

Item 2

Although not listed, we own a Model 2592 Serale Analytic "Cutie Pie" survey meter which covers the range 0-10 mR/hr, 0-100 mR/hr and 0-1000 mR/hr. A high level ion chamber, Model 2594 is also available extending the range an order of magnitude.

Item 3

The dose calibrator is checked daily with a Mallinckrodt Model 045 Cs-137 source. This source is plastic encapsalated and has a strength of 1 mCi. After the dose calibrator is given it's yearly calibration, the Cs source reading is recorded. This reading is used as a calibration mark until the dose calibrator is again sent out for yearly calibration.

Item 4

Radiation Safety Personnel Training Program

A. All persons working with or coming into contact with radionuclides will receive an in service training course before being allowed to come into contact with byproduct materials.

   Housekeeping and maintenance personnel who are required to work in a controlled area are not permitted to come into contact with by-product material. Their service will be employed only under the direct supervision of trained personnel who will ensure their safety.

B. Training Program:

   1. All users of radionuclides will receive an in service formal training course or must demonstrate equivalent prior experience.

   2. All users must have studied a copy of the Radiation Safety Manual (a copy is enclosed) and be familiar with its content.

   3. An annual refresher course is given to each user updating current regulations, procedures and practices.

4. The training course will cover the following:

   a. Radiation and Radionuclides

   b. Radiation Detectors

   c. Biological Effects of Radiation

   d. Good Radiological Safety Practices

   e. Current NRC and local Regulations

   f. Emergency Procedures

Item 5

A. As discussed in "Patient Safety Precautions" in the original application, step 5 calls for verification and recording of each patient dosage.

B. The "Radiation Safety Regulations" have been amended to include the monitoring of hands and clothing at the end of each working day.

C. The "Radiation Safety Regulations" and the "Notes on Radiation Handling Equipment" have been amended to include the wearing of disposable gloves and lab coats when handling radionuclides.

Item 6

Area Survey Procedures:

A. Large Quantity Areas: Q > 1-10 mCi

   1. These areas are surveyed daily with a thin window GM counter and weekly with a GM counter and wipe test.

   2. Personnel handling these quantities of radionuclides receive bio-assays at appropriate intervals, e.g.

      I-125: monthly thyroid
      I-131: weekly thyroid

B. Small Quantity Areas: Q < 100 uCi

   1. These areas are surveyed monthly with a thin window GM counter and wipe tests.

C. The area survey procedure and record keeping guidlines suggested in Appendix I of Regulatory Guide 10.8 of the NRC will be followed. Survey Results are posted at the same frequency surveys are done. All survey records and bio-assay results are reviewed quarterly by the Radio nuclide committee.

D. Records will include at least the following:

1. instrument readings and wipe test results
2. location of survey readings relatable to an area schematic appropriate to survey
3. time, date and personnel involved in survey
4. equipment used in survey
5. corrective action if necessary and results of a follow-up survey
6. for daily surveys where no corrective action is needed, results will be reported as background

E. Corrective action will be taken when any reading in excess of 100 DPM/100 cm^2 is observed.

Item 7

Therapeutic Use of Radionuclides

A. We intend to follow the procedure suggested in Appendix K of Regulatory Guide 10.8 of the NRC. Procedures are outlined therein for both items 7a and 7b of the NRC letter dated June 15, 1979 regarding our renewal.

Item 8

Radioactive Waste

A. All radioactive waste is handled in a similar fashion as outlined below.

1. long lived radionuclides: $T_{1/2} \geq 8$ day
   a. materials are separated into combustable and non-combustable types.
   b. materials are stored for decay either at the ^{60}Co teletharapy room (unused) or the roof of Tower 1. These are controlled areas. Radiation levels are kept below 10 mR/hr at 1 m.
   c. when the radiation levels are below 0.02 mR/hr, the materials are disposed of by incineration (combustable) or by disposal to normal waste (non-combustable).
2. short lived radionuclides:
   a. materials are separated into combustable and non-combustable.
   b. non-combustable items are removed to either ^{60}Co room or roof of Tower 1 where they are held for decay.

c. combustable items are retained at the origin and held for decay.

d. when the radiation levels are below 0.02 mR/hr, the materials are disposed of by incineration or normal solid waste disposal.

e. liquids are either held for decay or diluted until concentrations are below the levels specified in §30.71 Schedule A of Title 10, i.e.

H-3: 3xE-2 uCi/ml or 3xE-2 uCi/gm

I-125: 2xE-5 uCi/ml or 2xE-5 uCi/gm

These fluids or solids are then disposed of through normal waste.

Item 9

Calculations for Use of Xe-133 in Nuclear Medicine Suite of Madison General Hospital

A. Introduction

1. Room Volumes: (#'s refer to drawing H3/6910·F)

#386 Hot lab 576 ft^2 1.63xE7 ml

#387 Office Space 72 ft^2
#388-389 LFOV Camera 133 ft^2
#382 Probe Room 126 ft^2
#383 Pho-Gamma Camera 126 ft^2
#385 Hallway 160 ft^2
} 1.42xE8 ml

all rooms are restricted areas with controlled access.

2. Ventalation:

Room #386 vented by 500 CFM, 8x5E8 ml/hr, stack exhausting directly outside.

Rooms #382,383,385,387,388, and 389 are vented by 500 CFM, 8x5E8 ml/hr, stack exhausting directly to outside.

These rooms have a feeder supply of 490 CFM, 8.33xE8 ml/hr of discharge air.

3. Storage:

Xe-133 is stored in hot lab, #386, in selfcontained dispenser and is shielded by Pb bricks.

Beyond the details already supplied in the original renewal application, these specifics are supplied:

a. Xe-133 is administered in room #388-389 directly under exhaust intake.

b. the output breathing line is inserted directly into exhaust intake.

c. the typical dosage is 10 mCi, 1xE4 uCi, and a maximum work load of 4 patients per week is anticipated.

B. Loss of Xe-133 During Normal Usage

Fractional loss averaged over 1 week

1. accidental patient disconnect with complete loss of dosage: assume a rate of 1:50 patients:

$$f_{ax} = \frac{1}{50} \cdot \frac{1xE4\ uCi}{pt.} \cdot \frac{4\ pt.}{wk.} \Big/ \frac{40xE3\ uCi}{wk.}$$

$$\boxed{f_{ax} = 2\%}$$

2. routine loss during administration:

assume 5% loss per patient

$$f_{ad} = 5\%$$

3. total average loss

$$\boxed{f = 7\%}$$

C. Average Xe-133 Air Concentrations

1. average loss of 7%

$$\bar{C} = 40xE3\ \frac{uCi}{wk} \cdot 0.07 \Big/ 8x5E8\ \frac{ml}{hr} \cdot 40\ \frac{hr}{wk}$$

$$\bar{C} = 2.8E3\ uCi \Big/ 3x4E10\ ml/wk$$

$$\bar{C} = 8.24E\text{-}8\ uCi/ml$$

$\bar{C} <$ 1xE-5 uCi/ml which is the MPC (air) for radiation workers

$$\boxed{\bar{C} = 0.8\%\ MPC\ (air)}$$

2. Storage Loss:

1% of dosage

1% in diffusion

$$A = 0.01 \cdot 10xE3\ \frac{uCi}{pt} \cdot 4\ \frac{pt}{wk} + 0.01 \cdot 500xE3\ uCi$$

$$A = 5.4E3\ \frac{uCi}{wk}$$

$$\bar{C} = 5.4E3 \text{ uCi/wk} \Big/ 8.5E8 \frac{\text{ml}}{\text{hr}} \cdot 40 \frac{\text{hr}}{\text{wk}}$$

$$\bar{C} = 1.6E\text{-}7 \frac{\text{uCi}}{\text{ml}} < 1E\text{-}5 \frac{\text{uCi}}{\text{ml}}$$

$\bar{C}$ = 1.6% of MPC (air)

D. Concentration in Unrestricted Areas

The outlet of stack is the area of immediate concern since entire Nuclear Medicine Suite is at negative pressure.

Release: 40E3uCi/wk patient load

0.8E3uCi/wk from accidental disconnect

A = 40.8E3uCi/wk

A $\approx$ 41E3uCi/wk

$$\bar{C} = \frac{41E3\text{uCi/wk} \cdot 52 \text{ wk/yr}}{8.5E8 \text{ ml/hr} \cdot 24 \text{ hr/day} \cdot 365 \text{ day/yr}}$$

$$\bar{C} = \frac{2.13E6\text{uCi/yr}}{7.45E12 \text{ ml/yr}} = 2.86E\text{-}7 \frac{\text{uCi}}{\text{ml}}$$

$\bar{C}$ = 95% MPC (air) MPC (air) = 3E-7 $\frac{\text{uCi}}{\text{ml}}$

E. Emergency Procedures:

For all calculations, assume a single compartment model, i.e.

$V/\dot{V}$ = 1.42E8 ml/8.5E8 ml/hr

10 min to change air of suite exclusive of hot lab

$V/\dot{V}$ = 1.63E7 ml/8.5E8 ml/hr

1.2 min to change air of hot lab

$C/C_o = \exp(-\lambda t)$ where C, C_o = concentration at t and t_o respectively
λ = dilution constant

$\lambda = 0.07 \text{ min}^{-1}$ (suite)

$\lambda = 0.602 \text{ min}^{-1}$ (hot lab)

1. Patient disconnect

$\bar{C}_o$ = 10E3 uCi/1.42E8 ml

$\bar{C}_o$ = 7.04E-5 uCi/ml

$\boxed{t = 28 \text{ min}}$ to $C \leq$ E-5 $\frac{uCi}{ml}$

2. Release 40E3 uCi to Suite:

C_o = 40E3 uCi / 1.42E8 ml

$\boxed{t = 117 \text{ min}}$ to $C \leq$ E-5 $\frac{uCi}{ml}$

3. Release 500E3 uCi to hot lab

C_o = 500 E3 uCi/1.63E7ml

$\boxed{t = 13.3 \text{ min}}$ to $C \leq$ E-5 $\frac{uCi}{ml}$

During any of above emergencies, room is evacuated and all access restricted until 120% t-max has passed. Room is then surveyed to determine air concentrations before re-entry by staff.

F. Dynamic Indication of Air Concentration

An accidental release of Xe-133 can be deduced and monitoured by a tissue equivalent dosimeter, i.e. survey instrument.

1. Consider dispersal of 10E3 uCi into suite:

assume enough build up is available to employ "cloud" approximation:

$V_{LFOV\ room}$ = 3.5E7 ml

$$E_o = \frac{10E3 \text{ uCi} \cdot 3.7E4 \text{ DPS/uCi} \cdot 0.37 \cdot 0.081 \text{ MeV/dis} \cdot 3600 \text{ sec}}{3.5E7 \text{ ml} \cdot 1.293E\text{-}3 \text{g/ml}}$$

E_o = 8.82E5 MeV/g·hr 5.43E7 MeV/g·R

E_o = 16 mR/hr

but only hemisphere available: $\boxed{\dot{D} = 8 \text{ mR/hr}}$

NOTE: $\dot{D} = 0.138 \frac{R \cdot cm^2}{hr\ mCi} \cdot 10 \text{ mCi} \cdot \frac{1E3 mR}{R} \cdot \frac{1}{1E4 cm^2}$

$\dot{D}$ = 0.138 mR/hr @ 1m from a 10 mCi source

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