

JUL 17 1985

Riverside Methodist Hospital
ATTN: S. Jayaraman, Ph.D.
Radiation Safety Officer
3535 Olentangy River Road
Columbus, OH 43215

Gentlemen:

Enclosed is Amendment No. 62 to NRC License Number 34-01055-01 which authorizes Dr. Crnkovich to use materials specified in Group VI of Schedule A, 10 CFR 35.100.

Please note that we have not authorized Dr. Ralph Kennaugh to use materials specified in Group IV. We do not have sufficient documentation of his training and clinical experience with unsealed sources. We need evidence that he has:

1. Obtained a minimum of 80 hours of training in basic radioisotope handling techniques applicable to the use of unsealed sources for therapy procedures. (This information may be documented on Form NRC-313M Supplement A).
2. Obtained clinical experience as specified in Section 4(b) of Appendix A, Regulatory Guide 10.8 (enclosed) within the last five years under the supervision of a physician(s) authorized by the NRC or an Agreement State to use materials in Group IV. Dr. Kennaugh's experience with phosphorus-32 appears to be adequate, however the dates of his training should be indicated on the preceptor statement. We cannot consider his clinical experience with iodine-131 at the University of Cape Town because
 - a) it appears to have been obtained in excess of 5 years ago and
 - b) we do not know the criteria used by regulatory authorities in South Africa for approving physicians to use radioactive materials in humans.

We will be pleased to consider this request further upon submission of the above information. When replying, please indicate near the top of your letter "This Is Additional Information; Not A New Amendment Request".

Sincerely,

B.J. Holt
Materials Licensing Section

Enclosures:

1. Amendment No. 62
2. Regulatory Guide 10.8

8602190539 851213
REG3 LIC30
34-01055-01 PDR

RIII

Holt/cm
07/15/85

2/18/86

EXHIBIT A

FORM NRC-313M (8-78) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved GAO R0557
INSTRUCTIONS – Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.		
1.a. NAME AND MAILING ADDRESS OF APPLICANT (institution, firm, clinic, physician, etc.) INCLUDE ZIP CODE Ralph C. Kennaugh, M.D. Director, Radiation Oncology Riverside Methodist Hospital 3535 Olentangy River Road, Columbus, TELEPHONE NO.: AREA CODE (614) <u>261</u> <u>5560</u>	1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED (If different from 1.a.) INCLUDE ZIP CODE Riverside Methodist Hospital 3535 Olentangy River Road Columbus, Ohio 43214 Ohio 43214	
2. PERSON TO CONTACT REGARDING THIS APPLICATION Ralph C. Kennaugh, M.D. TELEPHONE NO.: AREA CODE (614) <u>261</u> <u>5560</u>	3. THIS IS AN APPLICATION FOR: (Check appropriate item) a. <input type="checkbox"/> NEW LICENSE b. <input checked="" type="checkbox"/> AMENDMENT TO LICENSE NO. _____ c. <input type="checkbox"/> RENEWAL OF LICENSE NO. _____	
4. INDIVIDUAL USERS (Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.) Ralph C. Kennaugh, M.D.	5. RADIATION SAFETY OFFICER (RSO) (Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.) S. Rayaraman, Ph.D. Radiation Safety Officer	
6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE		
RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		
ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.		
6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. (Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)		
ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM
DESCRIBE PURPOSE OF USE		

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 Rev. _____ Date: _____

7. MEDICAL ISOTOPES COMMITTEE		15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (Check One)	
<input type="checkbox"/>	Names and Specialties Attached; and	<input type="checkbox"/>	Appendix G Rules Followed; or
<input type="checkbox"/>	Duties as in Appendix B; or _____ (Check One)	<input type="checkbox"/>	Equivalent Rules Attached
<input type="checkbox"/>	Equivalent Duties Attached	16. EMERGENCY PROCEDURES (Check One)	
8. TRAINING AND EXPERIENCE		<input type="checkbox"/>	Appendix H Procedures Followed; or
<input type="checkbox"/>	Supplements A & B Attached for Each Individual User; and	<input type="checkbox"/>	Equivalent Procedures Attached
<input type="checkbox"/>	Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES (Check One)	
9. INSTRUMENTATION (Check One)		<input type="checkbox"/>	Appendix I Procedures Followed; or
<input type="checkbox"/>	Appendix C Form Attached; or	<input type="checkbox"/>	Equivalent Procedures Attached
<input type="checkbox"/>	List by Name and Model Number	18. WASTE DISPOSAL (Check One)	
10. CALIBRATION OF INSTRUMENTS		<input type="checkbox"/>	Appendix J Form Attached; or
<input type="checkbox"/>	Appendix D Procedures Followed for Survey Instruments; or _____ (Check One)	<input type="checkbox"/>	Equivalent Information Attached
<input type="checkbox"/>	Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS (Check One)	
<input type="checkbox"/>	Appendix D Procedures Followed for Dose Calibrator; or _____ (Check One)	<input type="checkbox"/>	Appendix K Procedures Followed; or
<input type="checkbox"/>	Equivalent Procedures Attached	<input type="checkbox"/>	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT		20. THERAPEUTIC USE OF SEALED SOURCES	
<input type="checkbox"/>	Description and Diagram Attached	<input type="checkbox"/>	Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM		<input type="checkbox"/>	Appendix L Procedures Followed; or _____ (Check One)
<input type="checkbox"/>	Description of Training Attached	<input type="checkbox"/>	Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL		21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon - 133)	
<input type="checkbox"/>	Detailed Information Attached	<input type="checkbox"/>	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS (Check One)		22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
<input type="checkbox"/>	Appendix F Procedures Followed; or	<input type="checkbox"/>	Detailed Information Attached
<input type="checkbox"/>	Equivalent Procedures Attached	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
<input type="checkbox"/>		<input type="checkbox"/>	Detailed Information Attached

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

STREET ADDRESS

CITY

STATE

ZIP CODE

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		
Sr-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			

**TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER**

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER

RALPH C. KENNAUGH, M.D.

2. STATE OR TERRITORY IN
WHICH LICENSED TO
PRACTICE MEDICINE

OHIO

3. CERTIFICATION

SPECIALTY BOARD
A

CATEGORY
B

MONTH AND YEAR CERTIFIED
C

THERAPEUTIC RADIOLOGY

JUNE 1982

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	1974-1975 University of Cape Town, S. Africa	100	40
b. RADIATION PROTECTION	1974-1975 University of Cape Town, S. Africa	20	10
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	1974-1975 University of Cape Town, S. Africa	20	40
d. RADIATION BIOLOGY	1975 University of Cape Town, S. Africa	50	00
e. RADIOPHARMACEUTICAL CHEMISTRY	1975-1976 University of Cape Town, S. Africa	20	00

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

CURRICULUM VITAE

RALPH CHRISTOPHER KENNAUGH, M.B., Ch. B.
222 Rustic Place
Columbus, Ohio 43214
614/268-4337 (R)
614/261-5560 (B)

EDUCATION

Falcon College, Bulawayo, Zimbabwe: AEB GCE O-levels achieved December 1963.
AEB GCE A-levels achieved in 1964.

University of Cape Town: Degrees (M.B., Ch.B.) achieved in medicine and surgery
December 1970.

Gained Colorado State Board Examination (FLEX), June 1980

Medical License to practice in the State of Colorado, August 1980. License NO. 23405

Board Certified in Radiation Therapy in June 1982.

Medical License to practice in the State of Ohio, July 1984. License No. 51061

Hold Medical License to practice in United Kingdom and Republic of South Africa.

EXPERIENCE

July 1, 1984 To present: Medical Director, Department of Radiation Oncology
at Riverside Methodist Hospital, Columbus, Ohio.

The Director of Radiation Oncology is responsible for the irradiation therapy delivered in the Department of Radiation Oncology at this Hospital, which contains 1100 beds. There are two treatment machines a Clinac 18 and a Clinac 14 and a simulator. Curative and palliative irradiation is undertaken together with intracavitary and interstitial work and we estimate to treat a minimum of 777 patients this year. In addition, In-services lectures are given to general physicians and specialist physicians and radiological medical students rotating thru the Department on a regular basis. There is a weekly Tumor Board Conference for the benefits of residents, interns and referring physicians where two patients are presented for teaching and diagnosis. The Department has three radiation oncologists in the Department at this time. I am currently Chairman of the Clinical Oncology Committee. In addition, I have a full time appointment on the Medical Education Committee, Radiation Safety Committee, Radiology Quality Assurance Committee, Executive Committee of the Clinical Oncology Program, a member of the Administrative Staff of Riverside Methodist Hospital, and I am on the Hospice Task Force for the same Hospital. Tumor Board Moderator at RMH in December 1984.

March 1980 to June 30,
1984

Assistant Professor, Division of Therapeutic Radiology,
Department of Radiology, University of Colorado Health
Sciences Center, Denver, Colorado.

Duties encompassed primary care and prescription of radiation therapy, teaching in clinical radiation therapy and patient cancer management and academic research in cancer and patient related care. Lecturing was at both the undergraduate and postgraduate levels. I attended Medical Board meetings, rotating with the Department Chairman, sat on the Tumor Boards at University Hospital, Denver Veterans Administration Medical Center, and Rose Medical Center, and served on the Prospective Payment System Task Force and the Management Review Committee. Other activities included participation on the Medical Records Committee (one of seven statutory and permanent committees of the Hospital), membership on the Cancer Committee and founding member of the Air-ICU Task Force: a group established to investigate the feasibility of an Air-ICU service, study the necessary components of such a service, i.e., financing, staffing, marketing, etc., and wrote a request for proposal for the service. I had also been the Radiology Department coordinator for the screening of faculty applications for King Saud University College, RYADH, and worked to promote the liaison between the two universities. Staff affiliations in Denver included those with Denver Veterans Administration Medical Center, Rose Medical Center, and Denver General Hospital. Member of Hospice of St. John Board of Directors, was actively engaged in the management and initial purchase of building, application for certificate of need of this non-profit hospice facility. Instrumental in obtaining a memorandum of understanding and working agreement between the Hospice and University Hospital.

February 1978 to
February 1980:

Assistant Radiation Oncologist, Cancer Control Agency of
British Columbia, Vancouver, British Columbia, Canada.

This position involved the direct primary care of all patients with cancer and the total treatment of those patients who were admitted under my care. Their radiation treatment was planned, prescribed and directed by myself. Clinical research and teaching were incorporated into the program.

June 1974 to
February 1978:

Resident in Radiation Oncology, Groote Schuur Hospital,
Cape Town, R.S.A.

This resident position provided instruction in basic sciences, including physics, machine construction, isotopes, statistics and radiobiology as well as instruction and participation in modalities of irradiation, chemotherapy and immunotherapy. The radiation therapists in this setting delivered all chemotherapy, except for blood malignancies, in addition to the irradiation therapy. Resident training was in these protocols. During my tenure I originated and was chairman of the Junior Hospital Doctors Association of Cape Town.

July 1973 to
May 1974:

Medical Officer in Medicine and Surgery, Frere Hospital,
East London, Cape, R.S.A.

There are five surgical and medical teams in this 900 bed facility, the only full service hospital in the whole of the Eastern Cape. I was full-time hospital appointee given the management of one of the teams. The duties included dealing with both inpatients and outpatients, all medical emergencies, and complete management of all patients on my team. During this appointment I received instruction in all forms of surgery, including pediatric, general, plastic, neurological and thoracic from specialists in charge of the relevant specialties.

April 1973 to
June 1973:

General Practice - Locum Tennes, Westonaria, Transvaal,
R.S.A., and Victoria West, Cape Province, R.S.A.

September 1972 to
February 1973.

Dublin, Ireland.

Attended the course for the Primary Fellow of the Royal College of Surgeons in Ireland examination.

August 1972

General Practice - Locum Tennes, Westonaria, Transvaal,
R.S.A.

February 1972 to
July 1972:

Trauma Unit Resident, Groote Schuur Hospital, University of
Cape Town, R.S.A.

This appointment involved primary care of all traumatic injuries as they arrived at the Hospital. The unit was designed to handle all trauma and especially multiple injuries. General casualty was covered by the same residents and there were special consultants available at all times.

January 1971 to
December 1971:

Intern in Medicine and Surgery, Frere Hospital, East
London, Cape, R.S.A.

Duties in this intership included management of the ward, direct care of the inpatients, attendance in the outpatient department and care of all emergency and routine admissions to the wards.

PUBLICATIONS

Carbon Tetrachloride Overdosage - S.A.M.J., April 5, 1975.

Cyclophosphamide, Vincristine, Lomustine, Cis-Platinum and Doxorubicin in the treatment of Non-small Cell Lung Cancer - 1983.

PAPERS SUBMITTED FOR PUBLICATION

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CLINICAL RESEARCH PROTOCOLS IN PROGRESS (registered as collaborator and co-author in all listed protocols)

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Advanced Head and Neck Cancer - A Combined Approach for Stage III and IV Disease.

Large Single Fraction Radiation Treatment for Advanced Chest or Abdominal Malignancy.

The Effect of Ectorin on Radiation Esophagitis - A Double Blind Controlled Study.

PERSONAL

Date of Birth: April 25, 1947.

Place of Birth: Johannesburg, Transvaal, Republic of South Africa.

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Place of Birth: Johannesburg, Transvaal, Republic of South Africa.