(0-08)	APPLICATION FOI	K BIPKUDUCI MATEKIAL LICENSE	
INSTRUCTIONS plete only Items supplemental she Commission, Was application, the accordance with ject to Title 10, (-Complete Items 1 through 16 if 1 through 7 and indicate new i ets where necessary. Item 16 mus hington 25, D. C. Attention: 1s applicant will receive an AEC 8 whe general requirements contain Code of Federal Regulations, Par	this is an initial application. If application nformation or changes in the program as re- t be completed on all applications. Mail the otopes Branch, Division of Licensing and Byproduct Material License. An AEC Bypro- ed in Title 10, Code of Federal Regulations rt 20.	n is for renewal of a licensi quested in Items 8 through ree copies to: U. S. Atomic Regulation. Upon approval duct Material License is is s, Part 30 and the Licensee
. (a) NAME AND STREE	ET ADDRESS OF APPLICANT (Institution	, firm, hospital, (b) STREET ADDRESS(ES) AT WHICH	BYPRODUCT MATERIAL WILL BE U
Department Fitzsimons Army Medica Laboratory.	of the Army General Hospital and U 1 Research and Nutrit: Denver, Colorado 80	JS Lon D240	AL HOSPITAL 80240
			If this is an application for sure
2. DEPARTMENT TO USE	BYPRODUCT MATERIAL	 PREVIOUS LICENSE NUMBER(5). license, please indicate and give num 	(If this is an application for rene iber.)
Radioisotop	e Section, Radiology S	Service Present License #	05=00046=13
 INDIVIDUAL USER(S). supervise use of byprod 9.) 	(Name and title of individual(s) who will luct material. Give training and experience	use or directly in litems 8 and bection officer if other than individual perience as in Items 8 and 9.)	Name of person designated as radii user. Attach resume of his training
As specifie Hospital Ra	d by Fitzsimons Genera dioisotope Committee	As specified by F Hospital Radioiso	itzsimons General tope Committee
5. (a) BYPRODUCT MATE and mass number	RIAL (Elements (b) CHEMICAL AND/ of each) ICAL FORM THAT number, number o	OR PHYSICAL FORM AND MAXIMUM NUMBER OF MILLI YOU WILL POSSESS AT ANY ONE TIME. (If second south of sources and maximum activity per source.)	CURIES OF EACH CHEM:CAL AND/ prce(s), also state name of manufactu
Cr ⁵¹	Na ₂ CrO ₄	6 mc	
 DESCRIBE PURPOSE For pleted in field of this re- which the source will be 	OR WHICH SYPRODUCT MATERIAL WILL f m If byproduct material is in the form of c estored and/or used.)	BE USED. (If byproduct material is for "human use," supported by sealed source, include the make and model number of model number.	plement A (Form AEC-313a) must be the storage container and/or dev
See Form AE	C 313a.		

The set of the set of the set of the	RIENCE OF E	ACH INDIVIDU	AL NAMED IN ITEM	A (Use supplemental s	heets if necessary)
. TYPE OF TRAINING			79 A 19 16 10	DURATION OF	ON THE JOB	FORMAL COURS
		WHERE	RAINED	TRAINING	(Circle answer)	(Circle answer)
Principles and practices of radiation protection	N/A			Yes No	Yes No	
Radioactivity measurement standardiza- tion and monitoring techniques and in-		N/A			Yes No	Yes No
Mathematics and calculations basic to the use and measurement of radioactivity		N/A			Yes No	Yes No
Biological effects of radiation		N/A			Yes No	Yes No
EXPERIENCE WITH RADIATION. (Actual	use of radioiso	topes or equivale	int experience.)			
	N/A					
0. RADIATION DETECTION INSTRUMENTS.	(Use supplem	ental sheets if m	ecessory.)			
TYPE OF INSTRUMENTS	NUMBER	RADIATION	SENSITIVITY RANGE	WINDOW THICKNESS	(Monitoring, sur	JSE veving, measuring)
See License #05=00046	-13 AY PROCEDURE	S USED. (For Ali	n badges, specify method	al calibrating and processin	ig, or name of supp	sliær.)
INI	FORMATIO	N TO BE SUB	MITTED ON ADDI	TIONAL SHEETS		
. FACILITIES AND EQUIPMENT. Describe la	boratory facilitie	s and remote han	dling equipment, storage	containers, shielding, fume	e hoods, etc. Exp	lanatory skatch
RADIATION PROTECTION PROGRAM. De	scribe the radio training, and ex	See Lic tion protection pr perience of perso See Lic	ense $\#05 < 0004$ rogram including control n to perform leak tests, ai ense $\#05 < 0004$	neasures. If application and arrangements for perfor 6=13	covers sealed source ming initial radiati	ces, submit leak on survey, serv-
icing, maintenance and repair of the source.		the second se			the state of the s	
 WASTE DISPOSAL. If a commercial waste be used for disposing of radioactive wastes 	disposal service and estimates o	is employed, spe f the type and an	city name of company. Jount of activity involved.	Otherwise, submit detailed	description of met	hods which will
 WASTE DISPOSAL. If a commercial waste be used for disposing of radioactive wastes 	disposal service and estimates o RTIFICATE	is employed, spe f the type and air (This item m	city name of company. Nount of activity involved. Ust be complated	Otherwise, submit detailed See License by applicant)	description of met e #05=0000	hods which will 46=13
WASTE DISPOSAL If a commercial waste be used for disposing of radioactive wastes THE APPLICANT AND ANY OFFICIAL EXEC PREPARED IN CONFORMITY WITH TITLE 10, SUPPLEMENTS ATTACHED HERETO, IS TRUE 12 October 1967	disposal service and estimates a RTIFICATE CUTING THIS CI CODE OF FEDEN E AND CORREC	is employed, spe f the type and an (This item m ERTIFICATE ON 8 LAL REGULATIONS T TO THE BEST O	city name of company. Nount of activity involved. Ust be completed E HALLS, THE APPLICAN PHOLE DE THAT PHOLE DE THAT PHO	Otherwise, submit detailed See License by applicant) NT NAMED IN ITEM 1, CEI ALL INFORMATION CONT. D BELIEF. . Of the Army Cer and Resea of the Army rman, Radioiso	description of met e #05=0002 RTIFY THAT THIS A ANNED HEREIN, IN FGH and L pch & Nutz Colore Col. MC	hods which will 46=13 PPLICATION IS CLUDING ANY IS Army 1 tion Lab 1 to 80240 1 ttee

Fegn AEC:2313 a 1:0-61 Page 1 Page 1	UNITED STATES ATOMIC ENERGY COMMISSION ION FOR BYPRODUCT MATERIAL LIC SE BUT SUPPLEMENT A HUMAN USE	m appraved. iget Bureau No.	38-R080 1
If byproduct material is for "human use	" (internal administration of pyproduct material, or the radiation therefrom the application for pyproduct material license.	to human b	eings),
 (a) USING PHYSICIAN'S NAME Department of the Army Fitzsimons General Hospita USA Med. Research & Nutriti THE USING PHYSICIAN INDICATED ABOVE IS LINOF THE UNITED STATES, THE DISTRICT OF COLU 	(b) NAME AND ADDRESS OF APPLICANT (If different from 1(a)) FITZSIMONS GENERAL HOSPITAL LONILAD. DENVER, COLORADO 80240 CENSED TO DISPENSE DRUGS IN THE PRACTICE OF MEDICINE BY A STATE OR TERRITORY MBIA. OR THE COMMONWEALTH OF PUERTO RICO.	(YES)	NO
As permitted by Fitzsimons 3. A STATEMENT OF USING PHYSICIAN'S CLINICAL OF THIS APPLICATION. IF ANSWER IS NO. L RELATED DOCUMENTS ON WHICH THIS INFORM	Gen. Hosp. Radioisotope Committee CIRCLE ANSW L RADIOISOTOPE EXPERIENCE (PAGE 3 OF THIS SUPPLEMENT) IS SUBMITTED IN SUPPORT ISE PAGE 2 OF THIS SUPPLEMENT TO EXPLAIN OR REFER TO OTHER APPLICATION OR LATION APPEARS.	FR YES	(NO)
As permitted by Fitzsimons	Gen, Hosp, Radioisotope Committee CRCLE ANSW	R	
	PROPOSED DIAGNOSIS OR TREATMENT		
(6) CHEMICAL FORM ADMINISTERED: Na2Cr04 (c) describe procedures which will be obsi See Licen	ryed to minimize hazard from handling, storage, and disposal of the byproduce $\#05{=}00046{=}13$	CT MATERIAL	
(d) DESCRIPTION AND SKETCHES OF SPECIAL DE (1) ATTACHED (LITERATURE REFERENCES WILL	VICES TO BE USED FOR ADMINISTERING BYPRODUCT MATERIAL TO HUMAN BEINGS ARE L SUFFICEI	YES	(NO)
(d) DESCRIPTION AND SKETCHES OF SPECIAL DE (1) ATTACHED (LITERATURE REFERENCES WIL (2) ON SILE WITH THE ISOTOPES EXTENSION REFER TO APPLICATION NO 5. (a) P2OPOSED DOSAGE SCHEDULE - In million	VICES TO BE USED FOR ADMINISTERING BYPRODUCT MATERIAL TO HUMAN BEINGS ARE L SUFFICEI See License #05=00046=13 CIRCLE ANSWE	R YES R (YES)	(NO) NO
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 (d) DESCRIPTION AND SKETCHES OF SPECIAL DA (1) ATTACHED (LITERATURE REFERENCES WIL (2) GAN FILE WITH THE ISOTOPES EXTENSION REFER TO APPLICATION NO	VICES TO BE USED FOR ADMINISTERING BYPRODUCT MATERIAL TO HUMAN BEINGS ARE L SUFFICE) CIRCLE ANSWE See License ≇05=00046=13 CIRCLE ANSWE ries for internally administered byproduct material other than discrete fixed sources, and in ro on from discrete fixed sources (gold seeds, cobail needles, etc.) state separately for each co dose range 0.015 = 0.003 millicuries. TAL, NEW OR UNUSUAL HUMAN USES IS ATTACHED. (Anochment aluated, including data from animal studies and/or abstract of literature s (i. e. age group, maribund, etc.))	R YES (YES) entgens or radio andition or disc radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio radio r	(NO) NO 5. at ease (NO)
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1. Applicant: Department of the Army	2. Control No. 96146
Address: Fitzsimons General Hospital and U. S. Army Medical Research & Nutrition Lab City: Denver State: Colorado 8024	3. Department
A. H. Janoski, Captain, MC Richard P. Carson, Captain, MC	5. Type program: Private practice. Private practice in hospital. Sinstitutional.
6. Review:	7. Previous application control No.(s)
X First. [] Second.	None
 A. All radioisotopes and uses stated in application. B. Use of C. Training and Experience of user. D. Doinee(a) indicated. 	for To be reviewed by: Drs. Raws Greenlaw, Armstrong
 A. All radioisotopes and uses stated in application. B. Use of C. Training and Experience of user. D. Doinge(s) indicated. E. Clinical techniques and procedures outlined. 	for To be reviewed by: Drs. Raws Greenlaw, Armstrong Christiar
 A. All radioisotopes and uses stated in application. B. Use of C. Training and experience of user. D. Doiage(o) indicated. E. Clinical techniques and procedures outlined. F. Type patient used (i.e., terminal, infants, normal). 	for To be reviewed by: Drs. Raws Greenlaw, Armstrong Christian
 A. All radioisotopes and uses stated in application. B. Use of C. Training and experience of user. D. Doiage(s) indicated. E. Clinical techniques and procedures outlined. F. Type patient used (i.e., terminal, infants, normal). G. Other 	for To be reviewed by: Drs. Raws Greenlaw, Armstrong Christian
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 A. All radioisotopes and uses stated in application. B. Use of C. Training and Experience of user. D. Doiage(s) indicated. E. Clinical techniques and procedures outlined. F. Type patient used (i.e., terminal, infants, normal). G. Other Action of Subcommittee on Human Applications: Approve. Disapprove. 	To be reviewed by: Drs. Raws Greenlaw, Armstrong Christian
 A. All radioisotopes and uses stated in application. B. Use of C. Training and experience of user. D. Doiage(o) indicated. E. Clinical techniques and procedures outlined. F. Type patient used (i.e., terminal, infants, normal). G. Other Action of Subcommittee on Human Applications: Approve. Bemarks: 	To be reviewed by: Drs. Raws Greenlaw, Armstrong Christian
 A. All radioisotopes and uses stated in application. B. Use of	To be reviewed by: Drs. Raws Greenlaw, Armstrong Christian

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	14	-6	§)	1.	

U.S. ATOMIC ENERGY COMMISSION MEDICAL ADVISORY COMMITTEE

APPRAISAL

1. Applicant: Department of the Army Address: Fitzsimons General Hospital and	2. Control No. 96146 3. Department			
Lab City: Denver State: Colorado 20240				
4. Name and title of trained individual A. H. Janoski, Captain, MC Richard P. Carson, Captain, MC	 5. Type program: Private practice. Private practice in hospital. Institutional. 			
6. Review:	7. Previous application control No.(s)			
🕅 First. 🔲 Second.	None			
C. Training and experience of user.	To be reviewed by:	Drs. Rawson, Greenlaw, Ross		
D. Dosage(s) indicated.		Greenlaw, Ross Armstrong, and Christian		
E. Clinical techniques and procedures outlined.	T.F.L	2		
F. Type patient used (i.e., terminal, intains, mornal).	anit is	No.		
G. Other Action of Subcommittee on Human Applications: Approve. Disapprove. Remarks:	SEP12 19 SEP12 19 LL AIDNIG ENE BALL AIDNIG ENE BOUNDING			
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(Date of appraisal)

9/7/67

Signature

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Form WA-272 (4-59)

U.S. ATOMIC ENERGY COMMISSION MEDICAL ADVISORY COMMITTEE

APPRAISAL

1. Applicant: Department of the Army	2. Control No. 96146			
Address: Fitzsimons General Hospital and U. S. Army Medical Research & Nutrition Lab City: Derver State: Colorado 80240	3. Department			
4. Name and title of trained individual A. H. Janoski, Captain, MC Richard P. Carson, Captain, MC	 5. Type program: Private practice. Private practice in hospital. Institutional. 			
6. Review:	7. Previous application control No.(s) None			
 8. Remark on checked items: A. All radioisotopes and uses stated in application. B. Use of 	for			
 C. Training and experience of user. D. Dosage(s) indicated. E. Clinical techniques and procedures outlined. F. Type patient used (i.e., terminal, infants, normal). G. Other 	To be reviewed by:	Drs. Rawson, Greenlaw, Rossi Armstrong, and Christian		
9. Action of Subcommittee on Human Applications:				

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(bla

August 21, 1967 (Date of appraisal)

Form WA-272 (4-59)

U.S. ATOMIC ENERGY COMMISSION MEDICAL ADVISORY COMMITTEE

APPRAISAL

1. Applicant: Department of the Army	2. Control No. 96146			
Address: Fitzsimons General Hospital and U. S. Army Medical Research & Nutrition Lab Giv: Denver State: Colorado 80240	3. Department			
4. Name and title of trained individual A. H. Janoski, Captain, MC Richard P. Carson, Captain, MC	 5. Type program: Private practice. Private practice in hospital. F3 Institutional. 			
6. Review:	7. Previous application control No.(s)			
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8. Remark on checked items:				
A. All radioisotopes and uses stated in application.				
B. Use of	for			
 C. Training and experience of user. D. Dosage(s) indicated. E. Clinical techniques and procedures outlined. F. Type patient used (i.e., terminal, infants, normal). 	To be reviewed by: Drs. Rawson Greenlaw, Ross Armstrong, and Christian			
9. Action of Subcommittee on Human Applications:				
Approve. Disapprove.				
Remarks:				
Approved with the understanding that the Form AEC-313 Item 4 are A.H. Janoski and	individual users as requested dan R.P. Carson			
August 16, 1967 Signature	(Blassier of allowing)			

Form WA-272 (4-59)

U.S. ATOMIC ENERGY COMMISSION MEDICAL ADVISORY COMMITTEE

APPRAISAL

1. Applicant: Department of the Army Address: Fitzsimons General Hospital and U. S. Army Medical Research & Nutrition Lab Giv: Denver State: Colorado 80240	2. Control No. 96146 3. Department	
4. Name and title of trained individual A. H. Janoski, Captain, MC Richard P. Carson, Captain, MC	 5. Type program: Private practice. Private practice in hospital. Institutional. 	
5. Review:	7. Previous application control No.(s) None	
 Kemark on checked items: A. All radioisotopes and uses stated in application. B. Use of C. Training and experience of user. D. Dosage(s) indicated. E. Clinical techniques and procedures outlined. F. Type patient used (i.e., terminal, infants, normal). 	To be reviewed by:	Drs. Rawson, Greenlaw, Ross: Armstrong, and Christian
G. Other		annen and an and an and a star star and
 Action of Subcommittee on Human Applications: Approve. Disupprove. Remarks: Although I continue in involving appreciable radicarried out by delegated involving appreciable radicarried out by delegated involves. 	my opposition to reseat iation exposure that is investigators.	rch AR ald H. Rossi
0130103	Har	ald H. Rossi

Form AEC-313 (5-58)	AFPLICATION FOR BYPRODU	ICT MATERIAL LICENSE	Form approved. Budget Bureau No. 38-R027 4
INSTRUCTIONS.—Cor plete only Items 1 th supplemental sheets v Commission, Washing application, the appli accordance with the g ject to Title 10, Code	nplete items 1 through 16 if this is an in rough 7 and indicate new information o where necessary. Item 16 must be complet ton 25, D. C. Attention: Isotopes Bran cant will receive an AEC Byproduct Ma eneral requirements contained in Title 11 of Federal Regulations, Part 20.	itial application. If application is f r changes in the program as request ed on all applications. Mail three ci ch, Division of Licensing and Reg terial License. An AEC Byproduct 0, Code of Federal Regulations, Pa	or renewal of a license, com ed in Items 8 through 15. Us opies to: U. S. Atomic Energy ulation. Upon approval of thi Material License is issued ir rt 30 and the Licensee is sub
(a) NAME AND STREET AD person, ek) Department of Fitzsimons Gen Army Medical P. Denver, Colo.,	DRESS OF APPLICANT (Institution, firm, hospital, the Army eral Hospital and U. S. asearch & Nutrition Lab 80240	(b) STREET ADDRESS(ES) AT WHICH BYPRO different from 1 (a)) Fort Lewis, Washington Summit of Pikes Peak,	DUCT MATERIAL WILL BE USED (1) n and Colorado
Physiology Div. U.S.Army Medica	DOUCT MATERIAL ision al Research & Nutrition Lab	3. PREVIOUS LICENSE NUMBER(S). (If this license, placese indicate and give number.) Present application is Lice No. 05-00046-13	is an application for renewal of a
(INDIVIDUAL USER(S) (No supervise use of byproduct m 9.) As specified an isotope Commit Hospital	me and title of individual(s) who will use or directly sterial Give training and experience in Items 8 and and approved by the Radio- tee, Fitzsimons General	5 RADIATION PROTECTION OFFICER (Name lection officer if other than individual user perience as in Items 8 and 9.) Same as 4	of person designated as radiation pro- Attach resume of his training and ex-
 (a) BYPRODUCT MATERIAL and mass number of east A. Carbon-14 B. Hydrogen-3 	(Elements h) (b) CHEMICAL AND/OR PHYSICAL FC ICAL FORM THAT YOU WILL POSS number, number of sources and mo A. 4- ¹⁴ C-cortisol B. 1,2- ³ H-aldoster	DRM AND MAXIMUM NUMBER OF MILLICURIES ESS AT ANY ONE TIME (If sealed source(s), ximum activity per source) A. 0.1 millic DDB B. 0.1 millic	OF EACH CHEM:CAL AND/OR PHYS also state name of manufacturer, mode urie urie
DESCRIBE PURPOSE FOR W pleted in lieu of this item if which the source will be stored See Form AEC-	HICH BYPRODUCT MATERIAL WILL BE USED. (If by byproduct material is in the form of a sealed source, i d and/or used.) 313a attached	product material is for "human use," supplemen nclude the make and model number of the si	I A (Form AEC-313a) must be com- brage container and/or device in

TRAINING AND EXPER	ISLUCE OF EACH INDIVIDUA	I NAMED IN ITEM A	Illes supplemental s	heats if nacessary)	
The second second	IENCE OF EACH INDIVIDUA	L HAMED IN HEM &		ON THE LOB	FORMAL COURS
TYPE OF TRAINING	WHERE TR	NINED	TRAINING	(Circle answer)	(Circle answer)
Principles and practices of radiation protection	Individuals will riate training &	have approp- experience		Yes No	Yes No
Radioactivity measurement stc lardiza- tion and manitoring techniques and in- struments	prior to their ap Radioisotope Com General Hospital	pproval by the nittee, Fitzsim	ons	Yes No	Yes No
Mathematics and colculations basic to the use and measurement of radioactivity				Yes No	Yes No
Biological effects of radiation				Yes No	Yes No
EXPERIENCE WITH RADIATION. (Actual	use of radioisotopes or equivalen	experience.)			
OTOPE MAXIMUM AMOUNT WH	ERE EXPERIENCE WAS GAINED	DURATION OF E	KPERIEMCE	TIPE O	FUSC
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Form AEC-313 a (10-61) PAGE 2

UNITED STATES ATOMIC ENERGY COMMISSION APPLICATION FOR BYPRODUCT MATERIAL LICENSE SUPPLEMENT A --- HUMAN USE

Form approved. Budget Sureau No. 38-R080.1

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March 1967

USAMRNL PHYSIOLOGY DIVISION PROTOCOL

Project No.3A104501B71R Research in Diomedical SciencesTask No. 05:Environmental MedicineWork Unit No. 82:Metabolic Effect of AltitudeStudy No. 4:Endocrine Effects of Altitude

I. INTRODUCTION

It has been establish d that acute exposure of man to high altitude causes the onset of a distressing, incapacitating syndrome, termed "mountain sickness." (1, 2, 3) This syndrome is characterized by impaired physical and psychomotor performance. The transitory effects of high altitude exposure - the most debilitating symptoms severe headache, nausea and vomiting, extreme fatigue and anorexia usually last up to 5 - 6 days in most subjects. These symptoms are variable in intensity in different people or in the same person at different times.

Various theories have been advanced in the attempt to explain the etiology of mountain sickness. Research has been concerned primarily with the evaluation of cardiopulmonary and acid-base alterations in man. Still, all of the reported, established alterations do not explain the phenomenon of acclimatization that occurs in most subjects within 5 - 7 days. Recently, in the attempt to discover the cause of mountain sickness and the mechanisms of adaptation, investigators have focused on endocrine function, shifts in body fluids, and electrolyte balance in man at high altitude. The following sections summarize the observed alterations of endocrine function, body fluids and electrolytes in man at high altitude. There is a wealth of literature of similar observations conducted on animals which is essentially consistent with the reports on man (4 - 14).

Body Fluids and Electrolytes in Man at High Altitude

When man ascends rapidly to high terrestrial locations, there is a continuous decrease in plasma volume, a decrease in extracellular fluid volume, and a rise in intraceilular fluid volume. Total body water increases (15). Total body potassium obtained from body scanning for K⁴⁰ is noted to be increased by one research group (16) but similar measurements made by USAMRNL show that total body potassium decreases (15). Excessive urinary excretion of sodium, potassium and chloride ions has been documented (15, 17). There is a significant rise in salivary sodium to potassium ratio (18) and urinary sodium to potassium ratio (17). In addition to electrolyte changes, urine volume increases at high altitude (19).

These observed effects of altitude on man resulting in body fluid shifts and electrolyte alterations suggest diminished aldosterone secretion by the adrenal glands. Very recently it has been reported that urinary aldosterone excretion does decrease at altitude, approaching zero within three days of high altitude exposure (19). These findings appear to be consistent with the observed pattern of urinary electrolyte excretion. Additional investigation is necessary in order to establish and correlate the electrolyte changes with aldosterone secretion at high altitude by means of balance studies with human volunteers. If aldosterone excretion is indeed diminished at high altitude in the face of sodium loss, diminished plasma and extracellular fluid volumes, the mechanism is unknown and is contrary to accepted physiological controls of aldosterone secretion.

Adrenocortical Function in Man at High Altitude

Various investigators using intermittent chamber studies in man (20, 21), or actual field studies at high altitude (17, 22, 23),

have observed a rise in the 24-hour urinary excretion of 17-ketosteroids and 17-hydroxycorticosteroids during acute exposure. One research group did note a difference in the excretion pattern of 17-hydroxycorticosteroids and 17-ketosteroids. The latter decreased initially. Adrenal function has been studied in a group of high altitude natives, and is the same as a comparable group living at sea level (24).

These studies are generally consistent with the known physiological control of pituitary adrenal function during stress. The correlation of adrenocortical function to "mountain sickness" and the magnitude of environmental adrenocortical steroid secretion and ACTH release during stress require additional investigation. The accurate measurement of these hormones during acute altitude exposure can determine the desirability of a possible therapeutic means of controlling the symptoms of high altitude stress in man.

Glucose Tolerance in Man at High Altitudes

Studies in man (25, 26, 27, 28) have established that there is a lower fasting blood glucose level and greater utilization of glucose at high altitude. Whether the cause of enhanced glucose utilization is secondary to increased insulin secretion or the effect of adrenocorticosteroids on glucose metabolism, is not known, and should be determined.

II. OBJECTIVE

The objectives of the present proposal to study human subjects at high altitude are (1) to evaluate through balance studies, the nature of electrolyte alterations: (2) to determine the magnitude of the stress response at altitude by evaluation of pituitary and adrenocortical function; (3) to measure and correlate the aldosterone secretion and excretion in relationship to electrolyte changes; and (4) to investigate the mechanism for increased glucose utilization.

The purpose of the study will be to correlate these findings with the severity of mountain sickness symptoms at 14, 100 feet.

III. JUSTIFICATION

Reports concerning the Indian Army (29) have furnished alarming evidence of incapacitating medical and personnel problems resulting from altitude sickness, when a military force attempts to function on mountain locations. An understanding of the physiological alterations during altitude acclimatization and the relationship of these to various mountain sickness symptoms might lead to successful methods of pre-selecting or preconditioning troops.

Knowledge of the endocrine function in man at high altitude would shed light on the adaptive changes that occur during the stress of hypoxia. Significantly patho-physiological alterations in hormone secretion can be dealt with therapeutically. Recent Army Research Office conferences (30, 31) have pointed to a military need for studies on physiology, pharmacology and performance in high terrestrial environments.

IV. EXPERIMENTAL DESIGN

A. The subjects will be ten U. S. Army volunteers (19 to 25 years old) who have signed a volunteer form indicating their knowledge of the scope of the procedures planned, including the intravenous administration of tracer quantities of radioactive steroid compounds and their willingness to serve as subjects. The radioactive concentration of these isotopes will be recorded in the subjects' Army Health Records. The subjects will be interviewed, examined and selected by a medical officer after review of their health records to exclude cardiopulmonary, renal or endocrine disorders. A medical officer is to be present during the entire study and is authorized to terminate the experiment at any time continuation would be detrimental to the health of the subject.

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The study will be conducted for a total period of 21 days beginning 11 September 1967. The sea level studies will be conducted at Fort Lewis, Washington. This site meets the requirements that the sea level site be located in a temperate climate. A hot, humid climate would make electrolyte balance studies inaccurate. In addition, heat exposure alters blood volume and this would interfere with studies on aldosterone secretion.

During the sea level test period, constituting days 1 to 14, the subjects will be started on a constant metabolic diet which will require eight days of equilibration of body electrolytes prior to initiating balance studies. This diet will be continued until the end of the study on day 21. On day 15 the subjects will be flown to Colorado Springs or Denver and transferred by Army vehicle to the Army mobile laboratory on Pikes Peak (14, 100 ft). The altitude test phase will be conducted there with living quarters provided for the subjects.

B. Clinical Study

1. Plan of study

a Sea level test period - 0900 hours day 1 to 0900 hours day 15.

b. Travel period - day 15.

c. Altitude test period - 0900 hours day 16 to 0900 hours day 21.

2. Diet

A prepared liquid diet comprising daily consumption of 2,800 calories as 55% carbohydrate, 15% protein, and 30% fat. The daily electrolyte and mineral intake will be 100 mEq. of sodium, 80 mEq. of potassium, 1600 mg of calcium, and 1200 mg of phosphorous. The diet and water content are to be constant and analysed. During the day of travel, the subjects will be maintained on this diet. On days 5 and 19, the subjects will fast from 21:00 hours until 14:00 hours the following day (glucose tolerance test). There will be no smoking during this interval.

3. Water intake

Distilled water will be used for drinking purposes. Daily water intake will be measured and recorded. A minimum of 1500 ml of water per subject per day is to be consumed.

4. Medications

a. Glucose - 100 grams in distilled water administered orally on days 6 and 20 at 09:00 hours

b. $4-C^{14}$ - cortisol (1µc) and 1, 2-H³- aldosterone (2µc) - administered intravenously in 10 ml sterile solution of 10% ethanol in water at 09:00 hours on days 9 and 17.

c. Sodium chloride - 500 mg in gelatin capsules in the event of diminished dietary intake to maintain constant daily sodium intake.

d. Potassium replacement elixir (5 ml contains 10 mEq. of potassium as gluconate and citrate salts) - to maintain constant daily potassium intake if intake of food diminishes when anoretic.

e. Calcium gluconate tablets - 500 mg if food intake diminishes when anoretic to maintain constant daily intake of calcium.

f. Aspirin and Darvon - administered orally at the discretion of the medical officer for headache. The dosage and time of administration are to be recorded.

g. Intravenous infusions of isotonic sodium chloride and potassium will be administered if severe vomiting occurs in order to maintain electrolyte and water balance.

- 5. Collections
 - a. Urine

Total 24-hour urine collections will be obtained from each subject starting at 09.00 hours each day. Each collection period will end on 09:00 hours the following day with the subjects voiding at this time and adding this specimen to the previous day's collection. The days of collection are 8 through 14 and 16 through 20. The urine will be stored in large plastic bottles and kept under refrigeration at all times during collection. At the end of each 24-hour collection period, all urine collected will be frozen and will be kept in this state until analysed at the USAMRNL. All specimen bottles will be labeled with name of subject, and the starting and ending dates of the 24-hour collection. Radioactivity labels will be affixed to all 24-hour urine samples collected after the administration of radioisotopes to the subjects.

- b. Blood
 - (1) Plasma insulin and glucose

At 08:30 hours on days 6 and 20, 5 ml of venous blood will be drawn into fluoride-oxalate vacuum tubes. Following oral glucose administration, similar samples will be taken at 15, 30, 45, 60, 90, 120, 240, and 300 minutes. The tubes will be labeled and the contents frozen. The subjects are to refrain from smoking from the period of fasting until the final blood sample is drawn.

(2) Plasma ACTH and cortisol

On days 9, 10, 13, 16, 17 and 18, venous blood will be taken at 08:45 hours. Thirty ml of blood will be drawn into a syringe containing heparin and transferred to centrifuge tubes and centrifuged. The plasma will be transferred to screw-cap glass tubes, labeled "cortisol and frozen. Forty ml

of venous blood will be collected through sterile plastic tubing directly into a large centrifuge tube containing heparin. The centrifuge tube will remain immersed in an ice-water bath during the collection, then immediately centrifuged at 12 degrees centigrade. The plasma will be transferred to screw-cap tubes labeled "ACTH" and frozen. All tubes will be labeled with name of subject, time and date.

3) Fifteen ml of venous blood will be taken at 15:00 hours on days 8, 9, 10, 13, 14, 16, 17, 18, 19, and 20. Following centrifugation, the serum will be transferred to labeled test tubes and frozen.

c. Feces

Feces will be collected in plastic bags on days 8, 9, 10, 11, 12, 13, 14, 16, 17, 18, 19 and 20.

d. Vomitus

Any vomitus will be collected in plastic bags for

analysis.

C. Measurements

1. Electrolytes

Concentrations of sodium and potassium in the diet, venous blood, stools and urine will be determined by AutoAnalyzer or flame photometry. Calcium will be measured by atomic absorption spectrophotometry. Chloride and creatinine will be measured by the Auto-Analyzer. The Fiske and Subbarow method will be used for phosphate concentrations.

2. Nitrogen

Urinary nitrogen content will be determined by the Auto-Analyzer. The macro-Kjeldahl technique will be used for nitrogen in the diet and in the feces.

3. Fat

Diet and stool fat will be determined by routine analytical methods.

4. Glucose and insulin

Plasma glucose will be measured by AutoAnalyzer. Plasma insulin will be determined by Captain J. Anderson, Metabolic Division of the USAMRNL employing the method of Morgan and Lazarow (32).

5. Steroids

a. Plasma cortisol by the Peterson modification (33) method of Silber and Porter (34) using the Beckman DU Spectrophotometer.

b. Total 24-hour urinary 17-ketosteroids and 17-ketogenic
 steroids by the Sobel (35) modification of the Norymberski method.
 Gas-liquid chromatography will be used to determine individual
 17-ketosteroids.

c. Twenty-four hour uninary aldosterone excretion by a modification of the double isotope technique of Kliman and Peterson (36) using $1, 2-H^3$ -aldosterone, $1, 2-H^3$ -tetrahydroaldosterone, and acetic-1-C¹⁴ anhydride.

d. Twenty-four urinary cortisol excretion by the method of Erlich (37), using 1,2-H³-cortisol and acetic-1-C¹⁴ anhydride.

6. Plasma adrenocorticotropic hormone

ACTH levels in plasma will be determined by the method of Vernikos-Danellis (38) by means of bioassay in hypophysectomized rats.

7. Plasma and urine osmolality

Camolality will be determined by means of the Fiske osmometer.

D. Radioactive Steroids as Tracers in Human Subjects

1. Purification

4-C¹⁴-cortisol (specific activity SA 15-30 mc/millimole)

and 1, 2-H³-aldosterone (SA 35 curies/millimole) obtained commercially from New England Nuclear Corporation will be tested for purity by chromatography on three separate systems. The purified isotopes will be dissolved in absolute ethanol, and sterilized rendering them pyrogenfree by Millipore filtration. The isotopes will be kept as a 10% solution of ethanol in sterile water in a sterile, multi-dose, stoppered vial. They will be administered intravenously to the subjects by a medical officer.

2. Dosage considerations and calculations

It has been determined that over 90% of injected radioactively labeled cortisol is excreted by human subjects via the kidney within the first 48 hours (39, 40). Furthermore, no radioactivity can be detected in the body fluids in four days (39). The biological half-life of radioactive cortisol in the human bloodstream is 60 - 80 minutes (41). Similarly, over 90% of radioactive aldosterone injected into human subjects is excreted in the urine within 48 hours (42). The location of the tritium and carbon-14 labels in the steroid nucleus is such that the labels remain an integral part of the compound in the body and are excreted intact as steroid metabolites without degradation. (43). This factor has enabled numerous investigators to employ these isotopically labeled steroids in clinical research without the hazards of critical organ concentration, the random labeling of body water by tritium, or the expiration of carbon-14 carbon dioxide in human subjects.

Based on knowledge gained from reports in the literature, one can make the safe assumption that the effective half-life (T 1/2) of these isotopes in man is one day (an over-assumption). The total body burden would be calculated as follows: (44)

1. $4-C^{14}$ -cortisol. 1 µc injected into a 70 kg man assuming total body distribution with an effective T 1/2 of one day.

DB~73.8 x C x EB x T rads

 $E\beta \approx 0.050$ Mev. for C^{14} $C \approx 1.0/70,000$ $T \approx 1$ day $D\beta \approx 73.8 \times 1.0/70,000 \times 0.050 \times 1$ rads $D\beta \approx 5.27 \times 10^{-5}$ rads

2. 1, $2-H^3$ - aldosterone. Two μ c injected into a 70 kg man **as**suming total body distribution with an effective T 1/2 of one day.

$$\begin{split} D\beta &\approx 73.8 \ \text{x C x E}\beta \ \text{x T rads} \\ \tilde{E}\beta &\approx 0.006 \ \text{Mev. for H}^3. \\ C &= 2.0/70,000 \\ T &\approx 1 \ \text{day} \\ D\beta &\approx 72.8 \ \text{x } 2.0/70,000 \ \text{x } 0.006 \ \text{x 1 rads} \\ D\beta &\approx 1.26 \ \text{x } 10^{-5} \ \text{rads} \end{split}$$

During the control period 1.0 μ c of 4-C¹⁴-cortisol and 2.0 μ c of 1,2-H³-aldosterone will be injected simultaneously (6.53 x 10⁻⁵ rads). This will be repeated once at high altitude the following week. The total radiation dose received by each individual will be no more than 1.3 x 10⁻⁴ rads which is considerably below the limits generally agreed upon for an internal emitter - approximately 0.1 rem per week (5 rem per year).

3. Monitoring radioactivity

During the experimental studies, after the administration of radioisotopes all excreta will be collected until levels of radioactivity are equal to background levels. All samples containing radioactivity will be returned to the U.S. Army Medical Research and Nutrition Laboratory at Denver, Colorado for analysis. All radioactive waste will be transported to Denver and disposed of by the Radioisotope Section of the USAMRNL as outlined in "Procedures for Use of Radioactive Material" (See Appendix E Application for Renewal and Amendment to AEC Byproduct Material License No. 5-46-13 (A66) dated June 1966). All areas where radioisotopes are used will be monitored by means of a PAC-3G with a beta probe (Eberline Instrument Company, Serial No. 1226). Also periodic wipes will be taken with moist gauze and returned to the U.S. Army Medical Research

and Nutrition Laboratory for counting in a Packard Model 3314 liquid scintillation counter (Serial No. A3314-05-00712).

All rules, regulations and limitations set forth by Army AEC and local authorities, including those embodied in AR 70-25; AR 40-37; Title 10, Part 20, Code of Federal Regulations "Standards for Protection Against Radiation"; and Handbook 69 of the National Bureau of Standards will be complied with.

Enclosed and attached to this protocol is the Voluntary Consent Statement relating to the intravenous administration of radioisotopically labeled steroid compounds as tracers. (See Appendix I)

4. Determination of the Secretory Rates of Cortisol and Aldosterone

a. Cortisol secretion rate

The cortisol secretion rate will be determined by the method of Roginsky, et al. (45) from the combined 48-hour urine collection following isotope injection.

b. Aldosterone secretion rate

This will be determined by the method of Kelly, et al. (46) using the double isotope derivative method.

V. ADMINISTRATION

A. The study will be the responsibility of the Physiology Division of USAMRNL.

B. The personnel and their responsibilities will be assigned as follows:

1. Captain A. H. Janoski, MC: Project leader; responsible medical officer.

2. John P. Hannon, Ph. D.: Project Co-leader.

3. J. L. Shields, Ph. D.: Project Co-leader.

- 4. Captain R. P. Carson, MC: Medical Officer
- 5. Captain B. Whitten, MSC: Administrative officer
- 6. George J. Klian, Ph. D.: Technical supervisor
- 7. Major C. G. Liddle, V. C.: Radiation officer
- 8. One NCOIC: Subject control and dietary supervisor
- 9. Four enlisted military technicians
- 10. Two civilian technicians

C. Continuous physician coverage during the study will be the responsibility of Captains A.H. Jancski and R.P. Carson of the U.S. Army Medical Corps.

D. Cost

1.	Equipment	800.00
2.	Chemicals, including solvents	\$4,000.00
3.	Per diem for subjects	210.00
4.	Travel for subjects	1,500.00
5.	Diet for subjects	500.00
6.	Air freight (samples collected during study)	700.00
7.	Class A Funds	600.00
8,	Travel for project personnel (7 investigators, 5 enlisted men, 2 civilians). Includes one round trip to Seattle	2,100.00
9.	Rental truck for equipment (30 days)	900.00
10.	GSA vehicles (2 for 21 days)	400.00
11.	Lab rats for bioassay (250 rats)	800.00
12.	Per diem for investigators	2,400.00
13.	Per diem for enlisted men	
	 a. Sea level site - 14 days (government quarters available, government mess not available). 	560.00

14.	Per diem for civilian technicians (21 days)	\$672.00
15.	Three investigators' per diem for three-day site survey	144.00
16.	Three investigators' travel to Seattle for site survey (3 round trips)	450.00
17.	Additional per diem for 3 investigators for four days at sea level site to set up study	192.00
18.	Additional per diem for 4 enlisted men for four days at sea level site to set up study (government quarters available; government mess not available)	128.00
19.	Miscellaneous expendable items	\$,200.00
	Total	\$18,816.00

E. Miscellaneous

Since the final approval by the AEC for the use of isotopes in human studies rests on the approval of the protocol and definite site selection for sea level studies, it is requested that final action on this protocol be no later than 5 June 1967. If the protocol is approved at this time, application would then be made to the AEC for action on the license amendment. Furthermore, final action on the protocol at this date would enable the investigators to prepare the isotopes for human administration and to obtain the necessary chemical supplies for the field study.

F. Additional Information

See Appendix I and Appendix II.

A. H. JANOSKI Captain, MC

VOLUNTARY CONSENT STATLMENT

Allitory	Military Patient	Civilian	Civilian Patient	
1,		, having th	ne capacity to consent,	
voluntarily and wi	thout force or duress conse	ent to participate i	n research involving the use	
of tracer amounts	of radioisotopes. I have b	een informed of, a	ind understand, the nature,	
duration, and purp	oose of the experiment, the	e method and mean	is by which it is to be conducte	ed,
the inconvenience	s and hazards to be expect	tea, and the effect	s upon my health and person	
which may possibly	y come from participation	in the experiment.		

Specifically, I agree to receive (intravenously) a small quantity of _________. I also agree to furnish urine and stool samples for the period following until no detectable radioactivity is present and submit to measurements of expired gases if Carbon-14 has been received.

I understand that I may at any time during the course of the experiment revoke my consent and withdraw from the experiment without prejudice.

I do not at this time nave any physical diseases, except for the following _______, or mental disease, to the best of my knowledge.

DATE

SIGNATURE

SIGNATURE OF WITNESS

APPROVAL

I have personally ascertained that the quality of the foregoing consent is sufficient to permit the volunteer to participate in the experiment.

ATTENDING PHYSICIAN

PROJECT LEADER

APPENDIX II

SUBJECT STATEMENT

Date

I voluntarily agree to participate as a subject in the experiment t. 52 conducted on high altitude. I am aware that I may withdraw from the experiment at any time without prejudice or penalty of any kind. It has been explained to me that constant medical supervision will be maintained and that neither the exposure to high altitude nor the experimental techniques used in this study are unduly hasardous. I realize that in some subjects the high altitude may cause any or all of the following symptoms: dryness of the mouth and nose, excitement, blurring of vision, dissiness, tiredness, tremor, lack of appetits, mild cramps, thirst, confusion, a sense of well-being, sleepiness, muscular aches, ringing in my ears, nausea, runny noss, headache, hunger, sleeplessness, coughing, rapid heart beat, chest pains, fatigue, constipation, fever, muscular stiffness, stomach ache, itching or sneesing.

The nature and purpose of the experiment have been explained to me and I sign this statement fully understanding the project, any hazards connected with it, and my rights.

(Name)

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Mathematics and calculation use and measurement of ra	s basic to the idioactivity		11			l m	0. (***) N	lo (Yes)
1. Biological effects of radiatio	20		. 11] m	Yes N	o (Yes)
EXPERIENCE WITH RADIATIC	DN. (Actual	use of radiois	otopes or equivale	nt experience)				******
SOTOPE MAXIMUM AMOUNT	WH	IERE EXPERIENC	E WAS GAINED	DURATION	OF EXPE	RIENCE	TYP	E OF USE
I ¹³¹ 10 Mc	Univ.	of Mi	ch. Med.	Center 1	. Mon	ith	Diagnost Therapeu	tic and utic
(e ¹³⁵ 1 Curie	Univ.	of Mid	ch. Med.	Center 1	Yea	r	Research	n
RADIATION DETECTION INS	STRUMENTS	(Use supplen	nental sheets if ne	(#ssory)		and the second product of the second		
TYPE OF INSTRUMENTS (Include make and model number	of each)	NUMBER	RADIATION	SENSITIVITY RANGE (mr /hr)	WINDO	W THICKNE	(Monitoring,	USE surveying, measur
2. FILM BADGES, DOSIMETERS, A	ND BIO ASSA	Y PROCEDURE	S USED. (For film	bodges, specify method	of calibra	ling and proc	essing, or name of s	upplier)
IN FACILITIES AND EQUIPMENT	FORMATIC	DN TO BE	SUBMITTED	ON ADDITIONA	L SHEE	TS IN DU	JPLICATE fume hoods, etc.	Explanatory sketch
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This page furnished	SUPPLEMENT A-HUMAN US	ERIAL LICENSE	Form approved. Budget Bureau No. 38-R080.1
	may be completed by the physician's proceptor (if any) in the medic by the preceptor, the name and present address of the preceptor (if a	al use of radioisotope any) should be shown	s. When the information is not in item 12 below.
RICHAI USAMRI	PHYSICIAN'S NAME rd P. Carson, Capt MC NL	(If different from 9(a))	
Denver	r, Colo.		
CUNKA	TRAINING AND EXPERIENCE OF PHYSICIAN WHO WILL USE BYPRODUCT MAT	ERIAL	
///	(8)	(C)	(D)
ISOTOPE	CONDITION(S) DIAGNOSED OR TREATED	NUMBER OF CASES	TYPE OF PARTICIPATION FOR ALL CASE IN COLUMN 8 (circle applicable num bers of items in accordance with key se forth below)
1-131	Diagnosis of thyroid function	24	1 2 3 4
	Treatment of hyperthyro. lism	6	() (2) (3) (4)
	Treatment of thyroid can er	3	() (2) (3) (A)
	Treatment of cardiac con litions	1	1 2 3 (4)
	Brain tumor localization		1 2 3 4
	Blood determinations	3	(1) (2) 3 (4)
	Kidney function		1 2 3 4
	Others		1 2 3 4
P-32	Treatment of polycythemia and leukemia	3	(1) (2) (3) (4)
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	Treatment of bone metastases		1 2 3 4
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CHO4	Treatment of clevral effusions and/or ascites		1 2 3 4
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108	Transment of prostatic cancer	A second character makes and a second s	1 2 3 4
Callaid	Transment of cervical concer		1 2 3 4
Comoro	Treatment of pleural effusions and/or ascites		1 2 3 4
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C. 53	Blood determinations	3	1 2 3 4
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U. S. ARMY MEDICAL RESEARCH AND NUTRITION LABORATORY FITZSIMONS GENERAL HOSPITAL DENVER, COLORADO, 80240

IN REPLY REFER TO

MEDEN-PH

7 July 1967

SUBJECT: Application for Amendment to AEC Byproduct Material License No. 05-00046-13

THRU: Commanding General U. S. Army Medical Research and Development Command ATTN: Chief, Medical Rsch Br. Office of The Surgeon General (20) 13 July 1967 Department of the Army Washington, D. C. 20315

TO: The Surgeon General ATTN: MEDPS-PO Department of the Army Washington, D. C. 20315

1. Submitted herewith is application for renewal and amendment to Byproduct Material License No. 05-00046-13 in six copies for appropriate processing.

2. Approval has been granted by the Office of The Secretary of the Army for the use of radioisotopes in human volunteers; therefore, this application is for an AEC amendment to use radioisotopes in humans and to use them at Ft. Lewis, Washington and Pikes Peak, Colo.

3. Request expeditious handling of the request to permit meeting the deadline imposed by the limited period of availability of the 14,100 ft altitude area of Pikes Peak for this study.

3 Incls:

1. AEC Forms 313 & 313a 2. Protocol 3. Trng & Exp

and a space JAMES C. SYNER

Colonel, MC Commanding



DEPARTMENT OF THE ARMY OFFICE OF THE SURGEON GENERAL

WASHINGTON, D.C. 20315

MEDPS-PO

2 August 1967

Isotopes Branch Division of Materials Licensing U. S. Atomic Energy Commission Washington, D. C. 20545

Gentlemen:

Recommend that the inclosed application for amendment to AEC Byproduct Material License for Fitzsimons General Hospital be approved.

Sincerely,

and the

HERSCHEL E. GRIFFIN Colonel, M. C. Chief, Preventive Medicine Division

l Incl as (in trip)

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NSTRUCTIONS_Complete less 1 through 16 if this is an initial application. If application is for reasonal of a license, complete the information or changes in the program as requested in less 6 through 15. Or of the second of application. Mult have capital in the sequence of a license, the sequence of all applications. Mult have capital in the sequence of a license, the sequence of the sequence of the license, the sequence of a license, the sequence of a license, the sequence of the license, the sequence of the sequence of the license is the sequence of the sequence of the license, the sequence of the license is the sequence of the sequence of the license of the license of the license of the license is the sequence of the sequence of the license of the license of the license is the sequence of the sequence of the license is the sequence of the license of the licen	Form AEC-313 (5-58)	PPLICATION FOR BYPRODU	CT MATERIAL LICENSE	Form approved Budget Bureau No. 38-R027 4
(1) NAME AND STREET ADDRESS OF APPLICANT (Institute, for., hughthin, hughthin, for., hughthin, for., hughthin, f	INSTRUCTIONSComplete Ite plete only Items 1 through 7 a supplemental sheets where nec Commission, Washington, D.C., application, the applicant will accordance with the general red ject to Title 10, Code of Feder	ms 1 through 16 if this is an init ind indicate new information or c essary. Item 16 must be complet 20545. Attention: Isotopes Bran receive an AEC Byproduct Mate quirements contained in Title 10 al Regulations, Part 20.	ial application. If application is for hanges in the program as requested ed on all applications. Mail three co ich, Division of Licensing and Regul- rial License. An AEC Byproduct Ma , Code of Federal Regulations, Part	renewal of a license, com- in Items 8 through 15. Use pies to: U.S. Atomic Energy ation. Upon approval of this sterial License is issued in 30 and the Licensee is sub-
OPERATINE TO USE REFERENCE CONTRACTERIAL Radioisotope Clinic Cardiac Catheterization Laboratory 1 PERVOLUCIONAL USERS: (Phone and hile of individual(s) who will use a description for remeal of pervolution of the of individual(s) who will use a description in times 8 and pervolution. USERS: (Phone and hile of individual(s) who will use a description in times 8 and pervolution. USERS: (Phone and hile of individual(s) who will use a description isotope Committee, Fitzsimons General Hospital 1 PERVOLUCION OFFICE There of pervolution of the distribution of the of the fit of the fit of the officient of the fit of the officient sotope Committee, Fitzsimons General * 0) PERCODUCI MATERIAL (10) PERCODUCI MATERIAL (11) (10) OFFICION OFFICE TORM AND MAXIMUM NUMBER OF MULLICURES OF EACH OFFICIAL AND/OR PERCENCIPS OFF	(o) NAME AND STREET ADDRESS OF perior, etc.) Department of the A Fitzsimons General U.S. Army Med. Rs Denver, Colorado	APPLICANT (Institution, firm, hospital, Army I Hospital and Sch. & Nutrition Lab. 80240	(b) STREET ADDRESS(ES) AT WHICH BYPROD different from 1 (a)) Same as 1 a	UCT MATERIAL WILL BE USED. (1
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 (a) BYPRODUCT MATERIAL (flement out down of a subbrack and the store of each.) (b) OHEMICAL AND/OR PHYSICAL FORM AND MAXIMUM NUMBER OF MULLICURES OF EACH CHEMICAL AND/OR PHYSICAL FORM ANY ONE TIE. (if weided source), only down of an and and and and and and and the store.) (c) OHEMICAL AND/OR PHYSICAL FORM ANY ONE TIE. (if weided source), only down of an and down and down and and into the store.) (c) OHEMICAL AND/OR PHYSICAL FORM ANY ONE TIE. (if weided source), only down of an and and the store and maximum and the store.) (c) OHEMICAL AND/OR PHYSICAL FORM ANY ONE TIE. (if weided source), only down of an and and the store and maximum and the store and of a subbrack and the store and of a subbrack and the store and of a subbrack and the store and any one time.) (c) OHEMICAL AND/OR PHYSICAL FORM ANY ONE TIE. (if weided source), only down on any of an and and maximum and the store and a subbrack and the store and any one time.) (c) OHEMICAL AND/OR PHYSICAL FORM ANY ONE TIE. (if weided source), only down on any of a subbrack and the store and any one store any one store and any one store and any one store any one store any one store and any one store and any one store any one s	INDIVIDUAL USER(S). (Name and title supervise use of byproduct material Gr 9.) As specified and ap isotope Committee, Hospital	e of individual(s) who will use or directly we training and experience in Items 8 and proved by the Radio- Fitzsimons General	5. RADIATION PROTECTION OFFICER (Name of techon officer if other than individual user perience as in Items 8 and 9.) Same as 4	f person designated as radiation pro Attach resume of his training and ex
7. DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED. (If byproduct material is for "human use," supplement A (form AEC-313a) must be completed in lieu of this item. If byproduct material is in the form of a sealed source, include the make and model number of the storage container and/or device is which the source will be stored and/or used.) See Form AEC 313a attached.	(a) BYPRODUCT MATERIAL (Elements and mass number of each.) Xenon-133	 (b) CHEMICAL AND/OR PHYSICAL FOR KALFORM THAT YOU WILL POSS number, number of sources and ma 1) Xenon-133 gas 2) 50 millicuries i each, obtained Forest Research 	DRM AND MAXIMUM NUMBER OF MILLICURIES (SESS AT ANY ONE TIME (If seeled source(s), or anoun activity per source.) dissolved in saline .n precalibrated ampules from Union Carbide Cor h Center.	of EACH CHEMICAL AND/OR PHY diso state name of manufacturer, mod of 3-4 millicurie poration, Sterling
00040 - / /	DESCRIBE PURPOSE FOR WHICH BYP plewed in lieu of this item. If byproduct which the source will be stored and or a See Form AEC 313	RODUCT MATERIAL WILL BE USED. (If b material is in the form of a sealed source, ised.)	yproduct material is for "human use," supplement include the make and model number of the sk	A (Form AEC-313a) must be com- orage container and/or device in

	TRAINING A	ND EXPER	RIENCE OF E	ACH INDIVIDI	UAL NAMED IN ITE	M 4 (Use supplementa	sheets if necessary	0
B. TYPE C	OF TRAINING			WHERE	TRAINED	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURS (Circle onswer)
 a. Principles and practices of radiation protection b. Radioactivity measurement standardization and monitoring techniques and instruments 			Individ trainin	iuals will	l have appro perience pri	priate or to their	Yes No	Yes No
			approv Fitzsin	al by the mons Ger	Radioisotop neral Hospit	e Committee al.	yes No	Yes No
. Mather use ar	matics and calculations b nd measurement of radio	pasic to the					Yes No	Yes No
1. Biolog	ical effects of radiation						Yes No	Yes No
P. EXPERI	ENCE WITH RADIATION	. (Actual	use of radioiso	topes or equival	ent experience.)			
Sa	me as 8.							
0 RADI		RUMENTS.	(Use supplem	nentāl sheets if n	ecessary.)			
(Include	TYPE OF INSTRUMENTS make and model number of	f each)	NUMBER	RADIATION	SENSITIVITY RANGE (mr/hr)	WINDOW THICKNESS (mg/cm ²)	(Monitoring, sur	JSE veying, measuring)
05	-00046-13 (A	.66) da	ited 21 J	une 1960	γ			
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a manufacture and sound of the providence of	United States Atomic Energy Commission		
Form AEC-313 a (10-61) PAGE 1	APPLICATION FOR BYPRODUCT MATERIAL LICENSE	orm approved. Judget Bureau Ni	o 38-R080
If byproduct material complete this supplem	is for "human use" (internal administration of byproduct mathematical or the radiation therefro ent and attach to the application for byproduct material license.	m to human	beings),
1. (a) USING PHYSICIAN'S N	AME (6) NAME AND ADDRESS OF APPLICANT (H different from 1(a))	Constant of the second s	
Dept of the Ar Gen Hosp & US Nutr Lab, Deny	my, Fitzsimons SA Med Rsch & Same as 1a ver, Colo 80240		
2. THE USING PHYSICIAN INC OF THE UNITED STATES, TH	DICATED ABOVE IS LICENSED TO DISPENSE DRUGS IN THE PRACTICE OF MEDICINE BY A STATE OR TERRITORY TE DISTRICT OF COLUMBIA, OR THE COMMONWEALTH OF PUERTO RICO.	(YES)	NO
As permitted k 3. A STATEMENT OF USING P OF THIS APPLICATION RELATED DOCUMENTS ON	DY Radioisotope Committee, Fitzsimons Gen Hosp circle ansi- physician's clinical radioisotope experience (page 3 of this supplement) is submitted in support if answer is <u>MO</u> , use page 2 of this supplement to explain or refer to other application or which this information appears.	YES	(NO
As permitted k	by Radioisotope Committee, Fitzsimons Gen Hosp CHICLE ANSY	WER	
and an and a second	PROPOSED DIAGNOSIS OR TREATMENT		
(b) CHEMICAL FORM ADMIN Xenon- (c) DESCRIBE PROCEDURES See atta	NISTERED 133 – gas dissolved in saline which will be observed to minimize hazard from handling, storage, and disposal of the byprodi achment 1	uct material	
(d) DESCRIPTION AND SKET (1) ATTACHED (LITERATI	tches of special devices to be used for administering byproduct material to human beings are ure references will suffice See attachment 2 circle answ	VER (YES)	NO
(2) ON FILE WITH THE I REFER TO APPLICAT	ISOTOPES EXTENSION CIRCLE ANSW	YES	(NO)
 (a) PROPOSED DOSAGE SC appropriate, for interna (use page 2 if necessar) 	CHEDULE. —In millicuries for internally administered byproduct material other than discrete fixed sources; and in r il or external irradiation from discrete fixed sources (gold seeds, cobalt needles, etc.) state separately for each y):	contgens or ra condition or di	ds, as sease
Four injectio subject - less	ns of 50 - 100 microcuries each of Xenon-133 (Total dos s than 500 Microcuries)	e per	
(b) INVESTIGATIVE PROPO should include outline reference if any, numb	ISAL FOR EXPERIMENTAL, NEW OR UNUSUAL HUMAN USES IS ATTACHED. (Attachment of conditions to be evaluated, including data from animal studies and/or obstract of literature CIRCLE ANSW er and type of patients (i. e. age group, moribund, etc.))	VER (YES)	NO
	116		
. IF BYPRODUCT MATERIAL V PARENTERAL ADMINESTRAT	will not be obtained in precalibrated form for oral administration or in precalibrated and s ion, describe identification, processing, and standardization procedures. Xenon-133 $_{\rm N}$	will be	M FOR
obtained from ted ampules co be accomplish an airtight ste	Union Carbide Corp., Sterling Forest Research Center 1 ontaining the gas dissolved in saline. Sterilization of the s ed by drawing up aliquots of the solution thru a millipore rile syringe prior to use.	filter i	will
7. THE PROPOSED USE OF BY	PRODUCT MATERIAL HAS BEEN, OR WILL BE, APPROVED BY THE MEDICAL ISOTOPE COM-	WER (YES)	NO
	HOSPITAL FACILITIES FOR INDIVIDUAL PRACTICE USE ONLY		and an example of
8. (a) THE APPLICANT HAS C	OMPLETED ARRANGEMENTS FOR A HOSPITAL TO ADMIT RADIOACTIVE PATIENTS WHEN	VES.	M
EVER ADVISABLE.	TONS TO BE FURNISHED TO THE HOSPITAL AS TO RADIOLOGICAL SAFETY PRECAUTIONS	WER	
TO BE TAKEN AND A	VAILABLE RADIATION INSTRUMENTATION IS ATTACHED.	WER YES	NO

UNITED STATES ATOMIC ENERO JOMMISSION Form AEC-313 u Form approved. Budget Bureau No. 38-R080.1 APPLICATION FOR BYPRODUCT MATERIAL LICENSE (10-61) PAGE 2 SUPPLEMENT A --- HUMAN USE This page may be used for providing additional information. Please cross reference to specific items. Item 3. See license # 05-00046-13 (A66) 1.1 The second end of the second second second the second s and the second of the tent of the second of the second of the second of the second of the The second s and the second second

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ATTACHMENT 1 (AEC 313, item 15 and 313a, item 4c)

The Xenon-133 gas dissolved in saline will be obtained in precalibrated ampules from Union Carbide Corp. The solution will be sterilized by passage through a Millipore filter as it is drawn up into a sterile airtight syringe just prior to use. The material will be stored in z shielded hood in the Radioisotope Clinic. The lead shielding will be of one centimeter or more thickness to keep exposure rate below 2.5 mrad/hcur. Disposable gloves will be used to handle the material. Used syringes will be handled by the Radio sotope Clinic as described in application for License No. 05-00046-13 (A66). Any Xenon-133 solution remaining at the end of the study will be allowed to decay for 2 months (10 half-lives) and then disposed of by pouring down a sink drain.

The injected Xenon is excreted from the body by the lungs, therefore expired air of the patients receiving the material will be collected in meterological balloons and subsequently released outside in an open area. As the volume of the catheterization laboratory is 88.5 cubic meters (88, 500 liters), the release of 250 microcuries of Xenon-133 gas into the room air would produce a concentration of less than 3 X 10^{-6} microcuries/ml of air (exempt concentration under Title 10, Chap. 1, Section 30. 70, Sched. A of the Federal Register). Because of the above and the low dose to be administered (less than 500 microcuries) contamination of laboratory air will be negligible.

ATTACHMENT 2 (AEC 313a, item 4d)

A complete description of the procedure for measuring myocardial blood flow by selective coronary injection of Xenon-133 in saline can be found in the following reference:

Ross, R.S., Ueda, K., Lichtlen, P.R., and Rees, J.R.: Measurement of Myocardial Blood Flow in Animals and Man by Selective Injection of Radioactive Inert Gas into the Coronary Arteries. Circ. Res. 15: 28, 1964.

Results of a clinical study utilizing this technique has also been reported:

Bernstein, L., Friesinger, G.C., Lichtlen, P.R. and Ross, R.S.: The Effect of Nitroglycerin on the Systemic and Coronary Circulation in Man and Dogs. Circ. 33:107, 1966.



6 April 1967

PROTOCOL: Effects of Selective Coronary Arteriography on Myocardial Blood Flow in Man

INTRODUCTION

Selective coronary arteriography has become an important addition to the list of diagnostic procedures available for the detection and evaluation of coronary artery disease. Studies of the coronary circulation utilizing this technique have materially aided our understanding of various aspects of this disease. The hemodynamic consequences of injection of radiopaque agents directly into the coronary circulation have been studied both in animals and man (1 - 3). Changes in myocardial blood flow (MBF) have been observed in opened-chest dogs (4, 5) and more recently in intact dogs, as well (6). However, we are not aware of any studies reporting the effect of coronary arteriography on MBF in man. The study to be described in this protocol is designed to fill this gap in our knowledge.

METHODS

MBF will be measured by selective intracoronary injection of Xenon-133 gas dissolved in sterile saline and calculated in ml min 100 gm from the precordial disappearance of radioactivity. The details of the procedure to be followed have been fully described by Ross, et al. (7). In addition, one of the investigators (Captain R. P. Carson) has had a year's experience with this technique, both in animals and man, while a postdoctoral fellow at the University of Michigan. Enclosed are three figures from his studies illustrating the method of calculating MBF from the precordial radioactivity curve (fig. 1), the reliability of the method for measuring MBF (fig. 2), and the results of sublingual administration of nitroglycerin on MBF in nine patients (fig. 3). Subjects will consist of patients with suspected or known coronary artery disease undergoing selective coronary arteriography during cardiac catheterization. Patient consent will be obtained after they are informed of the procedures to Le performed and the risks involved from the study and the use of a radioisotope.

The study will be conducted in the cardiac catheterization laboratory of Fitzsimons General Hospital. Four measurements of MBF will be made on each subject, two during a control period and then 30 seconds and again 300 seconds following coronary injection of contrast agent. Each measurement will require an injection of 50 - 100 microcuries of Xenon-133. the total amount of radioactivity administered to each subject being less than 500 microcuries.

It has been estimated that 90-95% of an administered dose of Xenon-133 is expired during the first passage through the lungs. Captain Carson was able to confirm this in a dog study. Because of this and the small doses used, the systemic radiation dose to the subject is small. The organs receiving the largest exposure are the heart and lungs. Lassen (3) has calculated the exposure dose from an intra-arterial injection of 5 millicuries of a saline solution of Xenon-133 as follows: tracheal mucosa -96.8 mrad, lung = 17.5 mrad, adipose tissue = 8.8 mrad, gonads = 1.1 mrad, and other tissues = 1.6 mrad. For the local organ being studied: brain (400 gm tissue exposed) = 36 mrad, kidney (150 gm tissue exposed) = 31 mrad. The average weight of an adult human heart is 300 gm. We will be injecting one tenth this dose of Xenon-133; thus, the exposure dose will be correspondingly reduced.

Since the injected Xenon is excreted from the body through the lungs, the expired air of the subjects will be collected in suitable containers such as meteorological balloons or other large-capacity containers and subsequently

released outside in an open area. As the total dose to be administered is low and the expired air will be collected, contamination of laboratory air will be negligible. In animal studies at the University of Michigan, no appreciable increase in room background could be detected using an ionizing chamber monitor under the conditions described.

The Xenon-133 will be obtained precalibrated in saline solution from the Sterling Forest Research Center, Union Carbide Corporation, New York. It will be stored in the Radioisotope Clinic in a hood with lead shielding of 1 cm or more thickness to keep the exposure rate below 2.5 mrad/hr. Disposable gloves will be used to handle the material. Aliquots of the solution will be drawn up through a Millipore filter into sterile airtight syringes and transported in lead shielded containers to the cardiac catheterization laboratory the day of the study. Contaminated syringes, gloves, etc., will be handled through the Radioisotope Division. Any Xenon solution remaining at the end of the study will be allowed to decay for two months (10 half-lifes) and then be disposed of by pouring down a sink drain.

The detecting and recording equipment will be mounted on a portable cart and will consist of a 2×3 inch sodium iodide crystal in an adjustable probe, a linear ratemeter, and a strip chart recorder. A portable instrument will be available for continuous monitoring of the room air during the study.

INVEST GATORS

Principal investigator for this study will be: Captain Richard P. Carson, MC.

Associate investigators will be: Captain Charles Peterson, MC; Lt. Colonel Robert Jones, MC: Major David Preston, MC.

> RICHARD P. CARSON Captain. MC

REFERENCES

1. Friesinger, G. C., et al.: Hemodynamic effects of the injection of radiopaque material. Circulation 31: 730, 1965.

2. Benchimol, A. and McNally, E. M.: Hemodynamic and electrocardiographic effects of selective coronary angiography in man. N. Eng. J. Med. 274: 1217, 1966.

3. Ross, R.S., et al.: Electrocardiographic and hemodynamic observations during selective coronary cineangiocardiography. J. Clin. Invest. 41: 1395, 1962. (Abst.)

4. Griggs, D. M., Jr., et al.: Effects of radiopaque material on phasic coronary flow and myocardial oxygen consumption. Clinical Res. 14: 274, 1966 (Abst.)

5. Guzman, S. V. and West, J. W.: Cardiac effects of intracoronary arterial injections of various roentgenographic contrast media. Am. Heart J. 58: 597, 1959.

6. Carson, R. P.: Unpublished data.

7. Ross, R.S., et al.: Measurement of myocardial blood flow in animals and man by selective injection of radioactive inert gas into the coronary arteries. Circ. Res. 15: 28, 1964.

 Lassen, N.A.: Assessment of tissue radiation dose in clinical use of radioactive inert gases with examples of absorbed doses from H₂ - 3, Kr - 85 and Xe - 133. Minerva Nucleare 8: 211, 1964.





FIG. 1

1.80

Above: Portion of record from closed-chest dog experiment showing typical precordial radioactivity curve following injection of Xenon-133 in saline through a catheter positioned within the ostium of the left coronary artery. Vertical lines represent 1 second time intervals.

Below: Semilogarithmic replot of the washout portion of the curve (after subtracting background). The half time of this line is used to calculate flow from the formula

Flow =
$$\frac{\frac{\log 2}{T} \times 100}{\frac{1}{5}}$$



FIG. 2

Results of 4 opened-chest dog experiments in which posterior circumflex branch of left coronary artery was cannulated and blood supplied from femoral artery via an externally controlled rotor pump. Xenon-133 in saline was injected through a side arm in the tubing between the pump and the coronary vessel. The scintillation probe was positioned over the thoracotomy at the level of the anterior chest wall. MBF was determined by the Xenon method at various pump speeds. Flow rates calculated from the Xenon washout curves were then plotted against the corresponding pump flow rates.



FIG. 3

Effects of sublingual administration of 0.3 mg nitroglycerin in 9 male subjects. MBF was calculated from the disappearance rate of precordial radioactivity following selective injection of Xenon- 33 in saline into the right coronary artery. Group I - One patient with no cardiac disease. Group II - Five patients with coronary artery disease. Group III - Three patients with myocardial hypertrophy.



13 Apr11 1967

X-OBXIZM

SUBJECT: Application for Assendment of Byproduct Material License

TO: The Sargeos General ATIN: MEMPS-P Department of the Army Washington, D. C. 20315

Submitted herewith is Application for Ammendment of Syproduct Material License Number 5-46-13 to permit the use of pre-calibrated Manon-133 gas dissolved in saline for measurement of myocardial blood flow AMC Form 313 and 313s are submitted in six copies for appropriate processing.

Incl

ROMMET E. BLOUMT Major General, MC Commanding



DEPARTMENT OF THE ARMY OFFICE OF THE SURGEON GENERAL WASHINGTON, D.C. 20315

IN REPLY REFER TO: MEDPS-PO

20 April 1967

Isotopes Branch Division of Materials Licensing U. S. Atomic Energy Commission Washington, D. C. 20545

Gentlemen:

Recommend approval of the inclosed application for amendment to AEC Byproduct Material License Number 5-46-13, Fitzsimons General Hospital, Denver, Colorado.

Sincerely,

WILLIAM E. FROEMMING Colonel, M. C. Preventive Medicine Division



1 Incl as (in trip)

			and a contract of the second
Form AEC-313 (5-58)	APPLICATION FOR BYPRODU	JCT MATERIAL LICENSE	Form appraved Budget Bureau No. 38-R027.4
INSTRUCTIONSComple plete only items 1 throug supplemental sheets whe Commission, Washington, application, the applican accordance with the gene ject to Title 10, Code of	ete Items 1 through 16 if this is an ini gh 7 and indicate new information or renecessary. Item 16 must be comple D.C., 20545. Attention: Isotopes Bro it will receive an AEC Byproduct Mat real requirements contained in Title 10 Federal Regulations, Part 20.	itial application. If application is for changes in the program as requested i ted on all applications. Mail three con nch, Division of Licensing and Regul erial License. An AEC Byproduct Ma D, Code of Federal Regulations, Part	renewal of a license, com- in Items 8 through 15. Use pies to: U.S. Atomic Energy ation. Upon appraval of this iterial License is issued in 30 and the Licensee is sub-
1. (a) NAME AND STREET ADDRE	SS OF APPLICANT. (Institution, firm, hospital.	(b) STREET ADDRESS(ES) AT WHICH BYPRODU	ICT MATERIAL WILL BE USED (IF
Department of the Fitzsimons Genera Medical Research Denver, Colorado	e Army al Hospital and U. S. Army a and Nutrition Laboratory 80240	Same as l(P.)	
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Users approved by Committee	the Radioisotope	As designated by Radiois	sotope Committee
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INFORMATION TO BE SUBMITTED ON ADDITIONAL SHEETS 3. FACILITIES AND EQUIPMENT. Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Explanatory sketch of facility is grached. (Circle argument) at 10 for AEC Byproduct Material License 05-00046-13 dated 21 4. RADIATION PROTECTION PROGRAM. Describe the radiation protection program including control measures. If application covers seeded sources, submit leak testing procedures where applicable, name, training, and experience of person to perform leak tests, and arrangements for performing initial radiation survey, serv- icing, maintegonce and ready of the sources. As specified in Application for AEC Byproduct Material License 05-00046-13 dated 21 J 3. WASTE DISPOSAL. If a commercial waste disposal service is employed, specify name of company. Otherwise, submit detailed description of methods which will be used for disposing of radioactive worstes and estimates of the same and or activity involved. As specified in Application for AEC Byproduct. Material License 05-00046-13 dated 21 J CERTIFICATE (This from must be company. Otherwise, submit detailed description of methods which will be used for disposing of radioactive worstes and estimates of the same and or activity involved. As specified in Application for AEC Byproduct Material License 05-00046-13 dated 21 CERTIFICATE (This from must be completed by applicant) 6. The APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICANTON IS prepared in Conformation with the ID CODE or FEGRAL REGULATIONS, PAT 30, AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMATY WITH TITLE 10 CODE or FEGRAL REGULATIONS, PAT 30, AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF CONFORMATY AND DED	FILM BADGES, DOSIMETERS, AND BIO-ASS	AY PROCEDURE	sused. (For All	m bodges, specify method	of calibrating and processing	g, or name of suppl	ier.)
INFORMATION TO BE SUBMITTED ON ADDITIONAL SHEETS 3. FACILITIES AND EQUIPMENT. Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Explanatory sketch of facility is grached. (Cache onswer) Yes. No S Specified in Application for AEC Byproduct Material License 05-00046-13 dated 21. 4. RADIATION PROTECTION PROGRAM. Describe the radiation protection program including control measures. If application covers sealed sources, submit leak testing procedures where applicable, name, training, and experience of person to perform leak tests, and arrangements for performing initial radiation survey, serv- icing, maintenance and repair of the source. As Specified in Application for AEC Byproduct Material License 05-00046-13 dated 21 J WASTE DISPOSAL. If a commercial waste disposal service is employed, specify name of company. Otherwise, submit detailed description of methods which will be used for disposing of radioactive wastes and estimates of the appendict. Material License 05-00046-13 dated 21 CERTIFICATE (This Hern must be completed by applicant) 6. The APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BENDER OF the APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMENT WITH THE 10/CODE OF FEDERAL REGULATIONS, PAT 30, AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF DOM KNOWLEDGE AND BELIEF. Department of the Army FGH & USAMRNLI Department of the Army FGH MUST FERSON	TTU Dadges processed a						
6. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMATY WITH TITLE 10/CODE OF FEDERAL REGULATIONS, PART 30, AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF. DEPART TIMENT OF THE ARMY FGH & USAMRNL FGH & USAMRNL DEPART BOY N THIN FROM 5000000000000000000000000000000000000	FACILITIES AND EQUIPMENT. Describe in of facility is ortached, (Circle onewoor) Specified in Application RADIATION PROTECTION PROGRAM. Du hesting procedures where applicable, name, icing, maintengance and repair of the source S Specified in Application WASTE DISPOSAL. If a commercial wastes be used for disposing of radioactive wastes as specified in Application Content of the source of the s	baratary facilities Yest No Lon for A escribe the radia training, and ex 10n for disposal service and estimates a <u>tid on for</u> RTMICATE	A TO BE SUB is and remote har LEC Bypro trian protection p periance of perso AEC Bypro is employed, spon the suppopt AEC Bypro (This item m	ndsing equipment, storage duct Materia rogram including control on to perform leak tests, co oduct Materia scily name of company mount of activity involved roduct. Materia	containers, shielding, fume containers, shielding, fume <u>Lidcense</u> 05-00 measures. If application c and arrongements for perform <u>Lidcense</u> 05-0 Otherwise, submit detailed <u>B1 License</u> 05- d by applicant	hoods, etc. Expl 2046-13 d overs sealed source ming initial radiation 20046-13 d description of meth 200046-13 d	anatory sketch ated 21 Ju ss. submit leak a survey, serv- ated 21. Jur ods which will ated 21 Ju
Approximation 2066	THE APPLICANT AND ANY OFFICIAL EXE PREPARED IN CONFORMITY WITH TITLE 10/ SUPPLEMENTS ATTACHED HERETO, IS TRU	COTING THIS CO CODE OF FEDES & AND CORREC	ERTIFICATE ON I	SE HALF OF THE APPLICA S. PATT 30, AND THAT DE DOM KNOWLEDGE AN De DAT FGH & FGH &	USAMRNL	TIFY THAT THIS AN	PLICATION IS
By: EDWIN L. OVERHOLT			0.00	By: EDWIN	L. OVERHOLT	Loll	
Chief, Radioisotope Committee	22 November 1966		1	Chief	, Radioisotope	Committee	
L'OIL CE OENDELIEL	Ne 22 November 1966		116	Title of cer	tifying official		

Form AEC+313b

APPLICAT FOR BYPRODUCT MATERIAL LICENS SUPPLEMENT B SEALED SOURCES

Form approved. Budget Bureau No. 58 R028.3

if application is for byproduct material to be used in or manufactured as a "sealed source" complete this supplement and attach to If application is for byproduct material to be used to inflation data of scaled source should complete Section 1. An applicant desiring the application for byproduct material license. Applicant for use of scaled source should complete Section 11. If information has been submitted previously and there are no changes in the scaled source and/or device design or other changes in information submitted previously, details requested below may be omitted provided reference is made on line below to the application or other document on which this information appears:

SECTION I-USE (See in structions)

Sealed Source:

1. IF SEALED SOURCE OR DEVICE CONTAINING SEALED SOURCE IS MANUFACTURED COMMERCIALLY, GIVE FOLLOWING INFORMATION U.S.Radium Corp., 4150 Old Berwick Rd., Bloomsburg, Pa. A. Manufacturer or supplier of sealed source and/or device Glowall Corp., 2530 Wyandotte Rd., Willow Grove, Pa.

B. Make and model number of sealed source and/or deviceModel AD=10 for use in Model 310 Gas Chromatog taph C. Person who will hold legal title to sealed source Pitzsimons General Hospital and U.S. Army Medical

Research and Nutrition Laboratory, Denver, Colo.

2. (a) HAME OF PERSON WHO WILL PERFORM NECESSARY PERIODIC LEAKAGE TESTS (A month intervals for beta-gamma: S-month period for alpha emiliters. See Instructione. Radiation Safety Officer, U.S. Army Medical Research & Nutrition Laboratory, Denver, Colo. (Charles G. Liddle, Capt., VC)

(6) IF ABOVE PERSON IS NOT THE \$ PPLIER. MANUFACTURER, NOR A COMMERCIAL LABORATORY ROUTINELY OFFERING SUCH SERVICES, GIVE BRIEF STATE-MENT OF EXPERIENCE OR TRAINING OF SUCH PERSON IN TECHNIQUES TO BE EMPLOYED. A STATEMENT OF LEAK TESTING PROCEDURES INCLUDING EVIDENCE OF ITS EFFICACY AND INSTRUMENTATION TO BE USED.

See attached for training and experience of individual who will perform leak tests.

Leak tests will be performed using wet gauze swipes. Swipes will be placed in vials containing a toluene scintillation solution and counted in a liquid scintillation counting system (either a Packard Model 314EX, a Packard Model 3314, or a Nuclear Chicago Mark I Liquid scintillation counter). The instruments can readily detect levels of contamination above 5 x 10-5 microcuries.

3. ARRANGEMENTS WHICH WILL PREVAIL FOR PERFORMING INITIAL RADIATION SURVEY (Happing date, SERVICING MAINTENANCE, REPAIR, CONTROL, AND DISPOSAL, ETC., OF THE SOURCE:

Initial radiation survey will be performed by U. S. Radium Corporation. Servicing maintenance or repair will be performed by The Glowall Corp. or the U. S. Radium Corp. Control and/or disposal will be carried out as with other radioisotopes possessed and used by this Laboratory under AEC License No. 05-00046-13.

SECTION II-MANUFACTURE

4. IF SEALED SOURCE TO BE MANUFACTURED OR FABRICATED BY THE APPLICANT IS DESIGNED TO TRANSMIT ONLY GAMMA RAYS AND CONTAINS IN ELEMENTAL FORM (but not powders) COBALT 60. INIDIUM 192, GOLD 138. TANTALUM 182, OR THULIUM 120. GIVE FOLLOWING INFORMATION AND DISREGARD QUESTIONS 5 THROUGH 12 ON THIS SUPPLEMENT:

(a) Quantity of byproduct material per source and model number

(b) Leak testing procedure to be employed:

(c) Attach annotated engineering drawing of source container and holder, if any:

(d) Describe label to be affixed to source container and/or source holder (or uttach copy. See instructions):

Training	and Exp. Dence:	Charles G. Liddle,	-) sapt VC		
Form AEC-3	13				
Item 8 Typ	pe of Training:	Where Trained	Duration Training	of	
a. Principi of radia	les and practices ation protection	Walter Reed Army Institute of Research	2 weeks	1	Formal
		Taft Sanitary Engineering Center	4 weeks	Ŧ	ormal
		University of Rochester	l year	F	ormal
b. Radioact standard itoring instrume	ivity measurementization and mon- techniques and nts	t "	n		
c. Mathemat basic to urement	ics and calculati the use and meas of radioactivity	Lons " I-	n		8
d. Biologic radiatio	al effects of n		n		"
item 9 Exp	erience with radi	ation			
Isotope	Maximum amount	Where experience ga	ined Dur	ation	Type of 1 Us
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		Walter Reed Army Ir of Research	stitute 2	yrs	research
		USAMRNL	1	yr	research
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(5-58)	APPLICATION FOR BYPRO	DUCT MATERIAL LICENSE	Form approved Budget Bureau No. 38-R027.4
INSTRUCTIONSCon plate only Itams 1 thr supplemental sheets w Commission, Washingt application, the appli accordance with the g ject to Title 10, Code	nplete Items 1 through 16 if this is an ough 7 and indicate new information where necessary. Item 16 must be com on, D.C., 20545. Attention: Isotopes 1 cant will receive an AEC Byproduct A eneral requirements contained in Title of Federal Regulations, Part 20.	initial application. If application in or changes in the program as reques pleted on all applications. Mail thre Branch, Division of Licensing and R Material License. An AEC Byproduc e 10, Code of Federal Regulations, 1	s for renewal of a license, com- ted in Items 8 through 15. Use e copies to: U.S. Atomic Energy egulation. Upon approval of this of Material License is issued in Part 30 and the Licensee is sub-
(a) NAME AND STREET AD perion, etc.) Deguerensee and Phonedensee Gase Redices. Restant Deguerense Colores	DRESS OF APPLICANT. (Institution, firm, hospit time Asmyr ones), Hengyd Anl, and V. S. A Soth and Henry Glem Labourd De BORG	tol. (b) STREET ADDRESS(ES) AT WHICH BYP different from 1 (a))	RODUCT MATERIAL WILL BE USED. (I
DEPARTMENT TO USE BYPRO	DOUCT MATERIAL BOOM BOOMBOOR OF OR OF	3. PREVIOUS LICENSE NUMBER(S). (H license, please indicate and give number	this is an application for renewal of c r.)
INDIVIDUAL USER(5). (No supervise use of byproduct m 9.)	ome and title of individual(s) who will use or direc alerial. Give training and experience in Items 8 c	ctly 5. RADIATION PROTECTION OFFICER (No nection officer if other than individual us perience as in Items 8 and 9.)	ime of person designated as radiation pro- er. Attach resume of his training and ex
(a) SYPRODUCT MATERIAL and mass number of equi	(Elements cb.) (b) CHEMICAL AND/OR PHYSICA ICAL FORM THAT YOU WILL I number, number of sources and	AL FORM AND MAXIMUM NUMBER OF MILLICU POSSESS AT ANY ONE TIME. (If sealed source d maximum activity per source.)	RIES OF EACH CHEMICAL AND/OR PHYS (s), also state name of manufacturer, modi
A. Strantino-9	0 A. Storentium en anunchotered Andium Garge Borwick Md., 19825. Supres Stil call for a g anomafrotered Carp. (See 1	A Same sealed searce A by United States mation, 430 384 Bloomoburg, M. be in a Sadal AS-10 ple chevanhagraph by the Glowall (tam (Y))	. 13 millionrios
DESCRIBE PURPOSE FOR V pleted in lieu of this item which the source will be store Peter table As a 2530 Uppended	WHICH SYPRODUCT MATERIAL WILL SE USED. If byproduct material is in the form of a sealed sour ed and/or used.) A BISMAL 310 gass charactering from the Billo , Wallion Grand, Ba	(If byproduct material is for "human use," supple ree, include the make and model number of the regula annual and angle by the	ment A (Form AEC-313a) must be com- te storage container and/or device in

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NAME AND ADDRESS OF TAXABLE PARTY OF TAXABLE PARTY.	NG AND EXP	ERIENCE OF E	ACH INDIVIDU	JAL NAMED IN ITE	M 4 (Use supplemental	sheets if necessary)
TYPE OF TRAINING			WHERE		DURATION OF	ON THE JOB	FORMAL COURS
		Baddev&Am	itte eta	be apprend	20		
Principles and practic protection	es of radiatio	the Radi	alastape	Connéttes		Yes No	Yes No
Radioactivity measurem tion and monitoring ter	ent standardiza chniques and in	n-				Yes No	Yes No
Mathematics and calcula use and measurement of	ations basic to the	he				Yes No	Yes No
Biological effects of rad	ligtion					Yes No	Yes No
EXPERIENCE WITH RADI	ATION. (Actua	al use of radioiso	topes or equivale	int experience.)			L
SOTOPE MAXIMUM AMOU	INT Y	HERE EXPERIENC	E WAS GAINED	DURATION	OF EXPERIENCE	TYPE O	FUSE
. RADIATION DETECTION	INSTRUMENTS	Use supplem	ental sheets if na	rcessary.)	r		
TYPE OF INSTRUM	ENTS	NUMBER	RADIATION	SENSITIVITY RANGE	WINDOW THICKNESS	(Monitoring, sun	ISE reying, measuring)
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APPL. AL N FOR BYPRODUCT MATERIAL LICENS SUPPLEMENT B SEALED SOURCES

Form approved. Radget Burean No. 58 R028.3

If application is for byproduct material to be used in or manufactured as a "scaled source" complete this supplement and attach to the application for byproduct material license. Applicant for use of scaled source should complete Section I. An applicant desiring to manufacture a scaled source should complete Section II. If information has been submitted previously and there are no changes in the scaled source and/or device design or other changes in information submitted previously, details requested below may be omitted provided reference is made on line below to the application or other document on which this information appears:

SECTION 1-USE (See instructions)

Sealed Source:

1. IF SEALED SOURCE OR DEVICE CONTAINING SEALED SOURCE IS MANUFACTURED COMMERCIALLY, GIVE FOLLOWING INFORMATION U.S.Radium Corp., 4150 Old Berwick Rd., Bloomsburg, Pa. Glowall Corp., 2530 Wyandotte Rd., Willow Grove, Pa. A. Manufacturer or supplier of sealed source and/or device B. Make and model number of sealed source and/or deviceModel AD-10 for use in Model 310 Gas Chromatograph

C. Person who will hold legal title to scaled source Fitzsimons General Hospital and U.S. Army Medical

Research and Nutrition Laboratory, Denver, Colo.

2. (a) NAME OF PERSON WHO WILL PERFORM NECESSARY PERIODIC LEAKAGE TESTS (n-month intereals for bird gamma: t-month period for alpha emiliera. See lastenation Radiation Safety Officer, U.S., Army Medical Research & Nutrition Laboratory, Denver, Colo. (Charles G. Liddle, Capt., VC)

(A) IF ABOVE PERSON IS NOT THE SUPPLIER, MANUFACTURER, NOR A COMMERCIAL LABORATORY ROUTINELY OFFERING SUCH SERVICES, GIVE BRIEF STATE-MENT OF EXPERIENCE OR TRAINING OF SUCH PERSON IN TECHNIQUES TO BE EMPLOYED, A STATEMENT OF LEAK TESTING PROCEDURES INCLUDING EVIDENCE OF ITS EFFICACY AND INSTRUMENTATION TO BE USED.

See attached for training and experience of individual who will perform leak tests.

Leak tests will be performed using wet gauze swipes. Swipes will be placed in vials containing a toluene scintillation solution and counted in a liquid scintillation counting system (either a Packard Model 314EX, a Packard Model 3314, or a Nuclear Chicago Mark I Liquid scintillation counter). The instruments can readily detect level: of contamination above 5×10^{-5} microcuries.

3. ARRANGEMENTS WHICH WILL PREVAIL FOR PERFORMING INITIAL RADIATION SURVEY OF A proprieter. SERVICING MAINTENANCE, REPAIR, CONTROL, AND DISPOSAL ETC., OF THE SOURCE:

Initial radiation survey will be performed by U. S. Radium Corporation. Servicing maintenance or repair will be performed by The Glowall Corp. or the U. S. Radium Corp. Control and/or disposal will be carried out as with other radioisotopes possessed and used by this Laboratory under AEC License No. 05-00046-13.

SECTION II-MANUFACTURE

4. IF SEALED SOURCE TO BE MANUFACTURED OR FABRICATED BY THE APPLICANT IS DESIGNED TO TRANSMIT ONLY GAMMA RAYS AND CONTAINS IN ELEMENTAL FORM (but not powders) COBALT 60, IRIDIUM 192, GOLD 198, TANTALUM 182, OR THULIUM 170, GIVE FOLLOWING INFORMATION AND DISREGARD QUESTIONS 5 THROUGH 12 ON THIS SUPPLEMENT:

(a) Quantity of byproduct material per source and model number

100

(b) Leak testing procedure to be employed:

to.

(c) Attach annotated engineering drawing of source container and holder, if any

W. or Star

(d) Describe label to be affixed to source container and/or source holder (or ablack copy. See instructions):

91213

18-61441

Construction of the second second

Training and Experience:	Charles G. Liddle,	Capt VC	
Form AEC-313			
Item 8 Type of Training:	Where Trained	Duration Training	of
a. Principles and practices of radiation protection	Walter Reed Army Institute of Research	2 weeks	Formal
	Taft Sanitary Engineering • Center	4 weeks	Formal ,
	University of Rochester	l year	Formal
b. Radioactivity measuremen standardization and mon- itoring techniques and instruments	t "	11	H
c. Mathematics and calculat basic to the use and mea urement of radioactivity	ions " s-	n	"
d. Biological effects of radiation	n	11	н
	iation		
Isotope Maximum amount	Where experience g	ained Dur	ation Use
H ³ 1 Mc	Fourth U S Army Me	d Lab l	yr research
	Walter Reed Army I of Research	nstitute 2	yrs research
	USAMRNL	1	yr research
C14 "	н		и и
P22 "			11 <u>11</u>
S-45 11			
$\frac{3}{2}$	11		n
Fe ⁵⁹ "	0		11 11
Co65 "	"		H H
Zn 85 "	"		п п
Sr 90 H			11 11
-125 "	11		11 11
1131 "	11		11 11
Ca ¹²⁷ "	11		11 11
Baili 140 "	11		0
Hg+91 "	11		11 U
Hg 20.3 "	Ħ		0



HEADQUARTERS DEPARTMENT OF THE ARMY OFFICE OF THE SURGEON GENERAL WASHINGTON, D.C. 20315

IN REPLY REFER TO MEDPS-PM

22 December 1966

Isotopes Branch Division of Material Licensing U.S. Atomic Energy Commission Washington, D. C. 20545

Gentlemen:

It is recommended that the attached application for amendment to Byproduct Material License No. 05-00046-13 be approved.

Sincerely,

elick HERSCHEL E. GRIFFI

l Incl as

Colonel, MC Chief, Preventive Medicine Division



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Form AEC-313 (5-58)	PPLICATION FOR BYPRODU	Form approved. Budget Bureau No. 38-R027 3	
INSTRUCTIONSComplete Iter plete only Items 1 through 7 a supplemental sheets where nece Commission, Washington 25, D. application, the applicant will accordance with the general rea ject to Title 10, Code of Federa	ns 1 through 16 if this is an in nd indicate new information o ssary. Item 16 must be complet . C. Attention: Isotopes Bran receive an AEC Byproduct Ma uirements contained in Title 11 I Regulations, Part 20.	nitial application. If application is for r changes in the program as requested ed on all applications. Mail three copi ch, Division of Licensing and Regula tarial License. An AEC Byproduct Ma 0, Code of Føderal Regulations, Part 3	renewal of a license, com in Items 8 through 15. Usi es to: U. S. Atomic Energy tion. Upon approval of thi terial License is issued in 30 and the Licensee is sub
(a) NAME AND STREET ADDRESS OF A	PPLICANT. (Institution, firm, haspital.	(b) STREET ADDRESS(ES) AT WHICH BYPRODU	CT MATERIAL WILL BE USED.
person, efc)		different from 1 (a).)	
Department of the A Fitzsimons General I US Army Medical Res Laboratory, Denver,	rmy Hospital and earch & Nutrition Colorado 80240	Same as la.	
DEPARTMENT TO USE BYPRODUCT MATER	IIAI	3. PREVIOUS LICENSE NUMBER(S). (IF this is	an application for renewal of
Radioisotope Section	n, Radiology Service	license, please indicate and give number.) IIcense #5-46-13	
INDIVIDUAL USER(S). (Nome and title a supervise use of byproduct material. Give	of individual(s) wha will use or directly training and experience in Items 8 and	5. RADIATION PROTECTION OFFICER (Name of j tection officer if other than individual user. All perience as in Items 8 and 9.)	person designated as radiation pro Mach resume of his training and ex
As specified by Fitz Radioisotope Committ	simons General Hospi ee	tal Same as 4.	
(a) BY PRODUCT MATERIAL. (Elements and mass number of each.)	(b) CHEMICAL AND/OR PHYSICAL FO ICAL FORM THAT YOU WILL POSS number, number of sources and ma	DRM AND MAXIMUM NUMBER OF MILLICURIES OF SESS AT ANY ONE TIME. (If sealed source(s), also atimum activity per source.)	EACH CHEMICAL AND/OR PHY o state name of manufacturer, moc
DESCRIBE PURPOSE FOR WHICH RYPRO	DUCT MATERIAL WILL BE USED (If by	rproduct material is for "human use," supplement A	(Form AEC-313a) must be com-
pleted in lieu of this item If byproduct mo	sherial is in the form of a sealed source, i	nclude the make and model number of the stora	ge container and/or device in
pleted in lieu of this item. If byproduct mo which the source will be stored and/or used See Form AEC 3138.	therial is in the form of a sealed source, i	nclude me make and model number of me shora	ge container and/or device in
pleted in lieu of this them. If byproduct mo which the source will be stored and/or used See Form AEC 3138.	sherial is in the form of a sealed source, i	nclude me make and model number of me shora	ge container and/or device in
pleted in lieu of this them. If byproduct mo which the source will be stored and/or used See Form AEC 3138.	therial is in the form of a sealed source, i	nclude me make and model number of me shora	ge container and/or device in

(Continued on reverse side)

CONTRACTOR OF STREET,	TRAIMING AND E	XPERIENCE OF	EACH INDIVID	UAL NAMED IN I	TEM 4 (Use supplemental	sheets if necessary)
 8. TYPE OF TRAINING a. Principles and practices of radiation protection b. Radioactivity measurement standardization and monitoring techniques and instruments 			WHERE	TRAINED		DURATION OF	ON THE JOB (Circle answer)	FORMAL COURS (Circle answer)
		ation	n/A				Yes No	Yes No
		diza- d in-	n/A				Yes No	Yes No
c. Mathe use a	matics and calculations basic t nd measurement of radioactivi	o the	n/A				Yes No	Yes No
d. Biolog	ical effects of radiation		N/A				Yes No	Yes No
. EXPER	INCE WITH RADIATION. (A	ctual use of radioise	atopes or equival	ent experience.)		ania I		
		N/A						
O. RADI	ATION DETECTION INSTRUMEN	MTS. (Use supplen	nental sheets if m	ecessary.)	-		an and the second second second second second	
(Include	TYPE OF INSTRUMENTS make and model number of each)	NUMBER	RADIATION DETECTED	SENSITIVITY RANG	E WINDO	OW THICKNESS (mg/cm²)	U (Monitoring, surv	SE eying, measuring)
					1	/		
1. METHO 2. FILM 8	DD, FREQUENCY, AND STANDAR See License #5 NADGES, DOSIMETERS, AND BIO See License #5	105 USED IN CAUBR -46-13 ASSAY PROCEDURE -46-13	ATING INSTRUME	nts LISTED ABOVE.	bed of calibre	ting and processin	g, or name of suppl	ier".)
1. METHO	DD, FREQUENCY, AND STANDAR See License #5 HADGES, DOSIMETERS, AND BIO See License #5	NDS USED IN CAUBR -46-13 ASSAY PROCEDURE -46-13	ATING INSTRUME S USED. (For film	NTS LISTED ABOVE.	d of colibro	thing and processin	g, or name of suppl	ieř.)
 METHO FILM 3 FACILI of faci RADIA testing icing, WASTI 	DD, FREQUENCY, AND STANDAR See License #5 ADGES, DOSIMETERS, AND BIO- See License #5 THES AND EQUIPMENT. Describ lity is attached. (Circle answer) See License #5- TION PROTECTION PROCRAM. procedures where applicable, no mointenonce and repair of the to See License #5- E DISPOSAL. If a commercial with the dimensional water attached with the commercial water attached with the dimensional statements of the total statements of	IDS USED IN CAUBR -46-13 ASSAY PROCEDURE -46-13 INFORMATION Yes No 46-13 Describe the radio me, training, and ex 46-13 Taste disposal service with and service	ATING INSTRUME S USED. (For film N TO BE SUB as and remate han ation protection pr operience of person is employed, spe-	NTS LISTED ABOVE. In badges, specify metho MITTED ON ADI dling equipment, stora to gram including contr in to perform leak tests	DITIONA ge containe ol measures , and arrang	tring and processin L SHEETS rs, shielding, fume If acplication gemer <i>is</i> for perfor e submit detailed	g, or name of suppl hoods, etc. Explo covers sealed source ming initial radiatio description of meth	ier".) anatory sketch is, submit leak n survey, serv- ods which will

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F-m ACC-313 0 (3-56) Page 1	APPLICATION FOR BYPRODUCT MATERIAL LICENSE SUPPLEMENT A HUMAN USE	Form a Budgar	pproved. 1 Burneu No.	38-R080
If byproduct material i	s for "human use" (internal administration of byproduct material, or the radiation	therefrom to	human b	eings),
epartment of th Mitzsimons Gener JSA Med. Rsch. &	(b) NAME AND ADDRESS OF APPLICANT (# different from 1(o)) e Army al Hospital and Denver, Colorado 80240 Nutr. Lab.			
2. THE USING PHYSICIAN INC OF THE UNITED STATES, TH B permitted by	ACATED ABOVE IS LITINGED TO DISPENSE DRUGS IN THE PRACTICE OF MEDICINE BY A STATE OR T E DISTRICT OF COLUMBIA, OR THE COMMONWEALTH OF PUERTO RICO. Fitzsimons General Hospital Radioisotope Committee	ERRITORY	(YES)	NO
3. A STATEMENT OF USING P OF THIS APPLICATION. I RELATED DOCUMENTS ON	HYSICIAN'S CLINICAL RADIOISOTOPE EXPLRIENCE (PAGE 3 OF THIS SUPPLEMENT) IS SUBMITTED IN F ANSWER IS NO. USE PAGE 2 OF THIS SUPPLEMENT TO EXPLAIN OR REFER. D OTHER APPLICA WHICH THIS INFORMATION APPEARS.	SUPPORT	YES	(NO)
s permitted by	Fitzsimons General Hcspital Radioisotope Committee	WICLE ANSWER		
	PROPOSED DIAGNOSIS OR TREATMENT			
(b) CHEMICAL FORM ADMIN	NISTERED. Pertechnetate Ion WHICH WILL BE OBSERVED TO MINIMIZE HAZARD FROM HANDLING, STORAGE, AND DISPOSAL OF T See Supplement A	HE BYPRODUCT A	RATERIAL	
(d) DESCRIPTION AND SKE (1) ATTACHED (LITERAT (2) ON FILE WITH THE	ICHES OF SPECIAL DEVICES TO BE USED FOR ADMINISTERING BYPRODUCT MATERIAL TO HUMAN BEI URE REFERENCES WILL SUFFICEI SOE SUDDIEMENT A ISOTOPES EXTERNION	NGS ARE IRCLE ANSWER	(YES)	NO
REFER TO APPLICAT PROPOSED DOSAGE SCHED (a) In millicuries for internal ation from discrete fixe	ION NO <u>Dee Litcense</u> #)-+0-13 WLE by administered byproduct material other than discrete fixed sources; and in raentgens or rads, as appropr d sources (gold seeds, cobalt needles, etc.) state separately for each condition or disease (use page 2 if Dosage range will be 5-10 millicuries for brain scar	Incle ANSWER	or external in	radi-
2	See Supplement A			
(b) INVESTIGATIVE PROPC should include outline refurence if any, numb	USAL FOR EXPERIMENTAL, NEW OR UNUSUAL HUMAN USES IS ATTACHED. (Attachment of conditions to be evaluated, including data from animal studies and/or abstract of literature or and type of patients (i. e. age group, moribund, etc.))	TELL ANSWER	YES	(110
6. IF BYPRODUCT MATERIAL V PAREMTERAL ADMINISTRAT See Form ABCE	WILL NOT BE OBTAINED IN PRECALIBRATED FORM FOR ORAL ADMINISTRATION OR IN PROCEDURES NON, DESCRIBE IDENTIFICATION, PROCESSING, AND STANDARDIZATION PROCEDURES , page 2, continuation of Para 4d, 1, 2.	TED AND STERIL	IZED FORM	FOR
7. THE PROPOSED USE OF BY	PRODUCT MATERIAL HAS BEEN, OR WILL BE, APPROVED BY THE MEDICAL ISOTOPE COM-	CIRCLE ANSWER	(YES)	NO
	HOSPITAL FACILITIES FOR INDIVIDUAL PRACTICE USE ONLY	1 -		ahunne :
8. (0) THE APPLICANT HAS C EVER ADVISABLE.	COMPLETED ARRANGEMENTS FOR A HOSPITAL TO ADMIT RADIOACTIVE PATIENTS WHEN-	CIRCLE ANSWER	YES	NO
(b) A COPY OF INSTRUCT	TIONS TO BE FURNISHED TO THE HOSPITAL AS TO RADIOLOGICAL SAFETY PRECAUTIONS	CIRCLE ANSWER	YES	NO

UNITED STATES ATOMIC ENERGY COMMISSION AEC-313 c Form approved. Budget Bureau No. 38-R080.1 APPLICATION FOR BYPRODUCT MATERIAL LICENSE PAGE 2 SUPPLEMENT A --- HUMAN USE This page may be used for providing additional information. Please cross reference to specific items. 4C continued, Radiation Protection. Technetope sterile generators will be used as directed by E. R. Squibb and Sons and the generator will not be removed from its protective shielding. Para.4d continued. 1. Furity. a. The procedure we use to determine the amount of molybdenum 99 in the Technetium 99m eluate will be as follows: Mo99 emits a gamma of 0.740 and 0 emits a gamma of 0.740 and 0.780 MEV, which together represent 16.8% of all Mo99 disintegrations. By setting Pulse Height Analyzer with a base of 700KEV only the emission above 700KEV will be recorded. From these counts a quantitative check can be made by comparison of a known standard of I-131 (with a gamma of 722 KEV which represents 3% of all its disintegrations. (uc of I131)(CPM of Mo99)(Mo99 Dil. factor) CPM 1-131)(5) The Mo99dilution factor will be 1000, as taken from Tc Assay step No. 1. b. R. E. Squibb & Sons will be the sole supplier for the Technetium generator. c. Testing for alumina leakage through the filtrate will be done according to instructions from R. E. Squibb & Sons. Assaying Technetium 99m activity:
 a. Assay of Tc⁹m can be accomplished by using the Squibb Cobalt-57 standard (Cobaltous Chloride Co57) provided with the generator. (1) Withdraw 0.5cc. from the vial of Tc99m and dilute with water to (Solution A) (Dilution Factor = 1000) make 500 cc. (2) Transfer 1.0cc. of this dilution (Solution A) to a 500cc. volumetric flask and dilute to volume with water. (Solution B) (3) Transfer 1.Occ. of the final dilution to a test tube (Solution B) and count it in a well-type scintillation counter. (4) Transfer 1.Occ. from the vial of Cobalt-57 Standard to a second test tube and count it in a well-type scintillation counter. (5) Calculate Tc99m activity using the following formula: $Tc^{99}m$ Activity (mc/cc.) = A x B x 10⁴ x 50 C x 0.885 Where: A = net counts per minute of diluted Tc⁹⁹m (Solution B) B = activity (in millicuries) of Cobalt-57 Standard, taken from the label and corrected for decay. C = net counts per minute of Cobalt-57 standard 10⁴ x 50 = dilution factor for Te⁹⁹m. 0.885 = factor for converting Cobalt-57 activity to equivalent Tom activity. 3. Equipment to be used: a. Equipment for assay will be sterile tuberculin syringes lcc. volumetric pipettes and 500ml glass flask with glass stoppers. Counting equipment. b. Twin scaler #2 model, #600-125, manufacturer, Picker-Nuclear. (1) (2) Magna Well, Model #610-050, manufacturer, Ficker-Nuclear. c. Disgnostic equipment. (1) Magnascanner, Model #6184D, modified to 120 cm/min. (a) An additional low energy medium focus collimator has been purchased and is on hand, manufacturer, Picker Nuclear. Pho/Gamma Scintillation Camera, Model #6401, manufacturer, (2)Nuclear-Chicago. U.S. GOVERNMENT PRINTING OFFICE : 1959 C - 528228

Para 5a, continued . . .

ORGAN	DOSE	FORM OF Tc99m	METHOD OF ADMINISTRATION	RAD DOSE
Whole Body Brain Brain Thyroid Stomach Stomach Liver Liver Large Bowel Large Bowel	l mc l mc l mc l mc l mc l mc l mc l mc	Pertechnetate Pertechnetate Pertechnetate Pertechnetate Pertechnetate Pertechnetate Pertechnetate Pertechnetate Pertechnetate Pertechnetate Pertechnetate	IV or Oral IV Oral IV or Oral IV Oral IV Oral IV Oral IV Oral	13.2 MRads 5.6 MRads 0.8 MRads 235 MRads 230 MRads 31.8 MRads 32 MRads 157 MRads 142 MRads 226 MRads

RA ATION ABSORBED DOSAGES FOR To99m



108.2