VRC Form 374

. NUCLEAR REGULATORY COMMISSION

AGE _____OF ____ PAGES

MATERIALS LICENSE

Amendment No. 18

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with application dated
	Actober 13 1989
1. Department of the Army	3. License number 08-01738-03 is amended in
Walter Reed Army Medical Center	its entirety to read as follows:
narber Keed King Hearbar benber	
2.	energen 1917 - Chenner Marine, and Antonio and
Washington, D. C. 20307-5001	4. Expiration date May 31, 1991
	5. Docket or Reference No. 030-06895
6. Byproduct, source, and/or 7. Chemical and	/or physical 8. Maximum amount that licensee
special nuclear material form	may possess at any one time
	under this license
A. Cobalt 60 ASSealed sour	rces (AFC) A. 2 sources not exceed
Models C-1	66. C-167 16.000 curies each
or C-198)	
B. Cesium 137 B. Sealed sou	rces (AECL B. 2 sources not to exceed
Model C-16	1 Type 8) 2,100 curies each
C. Cobalt 60 C. Sealed sou	rces (AECL C. 2 sources not to exceed
Model C-19	20,400 curies each
J. Lesium 13/ U. Sealed Sou Model C-16	TCes (AELL D. 2 Sources not to exceed
F Cestum 137 F Sealed sou	rces F
a. Authorized use	
A To be used in AECL Commonall 220 innadia	ton for modical research and development and
radiation dosimetry	tor for medical research and development and
3. To be used in AECL Gammacell 40 Irradiat	or for small animal irradiation. medical
research, development and radiation dosi	metry.
C. To be used in AECL Gammacell 220 Irradia	tor for medical research and development and
radiation dosimetry.	
 To be used in AECL Gammacell 40 Irradiat 	or for medical research and development and
radiation dosimetry.	investigation to investigate bland
E. To be used in a products	jirradiator to irradiate blood
CONDIT	TIONS
	1
 Licensed material shall be used at WRAIF Detrick, Maryland. 	R, Washington, D.C., and USAMRILD, Fort
Information in this record was deleted	
in accordance with the Freedom of Information	MUX "UPPICIAL RECORD COPY"
Act. exemptions 2+6	
FOIA 2006 -02 39	

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NRC Form 374A (5-84)	U.S. N	REGULATORY COMMISSION	Timer and	AGE	2	OF	3	PAGES
	MATERIALSLICE	NCE	License number	08-0	1738-	-03		
	SUPPLEMENTARY SH	IEET	Docket or Reference	e number 030-	06899	5		
				Amen	dment	t No.	18	

(Continued)

CONDITIONS

- 11. A. Licensed material shall be used by individuals designated by the individual approved by the Radiation Control Committee.
 - B. The Radiation Safety Officer for this license is Allen W. Anthony.
- 12. Sealed sources containing licensed material shall not be opened.
- 13. A. The sources specified in Items 7.A., 7.B., 7.C. 7.D. and 7.E. shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.
 - B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

- C. The licensee is authorized to collect leak test samples for analysis by individuals approved by the Radiation Control Committee, Walter Reed Army Medical Center or tests for leakage and/or contamination shall be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.
- 14. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiator shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.
- 15. Written instructions contained in application dated May 17, 1985 shall be followed and a copy of these instructions shall be made available to each individual using or having responsibility for use of licensed material. Any changes to these instructions shall have the prior approval of the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

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NRC Form 374A	U.S. M	REGULATORY COMMISSION	·	AGE	3	OF	3	PAGES
(5,84)	MATERIALSLICE	NSF	License number	08-0	1738-	03		
	SUPPLEMENTARY SH	IEET	Docket or Reference	number 030-	06895			
·				Amen	dment	: No.	18	

(Continued)

CONDITIONS

- 16. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - A. Application dated May 17, 1985
 - B. Letter dated April 8, 1986
 - C. Letter dated August 21, 1986

DEC 07 1989

Date

- D. Application dated October 13, 1989
- E. Letter dated November 22, 1989

For	r the U.S. Nuclear Regulatory Commission Original Signed By: Thomas K. Thompson
	Nuclear Materials Safety Branch Region I King of Prussia, Pennsylvania 19406

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DEC 07 1989

License No. 08-01738-03 Docket No. 030-06895 Control No. 111556

Department of the Army Walter Reed Army Medical Center Charles E. Day, III, LTC ATTN: HSHL-HP Washington, D.C. 20307-5001

Gentlemen:

Please find enclosed an amendment to your NRC Material License.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the Region I Material Licensing Section, (215) 337-5239, so that we can provide appropriate corrections and answers.

Please be advised that you must conduct your program involving licensed radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, please note the items in the enclosed, "Requirements for Materials Licensees."

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, the NRC expects licensees to pay meticulous attention to detail and to achieve the high standard of compliance which the NRC expects of its licensees.

You will be periodically inspected by NRC. A fee may be charged for inspections in accordance with 10 CFR Part 170. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in prompt and vigorous enforcement action against you. This could include issuance of a notice of violation, or in case of serious violations, an imposition of a civil penalty or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

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ML 08-01738-03/LTR - 0001.0.0 12/06/89

We wish you success in operating a safe and effective licensed program.

Sincerely,

2

Original Signed By: Thomas K. Thompson

Thomas K. Thompson, Health Physicist Nuclear Materials Safety Section C Division of Radiation Safety and Safeguards

Enclosures:

1. Amendment No. 18

2. Requirements for Materials Licensees

DRSS:RI Thompson/tlm

12/ /89

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ML 08-01738-03/LTR - 0002.0.0 12/06/89

ABUVE		ICE INVENIORY BURVEY	. •
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LICENSEE'S (HAM			
Licensee Name:	Department of An	mil	• ·
Contact Name: Title:	Chief RM (And	Branch	•
Department:	Walter Reed Army	Med ctr-	• _
Street:	Web DCc S	tate: Zin Code:	20307-5001
Phone Number:	() 427-5/04 E	xt.:	
Provide accurat	e and complete resp	onses to each question	1 below:
1) How many sea	led sources and/or	devices do you have th	at are
above Class	C (i.e. $Am-241 > 27$ mCi CS-137 > 910 C	mci, Pu-238 or -239 >	· 27 mCi,
27 mCi with	a half-life greater	than five years)? Id	lentify
each source	or device on the at	tached inventory sheet	• •
2) Por do rou d	4 Sour	res	
(check appro	priate box)	\sim / Δ	
	· IVOne	Olsposed of.	
Manufacturer	:		•
Other:	another incensee:		
If other, pl	ease elaborate:		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
	······································		
3)a. Are you ah	le to find and use	an authorized recipien	nt to
you po lor	dispose, or store a der want? (check (iny sources and/or dev:	ices that
Jog no ioi	iger want. (check t		
If no, ple	ase elaborate:		
b. Are there	any diffculties in	using this authorized	
recipient	(check one) ies	NO	, · ·
If yes, pl	lease elaborate:		·····
4) Additional (comments - check her	re and use back of	this
sheet.			
	~H	1 1	
Surveyor: 24	- Lokon Man	Date: <u>12/7/89</u>	
	•		•
Note: Activity	y levels described :	in guestion 1 were der	ived from
limits	established in 10 Cl	FR 61 section 61.55.	The leve is
were bas	sed on typical size	sources.	

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ABOVE CLASS C SOURCE/DEVICE INVENTORY SHEET

Manufacturer	Model #	T Y P E	lsotope	Activity mCi or Ci	Use	Active	Inactive	Explanation
AECL	(-161	8	Cs-137	22/00		\checkmark		
11	11	8	11	3490	······································	~		
/ (11	8	11	22100		\checkmark		
.11	(1	8	۲ ۲	L2100				
-								
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NOTE: List each source/device separately. If inactive or use is other, please explain.

CODES:

Isotope: Am-241 Inactive: D - Damaged X - Surplus Use: A - Well logging F - Fixed gauges Cm-244 L - Lost O - Other B - Irradiator t G - Broad licenses Cs-137 T - Wants to dispose or transfer C - Teletherapy H - Pacemakers D - X-ray fluorescence I - Waste brokers Pu-238 DT - Damaged and wants to Pu-239 dispose or transfer E - Portable gauges O - Other

MS-16 P-7



DEPARTMENT OF THE ARMY WALTER REED ARMY MEDICAL CENTER WASHINGTON, D.C. 20307-3001

REFLY TO ATTENTION OF:

HSHL-H-HP (385-11m)

22 NOV 1989

MEMORANDUM FOR US Nuclear Regulatory Commission, Region I,

Nuclear Material Section B, Attn: Mr. Tom Thompson, 475 Allendale Road, King of Prussia, Pennsylvania 19406

SUBJECT: Additional information requested to amend NRC License No. 08-01738-03

1. The information referred to (from our Broad Scope License No. 08-01738-02) in our amendment dated 16 October 1989 is enclosed. The material on training from Tab C Chapter 2 is provided (enclosure 1). The material on Personnel Monitoring from Tab C Chapter 5 and Tab D Condition No. 1 is provided (enclosures 2 & 3). Lists of radiation detection instruments available at Walter Reed and calibration procedures for same listed in Tabs E & F are provided (enclosures 4 & 5).

2. In addition to the lock on the irradiator itself and the key control procedures outlined in enclosure. 7 of the original amendment dated 16 October 1989, room (will be locked whenever not occupied or under the direct visual control of Blood Bank personnel.

3. Lieutenant Anthony has recently spent 4-6 hours with Dr. Bill Bass (the principle user for the AECL Gammacell 40 and AECL Gammacell 220 irradiators at building 40) to familiarize himself with the use of scaled source irradiators. This includes personnel monitoring, instrumentation, and mechanical layout of sources, shielding and exposure chambers within the irradiators. In addition the contract with J. L. Shepherd for the new irradiator includes 8 hrs. of hands on training for approved users and Lieutenant Anthony and one or two other members of the Health Physics Office will attend.

4. If any other information is needed the point of contact is Mr. David W. Burton. We appreciate all your help in expediting this amendment as the program is ready to go, and the irradiator ready to ship.

David W. Burton

David W. Burton Chief, RMC Branch Health Physics Office

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NOV 22 1989

WRAMC Reg 40-10

30 April 1987

CHAPTER 2

Training

2-1. GENERAL. The NRC requires that training be given to any employee who works in or frequents the vicinity of any area controlled by the licensee for protection of individuals from exposure to ionizing radiation. The Commander, WRAMC, has implemented training programs pertaining to the hazards of radiation and the methods for minimizing those hazards for radiation workers and other personnel.

2-2. PROGRAMS.

a. Initial Briefing.

(1) The Principal User is responsible for individuals who work under or are associated with work areas designated on his Authorization for the Use of Radioisotopes. He is required to give and document an initial and annual briefing to those individuals which covers, at a minimum, the following:

(a) WRAMC Notice to Employees

(b) Form NRC-3, Notice to Employees

(c) Title 10, Code of Federal Regulations, Parts 19, 20 and 21

(d) Information concerning the storage, transfer and use of radioisotopes allowed under his authorization

(e) Authorization to Use Radioisotopes (WRAMC Form 1661-R, Application for Authorization to Use Radioactive Material - Human Use and/or WRAMC Form 1662-R, Application for Authorization to Use Radioactive Material -Non-human Use)

(f) Hazards and protective measures associated with isotope usage

(g) Procedures for requesting a report of exposure to radiation

(2) This briefing will be given and acknowledged by signing WRAMC Form 538, Radiation Worker Briefing.

b. Introductory Principles of Radiation Protection Course: This twoday course, given by the staff of the HPO, is designed to complete and reinforce training given by the Principal User. It provides supplementary training, in an academic setting, required for the safe handling of

WRAMC Reg 40-10

30 April 1987

CHAPTER 5 Personnel Monitoring

5-1. GENERAL.

a. This chapter prescribes procedures and responsibilities for monitoring and recording occupational exposures to ionizing radiation from radiation producing devices and radioactive materials.

b. Each activity receiving personnel dosimetry service from HPO will designate a personnel dosimetry coordinator and alternate to assist HPO in the issue, exchange and collection of dosimetry devices.

c. Application for personnel dosimetry service must be initiated by the individual and submitted on a properly completed DD Form 1952, "Dosimeter Application and Record of Occupational Radiation Exposure", to the HPO. The HPO will evaluate the information on the application and issue appropriate dosimetry or provide written notification that dosimetry is not needed.

d. Assignment of a personnel dosimetry device to an individual does not automatically make him a radiation worker. Occasionally exposed individuals may be monitored to determine need for permanent issue of dosimetry devices.

5-2. FILM BADGES.

a. The whole body badge is the primary dosimetry device used at WRAMC and is the only device legally recognized for whole body dosimetry. Other devices such as TLD may be used to monitor portions of the body or as supplemental dosimeters.

b. A whole body badge will be worn only by the individual to whom it is issued.

c. WRAMC issued dosimetry will not be worn by personnel when occupationally exposed at other facilities.

d. Whole body badges will be worn on the front of the torso. In the event a protective garment, such as a lead apron, is worn the badge will be worn under the protective garment.

5-3. SUPPLEMENTAL MONITORING DEVICES. Additional personnel monitoring devices will be provided when necessary to monitor a portion of the body or to obtain more immediate data. These devices will be worn only by individuals to whom they are issued.

5-4. CARE OF MONITORING DEVICES. When not being worn, personnel monitoring devices will be stored in the designated place and turned in to the personnel dosimetry coordinator during designated exchange periods. Film badges are not

HEALTH PHYSICS WALTER REED ARMY MEDICAL CENTER Washington, D.C. 20307-5001

CONDITION NO. 1

For

RADIOACTIVE MATERIAL AUTHORIZATIONS

PERSONNEL DOSIMETRY

1. PERSONNEL DOSIMETRY ASSIGNMENT LEVELS

An appropriate personnel monitoring device or devices will be assigned to each individual as required by the Health Physics Officer. In addition, other personnel monitoring techniques (e.g., bioassay) will be utilized to evaluate personnel dosimetry as deemed necessary by the Health Physics Officer. Personnel monitoring devices will usually be assigned when individuals could potentially receive in excess of the following levels in a three (3) month period:

Whole Body, head and trunk, active blood forming organs, gonads or lens of the eye

63 millirems

Skin of the whole body (other than hands, wrists, feet or ankles), forearms, and cornea of the eye 375 millirems

Hands and wrists, or feet and ankles

Bone, thyroid, other organs, tissues and organ systems

250 millirems

938 millirems

2. APPLICATION FOR PERSONNEL DOSIMETRY SERVICE

a. Supervisors of individuals who are potentially exposed to occupational radiation doses in excess of the above values must require such individuals to submit an application for Personnel Dosimetry Service (DD Form 1952) to the Health Physics Office, WRAMC, prior to assignment to that work.

b. The procedure and responsibilities for processing the application are as follows:

(1) <u>Individual Application for Personnel Dosimetry Service</u>: The applicant has the responsibility to furnish:

(a) Individual data

(b) Previous occupational exposure history

REVISED - 3 SEP 86

LIST OF RADIATION DETECTION INSTRUMENTS

	NUMBERS	RADIATION		WINDOW THICKNESS	
Түре	AVAILABLE	DETECTION	RANGE	(mgm/cm ²)	USE
Eberline 6112	6	beta, gamma	0-1R/hr	30	Surveys
Eberline E 120	10	beta, gamma	0-50mR/hr	30	Lab Surveys
Eberline PAC-ISA	1	ganna	0-2000k cpm	1.5	Monitor
Eberline PAC-ISAGA	2	gama	0-2000kcpm	0.5	Monitor
Eberline PRM-5	1	beta/gamma	N/A	N/A	Monitor
Eberline 140 .	4	beta,gamma	0-60kcpm	N/A	Monitor
Eberline PRM-5-3	1	beta,gamma	N/A	N/A	Monit or
Eberline PRM-6	3	beta, gamma	0-500cpm	N/A	Survey
Eberline PRS-1 (Rascal)	14	beta, gamma	0-999,999cpm	N/A	Monitor
Eberline RM-16	10	gamma	10 ² -10 ⁶ срт	N/A	Monitor
Eberline MS-3	4	beta, gamma	N/A	N/A	Monitor
Eberline PRN-4	1	neutron	0-5kR/hr	N/A	Monitor
Gamma Industries 2508	20	beta, gamma	0-1000mR/hr	30	Survey
Gamma Industries 252B	10	beta, gamma	0-1000mR/hr	30	Survey

.

		NUMBERS	RADIATION		i wi	NDOW THICKNESS		
	туре	AVAILABLE	DETECTION		ANGE	(mgm/cm ²)	USE	
	Lud Ium 2	8	beta, gamma	0-	50mR/hr	1.5	Surve	y
	Ludlum 3	172	beta, gamma,	0-	00mR/hr	30	Surve	y .
	Ludium 3	7	alpha	0-!	500mR/hr	1.0	Survey	y
	Lud Jum 125	1	gamma	į	N/A	N/A	Monite	or
•	udlum 165	1	gamna	0-	00,000cpm	N/A	Monito	or
	Lud lum 28	31	gamma	1	N/A	30	Monite	or
	Ludium 2000	1	gainna		N/A	N/A	Monite	or
ı	Ludium 2200	1	gamma	,	N/A	N/A	Monito	or
!	Victoreen 440	3	gamma	-	N/A	1.0	Measur	re
i	Victoreen 440RF	1	gamma	0-	00mR/hr	N/A	Measur	re
1	Victoreen 471	10	alpha, beta, gamma		0-1R/hr	500mg/Cm ²	Measur	re
ł	Victoreen 808B 🗧 🗧	3	gamma	.1	nR/hr-100mR/hr	N/A	Measur	re
E	uclear Data ND660MCA	1	gamma		N/A	N/A	Measur	re
	Nuclear Data ND66	1	gannia	Ì	N/A	N/A	Measur	ne .
ŝ	Canberra 2201	1	alpha, beta		N/A	H/A	Measur	re
	Beckman LS-9800	1	beta		N/A	N/A	Measur	e
,	Packard AG-5780	1	gamna		N/A	NZA	Heasur	°e
	Keithly 36150	2	beta, gamma		0-20R/hr	50mg/Cm ²	Measur	.е
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CALIBRATION OF SURVEY INSTRUMENTS

- 1. Survey instruments will be calibrated at least annually and following repair.
- 2. Calibration will be performed at two points on each scale. The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within \pm 10% of the calculated or known values for each point checked. Readings with \pm 20 are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.
- 3. Survey instruments will be calibrated by an annually contracted company, whose procedures and sources are approved by the agreement state/NRC.

WRAMC Reg 40-10

30 Apr11 1987

to be worn during non-duty hours or when the individual is examined in medical or dental clinics.

5-5. BIOASSAY.

a. The HPO will designate individuals to participate in the bioassay program. Once so designated, individuals will participate until released, in writing, by the HPO.

b. Individual Responsibilities.

(1) Appearing for measurement at the time, place and frequency required.

(2) Providing required specimen for in-vitro counting.

(3) Informing HPO of changes in working conditions or other factors influencing the type or frequency of bloassay measurement.

5-6. RECORDS.

a. Records of individual radiation exposure are maintained on DD Form 1141, "Record of Occupational Exposure to Ionizing Radiation", or an Automated Dosimetry Report (ADR). The records are kept at the HPO until individuals depart WRAMC or are removed from dosimetry service. Records are then placed in the individual health record. Records may be reviewed at the HPO during normal duty hours.

b. Locator Cards.

(1) DD Forms 1141 or ADR are medical records. Locator cards identifying radiation workers will be furnished by HPO to the medical records section for placement in individual medical records.

(2) Individuals not maintaining medical records at the out-patient medical records section, WRAMC, must bring their records to the HPO to have the locator card inserted.

c. Personnel occupationally exposed at a facility outside the jurisdiction of WRAMC will furnish all exposure information to the HPO.

d. The DD Form 1141 or ADR is covered under the Privacy Act. Therefore a written authorization, signed by the individual must be forwarded to the HPO before occupational exposure information can be released.

5-7. TERMINATION OF PERSONNEL DOSIMETRY. Individuals who wish to terminate personnel dosimetry service for any reason will report to the HPO, Building 188, Forest Glen Section with their medical records during normal duty hours. The individual must provide HPO with the reason for termination and a forwarding address.

WRAMC Reg 40-10

30 Apr11 1987

111556

radioisotopes and protection of individuals from external and internal radiation hazards. It is required that all radiation workers attend this course, as soon as possible, after beginning work at WRAMC. An examination is given at the end of this course. If the student fails the exam it may be retaken, after additional preparation, or the student may elect to retake the course. Subsequent failure requires that the Principal User evaluate the advisability of retaining the individual in a position which requires the handling and use of radioisotopes.

c. Principal User Classes. The senior staff of the HPO conducts periodic classes on selected topics. These topics are based on the need to disseminate current information on license and regulation changes, to correct deficiencies which have been noted and to enhance the professional competency of individuals working in radiation environments. This is mandatory for Principal Users. Co-workers are encouraged to attend.

d. Nursing In-service: Briefings, designed for nursing and paraprofessional staff who come in contact with patients undergoing therapy with radioisotopes, are presented upon request to the HPO. Specific details on the types of therapy or other procedures are covered.

e. Briefing for Support Personnel: This class is designed for individuals whose duties take them into areas where radioisotopes are used. It familiarizes personnel with signs, placards and color schemes associated with radioactive material, gives a general outline of what radiation and contamination are and sets ground rules for what should and should not be done in these areas.

f. Briefing for Firefighters: This briefing covers methods of designating areas where radioactive materials are used, use of radiation detection instrumentation, notification procedures and procedures for ensuring protection from contamination and internal deposition.

g. Briefing for Military Police/Security Personnel: This class teaches the proper method for receiving, inspecting and storing incoming packages containing radioisotopes and addresses the procedures for dealing with problems such as a damaged container or leaking package.

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DATE 1/15/89 NRC FORM 218 U.S. NUCLEAR REGULATORY COMMISSION (4-78) NACH 0240 TIME /0:30 🖸 A.M. **TELEPHONE OR VERBAL CONVERSATION RECORD** 🗋 р.м. 13 INCOMING CALL OUTGOING CALL PERSON CALLING OFFICE/ADDRESS PHONE NUMBER | EXTENSION The Thompson RI 5303 PERSON CALLED OFFICE/ADOBESS PHONE NUMBER | EXTENSION A.mi/ David Burton *427-51*04 030- 06895 CONVERSATION SUBJECT Amend Request Sater 10/13/89 SUMMARY 1) Will new inadiator be kept in a locked over when unattended? 2) User Training, Josimetry, use of instruments refers to License 02. We must Please submitt these references on refer to references already Submitted under the O3 license. 3) What the experience does the proposed \$50 have with self shielded itradiators? Mr. Burton aggreed to answer these questions + Fax to Regim. **EFERRED TO:** ADVISE ME OF ACTION TAKEN. **\CTION REQUESTED** Fax to Rey h INITIALS DATE INITIALS **\CTION TAKEN** DATE OFFICIAL RECORD COPY MIL IU ILIKKI C FORM 218 (4-76)

30-06895



DEPARTMENT OF THE ARM Y OFFICE OF THE SURGEON GENERAL 5109 LEESBURG PIKE FALLS CHURCH, VA 22041-3258



REPLY TO ATTENTION OF

November 2, 1989

Preventive and Military Medicine Consultants Division

US Nuclear Regulatory Commission Region I 475 Allendale King of Prussia, Pennsylvania 19406

Dear Sir:

Enclosed are two copies of a request to amend Byproduct Material License Number 08-01738-03, Walter Reed Army Medical Center, Washington, District of Columbia.

Recommend approval.

Sincerely,

Charles E. Day, III () Lieutenant Colonel, U.S. Army Radiological Hygiene Consultant

Enclosure

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NOV 06 1989



DEPARTMENT OF THE ARMY WALTER REED ARMY MEDICAL CENTER WASHINGTON, D.C. 20307-5001

REPLY TO ATTENTION OF:

16 OCT 1989

HSHL-H-HP (385–11m)

MEMORANDUM THRU Commander, US Army Health Services Command, ATTN: HSCL-P, Fort Sam Houston, TX 78234-6000

FOR US Nuclear Regulatory Commission, Region I, Nuclear Material Section B, 475 Allendale Road, King of Prussia, PA 19406

SUBJECT: Amendment of US Nuclear Regulatory Commission License No. 08-01738-03

1. Request that NRC License No. 08-01738-03 for Walter Reed Army Medical Center be amended to include another Gamma Irradiator; an NRC Form 313 and other pertinent documents are provided (enclosure 3 thru 7).

2. This unit is a critical part of a new bone marrow transplant program coming on line at Walter Reed, we therefore request your assistance in the expeditious processing of this amendment.

3. Please be advised that Major General Richard D. Cameron is the new Commanding Officer of Walter Reed Army Medical Center and Colonel Russ Zajtchuk is the new Deputy Commander for Clinical Services and in that capacity is the new Chairman of the Radiation Control Committee of Walter Reed Army Medical Center. Copies of their curriculum vitae are provided (enclosure 1 & 2).

FOR THE COMMANDER:

7 Encls

LLEWELLYN E. PIPER LTC, MS Executive Officer

BIOGRAPHICAL INFORMATION

RICHARD D. CAMERON, M.D., MAJOR GENERAL, USA.

BA Degree, State University of Iowa Education: MD Degree, State University of Iowa MHA Degree, Baylor University, Texas Internship: Rotating Internship, Brooke Army Medical Center, San Antonio, Texas, 1965-66 Residency: Psychiatric Residency, Letterman Army Medical Center, San Francisco, 1966-69 · California, (with work at Center for Training in Community Psychiatry, Berkeley. Commanding Officer, 93d (KO) Neuro-Positions: psychiatric Team, RVN, 1969 Division Psychiatrist, 1st Air Cavalry Divison, RVN, 1970 Instructor, Behavioral Sciences Divison, Academy of Health Sciences, US Army, Fort Sam Houston, Texas, 1971 Instructor, US Army Alcohol and Drug Prevention Program, Yale Univer-1972 sity, FRG Project Officer, Deputy Chief of Staff for Professional Activities, HQ, US Army Health Services .Command, 1974 San Antonio, Texas, Chief, Inpatient Psychiatric Service, William Beaumont Army Medical 1974 Center, El Paso, Texas, Chief, Department of Psychiatry, William Beaumont Army Medical 1974-75 Center, El Paso, Texas, Chief, Department of Psychiatry, Landstuhl Army Medical Center, 1975-76 2d General Hospital, FRG Ex 6

Positions (continued)	Divison Surgeon, 3d Armored Division, Frankfurt, FRG,	1976-77
	Commander, 56th General Hospital, Baumholder FRG	1977-79
	Medical Team Chief-Saudi Arabian National Guard Medical Moderniza- tion Program,	1980
• •	Deputy Chief of Staff, Operations, HQ, US Army Health Services Command, Fort Sam Houston, Texas,	1980-1983
•	Commander, Darnall Army Community Hospital and III Corps Surgeon, Fort Hood, Texas,	1983 -8 6
	Commanding General, William Beaumont Army Medical Center, El Paso, Texas,	1986–8 8
	Deputy Assistant Secretary of Defense for Health and Medicine, Washington, D. C.,	1988-89
Current Position:	Commanding General Walter Reed Army Medical Center Washington, D. C.,	1989-
Certificate of License:	Medicine and Surgery, Iowa,	1965
Professional Boards:	Diplomate, American Board of Psychiatry and Neurology,	1973
Professional Societies:	American College of Physician Executives American Psychiatric Associaton Association of Military Surgeons	
Awards:	Legion of Merit (2) Meritorious Service Medal Air Medal Army Commendation Medal (5) Expert Field Medical Badge Parachutist Badge US Army Order of Military Merit	
Military Schooling:	AMEDD Officers' Basic AMEDD Officers' Advanced Command and General Staff College US Army-Baylor Hospital Administration Co Industrial College of the Armed Forces.	ourse

CURRICULUM VITAE

Russ Zajtchuk

CURRENT STATUS:

Colonel, Medical Corps, U. S. Army (Active, Regular) SSI*: 61K9A, 61J9B Date of Bank: 7 June 1978 SSN:

Deputy Commander for Clinical Services Walter Reed Army Medical Center Washington, DC 20307-5001

Professor and Chairman Division of Cardiothoracic Surgery Uniformed Services University of the Health Sciences Bethesda, 40 20814

Consultant, Cardiothoracic Surgery National Naval Medical Center Bethesda, MD 20814

BOARD CERTIFICATION

American Board of Surgery, 1969 American Board of Thoracic Surgery, 1970 Licensed: Coloradó and Illinois (current and fully active)

EDUCATION:

College: University of Illinois, 1955-1958 University of Chicago, 1958-1959

Medical School: University of Chicago, 1959-1963 - Degrees: BS

Internship: University of Chicago, 1963-1964

General Surgery Residency: University of Chicago, 1964-1968

Cardiothoracic Residency: University of Chicago, 1968-1970

PROFESSIONAL EXPERIENCE AND ASSIGNMENTS: University of Chicago, Assistant Professor of Surgery, Jan 1970 - Jul 1970

Chief. Thoracic Surgery, Fort Campbell, Kentucky, 1970-1971

Tour in Vietnam. Served as Chief, Professional Services at 24th Evac Hospital and 3rd Field Hospital. Also served as Consultant in Thoracic Surgery for Vietnam, Sep 1971 - Sep 1972

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PROFESSIONAL EXPERIENCE AND ASSIGNMENTS (CONT'D):

Assistant Chief, Thoracic-Cardiovascular Surgery Service, Fitzsimons Army Medical Center, Denver, CO, 1972-1977

Director of Surgical Research, Fitzsimons Army Medical Center, Denver, CO, 1972-1977

Assistant Professor of Surgery, University of Colorado School of Medicine, 1972-1976

Assistant Chief, Thoracic-Cardiovascular Surgery Service, Walter Reed Army Medical Center, Washington, DC, 1980-1981

Chairman and Program Director, Mational Maval Medical Center, Bethesda, MD, 1980-1981

Chairman and Program Director, Thoracic-Cardiovascular Surgery Service, Walter Reed Army Medical Center, Mashington, DC, 1981-1984

Professor and Chairman, Division of Cardiothoracic Surgery, School of Medicine, Uniformed Services University of the Health Sciences, Bethesda, MD, 1981 - Present

Consultant to The 'Army Surgeon General in Cardiac and Thoracic Surgery, Washington, DC, 1980-1984

Commander, 41st Combat Support Hospital and JTF Surgeon for Honduras, Jul 1983 - Apr 1984

Department of Defense Readiness Review Member for Secretary of Defense, Apr 1984 - Jun 1984

United States Southern Command, Command Surgeon, Quarry Heights, Panama, Jul 1984 - Jul 1985

Student at National Defense University, Aug 1985 -Jun 1986

Surgical Consultant to The Surgeon General, Chief Consultants Division, Jul 1986 - Jul 1988

Deputy Director, Professional Services, Office of The Surgeon General, Jun 1988 - Jun 1989

Chief, Consultants Division, Office of The Surgeon General, Jun 1987 - Jun 1989

-2-

MILITARY SCHOOLS/COURSES: AMEDD Officer Basic, 1970

AMEDD Officer, Advanced, 1978 Combat Casualty Course (AMEDD), 1982 USA Command and General Staff College, 1983 Baylor University Program in Health Care Administration, 1986 Industrial College of the Armed Forces, 1986

SOCIETIES:

American College of Surgeons

Association of Military Surgeons

Society for Thoracic Surgeons

Sigma Xi

The Western Thoracic Surgical Society

American Association for Thoracic Surgery

American College of, Cardiology

Association of Training Program Directors

CIVILIAN AWARDS/HONORS: NSF Fellowship, 1961 - 1962

Chicago Surgical Society Award for Surgical Research, 1965 (lst Prize)

Certificate of Merit from AMA for Exhibit on Hypercoagulability, 1976

Won Second Place at Southeastern Surgical Congress, Exhibit on Hypercoagulability, 1977

Dominique Larey Award for Excellence in Military Surgery, Awarded by USUHS, 1989

MILITARY AWARDS - U.S.:

Department of Defense Superior Service Medal

Legion of Merit with Oak Leaf Cluster (One from the Air Force)

Bronze Star

Deparment of Defense Meritorious Service Medal

-3-

MILITARY AWARDS -U.S.: (CONT'D)

....

Meritorious Service Medal with Two Oak Leaf Clusters (One from the Navy)

Department of Defense Commendation Medal

Army Commendation Medal with Oak Leaf Cluster

Army Achievement Medal

Humanitarian Assistance Medal

MILITARY AWARDS - Vietnamese Cross of Gallantry .

FOREIGN

Vietnamese Civic Action Medal

Honduran Merit Medal, First Class

MILITARY PROFES-SIGNAL SAWARD:

PUBLICATIONS:

Dawson, D., Allen, J.G., and Zajtchuk, R.: Monoalkylating Agents as therapeutic agents in plasma sterilization and plasma protein stabilization. J. Surg Res., 2:31-35, 1962.

Awarded 'A Prefix' by The Surgeon General for Out-

standing Performance in Cardiothoracic Surgery

Dawson, D., Zajtchuk, R., and Allen, J.G.: Use of chemotherapeutic agents for possible bacterial and viral contamination of blood. J. Surg. Res., 3:97-100, 1963.

Dawson, D. and Zajtchuk, R.: Effect of rapid rewarming on tissue survival after deep freezing injury. Research and proceedings of the Institute of Medicine Bulletin (Chicago), Mar, 1963.

Dawson, D., Zajtchuk, R., and Allen, J.G.: Infectious hepatitis and the role of chemotherapeutics in viral disease transmitted by blood transfusions. J. Surg. Res., 4:47-53, 1964.

Dawson, D. and Zajtchuk, R.: 'Use of chloracetate and formaldehyde as plasma additives in instability heat denaturation of plasma proteins. J. Clin. Chem., 10:793-799, 1964.

Kahan, B.D., Zajtchuk, R., Dawson, D., and Adams, W.G.: The kinetics of sensitization with whole and fractioned mouse spleen cells. Dig. Chest, 46:452-456, 1964.

Gago, O., Zajtchuk, R., Nigro, S., and Adams, W.E.: Canine pulmonary homografts with uncontrolled crosscirculation. J. Thor. Cardiovasc. Surg., 50:775-780, 1965.

Adams, W.G., Gago, O., and Zajtchuk, R.: Use of azathioprine in homotransplantation of pulmonary tissue. Bull. Soc. Int. Chi., 25:631-638, 1966.

Block, G.E., Evanz, R., and Zajtchuk, R.: Splenectomy for idiopathic thrombocytopenic purpura. Arch. Surg., 92:434-489, 1966.

Zajtchuk, B., Ake, V., Hamouda, I., Moulder, P.V., and Adams, W.E.: Maintenance of the circulation in cardiac asystole by the mechanical pulsator. Trans. Amer. Soc. Artif. Intern Organs, Vol. XII, 1966.

Zajtchuk, R., Kahan, B.D., and Adams, W.E.: The tissue distribution of a water soluble transplantation antigen. Dis. Chest, 50:368-371, 1966.

Evans, R., Zajtchuk, R., and Menguy, R.: Role of vagotomy and gastric drainage in the surgical treatment of duodenal ulcer (Result of 10-year experience at the University of Chicago Hospitals). Surg. Clin. N. Amer., 47:141-146, 1967.

Zajtchuk, R., Gago, O., and Adams, W.E.: Homotransplantation of the lung (influence of quantity of antigen on the survival of the graft). J. Thor. Cardiovasc. Surg., 53:109-115, 1967.

-Zajtchuk, R., Amato, J., Paloyan, E., and Baker, R.: Inhibition of external pancreatic secretion by glucagon. Surg. Forum, 18:410-411, 1967.

Zajtchuk, R., Mamouda, F., Moulder, P.V., and Adame. W.E.: Maintenance of Circulation in cardiac asystole by the mechanical pulsator. Dis Chest, 1967.

Bauer, R.J., Bass, R.T., Zajtchuk, R., and Strohl, E.L.: External pancreatic fistula following abdominal injury. Arch. Surg., 95:556-566, 1967.

Zajtchuk, R. and Baker, R.: Effects of hypoglycemia on external pancreatic secretion. J. Trauma, 9:629-637, 1969.

-5-

Menguy, R., Gadacz, R., and Zajtchuk, R.: Surgical management of acute gastric mucosal bleeding. Arch. Surg., 99:198-208, 1969.

Zajtchuk, R., Yacoub, M.H., and Kittle, C.F.: Spontaneous A-V fistula between common iliac vessels. Surgery, 69:194-200, Feb 1971.

Geis, P., Johnson, C.F., Zajtchuk, R., and Kittle. C.F.: Extrapericardial (mediastinal) cardiac tamponade. Arch. Surg., 100:305-306, 1970.

Daily, R., Ranniger, K., Zajtchuk, R., Evans, R., and Moulder, P.V.: Serum and plasma infusion in human pulmonary artery: Embolic implications. Arch. Surg., 101:26-31, Jul, 1970.

Baker, R.J., Zajtchuk, R., and Shoemaker, W.C., et al: Physiologic studies on external pancreatic secretion in man. Bull. Soc. Int. Chir., 27:81-88, 1968.

Zajtchuk, R., Resnekor, L., Ranniger, K., and Gonzales-Lavin, L.: Traumatic aorta to pulmonary artery fistula. Thoracic, 26(2):219, 1971.

Gonzales-Lavin, L. and Zajtchuk, R.: Surgical considerations in the treatment of acute acquired ventricular septal defect. Thorax, 26:610-614, Sep 1971.

Zajtchuk, R., Gonzales-Lavin, L., and Replogle, R.: Pulmonary artery aneurysm associated with ASD and absent pulmonary valve. J. Thorac. Cardiovasc. Surg. 65:699-701, May 1973.

Zajtchuk, R., Strevey, T., Heydorn, W., and Treasure, R.: Mediastinal histoplasmosis: Surgical considerations. J. Thorac. Cardiovasc. Surg., 66:300-304, Aug 1973.

Zajtchuk, R., Guiton, C.R., Sadler, T.R., Heydorn, W.H., and Strevey, T.E.: Surgical treatment of pulmonary melioidosis. J. Thorac. Cardiovasc. Surg., 66:838, Nov 1973.

Heydorn, W.H., Barry, M.J., Zajtchuk, R., and Strevey, T.W.: Tumor embolus death during pneumonectomy. J. Thorac. Cardiovasc. Surg., 67:308-309, Feb 1974.

Zajtchuk, R., Fitterer, J., Strevey, T.E., and Nelson, W.P.: Bilateral atrial myxoma (Preoperative diagnosis and successful removal). J. Thorac. Cardiovasc. Surg., 69:291-294, Feb 1975. Zajtchuk, R., Seyfer, A.E., and Strevey, T.E.: Use of intercostal muscle in primary repair of esophageal atresia with tracheoesophageal fistula. Ann. Thorac. Surg., 19:239-241, Mar 1975.

Zajtchuk, R., Corby, D.B., Miller, J.G., and O'Barr, T.P.: Treatment of digoxin toxicity with activated charcoal. Am. J. Cardiol. 35:178, Jan 1975.

Colling, G.J. and Zajtchuk, R.: Hypercoagulability in mesenteric venous occlusion: Report of two cases. Am. J. of Surg., 132(3):390-391, Sep 1976.

Collins, G.J., and Zajtchuk, R.: Hypercoagulability in patients with peripheral vascular disease. Am. J. Surg., 13c(1):2-6, Jul 1975.

Zajtchuk, R., et al: Revascularization of the heart through coronary veins, Ann. Thorac. Surg., 21(4):318-321, Apr 1976.

Heydorn, W.H., and Zajtchuk, R., et al: Surgical management of pectus deformity. Ann. Thorac. Surg., 23(5):417-420, May 1977.

Zajtchuk, R., and Collins, G.J., et al: Coagulation factors influencing thrombosis of aortocoronary bypass grafts. J. Thor. Cardiovasc. Surg., 73:309, 1977.

Collins, G.J. and Zajtchuk, R., et al: The effects of operative stress on the coagulation profile. Am. J. of Surg., 133:612, May 1977.

Seyfer, A.E. and Zajtchuk, R.: A clinical analysis of Ewing's sarcoma of the chest wall. Military Medicine, 142(10):778-779, Oct 1977.

Heydorn, W.H. and Zajtchuk, R., et al: Gore-Tex grafts for replacement of the superior vena cava. Ann. Thorac. Surg., 23(6):539-544, Jun 1977.

Bode, R. and Zajtchuk, R.: Evaluation of saphenous vein bypass surgery using multistage treadmill test and ventricular function studies. J. Thorac. Cardiovasc. Surg., 74:44, 1977.

Seyfer, A.E. and Zajtchuk, R.: Systemic vascular performance in endotoxic shock. Surg. Gynec. and Obst., 245:401, Aug 1977.

Zajtchuk, R. and Collins, G.J.: Coagulation abnormalities in patients undergoing myocardial revascularization. J. Thorac. Cardiovasc. Surg., 75:168, 1978.

Bowen, T.E., Brott, W.H., and Zajtchuk, R., et al: Thoracic traction for median sternotomy dehiscence. Ann. Thorac. Surg., 25, 1978.

Bowen, T.E., Zajtchuk, R., Green, D.C., and Brott, W.H.: Value of anterior mediastinotomy in bronchogenic carcinoma of the left upper lobe. J. Thorac. Cardiovasc. Surg., 76:269, 1978.

Zajtchuk, R., Seyfer, A.E., et al: Intrathoracic ganglioneuroblastoma. J. Thorac. Cardiovasc. Surg., 80(4):605-612, Oct 1980.

Chun. P., Leeburg, W.T., Coggin, J.T., and Zajtchuk, R.: Primary pericardial malignant epithelioid mesothelioma. Chest. 77, 558-561, Apr 1980.

Zajtchuk, R., Bowen, T.E., Albug, R.A., and Brott. W.H.: Surgical treatment of left main equivalent coronary artery disease. J. Thorac. Cardiovasc. Surg., 78(3):452-454, Sep 1979.

Bowen, T.E. and Zajtchuk, R.: Isolated mitral valve replacement with Kay Shiley disc valve (long-term followup). J. Thorac. Cardiovasc. Surg., 80(1):45-49, Jul 1980.

Graeber, G.M., Synder, T.R., Zajtchuk, R., and Brott, W.H.: A comparison of serum isoenzyme levels of creatinine phosphokinase and lactic dehydrogenase in patients undergoing thoracic operations and patients admitted to coronary care unit. Ann. of Thorac. Surg., 30(4):364-369, Oct 1980.

Bowen, T.E., Brott, W.H., Green, D., Zajtchuk, R.: Coarctation of the aorta with left aortic arch and right descending aorta: Case report. Military Medicine, 145(2), Feb 1980.

-8-

Graeber, G.M., Zajtchuk, E., et al: An analysis of the isoenzymes of creatinine phosphokinase and lactic dehydrogenase in the esophagus. Ann. of Thorac. Surg., 32(3), 230-234, Sep 1981.

Brott, W.H., Zajtchuk, R., et al: Incidence of thromboembolism in patients with Bjork-Shiley prosthesis on aspirindipyridamole treatment. J. of Thorac. Cardiovasc. Surg., 81(4):632-635, Apr 1981.

Giberly, G., and Zajtchuk, R.: Diagnosis and treatment of desmoid tumors: A review. Military Medicine, 147(4):278-284, Apr 1982.

Bowen, T. and Zajtchuk, R.: Diaphragmatic paralysis managed by diaphragmatic replacement. Ann. of Thorac. Surg., 33:194-185, Feb 1982.

Zajtchuk, R., Nelson, W.P., and Collins, G.J.: Ischemic heart disease and coronary thrombosis. Chapter 7, pp. 215-240, in Vascular Occlusive Disorders, Futura Publishing Company, Inc., Mount Kisco, New York, 1981.

Zajtchuk, R. and Zajtchuk, J.: Relationship of triglyceride levels to thrombosis in patients with coronary artery disease. Published in the Ann. Thorac. Surg. 1980.

Graeber, G., Grishkin, B., Cohen, D.J., and Zajtchuk, R.: A technique for successful replacement of the esophagus with an interposed substernal colon segment. Contemporary Surgery, pp. 17-26, Apr 1983.

Sherrill, P.J., Brishkin, B.A., Galal, F.S., Zajtchuk, R., and Graeber, G.M.: Radiation association malignancies of the esophagus. Cancer, 54:726, 1984.

Cohen. D.J., Ronningen, L.D., Graeber, G.M., Deshong, J.L., Jaffin, J. and Zajtchuk, R.: Management of patients with malignant thymoma. J. Thorac. Cardiovasc. Surg., 87(2):301-307. Feb 1984.

Graeber, G.M., Cafferty, P.J., Wolf, R.E., Cohen, D.J., and Zajtchuk, R.: Creatine kinase (CK) and lactic dehydrogenase (LD) in the muscles encountered during median sternotomy and in the myocardium of the cardiac chambers. J. Thorac. Cardiovasc. Surg., 89(5):700-705, May 1985.

Graeber. G.M. Thompson, L.D., Cohen, D.J., Ronnigen, L.D., Jaffin, J. and Zajtchuk, R.: Cystic lesions of the thymes: An occasionally malignant cervical and/or anterior mediastinal mass. J. Thorac. Cardiovasc. Surg., 87(2):295-300, Feb 1984.

Watkins. M.T., Sharefkin, J.B., Zajtchuk, R., Maciag, T.M., D'Amore, P.A., Ryan, U.S., Wart, H.V., Rich, N.M.: Adult human saphenous vein endothelial cells: Assessment of their reproductive capacity for use in endothelial seeding of vascular prostheses. J. Surg. Research 36:588-596, 1984.

Zajtchuk, R., Antopol, M.R., Graeber, G.M.: Thoracic Trauma, Medical Bulletin, 41(12):3-7, 1984.

Graeber, G.M., Cohen, D.J., Patrick, D.H., Wolf, R.E., Hotard, M.C., and Zajtchuk, R.: Rib fracture healing in experimental flail chest. Journal of Trauma 25:903-908, 1985.

Cohen, D.J., Benjamin, S.B., Graeber, G.M., Zajtchuk, R., Castell, D.O., and Patrick, D.H.: Evaluation of the Agelchik Antireflux prosthesis using a model for esophageal reflux in rhesus monkeys. Ann. Thorac. Surg. 41:135-142, 1986.

Graeber. G.M. and Zajtchuk, R.: Changes in serum creatine kinase and lactic dehydrogenase caused by acute perioperative myocardial infarction and by transatrial cardiac surgical procedures. J. Thorac. Cardiovasc. Surg., 92:63-72, Jul 1986.

Fall, S.M., Burton, N.A., Graeber, G.M., Mead, M.D., Lough, F.C., Albus, R.A., Zajtchuk, R.: Prevention of ventricular fibrillation after myocardial revascularization. Ann. Thorac. Surg. 43:182-184. Feb 1987.

Graeber, G.M. and Zajtchuk, R.: Serum creatine kinase and lactic dehydrogenase isoenzyme levels in patients after major esophageal surgery, esophageal dilatation, and acute myocardial infarction. Ann. Thorac. Surg., 43:279-284, Mar 1987.

Graeber, G.M. and Zajtchuk, R.: A comparison of patients with endoscopic esophageal perforations and patients with Boerhaave's Syndrome. Chest, 92:995-998, Dec 1987.

Edwards, F.H., Zajtchuk, R.: Use of a Bayesian statistical model for risk assessment in coronary artery surgery. Ann. Thorac. Surg.

Burton, W.A., Graeber, G.M., Zajtchuk, R.: An alternative method of ventricular venting. The pulmonary artery pump. Chest 85:814, 1984.

Edwards, F.M. and Zajtchuk, R.: A Quality Assurance Model of Operation Mortality for coronary artery surgery. Ann. Thorac. Surg.

Zajtchuk, R., Brown, F., Rumbaugh, J.: Medical Success in El Salvador, Military Medicine, Feb 1989.

PRESENTATIONS:

Soluble Transplantation Antigen. Presented at Chicago Surgical Society Meeting in 1965. (Awarded prize for best surgical research in 1965.)

Maintenance of Circulation with a Mechanical Cardiac Pulsator. Presented at the Meeting of the American Society for Artificial Organs in 1966.

Maintenance of Circulation with a Mechanical Cardiac Pulsator. Presented at 32nd Annual Meeting of American College of Chest Physicians, June 1966. (Received certificate of merit)

Inhibition of External Pancreatic Secretion by Glucagon. Presented at Surgical Forum in 1967.

Treatment of Digoxin Toxicity with Activated Charcoal. Presented at the 24th Annual Scientific Session of American College of Cardiology, 1974.

Measurement of Heart Valve Cross Section Area by Electrical Impedance. Presented at Biomedical Engineering Society. Apr 1975.

Coagulation Abnormalities in Patients Undergoing Myocardial Revascularization. Presented at Seminar on Thrombosis Research, May 1977, Walter Reed Army Medical Center.

Coagulation Abnormalities in Patients Undergoing Myocardial Revascularization. Presented at Samson Thoracic Society, Jun 1977.

Use of Intra-Aortic Balloon in Left Main Coronary Artery Lesions. Presented at the Army Cardiology Meeting, May 1978.

-11-

PRESENTATIONS: (CONT'D) Surgical Treatment of Left Main and Left Main Equivalent Coronary Artery Disease. Presented at University of Chicago, Jun 1978.

Left Ventricular to Aortic Stenogig. Presented at Cardiology Symposium, Madigan Army Medical Center, May 1979.

Asymptomatic Left Main Coronary Artery Disease (Clinical Profile). Presented at Military Cardiology Meeting, San Francisco, May 1980.

A Comparison of Serum Isoenzyme Levels of CPK and LDH in Patients Undergoing Thoracic Operations and Patients Admitted to Coronary Care Unit. Presented at Thoracic Surgery Society Meeting, Jan 1980.

Symposium Director for "The First Annual USUHS Cardiothoracic Surgery Symposium". Presented at Uniformed Services University of the Health Sciences, Bethesda, MD, Oct 1982.

Cardiac Trauma. Presented at the Hospital of the University of Pennsylvania, Nov 1982.

Evaluation of the Angelchik Antireflux Prosthesis using a Model for Esophageal Reflux in Rhesus Monkeys. Presented at the Southwestern Surgical Congress, 36th Annual Meeting, Hawaii, Apr 1984.

Preventing Ventricular Fibrillation after Aortic Cross Clamping. Presented at the Army Cardiology Meeting, Apr 1984.

The Use of Computerized Tomography (CT) in the Evaluation of Mediastinal Masses. Presented at the Western Thoracic Surgical Association, Jun 1985.

Results of Coronary Artery Bypass Grafting in Young Patients. Presented at the American College of Chest Physicians, 1985.

Central America - An Overview with Emphasis on Honduras. Presented at 22nd Medical Symposium of the 94th U.S. Army Reserve Command, October 1988.

MOVIES:

Apical Left Ventricular Aortic Bypass - A Method for Relief of Left Ventricular Outflow Obstruction (Presented at the Annual Meeting of the Society of Thoracic Surgeons, Los Angeles, CA, Jan 1981.

-12-

MOVIES: (CONT'D)

Resection of Giant Cell Tumor Involving the Clavicle and Chest Wall. (Presented at the Annual Meeting of the Society of Thoracic Surgeons, San Francisco, CA. Jan 1983).

Surgical Management of Sinus of Valsalva Fistula. Presented at American College of Surgery, 1984.

SCIENTIFIC EXHIBITS: Hyercoagulability - Importance in Surgical Practice. (Won Second Place at Southeastern Surgical Congress. Apr 1977).

Different Techniques for Replacing the Esophagus with Interposed Colon. (Presented at the 68th Annual Clinical Congress of the American College of Surgeons, Chicago, IL. Oct 1982.

The Use of Muscle and Musculo-Cutaneous Flaps for Reconstruction of Thoracic Defects. (Presented at the 68th Annual Clinical Congress of the American College of Surgeons, Chicago, IL, Oct 1982).

Medicine in Low Intensity Conflict (Presented at AMSUS, 1987).

Surgical Treatment of Snake Bites (Presented at AMSUS, 1987).

Management of Primary Cardiac Tumors. Displayed at The 69th Clinical Congress of the American College of Surgeons, 1983 and the 33rd Scientific Session of American College of Cardiology, 1984.

BOOKS:

Senior Editor of 18 Volume Series on Military Medicine.

-13-

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A. NEW LICENSE	Department of the Army
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PETER H. MYERS, LTC, MS, Health Physics Officiation	cer, WRAMĆ (301) 427-5104
NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION PETER H. MYERS, LTC, MS, Health Physics Office SUBMIT ITEMS 5 THROUGH 11 ON 8% × 11" PAPER. THE TYPE AND SCOPE OF INFORMATIC	cer, WRAMĆ (301) 427-5104
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CONTINUATION OF NRC FORM 313 (Items 5 - 11)

5. Radioactive material:

a. Cesium 137

b. Sealed source

c. (curies.

6. Purpose: Irradiation of blood products for transfusion, to kill lymphocytes in blood products and to prevent Graft versus Host disease.

maximum total curie amount:

7. Please add Lieutenant Allen W. Anthony to the license as the Radiation Protection Officer. Lieutenant Anthony has served at Walter Reed as the Assistant Health Physics Officer since January 1988. Lieutenant Anthony will replace Major Gerald M. Connock as the RPO on the License on 28 September 1989 as Major Connock is being transferred. A copy of his curriculum vitae is provided (enclosure 4) also reference amendment of NRC Materials License - Medical, No. 08-01738-02, 27 July 1989 and 17 September 1989.

8. Training: No Change - reference application for renewal of NRC Material License - Medical, No. 08-01738-02, 8 May 1987, Tab C chapter 2.

9. Facilities and equipment:

a. The irradiator will be located on the in of building 2, Walter Reed Army Medical Center. The room is bordered en one side by a corridor with no direct access to the room, on two sides by controlled access storage rooms (), and on the fourth side by an infrequently used controlled access hallway. The storage rooms will have intermittent occupancy by no more than two (2) employees per room. The overhead area is a controlled access interstitial space for piping and ventilation systems and would be occupied in case of repairs. A diagram of room () and surrounding areas is attached (enclosures 5 & 6). Room () is equipped with an automatically operated fire detection and control system (sprinkler) that is adequate to ensure the integrity of the irradiator and source in a fire.

10. Radiation safety program:

a. Personnel monitoring equipment - No Change, reference application for renewal of NRC Materials License - Medical, No. 08-01738-02, 8 May 1987, Tab C chapter 5 and Tab D condition number 1.

b. Radiation detection instruments - No Change, reference application for renewal of NRC Materials License, No. 08-01738-02, 8 May 1987, Tabs E and F.

c. Operating and emergency procedures - see enclosure 7.

d. Plans for installation and certain repairs - these tasks are to be performed by the supplier.

11. Waste management: No Change. \mathcal{L}_{χ} 2
CURRICULUM VITAE

for

ALLEN W. ANTHONY

Date & Place of Birth:

Home Address:

Home Telephone Number:

Office Address:

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Degrees:

Health Physics Office Walter Reed Army Medical Center Washington, DC 20307-5001

(301) 427-5104

B.S. - Education (Biology) University of Nebraska Lincoln, NE 68508

A.S. - X-ray Technology St. Philip's College San Antonio, TX

A.S. - Nuclear Medicine Technology George Washington University Washington, DC 20037

> American Registry of Radiologic Technologists (X-Ray and Nuclear Medicine)

Other Education and Training:

1989

Certification:

Laser and Microwave Hazards Workshop US Army Environmental Hygiene Agency Aberdeen Proving Ground, MD

1988

Introduction to Nuclear Medicine and Radiation Therapy Course George Washington University Washington, DC 20037

676

ANTHONY, Allen W. (Continuation of Curriculum Vitae) AMEDD Radiation Protection Officers Workshop 1988 US Army Environmental Hygiene Agency Aberdeen Proving Ground, MD Radiation Service Organization, Inc. Course 1988 -US Army Environmental Hygiene Agency Aberdeen Proving Ground, MD 1988 Medical Effects of Nuclear Weapons Course Armed Forces Radiobiology Research Institute Bethesda, MD 1988 US Army Medical X-Ray Survey Techniques Course Academy of Health Sciences, US Army Fort Sam Houston, TX 1988 AMEDD Officer Basic Course Academy of Health Sciences, US Army Fort Sam Houston, TX Chronological Experience: Feb 1988 - Present Walter Reed Anny Med. Ctr. Washington, DC 20307 Assistant Health Physics Officer Health Physics Office Supervise personnel in conduct of radiation protection surveys for radioisotope laboratories x-ray units, radiotherapy procedures, emergency response, and shielding evaluations. Oct 1987 - Jan 1988 Academy of Health Sciences, US Army Fort Sam Houston, TX Student AMEDD Officer Basic Course Sep 1986 - Sep 1987 USA MEDDAC Fort Bragg, NC Nuclear Medicine Technologist Nuclear Medicine Service Nov 1985 - July 1986 Madigan Army Medical Center Fort Lewis, WA Student (Phase II) Nuclear Medicine Service

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ANTHONY, Allen W. (Continuation of Curriculum Vitae)

Jun 1985 - Oct 1985

Naval School of Health Sciences Bethesda, MD Student (Phase I) Nuclear Medicine Technology Course

Jan 1983 - May 1985

97th General Hospital Frankfurt, West Genmany X-Ray & C.T. Technologist Radiology Department

3

Oct 1982 - Nov 1982

Walter Reed Army Medical Center Washington, DC 20307 Student (Phase II) Radiology Department

Jun 1982 - Oct 1982

Academy of Health Sciences, US Army Fort Sam Houston, TX Student (Phase I) X-Ray Technology Branch



SPECIAL PRODUCTS LAB BLOOD BANK SECTION CLINICAL PATHOLOGY SERVICE DEPARTMENT OF PATHOLOGY AND AREA LABORATORY SERVICES WALTER REED ARMY MEDICAL CENTER WASHINGTON, D.C. 20307-5001

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CHAPTER II. TECHNICAL PROCEDURES

C.1. IRRADIATED BLOOD PRODUCTS - POLICIES AND PERSONNEL RESPONSIBILITIES

1. <u>PURPOSE:</u>

The only purpose of this instrument is the irradiating of blood products for transfusion to prevent post-transfusion graft vs host disease (GVHD) in immunocompromised patients. This form of GVHD, although fairly rare, is usually fatal due to generalized infection. This condition does not usually respond to forms of treatment normally effective in the GVHD which follows marrow transplantation. It is known that Ionizing radiation at doses of 2000 rads or more destroys the lymphocyte's ability to proliferate without damaging other elements of the blood product.

2. PATIENTS TO RECEIVE IRRADIATED BLOOD PRODUCTS:

Patients at risk for post-transfusion GVHD are those with some types of congenital or acquired cell-mediated immune deficiencies, such as:

- Bone Marrow transplant recipients (Autologous, Allogeneic & Syngeneic) - Children and adults receiving cytotoxic therapy for:

leukemias, lymphomas and some solid tumors (i.e. glioma & neuroblastoma)
- Patients with genetic immunodeficiencies:

severe combined immunodeficiency (SCID), Wiscott-Aldrich syndrome, other T-cell defects

- Recipients of intrauterine transfusions

- Neonates receiving exchange transfusions and/or who have received intrauterine transfusions.

Patients will receive irradiated blood products only if the patient is so restricted; i.e. the Medical Director or his/her authorized representative must restrict the patient to irradiated blood products by noting on the patient's "CAUTION CARD" ..."Transfuse Irradiated Blood Products ONLY - (D te and Initial)". The "CAUTION CARD" must be conspicuously displayed as the top card of the patient's file. All orders from the ward for irradiated blood products mu t list the patient's diagnosis. Evaluation and approval will be at the dis retion of the Blood Bank Medical Director.

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(II. .1.page 1 of 3)

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3. <u>BLOOD PRODUCTS TO BE IRRADIATED:</u>

All blood products except fresh frozen plasma and cryoprecipitate theoretically contain sufficient immunocompetent lymphocytes to initiate the GVHD reaction. Therefore, the following blood products must be irradiated just prior to issue to the ward when prescribed for patients at risk for post-transfusion GVHD:

- Whole blood

- Red Blood Cells (including washed, leukocyte-poor, frozen/deglycerolized and washed/prefiltered aliquots)

- Platelets (including leukotrapped, random donor, single donor, and HLAmatched)

- Fresh single donor plasma

- Granulocyte concentrates

Irradiated blood products are not themselves radioactive and present no danger to the persons handling them or to the patients receiving them. Cellular elements other than lymphocytes are relatively unaffected by less than 5000 rads of gamma radiation. Therefore, irradiated products returned to the general inventory may be used for routine transfusions to other patients who do not require irradiated products.

4. DOSE:

The standard dose at WRAMC is 2500 rads which can be administered in approximately 1.6 minutes (96 seconds). All units, once irradiated, will be conspicuously labeled as per S.O.P.

5. <u>PERSONNEL RESPONSIBILITIES:</u>

a. Authorized Principal User (APU): This is the person designated and approved by the WRAMC Radiation Control Committee for use of the

Laboratory Team Leader. This person is directly responsible for the control & safe use of the firradiator and will designate individuals to operate the as approved by the WRAMC Radiation Control Committee. The APU will have the

following specific responsibilities:

1. Ensure that the is operated only by individuals authorized to do so by the WRAMC Radiation Control Committee, and in accordance with the conditions of the WRAMC Radiation Material authorization.

2. Instruction of individuals in safe operating procedures in accordance with the S.O.P.'s in this Manual pertaining to Irradiated Blood Products.

3. Ensuring that these instructions and references are available at all times.

4. Promptly reporting any source malfunction, accident, or other unplanned occurrence that could result in an unsafe condition or exposure to personnel to the WRAMC Health Physics Officer at (301)427-5107.

5. Assuring that all personnel operating the unit are monitored by appropriate personnel monitoring devices.

6. Ensuring that personnel operating the irradiator have been instructed in the hazards and nature of injuries resulting from over-exposure to ionizing radiation.

7. Maintain the operating log for the

PAGE:

Ex 2

(II.C.1.page 2 of 3)

b. WRAMC Health Physics Department:

1. Conducting routine radiation protection surveys and inspections.

2. Providing technical assistance as required.

3. Providing calibration and routine maintenance services for radiation detection and measuring instruments.

c. Individual Operators:

1. Operating the jin accordance with the operation and safety procedures delineated in the Special Products Lab S.O.P.

2. Recording all pertinent information in the operating log maintained by the APU.

3. Being familiar with the content of these instructions, requirements of the WRAMC authorization, and other regulations as may be prescribed by the APU.

4. Locking the irradiator upon completion of use.

5. Ensuring that the key to the ______is properly returned/signed back in to prevent unauthorized use.

6. Reporting all malfunctions, accidents, and any other unplanned occurrence that could result in an unsafe condition or exposure of personnel promptly to the APU.

6. REFERENCES:

a. Areman, E: Georgetown University Hospital - DLM, BB. S.O.P. -Irradiation of Blood Products. 1987.

b. Connock, G: Walter Reed Army Institute of Research S.O.P. - Operating and Safety Procedures for AECL Gammacell 40 Irradiator. 1989.

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(II.C.1.page 3 of 3)

SPECIAL PRODUCTS LAB BLOOD BANK SECTION CLINICAL PATHOLOGY SERVICE DEPARTMENT OF PATHOLOGY AND AREA LABORATORY SERVICES WALTER REED ARMY MEDICAL CENTER WASHINGTON, D.C. 20307-5001

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CHAPTER II. TECHNICAL PROCEDURES.

C.2. IRRADIATED BLOOD PRODUCTS - USE OF THE

BLOOD IRRADIATOR

1. **PRINCIPLE:**

2. <u>PROTECTIVE FEATURES / CAUTIONS:</u>

a. The has been designed for safe and efficient operation. The control system contains interlocks that prevent start-up if the correct procedure is not followed. To trouble-shoot the machine, see the following appropriate S.O.P. Faults that occur during operation cause the sample to return to the SAFE position.

c. Interlock System: The sample drawer is interlocked with two switches that, unless pushed at the same time, prevent the drawer from moving so that potential injury to hands is avoided. DO NOT try to override the interlock system. Any attempt to disable the interlock system will violate licensing requirements.

d. AC Power Failure: In case of a power failure during operation, the will complete the irradiation cycle in progress. However, a new cycle will not start until the AC power has been restored.

26

(II.C.2.page 1 of 5)

WRAMC Health Physics Department regulations, the dolly has been removed and it must be anchored to the floor at all times. DO NOT move the without proper authorization from the pertinent authority.

f. CAUTION: ONLY TRAINED BLOOD BANK STAFF will be permitted to operate the Other persons or departments needing samples or blood products Trradiated will contact the Special Products Lab Team Leader to arrange for this service. Failure to comply may result in loss of licensure to use radioactive materials.

g. CAUTION: Materials which are basically unstable, explosive, or highly exothermic WILL NOT BE IRRADIATED IN THIS UNIT.

h. CAUTION: All operators will.....

- fill out and sign the operator's log when using the machine

- obtain a personnel monitoring device and the machine key when the log has been signed. Personnel monitoring devices will be worn when working around (i.e. working in the and/or operating the

- return the machine key and personnel monitoring device, and sign the log when finished using the machine.

3. <u>SPECIMEN REQUIREMENTS:</u>

a. Blood products that must be irradiated are

- Whole blood

- Red Blood Cells (including washed, leukocyte-poor, frozen/deglycerolized and washed/prefiltered aliquots - i.e. neonate syringes)

- Platelets (including leukotrapped, random donor, single donor, and HLAmatched)

- Fresh single donor plasma (NOT FRESH FROZEN PLASMA)

- Granulocyte concentrates

b. DO NOT irradiate more than one unit/syringe/type of product at a time. Placing multiple units on the specimen turntable together can cause the mechanism to overload, jam-up or possibly rupture a unit of blood.

c. Blood Products to be irradiated should not be pre-irradiated hours prior to issue. Irradiate all blood products at the time of issue.

4. INSTRUMENTATION:

Blood Irradiator.

5. PROCEDURE:

a. Obtain a personnel monitoring device and the machine operation key from the Team Leader or the authorized designee & "sign them out" on the operator's log. ror an example of the log see the "Results Reporting / Unit Labeling" section of this S.O.P.

b. Insert the machine key into the power keyswitch. DO NOT turn the keyswitch to the "ON" position at this time.

c. Insert the sample/blood bag into the stainless steel sample can provided. Ensure that no parts of the sample protrude over the edge of the sample can. Place the sample can into the cavity, carefully centering it on the turntable and making sure no part of the can / contents extends past the opening of the cavity tube.

(II.C.2.page 2 of 5)

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d. Turn the power switch to the "ON" position. The indicator light will be illuminated at this point and the turntable will rotate. Observe that the sample can is rotating freely.

e. Press the red IRRADIATE buttons (one on the control panel and one on the left side of the irradiator) at the same time to begin the cycle.

f. Routinely, at WRAMC, blood products will receive a dose of 2500 rads which can be delivered in 1.6 minutes (96 seconds) with this irradiator (See section 6 "Calculations" for clarification). The timer should remain set at 1.6 minutes. At the end of each cycle the timer will <u>automatically</u> reset - DO NOT CHANGE SETTING!

g. When the sample drawer has reached the irradiate position, the irradiate light on the control panel will be illuminated. If this light is not illuminated, the preset timer will not function.

NOTE: If this occurs, time the irradiation cycle with an independent timer for approximately 96 seconds. Then push the LOAD button to return the sample drawer to the load position. The LOAD switch will override the preset irradiator timer and return the sample drawer to the load position. This switch is to be used to end a preset irradiation cycle prior to the time preset, or to release a sample if the machine's timer malfunctions.

h. At the end of the irradiation cycle (when the timer count reaches 1.6 minutes), the sample drawer will return to the load position and the timer will automatically reset to 1.6 minutes (DO NOT CHANGE SETTING!).

NOTE: In case of a power failure, the irradiation cycle in progress will be completed. However, AC power will have to be restored to start a new cycle.

i. Remove the sample can from the sample cavity and remove the irradiated blood. Label the blood product, data control card and patient record card as indicated in the "Result Reporting/Unit Labeling" section below.

j. Turn the POWER keyswitch to the OFF position. Remove the key and return it to the key-box. Return your personnel monitoring device and sign them back "in" on the operators log. Issue the irradiated blood product as soon as possible.

6. <u>CALCULATIONS:</u>

The time interval necessary to provide a dose of approximately 2500 rads is a function of the CENTRAL DOSE RATE. For each machine, the actual radioactive contents may vary +/- 20% from the nominal values associated with each model, hence the CDR will vary accordingly & will need to be recalculated when installed & on a periodic basis. The CDR is provided by J. L. Shepherd on a Measurement Certificate. The measurement is in air and requires conversion to liquids, which is assumed to be evenly distributed in the beaker, giving an Average Dose Rate. The CDR is measured in rads/hr, the ADR must be rads/min. The following calculation is used:

ADR (rads/min) = 0.89 x (CDR (rads/hr) x 6C: (For this machine, assume) Time interval for required dose = required DOSE / ADR



(II.C.2.page 3 of 5)

7. RESULTS REPORTING/UNIT LABELING:

When t irradiator is used to irradiate blood products, there are 4 logs/cards etc. that must be filled out: operator's log, the unit label, the unit data control card (IBM card), and the patient's transfusion record card.

a. Operator's Log: This log will be kept in the and is to be filled out by the operator each time the machine is used. The entries are:

- Date Used, in designated format listed at top of log

- Operator Name, print full name

- Time - Key Out, time the key is signed out

- Dosimeter Reading, record the reading from the dosimeter both signing out and signing in

- # of Prod. Irrad., record how many products you irradiated

- Time - Key Returned, time the key is signed back in

- Tech. Initials, initials of the operator

- APU, initials of the authorized principal user. On day shift, the SPL Team Leader, on other shifts, the shift leader

- Workl'd, this is for workload, to be left blank until results are captured.

b. Unit Label: When a blood product is irradiated, it must be conspicuously labeled. Apply one of the following supplied labels to the face label of the blood product being careful to not cover any other information required by standards.

c. Unit Data Control Card: When the blood product is irradiated, it must be documented on the "IBM" card. Place one of the "IRRADIATED" labels on the "IBM" card on the next line under the patient's name and write the date and your initials next to the label.

d. Patient Transfusion Record Card: When the blood product is irradiated, it must be documented on the patient's transfusion record card ("white" card). Write "IRRAD." in the margin beside the particular blood product irradiated.

For examples of each, see Figures 1 and 2, below and on the next page.

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Figure 1 - EXAMPLE OF UNIT DATA CONTROL CARD WITH THE APPROPRIATE CHANGES/LABELS.

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Figure 2 - EXAMPLES OF OPERATOR'S LOG AND PATIENT TRANSFUSION RECORD CARD WITH THE APPROPRIATE CHANGES/UPDATES.

8. LIMITATIONS OF PROCEDURE:

This S.O.P. is intended to address how to use the Blood Irradiator to irradiate blood products for transfusion. Specifically, it addresses: what products, when to irradiate, who may use the irradiator, how to operate it, limited problem solving and documentation or labeling necessary. Consult the appropriate S.O.P., the machine Operator's Manual or the Special Products Lab Team Leader for procedures that fall outside the scope of this S.O.P.

9. <u>REFERENCES</u>:

а.

Operator's Manual.

b. Areman, E: Georgetown University Hospital - DLM, BB. S.O.P. - Procedure: Irradiation of Blood Products. 1987.

c. Connock, G: Walter Reed Army Institute of Résearch S.O.P. - Operating and Safety Procedures for AECL Gammacell 40 Irradiator. 1989.

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(II.C.2.page 5 of 5)

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CHAPTER II. TECHNICAL PROCEDURES.

C.3. IRRADIATED BLOOD PRODUCTS - TROUBLE-SHOOTING THE IRRADIATOR

1. <u>PRINCIPLE:</u>

The is a self-contained unit consisting of a stationary Cesium-137 doubly encapsulated curie radiation source permanently secured within a biological shield. By placing the sample can in the sample drawer and lowering the drawer into the machine, the blood product is either exposed to or, by raising the drawer, removed from the radiation field.

Because of the importance of the machine's application in the Blood Bank, it is essential that the "down time" is minimal. Occasionally, parts of the equipment may break down. Should this occur, simple trouble-shooting with corrective action would be immediately necessary. The following S.O.P. lists potential problems with corrective action necessary.

2. <u>CAUTIONS:</u>

a. DO NOT attempt any <u>corrective</u> action requiring new parts beyond a fuse.
 b. DO NOT undertake <u>any</u> repair beyond changing a fuse, perform any maintenance, remove any interlock and/or safety device, or make any changes in and/or on the without prior approval of the Authorized Principal User or higher authority. Failure to comply may result in loss of licensure to use radioactive materials.

3. PROCEDURE:

a. If the or any of its components malfunction, follow the Trouble-shooting Charts in Figures 2 and 3. These charts will help identify the problem and suggest corrective action and Figure 1 is a diagram of the locations of the parts.

b. If the corrective action suggested is to change the fuse, record the problem, corrective action taken, date and initials on the Equipment Maintenance Worksheet (Med Lab Form 110) kept in the front of the Operator's Manual.

PAGE:

Ex 2

(II.C.3.page 1 of 5)

c. To change the fuse: refer to the operator's manual for location of and procedure for changing the fuse. (NOTE: this procedure with diagram for Figure 1 is to be supplied by the manufacturer upon delivery of the machine and placed in this S.O.P.)

d. Should the problem remain unsolved, or be more complex than any of the possibilities listed, contact the APU for further action and DO NOT attempt to use the irradiator. Refer to the S.O.P. - "Emergency Procedures..." for steps to follow in the event of complete or non-correctable equipment failure. Further, before proceeding, ensure that the correct operating procedure has been followed and the unit is plugged in.

4. LIMITATIONS OF PROCEDURE:

This S.O.P. is intended to address how to perform simple troubleshooting on Blood Irradiator. If the problem is too complicated or requires new parts to repair at this time, consult the machine Operator's Manual and the Special Products Lab Team Leader for additional instructions.

REFERENCES:

5.

Operator's Manual.

b. Connock, G: Walter Reed Army Institute of Research S.O.P. - Operating and Safety Procedures for AECL Gammacell 40 Irradiator. 1989.

Prepared by: David B. Drothler MT(ASCP)SBB

(II.C.3.page 2 of 5)







EX2

(II.C.3.page 4 of 5)

NOTE: THIS CHART IS UNDER PRODUCTION AND IS TO BE PROVIDED BY THE MANUFACTURER TRRADIATOR. UPON DELIVERY OF THE Figure 3 - TROUBLE-SHOOTING CHART FOR THE CONT'D (II.C.3.page 5 of 5) PAGE: Ex2 6

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CHAPTER II TECHNICAL PROCEDURES.

IRRADIATED BLOOD PRODUCTS - EMERGENCY PROCEDURES FOR THE C.4. IRRADIATOR FAILURE

1. POWER FAILURE:

In case of an AC power failure, the irradiation cycle in progress at the а. time will be completed and the sample drawer will return to the safe "LOAD" position powered by the DC power back-up.

However, the AC power will have to be restored to start a new irradiab. tion cycle. When the hospital Emergency Power starts, normal operation may resume.

2! EOUIPMENT FAILURE:

a.

c.

Should there be any mechanical difficulties with this instrument, see the preceding S.O.P. on trouble-shooting the machine. If the troubleshooting procedure does not correct the problem, or the problem is too complicated to correct at this time, arrange to have the products irradiated by another means* and contact the following:

Authorized Principal User -\Team Leader, Blood Bank, WRAMC, 6-1989/1990/1993.

b. Health Physics Officer - WRAMC, (301)427-5107.

Safety Officer - WRAMC, 6-1042/1044.

After duty hours, contact in order:

Authorized Principal User a. Bank, WRAMC, at home. If unable to contact, call the Technical Suppor: Staff member on call.

b. Staff Duty NCO - WRAMC (after duty hours), 6-1233.

If serious, the senior individual at the site shall clear the area (i.e. the , room of personnel and restrict access to the area until relieved by competent authority.

(*Alternative sources for irradiating blood products: see the followin page)

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*Alternative sources for irradiating blood products:

1.	N.I.H. Dept. of Transfusion Medicine	496-4506
2.	Children's Hospital Blood Bank	745-5347
з.	Georgetown University Hospital Blood Bank	784-3511

3. UNSAFE READING ON RADIATION MONITOR:

The senior individual at the site must clear the area (i.e. the

Immediately contact the personnel listed in #2 above.

4. IN THE EVENT OF FIRE:

The following individuals shall be notified:

ALWAYS FIRST:

a. Fire Department, WRAMC, 6-3317.

THEN: b. Authorized Principal User -

Bank, WRAMC, 6-1989/1990/1993.

c. Health Physics Officer - WRAMC, (301)427-5107.

d. Safety Officer - WRAMC, 6-1042/1044.

After duty hours, contact the fire department FIRST, then contact in order: a. Authorized Principal User - Team Leader, Blood Bank, WRAMC, at home. If unable to contact, call the Technical Support Staff member on call.

b. Staff Duty NCO - WRAMC (after duty hours), 6-1233.

PAGE

The senior individual at the site shall clear the area (i.e.)

room of personnel and restrict access to the area until relieved by competent authority. Fire fighters may enter the area after the radiation hazard has been determined. There is little likelihood of radiation hazard unless the temperature of the source shield reaches the melting point of lead (621 F). Water should be sprayed on the source shield if there is any possibility of the temperature approaching this value.

Following an emergency, the shall not be operated until an inspection and a radiation protection survey have been conducted by WRAMC Health Physics.

5. <u>REFERENCES:</u>

э.

Operator's Manual.

Team Leader, Blood

D. Areman, E: Georgetown University Hospital - DLM, BB. S.O.P. - Emergency Procedures, Gammacell-1000 Blood Irradiator. 1987.

Connock, G: Walter Reed Army Institute of Research S.O.P. - Operating and Safety Procedures for AECL Gammacell 40 Irradiator. 1989.

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Prepared by: David B. Drothler MT(ASCP)SBB.

(II.C.4.page 2 of 2)

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CHAPTER IV. QUALITY CONTROL / PREVENTIVE MAINTENANCE.

D.2. PREVENTIVE MAINTENANCE - FOR THE

BLOOD IRRADIATOR

1. <u>PRINCIPLE:</u>

The is a self-contained unit consisting of a stationary Cesium-137 doubly encapsulated curie radiation source permanently secured within a biological shield. By placing the sample can in the sample drawer and lowering the drawer into the machine, the blood product is either exposed to or, by raising the drawer, removed from the radiation field.

Because of the importance of the machine's application in the Blood Bank, it is essential that the "down time" is minimal. Periodically, parts of the will require maintenance to prevent this "down time". The following S.O.P. lists the specific maintenance recommended to keep the machine functioning properly.

2. <u>CAUTIONS:</u>

a. DO NOT undertake or perform any maintenance, remove any interlock and/or safety device, or make any changes in and/or on the without prior approval of the Authorized Principal User and the WRAMC Health Physics Officer. Failure to comply may result in loss of licensure to use radioactive materials.

b. Spills of materials inside the sample cavity could result in seizing of the turntable with subsequent loss of the uniformity of exposure to samples. NEVER place a unit of blood into the machine without placing the unit in the sample can first!

c. Disconnect the AC and DC power prior to any maintenance work.

3. GENERAL:

The will require minimum maintenance when operated in normal room conditions. The irradiator should be kept in clean condition, and any spills of liquids or powders inside the sample cavity should be thoroughly cleaned immediately.

PAGE: Ex2

(IV.D.2.page 1 of 3)

4. PERIODIC INSPECTION AND ADJUSTMENT:

a. The roller chain may require adjustment in the drive system. Electrical connections will require inspection and electrical switches may require adjustment or replacement.

b. This is to be performed on a yearly basis by a FACTORY REPRESENTATIVE ONLY. Prior to having this done, notify the Health Physics department to have a representative present when the machine cover panel is removed.

c. The FACTORY REPRESENTATIVE WILL:

- Unplug the _______ from the wall outlet. Remove the control and cover panels as per manufacturer's directions and as indicated in the drawing in Figure 1, next page.

- Inspect all electrical connections for looseness.

- Replace the panels and reconnect the control wires.

d. Due to the decay of Cesium, to ensure a consistent administration of a dose between 2000 and 2500 rads, the exposure time setting must be re-calculated and, if necessary, the timer reset. This is to be performed on a yearly basis at the same time as the periodic inspection and adjustment. The Authorized Principle User will be responsible for the re-calculation and possible resetting of the timer. The re-calculation will be based on the Cesium-137 decay curve in the operator's manual. If the result of the calculation differs from the current exposure setting by 0.1 minutes, reset the timer per manufacturer's instructions in the operator's manual and indicate the change in the S.O.P. - Chapter II, C.2. Use the following calculation:

(Fraction of Activity Remaining: from decay curve) x (Original CDR) = Central Dose Rate (rads/hr.) now being delivered

ADR (rads/min) = 0.89 x (CDR "now" x 60) New Time Interval = required DOSE

ADR

5. AC_FUSE_REPLACEMENT:

If it is necessary to replace an AC fuse, see the preceding S.O.P. - Chapter II, C.3. TROUBLE-SHOOTING THE

6. LIMITATIONS OF PROCEDURE:

This S.O.P. is intended to address how to perform preventive maintenance on the

PAGE:

7. <u>REFERENCES:</u>

a.

Operator's Manual.

b. Areman E: Georgetown University Hospital - DLM, BB. S.O.P. - Procedure: Irradiation f Blood Products. 1987.

Ex 2

Prepared by: David B. Drothler MT(ASCP)SBB

(IV.D.2.page 2 of 3)

	1. THIS A PATE	ED CROER		HATIN			PAGE OF PAGES
AWARD / CONTRACT	FI DPAS (15 CFR 35	o)			с9в		1 04
ONTRACT (Proc. Inst. Ident.) NO.	EFFECTIVE DATE		A, REC	UISITION/PURCHASE F	ECUEST/PROJECT	NO.	
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DIRECTORATE OF CONTRACTING WALTER REED ARMY MEDICAL CTR WASHINGTON, D.C. 20307-5000	2		Admain Pay/In	Inquiries See woice Info See	Block 6 Block 15	* .	
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VAME AND ADDRESS OF CONTRACTOR (No., street, city, co	ounty, State and ZIP Code)				8. DELIVERY		
						зім 🗶 от	HER (See below)
JL SHEPHERD & ASSOCIATES	*				9. DISCOUNT FO	OR PROMPT PAYN	MENT
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SAN FERNANDO , CA	91340-1822				00.000%00) Net	030
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See at	ttached Schedule(s)						
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X 8 SUPPLIES OR SERVICES AND PRICES/COSTS	2		ł	PART II - UST OF	DOCUMENTS, EX	HIBIT'S AND OTHE	RATTACHMENTS
X C DESCRIPTION/SPECS, WORK STATEMENT	2			List of Attachments	· ·		
X D PACKAGING AND MARKING	1			PART N - REPRE	SENTATIONS AND	NSTRUCTIONS	
X E INSPECTION AND ACCEPTANCE	1		K	REPRESENTATIONS,	CERTIFICATIONS AN	NO	
A F DELIVERIES OR PERFORMANCE	2			OTHER STATEMENTS	CF OFFERORS		
A G CONTRACT ADMINISTRATION DATA	6		L	INSTRS., CONDS., AN	O NOTICES TO OFF	ERORS	
H SPECIAL CONTRACT REQUIREMENTS			<u> M</u>	EVALUATION FACTOR	S FOR AWARD		
	RACTING OFFICER WI	LL COMPLI		VI 17 OP. 18 AS AP	PLICABLE	sion this dawn	ment) Your
quired to sign this document and return	Copies to issuing office	.)	Silfer on Se	vilcitation Number	ADA 15-89-	<u>-R-012</u> 2	······································
Contractor agrees to furnish and deliver sil items of forth or otherwise identified above and on any of consideration stated having The deliver of ability	or perform all the services to continuation sheets for to jations of the parties to following documents: (a) th) such provisions, represen-	vet france in the second secon	ncluding the are set fortion any co sists of the offer, and sery.	e additions or chang in fuil above, is he ntinuation sheets. Th a following document (b) this a vard / contra	ges made by yo reby accepted as is award consum s: (a) the Gove sct. No further c	a to the items nmates the con mment's solicit contracuet docu	xns or changes Ested above and ntract which con- ation and your ment is neces-
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SF 26 Continued.....

The following revisions are hereby mutually accepted and are hereby incorporated into subject contract:

1. Amendment #0001 dated 7/21/89, attached at rear of contract document.

2. Contractor's Best and Final Offer is made part of the award.

3. Sections K,L and M of Solicitation DADA15-89=R-0122 are made part of the award and are incorporated by reference.

111556

OFFICIAL RECORD COPY ML 10

PHILLI & ASSOCIATIS IR 1010 Arroyo ave., San Fernando, California 91340-1822

818-898-2361 FAX 818-361-8095

September 5, 1989

Mr. David D. Denton Contracting Division Directorate of Contracting -Supply & Equipment Branch

Your Fax of September 1, 1989 Requesting Clarification of Re: Proposal on Solicitation DADA15-89-R-0122

Dear Mr. Denton:

will provide to Walter Reed Army Médical Center a with Curies. We are currently in production on this model and can easily accommodate the 60 day delivery schedule.

As another added benefit, the 3,000 Rad dose will be delivered in 2-3 minutes, not 6. These are the only changes to Proposal 1, Revision A.

The pricing of \$53,285 shall be firm for this device.

Please do not hesitate to contact us if any further questions arise. We look forward to your favored reply.

Sinceraly,

J.L. SHEPHERD & ASSOCIATES

Jøseph S. Shepherd

(Director, Business Development

JSS/mp

J.L. SHEPHERD & ASSOCIATES BEST AND FINAL OFFER

Proposal 1 Revision A

Solicitation No. DADA15-89-R-0122

CESIUM-137 BLOOD PRODUCT IRRADIATOR

SAMPLE CHAMBER: 4" Dia. x 8" High - 1.64 Liters

Performance Specifications

- 1. Cesium-137 in "Special Form" encapsulation to be provided for gamma radiation to inactivate lymphocytes in blood and blood components.
- 2. The device shall be self-shielding encasing the Cesium-137 source in a double walled stainless steel holder.
- 3. The stainless steel holder shall be permanently installed and sealed in a lead encased biological shield.
- 4. The system shall contain <u>Curies Cesium-137 in 4 dis-</u> tinct sources. The dose rate variation shall be ± 15% over the sample chamber.
- 5. The external radiation levels shall be less than 2.0 mR/hr at the SURFACE of the device in all operating modes. This is below the requirements of ICRP #15.

6. A dose shall be delivered in minutes.

- 7. The sample chamber shall incorporate a built in turntable which rotates at approximately 7 rpm. The sample shall be automatically rotated towards and away from the Cesium-137 source.
- 8. A battery back-up system shall be provided to allow cycle completion in case of power failure. A <u>manual</u> return system shall <u>also</u> be provided.
- 9. A keyswitch shall control electrical power.
- 10. A sample chamber door shall be provided. The turntable shall not operate unless the door is closed.
- 11. An audible alarm shall sound upon completion of the irradiation cycle. The alarm shall NOT cease until the door is opened.

ÉxZ

Proposal 1 Revision A Page Two

Solicitation No. DADA15-89-R-0122

- 12. The device shall operate safely in accordance with the requirements of ICRP #15.
- 13. The device shall weigh approximately 3,000 lbs. Dimensions shall be 31" x 31" x 66" (78" with sample chamber in "LOAD" position).
- 14. An eight hour training session for at least six people shall be included.

Additional Features

- 15. An electronic timer (0000.00 min.) with <u>automatic reset</u> shall be provided.
- 16. The device shall be mounted on a rolling dolly with locking mechanism.
- 17. A baked enamel steel cover shall be standard.
- 18. A stainless steel sealable sample canister shall be provided.
- 19. The device shall be designed and certified to meet all US DOT 7A container specifications.

<u>Safety</u>

20. Dual "IRRADIATE" switches which are required to operate the sample drawer negate the possibility of operator being hurt during drawer travel.

Warranty

- 21. The warranty shall be as follows:
 - a. 12 months on parts and labor.
 - b. Additional <u>48 months</u> on parts.
- 22. PRICE (F.O.B. Destination) \$53,285

<u>Deli 'ery</u>

23. 60 Days ARO

SF 26 Continued.....

The following revisions are hereby mutually accepted and are hereby incorporated into subject contract;

1. Amendment #0001 dated 7/21/89, attached at rear of contract document.

2. Contractor's Best and Final Offer is made part of the award.

3. Sections K,L and M of Solicitation DADA15-89=R-0122 are made part of the award and are incorporated by reference.

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13. DISCOUNT FOR PROMPT PAYMENT		O CALENDAR D	AYS		20 CALE				DAYS		
(See Section I, Clause No. 52-232-8)				*			*	NET	*	-	<u> </u>
14. ACKNOWL EDGMENT OF AMENDMENTS				10.	1	DATE		AMENOMENT	NO.	1	DATE
(The offeror acknowledges receipt of amend- ments to in a SOLICITATION for offerors and											
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PREVICUS 33: N NOT USABLE									Pro FA	H (48 CFR) 5	A 3.214(c)

SECTION B SUPPLIES OR SERVICES AND PRICES/COSTS

8.1. SCOPE

B.1.1. This solicitation is for the acquisition and delivery of a Gammacell 1000 Elite Blood Product Irradiator, brand name or equal by Nordion International, Inc., for use by the department of Pathology and ALS Blood Bank, Walter Reed Army Medical Center, Washington, D.C.

B.2. COMMERCIAL WARRANTY

B.2.1. The contractor agrees that the supplies/equipment furnished under this contract shall be covered by the most favorable commercial warranties the contractor gives to any customer for such supplies/equipment and that the rights and remedies provided herein are in addition to and do not limit any rights afforded to the Government by any other clause of this contract. Offeror shall complete the following:

Warranty certificate shall be furnished with the items at time of inspection and acceptance.

B.3. BRAND NAME OR EQUAL

B.3.1. Offerors are cautioned as to the need to comply with the applicable terms of the Brand Name or Equal Clause, paragraph L-9.

Contractors offering products which differ from the reference brand name shall be considered for award when the Contracting Officer determines that the offered product is equal in all material aspects to the product referenced. Offers will not be rejected because of minor differences in design, construction, or features which do not affect the suitability of the product for its intended use. The product offered must meet the essential characteristics listed in Section C of this solicitation.

Offerors are also cautioned that the submittal of any statement (such as offerors descriptive literature) to the effect that specifications are subject to change without notice may render the offer non-responsive and cause its rejection.

B.4. BRAND NAME OR EQUAL PROPOSALS

The Contract Line Items (CLIN) requested in The Schedule are identified as Brand Name or Equal. The catalog or model numbers referenced for each CLIN are manufactured by the company identified below. Please provide the brand

ITEM	DESCRIPTION	QUANTITY	<u>U/H</u>	<u>U/P</u>	AMOUNT
name, r	manufacturers name and catalog/model numbers	s for the i	items yo	u are	
offeriı	ng in your proposal in the space below the	clin:			
Refere	nce Items are manufactured by: Gammacell	By Nordion			
B.5.	THE SCHEDULE				
ITEM	DESCRIPTION	QUANTITY	<u>U/M</u>	<u> </u>	AMOUNT
0001	6640-01- C14-197 4	. 1	EA	53285.000000	53285.00
	GAMMACELL 1000 ELITE BLOOD PRODUCT				
0001	(Continued)				
	IRRADIATOR 115 VAC. 60 Hz. MODEL D		•		
	OFFERING ON - BRAND NAME:				
	MANUFACTURER:				
	CATALOG/MODEL NUMBERS:	-			
0002	2 COPIES OF EACH TECHNICAL LITERATURE	2	EA	0.00000	0.00
	TO INCLUDE OPERATOR MANUAL, WIRING				
	DIAGRAMS, PARTS LISTING WITH PRICES,				
	AND PREVENTIVE MAINTENANCE RECOMMENDA-				
	TION, IN ADDITION TO ONE (1) FREE				
	COPY OF THE TECHNICAL LITERATURE.				
0003	STANDARD COMMERCIAL INSTALLATION	1	EA	1500.000000	1500.00
	(FURNISH AND INSTALL)				

END OF SECTION 8

SECTION C DESCRIPTION/SPECS./WORK STATEMENT

C. MINIMUM ESSENTIAL REQUIREMENTS

C.1. Must use gamma radiation to inactivate lymphocytes in blood and blood components.

C.1.2. The unit must be self-shielded encasing the radiation source in a double walled stainless steel holder.

C.1.3. The steel holder must be permanently installed and sealed in a lead encased biological shield.

C.1.4. The system must have three to four sources of radiation with a minimum Curie content of 1800 for even erradiation.

C.1.5. The external radiation level must meet or be below the requirements of the International Commission in Radiation Protection (ICRP#15).

C.1.6. A 3000 radiation dose must be delivered in two to seven minutes.

C.1.7. A turntable must be within the chamber for dose uniformity. The sample must automatically rotate towards and away from the irradiation source.

C.1.8. A battery back up system is required to allow cycle completion in case of power failure.

C.1.9. A key operated switch must control electrical power to the unit.

C.1.10. The sample chamber rotor must not operate until the front door is closed.

C.1.11. An audible alarm system must be in place to announce the end of irradiation process.

C.1.12. The unit must be able to operate safely in a laboratory environment in accordance with ICRP#15.

C.1.13. Dimensions must be approximately 66" high x 30" wide x 26" deep. Weight approximately 3500 pounds.

C.1.14. On-site training must be provided for at least six people for eight hours.

DADA15-89-R-0122

C-1

END OF SECTION C

°

DADA15-89-R-0122

C-2

SECTION D PACKAGING AND MARKING

0.1 52.000.4024

PACKAGING

The supplies or equipment shall be packaged to afford adequate protection against corrosion, deterioration and damage in transit from the supply source to the receiving activity. Contractor's standard commercial packaging will be considered acceptable, provided it satisfies the above criteria.

END OF SECTION D

DADA15-89-R-0122

SECTION E INSPECTION AND ACCEPTANCE

E.1 52.252-0002

(R 7-001)

CLAUSES INCORPORATED BY REFERENCE (JUN 1988)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their text available.

I. FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSES

II. DOD FAR SUPPLEMENT (48 CFR CHAPTER 2) CLAUSES

(End of clause)

E.2	52.246-0002	INSPECTION OF SUPPLIESFIXED-PRICE (JUL 1985) (Reference 46.302)
E.3	52.246-0016	RESPONSIBILITY FOR SUPPLIES (APR 1984) (Reference 46.316)
E.4	52.000-4026	INSPECTION AND ACCEPTANCE AT DESTINATION

Inspections and acceptance of the supplies or services to be furnished hereunder shall be made at destination by the receiving office or consignee shown in the contract.

END OF SECTION E

DADA15-89-R-0122

SECTION F DELIVERIES OR PERFORMANCE

F.1 52.252-0002

CLAUSES INCORPORATED BY REFERENCE (JUN 1988)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their text available.

1. FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSES

II. DOD FAR SUPPLEMENT (48 CFR CHAPTER 2) CLAUSES

(End of clause)

(R 7-001)

F.O.B. DESTINATION (APR 1984) (Reference 47.303-6(c))

F.3 52.000-4004

F.2 52.247-0034

CONTRACT PERIOD

This contract shall be effective AUGUST 17TH, or date of award, whichever is later, and shall continue FOR 60 DAYS, unless sooner terminated under the terms of the contract.

F.4 52.000-4025

PLACE OF DELIVERY . FOB DESTINATION

The articles to be furnished hereunder shall be delivered, all transportation charges paid by the contractor, and in accordance with FOB Destination clause (FAR 52.247-34) in Section I of this solicitation. Deliver to:

> DOL, PROPERTY MANAGEMENT BRANCH BUILDING #178 FOREST GLEN SECTION 2461 LINDEN LANE WRAMC) SILVER SPRING, MD 20910-1291

F.5 52.000-4027

OFFERS NOT DESIGNATED AS F.O.B. DESTINATION

Offers submitted on a basis other than f.o.b. Destination may be rejected as non-responsive in accordance with FAR 47.305.4(b).

F-1

F.6 52.212-0001

TIME OF DELIVERY (APR 1984) .

(a) The Government requires delivery to be made according to the following schedule:

REQUIRED DELIVERY SCHEDULE

	ITEM NO.	QUANTITY	WITHIN DAYS AFTER
			DATE OF CONTRACT
	1 AND 3	1 EA	60
	2	2 EA	60
_			

The Government will evaluate equally, as regards time of delivery, offers that propose delivery of each quantity within the applicable delivery period specified above. Offers that propose delivery that will not clearly fall within the applicable required delivery period specified above, will be considered nonresponsive and rejected. The Government reserves the right to award under either the required delivery schedule or the proposed delivery schedule, when an offeror offers an earlier delivery schedule than required above. If the offeror proposes no other delivery schedule, the required delivery schedule above will apply.

OFFEROR'S PROPOSED DELIVERY SCHEDULE

1	TEN NO.		QUA	TITY	WITHIN D	AYS	AFTER	
	1		1	each	DATE OF	CON	TRACT	
	2		2	each	60 DAY	S	- Items	1 & 2.
lease?	note	that	the	devices	offered a	IS	options	require

(b) Attention is directed to the Contract Award provision of the days for delivery. solicitation that provides that a written award or acceptance of offer mailed, or otherwise furnished to the successful offeror, results in a binding contract. The Government will mail or otherwise furnish to the offeror an award or notice of award not later than the day award is dated. Therefore, the offeror should compute the time available for performance beginning with the actual date of award, rather than the date the written notice of award is received from the Contracting Officer through the ordinary mails. However, the Government will evaluate an offer that proposes delivery based on the Contractor's date of receipt of the contract or notice of award by adding five days for delivery of the award through the ordinary mails. If, as so computed, the offered delivery date is later than the required delivery date, the offer will be considered nonresponsive and rejected.

> (End of clause) (R 7-104.92(b) 1974 APR) (R 1-1.316-5) (R 1-1.316-4(c))

END OF SECTION F
SECTION G CONTRACT ADMINISTRATION DATA

G.1 52.000-4000

CORRESPONDENCE AFTER AWARD

All correspondence after award of this contract shall be directed to the following address:

CONTRACTING OFFICER

Directorate of Contracting Walter Reed army Medical Center Washington, DC 20307-5000

G.2 52.000-4002 ii

INVOICING AND PAYMENT

Payment shall be made upon receipt and acceptance by the Government. Invoices shall be submitted in quadruplicate (one copy marked "original"), to the following address:

> Commercial Accounts Section Walter Reed Army Medical Center Washington, DC 20307--5000

G.3 52.000-4003

CONTRACTING OFFICER'S AUTHORITY

The Contracting Officer is the ONLY person authorized to approve changes to any of the requirements under this contract, and notwithstanding any provision contained elsewhere in this contract the said authority remains solely with the Contracting Officer. In the event the Contractor effects any changes at the direction of any person other than the Contracting Officer, the change will be considered to have been made without authority, and no adjustment will be made in the contract price to cover any increase in charges incurred as a result thereof.

G.4 52.000-4522

52.232-0025 PROMPT PAYHENT (APR 1989) (AL 89-10)

Notwithstanding any other payment clause in this contract, the Government will make invoice payments and contract financing payments under the terms and conditions specified in this clause. Payment shall be considered as being made on the day a check is dated or an electronic funds transfer is made. Definitions of pertinent terms are set forth in 32.902. All days referred to in this clause are calendar days, unless otherwise specified. The term "foreign vendor" means an incorporated concern not incorporated in the United States, or an unincorporated concern having its principl place of business outside the Jnited States.

DADA15-89-R-0122

(a) Invoice Payments.

(1) For purposes of this clause, "invoice payment" means a Government disbursement of monies to a Contractor under a contract or other authorization for supplies or services accepted by the Government. This includes payments for partial deliveries that have been accepted by the Government and final cost or fee payments where amounts owed have been settled between the Government and the Contractor.

(2) Except as indicated in subparagraph (a)(3) and paragraph (c) of this clause, the due date for making invoice payments by the designated payment office shall be the later of the following two events:

(i) The 30th day after the designated billing office has received a proper invoice from the Contractor.

(ii) The 30th day after Government acceptance of supplies delivered or services performed by the Contractor. On a final invoice where the payment amount is subject to contract settlement actions, acceptance shall be deemed to have occurred on the effective date of the contract settlement. However, if the designated billing office fails to annotate the invoice with the actual date of receipt, the invoice payment due date shall be deemed to be the 30th day after the date the Contractor's invoice is dated, provided a proper invoice is received and there is no disagreement over quantity, quality, or Contractor compliance with contract requirements.

(3) The due date on contracts for meat and meat food products, contracts for perishable agricultural commodities, contracts for dairy products, edible fats or oils, and food products prepared from edible fats or oils, and contracts not requiring submission of an invoice shall be as follows:

(i) The due date for meat and meat food products, as defined in Section 2(a)(3) of the Packers and Stockyard Act of 1921 (7 U.S.C. 182(3)) and further defined in Pub. L. 98-181 to include any edible fresh or frozen poultry meat, any perishable poultry meat food product, fresh eggs, and any perishable egg product, will be as close as possible to, but not later than, the 7th day after product delivery.

 (ii) The due date for perishable agricultural commodities, as defined in Section 1(4) of the Perishable Agricultural Commodities Act of 1930 (7 U.S.C. 499a(44)), will be as close as possible to, but not later than, the 10th day after product delivery, unless another date is specified in the contract.

(iii) The due date for dairy products, as defined in section 111(e) of the Dairy Production Stabilization Act of 1983 (7 U.S.C. 4502(e)), edible fats or oils, and food products prepared from edible fats or oils, will be as close as possible to, but not later than, the 10th day after the date on which a proper invoice has been received.

(4) An invoice is the Contractor's bill or written request for payment under the contract for supplies delivered or services performed. An invoice shall be prepared and submitted to the designated billing office

DADA15-89-R-0122

specified in the contract. A proper invoice must include the items listed in subdivisions (a)(4)(i) through (a)(4)(viii) of this clause. If the invoice does not comply with these requirements, then the Contractor will be notified of the defect within 7 days after receipt of the invoice at the designated billing office (3 days for meat and meat food products and 5 days for perishable agricultural commodities, edible fats or oils, and food products prepared from edible fats or oils). Untimely notification will be taken into account in the computation of any interest penalty owed the Contractor in the manner described in subparagraph (a)(6) of this clause.

(i) Name and address of the Contractor.

(ii) Invoice date.

(iii) Contract number or other authorization for supplies delivered or services performed (including order number and contract line item number).

(iv) Description, quantity, unit of measure, unit price, and extended price of supplies delivered or services performed.

(v) Shipping and payment terms (e.g., shipment number and date of shipment, prompt payment discount terms). Bill of lading number and weight of shipment will be shown for shipments on Government bills of lading.

(vi) Name and address of Contractor official to whom payment is to be sent (must be the same as that in the contract or in a proper notice of assignment).

(vii) Name (where practicable), title, phone number and mailing address of person to be notified in event of a defective invoice.

(viii) Any other information or documentation required by other requirements of the contract (such as evidence of shipment).

(5) An interest penalty shall be paid automatically by the Government, without request from the Contractor, if payment is not made by the due date and the conditions listed in subdivisions (a)(5)(i) through (a)(5)(iii) of this clause are met, if applicable. An interest penalty shall not be paid on contracts awarded to foreign vendors outside the United States for work performed outside the United States.

(i) A proper invoice was received by the designated billing office.

(ii) A receiving report or other Government documentation authorizing payment was processed and there was no disagreement over quantity, quality, or contractor compliance with any contract term or condition.

(iii) In the case of a final invoice for any balance of funds due the Contractor for supplies delivered or services performed, the amount was not subject to further contract settlement actions between the Government and the Contractor.

(6) The interest penalty shall be at the rate established by the Secretary of the Treasury under Section 12 of the Contract Disputes Act of 1978 (41 U.S.C. 611) that is in effect on the day after the due date, except where the interest penalty is prescribed by other governmental authority. This rate is referred to as the "Renegotiation Board Interest Rate," and it is published in the Federal Register semiannually on or about January 1 and Jul/ 1. The interest penalty shall accrue daily on the

DADA15-89-R-0122

invoice payment amount approved by the Government and be compounded in 30-day increments inclusive from the first day after the due date through the payment date. That is, interest accrued at the end of any 30-day period wiull be added to the approved invoice payment amount and be subject to interest penalties if not paid in the succeeding 30-day period. If the designated billing office failed to notify the contractor of a defective invoice within the periods prescribed in subparagraph (a)(4) of this clause, then the due date on the corrected invoice will be adjusted by subtracting the number of days taken beyond the prescribed notification of defects period. Any interest penalty owed the Contractor will be based on this adjusted due date. Adjustments will be made by the designated payment office for errors in calculating interest penalties, if requested by the Contractor.

(1) For the sole purpose of computing an interest penalty that might be due the Contractor, Government acceptance shall be deemed to have occurred constructively on the 7th day (unless otherwise specified in this contract) after the Contractor delivered the supplies or performed the services in accordance with the terms and conditions of the contract, unless there is a disagreement over quantity, quality, or contractor compliance with a contract provision. In the event that actual acceptance occurs within the constructive acceptance period, the determination of an interest penalty shall be based on the actual date of acceptance. The constructive acceptance requirement does not, however, compel Government officials to accept supplies or services, perform contract administration functions, or make payment prior to fulfilling their responsibilities.

(ii) The following periods of time will not be included in the determination of an interest penalty:

(A) The period taken to notify the Contractor of defects in invoices submitted to the Government, but this may not exceed 7 days (3 days for meat and meat food products and 5 days for perishable agricultural commodities, dairy products, edible fats or oils, and food products prepared from edible fats or oils).

(B) The period between the defects notice and resubmission of the corrected invoice by the Contractor.

(iii) Interest penalties will not continue to accrue after the filing of a claim for such penalties under the clause at 52.233-1, Disputes, or for more than 1 year. Interest penalties of less than \$1.00 need not be paid.

(iv) Interest penalties are not required on payment delays due to disagreement between the Government and Contractor over the payment amount or other issues involving contract compliance or on amounts temporarily withheld or retained in accordance with the terms of the contract. Claims involving disputes, and any interest that may be payable, will be resolved in accordance with the clause at 52.233-1, Disputes.

(7) An interest penalty shall also be paid automatically by the designated payment office, without request from the contractor, if a discount for prompt payment is taken improperly. The interest penalty will

DADA15-89-R-0122

be calculated as described in subparagraph (a)(6) of this clause on the amount of discount taken for the period beginning with the first day after the end of the discount period through the date when the contractor is paid.

(8) If this contract was awarded on or after October 1, 1989, a penalty amount, calculated in accordance with regulations issued by the Office of Management and Budget, shall be paid in addition to the interest penalty amount if the Contractor--

(i) Is owed an interest penalty;

(ii) Is not paid the interest penalty within 10 days after the date the invoice amount is paid; and

(iii) Makes a written demand, not later than 40 days after the date the invoice amount is paid, that the agency pay such a penalty.

(b) Contract Financing Payments.

(1) For purposes of this clause, "contract financing payment" means a Government disbursement of monies to a Contractor under a contract clause or other authorization prior to acceptance of supplies or services by the Government. Contract financing payments include advance payments, progress payments based on cost under the clause at 52.232-16, Progress Payments, progress payments based on a percentage or stage of completion (32.102(e)(1)) other than those made under the clause at 52.232-5, Payments Under Fixed-Price Construction Contracts, or the clause at 52.232-10, Payments Under fixed-Price Architect-Engineer Contracts, and interim payments on cost type contracts.

(2) For contracts that provide for contract financing, requests for payment shall be submitted to the designated billing office as specified in this contract or as directed by the Contracting Officer. Contract financing payments shall be made on the N/A day after receipt of a proper contract financing request by the designated billing office. In the event that an audit or other review of a specific financing request is required to ensure compliance with the terms and conditions of the contract, the designated payment office is not compelled to make payment by the due date specified.

(3) For advance payments, loans, or other arrangements that do not involve recurrent submissions of contract financing requests, payment shall be made in accordance with the corresponding contract terms or as directed by the Contracting Officer.

(4) Contract financing payments shall not be assessed an interest penalty for payment delays.

(c) If this contract contains the clause at 52.213-1, Fast Payment Procedures, payments will be made within 15 days after the date of receipt of the invoice.

DADA15-89-R-0122

G-5

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END OF SECTION G

DADA15-89-R-0122

SECTION I CONTRACT CLAUSES

1.1 52.252.0002

CLAUSES INCORPORATED BY REFERENCE (JUN 1988)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their text available.

I. FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSES

II. DOD FAR SUPPLEMENT (48 CFR CHAPTER 2) CLAUSES

(End of clause) (R 7-001)

- I.2 52.000-4509 52.209-7001 ACQUISITIONS FROM DEFENSE CONTRACTORS SUBJECT TO ON-SITE INSPECTION UNDER THE INTERMEDIATE-RANGE NUCLEAR FORCES (INF) TREATY (JUN 1988) (AL 88-16) (Reference)
- 1.3 52.000-4521 52.232-8 DISCOUNTS FOR PROMPT PAYMENT (APR 1989) (AL 89-10) (Reference)
- I.4 52.202-0001 DEFINITIONS (APR 1984) (Reference 2.2)
- I.5 52.203-0001 OFFICIALS NOT TO BENEFIT (APR 1984) (Reference 3.102-2)
- I.6 52.203-0003 GRATUITIES (APR 1984) (Reference 3.202)
- I.7 52.203-0005 COVENANT AGAINST CONTINGENT FEES (APR 1984) (Reference 3.404(c))
- 1.8
 52.203-0006
 RESTRICTIONS ON SUBCONTRACTOR SALES TO THE GOVERNMENT (JUL 1985) (Reference 3.503-2)
- I.9 52.203.0007 ANTI-KICKBACK PROCEDURES (OCT 1988) (Reference 3.502-3)

DADA15-89-R-0122

I.1152.215-0001EXAMINATION OF RECORDS BY COMPTROLLER GENERAL (APR 1984) (Reference 15.106-1(b))I.1252.215-0002AUDITNEGOTIATION (APR 1988) (Reference 15.106-2(b))I.1352.215-0033ORDER OF PRECEDENCE (JAN 1986) (Reference 15.406-3(b))I.1452.219-0008UTILIZATION OF SMALL BUSINESS CONCERNS AND SMALL DISADVANTAGED BUSINE CONCERNS (JUN 1985)	. · ·
I.12 52.215-0002 AUDITNEGOTIATION (APR 1988) (Reference 15.106-2(b)) I.13 52.215-0033 ORDER OF PRECEDENCE (JAN 1986) (Reference 15.406-3(b)) I.14 52.219-0008 UTILIZATION OF SMALL BUSINESS CONCERNS AND SMALL DISADVANTAGED BUSINE CONCERNS (JUN 1985)	
I.13 52.215-0033 ORDER OF PRECEDENCE (JAN 1986) (Reference 15.406-3(b)) I.14 52.219-0008 UTILIZATION OF SMALL BUSINESS CONCERNS AND SMALL DISADVANTAGED BUSINE CONCERNS (JUN 1985)	
1.14 52.219-0008 UTILIZATION OF SMALL BUSINESS CONCERNS AND SMALL DISADVANTAGED BUSINE CONCERNS (JUN 1985)	
(Reference 19.708(a))	SS
I.15 52.220-0003 UTILIZATION OF LABOR SURPLUS AREA CONCERNS (APR 1984) (Reference 20.302(a))	
1.16 52.222-0020 WALSH-HEALEY PUBLIC CONTRACTS ACT (APR 1984) (Reference 22.610(b))	
I.17 52.222-0026 EQUAL OPPORTUNITY (APR 1984) (Reference 22.810(e))	
1.18 52.222-0035 AFFIRMATIVE ACTION FOR SPECIAL DISABLED AND VIETNAM ERA VETERANS (APR 1984) (Reference 22.1308)	
I.19 52.222-0036 AFFIRMATIVE ACTION FOR HANDICAPPED WORKERS (APR 1984) (Reference 22.1408)	
I.20 52.222-0037 EMPLOYMENT REPORTS ON SPECIAL DISABLED VETERANS AND VETERANS OF THE VIETNAM ERA (JAN 1988) (Reference 22.1308(b))	

1.21	52.223-0006	DRUG-FREE WORKPLACE (MAR 1989) (Reference 23.505(c))
1.22	52.225-7001	BUY AMERICAN ACT AND BALANCE OF PAYMENTS PROGRAM (APR 1985) (Reference 25.109(d)(S)
1.23	52.225-7027	RESTRICTION ON CONTRACTING WITH TOSHIBA CORPORATION OR KONGSBERG VAPENFABRIKK (MARCH 1988) (Reference 25.7011(d))
1.24	52.227.0001	AUTHORIZATION AND CONSENT (APR 1984) (Reference 27.201-2(a))
1.25	52.227-000 2	NOTICE AND ASSISTANCE REGARDING PATENT AND COPYRIGHT INFRINGEMENT (APR 1984) (Reference 27.202-2)
1.26	52 .229-0 00 3	FEDERAL, STATE, AND LOCAL TAXES (APR 1984) (Reference 29.401-3)
1.27	52.229-0005	TAXESCONTRACTS PERFORMED IN U.S. POSSESSIONS OR PUERTO RICO (APR 1984) (Reference 29.401-5)
[.28	52.232-0001	PAYMENTS (APR 1984) (Reference 32.111(a)(1)
[.29	52.232-0011	EXTRAS (APR 1984) (Reference 32.111(d)(2)
1.30	52.232-0017	INTEREST (APR 1984) (Reference 32.617(a))
1.31	52.232-0023	ASSIGNMENT OF CLAIMS (JAN 1986) (Reference 32.806(a)(1)

DADA15-89-R-0122

1.32 52.233-0001 (Reference 33.214) r PROTEST AFTER AWARD (JUN 1985) 1.33 52.233-0003 (Reference 33.106(b)) CHANGES -- FIXED - PRICE (AUG 1987) 1.34 52.243-0001 (Reference 43.205(a)(1) PRICING OF ADJUSTMENTS (APR 1984) 1.35 52.243-7001 (Reference 43.205(S-71) TERMINATION FOR CONVENIENCE OF THE GOVERNMENT (FIXED-PRICE) (SHORT FORM) 1.36 52.249-0001 (APR 1984) (Reference 49.502(a)(1)

DISPUTES (APR 1984)

DEFAULT (FIXED-PRICE SUPPLY AND SERVICE) (APR 1984) 1.37 52.249-0008 (Reference 49.504(a)(1)

1.38 52.000-4525

52.209-6 PROTECTING THE GOVERNMENT'S INTEREST WHEN SUBCONTRACTING WITH CONTRACTORS DEBARRED, SUSPENDED, OR PROPOSED FOR DEBARMENT (MAY 1989) (FAC 84-46)

END OF SECTION I

DADA15-89-R-0122