FILE COPY

June 4, 1985

Blood Center of Central Iowa
ATTN: Charles W. Osier
Director
1050 Seventh Street
Des Moines, IA 50314

License No. 14-18765-01
Control No. 18941

SUBJECT: LICENSE RENEWAL APPLICATION

Gentlemen:

This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

Any correspondence regarding the renewal application should reference the control number specified and your license number.

Sincerely,

Bruce J. Mallett

Material Licensing Section
Region III

BSM
6/19/85

NRC Form 313 I (12-81) 10 CFR 30

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE
INDUSTRIAL

1. APPLICATION FOR: (Check and/or complete as appropriate)

	a. NEW LICENSE
X	b. AMENDMENT TO LICENSE NUMBER #14-18765-01
	c. RENEWAL OF LICENSE NUMBER

See attached instructions for details.

Completed applications are filed in duplicate with the Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety, and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 or applications may be filed in person at the Commission's office at 1717 H Street, NW, Washington, D. C. or 7915 Eastern Avenue, Silver Spring, Maryland.

2. APPLICANT'S NAME (Institution, firm, person, etc.)
The Blood Center of Central Iowa

TELEPHONE NUMBER: AREA CODE – NUMBER EXTENSION
(515) 288-0276

3. NAME AND TITLE OF PERSON TO BE CONTACTED REGARDING THIS APPLICATION
Larry Weldy, Laboratory Director

TELEPHONE NUMBER: AREA CODE – NUMBER EXTENSION
(515) 288-0276

4. APPLICANT'S MAILING ADDRESS (Include Zip Code)
(Address to which NRC correspondence, notices, bulletins, etc., should be sent.)
The Blood Center of Central Iowa
1050 Seventh St., Des Moines, IA 50314

5. STREET ADDRESS WHERE LICENSED MATERIAL WILL BE USED (Include Zip Code)
The Blood Center of Central Iowa
1050 Seventh St., Des Moines, IA 50314

(IF MORE SPACE IS NEEDED FOR ANY ITEM, USE ADDITIONAL PROPERLY KEYED PAGES.)

6. INDIVIDUAL(S) WHO WILL USE OR DIRECTLY SUPERVISE THE USE OF LICENSED MATERIAL
(See Items 16 and 17 for required training and experience of each individual named below)

	FULL NAME	TITLE
a.	Larry L. Weldy	Laboratory Director
b.	Dr. Clarence H. Denser, Jr., M.D.	Medical Director
c.		

7. RADIATION PROTECTION OFFICER
Larry L. Weldy

Attach a resume of person's training and experience as outlined in Items 16 and 17 and describe his responsibilities under Item 15.

8. LICENSED MATERIAL

LINE NO.	A ELEMENT AND MASS NUMBER	B CHEMICAL AND/OR PHYSICAL FORM	C NAME OF MANUFACTURER AND MODEL NUMBER (If Sealed Source)	D MAXIMUM NUMBER OF MILLICURIES AND/OR SEALED SOURCES AND MAXIMUM ACTIVITY PER SOURCE WHICH WILL BE POSSESSED AT ANY ONE TIME
(1)	Cesium 137	Solid	Gammacell 1000 Atomic Energy of Canada Ltd.	720 curies C.D.R. + 10% Rad/min/ci 0.833
(2)				
(3)				
(4)				

	E DESCRIBE USE OF LICENSED MATERIAL
(1)	To irradiate blood and blood components for transfusion to prevent GVH Disease
(2)	
(3)	~~8411030205~~ 840914 NMS LIC30 14-18765-01 PDR
(4)	

NRC FORM 313 I (12-81)

12pp.

9. STORAGE OF SEALED SOURCES

LINE NO.	CONTAINER AND/OR DEVICE IN WHICH EACH SEALED SOURCE WILL BE STORED OR USED. A.	NAME OF MANUFACTURER B.	MODEL NUMBER C.
(1)	Gammacell 1000 (self-contained - lead)	Atomic Energy of Canada,Ltd.	Gammacell 1000
(2)			
(3)			
(4)			

10. RADIATION DETECTION INSTRUMENTS

LINE NO.	TYPE OF INSTRUMENT A	MANUFACTURER'S NAME B	MODEL NUMBER C	NUMBER AVAILABLE D	RADIATION DETECTED (alpha, beta, gamma, neutron) E	SENSITIVITY RANGE (milliroentgens/hour or counts/minute) F
(1)	Victoreen Survey meter-model #493	Victoreen	#493	1	Gamma	0-500 mR/Hr
(2)						
(3)						
(4)						

11. CALIBRATION OF INSTRUMENTS LISTED IN ITEM 10

☒ a. CALIBRATED BY SERVICE COMPANY

NAME, ADDRESS, AND FREQUENCY

Mr. Myron Goede, Ph.D., Nuclear Medicine Dept.
Iowa Methodist Hospital, 1200 Pleasant St.,
Des Moines, Iowa 50308 -- Yearly

☐ b. CALIBRATED BY APPLICANT

Attach a separate sheet describing method, frequency and standards used for calibrating instruments.

12. PERSONNEL MONITORING DEVICES

TYPE (Check and/or complete as appropriate.) A	SUPPLIER (Service Company) B	EXCHANGE FREQUENCY C
☒ (1) FILM BADGE	R. S. Landauer, Jr. and Co. Glenwood Science Park Glenwood, IL 60425	☒ MONTHLY
☐ (2) THERMOLUMINESCENCE DOSIMETER (TLD)		☐ QUARTERLY
☐ (3) OTHER (Specify): _____		☐ OTHER (Specify)
_____		_____
_____		_____

13. FACILITIES AND EQUIPMENT (Check were appropriate and attach annotated sketch(es) and description(s).

☒ a. LABORATORY FACILITIES, PLANT FACILITIES, FUME HOODS (Include filtration, if any), ETC.
☐ b. STORAGE FACILITIES, CONTAINERS, SPECIAL SHIELDING (fixed and/or temporary), ETC.
☐ c. REMOTE HANDLING TOOLS OR EQUIPMENT, ETC.
☐ d. RESPIRATORY PROTECTIVE EQUIPMENT, ETC.

14. WASTE DISPOSAL

a. NAME OF COMMERCIAL WASTE DISPOSAL SERVICE EMPLOYED

b. IF COMMERCIAL WASTE DISPOSAL SERVICE IS NOT EMPLOYED, SUBMIT A DETAILED DESCRIPTION OF METHODS WHICH WILL BE USED FOR DISPOSING OF RADIOACTIVE WASTES AND ESTIMATES OF THE TYPE AND AMOUNT OF ACTIVITY INVOLVED. IF THE APPLICATION IS FOR SEALED SOURCES AND DEVICES AND THEY WILL BE RETURNED TO THE MANUFACTURER, SO STATE.

When use of the irradiator is discontinued, it will be returned to the manufacturer.

INFORMATION REQUIRED FOR ITEMS 15, 16 AND 17

Describe in detail the information required for Items 15, 16 and 17. Begin each item on a separate page and key to the application as follows:

15. RADIATION PROTECTION PROGRAM. Describe the radiation protection program as appropriate for the material to be used including the duties and responsibilities of the Radiation Protection Officer, control measures, bioassay procedures *(if needed)*, day-to-day general safety instruction to be followed, etc. If the application is for sealed source's also submit leak testing procedures, or if leak testing will be performed using a leak test kit, specify manufacturer and model number of the leak test kit.

16. FORMAL TRAINING IN RADIATION SAFETY. Attach a resume for each individual named in Items 6 and 7. Describe individual's formal training in the following areas where applicable. Include the name of person or institution providing the training, duration of training, when training was received, etc.

    a. Principles and practices of radiation protection.

    b. Radioactivity measurement standardization and monitoring techniques and instruments.

    c. Mathematics and calculations basic to the use and measurement of radioactivity.

    d. Biological effects of radiation.

17. EXPERIENCE. Attach a resume for each individual named in Items 6 and 7. Describe individual's work experience with radiation, including where experience was obtained. Work experience or on-the-job training should be commensurate with the proposed use. Include list of radioisotopes and maximum activity of each used.

18. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 2, certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Part 30, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

WARNING.–18 U.S.C., Section 1001; Act of June 25, 1948; 62 Stat. 749; makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

a. LICENSE FEE REQUIRED *(See Section 170.31, 10 CFR 170)* (We submitted our license fee with our previous application)	b. CERTIFYING OFFICIAL *(Signature)* Charles W Osier
	c. NAME *(Type or print)* Charles W. Osier
(1) LICENSE FEE CATEGORY:	d. TITLE Director
(2) LICENSE FEE ENCLOSED: $	e. DATE 6/1/94

SURVEY METER CALIBRATION

Instrument:

Manufacturer Victoreen

Model No. 493

Serial No. 2091

Battery Check: Low, replaced same

Zero Check: OK

Calibration Data:

Scale	Exposure Rate (mR/hr)	Instrument Reading (mR/hr)	Exposure Rate (mR/hr)	Instrument Reading (mR/hr)
0-50	30.2	30	15.4	16.5
0-5	3.8	3.9	1.9	2.0
0-0.5	0.3	0.3	0.15	0.16

Check Source Reading: 1.5 mR/hr

Comments: Probe cable shield is frayed. May need to be repaired.

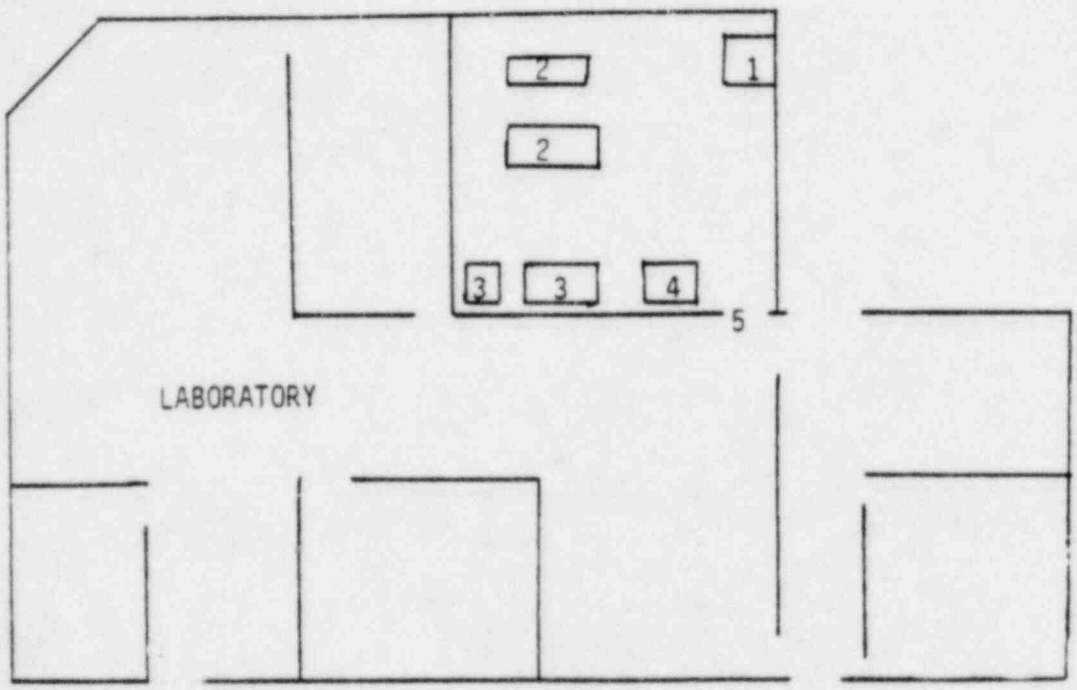
Calibrations Source(s):

Nuclide	Activity	Calibration Accuracy
Ra-226	10.14mg	± 5%
Ra-226	10.21 mg	± 5%

Calibrated by Robert J. Bischof, PhD Date 2/9/84

Item #13 Facilities and Equipment

The laboratory is an Office of Biologics and American Association of Blood Banks licensed blood drawing center currently operating under a Nuclear Regulatory Commission general license. The irradiator will be housed in an unused room with a lockable door. The room also houses extra centrifuges and a refrigerator.



1. Irradiator
2. Tables
3. Extra Centrifuges
4. Refrigerator
5. Door to be locked

Item #15 Radiation Protection Program

A. A detailed procedure for operating the irradiator will be included in the procedure manual and will also be posted by the irradiator.

B. Personnel will be required to wear film badges when using the irradiator.

C. Radiation checks will be made daily with a survey meter of the room in which the irradiator is located.

D. When the irradiator is not in use, the door to the room in which it is located will be locked.

E. Leak testing will be done twice yearly by using the head of the Radiology Department of Iowa Methodist Medical Center who also does our survey meter calibration.

F. If at any time abnormal radiation levels around the irradiator are detected, the door is to be locked and the radiation safety officer or/and the Medical Director are to be notified immediately for proper assessment and action.

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

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Dr. Clarence H. Denser, Jr., M.D.	Iowa

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Pathology (Clinical & Anatomical)		1953

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Oak Ridge Institute of Nuclear Studies	38	
b. RADIATION PROTECTION	Oak Ridge Institute of Nuclear Studies	9	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Oak Ridge Institute of Nuclear Studies	22	
d. RADIATION BIOLOGY	Oak Ridge Institute of Nuclear Studies	10	
e. RADIOPHARMACEUTICAL CHEMISTRY	Oak Ridge Institute of Nuclear Studies	33	33

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
I^{131}	1 mc	Private Practice of Clinical Pathology	1959-1984	In vitro Thyroid Testing
I^{125}	1 mc			

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

PRECEPTOR STATEMENT

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

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME: Dr. Clarence H. Denser, Jr., M.D.

STREET ADDRESS: 1073 5th Avenue

CITY: Des Moines | STATE: Iowa | ZIP CODE: 50314

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

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

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

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

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION	11	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME	3	
	LIVER FUNCTION STUDIES	0	
	FAT ARSORPTION STUDIES	4	
	KIDNEY FUNCTION STUDIES	0	
	IN VITRO STUDIES	0	
OTHER		0	
I-125	DETECTION OF THROMBOSIS	0	
I-131	THYROID IMAGING	0	
P-32	EYE TUMOR LOCALIZATION	0	
Se-75	PANCREAS IMAGING	0	
Yb-169	CISTERNOGRAPHY	0	
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	0	
OTHER		0	
Tc-99m	BRAIN IMAGING	0	
	CARDIAC IMAGING	0	
	THYROID IMAGING	0	
	SALIVARY GLAND IMAGING	0	
	BLOOD POOL IMAGING	0	
	PLACENTA LOCALIZATION	0	
	LIVER AND SPLEEN IMAGING	0	
	LUNG IMAGING	0	
	BONE IMAGING	0	
OTHER		0	

PRECEPTOR STATEMENT *(Continued)*

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

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	0	
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT	0	
I-131	TREATMENT OF THYROID CARCINOMA	3	
	TREATMENT OF HYPERTHYROIDISM	4	
Au-198	INTRACAVITARY TREATMENT	0	
Co-60 or Cs-137	INTERSTITIAL TREATMENT	0	
	INTRACAVITARY TREATMENT	0	
I-125 or Ir-192	INTERSTITIAL TREATMENT	0	
Co-60 or Cs-137	TELETHERAPY TREATMENT	0	
Sr-90	TREATMENT OF EYE DISEASE	0	
	RADIOPHARMACEUTICAL PREPARATION	0	
Mo-99/ Tc-99m	GENERATOR	0	
Sn-113/ In-113m	GENERATOR	0	
Tc-99m	REAGENT KITS	0	
Other Cr^{51} Fe^{59} Co^{60}	 Blood determinations Blood determinations B-12	 4 4 3	

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

112 hours - 1959

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

a. NAME OF SUPERVISOR
Marshall Brucer, M.D.

b. NAME OF INSTITUTION
Oak Ridge Institute of Nuclear Studies

c. MAILING ADDRESS

d. CITY
Oak Ridge, Tennessee

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE
Clarence Denser, Jr. M.D.

7. PRECEPTOR'S NAME *(Please type or print)*
Dr. Clarence H. Denser, Jr., M.D.

8. DATE
February 21, 1984

NRC FORM 313M SUPPLEMENT 8
(9-81)

GPO 890-813

PRECEPTOR STATEMENT

Oak Ridge Institute of Nuclear Studies
Medical Division

This is to certify that Dr. Clarence H. Denser, Jr. has received 38 hours of didactic and laboratory training in the use of radioactive materials for diagnostic and therapeutic procedures. This is the first week of a three-week course. The subjects studied can be outlined as follows:

		Didactic and Laboratory Course Hours
1.	Principles and practices of radiological safety	1
2.	Radioactivity measurements, standardization and monitoring techniques and instruments	13
3.	Mathematics and calculations basic to the use and measurement of radioactivity.	13
4.	Biological effects of radiation	4
5.	Actual use of radioisotopes in the types and quantities for which application is being made, or equivalent experience	7

Signed this 6th day of February 1959.

Marshall Brucer, M.D.
Chairman, The Medical Division

Bill M. Nelson, M.D.
Pathologist

Raymond L. Hayes, Ph.D.
Chemist

Item #16 & #17

PRECEPTOR STATEMENT
Oak Ridge Institute of Nuclear Studies
Medical Division

This is to certify that Dr. Clarence H. Denser, Jr. has received 35 hours of didactic and laboratory training in the use of radioactive materials for diagnostic and therapeutic procedures. This is the second week of a three week course. The subject studied can be outlined as follows:

	Didactic and Laboratory Course Hours
1. Principles and practices of radiological health safety	6
2. Radioactivity measurements, standardization and monitoring techniques and instruments	12
3. Mathematics and calculations basic to the use and measurement of radioactivity	3
4. Biological effects of radiation	4
5. Actual use of radioisotopes in the types and quantities for which application is being made, or equivalent experience	10

Isotope	Amount	Condition(s) Diagnosed or Treated	Number of Cases	Type of Participation*
I-131	130 mc	Thyroid Carcinoma	1	(1) 2 3 (4)
	0.1 mc	Treatment of Hyperthyroidism	1	(1) 2 3 (4)
	0.1 mc	Thyroid Uptake	3	(1) 2 3 (4)
Cr-51	.02 mc	Blood Determinations (given i.v.)	2	(1) (2) (3) (4)
Fe-59	.012 mc	Blood Determinations (given i.v.)	2	(1) (2) (3) (4)

* Key to above numbers:

1. Examination of patients to determine suitability for radioisotope diagnosis and/or treatment and recommendations on dosage to be prescribed.
2. Collaboration in calibration and administration of dosages including related measurements and plotting of data.
3. Active period of training and experience of sufficient duration to permit follow-up of patients through diagnostic period including re-evaluation as to effectiveness and complications.
4. Study and discussion of case histories to establish most efficacious diagnostic and/or therapeutic techniques for this radioisotope use.

This physician also performed autopsies on dogs given large doses of radioactive iodine, gold, chromium, iron, and yttrium, preparing gross autoradiograms and samples for assay.

Signed this 1st day of May 1959.

ORIGINAL SIGNED BY
MARSHALL BRUCER

Marshall Brucer, M.D.
Chairman, Medical Division

ORIGINAL SIGNED BY
BILL M. NELSON, M. D.

Bill M. Nelson, M.D.
Pathologist

Original signed by
Granvil C. Kyker

Granvil C. Kyker, Ph.D.
Biochemist

PRECEPTOR STATEMENT
Oak Ridge Institute of Nuclear Studies Medical Division
Oak Ridge, Tennessee
September 14-18, 1959

This is to certify that Dr. Clarence H. Denser, Jr. has received 39 hours of clinical training in the use of radioactive byproduct materials for diagnostic and therapeutic procedures.

	Formal Course Hours
1. Principles and practices of radiological health safety	2
2. Radioactivity measurements, standardization and monitoring techniques and instruments	13
3. Mathematics and calculations basic to the use and measurement of radioactivity	6
4. Biological effects of radiation	2
5. Actual use of radioisotopes in the types and quantities for which application is being made, or equivalent experience	16

Isotope	Maximum Amount	Condition(s) Diagnosed or Treated	Number of Cases	Type of Participation*
I-131	0.015 mc	Diagnosis of thyroid function	6	(1) (2) (3) (4)
	0.10 mc	Diagnosis of thyroid function	2	(1) (2) (3) (4)
	6.0-15 mc	Treatment of hyperthyroidism	2	(1) (4)
	0.015 mc	Blood determinations (labeled serum albumin i.v.)	3	(1) (2) (3) (4)
	150 mc	Scanning and treatment of thyroid carcinoma metastases	2	(1) (3) (4)
	0.50 mc	Intestinal absorption of labeled fat	4	(1) (2) (3) (4)
Cr-51	0.2 mc	Blood determinations (given i.v.)	2	(1) (2) (3) (4)
Fe-59	0.04 mc	Blood determinations (given i.v.)	2	(1) (2) (3) (4)
Co-60	0.005 mc	Test for pernicious aremia (as labeled vitamin B-12)	3	(2) (3) (4)

* Key to above numbers:

1. Examination of patients to determine suitability for radioisotope diagnosis and/or treatment and recommendations on dosage to be prescribed.
2. Collaboration in calibration and administration of dosages including related measurements and plotting of data.
3. Active period of training and experience of sufficient duration to permit follow-up of patients through diagnostic period including re-evaluation as to effectiveness and complications.
4. Study and discussion of case histories to establish most efficacious diagnostic and/or therapeutic techniques for this radioisotope use.

Signed this 18th day of September 1959.

Ralph M. Kniseley, M.D.
Chief of Clinical Research and Training

Bill M. Nelson, M.D.
Pathologist

Item #16 & #17

(2-70)
10 CFR 30

U. S. ATOMIC ENERGY COMMISSION License No. 14-04606-01
Page 1 of 2 Pages

This Copy is For Your File

BYPRODUCT MATERIAL LICENSE
(Medical - Groups I & II)

Amendment No. 10

Pursuant to the Atomic Energy Act of 1954 and Title 10, Code of Federal Regulations, Chapter 1, Parts 30, 32, 33, 34, and 35, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, own, possess, transfer and import byproduct material listed below, and to use such byproduct material for the purpose(s) and at the place(s) designated below. 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 Atomic Energy Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Drs. Coleman and Denser	In accordance with application dated December 26, 1972,
2. 1073 Fifth Street Des Moines, Iowa 50314	3. License Number 14-04606-01 is amended in its entirety to read as follows:
	4. Expiration date January 31, 1978
	5. Reference No.

6. Byproduct material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of radioactivity which licensee may possess at any one time
A. Any byproduct material listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	A. Any radiopharmaceutical listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	A. As necessary for uses authorized in Subitem 9. A.
B. Iodine 131	B. Iodinated Human Serum Albumin	B. 1 millicurie
C. Iodine 125 or 131	C. Triiodothyronine and Thyroxine	C. 1 millicurie

9. Authorized use

A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
B. Placenta localization.
C. In vitro studies.

CONDITIONS

10. Byproduct material shall be used by F. C. Coleman, M. D., C. H. Denser, Jr., M. D., or M. A. Mahervey, M. D.

Conditions numbered 1, 2, 3 and 4 printed on the reverse side of this page shall apply to this license.

030-04694

Date JUL 18 1973

For the U. S. Atomic Energy Commission

by Materials Branch
Directorate of Licensing
Washington, D. C. 20545

8411030213 840914
NMS LIC30
14-18765-01 PDR

CONDITIONS

1. Byproduct material may only be used at the licensee's address stated in Item 2 above.

2. The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 20, "Standards for Protection Against Radiation."

3. Except as otherwise specifically provided by this license, byproduct material to be administered to humans shall be procured in prepackaged, precalibrated form from a supplier who manufactures or repackages the product under appropriate pharmaceutical controls related to assay, identity, quality, purity, sterility, and nonpyrogenicity.

4. Iodine 131 labeled Macroaggregated Iodinated Human Serum Albumin, Chromium 51 labeled Human Serum Albumin, and Iodine 131 labeled Colloidal (Microaggregated) Human Serum Albumin shall be procured from a supplier who holds an unsuspended or unrevoked license issued by the Secretary, Department of Health, Education, and Welfare, to propagate or manufacture and prepare, label, or distribute this material pursuant to Title 42, Chanter 1, Code of Federal Regulations, Part 73, "Biological Products."

5. Needles or standard medical applicator cells containing Cobalt 60 as wire shall not be opened by the licensee unless specifically authorized by a condition in this license.

6. Patients containing Cobalt 60, Cesium 137, and/or Iridium 192 implants shall remain hospitalized until the implants are removed.

7. Patients containing Iodine 131 for the treatment of thyroid carcinoma or patients containing therapeutic quantities of Gold 198 shall remain hospitalized until the residual activity is 30 millicuries or less.

Item #16 & #17

U. S. ATOMIC ENERGY COMMISSION
BYPRODUCT MATERIAL LICENSE
Supplementary Sheet

License Number 14-04606-01

Amendment No. 10

(continued) CONDITIONS

11. Except as specifically provided otherwise by this license, the licensee shall possess and use byproduct material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated December 26, 1972, letter dated May 25, 1973 and application dated October 2, 1964.

Date JUL 18 1973

For the U. S. Atomic Energy Commission

by Materials Branch
Directorate of Licensing
Washington, D. C. 20545

Item #16 & #17

Form AEC-483
(6-68)
10 CFR 31

U.S. ATOMIC ENERGY COMMISSION

REGISTRATION CERTIFICATE—IN VITRO TESTING WITH BYPRODUCT MATERIAL UNDER GENERAL LICENSE

Form Approved
Budget Bureau No.
38-R0160

Section 31.11 of 10 CFR 31 establishes a general license authorizing physicians, clinical laboratories, and hospitals to possess certain small quantities of byproduct material for in vitro clinical or laboratory tests not involving the internal or external administration of the byproduct material or the radiation therefrom to human beings or animals. Possession of byproduct material under 10 CFR 31.11 is not authorized until the physician, clinical laboratory, or hospital has filed Form AEC-483 and received from the Commission a validated copy of Form AEC-483 with registration number.

INSTRUCTIONS

Submit this form in triplicate to: United States Atomic Energy Commission, Washington, D.C. 20545, Attention: Director, Division of Materials Licensing. *A registration number will be assigned and a validated copy of Form AEC-483 will be returned.*

1. Please print or type within the shaded area, below, the name and address (including ZIP Code) of the registrant physician, clinical laboratory, or hospital for whom or for which this registration form is filed.

Drs. Coleman and Denser
Clinical Pathology Laboratory
1073 5th Street
Des Moines, Iowa 50314

2. I hereby apply for a registration number pursuant to § 31.11, 10 CFR 31 for use of byproduct materials for *(please check one)*:

- ☐ a. Myself, a duly licensed physician authorized to dispense drugs in the practice of medicine.
- ☒ b. The above-named clinical laboratory.
- ☐ c. The above-named hospital.

3. To be completed by the Atomic Energy Commission

Registration number: 1135

U. S. ATOMIC ENERGY COMMISSION

BY: Clarence A. Hebren Aug. 23, 1971

(Leave this space blank—number to be assigned by AEC)

4. If place of use is different from address in Item 1, please give complete address:

5. Certification:

I hereby certify that:

a. All information in this registration certificate is true and complete.

b. The registrant has appropriate radiation measuring instruments to carry out the tests for which byproduct material will be used under the general license of 10 CFR 31.11. The tests will be performed only by personnel competent in the use of the instruments and in the handling of the byproduct materials.

c. I understand that Commission regulations require that any change in the information furnished by a registrant on this registration certificate be reported to the Director, Division of Materials Licensing, within 30 days from the effective date of such change.

d. I have read and understand the provisions of Section 31.11 of AEC regulations 10 CFR 31 (reprinted on the reverse side of this form); and I understand that the registrant is required to comply with those provisions as to all byproduct material which he receives, acquires, possesses, uses, or transfers under the general license for which this Registration Certificate is filed with the Atomic Energy Commission.

Date August 9, 1971

By C. H. Denser, M.D.
Signature of person filing form

C. H. Denser, Jr., M. D.

Pathologist

Printed name and title or position of person filing form

WARNING—18 U.S.C., Section 1001: Act of June 25, 1948; 62 Stat. 749; makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

Item #16 & #17

Form AEC-313 (8-64) 10 CFR 30

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

Form approved Budget Bureau No. 38-R027

INSTRUCTIONS — Complete Items 1 through 10 if this is an initial application or an application for renewal of a license. Information contained in previous applications filed with the Commission with respect to Items 8 through 15 may be incorporated by reference provided references are clear and specific. Use supplemental sheets where necessary. Item 16 must be completed on all applications. Mail two copies to U.S. Atomic Energy Commission, Washington, D.C. 20545, Attention: Isotopes Branch, Division of Materials Licensing. Upon approval of this application, the applicant will receive an AEC Byproduct Material License. An AEC Byproduct Material License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Part 20.

1 (a) NAME AND STREET ADDRESS OF APPLICANT (Institution, firm, hospital, person, etc. Include ZIP Code)

Doctors Coleman and Denser
1073 Fifth Street
Des Moines, Iowa 50314

(b) STREET ADDRESS(ES) AT WHICH BYPRODUCT MATERIAL WILL BE USED (If different from 1(a). Include ZIP Code.)

Same

2 DEPARTMENT TO USE BYPRODUCT MATERIAL

Private use

3 PREVIOUS LICENSE NUMBER(S) (If this is an application for renewal of a license, please indicate and give number.)

14-4606-01 (A68)

4 INDIVIDUAL USER(S) (Name and title of individual(s) who will use or directly supervise use of byproduct material. Give training and experience in Items 8 and 9.)

F. C. Coleman, M. D., Pathologist
C. H. Denser, Jr., M. D., Pathologist
M. A. Meservey, M. D., Pathologist

5 RADIATION PROTECTION OFFICER (Name of person designated as radiation protection officer if other than individual user. Attach resume of his training and experience as in Items 8 and 9.)

C. H. Denser, Jr., M. D.

6 (a) BYPRODUCT MATERIAL (Elements and mass number of each)

(b) CHEMICAL AND/OR PHYSICAL FORM AND MAXIMUM NUMBER OF MILLICURIES OF EACH CHEMICAL AND/OR PHYSICAL FORM THAT YOU WILL POSSESS AT ANY ONE TIME (If sealed source(s), also state name of manufacturer, model number, number of sources and maximum activity per source.)

Iodine 131	Iodide	60 millicuries
Iodine 131	Iodinated Human Serum and albumin	10 millicuries
Iodine 131	Triolein or Oleic Acid	10 millicuries
Chromium 51	Chromate	10 millicuries
Iodine 131	Labeled Fats	10 millicuries
Iodine 131	Rose Bengal	10 millicuries
Cobalt 60	Labeled Vitamin B-12	25 microcuries
Cobalt 58	Labeled Vitamin B-12	25 microcuries
Iron 59	Ferric Chloride	10 millicuries
Phosphorus 32	Soluble Phosphate	25 millicuries
Iodine 131 and 125	Triiodothyronine	1 millicurie
Iodine 131	Hippuric acid	2 millicuries
Mercury 197 or Mercury 203	Chlormerodrin	10 millicuries
Gold 198	Colloidal	50 millicuries

7 DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED. (If byproduct material is for human use, supplement A (Form AEC-313a) must be completed in lieu of this item. If byproduct material is in the form of a sealed source, include the make and model number of the storage container and/or device in which the source will be stored and/or used.)

Human Use

~~8411030250~~ 840914
NMS LIC30
14-18765-01 PDR

(Continued on reverse side)

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 4 (Use supplemental sheets if necessary)

8 TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
a Principles and practices of radiation protection	Oak Ridge Institute of Nuclear Studies; Univ. of Michigan Sch. of Med.; Mercy Hospital, Des Moines, Iowa	3 wks '59 4 wks '57	(Yes) No	(Yes) No
b Radioactivity measurement standardization and monitoring techniques and instruments	(On file in connection with License No. 14-4606-1 (A66)		(Yes) No	(Yes) No
c Mathematics and calculations basic to the use and measurement of radioactivity			(Yes) No	(Yes) No
d Biological effects of radiation			Yes No	Yes No

9 EXPERIENCE WITH RADIATION (Actual use of radioisotopes or equivalent experience)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
		Refer to preceptor statements on file for Drs. F. C. Coleman, C. H. Denser, Jr., or M. A. Meservey (License No. 14-4606-1 (A66)		

10 RADIATION DETECTION INSTRUMENTS (Use supplemental sheets if necessary)

TYPE OF INSTRUMENTS (Include make and model number of each)	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE (mr/hr)	WINDOW THICKNESS (mg/cm²)	USE (Monitoring, surveying, measuring)
Scintillation well counter, 1" by 1 35/64 2x2" sodium iodide crystal	1	Gamma, beta			Measuring
Spectroscaler IIA pulse height analyzer and discriminator	1	Alpha, beta, gamma	250-4000 KeV & GM Range		Monitoring & measuri
GM Survey NICC	1	beta, gamma	0.5-20	30 mg/cm²	Monitoring

11 METHOD, FREQUENCY, AND STANDARDS USED IN CALIBRATING INSTRUMENTS LISTED ABOVE

Calibrated against Simulated I-131 Standard each day.
Calibrated against certified Standard once each month

12 FILM BADGES, DOSIMETERS, AND BIO ASSAY PROCEDURES USED (For film badges, specify method of calibrating and processing, or name of supplier)

Picker X-ray Company Film Badge Service. Frequency - once per month.

INFORMATION TO BE SUBMITTED ON ADDITIONAL SHEETS IN DUPLICATE

13 FACILITIES AND EQUIPMENT. Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Explanatory sketch of facility is attached. (Circle answer) Yes (No)

14 RADIATION PROTECTION PROGRAM. Describe the radiation protection program including control measures. If application covers sealed sources, submit leak testing procedures where applicable, name, training, and experience of person to perform leak tests, and arrangements for performing initial radiation survey, servicing, maintenance and repair of the source.

15 WASTE DISPOSAL. If a commercial waste disposal service is employed, specify name of company. Otherwise, submit detailed description of methods which will be used for disposing of radioactive wastes and estimates of the type and amount of activity involved.

CERTIFICATE (This item must be completed by applicant)

16 THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1 CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PART 30, AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

Doctors Coleman and Denser
Applicant named in Item 1

Date December 12, 1967

By _____

C. H. Denser, Jr., M.D., Partner
Title of certifying official

WARNING — 18 U. S. C. Section 1001, Act of June 25, 1948, 62 Stat. 749, makes it a criminal offense to make a willfully false statement or [illegible]

Item #16 & #17

Form AEC-313a
(11-63)
10 CFR 30
PAGE 1

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—HUMAN USE

Form approved
Budget Bureau No. 38-R080

If byproduct material is for "human use" (internal administration of byproduct material, or the radiation therefrom to human beings), complete this supplement and attach to the application for byproduct material license.

1. (a) USING PHYSICIAN'S NAME

Drs. Coleman and Denser
1073 5th St.
Des Moines, Iowa 50314

(b) NAME AND ADDRESS OF APPLICANT (If different from 1 a. Include ZIP Code)

Same

2. THE USING PHYSICIAN INDICATED ABOVE IS LICENSED TO DISPENSE DRUGS IN THE PRACTICE OF MEDICINE BY A STATE OR TERRITORY OF THE UNITED STATES, THE DISTRICT OF COLUMBIA, OR THE COMMONWEALTH OF PUERTO RICO — CIRCLE ANSWER: (YES) NO

3. A STATEMENT OF USING PHYSICIAN'S CLINICAL RADIOISOTOPE EXPERIENCE (PAGE 3 OF THIS SUPPLEMENT) IS SUBMITTED IN SUPPORT OF THIS APPLICATION. IF ANSWER IS NO, USE PAGE 2 OF THIS SUPPLEMENT TO EXPLAIN OR REFER TO OTHER APPLICATION OR RELATED DOCUMENTS ON WHICH THIS INFORMATION APPEARS. — CIRCLE ANSWER: YES (NO)

Refer Licensee No. 14-4606-1 (A66 and A68)

PROPOSED DIAGNOSIS OR TREATMENT

4. (a) DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED INCLUDING SPECIFIC CONDITIONS OR DISEASES TO BE DIAGNOSED OR TREATED (Use page 2 if necessary)

(No changes from those presently covered in the license.)

(b) CHEMICAL FORM ADMINISTERED

(c) DESCRIBE PROCEDURES WHICH WILL BE OBSERVED TO MINIMIZE HAZARD FROM HANDLING, STORAGE, AND DISPOSAL OF THE BYPRODUCT MATERIAL

(d) DESCRIPTION AND SKETCHES OF SPECIAL DEVICES TO BE USED FOR ADMINISTERING BYPRODUCT MATERIAL TO HUMAN BEINGS ARE — CIRCLE ANSWER

(1) ATTACHED (LITERATURE REFERENCES WILL SUFFICE) — YES NO

(2) ON FILE WITH THE ISOTOPES BRANCH
REFER TO APPLICATION NO _____ — YES NO

5. PROPOSED DOSAGE SCHEDULE
(a) In millicuries for internally administered byproduct material other than discrete fixed sources, and in roentgens or rads, as appropriate, for internal or external irradiation from discrete fixed sources (gold seeds, cobalt needles, etc.) state separately for each condition or disease (use page 2 if necessary)

No changes from those presently covered in the license.

(b) INVESTIGATIVE PROPOSAL FOR EXPERIMENTAL, NEW OR UNUSUAL HUMAN USES IS ATTACHED. (Attachment should include outline of conditions to be evaluated, including data from animal studies and/or abstract of literature reference if any, number and type of patients (i. e. age group, moribund, etc.)) — CIRCLE ANSWER: YES NO

6. IF BYPRODUCT MATERIAL WILL NOT BE OBTAINED IN PRECALIBRATED FORM FOR ORAL ADMINISTRATION OR IN PRECALIBRATED AND STERILIZED FORM FOR PARENTERAL ADMINISTRATION, DESCRIBE IDENTIFICATION, PROCESSING, AND STANDARDIZATION PROCEDURES.

7. THE PROPOSED USE OF BYPRODUCT MATERIAL HAS BEEN, OR WILL BE, APPROVED BY THE MEDICAL ISOTOPE COMMITTEE **None** — CIRCLE ANSWER: YES NO

HOSPITAL FACILITIES FOR INDIVIDUAL PRACTICE USE ONLY

8. (a) THE APPLICANT HAS COMPLETED ARRANGEMENTS FOR A HOSPITAL TO ADMIT RADIOACTIVE PATIENTS WHENEVER ADVISABLE — CIRCLE ANSWER: (YES) NO

(b) A COPY OF INSTRUCTIONS TO BE FURNISHED TO THE HOSPITAL AS TO RADIOLOGICAL SAFETY PRECAUTIONS TO BE TAKEN AND AVAILABLE RADIATION INSTRUMENTATION IS ATTACHED — CIRCLE ANSWER: YES (NO)

Form AEC-374 (7-68) 10 CFR 30

This Copy is For Your Files

U. S. ATOMIC ENERGY COMMISSION

BYPRODUCT MATERIAL LICENSE

Amendment No. 09

Pursuant to the Atomic Energy Act of 1954 and Title 10, Code of Federal Regulations, Chapter 1, Parts 30, 32, 33, 34, and 35, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, own, possess, transfer and import byproduct material listed below; and to use such byproduct material for the purpose(s) and at the place(s) designated below. This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, and is subject to all applicable rules, regulations, and orders of the Atomic Energy Commission now or hereafter in effect and to any conditions specified below. In accordance with application dated December 12, 1967 and letter dated January 19, 1968, signed by C. H. Denser, Jr., M.D.

Licensee	
1. Drs. Coleman and Denser	3. License number 14-04606-01 is amended in its entirety to read as follows:
2. 1073 Fifth Street Des Moines, Iowa 50314	4. Expiration date January 31, 1973
	5. Reference No.

6. Byproduct material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of radioactivity which licensee may possess at any one time
A. Iodine 131	A. Iodide	A. 60 millicuries
B. Iodine 131	B. Iodinated Human Serum Albumin	B. 10 millicuries
C. Iodine 131	C. Labeled Fats and/or Fatty Acids	C. 20 millicuries
D. Iodine 131	D. Rose Bengal	D. 10 millicuries
E. Chromium 51	E. Chromate	E. 10 millicuries
F. Cobalt 60	F. Labeled Vitamin B-12	F. 25 microcuries
G. Cobalt 58	G. Labeled Vitamin B-12	G. 25 microcuries
H. Iron 59	H. Ferric Chloride	H. 10 millicuries
I. Iodine 131	I. Triiodothyronine	I. 1 millicurie
J. Iodine 131	J. Labeled Renal Function Compounds	J. 2 millicuries
K. Mercury 197	K. Chlormerodrin	K. 10 millicuries
L. Gold 198	L. Colloidal	L. 50 millicuries
M. Mercury 203	M. Chlormerodrin	M. 10 millicuries

9. Authorized use

A. Diagnosis of thyroid function.
B. Blood volume determinations. Brain tumor localization. Determine the localization of the placenta in cases of suspected placenta previa.

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NMS LIC30
14-18765-01 PDR

Item #16 & #17

AEC-374A
(3-68)

U. S. ATOMIC ENERGY COMMISSION
BYPRODUCT MATERIAL LICENSE
Supplementary Sheet

License Number 14-04606-01

Amendment No. 09

Continued from Page 1

9. Authorized use (Continued)

C. Determination of pancreatic function.
D. Liver function studies.
E. Plasma and blood volume determinations.
F. and G. Diagnosis of pernicious anemia.
H. Iron absorption studies.
I. In vitro thyroid uptake studies.
J. Renograms.
K. Brain and renal scans.
L. Liver scans.
M. Brain scans.

CONDITIONS

10. Byproduct material may only be used at the licensee's address stated in Item 2 above.

11. The licensee shall comply with the provisions of Title 10, Part 20, Code of Federal Regulations, Chapter 1, "Standards for Protection Against Radiation."

12. Byproduct material shall be used by F. C. Coleman, M.D., C. H. Denser, Jr., M.D., or M. A. Meservey, M.D.

13. Byproduct material shall not be used in humans until its pharmaceutical quality and assay have been established.

For the U. S. Atomic Energy Commission

by Isotopes Branch
Division of Materials Licensing
Washington, D. C. 20545

Date JAN 31 1968

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

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Larry Weldy	

3. CERTIFICATION

SPECIALTY BOARD (A)	CATEGORY (B)	MONTH AND YEAR CERTIFIED (C)
ASCP	MT	1975
ASCP	SBB	1982

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING (A)	LOCATION AND DATE(S) OF TRAINING (B)	TYPE AND LENGTH OF TRAINING: LECTURE/LABORATORY COURSES (Hours) (C)	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) (D)
a. RADIATION PHYSICS AND INSTRUMENTATION	South Bend Med. Foundation 1975 Univ. of Texas Med. Branch - Galveston 1977 Central Indiana Reg. B. C. 1978	> 10	> 20 > 10
b. RADIATION PROTECTION	South Bend Med. Foundation 1975	> 10	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	South Bend Med. Foundation 1975	> 10	
d. RADIATION BIOLOGY	South Bend Med. Foundation 1975	> 10	
e. RADIOPHARMACEUTICAL CHEMISTRY	South Bend Med. Foundation 1975 U. of Texas Med. Branch - Galveston 1977 Central Indiana Reg. B.C. 1978-82	> 10	> 20 > 10

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
I^{125}	.5 mc	University of Texas Medical Branch - Galveston	1 year	HBsAg testing
		Central Indiana Regional Blood Center	4 years	HBsAg testing
		The Blood Center of Central Iowa	1½ years	HBsAg testing and markers

Atomic Energy of Canada Limited
L'Énergie Atomique du Canada, Limitée

Commercial Products
Produits Commerciaux

P.O. Box 6300
Ottawa, Canada
K2A 3W3

C.P. 6300
Ottawa, Canada
K2A 3W3

Tel. (613) 592-2790
Telex 053-4162

1984 May 31

Mr. Larry Weldy
The Blood Center of Central Iowa
1050 Seventh Street
DES MOINES, Iowa
U.S.A. 50314

Dear Mr. Weldy,

In response to your telecon on May 29, 1984, please note the following training procedures on the Gammacell-1000.

1. During installation of the Gammacell 1000 customer's maintenance personnel will be encouraged to watch installation procedures; thereby obtaining first hand experience on how unit is assembled.

2. The customer will be familiarized on the operation and maintenance of the unit. This will be done by going through, step by step, the Gammacell 1000 operator's manual (copy enclosed)

3. The customer will be shown how to operate unit, perform minor maintenance, conduct wipe tests plus how to perform survey checks.

4. AECL technician will answer customer's questions on the radiation and the Gammacell 1000.

Should you require further information or assistance, please do not hesitate to contact us.

Yours truly,

Paul Moses
Area Manager
Industrial Irradiators

PM:mr

Item #18

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

MAR 1 5 1984

The Blood Center of Central Iowa
ATTN: Mr. Charles W. Osier
1050 7th Street
Des Moines, Iowa 50314

REFUND OF APPLICATION FEE

1. BACKGROUND:

Check Received March 5, 1984

Application Dated February 21, 1984

Check Number 16562

Check Amount $390

2. REFUND:

Amount $200

This refund is now being processed by the Office of Resource Management and will be sent as soon as possible.

3. REASON FOR REFUND:

Overpayment of application fee specified in fee category 3E ($190) of 170.31, 10 CFR 170, for application dated February 21, 1984, for an amendment to Materials License 14-18765-01 to include an irradiator.

Glenda Jackson
License Fee Management Branch
Office of Administration

2pp.

THE
BLOOD CENTER
OF CENTRAL IOWA

16562

33-59
730

1050 SEVENTH STREET DES MOINES, IOWA 50314
(515) 288-0276

HAWKEYE BANK & TRUST OF DES MOINES
DES MOINES, IOWA

PAY ***390 00 CTS

DOLLARS

TO THE ORDER OF U.S. Nuclear Regulatory Comm.

DATE	NET CHECK
2-22-84	390.00

⑈016562⑈ ⑆073000590⑆ 016 602 5⑈

REFERENCE		AMOUNT
16562	7165	390 00
CHECK NO.	DISCOUNT	GROSS

IN PAYMENT OF THE ABOVE INVOICES
PLEASE DETACH BEFORE DEPOSITING

THE BLOOD CENTER
OF CENTRAL IOWA
1050 SEVENTH STREET
DES MOINES, IOWA 50314
(515) 288-0276

Item #18

The Blood Center OF CENTRAL IOWA

June 4, 1984

U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Dear Sirs:

I have enclosed an application in addition to our original application which is an amendment to our license #14-18765-01. Our application is mail control #17075.

We would appreciate it if you would expedite this application as soon as possible, since the physicians in this area are in need of the service that an irradiator will supply. If there are any problems or if you have any questions, please feel free to contact me.

Sincerely,

Charles W. Osier

Charles W. Osier
Director

CWO:nh

Enclosures

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NMS LIC30
14-18765-01 PDR

JUN 6 1984

38pp

1050 SEVENTH STREET • DES MOINES, IOWA 50314 • 515-288-0276
A NON-PROFIT ORGANIZATION

GAMMACELL 1000

OPERATOR'S MANUAL

EDITION 2
MAY 1983
TECHNICAL PUBLICATIONS
DOCUMENT No. IN-J1100-83-04A
STOCK No. 2M002111

Atomic Energy
of Canada Limited
Radiochemical Company

413 March Road,
P.O. Box 13500,
Kanata, Ontario,
Canada,
K2K 1X8

RECORD OF REVISIONS

EDITION NO.	ISSUE DATE	PAGE NO.
	NOTE	
	The portion of the text affected by the changes is indicated by a vertical line in the outer margins of the pages.	
1	February 1983	Original Issue
2	May 1983	General Revision

TABLE OF CONTENTS

LIST OF ILLUSTRATIONS AND TABLES

PART 1
INTRODUCTION

1.1 GENERAL

This manual describes the operation of the Gammacell-1000 (GC-1000).
The operator is expected to operate the GC-1000 according to this manual. Any unauthorized deviation from the procedures laid down in this manual, can affect the contractual obligations between buyer and seller as pointed out in paragraphs 1.1.1 and 1.1.2.

1.1.1 IMPORTANT NOTICE

(a) Concerning the Manner of Use of GC-1000

Atomic Energy of Canada Limited, Radiochemical Company (AECL-RCC), assumes no responsibility for the use or misuse of the equipment. Since AECL-RCC cannot control the use of this equipment, they shall not be responsible for personal injury or damage resulting therefrom.

The customer is advised

- to operate the equipment according to the instructions contained herein,
- to observe all cautions and warnings,
- to assure the proper maintenance of the equipment,
- to consult local, state and federal regulations, and
- to ensure that only properly instructed personnel is permitted to operate the unit.

(b) Concerning this Publication

Information contained in this publication is subject to change without notice.

AECL-RCC makes no warranty, either expressed or implied, including but not limited to any implied warranties of merchantability and fitness for a particular purpose, regarding this publication, and makes publications such as this available solely on an 'as is' basis. In no event shall AECL-RCC be liable to anyone for direct, indirect, special, collateral, incidental, or consequential damages in connection with or arising out of the purchase or use of this publication and the sole and exclusive liability to AECL-RCC shall not exceed the purchase price of this material. Moreover, AECL-RCC shall not be liable for any claim of any kind whatsoever against the user of this publication by any other party.

1.1.2 ABOUT THE WARRANTY OF THE EQUIPMENT

An installed GC-1000 is warranted to the original purchaser to be free from defects in materials or workmanship under prescribed service and operating conditions for a specified period from the date of acceptance. AECL-RCC agrees to repair, adjust, or replace -- as AECL determines -- any part or parts found to be defective.

AECL requires that the operator operates the GC-1000 properly as specified in this manual and assures its proper maintenance. Any misuse, modification or alteration of the GC-1000 cancels this warranty. Warranty service can only be provided by AECL-RCC or its authorized representative.

These terms, more expressly stated in Terms and Conditions (of purchase), constitute the sole and exclusive liability of the company and remedy of the purchaser respecting the GC-1000 and is in lieu of all warranties, whether written, oral, implied or statutory including, but not limited to, warranties of merchantability and fitness for a particular

purpose and all other obligations or liabilities either in contract, tort, or otherwise, including negligence. In no event shall AECL-RCC be liable to anyone for direct, indirect, special, collateral, incidental or consequential damages. Moreover, AECL-RCC shall not be liable for any claim of any kind whatsoever against the user of the GC-1000 by any other party. The product life of the GC-1000 under normal conditions of use with scheduled maintenance is expected to be 20 years.

1.2 DEFINITIONS

Warnings, cautions and notes are included in this manual as a means of bringing crucial information to the operator's attention.

WARNING

A WARNING is a statement describing known situations which could result in injury or death of personnel.

CAUTION

A CAUTION is a statement describing known situations which could result in damage to equipment or product.

NOTE

A NOTE is a statement of additional information about situations known to require special attention.

1.3 RELATED PUBLICATIONS

The following publications are available:

- sales brochures
- selected bibliography related to blood irradiation
- Gammacell-1000 Technical Specification (IN/PR 0009 J1100)

1.4 ABBREVIATIONS AND SYMBOLS

Non-standard abbreviations and symbols used in this manual are explained in the text on first mention. For easy reference these non-standard abbreviations and symbols have also been compiled in Table 1-1.

Table 1-1. Non-standard Abbreviations and Symbols

ABBREVIATION/ SYMBOL	DEFINITION
AECL-RCC	Atomic Energy of Canada Limited (Radiochemical Company)
GC-1000	Gammacell-1000 Irradiator
CDR	Central Dose Rate
ICRP	International Commission on Radiation Protection
ADR	Average Dose Rate

PART 2
DESCRIPTION

2.1 GENERAL

The Gammacell-1000 is a self-contained irradiator designed for small biological samples. The unit consists of stationary Caesium-137 doubly encapsulated radiation source permanently secured within the biological shield. The biological shield is mounted on a steel frame and covered with sheet-metal panels for aesthetic purposes. The biological shield contains the sample chamber rotor. By turning the rotor through an arc of up to 180°, the sample chamber is either exposed to or removed from the radiation field. The movement of the rotor is accomplished by an electrical drive assembly mounted on the top of the biological shield. A control panel is located at the top of the front face of the unit. A cross-sectional view identifying all the main components of the unit is shown in Fig. 2-1.

2.2 RADIOACTIVE SOURCE

The radioactive source consists of an array of up to four pencils, Model ISO-1000, containing Caesium-137. The unit comes in four models depending on the number of ISO-1000 pencils used. Table 2-1 lists the unit model, number of pencils and associated nominal activity.

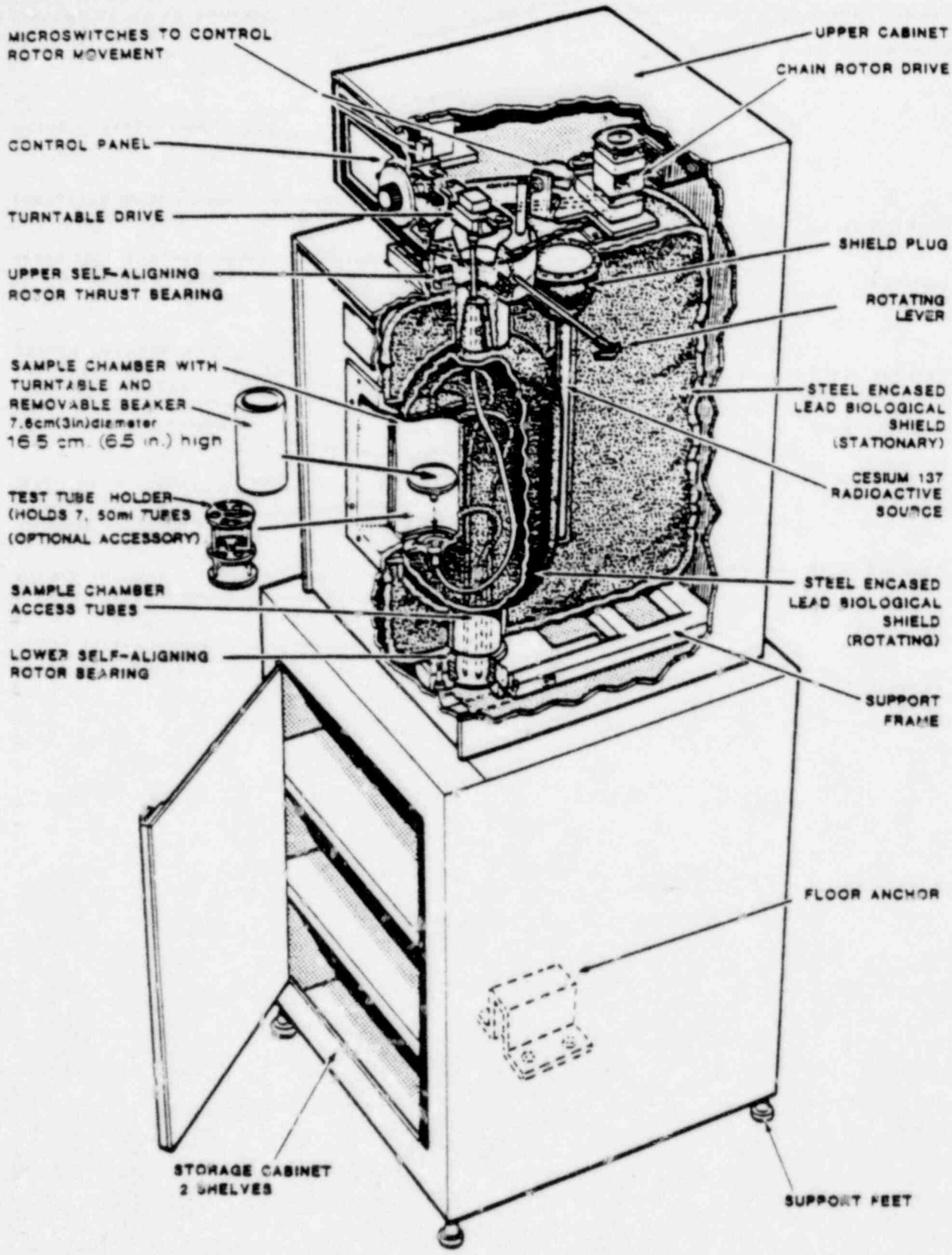


Fig. 2-1. Gammacell-1000 Irradiator

Table 2-1. **Gammacell-1000 Radioactivity for Models A,B,C and D**

UNIT MODEL	NUMBER OF PENCILS	NOMINAL ACTIVITY [Ci ± 20%]
A	1	600
B	2	1200
C	3	1800
D	4	2400

The radioactive source is stationary and permanently housed within the stator section of the biological shield.

The ISO-1000 pencils consist of Caesium-137, doubly encapsulated in stainless steel.
The Caesium-137 is normally in a form of caesium chloride.

2.3 BIOLOGICAL SHIELD

The biological shield consists of two parts; the stator containing the radiation source, and the rotor containing the sample chamber. Both parts of the shielding are fabricated of lead totally encased in steel jackets. The maximum radiation levels on the outside surface of the fully loaded unit (models) are within the levels specified by ICRP-33 which are summarized in Table 2-2.

Table 2-2. Radiation Leakage Limits

POSITION	RADIATION LEVEL (mrem/h)
5 cm from the surface*	20
100 cm from the source	2

*For this purpose the outside surface of the unit is defined as that of the sheet-metal cabinets.

2.4 CONTROLS AND SAFETY FEATURES

All controls are located at the control panel which is shown in Fig. 2-2.

2.4.1 SAFETY SWITCH (S-5)

The safety switch must be depressed at the same time as the START/STOP switch (S-3) is depressed to the START position. This ensures that both hands of the operator are away from the sample chamber to avoid potential injury.

2.4.2 POWER KEYSWITCH (SW-1)

The keyswitch is a three-position switch (off, on, and momentary). The switch, through its "momentary reset" and "on" contacts activates the control circuitry and primes the unit for use.

2.4.3 POWER RESET LIGHT (WHITE)

This light is turned on by the 'momentary reset' contacts of SW-1. It indicates that the control circuitry is activated and ready. In case of a power failure during irradiation

2.4.8 START/STOP SWITCH (S-3)

Switch S-3 in the START position, together with safety control (S-5) causes the sample chamber to move into the irradiate position. It is used in both the automatic and manual modes of operation. Both switches must be held closed simultaneously until the chamber reaches the irradiate position. The STOP position is used to terminate irradiation.

2.4.9 AUTO/MANUAL SWITCH

This is a selector switch. When switched to MAN, the timer is bypassed and the irradiation period must be terminated by the START/STOP switch (S-3). When the switch is set to AUTO, the irradiation is terminated automatically by the timer.

2.4.10 TURNTABLE SWITCH (S-1)

This switch actuates the turntable inside the sample chamber.

2.4.11 EMERGENCY HANDLE

Should there be a need to retrieve a sample during a power failure, the sample chamber can be returned to its load position manually. For this purpose, the unit is equipped with a handle which, when inserted into the drive drum (visible in a slot just below the control panel), can be used to turn the rotor.

CAUTION

This feature is included to facilitate retrieval of samples. To avoid damage to the equipment, it should not be used under any circumstances for routine operation.

2.5 SAMPLE CHAMBER

The sample chamber is equipped with a turntable and a removable stainless-steel beaker. **The combination of the turntable and the beaker ensures that the radiation characteristics of the unit described in Part 4 are attained.**

The useable irradiation volume, based on the internal dimensions of the beaker, is 750 cubic centimeters (7.6 cm diameter x 16.5 cm high).

Further, the sample chamber is equipped with three instrumentation access tubes (3/8-inch ID) which terminate at the bottom of the rotor inside the storage cabinet. On the chamber side, one tube terminates at the top, and two terminate at the side wall.

2.6 TEST TUBE HOLDER (optional)

A test tube holder is available with the unit as an option. It is designed to accommodate seven standard 50-ml test tubes. The tube holder may be used to irradiate small liquid samples. It is placed into the sample chamber in the same manner as the standard beaker; i.e., on top of the turntable.

The user is advised to confirm the dose and dose rate distribution within given test samples.

PART 3
OPERATING INSTRUCTIONS

3.1 SWITCHING THE UNIT ON

(1) Ensure that the electrical supply cord (located at the rear of the unit) is plugged into a suitable wall outlet.

(2) Insert the machine key. Turn the power keyswitch to MOMENTARY RESET position, and release it.

(3) Observe that the switch remains in the ON position. The white POWER RESET light and green LOAD POSITION light are illuminated.

The unit is now ready for either manual or automatic control operation.

3.2 LOADING OF SAMPLE INTO THE IRRADIATION CHAMBER

(1) Insert the sample (blood bag) into the beaker provided.

(2) Ensure that there are no parts of the sample protruding outside the edges of the beaker. Tape the sample down, if necessary.

(3) Place the beaker onto the turntable, and set the TURNTABLE switch to ON.

(4) Observe and ensure that the beaker rotates without interference.

CAUTION

Improper loading could cause the beaker not to rotate with consequent non-uniform exposure of the sample.

3.3 VARIABLE DOSE RATE

The variable dose rate feature can be used with either manual or automatic control operation.

(1) Referring to Table 4-2, select the guide number (0 through 100) which corresponds to the desired dose rate.

(2) Loosen the locking screw on the dial (located at 9 o'clock position), and rotate the dial to the selected guide number.

(3) Tighten the locking screw.

3.4 MANUAL CONTROL OPERATION

NOTE

This mode is used only when automatic operation; i.e., 99.9 minutes, would not provide a sufficient dose to the sample.

(1) Ensure that a stopwatch or a suitable clock is on hand.

(2) Load the sample (see 3.2).

(3) Move the selector switch to MANUAL.

(4) Press the START switch and SAFFTY switch simultaneously, and hold them until the IRRADIATE POSITION light comes on.

(5) Start the stopwatch or clock.

(6) To terminate the irradiation, push the STOP switch momentarily.

3.5 AUTOMATIC CONTROL OPERATION

(1) Load the sample (see 3.2).

(2) Move the selector switch to AUTO.

(3) Dial the desired irradiation time on the timer by turning the knobs located below each display digit.

(4) Press the START switch and SAFETY switch simultaneously, and hold until the IRRADIATION POSITION light comes on.

WARNING

Failure to keep hand out of the sample chamber while the rotor is turning could result in injury to hands and fingers.

The irradiation is terminated automatically when the timer count reaches zero (00.0).

3.6 EMERGENCY OPERATION

CAUTION

The handle used in an emergency is included to facilitate retrieval of samples. To avoid damage to the equipment, it should not be used under any circumstances for routine operation.

(1) Insert the handle, which is normally stored on the upper shelf of the storage cabinet, into the drive drum. For this purpose, a blind hole is located in the drum perimeter which is visible in the slot just below the control panel. With the sample chamber in the IRRADIATE position, the hole is on the left-nand side of the drum.

(2) Press the spring-loaded handle in, and slowly rotate the drum counterclockwise until the chamber is fully in the LOAD POSITION.

PART 4
RADIATION CHARACTERISTICS

CAUTION

The user is responsible for selecting the correct radiation dose and ensuring that it has been delivered.

4.1 GENERAL

The radiation characteristics of the unit vary with model number and actual radioactive contents. The actual radioactive contents may vary ±20% from the nominal values associated with each model (Table 2-1), hence the central dose rate (CDR) varies accordingly. The actual CDR and the actual radioactive contents (curies) are measured by AECL-RCC for each individual unit and their values are provided to customers in a form of a Measurement Certificate (refer to Appendix A for a sample copy). The dial-a-dose and dose rate distribution values are given as percentages of the CDR. They are not functions of the radioactive content but constants based on the designed configuration of the unit.

NOTE

All information provided on the radiation performance of the unit is for the 'as designed' condition. Therefore, for the data to be applicable, the unit must be used with the beaker and the sample chamber turntable operating.

4.2 CENTRAL DOSE RATE

The central dose rate provided on the Measurement Certificate is measured in air and its location corresponds to the geometrical center of the available irradiation volume.

For liquids (such as a blood bag), which are for all intents and purposes evenly distributed in the beaker, the CDR value in air can be converted to an average dose rate (ADR) to the liquid by the following relation:

Average dose rate = 0.89 x CDR

The CDR and the curie content are functions of time. The rate of Caesium-137 decay with respect to time is shown in Table 4-1. The table lists fractions of the original curie content as a function of time in one-month intervals.

4.3 VARIABLE DOSE RATE

The relationship between the guide number (0-100) and a percentage of a given CDR is shown in Table 4-2. The actual values may vary slightly from unit to unit as a function of manufacturing tolerances. This variation is within ± 2 guide numbers from the nominal values shown.

4.4 DOSE RATE DISTRIBUTION

The dose rate distribution in air within the sample beaker with the chamber turntable rotating is shown in Fig. 4-1. It is given as a percentage of a given CDR.

YEARS	Months 0.0	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0
0.00	1.0000	.9980	.9961	.9942	.9923	.9904	.9885	.9866	.9847	.9828	.9809	.9790
1.00	.9771	.9752	.9734	.9715	.9696	.9677	.9659	.9640	.9622	.9603	.9585	.9566
2.00	.9548	.9530	.9511	.9493	.9475	.9456	.9438	.9420	.9402	.9384	.9366	.9348
3.00	.9330	.9312	.9294	.9276	.9258	.9240	.9223	.9205	.9187	.9170	.9152	.9134
4.00	.9117	.9099	.9082	.9064	.9047	.9029	.9012	.8995	.8977	.8960	.8943	.8926
5.00	.8908	.8891	.8874	.8857	.8840	.8823	.8806	.8789	.8772	.8755	.8739	.8722
6.00	.8705	.8688	.8672	.8655	.8638	.8622	.8605	.8588	.8572	.8555	.8539	.8523
7.00	.8506	.8490	.8473	.8457	.8441	.8425	.8408	.8392	.8376	.8360	.8344	.8328
8.00	.8312	.8296	.8280	.8264	.8248	.8232	.8216	.8201	.8185	.8169	.8153	.8138
9.00	.8122	.8106	.8091	.8075	.8060	.8044	.8029	.8013	.7998	.7982	.7967	.7952
10.00	.7937	.7921	.7906	.7891	.7876	.7860	.7845	.7830	.7815	.7800	.7785	.7770
11.00	.7755	.7740	.7725	.7711	.7696	.7681	.7666	.7651	.7637	.7622	.7607	.7593
12.00	.7578	.7564	.7549	.7534	.7520	.7505	.7491	.7477	.7462	.7448	.7434	.7419
13.00	.7405	.7391	.7377	.7362	.7348	.7334	.7320	.7306	.7292	.7278	.7264	.7250
14.00	.7236	.7222	.7208	.7194	.7180	.7167	.7153	.7139	.7125	.7112	.7098	.7084
15.00	.7071	.7057	.7043	.7030	.7016	.7003	.6989	.6976	.6962	.6949	.6936	.6922
16.00	.6909	.6896	.6883	.6869	.6856	.6843	.6830	.6817	.6803	.6790	.6777	.6764
17.00	.6751	.6738	.6725	.6712	.6699	.6687	.6674	.6661	.6648	.6635	.6622	.6610
18.00	.6597	.6584	.6572	.6559	.6546	.6534	.6521	.6509	.6496	.6484	.6471	.6459
19.00	.6446	.6434	.6422	.6409	.6397	.6385	.6372	.6360	.6348	.6336	.6323	.6311
20.00	.6299	.6287	.6275	.6263	.6251	.6239	.6227	.6215	.6203	.6191	.6179	.6167
21.00	.6155	.6143	.6132	.6120	.6108	.6096	.6085	.6073	.6061	.6049	.6038	.6026
22.00	.6015	.6003	.5992	.5980	.5968	.5957	.5946	.5934	.5923	.5911	.5900	.5889
23.00	.5877	.5866	.5855	.5843	.5832	.5821	.5810	.5799	.5787	.5776	.5765	.5754
24.00	.5743	.5732	.5721	.5710	.5699	.5688	.5677	.5666	.5655	.5644	.5633	.5623
25.00	.5612	.5601	.5590	.5579	.5569	.5558	.5547	.5537	.5526	.5515	.5505	.5494
26.00	.5484	.5473	.5463	.5452	.5442	.5431	.5421	.5410	.5400	.5389	.5379	.5369
27.00	.5358	.5348	.5338	.5328	.5317	.5307	.5297	.5287	.5276	.5266	.5256	.5246
28.00	.5236	.5226	.5216	.5206	.5196	.5186	.5176	.5166	.5156	.5146	.5136	.5126
29.00	.5116	.5107	.5097	.5087	.5077	.5067	.5058	.5048	.5038	.5028	.5019	.5009
30.00	.5000	.4990	.4980	.4971	.4961	.4952	.4942	.4933	.4923	.4914	.4904	.4895
31.00	.4885	.4876	.4867	.4857	.4848	.4838	.4829	.4820	.4811	.4801	.4792	.4783
32.00	.4774	.4765	.4755	.4746	.4737	.4728	.4719	.4710	.4701	.4692	.4683	.4674
33.00	.4665	.4656	.4647	.4638	.4629	.4620	.4611	.4602	.4593	.4585	.4576	.4567
34.00	.4558	.4549	.4541	.4532	.4523	.4514	.4506	.4497	.4488	.4480	.4471	.4463

Table 4-1. Caesium-137 Decay Function

Table 4-2. Percentage of CDR as a Function of Guide Number

GUIDE NUMBER SETTING	PERCENTAGE OF CDR FOR EACH MODEL			
	A	B	C	D
100	100	100	100	100
95	99.8	99.8	99.8	99.9
90	99.0	99.2	99.2	99.8
85	97.6	98.0	98.0	99.1
80	95.8	96.3	96.3	97.9
75	93.6	94.3	94.3	96.2
70	91.0	92.1	92.1	94.2
65	88.1	89.4	89.4	92.1
60	85.2	86.6	86.6	89.6
55	82.1	83.8	83.8	85.8
50	79.0	80.5	80.5	79.9
45	76.0	77.1	77.1	72.8
40	72.6	71.9	72.1	65.4
35	69.0	64.0	66.0	58.8
30	64.6	54.2	58.2	52.0
25	59.1	44.2	50.3	45.1
20	49.8	34.2	44.0	38.6
15	34.8	24.1	38.0	33.3
10	23.1	16.2	32.0	28.1
5	15.0	10.0	26.0	23.0
0	9.1	5.9	20.0	17.8

For in-between values, linear interpolations is permissible.

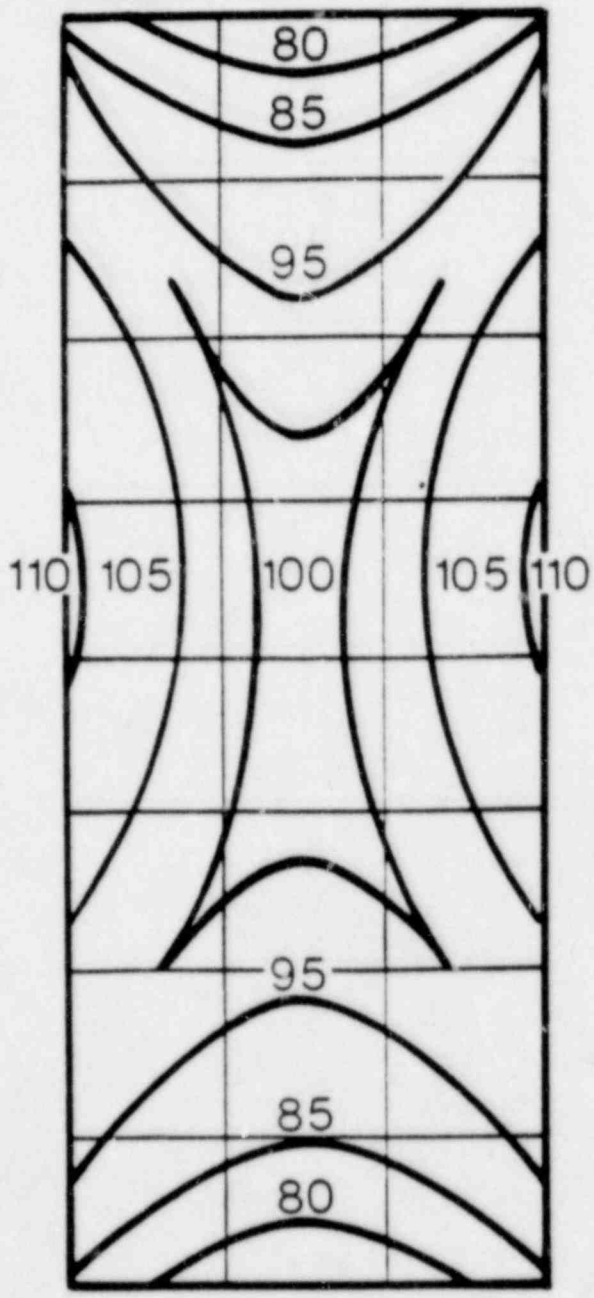


Fig. 4-1. Dose Rate Distribution as a Percentage of CDR

PART 5
PERIODIC MAINTENANCE AND INSPECTION

5.1 GENERAL

The unit, when operated in normal room conditions (room temperatures and no excessive dust), requires minimum maintenance. The unit should be kept in clean condition, and any spills of liquids or powders inside the sample chamber should be cleaned thoroughly and immediately.

CAUTION

Spills of materials inside the sample chamber could result in seizing of the turntable with subsequent loss of the uniformity of exposure to samples.

5.2 PERIODIC LUBRICATION AND INSPECTION

Several moving parts require lubrication, electrical connections require inspection, and electrical switches may require adjustment or replacement.

5.2.1 EVERY 6 MONTHS

For component layout and identification, refer to Fig. 5-1.

(1) Disconnect the unit from the wall outlet.

(2) Remove the top panel of the upper cabinet.

(3) Inspect all electrical connections for looseness.

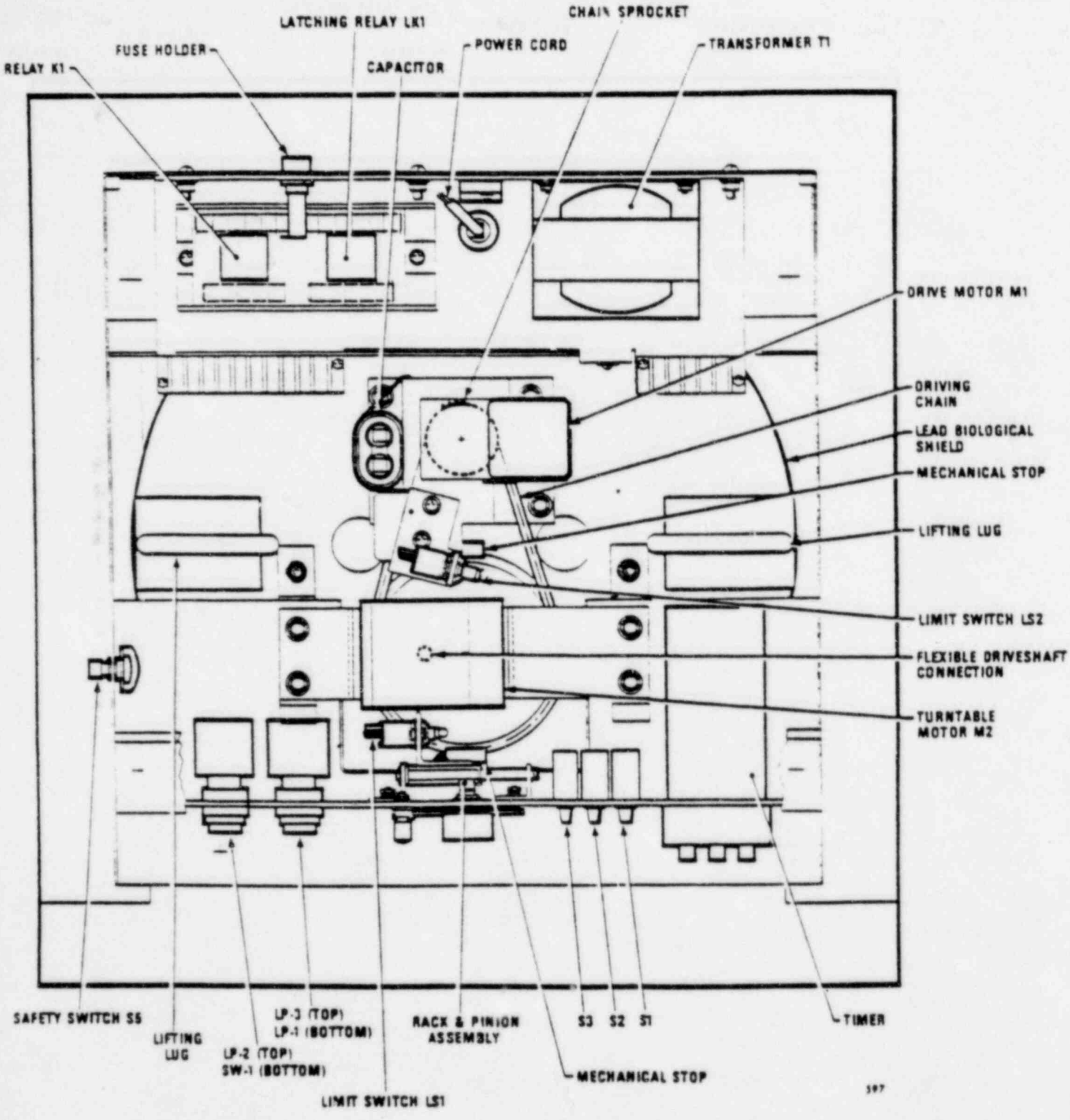


Fig. 5-1. Gammacell-1000 Identification of Control Components

(4) Wipe clean and lightly lubricate (with SAE10 oil) the driving chain.

(5) Wipe clean and lightly lubricate (with SAE10 oil) the rack-pinion mechanism and its guiding rails.

(6) Replace the top panel, and reconnect the cord of the unit to the power outlet.

(7) Switch the unit to manual mode of operation. With the dial-a-dose set at 100, observe the mechanical stops on the drive drum (visible in a slot below the control panel). For both load and irradiate positions the stops should come to a near contact (0.010-inch separation). If "hard" contact is observed at either position, the limit switches (LS-1 and LS-2) must be readjusted.

5.2.2 ANNUALLY

Replace rotor limit switches (LS1 and LS2).

PART 6
CONTAMINATION CHECK

6.1 GENERAL

The installation and use of the GC-1000 are subject to conditions of a license issued by the local regulatory or health authority. A usual condition of such license is a periodic contamination check. Any (real or suspected) contamination must be immediately reported to the local regulatory or health authority and AECL-RCC. Since all accessible surfaces of the unit are by design essentially contamination-free, presence of Caesium-137 on the wipes represents a potentially hazardous situation. Notwithstanding conditions of a license, AECL-RCC recommends that the contamination check is carried out and documented at least every six months.

The following paragraph describes a recommended contamination check procedure and instrumentation requirements.

6.2 REMOVABLE CONTAMINATION

Usually the maximum permissible level of removable radioactive contamination from the unit is 0.050 microcuries from components most likely to be contaminated. (See 6.4.)

6.3 INSTRUMENTATION

Most detection instruments read in counts per minute rather than curies. To convert counts per minute into curies, one must use the following relationship:

Permissible Rate* (c/min) = 0.050 (μCi)/IDE (μCi/min/c)

where IDE is the calibrated instrument detection efficiency for Caesium-137 (beta/gamma).

6.4 WIPE PROCEDURE

(1) Thoroughly wipe the entire surface of the sample chamber cavity with high wet strength material and outside of rotor with sample chamber in IRRADIATE position.

(2) With new piece of material repeat the wipe on the top and bottom of the biological shield.

WARNING

To access the top of the biological shield, the top cabinet panel must be removed. Before the panel is removed, ensure that the power supply cord has been disconnected to avoid electrical shock.

(3) Count all three wipes in the area where there is background radiation only.

If the count rate is below the permissible rate but above background, repeat the test. If same results are obtained, notify local regulatory or health authority and AECL-RCC immediately.

If the count rate exceeds the permissible rate, take the unit out of service and notify the local regulatory or health authority and AECL-RCC immediately. In this case, isolate the unit by covering it with a plastic sheet and close off the surrounding area. Begin monitoring personnel for potential contamination.

*Above background.

PART 7
TROUBLESHOOTING GUIDE

In case the unit or any of its components malfunction Table 7-1 (Troubleshooting Chart) can help identify the cause of the problem and suggests possible corrective actions. Should the problem remain unresolved or be more complex than any of the possibilities listed in Table 7-1, contact AECL-RCC or its authorized representative for further advice.

NOTE

Before proceeding with the steps listed in Table 7-1, ensure that the correct operating procedure, described in Part 3, has been followed.

For component identification and schematic of electrical wiring, refer to Fig. 5-1 and Fig. 7-1.

Table 7.1. Troubleshooting Chart

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
POWER RESET light does not come ON	Faulty fuse	Replace
	Burned light bulb	Replace
	Faulty switch (SW-1)	Replace
	Faulty relay (K-1)	Replace
TURNTABLE does not turn	Slipping or worn flexible drive shaft	Tighten set screw on motor shaft Replace
	Faulty drive motor	Replace
	Foreign matter built-up at the bottom of the cavity	Clean up
SAMPLE CHAMBER does not turn	Faulty safety switch (S5)	Replace
	Faulty start switch (S3)	Replace
	Faulty limit switches (LS-1 and/or LS-2)	Replace
	Faulty drive mechanism - broken chain - chain sprocket slipping on the motor shaft - burnt-up motor	 Replace Tighten sprocket set screw Replace
	Faulty latching relay (LK-1)	Replace
	Faulty relay (K-1)	Replace
TIMER not counting	Faulty limit switch (LS-1)	Replace
	Faulty timer	Replace/repair

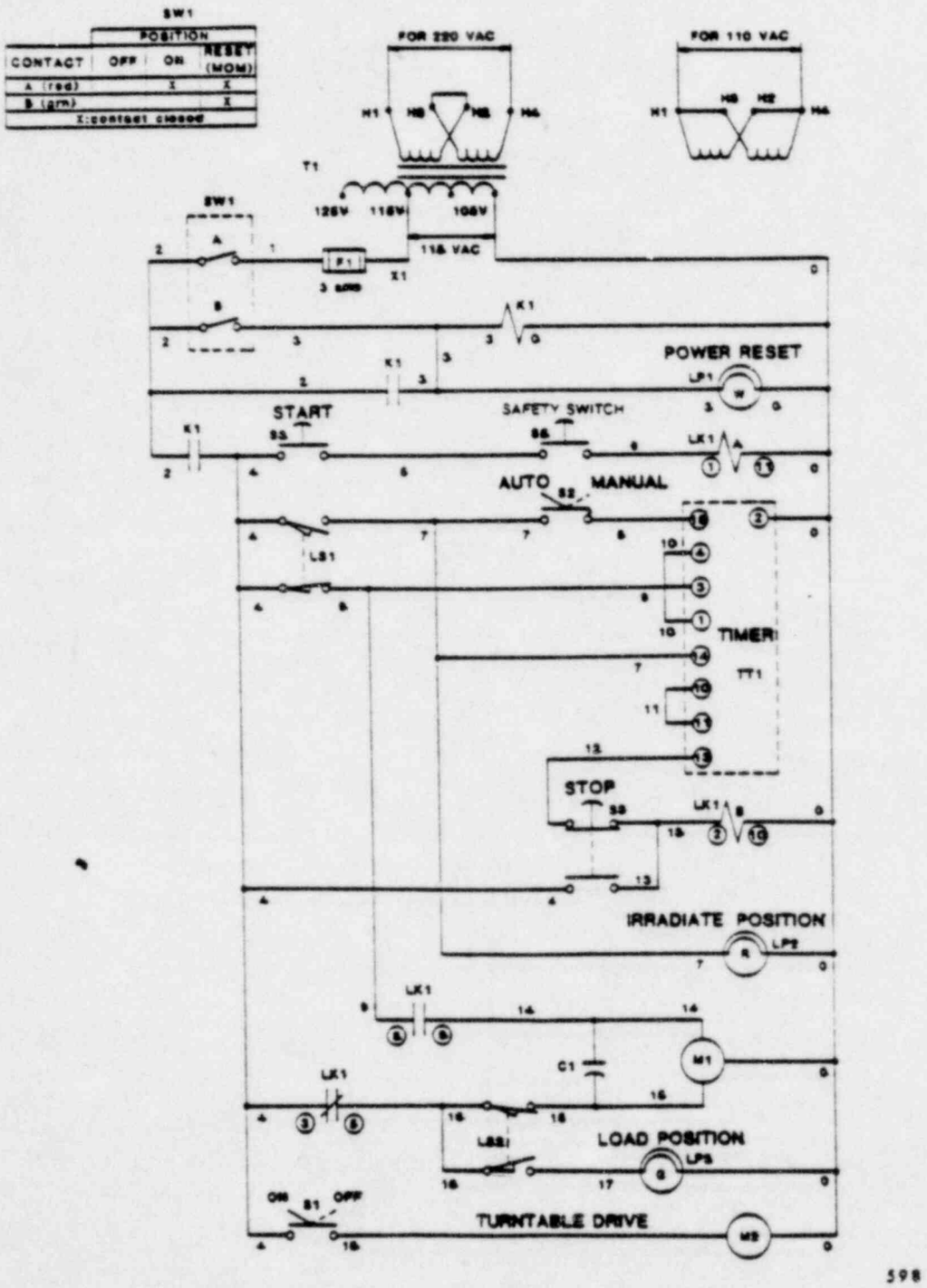


Fig. 7-1. Gammacell-1000 Schematic of Electrical Wiring

A

APPENDIX A

Certificate Of Measurement

GAMMACELL 1000 No.

This Gammacell is loaded with source no.
containing curies of Cesium-137 in Pencil
( ).

When the dose rate at the centre of the chamber
was measured on , it was:

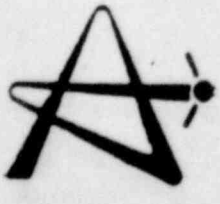
The dose rate at the centre of the chamber was measured by Ferrous Sulphate dosimetry placed in a stainless steel beaker provided, as per Quality Control Specification QC-16-3516.

Accuracy of estimated dose rate is ± % at the % confidence limits.

ISSUED_____

_____Quality Control

M.T. Antoniades



ATOMIC ENERGY OF CANADA LTD., RADIOCHEMICAL COMPANY,
KANATA, ONTARIO, CANADA

QUALITY CONTROL SPECIFICATION QA3-2

TITLE: CHEMICAL DOSIMETRY

The absorbed gamma radiation dose rate was measured by Fricke dosimetry (ASTM D1671-63) which is calibrated spectrophotometrically with acidified ferric sulphate at a constant temperature.

QUALITY CONTROL SPECIFICATION QM2 (DG 0295)

TITLE: CAVITY ION CHAMBER.

The photon exposure rate was measured with a cavity ionization chamber which has been calibrated in a cobalt 60 exposure rate certified by the National Research Council of Canada.

QUALITY CONTROL SPECIFICATION QM6

TITLE: NEUTRON MEASUREMENT.

The neutron output was compared to that from a radium: beryllium neutron standard which has been certified by the National Research Council of Canada. A boron trifluoride gas counter in a wax moderator was used.

NOTES:

1. CHAMBER CALIBRATION. All ion chamber calibrations are based on graphite walled ionization chamber measurements of the photon emissions from cobalt 60, and are consistent with the internationally agreed output from radium of 0.825 roentgens per hour at one metre from 1 gram in 0.5 mm platinum.
2. COMPARATIVE MEASUREMENTS. In all comparative measurements identical geometry is used for the source and standard and a standard of similar output to the source is chosen.
3. DISTANCE. All quotations of gamma output are corrected by inverse square law to 1 metre from the reference point on the source. The measurement distance used is large compared to the longest dimension of source or detector.
4. SCATTER. All quotations of photon exposure rate and corresponding curie values have been corrected for the contribution to the reading by the scatter radiation inherent in the measurement position, unless otherwise stated.
5. RADIUM. Sources sealed less than 30 days prior to measurement and which are not at equilibrium are measured several times during the growth period and the maximum value of the output and content extrapolated to the equilibrium value.
6. NEUTRON SOURCES. Note 5 applies to sources of radium: beryllium. The neutron output is also extrapolated to the equilibrium value.
7. THE CURIE. Curie content values have been corrected for self absorption of the photon exposure rate by the source and its encapsulation. Curie effective values are the product of this corrected exposure rate and the appropriate specific gamma ray emission for the isotope.
8. SI UNITS. The curie or rad quantities shown on this certificate may be converted to the special S.I. units, becquerel (Bq) and gray (Gy) using the following factors:

   for activity: 1 curie = 37 gigabecquerels (GBq)
   for absorbed dose: 1 rad = 10 milligrays (mGy)