NRC FORM 313 U. S. NUCLEAR REGULATORY COMMISSION

(7-96)
10 CFR 30, 32, 33
34, 35, 38, 39 and 40

APPLICATION FOR MATERIAL LICENSE

APPROVED BY: NO. 3150-0120 EXPIRES: 7/31/99

Estimated burden per response to comply with this information collection request: 7 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Forward comments regarding burden estimate to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0120), Office of Management and Budget, Washington, DC 20503. NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a curently valid OMB control number.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

LL 30367
030-34337
02200

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*
   - [X] A. NEW LICENSE
   - [ ] B. AMENDMENT TO LICENSE NUMBER _____
   - [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip code)*

Cedarbrook Cardiology
1314 Park Avenue
Plainfield, NJ 07060

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

1314 Park Avenue
Plainfield, NJ 07060

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Dr. Saleem Husain

TELEPHONE NUMBER
(908) 756-1703

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL. SEE ATTACHED
   a. Element and mass number; b. chemical and/or physical form; and c. maiximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED. SEE ATTACHED

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE. SEE ATTACHED

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS. SEE ATTACHED

9. FACILITIES AND EQUIPMENT. SEE ATTACHED

10. RADIATION SAFETY PROGRAM. SEE ATTACHED

11. WASTE MANAGEMENT. SEE ATTACHED

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
    FEE CATEGORY 7-C
    AMOUNT ENCLOSED $ 1400.00

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OFJUNE 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.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Saleem Husain.,M.D.		1/14/97

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		124129

APPROVED BY _____ DATE _____ JAN 22 1997

CENTRAL RECORD COPY MI 10 REC'D IN LAS

APPLICATION FOR MATERIAL LICENSE

Documentation Of Attachments To This Application		
Section	**Description**	**Item**
A.	Description of the Scope of the Operation	
B.	Radioactive Materials Requested in this	5&6
	Application	
C.	Training and Experience of the RSO and	7 ,7.1, &7.3
	Authorized user	
D.	Personnel Qualifications and Training	8&8.1
E.	Facility Layout	9.1
F.	The Survey Instrument Calibration	9.2
G.	The Dose Calibrator Calibration	9.3
H.	Personnel External Exposure	9.4
I.	Imaging Equipment Quality Control	9.5
J.	Other Equipment and Facility	9.6
K.	Radiation Safety Committee / RSO	10.1
L.	ALARA Program	10.2
M.	Leak Test, Inventory, and Storage of	10.3
N.	Rules for the Safe Use of Radiopharmaceuticals	10.4
O.	Procedure for Spills / Decontamination	10.5
P.	Procedure for Ordering Radioactive Materials	10.6
Q.	Procedure for Handling and Opening Packages	10.7
R.	Unit and Multi Dosage Records	10.8&10.9
S.	Mo-99 Concentration Records	10.10
T.	Procedure for Area Surveys, Daily and Weekly	10.12
U.	Radioactive Waste Management	11.1
V.	QMP	
W.	License Fee	12

Description of the Scope of the Operation

This license application is only for Nuclear Cardiology Procedures implemented in a private practice facility. The material used will be obtained from a Radiopharmacy. The applicant will not obtain a Mo / Tc-99m generator. All the sources will be obtained either in a unitdose or bulk quantity from the radiopharmacy.

All radioactive waste such as unused doses or used syringes that contain residual activity will be returned to the radiopharmacy for the disposal in accordance with 10CFR20.301, 20.303, 20.306, 35.92 and in accordance with NJ Administrative Code, Title 7, Chapter 28- 11.2, 11.5 and 11.7. **Wastes, such as wipes and contaminated material generated at the facility will be stored by the applicant for decay in storage (DIS)** and will meet the requirements as stated in 10CFR20.301, 20.303, 20.306 and 35.92 and 28-11.7.

The facility design and the procedure for handling and usage of the radioactive material will be established to meet 10CFR20.105 and 7:28-6.

If the needs of the applicant-physician requires the operational scope to change, the application / license will be amended before the applicant-physician makes those changes.

The license application dose not include the **Quality Management Program** since the facility will **not acquire, possess or use I-131**.

NRC form 312, Item 5 and 6

Radioactive Materials Requested in this Application

Radiopharmaceuticals

The applicant wishes to receive a license for all the radiopharmaceuticals allowed under 10CFR35.200 and sealed sources for quality control.

These radiopharmaceuticals and sealed sources, to be used in the out-patient facility will be limited to:

Radioisotope	Form	Amount (mCi) of each form	Item 6: Purpose of use
^{99m}Tc *	Pertechnetate	As Needed	Human Use
	FDA approved forms	As Needed	Human Use
^{201}Tl *	Chloride	As Needed	Human Use
^{57}Co	Sealed	30 mCi	Quality Control and Calibration
^{137}Cs	Sealed	200.0 uCi	Quality Control and Calibration

Note (*):

The radiopharmaceutical sources will be acquired from the radiopharmacy in the unitdose or multidose form. The applicant will not obtain a Mo/Tc generator, but may make FDA approved "kits" using the radiopharmaceuticals listed in the application.

All unused sources, contaminated syringes, ect., that are obtained from the radiopharmacy will be returned to the radiopharmacy for disposal. Only those materials originating at the facility (wipes other contaminated waste) will be kept in the facility for decay in storage (DIS).

Item7, 7.1, 7.2, & 7.3

Training and Experience of Authorized User and Radiation Saftey Officer

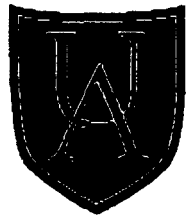
Radiation Safety Officer and Authorized User

SALEEM HUSAIN, M.D.

The attached documents evidence the training and experience of he physician applicant. These documents indicate minimum of 200 hours of traning in Basics of Radioisotope handling. The applicant has also completed the required Level I & II traning in clinical Nuclear Cardiology.

The training program provided by both Allegheny University Hospital and Health Physics Services,Inc. is in accordance with the requirements of the U.S. nuclear Regulatory Commission (10CFR 35.920).

Elmo R. Acio, M. D.
Assistant Professor of Medicine
Nuclear Cardiology Laboratory
Telephone: (215) 762-7520
Fax: (215) 246-5389



ALLEGHENY
UNIVERSITY
HOSPITALS
CENTER CITY

Broad & Vine
Philadelphia, PA 19102-1192
215-762-7000

October 22, 1996

RE: DR. SALEEM HUSAIN - VERIFICATION OF LEVEL II TRAINING IN NUCLEAR CARDIOLOGY

To Whom It May Concern:

This letter is to verify that Dr. Saleem Husain successfully completed a Level II training in Nuclear Cardiology, during his fellowship training in Cardiology at our institution.

Dr. Husain successfully completed his 6-month clinical rotations in our Nuclear Cardiology Laboratory during the following months, comprising of a total of 500 clinical hours and 500 technical hours:

Level I:	January 1994, November 1994, February 1995
Level II:	June 1995, July 1996, August 1996

Dr. Husain also successfully completed a 200-hr. radiation physics course with Health Physics Services Inc. in April, June, July, and September 1994 (Course Director: Billy G. Bass, Ph.D.; Rockville, Maryland).

Please let me know if you require further information.

Sincerely,

Elmo R. Acio

Elmo R. Acio, M.D.

CERTIFICATION COUNCIL OF NUCLEAR CARDIOLOGY

Incorporated 1996

CERTIFIES THAT

Saleem Husain, M.D.

HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS COUNCIL
AND HAVING SATISFACTORILY PASSED THE REQUIRED EXAMINATION,
IS HEREBY DESIGNATED
A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF

NUCLEAR CARDIOLOGY

PRESIDENT

SECRETARY

CERTIFICATE # 183

CCNC

OCTOBER 22, 1996

YOUNUS A. RAKLA, M.D. 9087561793 P.04

Health Physics Services, Inc.

Hereby certifies that

Saleem Husain, M.D.

has successfully completed the 200 Hour Physician Training Program in Basic Radioisotope Handling conducted in accordance with the requirements of the U.S. Nuclear Regulatory Commission (10 CFR 35).

COURSE OUTLINE

Radiation Physics and Instrumentation - 100 hours
Mathematics pertaining to the use and measurement of radioactivity - 20 hours
Radiopharmaceutical Chemistry - 30 hours
Radiation Biology - 20 hours
Radiation Protection - 30 hours

Mark A. Melanson
Mark A. Melanson, CHP, ABHP
Course Coordinator

September 11,1995
Date

Joseph P. Mount
Joseph P. Mount, Ph.D.
President

YOUNUS A. RAKLA, M.D. 9087561793 P.03

Appendix A

Personnel Qualifications and Training (Item 8,8.1)

Technologist Qualifications

All nuclear medical technologists will be registered or certified in nuclear medicine by the ARRT, CMNT, or ASCP, *or* they will, if allowed by the local or state laws, have the equivalent training in nuclear medicine. If local or state laws require regitration/certification and a state license, then the applicant will comply with those laws.

In addition to the above, the physician applicant will interview the technologist, obtain a resume of his/her experience, and evaluate the technologist through close observation of her/his nuclear medical techniques in actual operation.

Personnel Training Program

Who will be instructed:
All personnel (professional/technical and ancillary) will be instructed. The professional/technical personnel will include, but not be limited to: technologists, authorized users, physicists, and physicians who are not authorized users, but may be present when by-product material is being used. The ancillary personnel include nursing, clerical housekeeping, and other personnel who may frequent the area where material is being used.

Instruction Frequency:
Personnel will be instructed before assuming duties within the vicinity of radioactive materials, during an annual refresher training program, and whenever there is a significant change in the duties, regulations or terms of the license. There will also be instruction as deemed necessary by the RSO for all personnel after spills, misadministration, and other incidents, including monitored high personnel exposure.

Topics of Instruction: Instruction will include, but not be limited to, the following subjects:

A. Applicable regulations, license conditions and workers' rights.
B. Areas where radioactive materials are used or stored
C. Potential hazards associated with radioactive materials and bio-hazards, and procedures for each area where employees or physician staff work
D. Appropriate radiation safety procedures

Appendix A

E. Licensees' in-house work rules
F. F. Each individual's obligation to report unsafe conditions to the RSO
G. Appropriate responses to emergencies or unsafe conditions personnel who work with the materials will also receive copies of procedures for the following: monitoring the performance of imaging equipment, ordering and receiving radioactive material, opening packages, recording by-product material use, surveying radiation areas, safely using radiopharmaceuticals, disposing of waste, and responding to emergencies.

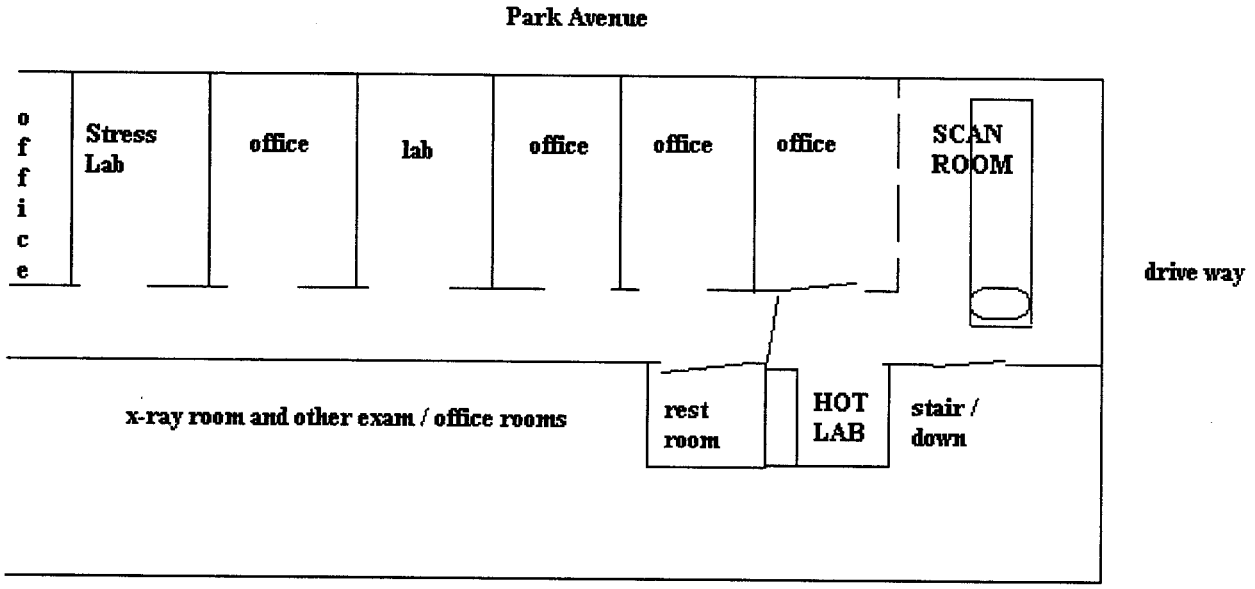
Method of Instruction:

Instruction will be formal, didactic, and/or individual, as needed. It will include, but not be limited to: personnel monitoring programs, ALARA, rules for safe use of radiopharmaceuticals, emergency procedures, floor plans showing areas of use and storage, and a tour of the facility.

Method of Evaluation:
The RSO of her/his agent will evaluate and informally observe the individual's work activities.

Item 9.1

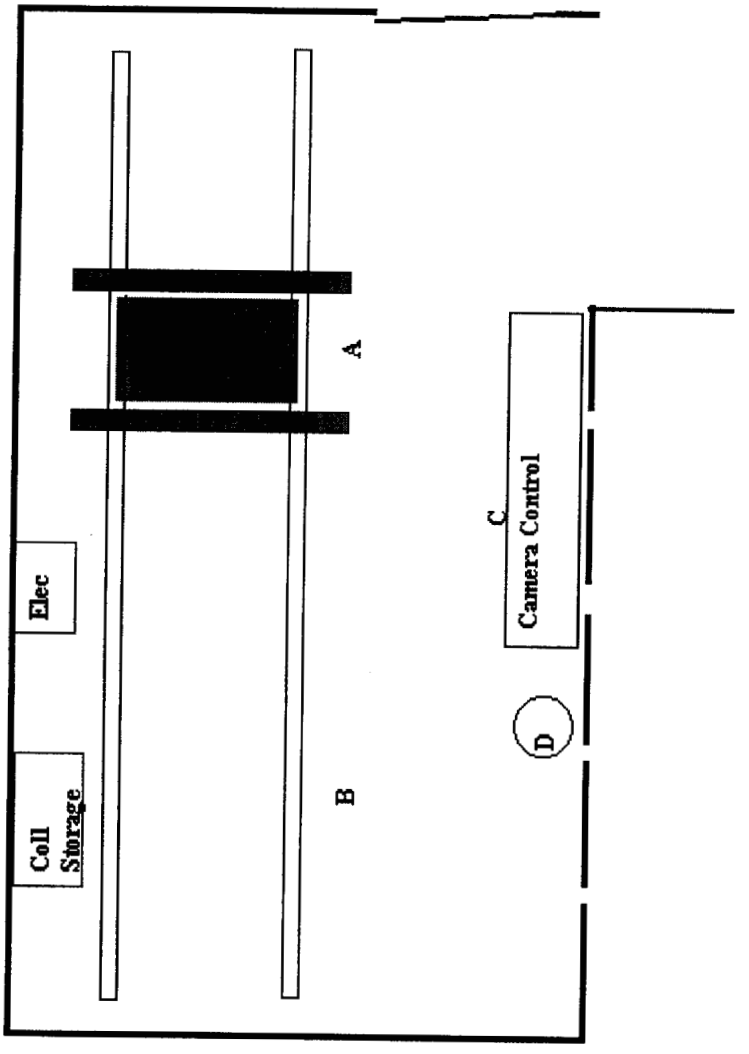
Annotated Drawing (See Attached)



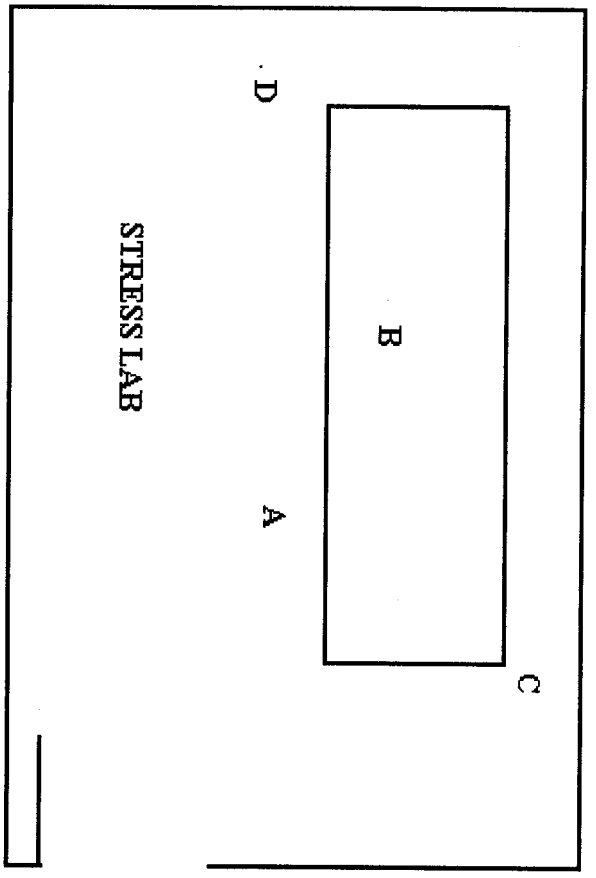
Cedarbrook Cardiology

Item : 9.1

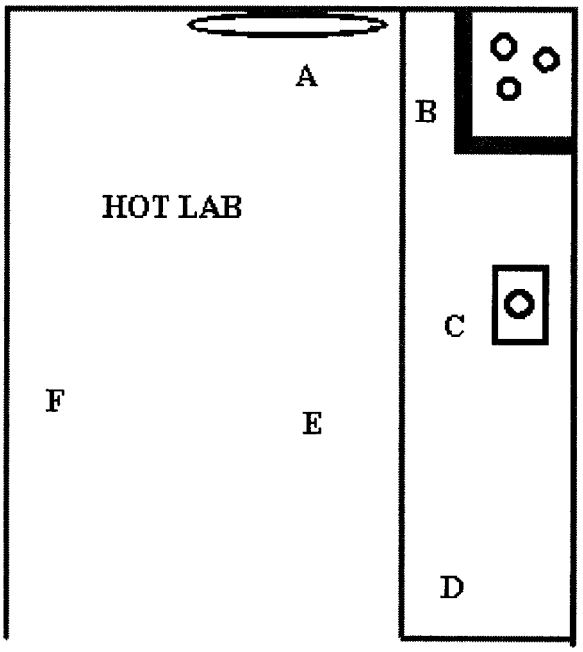
Cedarbrook Cardiology **Item: 9.1**



Cedarbrook Cardiology **Item 9.1**



Item : 9.1



ITEM 9.2

APPENDIX B

Procedure For the Survey Instrument Calibration

The applicant will not calibrate the survey instrument at their facility, but will have a qualified NRC approved contractor perform the calibration on an annual basis, or after any repair other than the replacement of the batteries. The procedure for obtaining this calibration is as follows:

[1]. The survey instruments will be sent to the NRC approved Lab annually for calibration .

[2]. Calibration will be performed in accordance with the procedure described in a model procedure in Reg. guide 10.8 (ATT 9.2) and as required by 10 CFR, Part 35.51

[3]. **We also assure that a survey instrument will be on site all the time. A loaner will be acquired if needed when our instrument is out for calibration or service. Facility will not operate during the time the survey instrument is not present at the facility.**

[4]. The Check source will be read and documented at the time of calibration.

[5]. Upon the receipt of the instrument from calibration lab or service, the applicant will check its apparent rate of exposure with a built-in or independent check source (licensed exempt), and note the level of exposure on the survey meter.

[6]. Prior to the operation, the instrument will be checked once daily, to determine that the instrument is functioning properly, batteries are OK, and the check source reading is still the same as noted on the instrument at the time of calibration, indicating that the instrument is still calibrated.

[7]. Appropriate and pertinent information will be attached to the instrument.

[8]. All the daily checks will be documented immediately after the checks are performed. (SEE ATTACHED FORM).

Cedarbrook Cardiology

Daily Check
Survey Meter

CHECK SOURCE: ______________________________

CALIBRATION DATE: ______________________________

READING: ______________________________

DATE	MODEL	SOURCE READING	BATTERY CHECK	PERFORMED BY	ACTION TAKEN

RMC

CERTIFICATE OF CALIBRATION

Radiation Management Consultants certifies that the instrument listed below was calibrated and inspected before shipment and has met the manufacturer's published specifications. RMC certifies that our calibration measurements are traceable to the National Bureau of Standards. Applicable corrections are made to correct to 22° C and 760 mmHg.

RMC SERVICE NO. 019562

INSTRUMENT IDENTIFICATION LUDLUM (Manufacturer) #3/44-3 (Model) 17315/P3123 (Serial Number)

CALIBRATION SOURCE ID. MP-1 Pulser SN 533 ^{129}I SN420 ^{133}Ba SN7R365

RANGE	CALIBRATION POINT	INSTRUMENT READING Before Adjustment	After Calibration
X0.1	100 CPM	95 cpm	100 CPM
	400	374	385
X1	1000	950	980
	4000	3930	4000
X10	10000	9700	10000
	40000	38800	40000
X100	100000	94000	100000
	400000	392000	400000
	0.09 μCi ^{125}I @ 1cm	15500 CPM: APPROX. 17.6% EFF.	193300 CPM/μCi ^{125}I
	0.54 μCi ^{133}Ba @ 1cm	160000 cpm: APPROX. 26% EFF.	293000 CPM/μCi ^{133}Ba
	CHECK SOURCE RESPONSE AT CONTACT: APPROX.		7500 CPM

COMMENTS

Calibration Performed by Charles E. McGee Date July 1, 1994

I certify that the above information is correct.

Authorized Agent C. E. McGee

Title RSO Date 7-1-94

(RMC is not responsible for damage incurred during shipment or use of this instrument)

ITEM 9.3

APPENDIX C

THE DOSE CALIBRATOR CALIBRATION

The dose Calibrator QC will include:

A. Daily QC using CO-57 (5 mCi) and Cs-137 (200.0 uCi) source
(**See Attached Example**)

B. On a quarterly bases the Linearity will be performed by either

[1]. Decay method
and /or [2]. Attenuator method

The linearity will be checked between maximum activity used by the facility for diagnostic procedure and **30 uCi**.
(**See Attached Example**)

C. The Geometrical Variation Dependence of the instrument will be checked initially when the instrument is acquired and after any major service or changes.
(**See Attached Example**)

D. Accuracy will be performed quarterly using Cs-137 and Co-57 sources.
(**See Attached Example**)

E All above testing will be performed after any major service and before putting the instrument in service after repair.

F. All above testing will be in accordance with the regulatory guide 10.8, rev:2.

DAILY QC

Dose Calibrator: Accu Cal **Mn: 2002**

1994 DEC Date	Dial Set	SN: S206077-041 Co-57 -5%	5%	Mead Act	SN :3560034-39 Cs-137 Dial Set	- 5 %	+ 5 %	Cs-137 Mead Act	SN :3560034-39 Channel check Tc 99m	C0 57	Tl 201	Tech Init
1		2.37	2.62			178.73	197.54					
2		2.36	2.61			178.72	197.53					
3		2.36	2.60			178.71	197.52					
4		2.35	2.60			178.69	197.50					
5		2.34	2.59			178.68	197.49					
6		2.34	2.59			178.67	197.48					
7		2.33	2.58			178.66	197.47					
8		2.33	2.57			178.65	197.45					
9		2.32	2.57			178.64	197.44					
10		2.32	2.56			178.63	197.43					
11		2.31	2.55			178.62	197.42					
12		2.30	2.55			178.60	197.40					
13		2.30	2.54			178.59	197.39					
14		2.29	2.53			178.58	197.38					
15		2.29	2.53			178.57	197.37					
16		2.28	2.52			178.56	197.35					
17		2.27	2.51			178.55	197.34					
18		2.27	2.51			178.54	197.33					
19		2.26	2.50			178.53	197.32					
20		2.26	2.49			178.51	197.30					
21		2.25	2.49			178.50	197.29					
22		2.25	2.48			178.49	197.28					
23		2.24	2.48			178.48	197.27					
24		2.23	2.47			178.47	197.25					
25		2.23	2.46			178.46	197.24					
26		2.22	2.46			178.45	197.23					
27		2.22	2.45			178.43	197.22					
28		2.21	2.44			178.42	197.21					
29		2.21	2.44			178.41	197.19					
30		2.20	2.43			178.40	197.18					
31		2.19	2.43			178.39	197.17					

Order a New Source: YES: ☐

Cedarbrook Cardiology

EXAMPLE

Dose Calibrator Linearity

Date:		**Method:**	Cal Check
Dose Calibrator:		**Source Type:**	Vial
Model No.:		**Source (mCi):**	1027.5
Test Performed by:	RFP		

Tube Color	Displayed Activity [D]	*	Calibration Factor [C]	Product [D * C]
Black	1027.50	*	1.00	1027.50
Black & Red	327.00	*	3.14	1027.50
Black & Orange	83.75	*	12.27	1027.50
Black & Yellow	41.80	*	24.58	1027.50
Black & Green	9.68000	*	106.15	1027.50
Black & Blue	4.98500	*	206.12	1027.50
Black & Purple	1.56300	*	657.39	1027.50
Purple & Red	0.46550	*	2207.30	1027.50
Purple & Orange	0.12975	*	7919.08	1027.50
Purple & Yellow	0.07045	*	14584.81	1027.50
Purple & Green	0.01860	*	55241.94	1027.50
Purple & Blue	0.01043	*	98513.90	1027.50

Mean:	**1027.50**		
Upper Limit:	**1078.88**	**Maximum:**	1027.50
Lower Limit:	**976.13**	**Minimum:**	1027.50

Minimum and Maximum Must be within Lower and Upper Limits.

****** IF THE DATA ARE NOT WITHIN LIMITS ******

******* DO NOT USE THE DOSE CALIBRATOR *******

******* NOTIFY YOUR SUPERVISOR *******

******* NOTIFY YOUR MEDICAL PHYSICIST / RSO *******

Performed By: _____

Checked By: _____

Medical Physicist /RSO

Dose Calibrator Linearity

Date: June 6, 1994

Dose Calibrator: Accu Cal
Model No.: 2002
Test Performed by: RFP

Source Type: 20 cc Vial

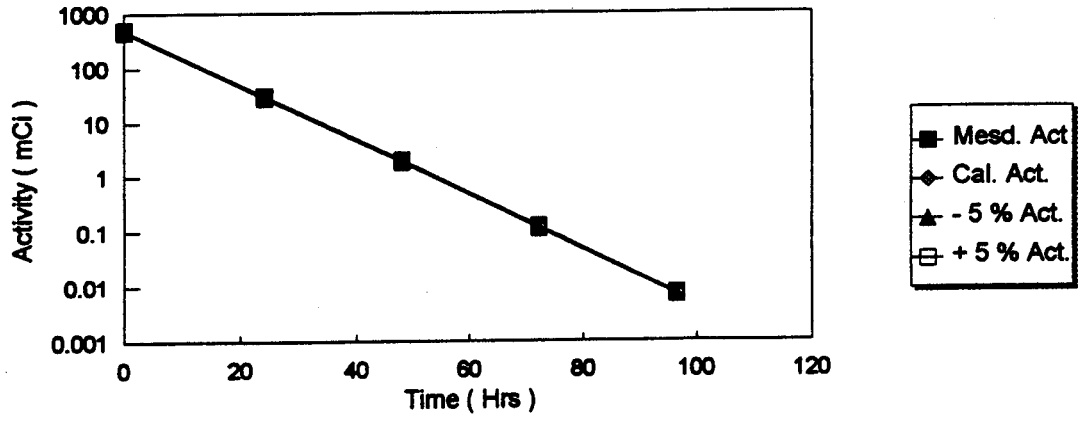
Hours	Mesd Activity		Cal. Activity		% Error	[- 5 %]	[+ 5 %]
0.00	487	mCi	487.000	mCi	0.00	462.65	511.35
24.17	30.3	mCi	29.863	mCi	1.46	28.37	31.36
48.00	1.9	mCi	1.905	mCi	-0.24	1.81	2.00
72.25	0.119	mCi	0.116	mCi	2.84	0.11	0.12
96.42	0.0075	mCi	0.0071	mCi	**5.70**	0.01	0.01

Maximum % Error: 5.70
Minimum % Error: -0.24

Do Not Use the Dose Calibrator If MAXIMUM & MINIMUM % Error is NOT within +/- 5% range

NOTIFY: Medical Physicist /RSO and Chief Technologist

Activity vs Time



Dose Calibrator Accuracy

Date: April 7, 1994 **Activity (mCi):** 191.60

Dose Calibrator: Accu Cal **Source Type:** Cs-137 SN: S356004-39
Model No.: 2002 **Calibration:** 221 uCi, Feb 1, 1988
Test Performed by: RFP

MEASUREMENTS

190.1	190.0	189.8	190.1	189.9
190.1	189.9	189.9	190.0	189.9
190.2	189.5	190.0	190.1	190.0
190.2	190.1	190.1	190.0	190.0
190.1	190.0	190.2	190.0	190.1

AVERAGE ACTIVITY OF CS-137 MEASURED: **190.012**

[- 5 % Activity]: **182.02**
[+ 5 % Activity]: **201.18**

If the Average Activity is not within + / - 5 % range:

DO NOT: USE THE DOSE CALIBRATOR

NOTIFY: [a]. Chief Technologist
[b]. Medical Physicist / RSO

_____
Test Performed By;

_____
Medical Physicist / RSO

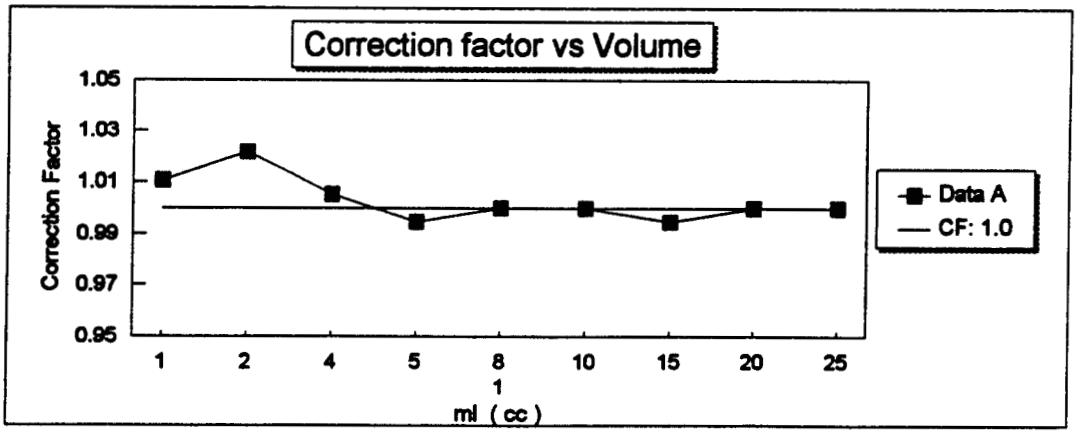
Geometrical Dependence & Variation

Date: Jan 26, 1994

Dose Calibrator: Accu Cal
Model No.: 2002
Test Performed by: RFP

Source Type:

Volume ml	Activity mCi	% Error	Correction Factor
1	1.89	0.00	1.01
2	1.87	-1.06	1.02
4	1.90	0.53	1.01
5	1.92	1.59	0.99
8	1.91	1.06	1.00
10	**1.91**	**1.06**	**1.00**
15	1.92	1.59	0.99
20	1.91	1.06	1.00
25	1.91	1.06	1.00



Item 9.4

APPENDIX D

Personnel External Exposure Monitoring Program

Film Badges Whole Body	Furnished By: R.S. Landauer	*Whole body monitoring for all individuals who frequent area where radioactive materials are received, used and stored.*
TLD Ring Extremity	Furnished By: R.S. Landauer	*Extremity Monitoring for all individuals who handle radioactive source or handle patients who are inject with radioactive materials.*

Our Personnel Exposure Monitoring Program will include, but not be limited to, the following activities:

1) The RSO will promptly review all exposure reports and look for workers whose exposure is unexpectedly high or low.
2) All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a whole body film badge. A contract service will process these badges monthly.
3) All individuals who are exposed to radioactive material that emits ionizing photons on a regular basis will be issued a TLD finger monitor. A contract service will process these TLD rings monthly.
4) Other individuals who are exposed to radiation on an occasional basis, such as security personnel who deliver packages, secretarial staff, and nurses who care for patients contain diagnostic quantities of radiopharmaceuticals, will not be normally issued dosimeters. If the RSO deems that such personnel must be measured for exposure, a whole body dosimeter will be issued as required.
5) All monthly personnel dosimeters will be posted for workers to read. Workers should sign the report when they have read it.

ITEM 9.5

APPENDIX E

THE IMAGING EQUIPMENT QC:

The QC for the gamma camera is based on the manufacturer's and AAPM' s recommended procedure.

The QC will performed on a daily bases when camera is used.

Item 9.6

Other Equipments and facilities

Instrument	Supplier/Model	Use
Gamma Camera Sys.	ADAC	Nuclear Medicine Imaging for nuclear cardiology procedure
Dose Calibrator	Atom Lab 100 or equivalent	Radiopharmacuetical quality control and calibration of patient doses
Survey Meter	Bicron Surveyer 2000 with external GM Probe (range: 0 - 2000 mR/hr) or equivalent	Daily Surveys, ambient exposure surveys, package surveys, spill and contamination surveys, and other measurements
Sample Analysis Wipe Testing	Victoreen Deluxe Wipe test counter	Counting of samples, wipes, or swipes of contamination surveys, spills and other sample analysis
Film Badges-Body Personnel Dosimeters *	Furnished by: R.S. Landauer, Tech/Ops Landuer, 2 Science Road Glenwood, IL 60425	Whole body personnel monitoring of all individuals who frequent areas where radioactive materials are received, used, manipulated or stored.
Extremity Dosimeters *	Furnished by: R.S. Landauer, Tech/Ops Landauer, 2 Science Road Glennwood, IL 60425	Monitoring the extremities TLD dosimeters described of all personnel who handle above sources, or of patients who have been recently injected
Radiation safety devices:	Lead Bricks, Syringe Shield Leaded face glass shield Leaded waste container Lead Apron	

*These dosimeters will be exchanged on a monthly basis, at the beginning of each month.

ITEM 10.1

APPENDIX F

RADIATION SAFETY COMMITTEE:

The applicant being a private practice facility will not establish the Radiation Safety Committee, since no such committee is possible in a private office. The RSO will, however, carry out the activities as established in 35.21, 35.22 and 35.23 of 10 CFR, the Model Radiation Safety Committee Charter, and Radiation Safety Officer Delegation of Authority under the Appendix F of the Regulatory Guide 10.8, Rev.2, NRC, or an equivalent State Regulation.

Item 10.1

Routine Responsibilities of the Radiation Safety Officer

The license has been appointed a Radiation Safety Officer (RSO) to implement the radiation safety program. Through the RSO, the license will insure that radiation safety activities are being performed according to ALARA and other approved procedures, conditions, and regulatory requirements. The RSO's activities include, but are not limited to, the following:

1. Investigating all incidents, including unexpected exposures, accidents, spills, losses, and theft; unauthorized receipts, uses, transfers, and disposals; and misadministration, adverse reactions and other deviations, including biohazard incidents.

2. Holding all of the materials required for the radiation safety program in a single program in a single binder or file, including notices, regulations, and related documents and procedures for the following:

   a. Authorizing the purchase of radioactive material
   b. Receiving and opening packages of radioactive materials
   c. Inventorying radioactive materials
   d. Storing and using radioactive material
   e. Taking emergency action if material is lost, stolen, spilled or subjected to other operational deviations [1]
   f. Checking survey meters, safety, quality control, and performance
   g. Disposing of radioactive material
   h. Training personnel who frequent areas where radioactive material is received, used or stored
   i. Record keeping required by the regulatory agencies, including OSHA

3. Briefing management (the license) once each year on the radioactive material program.

4. Establishing personnel investigational levels, investigating the causes, and developing preventative actions when these are exceeded.

5. Approving or disapproving minor changes in the radiation safety procedures that do not interfere with safety, with the advice and consent of management (the license).

1

Item 10.1

Routine Responsibilities of the Radiation Safety Officer

6. Removing the workers from an exposed area, documenting the investigation, retraining Workers, and modifying procedures and/or the physical facility when reportable exposures occur (of more than 1,250 mrem per 13 weeks to the whole body or 18,750 mrem to the hands). If and when the RSO finds that it is reasonable to resume activities, the workers ill be allowed to return to their duties.

7. Providing female radiation workers who are anticipating pregnancy with a second, abdominal film badge. The worker will be instructed to tell the RSO when pregnancy is confirmed. When pregnancy occurs, female workers will wear an abdominal film badge to monitor the potential prenatal exposure. The workers' abdominal exposure will be limited to 0.5 rem for the remainder of the gestation period.

8. Immediately investigation and documenting spills, contradictions, and other abnormal occurrences. Corrective actions will be guided by the individual event.

9. Bioassay will not be necessary, as no I unsealed sources will be used. If the RSO suspects that radioactive material was absorbed or ingested, he/she will bioassay the worker's urine, saliva, and/or blood with gamma camera. As with all other monitoring, the RSO will hold these records in the facility.

10. Establishing a "Quarterly ALARA Audit." This audit will review personnel exposure, surveys, incidents, biohazards, and all events related to the safety of personnel. This audit will be used by management to review the program, evaluate risks, and establish changes that may be required to keep all exposures ALARA.

11. Establishing an "Annual Facility Review," evaluating all incidents and the overall safety of personnel. The yearly review will be presented to management, all radiation personnel, and others involved in facility operation. This review will be included in an annual educational program for all radiation workers.

Item 10.2 APPENDIX G

ALARA PROGRAM

The applicant will establish an ALARA program as outlined in Appendix G to the Regulatory Guide 10.8, Rev. 2, NRC, or an equivalent Agreement State Regulation, expecting the formation of a Radiation Safety Committee. The ALARA concept will be applied on an informal basis by the RSO. The key elements of this program will be:

1) Commitment to keeping individual and collective doses as low as is reasonably achievable.
2) An ongoing review of the radiation safety program, with a more formal review performed at least annually.
3) Modifications of the radiation safety program, equipment and/or procedures, if such changes will reduce personnel exposure.
4) Establishment of "Investigational Levels" below the applicable limit, as stated in page two of this section.
5) Routine reviews by the RSO of the safety program (annually), occupational exposures (quarterly and monthly), and radiation surveys (monthly).
6) Cooperation with workers to reduce exposures.
7) An educational program for all workers on radiation safety (see the "Training Program").

Specific Elements of the ALARA Program Management

We follow these procedures in addition to standard procedures fro receiving, using, and disposing of radionuclides for routine equipment surveys and procedures, and for radionuclide and incident handling.

1. We document all radiation workers' prior exposure history before issuing them dosimeters.
2. We issue a body dosimeter, or film badge, to all radiation workers. In addition, we issue a finger TLD dosimeter to workers who use radionuclides (receipt, administration, etc.), and change the dosimeters a monthly intervals.

Item 10.2 APPENDIX G

Specific Elements of the ALARA Program Management

3. Before use of radionuclides, we instruct each employee in the following areas:
   a. fundamental radiation effects and levels of exposure
   b. investigational levels established in the facility for ALARA management
   c. standard ALARA procedures
   d. parental exposure policy
   e. license authorization and conditions
   f. standard operational procedures
   g. location and control of all hazards in the facility

4. The authorized user/RSO or another experienced worker closely observes all new employees in person for the first few days f operation, to confirm proper techniques and answer any questions.

5. We evaluate personnel exposure on a monthly basis. All exposures should be at or below level 1 (40 mrem for whole body or 625 mrem for the hands). We closely review any exposure above this level to decide whether the work activity justifies the higher exposure. If a worker receives more than Level II exposure (i.e.,125 mrem to the whole body, or 1,875 for the hands), our facility will open an immediate investigation. We explore the exposure's cause and possible techniques for exposure reduction with the effected individual. We implement all reasonable methods for exposure reduction. If exposure exceeds Level III (i.e.,417 mrem whole body, or 6,250 mrems to the hands), we will formally investigate and record the exposure to determine the cause. We may modify operational procedures to prevent further exposures at these levels. Additional dosimeters, measurements, etc., may be considered at this time.

NOTICE TO WORKERS

This facility operates under a medical radioactive materials license. The license, its application, documents incorporated into the license by reference, license conditions, amendments, operational procedures, and all related materials and communication can be examined by contacting the individual listed below.

License Number: _____ **Issued:** _____
Contact: _____ **Telephone:** _____

Complete all information on this notice before posting.

NOTICE

Radioactive materials may be located in this room. If present, the location of radioactive materials is clearly identified by the radiation symbol of the words, "Caution: Radioactive Materials." In case of an emergency involving this room or the materials within the room, contact the Radiation Safety Officer (RSO) listed below.

Contact: _____ **Telephone:** _____

Complete all information on this notice before posting

ALARA Program -- Posting of Notice/Evaluation of Dosimeters

The following notices will be posted at the same location as the film badge (whole body) reports.

ALARA

(AS LOW AS REASONABLY ACHIEVABLE)

CAN YOU LOWER YOUR EXPOSURE

This facility is dedicated to maintaining all occupational exposures at the lowest possible level. Please tell the Radiation Safety Officer (RSO) your ideas for lowering exposures. Be aware of work activities that can reduce your exposure. Let's get everyone into Level I.

NOTICE TO ALL RADIATION WORKERS

Emergency Notification/Posting of Notices

The following notices will be posted with complete information. The information required on these notices cannot be obtained until a license is issued and the facility is implemented. The notices should be posted 1)at room entrances where radioactive materials are used and 2) in the room's radioisotope storage and manipulation area. The "Notice to Workers" sign will be also posted on the employee notice board for employee viewing.

The signs are shown smaller than actual size.

ITEM 10.3

APPENDIX H

LEAK TESTING, INVENTORY OF SEALED SOURCES AND SURVEY OF SOURCES STORAGE AREA:

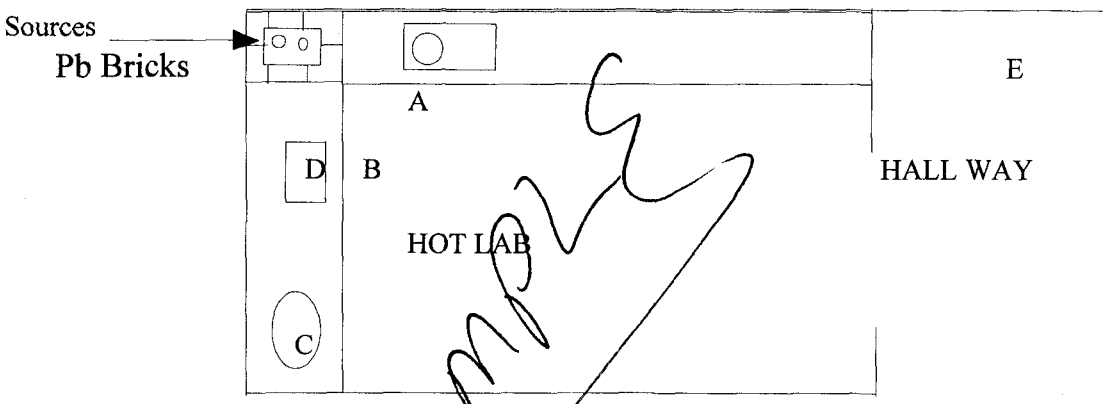
Procedure for this requirement is established such that it meets 10CFR, 35.59

SEE ATTACHED FORMS AND DOCUMENTS

Cedarbrook Cardiology

AREA SURVEY

LOCATION: Sources are located in Hot Lab behind Lead Bricks



Following procedure were performed in Nuclear Medicine Department:

[a]. Survey of the area around the sealed sources storage.
[b]. Inventory of the sources and security of the sources was checked.
[See page for inventory]

SURVEY mR / hr				
1995	**1st Quarter**	**2nd Quarter**	**3rd Quarter**	**4th Quarter**
Date:	3-28-1995			
Back Ground:	0.03			
Exposure near flood:	0.05			
Exposure near flood:	0.1			
RSO Signature:				

Comments: _____

Cedarbrook Cardiology

INVENTORY

NCIC has following sources on hand. These sources were tested for leakage and no removable contamination has been found. Results are on next page.

Source ON HAND: **YES**
Source Disposed: **DISP**

YEAR: **1995**

	SOURCES / SN:#	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	
	DATE:	3-28-1995				
[1].	**Cs-137, E-Vial** **202.4 uCi** **SN: A3125**	YES				
[2].	**Co-57,E - ViaL** **5.66 mCi** **SN: A2949**	YES				
[3].	**Co-57, Flood** **10 mCi nes 8012** **SN: S8012557-01**	YES				

RSO Signature: _____

Comments: _____

Cedarbrook Cardiology

Sealed Radioactive Source Leak Test

Date: March 28, 1995

				Bkg	cpm	T1/2
Reference Source:	Cs-137	0.25 uCi	1-91	15	41850	30 Y
	Co-57	0.103 uCi	2-13-90	21	1604	271.7 day

Instrument Used: Canberra well and MCA

Method: Smear test was performed by taking a moist swab. All external surfaces of the source were wiped with the swab. The swab was then placed in the glass tube and the activity was measured in the well counter for 5 minutes to achieve reasonable statistical validity of the obtained cpm. NBS traceable standard was also measured at the same time to check the instrument performance and to convert the CPM to DPM and uCi.

	Source Type	Surface	cpm	uCi	DPM	Removable Contamination	
[1].	**Cs-137, E-Vial** **202.4 uCi** **SN: A3125**	In Side Out Side	21 17	3.26E-05 1.09E-05	72.41 24.14	NONE NONE	
[2].	**Co-57,E - vial** **5.66 mCi** **SN: A2949**	In Side Out Side	23 24	1.34E-06 2.01E-06	2.98 4.46	NONE NONE	
[3].	**Co-57, Flood** **10 mCi NES 8012** **SN: S8012557-01**	In Side Out Side	27 25	4.02E-06 0.00E+00	8.93 0.00	NONE NONE	

If the total activity smeared from the source is less than 5.0E-4 microcuries , then the source shall be considered leak free.
If the total activity measured is significantly greater than previous leak test value further test must be performed to verify that there is no leakage. Otherwise remove the source from usage.

Test Performed By: _____

Radiation Safety Officer _____

ITEM 10.4

APPENDIX I

Rules for The Safe Use of Radiopharmeceuticals

As required under 10 CFR, Part 35.21, Cedarbrook Cardiology has established following **Rules for Safe Use of Radiopharmeceuticals**. Individuals working in the areas where radioactive material is used must follow the following rules:

[1]. Wear laboratory coats or other protective clothing at all times in the area where radioactive material is used.

[2]. Wear disposable gloves at all times while handling radioactive materials.

[3]. Monitor your hands and other body parts when leaving the area with either thin end window GM survey meter, or NaI crystal probe or scintillation camera. Log the survey in the survey forms.

[4]. Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated. In these cases use other methods to minimize the exposure.

[5]. No eating , drinking, smoking, or applying cosmetics in any area where radioactive material is used is allowed.

[6]. Do not store food, drink, or personal effects in the areas where radioactive material is used or stored.

[7]. Wear personal monitoring devices at all times while in the areas where radioactive materials are used or stored. These devices should be worn as prescribed by Radiation Safety Officer. Review the policy " Handling of Monitoring Devices" for proper use and special instructions for the use of the monitoring devices.

[8]. Wear finger exposure monitoring device (ring) during elution of the generator, during the preparation, assay, and injection of the radiopharmaceuticals; and when holding the patients during positioning and procedure.

ITEM 10.4

APPENDIX I

Rules for The Safe Use of Radiopharmeceuticals

[9]. Dispose of radioactive waste only in designated receptacles. Follow the waste disposal policy and procedure.

[10]. Never pipette by mouth.

[11]. Follow the daily room survey and weekly wipe test policy. If any contamination is detected follow the radioactive decontamination policy.

[12]. Follow the policy established for dose preparation, and log all the information in the log book as required by the policy.

[13]. Perform all the daily QC and checks as the policy call for.

[14]. Follow the Quality Management Program for I-131 doses greater than 10 uCi. Document all the important information immediately.

[15]. Always keep all the radioactive sources , flood sources, radioactive waste and any contaminated material in the assigned area to minimize the personal exposure.

[16]. Notify Supervisor, RSO of any hazardous situation that could unnecessary exposure to patient, staff or contamination of the facility.

[17]. Do not cover up any mistake or situation. Prompt notification may prevent serious situation.

Item 10.5 APPENDIX J

Procedure for Spills

3. Confine potentially contaminated personnel to an area in the same room where they can be monitored and decontaminated. Take care that personnel do not spread the contamination. Survey personnel and have them leave the area if no contamination is found.
4. If practical (without spreading contamination), shield the spill. Don't allow the contamination to spread or your exposure to increase.
5. Close the room and secure the area to prevent entry. Post a notice on the door to indicate that entry is prohibited.
6. Notify the Radiation Safety Officer (RSO).
7. Follow the direction of the RSO to decontaminate the area, complete required documentation, and evaluate the incident.

Personnel Decontamination Suggestions (First Steps):

a) Remove contaminated clothing and store for evaluation and decay.
b) Flush the skin with tepid water, wash with mild soap and dry with absorbent paper. Repeat this step as required as long as at least 15% of the counts are removed with each washing. Avoid contamination from the wash water. Use as little water as practical.
c) Radioactive material in the eyes should be flushed with water or eye wash and an eye cup.

*The applicant considers a "major" spill to be a release of more than 50 mCi of Tc, or more than 25 mCi of Tl. A major spill may also be defined as one in which a potential exposure rate of more than 10 millirems per hour could occur. Sealed sources, being solid material, cannot spill. If sealed sources could spill, values for a spill considered "major" would be adjusted upward.

Item 10.5

APPENDIX J

Procedure for Spills
Decontamination Procedures

I. General Rules

A. Contain the contamination--never allow uncontaminated areas to be contaminated in the clean-up process
B. Avoid any activity release from the restricted area by immediately isolating the suspected area. It is acceptable to "overreact" to the spill by initially isolating an area significantly larger than the initial spill site.
C. Address personnel contamination before decontaminating the facility.
D. Obtain other's help to monitor and carry out decontamination procedures and documentation.

II. Personnel Decontamination

A. If a physical injury requires medical attention, administer care immediately. Keep in mind that contamination may be present.
B. Decontaminate eyes by washing them with the eye wash solution from the "decontamination kit." Wash eyes over the sink, and allow the water to flush down the drain.
C. Remove all contaminated garments, i.e., laboratory coat, gloves, etc., and step onto an uncontaminated surface to monitor residual activity.
D. Use the following decontamination techniques for skin decontamination. Take great care not to spread the contamination to clean surfaces during these procedures. Decontaminate in a sink, and allow the water to flush down the drain.
   1. Flush the surface with tepid water, and remonitor for removal/residual activity.
   2. Wash with NUC-WASH A and rinse the tepid water. Remonitor for removal/residual activity.
   3. Wash the NUC-WASH B, NUC-WASH C, and NUC WASH D, if necessary. With each wash, and rinse with tepid water and remonitor for removal/residual activity.
   4. If NUC-WASH D is used, and residual activity exists, use a soft brush on the skin. AVOID BREAKING OR IRRITATING THE SKIN.
   5. If residual activity persists after all decontamination steps are completed, and if the RSO agrees that additional decontaminates are not warranted or practical, then ensure that the contaminated area is not further spread and contaminated materials are not ingested.

   Adding moisture to the skin allow contaminated skin to release more activity after a few hours. At that time, washing the skin again may be helpful. If hands are contaminated, cotton gloves may absorb moisture containing activity and prevent contamination from spreading.

Item 10.5 APPENDIX J

Procedure for Spills

The following procedures for major* and minor* spills will be followed in or facility. These procedures will be posted, in larger form, and used in the employee training program, as indicated in that section.

NOTICE
SPILL PROCEDURE

MINOR SPILLS

1. Notify all persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill area with absorbent paper. Secure the area.
3. Survey all personnel in the area to ensure that they are not contaminated. If contamination is present, decontaminate.
4. With the RSO or another person (not involved in the spill), monitor with a GM survey meter. Determine the margins of the contaminated area.
5. Clean up the spill using disposable gloves, foot coverings if needed, and absorbent paper. Remove the paper covering the area, clean side out to avoid contamination, and place in a plastic bag for transfer to the radioactive waste container. Clean the area, decontaminate, and place all wipes, papers and gloves in the bag for transfer to the waste container.
6. After decontamination, survey the area with the GM survey meter. Include the area around the spill area in the survey. Check your hands, clothing and shoes for contamination.
7. Complete the "Radioactive Spill Report" and the "Radioactive Spill Contamination Survey."
8. With the RSO, evaluate measures to be taken to prevent such spills in the future.

MAJOR SPILLS

1. Clear the area by notifying all persons in the room that a spill has occurred. Use caution that no contaminated individuals leave the area.
2. Prevent the spread of contamination by covering the spill area with absorbent paper. Secure the area.

Item 10.5 Appendix J

Procedure for Spills

6. Determine the value of performing Bio-Assays on the individual for any ingested or inhaled activity. These Bio-Assay techniques include, but are not limited to: nose wipes, saliva samples, and/or after a few hours, blood and/or urine samples. If any Bio-Assay samples are obtained, the personnel exposure records must show the nature of the samples, and the numerical results of their analysis.
7. Complete all required records, including the appropriate spill, personnel exposure, ingestion, or incident reports.

Item 10.6

APPENDIX K

ORDERING AND RECEIVING OF LICENSED MATERIAL

The Cedarbrook Cardiology uses radionuclide and Radiopharmaceuticals Diagnostic procedures only. The doses for the procedures are prescribed by Dr. Sallem Husain. 10CFR,20.205 and 10 CFR, 30.51 requires the establishment of procedure and authorization of ordering the radionuclide and Radiopharmaceuticals.

When ordering radiopharmaceuticals or radionuclide, technologists must follow the list of the doses prescribed by the *Dr. Saleem Husain.* All Nuclear Medicine technologists, as required under 10CFR, 20.205 and 10CFR, 30.51, are authorized under this policy and procedure to order the radiopharmaceuticals and radionuclide as prescribed by *Dr. Saleem Husain.*

UNDER NO CIRCUMSTANCES will dose limits or quantities be changed unless an authorization or a directive is obtained from the authorized users prior to ordering and administration of licensed material.

[1]. Please follow the following procedure:

- [a]. Receipt and Delivering of Radioactive Shipment
- [b]. Handling and monitoring packages containing Radioactive material

[2]. Confirm that the material ordered. quantity ordered, chemical form of the material , etc. is as ordered.

[3]. After monitoring the packages log all the pertinent information as required in an appropriate forms.

Item 10.7

APPENDIX L

Handling And Monitoring Packages Containing Licensed Material

Special care must be taken when handling the packages containing radioactive material. According to NRC under 10 CFR, Part 20 all the packages containing radioactive material must be monitored for surface contamination and external exposure. Packages received during working hours will be monitored immediately. The packages received during off hours will be monitored as soon as the Nuclear Medicine staff gets on duty.

PROCEDURE:

A. RECEIVING PACKAGES

1. Put on disposable gloves to prevent contamination.
2. Make sure the packages are kept on absorbent pads.
3. Visually inspect the packages for any sign of damage. If the package appears to be damaged or wet, **NOTIFY THE RSO.**
4. Wipe test the external surface of the package and count in the well counter. **Do not** open the package until determining that the package wipe results are within the established limits. (See **NRC table N-1**).
5. Take a background survey in the hallway.
6. Move the package from the blue pad to the cart in the hot lab.
7. Survey the package at 1 meter and at Surface:

SURVEY PACKAGE LIMITS

SURFACE	ONE METER
I - <0.5 mR/hr	< 0.1 mR/hr
II - 0.5 - 50 mR/hr	0.1 - 1 mR/hr
III - 50 - 200 mR/hr	1.0 - 10 mR/hr

Item 10.7 **APPENDIX L**

Handling And Monitoring Packages Containing Licensed Material

8. Empty the contents of the box if the survey readings are within acceptable limits.

9. **DO NOT EMPTY** the contents of the box if the survey readings are not within acceptable limits. Contact the following personnel: **1. RSO**

10. Open the outer package after determining that both the survey and the wipe test are within acceptable limits.

11. Open the inner package and check the final container for breakage or discoloration.

12. Verify the **Activity** and the **Contents** by comparing the Requisition, Packaging slip and the Label on the Vial and/or the Syringe (Unit Dose).

13. Remove the contents of the box and place behind the shield in an appropriate area or place the contents of the box in the appropriate lead lined drawers.

14. Survey the empty box and the packaging material with a thin end window G.M. Survey meter. Survey the empty box and other packaging material with extra care. Make sure the readings obtained from the empty box and the packaging material do not exceed the background reading in the room. Record the reading on the appropriate forms. Perform wipe tests both outside and inside of the of the empty box.

15. **If the reading of the box is higher than the room background, wipe the external surface of the final source container and measure the removable contamination and record it.** (follow the established wipe test procedure)

16. If the boxes and the packaging material are:

    a. **Contaminated**, handle as radioactive material and **Notify RSO.**

    b. Not contaminated deface the radioactive material label and discard in the regular trash.

17. Maintain accurate records of all the surveys and receipt of all the radioactive shipments received

Item 10.7 **APPENDIX L**

Handling And Monitoring Packages Containing Licensed Material

18. **UNDER NO CIRCUMSTANCES is the survey procedure to be eliminated.**

19. Any time during the survey:
    - **a. Surface exposure exceeds 200 mR/hr**
    - **b. Package is found to be damaged**
    - **c. Package integrity is questionable**
    - **d. Package content and amount do not match the requested material**

    Do Not use the material and Immediately:

    NOTIFY:

    1. Radiation Safety Officer

20. The RSO or the Medical Physicist should make sure that the measurements are accurate and if so **NOTIFY THE NRC**

B. RETURNING PACKAGES TO THE RADIOPHARMACY

1. Before any packages are shipped out to the Radiopharmacies, one must follow the

2. Perform the following wipe tests:

    a. Take a wipe from the outside of the empty box.
    b. Count the wipes on the well counter using the programmed protocol on the well counter computer.
    c. A box is considered free of contamination if the dpm falls below the guide line established by **NRC table N-1.**

3. Place the containers to be returned in the box.

4. Place the appropriate DOT labels and close the box.

5. **<u>DO NOT</u> TURN THE RADIOACTIVE TRANSPORT SIGNS AROUND UNTIL YOU CHECK THE WIPE TESTS RESULTS.**

6. If there is a problem rewipe the packages, but also notify the RSO.

TABLE N-1

Recommended action levels in **dpm/100 cm2** for the surface contamination by a Radiopharmaceutical.

		P-32, Co-58, Fe-59, Co-60, Se-75,Sr-85, In-111, I-123, I-125,I-131, Yb-169, Au-198	Cr-51, Co-57, Ga-67, Tc-99m Hg-197, T1-201
(1)	Unrestricted areas personal clothing	200	2,000
(2)	Restricted areas, protective clothing used only in restricted areas, skin.	2,000	20,000

ITEM 10.8 & 10.9

APPENDIX M1 , M2, & M3

UNIT AND MULTI DOSE RECORDS:

Unit and Multi Dose Recording :

SEE ATTACHED FORM: ***Radionuclide Usage Log Form***

Labels from the unit doses will be taped on the ***Radionuclide Usage Log Form***.

Item 10.10:

MOLYBDENUM CONCENTRATION RECORDS:

Since the facility will receive either unit doses or multi doses of Tc-99m from the local radiopharmacy, Mo-99 concentration records will be received from the local radiopharmacy and will be kept with the unit and/or multi dose records.

Cedarbrook Cardiology

RADIONUCLIDE USAGE LOG

Date: _____

Product: _____

Total Activity: _____

Total Volume: _____

Cal. Time: _____

mCi / ml : _____

Lot No.: _____

Expiration Time: _____

Package Survey

Package Condition: _____ Surface: _____ mR/hr

Instrument Used: _____ 1 meter: _____ mR/hr

Package Wipe

	IN	Return
Pass:		
Fail:		

For Tc-99m only
Multi dose Tc-99m only

Action Level : < 0.15 uCi of Mo-99/ mCi of Tc-99m

$$\text{Mo-99} = \frac{\text{uCi of Mo}}{\text{mCi of Tc-99m}} = \_\_\_\_$$

TIME	PATIENT'S NAME	ACTIVITY DESIRED	VOLUME (ml)	ASSAYED ACTIVITY	TECH'S INITIAL

ITEM 10.12

APPENDIX N

AREA SURVEY (DAILY & WEEKLY):

This procedure is established as required by 10 CFR Part 35.70. Monitoring and survey of an area will detect radioactive contamination and allow evaluation of the shielding of the radioactive material or waste storage area. Daily survey and weekly wipes will detect any accidental contamination of any unusually high background radiation levels which can cause unnecessary exposure. Therefore such surveys are a good practice for personnel protection. Procedure for monitoring of Nuclear Medicine imaging and waste storage area follow:

PROCEDURE

I. DAILY AMBIENT EXPOSURE RATE SURVEY

For these surveys, one should use a GM Survey meter with a thin end window GM tube that is capable of detecting dose rates of as low as 0.1 mR/hr.
For this survey follow the following procedure:

A. Survey all the potential locations in the Hot Lab, injection areas and carts, Imaging rooms, Stress Labs and Patients waiting areas that can be contaminated.

B. In the Hot lab survey all counter tops, floor, cold waste container, sink, door knobs and face shield.

C. In the imaging rooms, survey the camera console, imaging table, laundry bags, floor underneath the camera and imaging table and cold waste container.

D. In the stress labs, survey the treadmill railings, belt, floor near the IV pole and the injection carts.

E. Survey all injection areas and carts.

F. Record all the readings in the appropriate forms.

G. Take a background reading in the hallway and record It on the form.

ITEM 10.12

APPENDIX N

AREA SURVEY (DAILY & WEEKLY):

II. WEEKLY WIPE TESTS. (Removable Contamination)

A. Weekly wipes will be done in the following areas. The location of the wipes are indicated on the floor plans of each room.

1. All the imaging rooms
2. Radioactive Waste Storage Area.
3. Hot Lab
4. Injection Rooms and Injection Carts.
5. Stress Labs.

B. Measure the wipes in Victoreen Deluxe Wipe Test Counter.

C. Measure the Standard.

D. Take a Background count.

E. Record PASS / FAIL in an appropriate form.

III. CORRECTIVE ACTION.

A. Daily Survey.

1. If the reading is above:
   a. 0.5 mR/hr for Unrestricted areas
   b. 5.0 mR/hr for Restricted areas.

2. Mark the area for contamination.
3. Restrict the entry of others to the area
4. Inform the Staff working in the area of the contamination
5. Notify the RSO
6. Investigate the cause of the high reading.
7. Decontaminate the area. Follow the minor and major decontamination procedures.

ITEM 10.12

APPENDIX N

AREA SURVEY (DAILY & WEEKLY):

8. If needed, cover the area with absorbent pads.
9. Document the readings before and after the decontamination procedure.
10. Document the corrective action taken and results obtained.

B. WEEKLY WIPES.

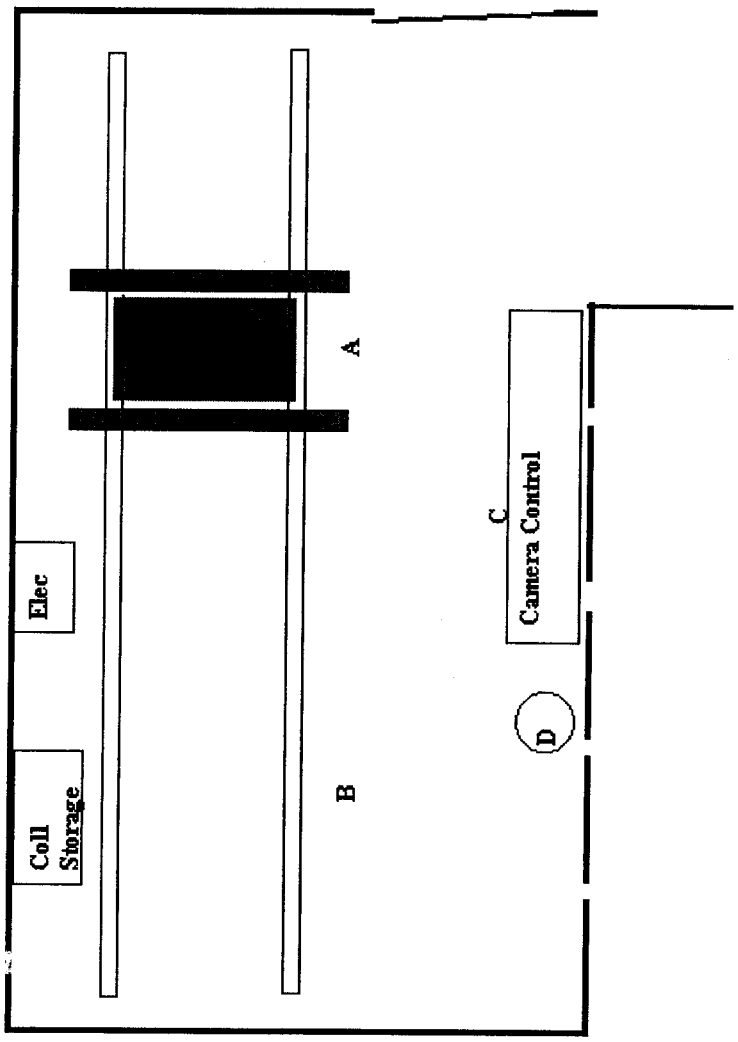
The surface is considered contaminated when removable contamination measurements **FAIL**.

IV. CORRECTIVE ACTION.

If the surface is contaminated:

1. Mark the contaminated area.
2. Restricted the entry of others to the area.
3. Inform the staff working in the area of contamination.
4. Notify RSO
5. Investigate the cause of high readings.
6. Decontaminate the area. Follow the minor and major decontamination procedures.
7. If needed, cover the area with absorbent pads.
8. Document the readings before and after the decontamination procedure.
9. Document the corrective action taken and results obtained.

APPENDIX N



Appendix N

Cedarbrook Cardiology

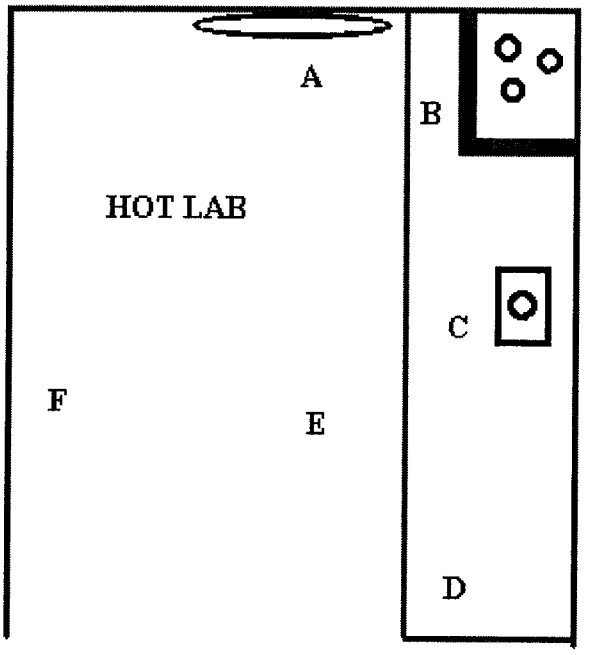
SCAN ROOM

Room Survey
Daily and Weekly

LOCATIONS Record mR/hr for room survey and P (Pass) or F (Fail) for weekly wipes										Corrective Action
DATE	Bkg	A	B	C	D	Trash				

Decontaminate the area if above background or if Fail the wipe.
Notify the RSO immediately

APPENDIX N



Appendix N

Cedarbrook Cardiology

HOT LAB

Room Survey
Daily and Weekly

	LOCATIONS Record mR/hr for room survey and P (Pass) or F (Fail) for weekly wipes									Corrective
DATE	**Bkg**	**A**	**B**	**C**	**D**	**E**	**F**	**Trash**	**Sink**	**Action**

Decontaminate the area if above background or if Fail the wipe.
Notify the RSO immediately

Appendix N

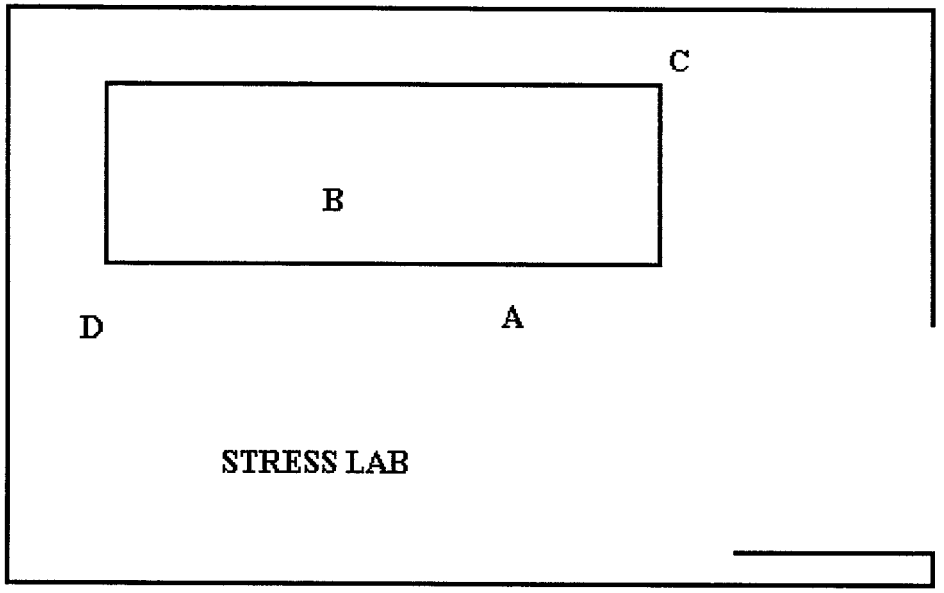
Cedarbrook Cardiology

Room Survey
Daily and Weekly

STRESS LAB

	LOCATIONS Record mR/hr for room survey and P (Pass) or F (Fail) for weekly wipes									
DATE	**Bkg**	**A**	**B**	**C**	**D**	**Trash**				**Corrective Action**

Decontaminate the area if above background or if Fail the wipe.
Notify the RSO immediately



Appendix N

APPENDIX R

Item 11.1

RADIOACTIVE WASTE MANAGEMENT

PURPOSE

The Nuclear Medicine Department uses radionuclides for both Diagnostic and Therapeutic procedures. These radionuclides have different half lives (T 1/2). The dose preparations and injections produce waste which is contaminated by the radionuclides and therefore is classified as **Radioactive Waste.** It is the responsibility of the **Nuclear Medicine Department Staff to handle and dispose of this radioactive waste APPROPRIATELY.**

Radioactive Waste if not **handled properly becomes a RADIATION HAZARD** and can cause unnecessary exposure to the members of the general public and can contaminate the Environment. Therefore proper waste management is a very important function of the Nuclear Medicine Department.

Under no circumstances should Radioactive Waste be disposed of through the regular waste WITHOUT PROPER MONITORING.

PROCEDURE

In the Nuclear Medicine Department approximately 75% of the time short half life Radionuclides (99m Tc). Therefore it is very easy to separate the waste by it's half life and store it for decay before disposal.

Short Half Life: Any radionuclide with Half Life of seven (7) hours or less.

Long Half Life: Any radionuclide with Half Life of seven (7) hours or more.

Collection f Short Half Life and Long Half Life Radioactive Waste:

Sine the Nuclear Medicine Department operates from Monday to Saturday, it is easy to collect the waste from Saturday to Friday Every Friday, remove the waste from the Hot Lab and store it for decay in the Hot Trash Storage Area. This Storage area is located in the in the room near the hot lab.

APPENDIX R

APPLICATION FOR MATERIAL LICENSE . Attachment U1

Item 11.1

RADIOACTIVE WASTE MANAGEMENT

Collect ALL Short and Long half life waste separately and label them appropriately as follows:

(a.) All 99m Tc waste
(b.) All 201 TI waste
and (e.) All other waste SEPARATELY in the containers prided for these wastes.

DO NOT MIX SHORT AND LONG HALF LIFE MATERIALS.

1. Syringes/Needles:

Place all the syringes and needles in the lead container that was received from the local pharmacy. Place all the lead syringe container in the boxes provided by the local pharmacy. Ship this boxes to the pharmacy after wipe tested and when the boxes are found to be contamination free.

Log the wipe test results in the appropriate forms.

All other contaminated trash must be placed in the appropriate lead lined container for storage.

Store this container in the hot trash storage area for decay **(10 half lives)** before disposal. (follow disposal procedure)

Follow the same procedure for **Thallium 201 and other long half life materials. These wastes must be collected separately in the containers provided. NO MIXING OF THESE WASTES IS ACCEPTABLE.**

Every Friday remove the trash from these containers and Label the trash as follows:

Date the collection was transferred
Radionuclide enclosed

Store this trash for decay **(10 half lives)** before disposal. Follow the disposal prouder.

Appendix R

Item 11.1

RADIOACTIVE WASTE MANAGEMENT

When the trash is placed in the Hot Trash Storage area for decay, record the following information on the form provided:

1. **Storage Date:** the day the trash is placed in the Hot Trash storage area, in the basement.

2. **Half Life:** e.g. 6 hrs for 99m Tc waste.

3. **Isotope.**

4. **Proposed Disposal Date:** e.g. for 99m Tc waste disposal is after 60 hrs (10 half lives). So if the waste was stored on the first of the month, then the proposed disposal date would be the third of the month.

5. **Date Waste was Disposed:** Actual date when the waste is removed from the Hot storage area for disposal after 10 half lives.

6. **Survey.**
   a. BKG: background reading taken outside of the storage room in the hallway.
   b. Waste: reading of the trash bag surveyed.

7. **Remarks:** Any unusual findings such as high readings after 10 half lives or if the trash was placed for further decay.

Store this trash for decay **(10 half lives)** before disposal. (follow the disposal procedure)

DISPOSAL PROCEDURE:

Short Half Life / Long waste stored for decay will be disposed as follows:

1. Whenever handling radioactive trash always use gloves , lab coat, film badge, and ring badge.

2. Every Friday remove the 99m Tc waste from the previous week from the Hot Storage area.

APPENDIX R

Item 11.1

RADIOACTIVE WASTE MANAGEMENT

3. Check the battery on the survey instrument. Take a background radiation reading outside the Hot Trash area in the hallway.

4. Make sure that the survey instrument is operating at the lowest scale(0.05-0.1 mR/hr).

5. Record the background radiation level on the disposal form. (see attached)

6. Place the trash on absorbent pads and place in the front room or hallway and survey the trash thoroughly from all sides,

7. If the survey readings are **NOT ABOVE THE BACKGROUND RADIATION LEVEL READINGS THEN DISPOSE OF THE TRASH IN THE REGULAR TRASH.**
Follow the facility guidelines for the regular trash.

8. **IF THE SURVEY READINGS ARE ABOVE THE BACKGROUND RADIATION LEVEL: DO NOT DISPOSE THE TRASH. STORE THE TRASH FOR ANOTHER 24 HOURS.**

9. Survey the trash after 24 hours. If the reading is **NOT ABOVE THE BACKGROUND RADIATION LEVEL THEN DISPOSE OF THE TRASH AS REGULAR TRASH.** Follow the hospital guidelines for the trash. **If the survey readings are still above BACKGROUND RADIATION LEVEL: DO NOT DISPOSE OF THE TRASH. NOTIFY THE RADIATION SAFETY OFFICER. NOTIFY THE CHIEF TECHNOLOGIST.**

10. After the completion of the disposal procedure the Technologist must **monitor** his/her :
    a. Hands
    b. Clothes
    c. Bottoms of the shoes.
    d. Record the readings in the appropriate forms.

APPENDIX R

Cedarbrook Cardiology

WASTE DISPOSAL LOG

Isotope: Tl-201

No other radionuclide is used at this facility

Date			Reading			
Collection	**Proposed Disposal**	**Disposal**	**Background mR/hr**	**Waste mR/hr**	**Instrument Used**	**Tech's Signature**

Do Not Dispose Any Waste If Waste Survey Reading Exceeds Back Ground Reading

APPENDIX R

Cedarbrook Cardiology

WASTE DISPOSAL LOG

Isotope: TcO-4
No other radionuclide is used at this facility

Date			Reading			
Collection	Proposed Disposal	Disposal	Background mR/hr	Waste mR/hr	Instrument Used	Tech's Signature

Do Not Dispose Any Waste If Waste Survey Reading Exceeds Back Ground Reading

Cedarbrook Cardiology

DAILY HANDS AND BODY SURVEY

DATE	NAME	HANDS AM	HANDS PM	WHOLE BODY	Instrument Used	CHECKED BY

OFFICIAL RECORD COPY ML 10 124129