

VOID SHEET

TO: License Fee Management Branch  
FROM: RTT  
SUBJECT: VOIDED APPLICATION

Control Number: 89643  
Applicant: Mr. Ruddy  
Date Voided: 9/18/90  
Reason for Void: \_\_\_\_\_

No resp. to def. letter  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

DMB 9/25/90  
Signature Date

Attachment:  
Official Record Copy of  
Voided Action

FOR LFMB USE ONLY

Final Review of VOID Completed:

- Refund Authorized and processed
- No Refund Due *after rev.*
- Fee Exempt or Fee Not Required

*ML20*

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Log completed   
Processed by: eg

SEP 25 1990

C. G. Reddy, M.D., F.A.C.C.  
Suite 1603  
1492 E. Broad Street  
Columbus, OH 43205

SUBJECT: ABANDONMENT OF YOUR REQUEST FOR A NEW BYPRODUCT MATERIAL LICENSE  
DATED JUNE 18, 1990

Gentlemen:

This refers to your request for a new Byproduct Materials License dated June 18, 1990 and our letter dated July 27, 1990 in which we requested additional information and notified you that unless a response was received in 30 days we would void your request.

We have not received a response to date.

You are hereby notified that we consider that you have abandoned your application and we have voided the request. This action is without prejudice to resubmission.

If you resubmit the same request within one year of the date of this letter, we will reactivate our review. Information submitted in response to this letter should refer to VOIDED CONTROL NUMBER 389643

Sincerely,

Original Signed By  
Patricia M. Vacherlon  
Materials Licensing Section

Enclosure: Ltr dtd July 27, 1990

RIII

Vacherlon/dsv  
09/ /90

90  
SEP 28 P2:52  
RECEIVED

F

JUL 27 1990

C. G. Reddy, M.D., F.A.C.C.  
Suite 1603  
1492 East Broad Street  
Columbus, OH 43205

Docket No. 030-31797  
Control No. 389643

Gentlemen:

We have reviewed your application for a new nuclear medicine license and find that we will need additional information as follows:

10 CFR Part 35, Sections 35.910 and 35.920 outline the minimum acceptable training required for an individual to become an authorized user of nuclear material. One of the requirements listed in 35.920 is 500 hours of clinical training under the supervision of an authorized user.

Dr. Reddy's preceptor statement lists only 350 hours of supervised clinical training. We cannot authorize Dr. Reddy as a user until he provides us with written documentation of 150 additional hours of clinical training under the supervision of an authorized user.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 89643.

Upon failure to file an answer within the specified time, we will consider that you have abandoned your request and will void this action. This is without prejudice to resubmission of the application.

If you have any questions or require clarification on any of the information stated above, you may contact us at (708) 790-5625.

Sincerely,

Original Signed By  
Patricia M. Vacherlon  
Materials Licensing Section

RIII  
*P. M. Vacherlon*  
Vacherlon/mc  
8/23/90





**TOWER CARDIOLOGY SERVICE, INC.**

*C.G. Reddy, M.D., F.A.C.C.*  
1492 East Broad Street, Suite 1603  
Columbus, Ohio 43205  
614-252-3302

Diplomate of American Board of Internal Medicine • Diplomate of American College of Cardiology

June 18, 1990

N.R.C. Licensing Section  
799 Roosevelt Rd.  
Glen Ellen, IL 60137

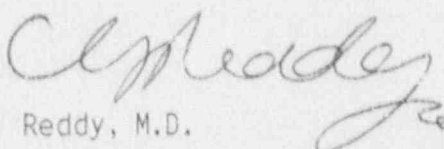
RE: Nuclear License

Dear Sirs,

Please find enclosed application forms completed along with application fee of \$580.00. I will await your favorable consideration for issuance of my nuclear license.

Thank you for expediting this matter.

Sincerely yours,

  
C. G. Reddy, M.D.

CGR:gw

Encl/

RECEIVED  
JUN 19 1990  
REGION III

JUN 19 1990

*Cardiac Catheterisation*  
*Interventional Cardiology:*  
-Coronary Thrombolysis  
-Coronary Angioplasty

*Tower Holter Monitoring*  
*Electrocardiography*  
*Exercise Testing*

*Pacemaker Clinic*  
*Echocardiography*  
*Cardiac Doppler Studies*

CONTROL NO. 89643

# APPLICATION FOR MATERIAL LICENSE

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.

**APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:**

U.S. NUCLEAR REGULATORY COMMISSION  
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS  
WASHINGTON, DC 20545

**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:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I  
NUCLEAR MATERIALS SAFETY SECTION B  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PA 19406

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION II  
NUCLEAR MATERIALS SAFETY SECTION  
101 MARIETTA STREET, SUITE 2900  
ATLANTA, GA 30333

**IF YOU ARE LOCATED IN:**

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION III  
MATERIALS LICENSING SECTION  
799 ROOSEVELT ROAD  
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV  
MATERIAL RADIATION PROTECTION SECTION  
611 RYAN PLAZA DRIVE, SUITE 1000  
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V  
NUCLEAR MATERIALS SAFETY SECTION  
1450 MARIA LANE, SUITE 210  
WALNUT CREEK, CA 94506

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 JURISDICTION.

<p>1. THIS IS AN APPLICATION FOR (Check appropriate item)</p> <p><input checked="" type="checkbox"/> A. NEW LICENSE</p> <p><input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____</p> <p><input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____</p>	<p>2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code)</p> <p>C. G. Reddy, MD, FACC 1492 East Broad Street, Suite 1603 Columbus, Ohio 43205</p>
---	---

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

Suite 1603  
1492 East Broad Street  
Columbus, Ohio 43205

<p>4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION</p> <p>C. G. Reddy, MD, FACC</p>	<p>TELEPHONE NUMBER</p> <p>614-252-3302</p>
--	---

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.

<p>5. RADIOACTIVE MATERIAL a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.</p> <p>see attached</p>	<p>6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.</p> <p>see attached</p>				
<p>7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.</p> <p>see attached</p>	<p>8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.</p> <p>see attached</p>				
<p>9. FACILITIES AND EQUIPMENT.</p> <p>see attached</p>	<p>10. RADIATION SAFETY PROGRAM</p> <p>see attached</p>				
<p>11. WASTE MANAGEMENT.</p> <p>see attached</p>	<p>12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)</p> <table border="1"> <tr> <td>FEE CATEGORY</td> <td>7 C</td> <td>AMOUNT ENCLOSED</td> <td>\$580.00</td> </tr> </table>	FEE CATEGORY	7 C	AMOUNT ENCLOSED	\$580.00
FEE CATEGORY	7 C	AMOUNT ENCLOSED	\$580.00		

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, 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 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.

SIGNATURE—CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
	C.G. REDDY	M.D.	6-18-1990

RECEIVED

FOR NRC USE ONLY				APPROVED BY JUN 19 1990 REGION III CONTROL NO. 89643
TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	
AMOUNT RECEIVED	CHECK NUMBER			
580	1622	7/6/90		

## APPLICATION FOR MATERIAL LICENSE

### DOCUMENTATION OF ATTACHMENTS TO THIS APPLICATION

Attachment Section	Description Of The Attachment Enclosed
A.	Description Of The Scope Of The Operation
B.	Radioactive Materials Requested In This Application
C.	Training And Experience Of Authorized User And Radiation Safety Officer
D.	Personnel Qualifications And Training
E.	Facilities And Related Equipment
F.	Radiation Detection Instrumentation
G.	Calibration Of The Survey Instrument
H.	Calibration Of The Dose Calibrator
I.	Quality Control Of The Gamma Camera
J.	Personnel External Monitoring Program Radiation Safety Committee ALARA Program
K.	Leak Testing Of Sealed Sources
L.	Rules For The Safe Use Of Radiopharmaceuticals
M.	Procedure For Spills
N.	Procedure For Ordering Radioactive Materials
O.	Procedure For Opening Packages
P.	Radiopharmaceutical Records
Q.	Procedure For Area Surveys
R.	Radioisotope Waste Disposal Procedure

The above documents will be found in this order in the following pages.

## DESCRIPTION OF THE SCOPE OF THE OPERATION

This license application is for nuclear cardiology procedures only. The procedures will be implemented in a private practice facility. The materials used will be obtained from a radiopharmacy. The applicant will not obtain a  $^{99m}\text{Tc}/^{99}\text{Mo}$  generator. There is no intent to purchase any materials in "bulk" form, and all sources will be obtained in unit dose form from the radiopharmacy.

All radioactive wastes that came from the radiopharmacy, ie spoiled unit doses or used syringes that contain residual activity, will be returned to the radiopharmacy for disposal and records of this transfer will be maintained by the applicant. Other wastes, ie wipes and contaminated materials will be stored by the applicant for decay in storage (DIS).

If the scope of the operation needs to be changed to meet the medical needs of the applicant-physician the application will be amended prior to those changes.

## RADIOACTIVE MATERIALS REQUESTED IN THIS APPLICATION

## Radiopharmaceuticals

The applicant wishes to receive a license for only nuclear cardiology procedures. These procedures, to be performed in an out-patient facility, will be limited to:

<u>Radioisotope</u>	<u>Form</u>	<u>Amount, mCi Of Each Form</u>	<u>Item 6. Purpose Of Use</u>
99m Tc*	Pertechnetate	80.00	Human Use
	HSA	40.00	Human Use
	PYP	40.00	Human Use
201 Tl*	Chloride	60.00	Human Use
-----			
99m Tc*	Pertechnetate	5.00	Quality Control & Calibration
201 Tl*	Chloride	1.00	Quality Control & Calibration
-----			

Sealed Sources for Quality Control and Calibration as described on the next page.

\* Note: The sources of 99m Tc and 201 Tl will be obtained from the radiopharmaceutical supplier in unidose or multidose form. The applicant will not obtain a generator for 99m Tc or make "kits" using the radiopharmaceuticals listed in this application. (The "supplier" includes the radiopharmacy)

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

It is recognized that the <sup>201</sup>Tl and <sup>57</sup>Co are licensed by the "State" including Agreement States.



## Sealed Sources

The sealed sources will be obtained from Atomic Products Corporation, P.O. Box R, Shirley, New York 11967

The Sources used for the dose calibrator are:

<u>Element and Mass Number</u>	<u>Form</u>	<u>Max., mCi</u>	<u>Catalogue Number</u>
Ba 133	sealed	0.250	063-562
Cs 137	sealed	0.200	101-356
Co 57	sealed	5.000	063-261

The Sources used for the gamma camera are:

<u>Element and Mass Number</u>	<u>Form</u>	<u>Max., mCi</u>	<u>Catalogue Number</u>
Co 57	sealed	5.000	062-295

A description of the sources, as provided by the supplier, are given in the information below.

## Isotope Calibrator Reference Sources

- For checking calibrator accuracy, performance and consistency.

Good practice dictates, and regulatory agencies recommend, that isotope calibrators used for measuring diagnostic and therapeutic doses of radiopharmaceuticals be checked regularly over the calibrator's range of measurements. Calibrator performance is easily monitored by using the following calibrated standards to verify the accuracy of its assays:

- A long-lived source, such as  $^{137}\text{Cs}$  ( $T_{1/2} = 30$  yrs.), to avoid the tedium of constant decay corrections.
- A  $^{57}\text{Co}$  source ( $T_{1/2} = 270$  days) that simulates  $^{99\text{m}}\text{Tc}$ , the most common radioisotope in nuclear medicine.

By keeping a daily log of the values obtained on selected ranges with both standards, the user develops a performance record that detects calibrator error or failure before a mistake is made in a patient's dose.

Both sources are supplied in 20ml epoxy in a 27ml plastic vial, 85 mm H x 30 mm D. Calibrated to  $\pm 5\%$ .

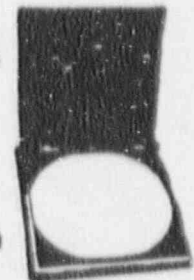
- 063-562 Calibrated Barium 133 Source,  
250 $\mu\text{Ci}$
- 101-356 Calibrated  $^{137}\text{Cs}$  Source  
200 $\mu\text{Ci}$
- 063-261 Calibrated Simulated  $^{99\text{m}}\text{Tc}$  Source  
(Cobalt-57), 5mCi



## Cobalt-57 Flood Sources

Intended Uses:

- Daily intrinsic uniformity checks
- Extrinsic collimator checks
- Linearity and resolution checks with bar phantom
- As transmission sources
- Quality control for accreditation and regulatory requirements



The Sources contain Cobalt-57, uniformly dispersed in a plastic disc, which is completely encased in an attractive aluminum cover. Each source is supplied in a lead-shielded wooden carrying case. The shielding reduces the exposure rate at the front surface to approximately 1.4mR/hr.

Emission non-uniformity (distribution) less than 1%. Available in three sizes.

Flood Source:

- 062-295 14" diameter, 5mCi

**SUBSTITUTE NRC 313 M  
SUPPLEMENT A**

**TRAINING OF  
AUTHORIZED USER OR RADIATION SAFETY OFFICER**

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER

C. G. Reddy, MD, FACC

2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE

OHIO

ADDRESS

1492 East Broad Street, Suite 1603  
Columbus, Ohio 43205

**3. CERTIFICATION**

SPECIALTY BOARD  
A

CATEGORY  
B

MONTH AND YEAR CERTIFIED  
C

**4. Training Received in Basic Radioisotope Handling Techniques**

Field of Training A	Location and Date(s) of Training B	Type and Length of Training				
		Principles of Radiation	Medical Radiation Instrumentation	Medical Radiation Protection	Lecture Laboratory Courses (Hours)	Radio-pharmaceuticals and Chemistry
35.920(b)(1)	September 18-27, 1986  Columbus, Ohio					
a. RADIATION PHYSICS AND INSTRUMENTATION		39	31	8	22	100
b. RADIATION PROTECTION		2	4	20	4	30
c. MATHEMATICS PERTAINING TO THE USE AND MANAGEMENT OF RADIOACTIVITY		5	6	6	3	20
d. RADIATION BIOLOGY		2	3	12	3	20
e. RADIOPHARMACEUTICAL CHEMISTRY		2	6	4	18	30

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
-----see the attached sheets-----				

**6. TRAINING WAS COMPLETED UNDER THE DIRECT SUPERVISION OF:**

NAME: Institute For Nuclear Medical Education, Inc.  
 ADDRESS: 5785 Arapahoe Suite D  
 CITY: Boulder STATE: Colorado ZIP: 80303  
 Authorized Signature: Charles H. Rose, MA, MSPH, D (ABSM) TELEPHONE: 303-443-7358



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		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.
FULL NAME <i>C.G. Reddy MD</i>	STREET ADDRESS <i>1492 E Broad St Suite 1603</i> CITY <i>Columbus OH</i> STATE <i>OH</i> ZIP CODE <i>43205</i>	

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION		
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
IN VITRO STUDIES			
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING		
P-32	EYE TUMOR LOCALIZATION		
Sr-76	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER			
Tc-99m	BRAIN IMAGING		
	CARDIAC IMAGING	80	
	THYROID IMAGING		
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING	20	
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING		
	LUNG IMAGING		
BONE IMAGING			
OTHER			

**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 <small>(Additional information or comments may be submitted in duplicate on separate sheets.)</small>  D
P-32 <small>(Sodium)</small>	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 <small>(Colloid)</small>	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
	TELE THERAPY TREATMENT		
Cs-137 or Co-60	TELE THERAPY TREATMENT		
	TREATMENT OF EYE DISEASE		
Other	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Br-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other	201Tl Cardiovascular	40	
Other	57Co QC & Calibration	NA.	

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

October 1985 - September 1986  
350 hrs.

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

a. NAME OF SUPERVISOR

J. Pala, MD

b. NAME OF INSTITUTION

Knox Community Hospital

c. MAILING ADDRESS

MT Vernon, OH

d. CITY

**5. PRECEPTOR'S SIGNATURE**

X J. Pala, MD.

7. PRECEPTOR'S NAME (Please type or print)

J. Pala, MD  
[aka JAWAHAR PA-PIYAPPAN M.D.]

8. DATE

10. 8. 86.

6. MATERIALS LICENSE NUMBER(S) -

# 34-18120-01

FORM NRC-313M-SUPPLEMENT B (8-78)

(expiry date July 1988)



MOUNT CARMEL MEDICAL CENTER

793 WEST STATE STREET COLUMBUS, OHIO 43222 614-225-5000

10-10-86

TO WHOM IT MAY CONCERN:

RE: Nuclear Medicine Licensure

This is to certify that C.G. Reddy, M.D. is authorized to treat and admit patients containing radioactive materials, to the hospital. He is certified in the specialty board of Internal medicine and subspecialty Board of American College of Cardiology.

Sincerely

Mary Starrett



## PERSONNEL QUALIFICATIONS AND TRAINING

## Technologist Qualifications

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

In addition to the above, the physician applicant will interview the technologist and obtain a resume of his/her experience and will evaluate the technologist through close observation of the nuclear medical techniques of the technologist in the 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 byproduct material is being used. The ancillary personnel include the 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 with or in 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, misadministrations, and other incidents including high personnel exposure as determined by personnel monitoring.

## Topics of Instruction:

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

- a) Applicable regulations and license conditions and workers rights
- b) Areas where radioactive materials are used or stored
- c) Potential hazards associated with radioactive materials and procedures for each area where employees work including bio-hazards
- d) Appropriate radiation safety procedures
- e) Licensee's in-hours work rules
- f) Each individual's obligation to report unsafe conditions to the RSO
- g) Appropriate response to emergencies or unsafe conditions
- h) Personnel who work with the materials will also receive copies of the procedures for monitoring the performance of imaging equipment, ordering and receiving radioactive material, opening packages, records of byproduct material use, radiation area surveys, safe use of radiopharmaceuticals, waste disposal and emergency procedures

## Method of Instruction:

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

## Method of Evaluation:

Evaluation will be by the RSO or his/her agent and will be informal by actual observation of the individuals work activities.

FACILITIES-ANNOTATED DRAWING OF THE RADIOISOTOPE FACILITY

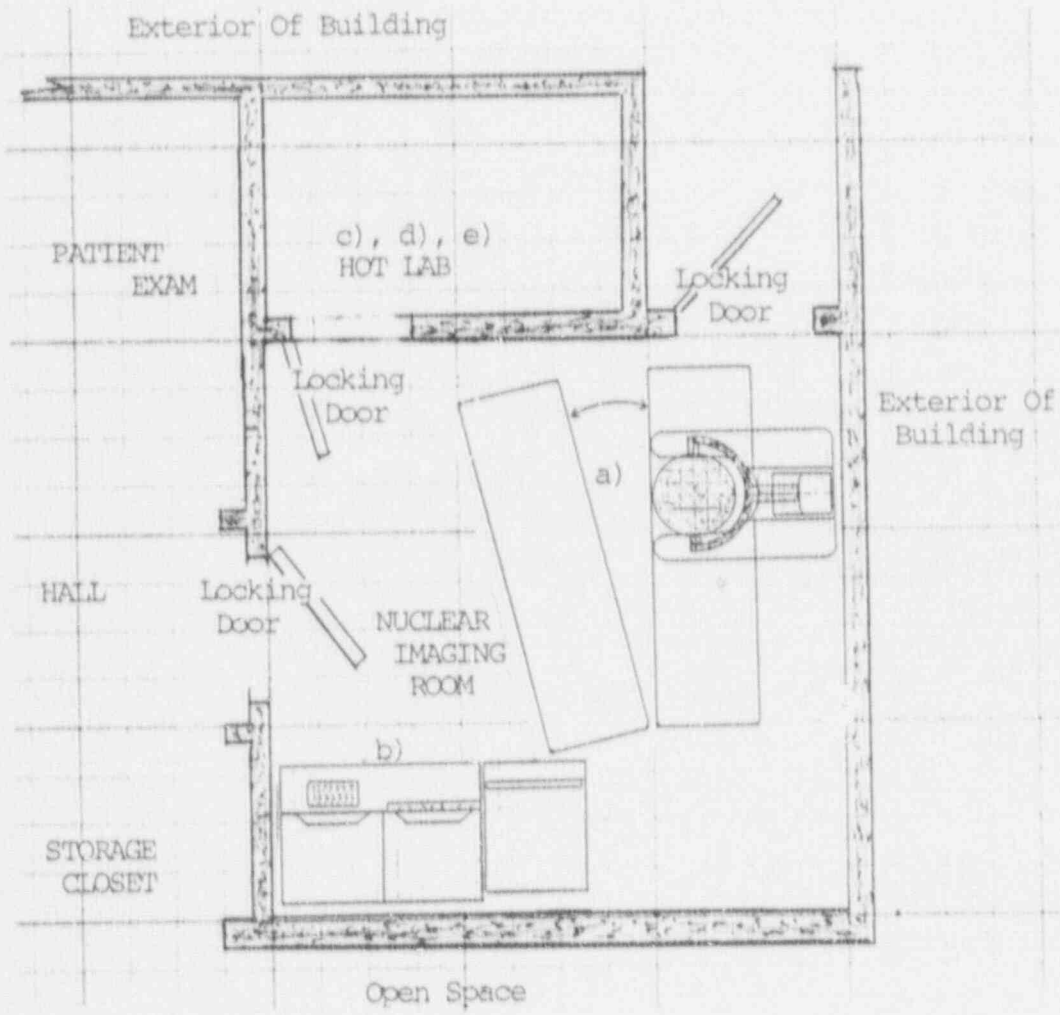
Scale: 1/4" = 1'-0"

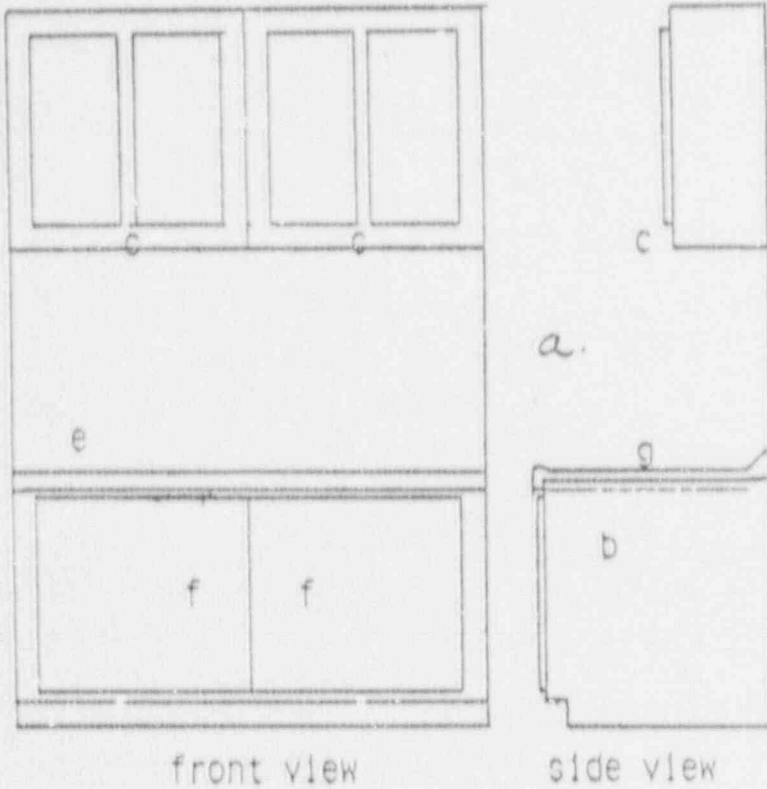
Direction of North

Shielding is indicated on the drawing and on the following sheets of this application.

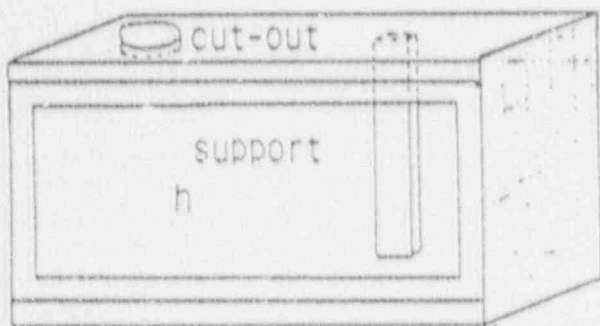
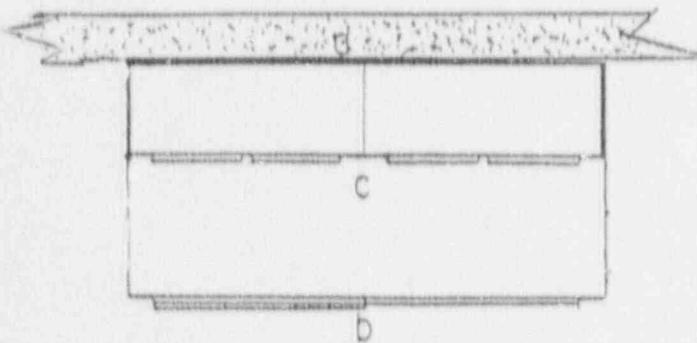
- Identification of Areas
- a) nuclear imaging area
  - b) computer area
  - c) radioisotope receipt
  - d) radioisotope storage
  - e) radioisotope waste

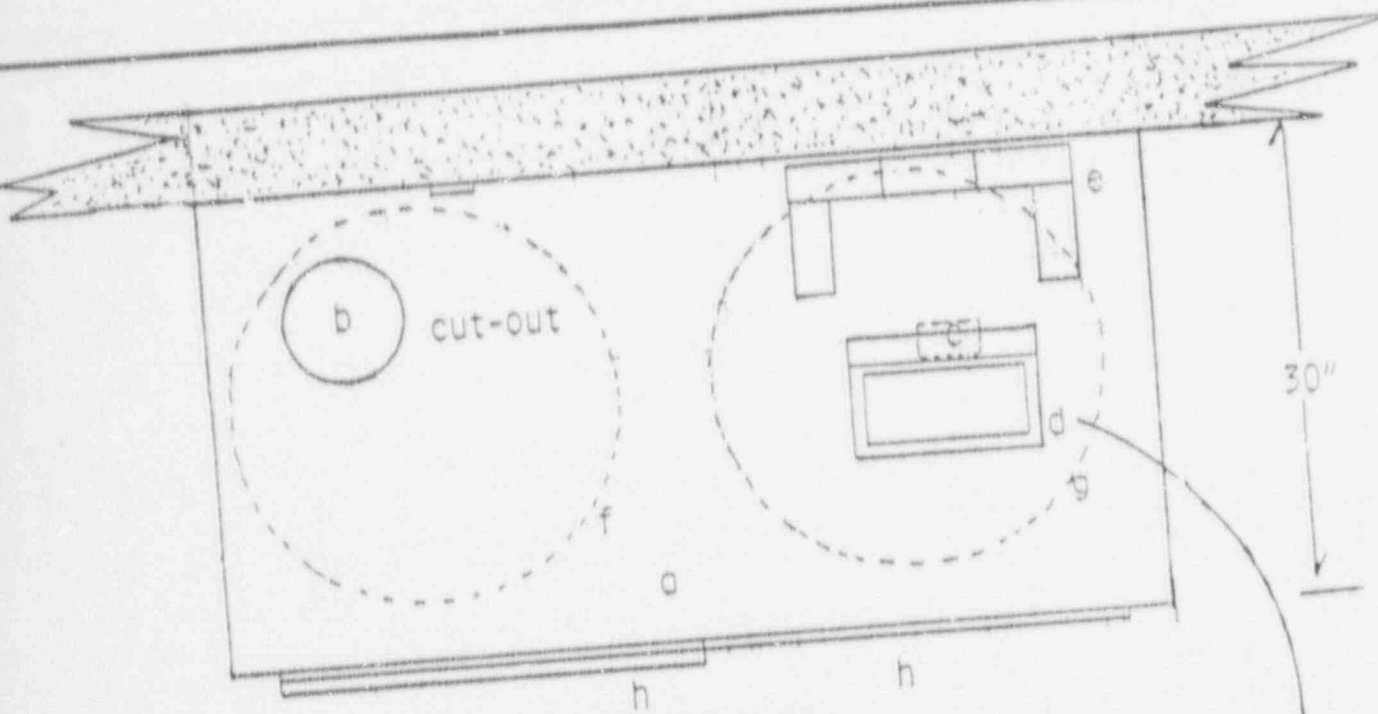
Tower Cardiology  
 C. G. Reddy, MD, FACC  
 1492 East Broad Street, Suite 1603  
 Columbus, Ohio 43205



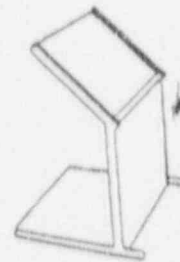


LEGEND	
IDENT	DESCRIPTION
a.	Hot Lab Detail
b.	base cabinet
c.	wall cabinet
d.	general construction & no shielding
e.	above counter outlet
f.	sliding doors
g.	counter top detail
h.	counter top support





LEGEND	
IDENT	DESCRIPTION
a.	COUNTER TOP
b.	CUT OUT for waste
e.	Shield
d.	Shield detail
e.	Pb bricks or other metal shield
f.	DIS container "active"
g.	DIS container in decay
h.	sliding doors



## FACILITIES-TABLE TOP BARRIER SHIELD

## Table Top Lead Barrier Shield

Protect head and body from radiation when working with radioactive material.

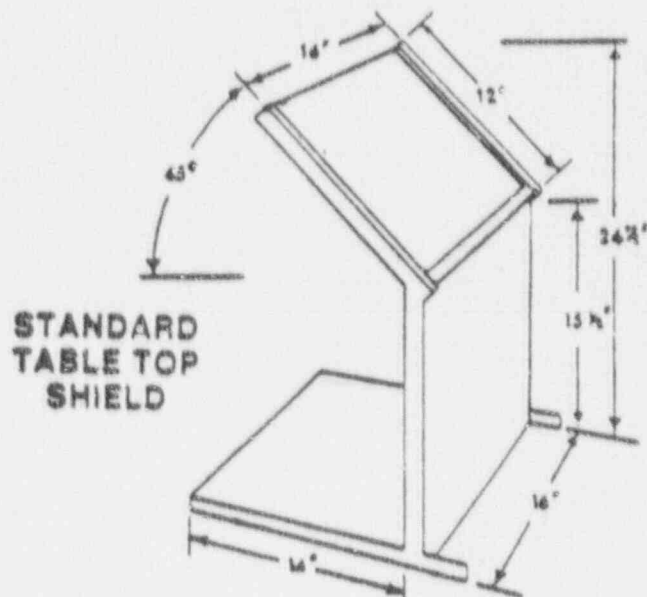
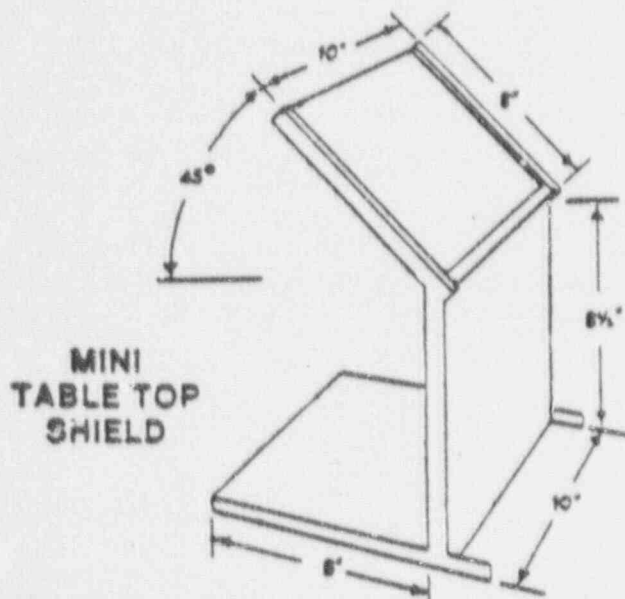
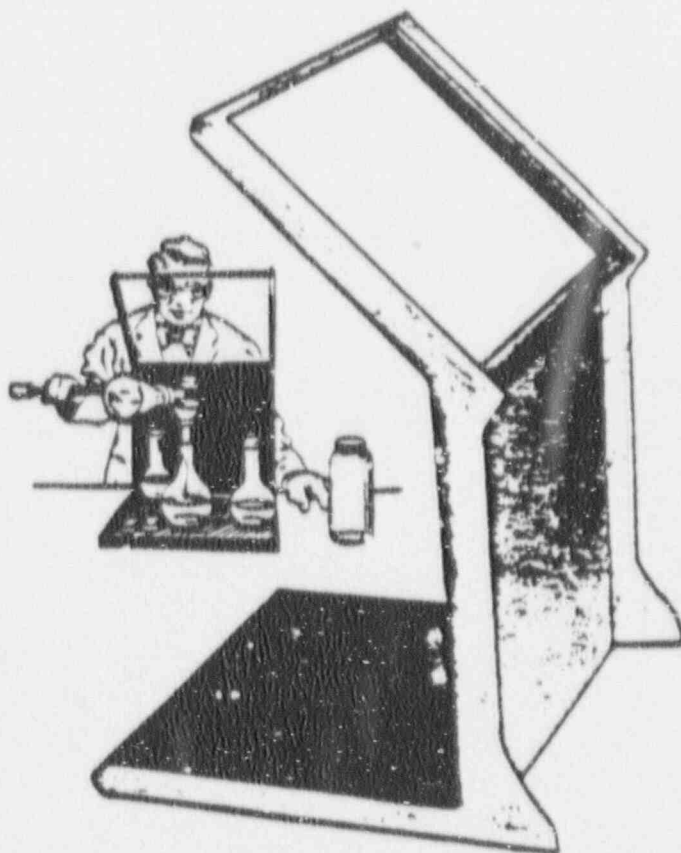
**MINI TABLE TOP SHIELD** for small jobs in limited working areas.

**STANDARD TABLE TOP SHIELD** for all routine work requiring protection against exposure to radiation.

Select the shield most suited to your workload. Both units provide exceptional protection to the clinician when setting up technetium generators, filling syringes, performing radium loading procedures, etc.

$\frac{1}{2}$ " thick lead wall protects the torso while the base provides ample working surface and balance against tipping. Face shielding is optically clear  $\frac{1}{4}$ " thick lead glass (1 or 2 pieces may be specified when ordering), cantilevered for unimpaired viewing or work area. The lead equivalent of each thickness of glass is 2.00mm.

Both units can be moved with little effort to any convenient location, allowing total flexibility in choice of work area.





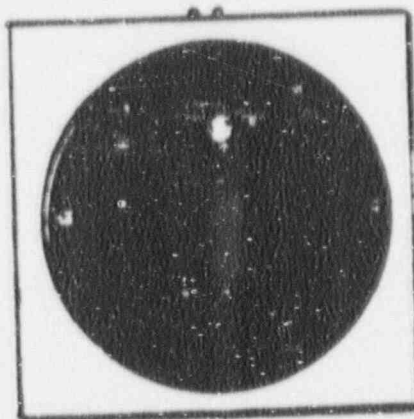
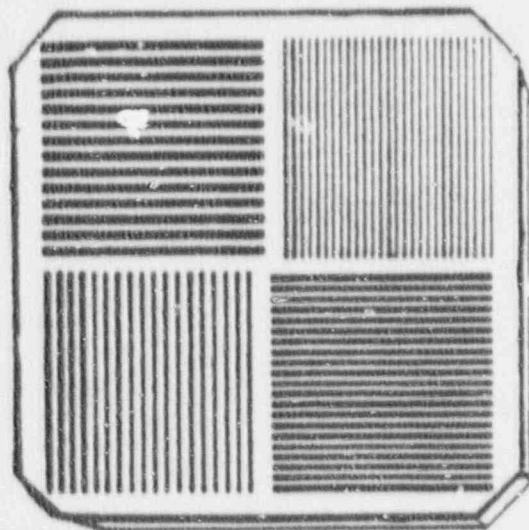
## EQUIPMENT QUALITY CONTROL PHANTOMS

Also, see the source listed in this application under "Sealed Sources"

EMISSION PHANTOM

## Extra Large Flood Phantom Source

- 15" diameter pool will totally include a patient's lungs, allowing accurate patient position when using a diverging collimator.
- 16 1/2" x 16 1/2" 1" thick with 15" diameter x 1/2" cavity for suitable radionuclide.
- Easy to fill... drain ports provided.

TRANSMISSION PHANTOM

## Standard High Resolution Bar Phantom

- Bar Widths: 1/4", 3/16", 1/32" and 1/8"
- (6.35 mm, 4.77 mm, 3.97 mm, 3.18 mm)
- 15" field across bar configurations (38.1 cm)

FACILITIES- RADIATION SAFETY EQUIPMENT

### Vial Shields

This lead shield, available in either 1/4" or 1/2" thickness, was designed to permit safe, convenient handling of vials containing liquid radioisotopes. It is particularly important when milking "cows". The vial provided with the generator may be placed in the shield, and the generator eluted in accordance with the manufacturer's instructions.

The shield has a high density lead-glass panel, with shielding thickness equivalent to that of the lead wall, so that the entire process may be viewed. The shield has a screw-type cover with an opening through which a syringe needle may be inserted for withdrawal of the radioisotope from the vial.



1/2" Thick

### Pro-Tec® Syringe Shield

Pro-Tec Syringe Shields are the first functional, safe, unobtrusive, easy-to-use, unbreakable, and lightweight syringe shields available. The simple design is comfortable for both patient and clinician. The patented spring loaded twist lock or the stainless steel and brass screw lock keep disposable syringes snug inside the shield. Pro-Tec Syringe Shields are half the weight of other syringe shields, yet the Pro-Tec will nominally reduce exposure from  $^{99m}\text{Tc}$  by a factor of 20. The standard models are used by loading the syringe outside the shield. The Pro-Tec Vu-Thru has a viewing port, so that drawing and injecting can be accomplished with the syringe in the shield. A special optical glass window with a density of 2.3 gmv/cc covers the port.

The VU-THRU



6-0 disposable syringes (twist lock)

U.S. Pat. #2,830,541

VU-THRU (Glass)

- 807-303 Pro-Tec Syringe Shield 3cc
- 807-505 Pro-Tec Syringe Shield 5cc

### Lead Lined Storage Container

For Contaminated Syringes

- Safely holds used hot syringes
- Rapid, safe disposal



SPECIFICATIONS:

1/4" Lead Shielding

Measures: 6 1/2" high  
5" diameter  
Weight: 7 lbs

### Lead Shielded Syringe Holder

For syringes that radioisotopes. Accommodates syringes up to 5cc, or a syringe in a PRO-TEC shield. Entire unit is sheathed in steel. Large diameter base prevents toppling. Ideal for safe storage and transport of syringes.

SPECIFICATIONS:

Height: 6.5"  
Weight: 6 lbs



## RADIATION DETECTION INSTRUMENTATION

Instrument	Supplier/Model	Use
Gamma Camera System	Cardio-Cam I, II or SPECT System as furnished by: Cardio-Cam Corporation 5785 Arapahoe, Suite D Boulder, CO. 80303	Nuclear Medical Imaging for Nuclear Cardiology Procedures
Nuclear Medical Computer	As Supplied by Cardio-Cam Corporation as described above	Nuclear Medical Data Presentation and Analysis
Dose Calibrator	Atomlab 100 Dose Calibrator Catalogue # 086-250 from: Atomic Products Corp. P.O. Box 702 Shirley, New York 11967	Radiopharmaceutical Quality Control of Patient Dose's
Survey Meter	Bicron Surveyor 2000 Portable Survey Meter as supplied by: Bicron Corporation 12345 Kinsman Road Newbury, Ohio 44065	Daily Surveys, Ambient Exposure Surveys, Package Surveys, Spill and Contamination Surveys and other measurements.
	External GM Probe Model: SWGM as furnished by the Bicron Corporation as is listed above	As described above
Sample Analysis	Cardio-Wipe I System as is provided by: Cardio-Cam Corporation as described above	Counting of samples, wipes or swipes for Contamination Surveys, Spills and other sample analysis
Film Badges-Body Personnel Dosimeters *	As furnished by R. S. Landauer, Tech/Ops Landauer, 2 Science Road Glenwood, IL 60425	Whole Body Personnel Monitoring of all individuals who work with or frequent areas where radioactive materials are received, used, manipulated or stored.
Extremity Dosimeters *		
Extremity Dosimeters TLD Dosimeters	As furnished by R. S. Landauer, Tech/Ops Landauer as described above	Personnel Monitoring of the extremities of all personnel who handle sources or patients who have been recently injected.

Note: See the attached pages for the description of the systems described in the above list.

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

## ATOMLAB 100

Activity Range:	0.01 $\mu$ Ci to 9999 mCi (or Bq equivalent)
Detector Linearity:	$\pm 1\%$ or 0.2 $\mu$ Ci, whichever is greater
Electrometer Accuracy:	$\pm 1\%$ or 0.1 $\mu$ Ci, whichever is greater
Electrometer Resolution:	$\pm 1\%$ or 0.1 $\mu$ Ci, whichever is greater
Response Time:	Less than five seconds to reach 95% of final reading
Overall Accuracy:	$\pm 3\%$ or 0.3 $\mu$ Ci, whichever is greater

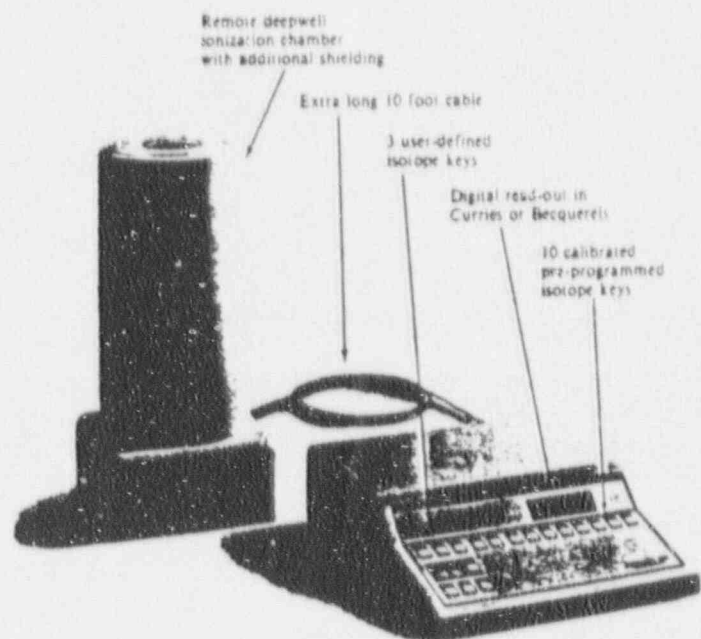
Overall accuracy is affected by such factors as the accuracy of the specific source calibration, geometric variations due to sample volume or configuration, detector linearity, electrometer accuracy and readout accuracy.

Repeatability:	$\pm 0.3\%$ above 1 mCi short term (24 hr); 1% long term (1 yr)
Digital Readout:	4-Digit LED
Power Requirements:	100 to 120 VAC @ 1/2 A; 200 to 240 VAC @ 1/4 A
Frequency:	50/60 Hz
Display Unit:	<ul style="list-style-type: none"> <li>• Dimensions: 3.5" <math>\times</math> 12" <math>\times</math> 14.3" (8.9 cm <math>\times</math> 30.5 cm <math>\times</math> 36.3 cm)</li> <li>• Weight: 6 lbs (2.7 kg)</li> </ul>
Detector Unit:	<ul style="list-style-type: none"> <li>• Dimensions: 7.5" <math>\times</math> 7.5" <math>\times</math> 16" (19 cm <math>\times</math> 19 cm <math>\times</math> 40.6 cm)</li> <li>• Overall Weight: 35 lbs (15.75 kg)</li> <li>• Well Diameter: 2.5" <math>\times</math> 10" (6.4 cm <math>\times</math> 25.4 cm)</li> <li>• Well Shielding: 1/4" Lead</li> </ul>

086-250

### The Atomlab 100 Features:

- Computerized, highly accurate dose calibration
- Activity display with bright, easy-to-read 4-digit LED
- 10 pre-programmed isotope selection push buttons
- Electronic thumbwheel with 4-digit LED display for isotope calibration settings
- Switch between activity display in curies or becquerels
- Remote ionization chamber with double the standard shielding and 10-foot cable
- Software controlled, automatic background correction, display zeroing and range selection
- Optional computer interface: RS232 bi-directional serial communications port
- Coded error messages: almost instant display, update, memory protection
- All functions performed under push button control
- Industry exclusive 2-year warranty
- Lineator option available



## Model: SURVEYOR 2000™ Portable Survey Meter

**RADIATION DETECTED:** Alpha, beta, gamma with external probe, gamma and x-ray with internal detector

**DETECTOR:** GM tube, internal; choice of GM probes external

**RANGE:** 0-2000 mR/h in 5 linear ranges, 0-240,000 cpm

**HIGH VOLTAGE:** Electronically stabilized, factory set at 900 V

**HV TEST:** Exclusive self test to verify detector HV power supply

**CONNECTOR:** MHV

**ACCURACY:** Within 10% of reading for <sup>137</sup>Cs when calibrated according to NRC Reg. Guide 10.8

**ENERGY RESPONSE:** ±20% from 40keV to 1.2MeV (internal detector)

**WARMUP TIME:** None

**SATURATION:** Typically >1000R/h for most GM probes (provided by exclusive anti-saturation circuit); >5R/h for pancake GM probes

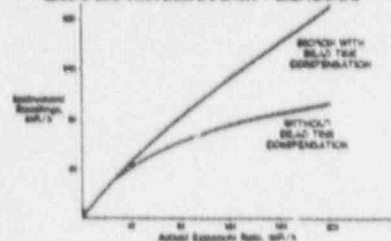
**RESPONSE TIME:** Switch-selectable, optimized for each range, 0-90% of final reading as follows:

Range	Time	
	Fast	Slow
X0.1	6 sec.	25 sec.
X1	2 sec.	6 sec.
X10	1 sec.	3 sec.
X100	<1 sec.	1 sec.
X1000	<1 sec.	1 sec.

**DEAD TIME COMPENSATION:**

Exclusive circuitry provides near linear response

**Effect of dead time compensation on response linearity.**  
Model 2000 Survey Meter probe and circuitry - same features.



**BATTERY COMPLEMENT:** Single 9-volt (MN1604 or equal). The additional battery holder may be used as storage of spare or parallel-wired

**BATTERY LIFE:** > 100 hours or > 200 hours with parallel option

**TEMPERATURE:** Operational from -40° to +60°C

**HUMIDITY:** <5% change in reading from 10-95% RH

**CONTROL:** Eight-position rotary switch as indicated

**DISPLAY:** Ruggedized, recessed, high-torque 1mA meter with 3.35 inch (8.51cm) scale marked 0-2 mR/h, 0-2400 cpm, 'Bat. ok', 'HV ok'. Meter protected by impact-resistant Lexan® polycarbonate window

**GEOTROPISM:** Within ±2% of full scale

**SHOCK:** 100g per lightweight machine of MIL-STD 202C, method 202B

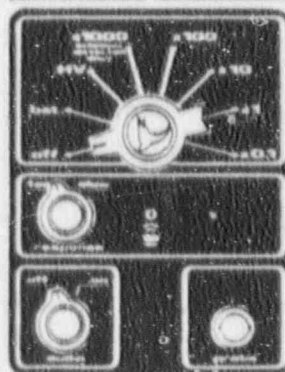
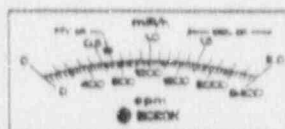
**VIBRATION:** 5g in each of three mutually orthogonal axes at one or more frequencies from 10-33Hz

**AUDIO:** A built-in speaker with panel mounted on-off switch provides audible "click" for each detector pulse. With the speaker off, an audible alarm sounds (if desired) when meter is > full scale on any range

**CONSTRUCTION:** Splash-proof, shock proof, two-piece all-metal case. Scratch-resistant laminated control panel and Baron Kleen-Krome® trim on case top, durable black polyurethane paint on handle and case bottom

**SIZE:** 4.25 x 8 x 6.8" including handle and probe clip (10.8 x 20.3 x 17.3 cm)

**WEIGHT:** 2.2 lbs. (1 kg.) excluding probe



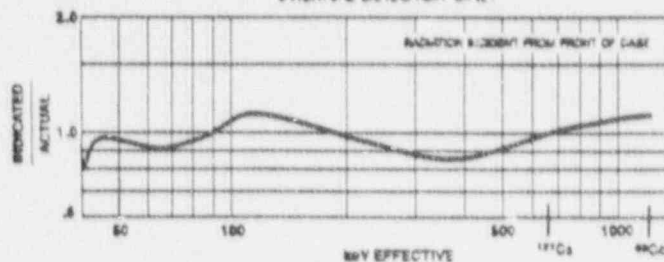
### Model: SWGM

- Rugged Housing
- Sliding Beta Shield
- Solid Internal Connectors
- Energy Compensated
- Beta & Gamma Sensitivity



### Typical Energy Response

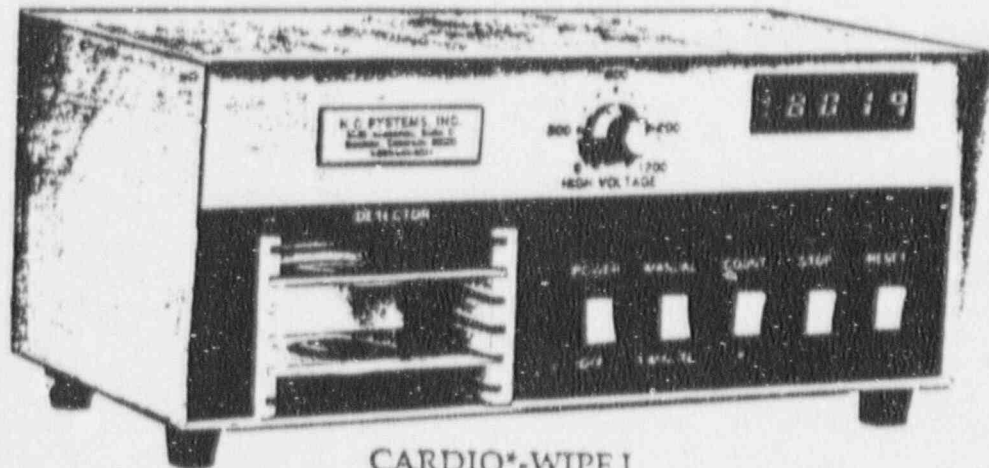
INTERNAL DETECTOR ONLY





**N C SYSTEMS, INC.**  
 578. Arapahoe, Suite D  
 Boulder, Colorado 80303  
 1-800-548-4024

### WIPE/SWIPE TESTING SYSTEMS



**CARDIO\*-WIPE I**

### WIPE/SWIPE TESTING SYSTEMS

The following systems are recommended for the counting of wipe/swipe samples and leak testing of sealed sources. The systems are complete with all necessary materials and sources for a complete system. All systems carry a one year warranty and are delivered free of charge. State/local taxes, if any, are not included in this quotation.

#### **CARDIO\*-WIPE I**

A simple, efficient yet rugged system that is extremely reliable. All solid state with a five decade numerical LED readout, variable high voltage, preset timer or manual operation, instant warm-up, rugged steel cabinet, built-in GM detector, six position sample holder with two slide trays, and very simple controls. A check/reference source reference calibrated to a NBS source is included.

## PROCEDURE FOR CALIBRATION OF THE SURVEY INSTRUMENT

The applicant will not calibrate the survey instrument but will have a contractor do the calibration on an annual basis or after any repair other than the replacement of the batteries. The procedure for obtaining this calibration will be:

- 1) The contractor selected will have a NRC or Agreement State license to perform calibrations and this license will be documented by the applicant prior to contracting this service. It is anticipated that the calibration will be done by the manufacturer of the instrument or by Berlin Instrument Corporation of both 312 Miami Street in West Columbia, SC (800-234-4212) and 504 Airport Road in Santa Fe, New Mexico (800-274-4212) or KNS Associates, Inc. or 1854 Airline Drive in Nashville, TN 37210 (615-883-9760) License # R-1975-C1.
- 2) If a contractor remote from the location of the facility is used, either a replacement survey meter will be obtained during the calibration or the facility will not operate during the time the system is not present.
- 3) Upon receipt of the instrument from calibration, the applicant will check its apparent rate of exposure with a built-in or independent check source, license exempt, and note that level of exposure on the survey meter. Prior to each operation, the instrument will be checked to determine that the reading is still the same indicating the instrument is still in calibration.
- 4) The report of survey meter calibration, obtained from the contractor after calibration, will include but not be limited to, the following information:

Identification Of who Did The Calibration  
 Their License Number  
 The Name of The Owner Of The Instrument  
 Description Of The Instrument  
   Manufacturer  
   Model Number  
   Serial Number  
   Type Of Detector  
 A Description Of The Calibration Source &  
   Its Exposure Rate On A Specific Date  
 The Calibration Procedure  
 For Each Calibration Point The  
   Calculated Exposure Rate  
   Indicated Exposure Rate  
   Deduced Correction Factor  
   Scale Selected  
 The Reading Indicated By The Battery-Check  
 The Angle Between The Flux Field & Detector  
 The Position Of The Detector & Its Shield  
 The Apparent Exposure Rate From The Check Source  
 The Name Of The Person Performing The Calibration



## CALIBRATION AND QUALITY CONTROL OF THE DOSE CALIBRATOR

The following procedures will be followed in performing calibration and quality control procedures on the dose calibrator. They may be performed at more frequent intervals as determined by the RSO.

### Geometry Dependence

**Frequency:** At time of installation and following repair or replacement of the chamber or relocation of the device.

**Acceptable Range:** +/-5% with the types of containers used by the applicant

- a) Fill a syringe of the type used for routine procedures with 0.5 cc's of  $^{99m}\text{Tc}$  containing 1-10 mCi of  $^{99m}\text{Tc}$ .
- b) "Count" the syringe in the dose calibrator in the same way that patient doses are measured.
- c) Draw an additional 0.5 cc's of water into the syringe and it will again be "counted" as in b) above.
- d) Repeat the procedure until there is no less than 2.0 cc's in the syringe.
- e) Select the volume closest to that normally used for patients as the "standard" and divide the millicuries indicated by each of the other volumes into the standard to determine the volume correction factors.
- f) If any of the correction factors are greater than 1.05 or less than 0.95, make a correction table for the calibrator showing indicated activity at that volume vs. true activity at that volume.

### Accuracy

**Frequency:** At time of installation and not less than annually thereafter as well as after repair, adjustment or relocation.

**Acceptable Range:** +/-5% of the expected activity

- a) Use the calibrated reference sources of  $^{57}\text{Co}$ ,  $^{133}\text{Ba}$ , and  $^{137}\text{Cs}$  as authorized under this license for this procedure (see "sealed sources").
- b) "Count" each source at its correct setting on the calibrator, subtract the measure of background on that setting, and record the activity. Repeat this procedure for three measurements of each of the sources.
- c) Average the three readings, of each source, and divide into certified activity of the source after corrected for decay.
- d) The results of the calculations, section c) must fall within the range of 1.05 and 0.95 (to fit within +/-5%). If it does not fall within this range, consider repair or recalibration. However, if it exceeds 1.10 and .90 (+/-10% range) repair, recalibration or replacement must be made.
- e) Because these same sources are used for the daily constancy tests, use the  $^{57}\text{Co}$  source to measure the reading on both the  $^{57}\text{Co}$  setting and the  $^{201}\text{Tl}$  setting during the accuracy measurement.
- f) Place a sticker on the dose calibrator indicating when the next accuracy test is due.

### Linearity

**Frequency:** At time of installation and not less than quarterly thereafter, as well as after repair, adjustment, or relocation.

**Acceptable Range:** +/-5% of the expected activity

- a) Obtain a syringe containing not less than 20 mCi of  $^{99m}\text{Tc}$  from the radiopharmacy.
- b) "Count" the syringe in the dose calibrator at the earliest time in the morning, i.e. 8:00 am, and record the mCi indicated, minus background.
- c) "Count" the syringe again not less than six times during a 78 hour period of time (3.25 days). Record the readings, minus background.
- d) Plot the values obtained on semi-log graph paper and draw the best-fit line through the values. Draw a second line through the expected points as calculated using decay factors of the expired time.
- e) Calculate the maximum deviation of the observed line from the calculated line. If the deviation is more than +/- 5% (0.05) the instrument will be adjusted or repaired. If it can not be adjusted or repaired, a correction table or graph that will allow conversion from activity indicated to true activity will be made and placed on the calibrator.  
\*The activity to be equal to not less than the maximum amount ever obtained from a supplier and counted to 10uCi by decay.

On a quarterly basis, the applicant will determine that the measurement chamber is in place and that the instrument is zeroed according to the manufacturer's instruction.

### Constancy

**Frequency:** Once prior to use on each day of use as well as after repair, adjustment or relocation.

**Acceptable Range:** +/-5% of the anticipated value

If no radioisotopes are received or used during the day, no operations take place, then constancy will not be checked on that day.

- a) Measure the  $^{57}\text{Co}$  sealed, dose calibrator source on the  $^{201}\text{Tl}$ ,  $^{57}\text{Co}$ , and  $^{99m}\text{Tc}$  settings. Measure the  $^{137}\text{Co}$  source similarly if deemed necessary by the RSO.
- b) Record the background at the same settings.
- c) Determine the activity indicated, at the settings, by subtracting the background, b), from the readings determined in a), and record this value.
- d) Compare the measured  $^{57}\text{Co}$  activity to activity calculated from a  $^{57}\text{Co}$  decay table or graph.
- e) Determine action levels for the reading at each setting reflecting the range of +/- 5% of the anticipated reading. If the value is greater than +/- 5%, notify the RSO and if it is 10% or greater from the expected value, the instrument will be repaired or replaced.
- f) Record above constancy measurement.



Constancy Check with  $^{57}\text{Co}$  NBS Source

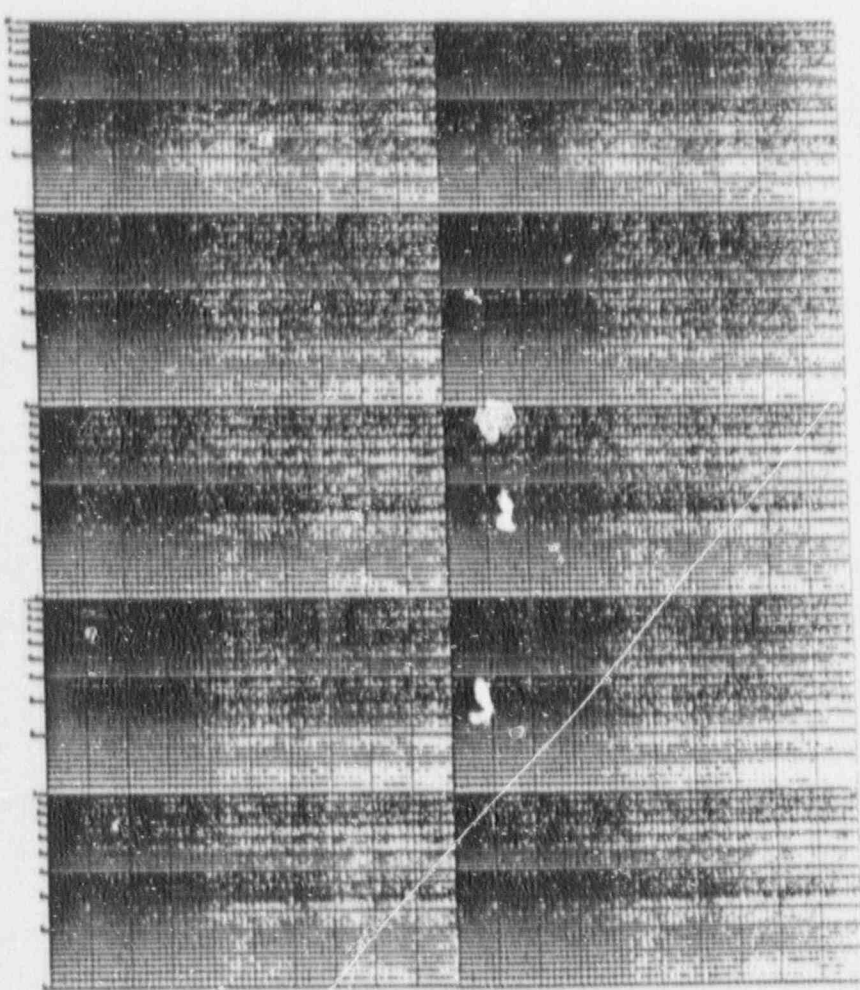
This Decay Table can be used to correct the decay of the  $^{57}\text{Co}$  source for the correction of the activity for Q.C. on the Dose Calibrator:

time, t, days	$e^{-0.00116/T_{1/2} t}$
1.0	0.9975
2.0	0.9949
3.0	0.9924
4.0	0.9896
5.0	0.9873
6.0	0.9848
7.0	0.9823
8.0	0.9793
9.0	0.9770
10.0	0.9748
11.0	0.9723
12.0	0.9698
13.0	0.9674
14.0	0.9649
28.0	0.9311
29.0	0.9287
30.0	0.9263
31.0	0.9240
365.0	0.3941
730.0	0.1553
1,095.0	0.0612
1,460.0	0.0241

\*\*\*

### DOSE CALIBRATOR LINEARITY TEST

Licensee: \_\_\_\_\_  
License #: \_\_\_\_\_ Amendment: \_\_\_\_\_  
Date: \_\_\_\_\_ Dose Calibrator Model: \_\_\_\_\_ Sr. #: \_\_\_\_\_  
Radioisotope: \_\_\_\_\_ Activity: \_\_\_\_\_ Volume: \_\_\_\_\_

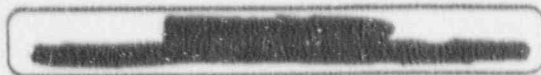


Measurements			
Date	Time	Assay - mCi	Elapsed Time
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Evaluation: Worst point deviation analysis: Point indicated by: \_\_\_\_\_

\_\_\_\_\_

Signed: \_\_\_\_\_ Date: \_\_\_\_\_

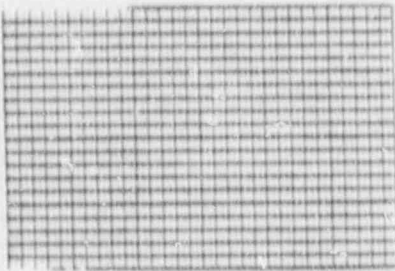


Dose Calibrator: Geometry

DOSE CALIBRATOR GEOMETRY TEST

Licensee: \_\_\_\_\_  
License Number: \_\_\_\_\_ Amendment: \_\_\_\_\_  
Date: \_\_\_\_\_ Dose Calibrator Model: \_\_\_\_\_ Sr. #: \_\_\_\_\_  
Radioisotope: \_\_\_\_\_ Form: \_\_\_\_\_

Syringe Geometry Dependence

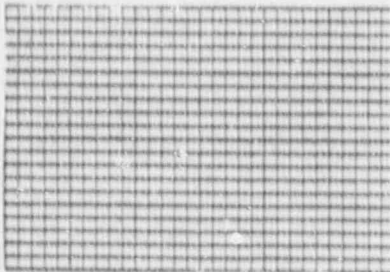


CF \_\_\_\_\_

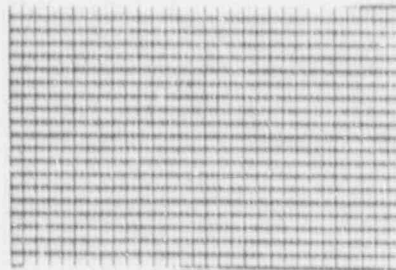


CF \_\_\_\_\_

Vial Geometry Dependence



CF \_\_\_\_\_



CF \_\_\_\_\_

Analysis of Geometry Dependence Data From Above: \_\_\_\_\_

Signed: \_\_\_\_\_ Date: \_\_\_\_\_



# Dose Calibrator-Accuracy

## DOSE CALIBRATOR ACCURACY TEST

Licensee: \_\_\_\_\_

License Number: \_\_\_\_\_ Amendment: \_\_\_\_\_

Date: \_\_\_\_\_ Dose Calibrator Model: \_\_\_\_\_ Sr. #: \_\_\_\_\_

Source: Radioisotope: _____	Activity: _____	Model: _____
Assay		
A. _____	Calibration Date: _____	
B. _____	Decay Factor: _____	
C. _____	Decay Corrected _____	
Avg. _____	Activity: _____	
Calculated Deviation: _____		

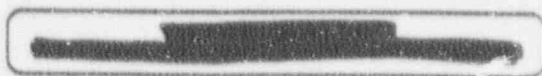
Source: Radioisotope: _____	Activity: _____	Model: _____
Assay		
A. _____	Calibration Date: _____	
B. _____	Decay Factor: _____	
C. _____	Decay Corrected _____	
Avg. _____	Activity: _____	
Calculated Deviation: _____		

Source: Radioisotope: _____	Activity: _____	Model: _____
Assay		
A. _____	Calibration Date: _____	
B. _____	Decay Factor: _____	
C. _____	Decay Corrected _____	
Avg. _____	Activity: _____	
Calculated Deviation: _____		

### Evaluation

\_\_\_\_\_

Signed: \_\_\_\_\_ Date: \_\_\_\_\_







## QUALITY CONTROL PROCEDURES FOR GAMMA CAMERAS

I. It is important to implement a routine quality control program for the gamma camera. This program may be modified for specific problems associated with the device. However, a routine program should include the following daily quality control activities: All records must be retained for two (2) years.

1. **Collimator.** The camera should be evaluated intrinsically, with the collimator on the detector. The same frequently used collimator should always be used for proper reproducibility.
2. **Pulse Height Analyzer.** The *Pulse Height Analyzer (PHA)* should be adjusted according to the manufacturer's instructions. It is important that it be rechecked with the actual gamma spectrum emitted from the patient prior to performing procedures. Any change in line voltage, ambient room temperature, or camera high voltage will cause changes in the PHA adjustment and thus a check should be made of the PHA under these conditions.
3. **Resolution-Distortion.** A four-quadrant resolution bar phantom should be placed diagonal to the x and y axis directly on the collimator and the flood field phantom or flood field source placed on the bar phantom. An image should be obtained with a clinical PHA window of 20 - 30% and a total of 0.5 - 1 million counts. The acquisition should be for pre-set counts, the total number of counts, as well as the acquisition time recorded.

**Note:** The resolution-distortion image will reveal resolution-distortion or significant uniformity changes. This is a clinically important procedure as these are the factors that will effect the analysis of the study. The uniformity flood image will only provide information on uniformity and as uniformity will appear satisfactory in the presence of deteriorating resolution, resolution imaging should be done daily.

II. The following additional quality control activity should be performed not less than weekly. The records must be retained for two (2) years.

1. **Flood Field Uniformity.** A *flood field uniformity image* should be obtained with the frequently used collimator on the detector. The flood field phantom or source should be placed on the collimator and an image obtained. The PHA window should be 20 - 30% and a total of 0.5 - 1 million counts obtained. The acquisition should be for pre-set counts and the total number of counts as well as acquisition time recorded.

**Note:** Evaluate the image for uniformity errors and perform specific uniformity performance determinations if uniformity problems are noted.

III. Other quality control procedures may be performed at monthly or quarterly intervals. These procedures include, but are not limited to:

1. **Background Flood.** A flood field done without a flood source to determine noise, background, electronic noise and other factors effecting image quality. An image should be obtained with the collimator on the detector, for a preset time of not less than 20 minutes. The PHA setting should be 20 - 30% and the image intensity should not be increased. Record the time, counts obtained and image evaluation.
2. **Check of Maximum Count Rate Capacity.** With the detector directed horizontally into the room and with the collimator removed, a 20 - 30% clinical window is set and the machine turned on to display the count rate received.

A syringe, containing a patient dose of 5 - 20 mCi of  $^{99m}\text{Tc}$  is placed in a syringe shield. The technologist then brings the syringe shield toward the detector with the long axis of the shield directed at the detector. The count rate will increase to the maximum count rate and then remain the same, saturate, or go down, paralyze.

3. **Safety Checks.** All "safety checks" must be performed at least quarterly. They may be performed more often as indicated by the protocol "safety checks of gamma cameras".

IV. The following quality control procedures must be performed at least annually. As the results may dictate, some may be performed at more frequent intervals.

1. **Crystal, Detector, Resolution.** The detector resolution should be determined using a small, point, dry, source of  $^{99m}\text{Tc}$  or  $^{57}\text{Co}$ . The activity should not exceed 50  $\mu\text{Ci}$ . The procedure should be performed with the collimator off the detector, intrinsic. The actual procedure will depend on the electronics available and the technique of the operator.

If the resolution as expressed in % full width half max has changed by 50 - 60% from the anticipated value, further investigation of the detector quality, PHA calibration, and measurement technique may be required.

2. **Count Rate Linearity and 20% Count Rate Loss Determination.** This should be performed if there appears to be changes in the detector efficiency, a shift in detector resolution, changes in dynamic procedure accuracy or increased count rates in clinical studies due to changes in techniques or radiopharmaceutical agents. The protocol for these procedures should be followed in making these determinations.

V. From time to time, additional studies of the system performance may be required as dictated by the operating conditions of the system. These may include point sensitivity, linearity and analysis of the entire imaging chain including the computer, ECO gate and other accessories.



## PERSONNEL EXTERNAL EXPOSURE MONITORING PROGRAM

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 any workers or groups of 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 and it will be processed by a contract service on a monthly basis.
- 3) All individuals who, on a regular basis, handle radioactive material that emits ionizing photons will be issued a TLD finger monitor that will be processed by a contract service on a monthly basis.
- 4) Other individuals who are exposed to radiation on an occasional basis such as security personnel who deliver packages, secretarial personnel and nurses who may care for patients containing diagnostic quantities of radiopharmaceuticals will not normally be issued dosimeters. If they are issued a dosimeter for measurement of their exposure, if it is deemed necessary by the RSO, the whole body dosimeter will be issued for 3 months.
- 5) All monthly personnel dosimeter reports will be posted for all of the workers to read and to note on the report that they read the report.

## RADIATION SAFETY COMMITTEE

The applicant will not establish a Radiation Safety Committee because this is a private office and not a hospital and thus no such committee is possible. The RSO will, however, carry out the activities as are established in 35.21, 35.22, and 35.23 of the CFR and 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.

## ALARA PROGRAM

The applicant will establish an ALARA program as established in Appendix G to the Regulatory Guide 10.8, Rev.2, NRC with the exception that there will be no Radiation Safety Committee and the entire application of the ALARA concept will be done in a more 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 and
- 2) A ongoing review of the radiation safety program with a more formal review on not less than an annual basis and
- 3) Modifications of the radiation safety program, including equipment and procedures if they will reduce personnel exposure and
- 4) Establishment of "Investigational Levels" below the applicable limit as stated in page 2. of this section and
- 5) Provision of routine reviews by the RSO of the safety program(annual), occupational exposures(quarterly & monthly) and radiation surveys (monthly) and
- 6) Cooperation with workers in reduction of exposures and
- 7) An educational program for all workers on radiation safety(see the "Training Program")



RADIATION SAFETY AND QUALITY CONTROL SCHEDULE TABLE

RADIATION SAFETY OFFICER AND NUCLEAR PERSONNEL GUIDE  
TO ACTIVITIES REQUIRED OF THE NUCLEAR MEDICAL FACILITY

	Daily	Weekly	Monthly	Quarterly	6 months	Annually	Other Frequencies
<b>Survey Instruments</b>							
Battery Check	X						
Reference Check		X					
Calibration						X	& after service
<b>Dose Calibrator</b>							
Geometry	X						on installation & service
Constancy				X			& after service
Linearity						X	& after service
Accuracy							on installation & service
<b>Gamma Camera</b>							
PHA	X						& after service
Resolution	X						& after service
Uniformity		X					& after service
Mask CR		X					& after service
Background Flood				X			& after service
CR @ 20% loss				X			& after service
Interlocks & Switches				X			& after service
<b>Area Surveys (Contamination)</b>							
Exposure Survey	X						upon any incident
daily use areas							
storage		X					
Wipe Survey		X					upon any incident
<b>Sealed Source Leak Testing</b>							
Leak Test					X		or upon damage
<b>Worker Instruction</b>							
Initial Instruction						X	& prior to first entry
Training						X	& prior to first entry
<b>Personnel Monitoring</b>							
Prior Dose							prior to first entry
Personal Exposure							prior to first entry
Exposure Reports			X				
Annual Exposure							
Accumulated Exposure			X				
ALARA						X	upon termination
							& upon changes in work

Note: This is a guide, check your license for specific requirements  
References: Title 10 Parts 19, 20 and 35 of the Federal Code of Regulations and State Requirements



## ALARA PROGRAM-POSTING OF NOTICE AND EVALUATION OF DOSIMETERS

The following notices will be posted, larger than indicated below, at the location of the film badge, whole body, reports.

# A L A R A

## As Low As Reasonably Achievable Can You Lower Your Exposure?

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

### NOTICE TO ALL RADIATION WORKERS

This notice is to be posted with the personnel dosimetry reports.

Please review the personnel dosimetry information on the dosimeter report. Note any exposure levels that are lower or higher than would be expected. As a facility committed to maintaining occupational radiation exposure As Low As Reasonably Achievable (ALARA), we have established levels of exposure lower than those established by current regulations. Please compare your current levels to those given in the following table.

Acceptable Levels of Radiation Exposure (mRems)

	Level I		Level II		Level III*	
	month	13 weeks	month	13 weeks	month	13 weeks
Whole Body, head and trunk, blood forming organs, lens of eyes or gonads	42	125	125	375	417	1,250
Hands and forearms, feet and ankles	625	1,875	1,875	5,625	6,250	18,750
Skin of whole body due to beta exposure	250	750	750	2,250	2,500	7,750

\*From Title 10, Part 20.101(a)

After reviewing the current report, please contact the Radiation Safety Officer if you have any suggestions on how your exposure may be reduced. Also contact the Radiation Safety Officer if your exposure status has changed or may change. This includes changes in your activities, types of procedures or techniques. Please immediately contact the Radiation Safety Officer if you are pregnant.

After reviewing the report, please initial the report next to your name to indicate your review.

NOTE: This report has been reviewed by the Radiation Safety Officer and if areas of concern have been noted, you will be contacted for a safety review.

See the next page for the posting of other notices related to ALARA and the Radiation Safety of the facility.

## ALARA PROGRAM/EMERGENCY NOTIFICATION-POSTING OF NOTICES

The following notices will be posted, larger than indicated below and complete with the required information which can not be obtained until a license is issued and the facility is implemented, at the entrance to the room where radioactive materials are used and in the radionuclide storage and manipulation area of that room and the "Notice to Workers" will be also posted on the employee notice board for all workers to see.

## 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 and any amendments, operational procedures and all related materials and communication can be examined by contacting the individual listed below.

License Number: \_\_\_\_\_ Issued: \_\_\_\_\_

Contact: \_\_\_\_\_ Telephone: \_\_\_\_\_

\_\_\_\_\_

All information on this notice will be completed prior to posting

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## NOTICE

Radioactive materials may be located within this room and, if present, their location is clearly identified by the radiation symbol and the words "Caution Radioactive Materials." In case of any emergency involving this room or the materials herein, contact the Radiation Safety Officer, RSO, as listed below.

Contact: \_\_\_\_\_ Telephone: \_\_\_\_\_

\_\_\_\_\_

All information on this notice will be completed prior to posting

## ***SPECIFIC ELEMENTS OF THE ALARA PROGRAM MANAGEMENT***

These procedures are implemented in addition to the standard procedures for the receipt, use, and disposal of radionuclides, and the routine surveys and procedures for the use of the equipment and the handling of radionuclides, including incidents.

1. All radiation workers will have their prior exposure history documented before being issued dosimeters.
2. A body dosimeter, film badge, will be issued and worn by all radiation workers, those who use radionuclides, i.e. receipt, administration, etc., will also be issued and wear a finger, TLD dosimeter. The dosimeters will be changed on monthly intervals.
3. Prior to use of radionuclides, in addition to the issue of proper dosimeters, each employee will receive instruction on, but not limited to:
  - a. Fundamental radiation effects and levels of exposure
  - b. The investigational levels established in this facility for ALARA management
  - c. Standard ALARA procedures
  - d. Prenatal exposure policy
  - e. License authorization and conditions
  - f. Standard operational procedures
  - g. Location and control of all hazards in the facility
4. All new personnel will be closely physically observed by the authorized user/RSO or another experienced worker for the first few days of operation to determine proper techniques and to answer any questions.
5. Personnel exposure will be evaluated on a monthly basis. All exposures will be anticipated to be at or less than Level I or 40 mrem for whole body or 625 mrem for the hands. Any exposure above this level will be closely reviewed to determine if the work activity justifies the higher exposure. If a worker receives more than Level II, 125 mrem to the whole body or 1,875 for the hands, an immediate investigation will be implemented. The cause of the exposure and possible techniques for reduction of the exposure will be explored with the exposed individual. All reasonable methods for exposure reduction will be implemented. If exposure exceeds Level III, 417 mrem whole body, or 6,250 mrems to the hands, the exposure will be investigated and a formal, written, determination of the source and causes made. The operational procedures may be modified to prevent additional exposures at these levels. Additional dosimeters, measurements, etc., may be appropriate at this time.

## *ROUTINE RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER*

The licensee has appointed a Radiation Safety Officer, RSO, responsible for implementing the radiation safety program. The licensee, through the RSO, shall assure that radiation safety activities are being performed in accordance with the approved procedures, condition and regulatory requirements and are consistent in maintaining all exposures ALARA. The RSO's activities include, but are not limited to the following:

1. Investigation of all incidents including unexpected exposures, accidents, spills, losses, theft, unauthorized receipts, uses, transfers, disposals, misadministration, adverse reactions and other deviations including biohazard incidents.
2. Establishing in a single binder or file, all of the materials required for the radiation safety program including notices, regulations, and related documents and procedures for:
  - a. Authorization for the purchase of radioactive material
  - b. Receiving and opening packages of radioactive material
  - c. Keeping an inventory of radioactive materials
  - d. Storing radioactive material
  - e. Using radioactive material
  - f. Taking emergency action if material is lost, stolen, spilled or other operational deviations
  - g. Performing checks of survey meters and other safety, quality control and performance checks
  - h. Disposing of radioactive material
  - i. Training personnel who work in or frequent areas where radioactive material is received, used or stored
  - k. Keeping all records required by the regulatory agencies including OSHA
3. Brief management, the licensee, once each year, on the radioactive material program.
4. Establish personnel investigational levels that, when exceeded, will initiate an investigation by the RSO of the cause of the exposure.
5. Establish personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the RSO of the cause of the exposure and actions that may be taken to reduce the probability of recurrence.
6. Approve or disapprove minor changes in the radiation safety procedures that are not potentially important to safety with the advise and consent of management, the licensee.



Exposures that result in reportable exposures, more than 1,250 mrem per 13 weeks to the whole body or 18,750 mrem to the hands, will result in removing the worker from the exposure area, documenting investigation, retraining, modification of procedures, or the physical facility, as may be deemed necessary to prevent additional exposures. If and when the RSO determines that it is reasonable to resume activities, the worker will be allowed to return to their duties.

6. Female radiation workers will be provided with a second, abdominal, film badge if they are anticipating pregnancy. When pregnancy occurs, they will be required to wear an abdominal film badge to monitor the potential prenatal exposure. The pregnant worker will be instructed to tell the RSO when pregnancy is confirmed. The workers abdominal exposure will, upon confirmation of pregnancy, be limited to 0.5 rem for the balance of the gestation period.
7. Spills, contamination and other abnormal occurrences will be immediately investigated and documented. The individual events will determine the corrective action, if any, to be implemented.
8. Bioassay will not be necessary as no <sup>191</sup>I unsealed sources will be used. If any ingestion or other absorption of radioactive material is suspected or known, bioassay of urine, saliva, and/or blood, and the worker will be counted with the gamma camera. As with all other monitoring, these records will be maintained in the facility.
9. On quarterly intervals, the RSO will establish or cause to establish a "Quarterly ALARA, Audit". This audit will review the personnel exposure, surveys, incidents, biohazards, and all events related to the safety of personnel. This audit will be used as a management tool to review the program, evaluated risks, and establish changes that may be required to keep all exposures ALARA.
10. On an annual basis, the RSO will establish or cause to establish an "Annual Facility Review", including all safety of personnel and incidents. This annual review will be presented to management and reviewed with all radiation personnel and others involved in the operation of the facility. This review will be part of an annual education training program for all radiation workers.



LEAK TESTING OF SEALED SOURCES

The procedure for the leak testing of the sealed sources requested in this application is given below. It will be done every 6 months.

- 1) A list of all sources to be leak tested will be made. It will include the following information:
  - a) radioisotope b) activity at a specific date c) the physical form
- 2) Each source will be wiped, "swiped" with a cotton swab using caution to not touch the source except with the swab and keeping the source shielded as much of the time as possible. Each swab will be identified to know which source was tested and caution will be used to assure that the operator will not become contaminated with the swab or source and that the swabs will not be cross contaminated.
- 3) Count the "swipe swabs" with the GM survey meter to determine if any counts, activity indication, is present after counting a gamma reference source of  $^{133}\text{Ba}$  or  $^{137}\text{Cs}$  under the same conditions to determine the operation of the system and sensitivity of its detection.
- 4) If no swipe-swab counts are present, above background, record all information as cpm and note that the leak testing was completed on the container of each source. If swipe-swab counts are present, calculate the  $\mu\text{Ci}$  present using the  $\mu\text{Ci}$  determined from the reference source. (These are the same calculations as are performed in the Removable Contamination Survey).
- 5) If the swipe-swab activity is  $0.005\mu\text{Ci}$  or more the RSO will be notified, the source withdrawn from use and repaired, replaced or it must be discarded according to the Waste Disposal Procedures.

Sample Record Form For Wipe Testing Of Sealed Sources

Date \_\_\_\_\_ Time \_\_\_\_\_ By \_\_\_\_\_ Assay: Date \_\_\_\_\_ Time \_\_\_\_\_ By \_\_\_\_\_

SAMPLE ANALYSIS

Radioactive Material			Swipe #	Gross cpm	Bkg cpm	Net cpm	$\times \frac{\mu\text{Ci}}{\text{cpm}}$	$= \mu\text{Ci}$	Action Taken
Isotope	Activity	Form							
133 Ba									
57 Co									
I.									
II.									

STANDARD ANALYSIS

A. Assay  $\mu\text{Ci}$  \_\_\_\_\_  $\times$  Decay Factor \_\_\_\_\_  $= \mu\text{Ci}$  \_\_\_\_\_

B. Gross cpm \_\_\_\_\_  $-$  Bkg cpm \_\_\_\_\_  $=$  Net cpm \_\_\_\_\_

C. Calibration Factor  $A/C = \frac{\mu\text{Ci}}{\text{cpm}}$

Instrument: \_\_\_\_\_

Standard: Radionuclide \_\_\_\_\_ Assay: Activity \_\_\_\_\_ Date \_\_\_\_\_

## NOTES ON ABSOLUTE COUNTING FOR CONTAMINATION, SPILLS AND SEALED SOURCES

## Reference Sources

The reference sources used for absolute counting analysis to convert cpm to dpm or to uCi and to assure the sensitivity of the detector, are license exempt thus are not part of this application. These sources will be of  $^{133}\text{Ba}$  or  $^{137}\text{Cs}$  and will be obtained from NEN/DuPont of North Billerica, MA. 01862. These sources are registered with the USNRC or BRH/FDA, according to NEN, and are NBS traceable with the error analysis calculated following the format of the recommendations of the International Commission on Radiation Units and Measurements, Report 12. Each source has a certificate of radioactivity calibration from NEM.

Each source will be of 0.1uCi calibrated to +/- 3-5% accuracy. These sources can be expected to produce, with the GM survey detector system, more than 2,220 cpm per 0.1uCi or 111 cpm/0.005uCi, even if the efficiency of the system is only 1%. This efficiency would produce 0.01 dpm per cpm for counting contamination swipes from routine surveys and from radioactive spills.

## Documentation of Wipe Testing

Each sealed source wipe tested will be identified with a label or tag indicating the following information:

Wipe Testing Completed

Date \_\_\_\_\_ Operator \_\_\_\_\_  
This source was wipe tested on the above date and analysis of the sample indicated \_\_\_\_\_ uCi of removable contamination which meets the requirements as established under this license.

If the sealed source does not meet the requirements as established under the license, more than 0.005 uCi of activity can be removed, the source will be removed from service and labeled with the following information:

Leaking Source-Do Not Use

Date \_\_\_\_\_ Operator \_\_\_\_\_  
This source was wipe tested on the above date and analysis of the sample indicated \_\_\_\_\_ uCi of removable contamination which does not meet the requirements as established under this license. This source **MUST NOT BE USED UNDER ANY CONDITIONS UNTIL CERTIFIED AS REPAIRED OR RENDERED SAFE BY THE RADIATION SAFETY OFFICER.** If you have questions call \_\_\_\_\_.

Note: The reference source will be of the same type or spectrum/energy-gamma flux as the sample to be assayed.

SEALED SOURCE LEAK TESTING

Leak Test: Date \_\_\_\_\_ Time \_\_\_\_\_ By \_\_\_\_\_ Assay: Date \_\_\_\_\_ Time \_\_\_\_\_ By \_\_\_\_\_  
 Instrument: \_\_\_\_\_ PHA E \_\_\_\_\_ KeV to \_\_\_\_\_ KeV  
 Standard: Radionuclide \_\_\_\_\_ Assay Activity \_\_\_\_\_ Date \_\_\_\_\_

I. LEAK TESTING

Swipe/Sample #	Activity mCi	Assay Date	Form	Use	Swipe/Sample Method
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____

II. SAMPLE ANALYSIS

Swipe/Sample	Gross - cpm	Bkg = cpm	Net cpm	$\times \frac{\text{dpm}^*}{\text{cpm}}$	dpm	Action Taken**
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____

\*From "Standard Analysis" below-line D.  
 \*\*See "Leak Test Action Levels" below

III. STANDARD ANALYSIS

- A. Gross cpm \_\_\_\_\_ - Bkg cpm \_\_\_\_\_ = Net cpm \_\_\_\_\_
- B. Assay uCi \_\_\_\_\_ x Decay Factor \_\_\_\_\_ = uCi \_\_\_\_\_
- C. uCi \_\_\_\_\_ x  $2.22 \times 10^6$  dpm/uCi = dpm \_\_\_\_\_
- D. Calibration Factor C/A = dpm/Net cpm = \_\_\_\_\_ / \_\_\_\_\_ = dpm/cpm \_\_\_\_\_

IV. LEAK TEST ACTION LEVELS

If the above test reveals 0.005 uCi,  $1.11 \times 10^4$  dpm, of removable activity, the source must be removed from service, repaired or replaced. Any required repair or disposal will be done in accordance with the license conditions and current regulations. In addition, a contamination survey, for removable contamination, will be performed to assure no contamination exists in the facility, and the source will be labeled "Leaking Source — Do Not Use".

## RULES FOR THE SAFE USE OF RADIOPHARMACEUTICALS

The "Notice" shown below will be the procedure for the safe use of radiopharmaceuticals in this facility. This procedure will be posted, in a larger form, in the room where radiopharmaceuticals are used.

## NOTICE

## RULES FOR THE SAFE USE OF RADIOPHARMACEUTICALS

1. Read and understand the license, its application and all documents related to the license and its operating conditions
2. Only authorized personnel are allowed to use radiopharmaceuticals and only in those ways that are authorized by the license
3. Personnel dosimeters, body film badges, must be worn in the area where radiopharmaceuticals are being stored, prepared or used and when the radiation worker attends patients containing radiopharmaceuticals
4. Finger dosimeters, TLD's, must be worn during the preparation, assay and administration of radiopharmaceuticals and when holding patients during nuclear procedures
5. Laboratory coats or other protective clothing must be worn at all times when in areas where radioactive materials are stored or used
6. Disposable gloves must be worn at all times while handling radioactive materials including administration to the patients
7. Use shielded containers or tongs when handling sources and never touch the sources with your hands
8. Never pipette any materials, radioactive or non-radioactive, by mouth
9. Do not store food, drink or personal effects in areas where radioactive material is stored or used
10. Do not eat, drink, smoke or apply cosmetics in any area where the radioactive material is stored or used
11. All radioactive materials must be kept in shielded containers, including sealed sources, syringes and active waste. All containers will be clearly labeled with the name of the radionuclide, form, date and activity
12. Use syringe shields for preparation and administration of patient doses
13. Assay each patient dosage in the dose calibrator before administration to assure it is within 10% of the prescribed activity. If not within 10% do not administer the radiopharmaceutical
14. Place radioactive waste only in the designated, labeled and properly shielded receptacles. Do not dispose of radioactive materials in any other manner
15. Use a cart, wheelchair or trolley to move all radioactive materials and never leave them unattended
16. Prior to administration of the patient dosage, complete all radiopharmaceutical quality control procedures and records. Check the patient's name and identification, the requested procedure and radiopharmaceutical. Check for any technical or medical contraconsiderations
17. Use great care to avoid contamination during the preparation, administration or disposal of the radioactive material. Use equal care to avoid any contact with the patient's blood or body fluids
18. After each procedure or before leaving the radioactive materials area, monitor your hands and clothing for contamination
19. Monitor, at the end of each working day, with the low range of the GM survey meter, the preparation and administration areas for contamination. If contamination is found, notify the Radiation Safety Officer and decontaminate or secure the area for decay
20. Survey, at the end of each week in which radioactive materials were received, manipulated or used, by wipe test (wipe, smear or swipe), all radioactive material storage, preparation and administration areas for contamination. If contamination is found, notify the Radiation Safety Officer and decontaminate or secure the area for decay.



RADIOPHARMACEUTICAL CONTROL NOTICES

The following notices will be used as part of the radiopharmaceutical control program.

**RADIOPHARMACEUTICAL RECEIPT  
AREA**

**Place All Packages Here**

RECEIPT OF PACKAGES

**RADIOPHARMACEUTICALS  
TO BE RETURNED  
TO THE RADIOPHARMACY**

DISPOSAL BY TRANSFER

**DO NOT EMPTY  
RADIOACTIVE  
WASTE MATERIALS**



**RESTRICTED  
RADIOISOTOPE STORAGE AREA**

ADMITTANCE ONLY BY AUTHORIZED PERSONNEL  
WITH DOSIMETERS AND IN COMPLIANCE  
WITH OPERATIONAL PROCEDURES

  
RADIOISOTOPE STORAGE AREA

## PROCEDURE FOR SPILLS

The following procedures for major\* and minor\* spills will be followed in our facility. This procedure will be posted, in larger form, and it will be 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 the contamination by covering the spill area with absorbent paper and secure the area.
3. Survey all personnel in the area to assure they are not contaminated. If contamination is present, decontaminate.
4. With the RSO or another person not involved in the spill doing the monitoring with the GM survey meter, determine the margins of the contaminated area for decontamination.
5. Clean up the spill using disposable gloves, foot coverings if indicated, and absorbent paper. Remove the paper, clean side out, avoiding 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 in the survey the area around the spill area. Check your hands, clothing and shoes for contamination.
7. Complete the "Radioactive Spill Report" and "Radioactive Spill Contamination Survey".
8. With the RSO, evaluate measures to be taken to prevent such spills.

**MAJOR SPILLS**

1. Clear the area by notifying all persons in the room that a spill has occurred but use caution that no individual who is contaminated will leave the area.
2. Prevent the spread of the contamination by covering the spill area with absorbent paper and secure the area.
3. Confine the movement of potentially contaminated personnel to an area, in the same room, where they can be monitored and decontaminated.\* Be sure that they don't spread the contamination. Survey these people and if not contaminated, have them leave the area.
4. If practical, without spreading the contamination, shield the spill but don't allow the spread of contamination or increase your exposure.
5. Close the room and lock or otherwise secure the area to prevent entry and post a notice on the door indicating that entry is prohibited.
6. Notify the Radiation Safety Officer (RSO).
7. Follow the direction of the RSO for decontamination of the area, completion of required documentation and evaluation of the incident.

## \*Personnel Decontamination Suggestions (First Steps):

- a) Remove contaminated clothing and store it 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 and 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 difference between a major and minor spill for the radionuclides for which application is being made is considered by the applicant to be major if it is more than 50mCi of <sup>99m</sup>Tc, 25mCi of <sup>201</sup>Tl and the sealed sources, being solid material, can not spill. If the sealed sources could spill, more than the amount being requested would have to be spilled to be a major spill.

Radioactive Spill Documentation-Continued

The following report, "Radioactive Spill Contamination Survey", will be used to determine the location, extent and decontamination of radioactive spills. This document will be used in addition to the "Radioactive Spill Report" of the prior page in this application.

**RADIOACTIVE SPILL CONTAMINATION SURVEY**

(See the "Radioactive Spill Report" of this incident)

I. INCIDENT

Spill Date \_\_\_\_\_ Time \_\_\_\_\_ Location \_\_\_\_\_

Radioactive Isotope \_\_\_\_\_ Form \_\_\_\_\_ Est. Activity \_\_\_\_\_

Person in Control of Incident: \_\_\_\_\_

II. SPILL AREA

Note: Show the spill area and extent of the spill on this drawing

III. SURVEY

A. Exposure Instrument \_\_\_\_\_ Probe \_\_\_\_\_

B. Swipe Instrument \_\_\_\_\_ PHA L E \_\_\_\_\_ Key to \_\_\_\_\_ Key \_\_\_\_\_

Location	Initial mR/hr	Decontamination		Comments
e		mR/hr	dpm/100cm <sup>2</sup>	
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____

IV. ADDITIONAL CONTAMINATION NOTES (Personnel, Cloths, Equipment, Etc.)

Description	Contamination	Disposition
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

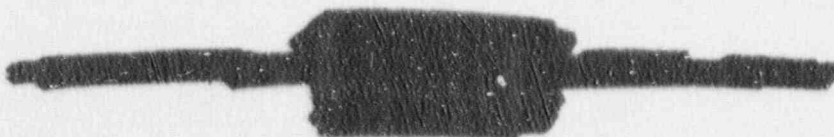
**EMERGENCY MATERIALS**

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**PERSONNEL DECONTAMINATION  
SYSTEM**

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**Do Not Obstruct Access  
To These Materials**



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**RADIOISOTOPE CONTAMINATION  
AREA**

**DO NOT ENTER THIS AREA WITHOUT PERMISSION  
OF THE RADIATION SAFETY OFFICER**



## DECONTAMINATION PROCEDURES

### I. General Rules

1. Contain the contamination and never allow uncontaminated areas to be contaminated in the "clean-up" process.
2. Avoid any release of the activity from the restricted area by immediately isolating the area that is suspected of being contaminated. It is acceptable to "over-react" in the initial response to the spill by isolating an area significantly larger than the initial spill site.
3. Address personnel contamination prior to decontamination of the facility.
4. Obtain assistance from others in decontamination procedures for monitoring and other activities.
5. Always follow the license conditions and established protocols for spills, surveys and documentation.

### II. Personnel Decontamination

1. If physical injury has occurred that requires medical attention administer such care immediately but with full knowledge that contamination may be present.
2. Decontaminate the eyes by washing the eyes with the eye wash solution from the "decontamination kit". The washing should be done over a sink and flushed down the drain.
3. Remove all contaminated garments, ie laboratory coat, gloves, etc. and step onto a pad on an uncontaminated surface to monitor residual activity.
4. Use the following decontamination techniques for skin decontamination. Use great care not to spread the contamination or to contaminate clean surfaces during these procedures. Do the decontamination in a sink and allow the water to go down the drain.
  - a. Flush the surface with tepid water, not hot or cold, and remonitor for removal/residual activity\*.
  - b. Wash with NUC-WASH A, rinse with tepid water and remonitor for removal/residual activity\*.
  - c. Wash with NUC-WASH B, NUC-WASH C and NUC-WASH D if necessary using the same procedure as in b. above. With each wash rinse with tepid water for removal/residual activity\*.
  - d. If necessary, after NUC-WASH D is used and residual activity exists, a soft brush may be used on the skin but AVOID BREAKING OR IRRADIATING THE SKIN.
  - e. If residual activity persists after all of the decontamination steps are completed and if, after consultation with the RSO, it is determined that additional decontamination is not warranted or practical, the use great care not to allow contamination or injection from the contaminated surfaces at later times. Return of moisture to the skin may allow contaminated skin to release more activity and thus additional washing after a few hours may be helpful. If the hands are contaminated, cotton gloves may prevent spreading of contamination and absorb moisture containing activity.
5. Determine the value/necessity of determining Bio-Assay of the individual for any injected or inhaled activity. These Bio-Assay techniques include but are not limited to nose wipes and  

\*Three consecutive washings are usually sufficient to remove all activity that will be removable with this procedure. After each wash monitor the surface to determine the amount of reduction in the exposure levels. Note: Use care not to contaminate the survey meter.



saliva samples and/or at a later time, 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.

6. Complete all required records including the appropriate spill reports and personnel exposure, injection or incident reports.

## II. Surface Decontamination

1. Avoid all unnecessary exposure of personnel during decontamination and never allow uncontaminated areas to become contaminated during these procedures.
2. Consider the possibility of utilizing "radioactive decay" as a decontamination alternative if the activity can be isolated and secured.
3. Wear booties, gloves, laboratory coat and, if possible, an apron, or other materials that will allow easy removal of contaminated articles.
4. Cover all "wet" areas with absorbant papers.
5. Monitor the area suspected of being contaminated and identify its outer limits with a marker of barrier.
6. Place absorbant pads adjacent to the area to prevent contamination of decontamination personnel.
7. Decontaminate the outer margins of the area with the appropriate NUC CONTAM Solution: I, II, and/or III, working toward the major area of the spill.
  - a. Use a minimum of solution and water.
  - b. Clean a small area, then go to another area.
  - c. Do not touch the wipes or decontamination materials, use tongs.
  - d. Place all contaminated materials in plastic bags for Decay In Storage (DIS).
  - e. After decontamination, place absorbant paper over the "clean" area to avoid contact with residual activity or recontamination.
  - f. When all areas are decontaminated, they must be swipe tested for residual activity prior to release.
8. Complete all required spill reports and records and document the decontamination.

\*Notes: If the surface is waxed, a wax remover may be used to remove the contamination. Use care when using a brush or abrasive instrument not to damage the surface, puncture the protective gloves or spread the contamination due to moisture drops or mists.

## PROCEDURE FOR ORDERING RADIOACTIVE MATERIALS

We will follow the following procedure in ordering radioactive materials

- 1) The RSO or a designee must authorize each order for radioactive materials to ensure that each material ordered is authorized under the license and the amount does not exceed the possession limits under that license.
- 2) A record of all orders will be maintained which shows the isotope, activity, form and supplier of the radioactive material (see the "Radioactive Material Package Order and Receipt Record")
- 3) Radioactive materials will only be received during normal working hours and the materials will be delivered directly to the nuclear medical area and placed on the table, as indicated in the floor plan, by the nuclear medical technologist or RSO.  
If the technologist or RSO are not present when the material is delivered, the reception staff will follow the procedure which is listed below and it, the procedure, will also be posted in both the reception office and in the nuclear medical room.
- 4) The technologist or RSO will check the package to determine that the material is the material which was ordered.
- 5) The technologist or RSO will then follow the Procedure For Safely Opening Packages Containing Radioactive Material.

## NOTICE

## RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIALS

When packages containing radioactive material are delivered, have the carrier agent wait in the reception area and call the nuclear technologist or the Radiation Safety Officer.

The nuclear technologist or the Radiation Safety Officer are not available then follow the following instructions:

Have the carrier place the package on a cart or wheelchair

If the package is damaged or shows signs of being wet or having been wet, immediately contact one of the individuals listed below and

Demand that the carrier's agent, the delivery person, remain at the facility to be monitored to determine that neither this person nor the vehicle is contaminated, and

Do not touch the package or allow others to touch the package but remove it, on the cart or wheelchair, to a secure area, i.e. the nuclear medicine room where it will be examined by the RSO or other authorized personnel.

If the package is not damaged and shows no signs of being wet

Sign the receipt and retain a copy.

Transport the package to the nuclear medicine area on the cart or wheelchair and

Place the package at the location marked

Radio pharmaceutical Receipt  
Area

And secure, lock, the room.

Note to cleaning, security and other personnel. If packages should be delivered during non-working hours but while you are present, you are not authorized to make a receipt and the package must be refused. The carrier's agent may not leave the package at the facility during non-working hours. If you have any questions, contact one of the individuals listed below.

Radiation Safety Officer:

Nuclear Medical Technologist:

## PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

The procedure for safely opening packages we will follow is:

- 1) Put on gloves to prevent hand contamination.
- 2) Visually inspect the package for any sign of damage such as wetness, physical damage, stains, etc and if any is noted, stop and notify the RSO.
- 3) Measure the exposure rate from the package at 1 meter and then at the surface. If it is higher than expected, stop and notify the RSO for more specific instructions and notifications.

Note: The surface exposure rate, maximum, of labeled packages is: White I 0.5mR/hr; Yellow II 50mR/hr and Yellow III 200mR/hr. None of these rates should be exceeded.

- 4) Open the package with the following steps:
  - a) Remove the packing slip.
  - b) Open the outer package following the supplier's instructions, if such instructions are provided.
  - c) Open the inner package and verify that the contents agree with the packing slip.
  - d) Check the integrity of the final source container. Look for any broken seals, loss of volume, moisture or stains on the packing material. If anything is found to be other than expected, stop and notify the RSO.
  - e) Remove the source container and place it on an absorbent pad.
  - f) Remove the now empty shipping box to an area with low background exposure and survey with a sensitive GM survey meter. If contaminated:
    - (1) Treat as radioactive waste and remove for DIS and
    - (2) Wipe the external surface of the final source container and assay the wipe, in a low background area, for any removable radioactivity. Use the procedure for assay of wipes as established in the "Contamination Survey Record" section III to determine the sample counts to dpm and
    - (3) Notify the RSO.

If not contaminated, remove and obliterate the radiation labels prior to discarding in the in-house trash.
- 5) Recheck the contents of the package to be sure it is the material that was ordered.
- 6) Check the activity of the source in the Dose Calibrator.
- 7) Log the material "in" on the correct Radioisotope Distribution Record.
- 8) Finish the Radioactive Material Package Order and Receipt Record as provided on the next page of this section.

# **RADIOPHARMACEUTICAL QUALITY ASSURANCE PROGRAM**

Note: In addition to this program there are additional Q.A. procedures for equipment, i.e., survey meters, calibrators, etc., that must be addressed as outlined in those protocols.

1. The facility management designates to the RSO the authority to establish and implement this program.
2. The RSO will conduct audits, evaluation, and corrective measures and regularly review the efficacy and adequacy of this Q.A. program.
3. The RSO will conduct audits at intervals of no less than twelve months, following any misadministrations and commencing with the implementation of any changes in this Q.A. program.
4. All audits will be documented, reviewed with the management and all authorized users and personnel involved. These documents will be maintained for inspection.
5. Deficient conditions requiring corrective action, changes in the Q.A. program, records or procedures, will be followed by the RSO and reaudited as necessary.
6. New workers, technical and professional, will be given specific instruction on this Q.A. program which will include, but not be limited to:
  - a. Radiation Safety Officer, RSO, and Bio-Safety Officer, BSO, designation
  - b. License authorizations and conditions
  - c. Quality Control, Q.C., and Quality Assurance, Q.A., procedures
  - d. ALARA procedures
  - e. Clinical procedures and protocols
7. The personnel will not proceed with a procedure unless:
  - a. All documentation, prescriptions, referrals, and other written instructions are legible, written clearly, precisely, and free of any possible misunderstanding, and.
  - b. All records agree with the clinical procedures manual, license conditions, and other written protocols and procedures, and.
  - c. It is clear that no element of a prescription, diagnostic referral, and other written instruction is unclear, ambiguous or apparently erroneous.
  - d. All checks of the activity as determined by the dose calibrator and calculations agree as to the radionuclide, chemical form and activity.
  - e. The visual, if possible, inspection of the radiopharmaceutical and/or calculation of specific activity, particles, etc., agree with the clinical indications of the procedure.
8. The specific activities of the radiopharmaceutical quality assurance program will include, but not be limited to:
  - a. A prescription written by or under the direction of an authorized user will be obtained. It will include:
    - (1) patient name and number
    - (2) diagnostic use
    - (3) radionuclide



- (4) form of radionuclide
- (5) dosage (activity to be administered)
- (6) chemical form
- (7) route of administration

The prescription will be signed and dated.

- b. The radiopharmaceutical will be ordered or prepared in accordance with operational procedures.
  - c. The radiopharmaceutical will be checked in the dose calibrator to determine radionuclide accuracy.
  - d. All documentation will be completed, in writing.
  - e. The prescription, patient identification, clinical procedure, activity prescribed and activity present, chemical form and possible contraindications/contraconsiderations and anticipated adverse reactions will be checked.
  - f. The radiopharmaceutical will be administered by the route prescribed.
9. Any misadministrations, adverse reactions, or any discrepancies will be immediately reported to the RSO for immediate investigation.

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## PROCEDURE FOR AREA SURVEYS

## Ambient Exposure Surveys

- 1) All areas where radiopharmaceuticals are used including their active storage, preparation and administration, will be subject to a survey with the GM survey detector at the end of each day in which the materials are used.
- 2) Areas that are used for only radiopharmaceutical waste storage and in which there are no daily activities, will be subject to a survey with the GM survey detector at the end of each week.
- 3) The survey information will be recorded on the "Ambient Exposure Survey" report form, see the next page, and the RSO will be notified if there are any unexpectedly high or low levels found, any level found where radionuclides should not be present or levels exceed those as established for unrestricted or restricted areas.
- 4) Surveys will be completed as part of the "spill" procedure.

## Removable Contamination Surveys

- 1) All areas where radiopharmaceuticals are used including their active storage, preparation and administration, will be subject to a survey with the GM survey detector at the end of each week in which the materials are used.
- 2) Areas that are used for only radiopharmaceutical waste storage and in which there are no daily activities, will be subject to a survey with the GM survey detector at the end of each week in which the materials are used.
- 3) The survey information will be recorded on the "Contamination Survey Record" report form, see the 3rd page, and the RSO will be notified if removable contamination of 1000 dpm/100cm<sup>2</sup> of 57Co, 99mTc, or of 201Tl is found or if 100dpm/100cm<sup>2</sup> of any other radioisotope is found or if any removable contamination is found in a unrestricted area. The assay will be sufficiently sensitive to detect the presence of 2000 dpm/100 cm<sup>2</sup> of 57Co, 99mTc or 201Tl and 200 dpm/100cm<sup>2</sup> of any other radioisotope and this assay will use the technique of absolute counting as outlined in the "Contamination Survey Record". The survey will use "Swipes" as indicated on the 3rd page of this section.
- 4) Surveys will be completed as part of the "spill" procedure.

Contamination Action Levels: ( dpm/100cm<sup>2</sup> of surfact contamination)

Area	Contaminant Radionuclide	
	57Co, 99mTc, 201Tl	All Others
Unrestricted Areas & Personnel Clothing	2,000	200
Restricted Areas, Protective Clothing, Skin	20,000	2,000









## RADIOISOTOPE WASTE DISPOSAL PROCEDURE

## Disposal by Transfer

- 1) Spent syringes and unused sources obtained from the radiopharmacy will be returned to the radiopharmacy. Only materials from the radiopharmacy will be returned to this supplier. Records will be made and kept of all materials returned to the radiopharmacy on the "Unidose Record-Radiopharmacy Radiopharmaceutical Unidose Record" form located in the Radiopharmaceutical Record section of this application.

## Disposal By Decay-In-Storage(DIS)

- 1) Short-lived material, that with a physical half-life of less than 65 days, will be disposed of by DIS.
- 2) Radioisotopes that are currently active, activities not used and not returned to the radiopharmacy, will be kept in the lead storage container for not less than two half-lives. These will then be transferred to the DIS storage container, as described below, after the radiation label has been violated and shielding removed.
- 3) Syringes and capped needles will be placed in a separate container for eventual disposal, after DIS, in compliance with state and local public health regulations.
- 4) Injection paraphernalia such as swabs and gauze as well as tubes, and other contaminated materials will be placed directly in the DIS containers.
- 5) All materials placed in the DIS container will have the radiation labels violated and the shielding removed. These materials will be placed in plastic bags, 2 ply, inside the container. When the bag is full or every few weeks, the bag will be sealed with string or tape, identified with the date sealed, the longest lived radioisotope in the container and the initials of the person sealing the container. The bag will then be contained for additional DIS, if required. No material will be disposed in less than 10 half-lives of the longest half-life in the container.
- 6) Prior to disposal, as in-house waste, the bag will be monitored with the following technique:
  - a) The GM survey detector will be checked for proper operation
  - b) The bag will be removed to a low-level background area, less than 0.05 mR/hr
  - c) All surfaces of the bag will be monitored, at the surface
  - d) If there is no exposure above background, the bag may be discarded, if there is exposure, it will be returned to DIS.
  - e) Complete records of DIS will be maintained on the "Disposal By Decay-In-Storage Record" form located on the next page.

**Note:** Sealed sources,  $^{57}\text{Co}$ ,  $^{133}\text{Ba}$ ,  $^{137}\text{Cs}$  that must be disposed by the applicant will be disposed by transfer to a supplier who has a license to receive such material and will be completely documented by the applicant prior to disposal.

