NRC FORM 313
(10-87)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 6-30-90

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 20555

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 30323

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

L&L 28728
030-32637
02200

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 94596

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.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [X] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] C. RENEWAL OF LICENSE NUMBER _____

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

Raritan Cardiology Group
533 New Brunswick Avenue
Perth Amboy, NJ 08861

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

same

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION: AARON J. FEINGOLD, M.D.

TELEPHONE NUMBER: 908 442-5454

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

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. Attached

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

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE. See Attachment C

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS. Attached

9. FACILITIES AND EQUIPMENT. Attached

10. RADIATION SAFETY PROGRAM. Attached

11. WASTE MANAGEMENT. Attached

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY Medical 7C
AMOUNT ENCLOSED $ 710.00

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
Alan Feingold	AARON J. FEINGOLD, M.D.	owner/applicant	1/9/92

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
APP	Jan-12	7C	(Arthur L. Roth, etc.) 115979	AR
AMOUNT RECEIVED	CHECK NUMBER			DATE
$710	12779			1/22/92

115979 1/10/92

OFFICIAL RECORD COPY ML 10

DOCUMENTATION OF ATTACHMENTS TO THIS APPLICATION

Attachmnet Section	Description of the Attachment Enclosed
A.	Description o f 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 primarily obtained from a radiopharmacy. The applicant will not obtain a 99mTc/99Mo generator. FDA approved cardiology imaging agents which do not have long shelf lives may be produced by obtaining a bulk supply of technetium from the radiopharmacy and compounding the final form on site . In these cases all appropriate radiopharmaceutical quality control will also be performed on the premesis and made an appropriate part of the facilities' records as part of the Radiopharmaceutical Quality Control program.

All radioactive wastes that came from the radiopharmacy, i.e., spoiled unidoses or used syringes that contain residual activity, will be returned to tht radiopharmacy for disposal and records of this transfer will be maintained by the applicant. Other wastes, i.e., wipes and contaminated materials from multi-dose vials and patient administration paraphrenalia, 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:

Radioisotope	Form	Amount, mCi of Each Form	Item 6 Purpose of Use
^{99m}Tc*	Pertechnetate	80.00	Human Use
	HSA	40.00	Human Use
	PYP	40.00	Human Use
	Other FDA approved forms	200.00	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 radiopharmacuetical supplier in unidose or multidose form. The applicant will not obtain a generator for 99m Tc. "Kits" using the radiopharmaceuticals listed in this application may be compounded on site in the case of FDA approved pharmaceuticals with short shelf lives. (The "supplier" includes the radiopharmacy)

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

It is recognized that the 201Tl and 57Co 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:

Element and Mass Number		Form	Max., mCi	Catalogue Number
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:

Element and Mass Number		Form	Max.,mCi	Catalogue Number
Co	57	sealed	5.000	062-297

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) A long-lived source, such as ^{137}Cs (T½ = 30 yrs.), to avoid the tedium of constant decay corrections.

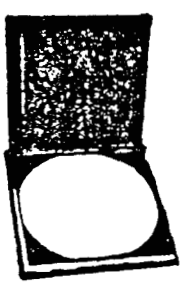
(b) A ^{57}Co source (T½ = 270 days) that simulates 99m-Tc, the most common radioisotope in nuclear medicine.

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 ±5%.

063-562 Calibrated Barium 133 Source, 250uCi
101-356 Calibrated ^{137}Cs Source 200uCi
063-261 Calibrated Simulated 9m-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 accredidation 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 wooded 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

TRAINING AND EXPERIENCE OF AUTHORIZED USER AND RADIATION SAFETY OFFICER

The Authorized User is Michael M. Zukowski, M.D. Dr. Zukowski is an experienced Authorize User on New York license number 2661-1, Cardiac Diagnostics, Dr. Jeffrey Borer, M.D., 340 East 64th Street, New York, New York 10021.

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

Method of Evaluation:

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

6

APPLICATION FOR MATERIAL LICENSE

Attachment E.

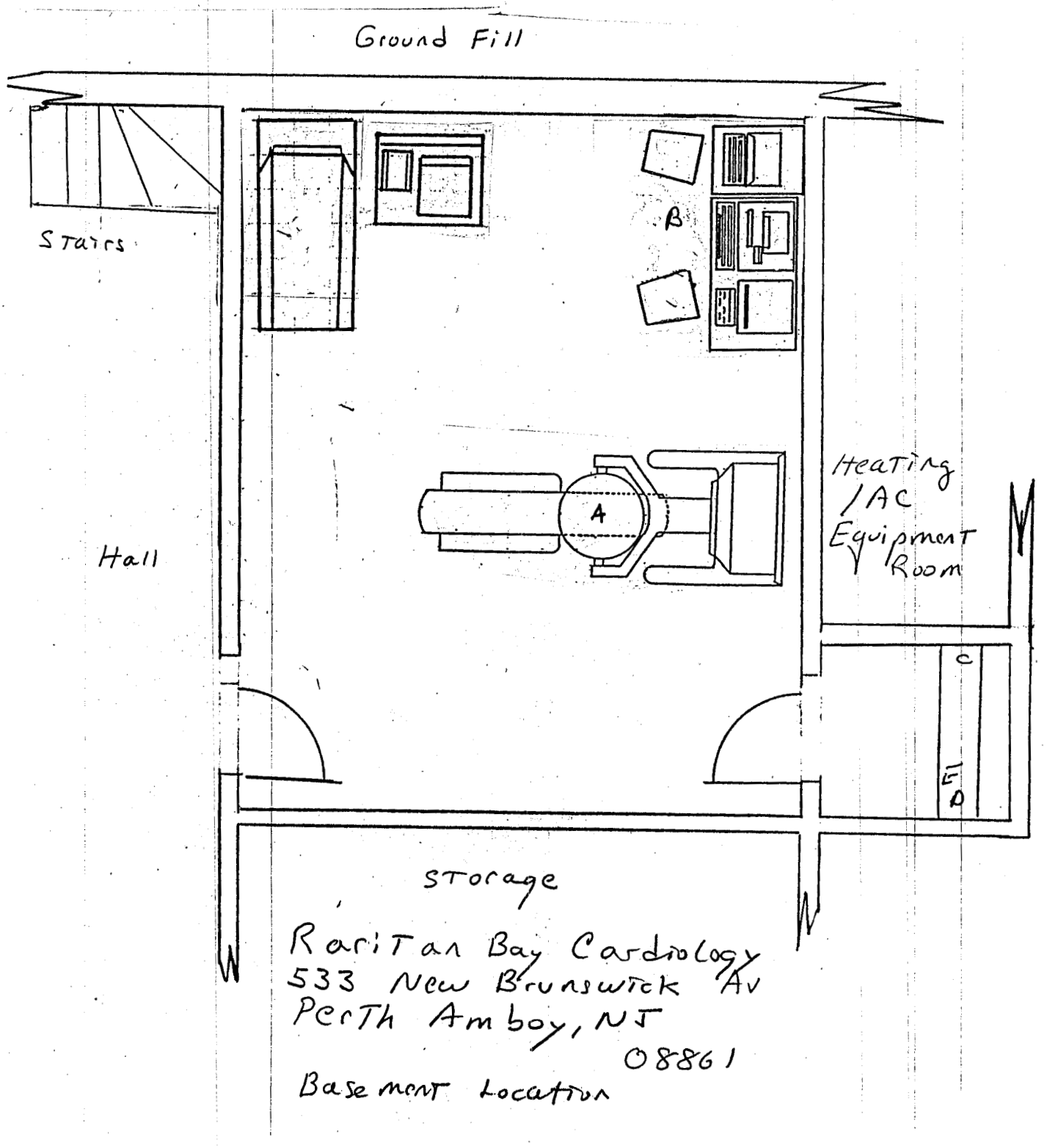
FACILITIES-ANNOTATED DRAWING OF THE RADIOISOTOPE FACILITY

Scale: ¼"= 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



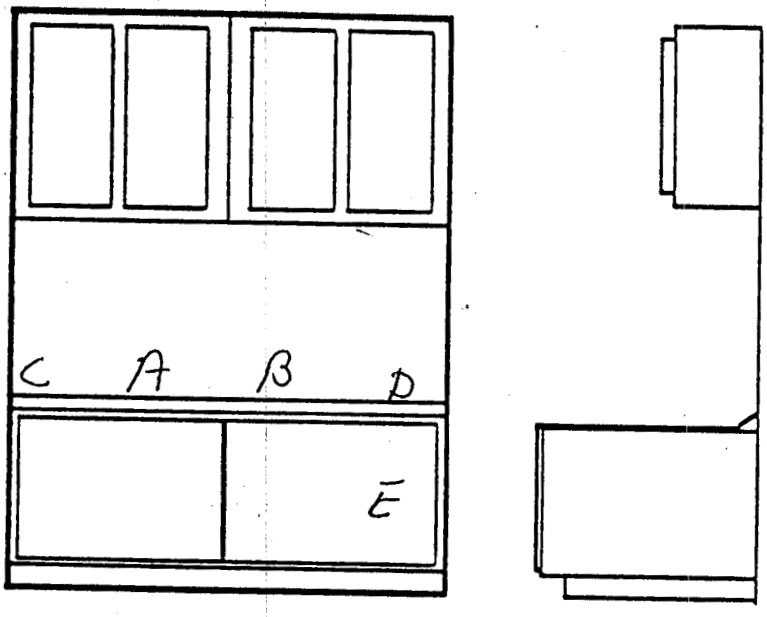
NC Systems
5785 Arapahoe, Suite D
Boulder, Colorado 80303
1-800-548-4024

Plans developed for:

RARITAN BAY CARDIOLOGY

DATE:	SCALE:	SHEET:	BY:
12-91	N/A		gw

Attachment E2



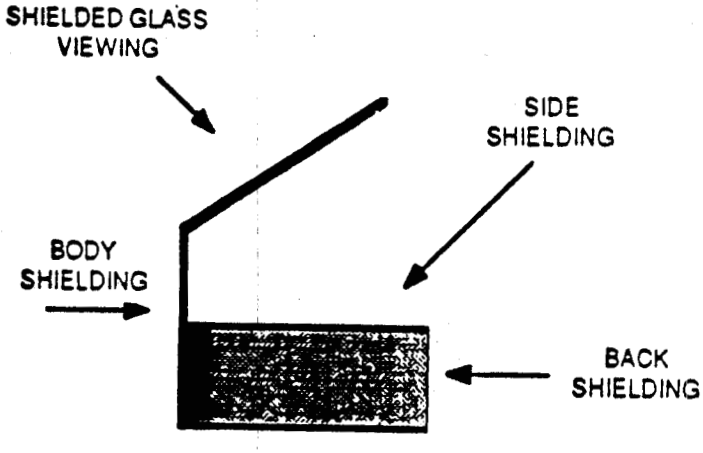
FRONT VIEW

SIDE VIEW

REPRESENTATION - not necessarily to scale

LEGEND	
IDENTIFICATION	DESCRIPTION
A	DOSE CALIBRATOR
B	BODY SHIELD
C	RADIOISOTOPE RECEIPT
D	RADIOISOTOPE STORAGE
E	RADIOISOTOPE WASTE

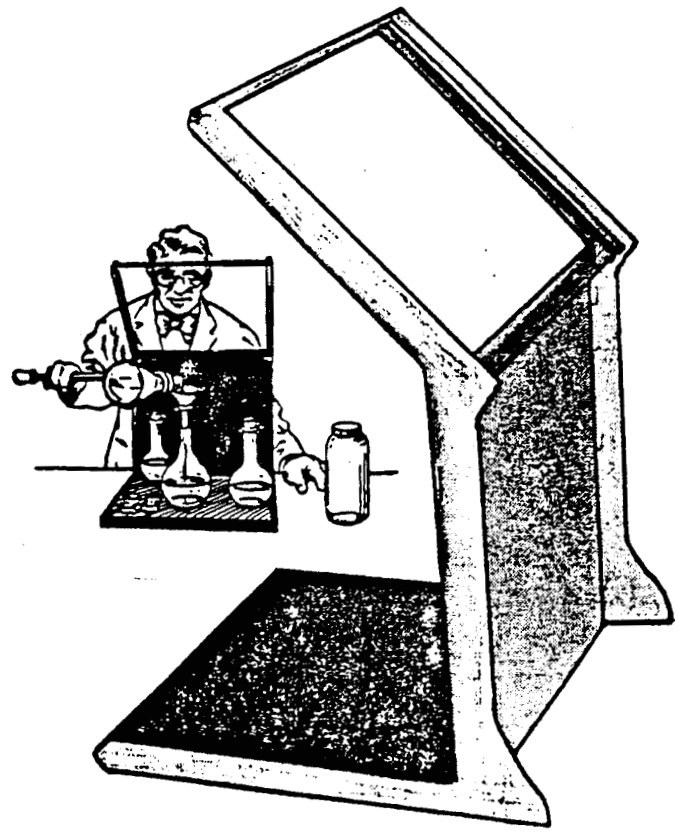
BODY SHIELD



FACILITIES-TABLE TOP BARRIER SHIELD

Table Top Lead Barrier Shield

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



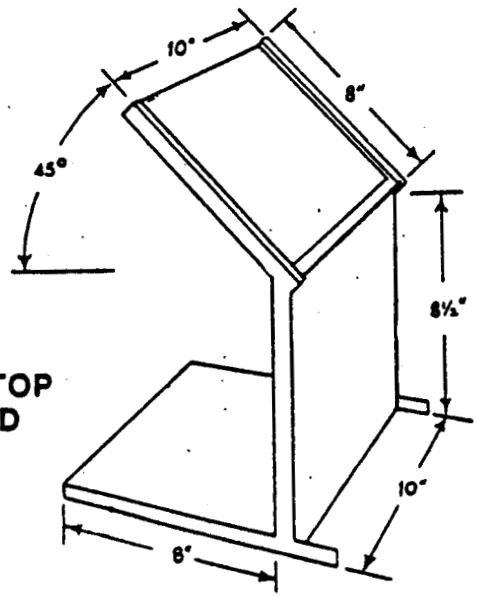
MINI TABLE TOP SHIELD for small jobs in limited working areas.

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

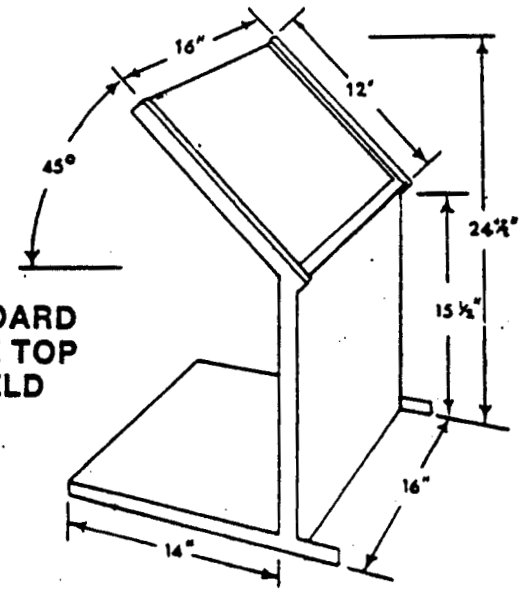
Select the shield most suited to your workload. Both units provide exceptional protection to the clinician when setting up technetium generators, filing syringes, performing radium loading procedures, etc.

½" thick lead wall protects the torso while the base provides ample working surface and balance against tipping. Face shielding is optically clear ¼" 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.



MINI TABLE TOP SHIELD

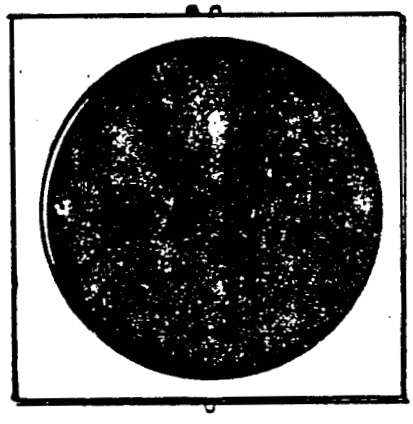


STANDARD TABLE TOP SHIELD

EQUIPMENT QUALITY CONTROL PHANTOMS

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

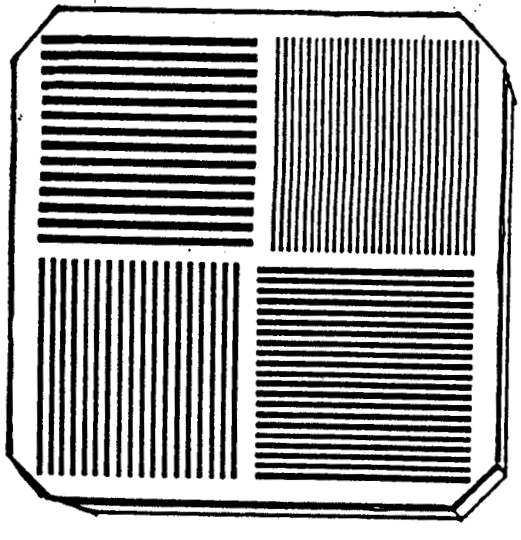
EMISSION PHANTOM



Extra Large Flood Phantom Source

- 15" diameter pool will totally include a patient's lungs, allowing accurate patient position when using a diverging collimator.
- 16½" x 16½" 1" thick with 15" diameter x ½" cavity for suitable radionuclide.
- Easy to fill... drain ports provided.

TRANSMISSION PHANTOM

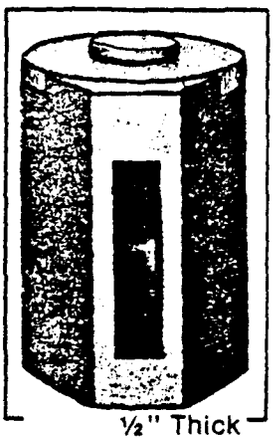


Standard High Resolution Bar Phantom

- Bar Widths: 1/4", 3/16", 5/32" 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



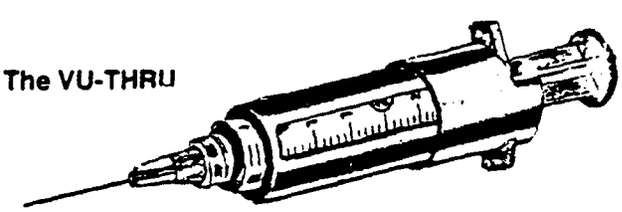
This lead shield, available in either ¼" or ½" thickness, was designed to permit safe, convenient handling of vials containing liquid radioisotopes. It is particularly important when milking "cows". The vial provided with the generator may be placed in the shield, and the generator eluted in accordance 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.

Pro-Tec® Syringe Shield

Pro-Tec Syringe Shields are the first functional, safe, unobtrusive, easy-to-use, unbreakable, and lightweight syringe shields available. The slimline 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}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 gm/cc covers the port.

The VU-THRU



B-D disposable syringes (twist lock) *U.S. Pat. #3,820,541

VU-THRU (Glass)

007-303 Pro-Tec Syringe Shield 3cc
007-505 Pro-Tec Syringe Shield 5cc

Lead Lined Storage Container

For Contaminated Syringes

- **Safely holds used hot syringes**
- **Rapid, safe disposal**

SPECIFICATIONS:

½" Lead Shielding

Measures: 6¾" 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, Colorado 80303	Nuclear Medical Imaging for Nuclear Cardiology Procedures
Nuclear Medical Computer	As supplied by CARDIO-CAM Corp. as described above	Nuclear Medical Data Presentation and Analysis
Dose Calibrator	Atomlab 100 Dose Calibrator Catalog #086-250 from: Atomic Products Corp. P.O. Box 702 Shirley, New York 11967	Radiopharmaceutical Quality Control of Patient Doses
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-Wipell 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 radioacitve materials are received, used manipulated or stored.
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.

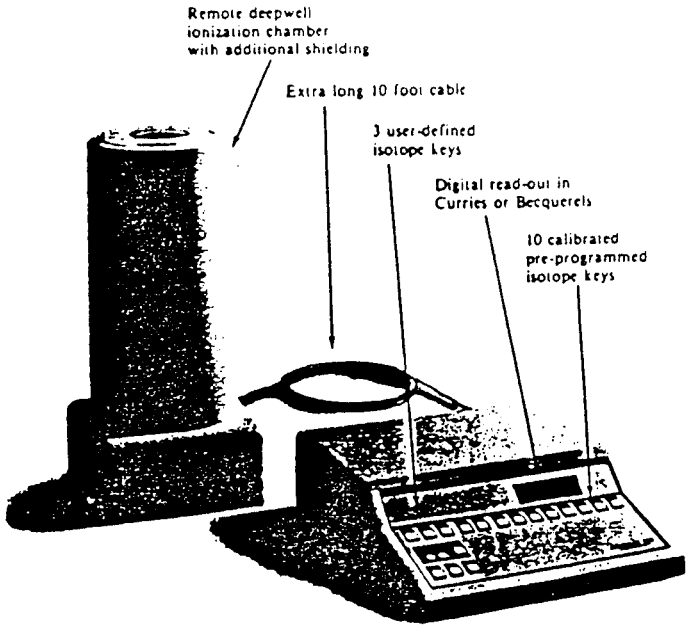
ATOMLAB 100

Activity Range:	0.01 µCi to 9999 mCi (or Bq equivalent)
Detector Linearity:	± 1%or 0.2 µCi, whichever is greater
Electrometer Linearity:	± 1% or 0.1 µCi, whichever is greater
Electrometer Accuracy:	± 1% or 0.1 µCi, whichever is greater
Response Time:	Less than five seconds to reach 95% of final reading
Overall Accuracy:	± 3% or 0.3 µCi, 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:	± 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:	• Dimensions: 3.5" × 12" × 14.3" (8.9 cm × 30.5 cm × 36.3 cm) • Weight: 6 lbs (2.7 kg)
Detector Unit:	• Dimensions: 7.5" × 7.5" × 16" (19 cm × 19 cm × 40.6 cm) • Overall Weight: 35 lbs (15.75 kg) • Well Diameter: 2.5" × 10" (6.4 cm × 25.4 cm) • Well Shielding: 1/4" Lead

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 ^{137}Cs when calibrated according to NRC Reg. Guide 10.8

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

WARMUP TIME: None

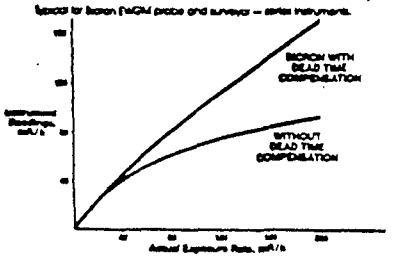
SATURATION: Typically >1000R/h for most GM probes (provided by exclusive anti-saturation circuit); >5R/h for pancake GM probes

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

	Time	
Range	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.



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

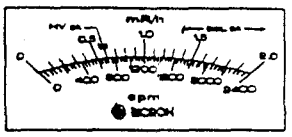
BATTERY LIFE: > 100 hours or > 200 hours with parallel option

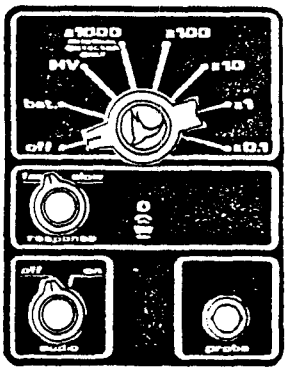
TEMPERATURE: Operational from −40° to +60°C

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 Bicron 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)

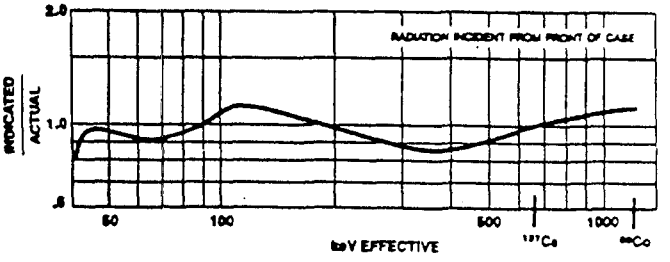
WEIGHT: 2.2 lbs. (1 kg.) excluding probe

Model: SWGM

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

Typical Energy Response

INTERNAL DETECTOR ONLY



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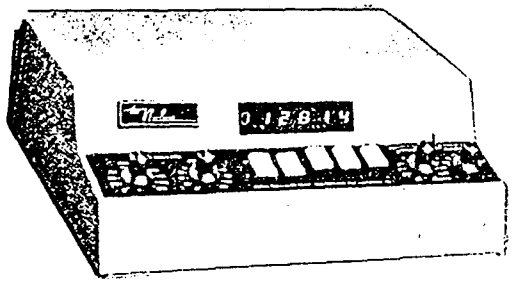
Litho in U.S.A. on recycled materials 5/87

CARDIO-WIPE II

A scaler/timer system interfaced to a NaI crystal detector. The scaler/timer features a built in power supply with full-range control form zero through 2000 volts. Separate lighted switches are provided for on-off, line frequency test, count, stop, and reset functions. A sungle MHV connector is provided on the back panel, along with a line fuse holder. The NaI(Tl) well scintillation probe is mounted in a base which provides 1.9cm of virgin lead shielding to all externally exposed surfaces. The 4.5 x 5.1 cm crystal contains a 3.8 cm deep well of 1.7 cm diameter. The well is lined with .25mm aluminum. A single MHV cable connector is provided for interface.*



MODEL WP-2000 WELL SCINTILLATION PROBE (FOR TEST TUBE SAMPLES)

Scintillator:	1.75" (4.5 cm) x 2" (5.1 cm) NaI(Tl) well crystal; well: .7" (17 mm) diameter x 1.5" (3.8 cm) deep; well entrance window: .01 inch aluminum (.25 mm)
PM Tube:	2" (5.1 cm) diameter
Resolution:	9% or better full-width-half-maximum for Cs-137 (0.662 Mev)
Shielding:	.75" (1.9 cm) virgin lead surrounds crystal
Dimensions:	Height: 10.75" (27.3 cm) Base diameter: 6" (15.2 cm) Lead height: 5" (12.7 cm) Lead diameter: 4" (10.2 cm)
Connectors:	High voltage cable: MHV Signal cable: BNC

Note: With AA-2010 System only one cable is required for both high voltage and signal; single MHV

TECHNICAL DATA FOR MODEL 500 SCALER/TIMER

Readout:	999,999 counts, all electronic, no mechanical register
Resolving Time:	better than one microsecond
Input Sensitivity:	0.25 volt negative
Voltage:	0 to 2000 volts, continuously variable; zener regulated; coarse and fine controls
Preset Timing:	0.5, 1, 2, 5, 10 minutes and manual; derived from power line frequency; accuracy to 0.03%
Power Requirement:	105-125 volts, 60 Hz (230 volts, 50 Hz optional)
Detector Input:	MHV connector
Shipping Weight:	14 pounds (6.4 kg)
Dimensions:	4.5" (11.4 cm) high x 11" (27.9 cm) wide x 10.5" (26.7 cm) deep
In Line Fuse:	1 amp

WP-2000
(Without Lead Shield)

* Manufacturer of origin is The Nucleus, 761 Emory Valley Road, Oak Ridge, TN 37830-2561.

CARDIO-WIPE II

Technical Specifications

The following empirical data were obtained in a controlled bench-top environment to determine the Minimum Detectable Activity (MDA) and Lower Limit of Detection (LLD) of the system as required by 10 CFR 35.70. The instrument was operated without pulse height analysis. An NIST traceable ^{57}Co source was used to approximate the response of the system to ^{99m}Tc. Calculations were performed using the method described in the Appendix to Regulatory Guide 4.14 Revision 1 by the Nuclear Regulatory Commission. Because the system will be used to perform analysis of wipe and swipe samples, no correction factors were used for variations in sample volume or fractional radiochemical yield.

RAW DATA:

Average background - 390 cpm - 6.5 cps
Standard deviation of background - 20 cpm - 2.5 cps

57Co NIST Standard source - Serial Number C-113-3
.69 uCi (1,528,572 dpm) on date of testing
Net yield in well 1,050,610 cpm

CALCULATIONS:

System efficiency

1050610cpm/1528572dpm = .68 cpm/dpm = 68% efficient

Lower Limit of Detection for ^{99m}Tc

$$\frac{4.66 \times 2.5}{3.7 \times 10^4 \times .68 \times e^{-.693/6h \times 1h}} = .0005uCI \ (1144dpm)$$

Thus this instrument meets the requirements of 10 CFR 35 to detect 2000 disintigrations per minute.

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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 documentated by the applicant prior to contracting this service. It is anticipated that the calibration wlll be done by the manufacturer of the instrument or by Eberline Instrument Corporation of both 312 Miami Street in West Columbia, SC (1800-234-4212) and 504 Ariport Road in Santa Fe, New Mexico (800-274-4212) or KNS Associates, Inc. or 1854 Airlane Drive in Nashville, TN 37210 (615-883-9760) License # R-1975-Cl.

2) If a contractor remote from the location of the facility is used, either a repalcement 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
  - Duduced 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

5) The following information will be attached to the instrument as a calibration sticker or tag:
   - The Source That Was Used
   - Proper Deflection In The Battery-Check Mode
   - For Each Scale or Decade, One Of The Following
     - The Average Correction Factor
     - A Graph Or Graphs From Which The Calibration Factor For Each Scale or Decade May Be Duced or
     - An Indication That The Scale Was Checked For Fucction But Not Calibrated Or That The Scale Was Inoperative
   - The Angle Between The Radiation Flux And The Detector
   - The Apparent Exposure Rate From The Check Source

6) The form, below, will be used to document the meters calibration and service.

SURVEY INSTRUMENT CALIBRATION AND SERVICE RECORD

Survey Instrument Type: _____ Mfg.: _____ Model: _____ Probe: _____ mg/cm² _____ Sr. Number: _____

Check Source: Isotope: _____ Calibration: _____ Activity: _____ Exposure Rate: _____ mR/hr

Instrument Calibration* Date: _____ By: _____

Action		Check Source, mR/hr	Battery Check	Background mR/hr	Action Taken	By
Date	Time					

*Calibration must be no less than annual and after each servicing that involves more than replacement of the batteries.

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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 of 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}Tc containing 1-10 mCi of ^{99m}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}Co, ^{133}Ba, and ^{137}Cs as authorized under this license for this procedure (see "sealed sources").

b) "Count" each source at its correct setting on the calibrator, subtact 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}Co source to measure the reading on both the ^{57}Co setting and the ^{201}Tl setting during the accuracy measurement.

f) Place a sticker on the dose calibrator indicating when the next accuracy test is due.

Dose Calibrator: Geometry

CALIBRATION AND QUALITY CONTROL OF THE DOSE CALIBRATOR GEOMETRY DEPENDENCE - VIALS

To test the geometry dependence for a 30cc glass vial, draw 1.0cc of the ^{99m}Tc solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.

Remove the vial from the calibrator and, using a clean syringe, inject 2.0cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

Repeat the process until you have assayed a 19.0cc volume. The entire process must be completed within 10 minutes.

Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5% error lines above and below the chosen "standard volume."

If any correction factors are greater than 1.05 or less than 0.95 or if any data points lie outside the 5% error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "vial geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

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) From the pharmacy obtain a syringe containing not less than the amount of the highest dose ever administered to a patient of ^{99m}Tc .

b) "Count" the syringe in the dose clalibrator 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. Circle the point of greatest deviation from its value on the line.

e) Calculate the maximum deviation of the circled point from its value on the 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.

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}Co sealed, dose calibrator source on the ^{201}Tl, ^{57}Co, and ^{99m}Tc settings. Measure the ^{137}Cs source similarly.

b) Record the background at the same settings.

c) Determine the activity indicated, at the settings, by subracting the background, b), from the readings determined in a), and record this value.

d) Compare the measured ^{137}Cs activity to activity calculated from a ^{137}Cs 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}Co NBS Source

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

^{57}Cobalt Decay Table

time, t, days	$e^{-0.69315/T1/2\ t}$
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

***

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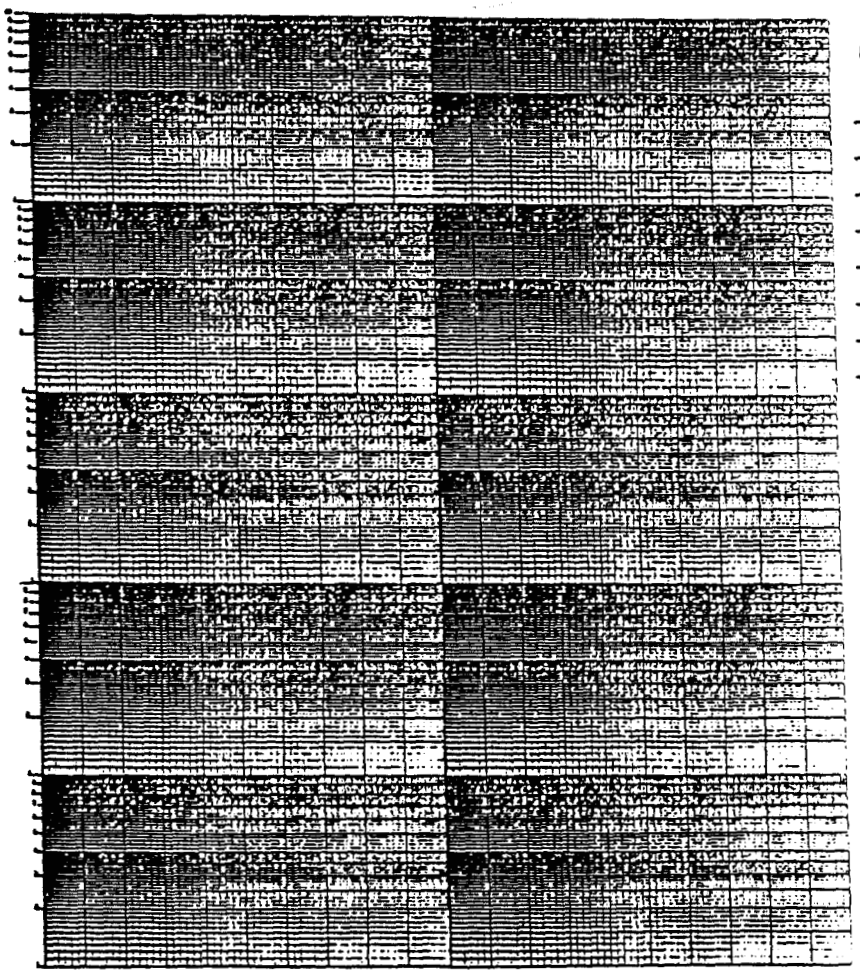
DOSE CALIBRATOR LINEARITY TEST

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: _____

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Dose Calibrator: Geometry

DOSE CALIBRATOR GEOMETRY TEST

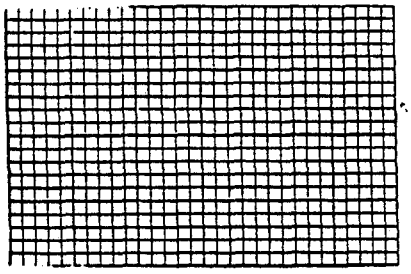
Licensee: _____

License Number: _____ Amendment: _____

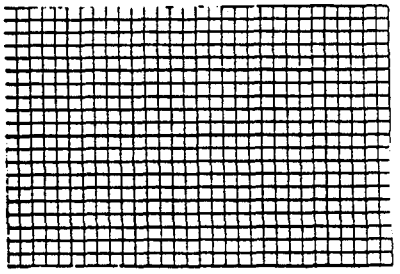
Date: _____ Dose Calibrator Model: _____ Sr. #: _____

Radioisotope: _____ Form: _____

Syringe Geometry Dependence



CF ___ ___ ___ ___



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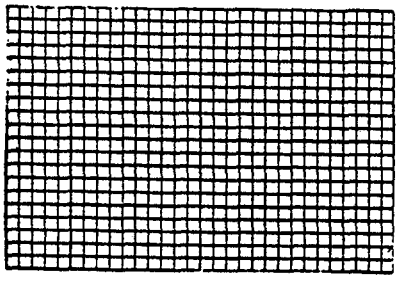
Vial Geometry Dependence



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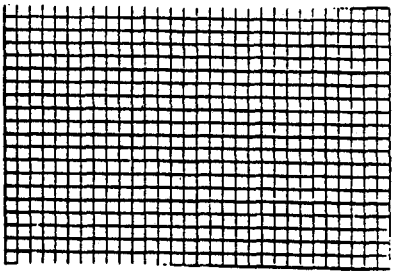

CF ___ ___ ___ ___

Analysis of Geometry Dependence Data From Above: _____

Signed: _____ Date: _____

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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:** _____

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DOSE CALIBRATOR QUALITY CONTROL AND CONSTANCY CHECK

Dose Calibrator Identification: _____ Sealed Q.C. Sources Isotope Calculated Activity

Action Level													
Date	Time											Notes	Initials
		Calc. Act.		bkg	^{201}Tl	bkg	^{99m}Tc	bkg	Cal. Act.		bkg		

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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 intrinsicly, 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 will be performed weekly.

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. Flood field uniformity will be performed daily.
   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 ^{99}mTc 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 protocal **"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 ^{99}mTc or ^{57}Co. The activity should not exceed 50μCi. 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 - 80% 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, ECG gate and other accessories.

GAMMA CAMERA QUALITY CONTROL AND PERFORMANCE RECORD

Gamma Camera Identification: _____ Computer: _____

Quality Control		Source		PHA	Uniformity		Resolution		Background	Other	Analysis	By
Date	Time	Isotope	Activity	Δ E	Cts	Time	Cts	Time	Cts/Minute			

Note: Routine QC should include at least —
Daily a) PHA adjustment b) Resolution Weekly a) Uniformity b) Max CR Capacity
Quarterly a) Background Flood b) CR at 20% loss c) Interlocks & Switches Service/Repairs a) Review all weekly and quarterly routines as necessary

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 regualr 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 expsoure, 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, carryout 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 Gyide 10.8, Rev.2, NRC.

ALARA PROGRAM

The applicant will establish an ALARA program as established in Appendix G to the Regularory 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 safey program with a more formal review on not less than an annual basis and
3) Modifications of the radiation safety program, incuding 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 saftey(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
Survey Instruments							
Battery Check	X						
Reference Check	X						
Calibration						X	& after service
Dose Calibrator							
Geometry							on installation & service
Constancy	X						& after service
Linearity				X			& after service
Accuracy						X	on installation & service
Gamma Camera							
PHA	X						& after service
Resolution	X						& after service
Uniformity		X					& after service
Max CR		X					& after service
Background Flood				X			& after service
CR @ 20% loss				X			& after service
Interlocks & Switches				X			& after service
Area Surveys (Contamination)							
Exposure Survey							
daily use areas	X						upon any incident
storage		X					
Wipe Survey		X					upon any incident
Sealed Source Leak Testing							
Leak Test					X		or upon damage
Worker Instruction							
Initial Instruction						X	& prior to first entry
Training						X	& prior to first entry
Personnel Monitoring							
Prior Dose							prior to first entry
Prenatal Exposure							prior to first entry
Exposure Reports			X				
Annual Exposure						X	
Accumulated Exposure							upon termination
ALARA			X	X			& 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.

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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.

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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.

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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 radioisotope 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: _____

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All information on this notice will be completed prior to posting

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: _____

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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 dosimter. 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.

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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 consistant 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
   i. Disposing of radioactive material
   j. 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.

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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 occurances 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 ^{131}I unsealed sources will be used. If any ingestion or other absorbtion 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.

***

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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 NaI well/scaler to determine if any counts, activity indication, is present after counting a gamma reference source of 133Ba or 137Cs 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 μCi present using the cpm/μCi 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 0.005μCi 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	– Bkg	= Net	× uCi/cpm	= uCi	
Isotope	Activity	Form	#	cpm	cpm	cpm			on Taken
133 Ba									
57 Co									
I.									
II.									

STANDARD ANALYSIS

A. Assay uCi _____ x Decay Factor _____ = uCi _____

B. Gross cpm _____ – Bkg cpm _____ = Net cpm _____

C. Calibration Factor A/C = _____ uCi/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 cpm to uCi and to assure the sensitivity of the detector, are lecense exempt thus are not part of this application. These sources will be of 133Ba or 137Cs 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 analysys calcualted 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 NaI well/scaler 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 efficency 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:

<u>Wipe Testing Completed</u>

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 establsihed under this license.

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

<u>Leaking Source-Do Not Use</u>

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.

APPLICATION FOR MATERIAL LICENSE Attachment K. 3.

Licensee: _____ License #: _____

Address: _____ _____

City: _____ State: _____ Zip: _____

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 #	Isotope	Activity mCi	Serial #	Assay Date	Form	Use	Swipe/Sample Method

II. Sample Analysis

Swipe/ Sample	Gross - cpm	Bkg cpm	=	Net cpm	x	dpm* / cpm	x	1 u Ci / 2.2x10⁶ dpm	=	uCi	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 x 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 x 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 regulation. 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".

By: _____ Date: _____

NC Systems, Inc. License #: Colo. 751

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RULES FOR THE SAFE USE OF RADIOPHARMACEUTICALS

The "Notice" shown below will be the procudure 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 tray 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.

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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

DISPOSAL BY DIS

RESTRICTED
RADIOISOTOPE STORAGE AREA

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

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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 covering the area, 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.

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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 99mTc, 25mCi of 201Tl and the sealed sources, being solid material, can not spill. If the sealed souces could spill, more than the amount being requested would have to be spilled to be a major spill.

RADIOACTIVE SPILL DOCUMENTATION

The following document, "Radioactive Spill Report", will be completed for all radioactive spills, both major and minor. This report will be used as an operational document for evaluation and documentation of all such incidents. In addition, each incident will also have a "Radioactive Spill Contamination Survey" report completed for each such incident.

RADIOACTIVE SPILL REPORT
(Complete For All Radioactive Spills)

I. INCIDENT

Spill: Date _____ Time _____ Location _____

Radionuclide: 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. EVENT

A. Personnel Present* Personnel Contamination Results**

_____ _____

_____ _____

_____ _____

_____ _____

*Include patients and other "non-personnel"

**Use the back of this sheet to indicate decontamination, monitoring, bioassay or other actions taken

B. Description of incident _____

C. Evaluate the magnitude of hazards associated with the event _____

D. Describe all reporting and related actions taken _____

E. Describe follow-up actions taken to prevent recurrence _____

Report completed by _____ Date _____
Signature

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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 _____

Radionuclide: 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 △E _____ Kev to _____ Kev

Location #	Initial mR/hr	Decontamination mR/hr	Decontamination dpm/100cm²	Comments

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

Description	Contamination	Disposition

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See Attachment K. 2.
Note: The survey will be done with the GM survey detector system

EMERGENCY MATERIALS

PERSONNEL DECONTAMINATION SYSTEM

Do Not Obstruct Access To These Materials

NCSystems, Inc.

1-800-548-4024

RADIOISOTOPE CONTAMINATION AREA

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

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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 occured 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 irritating 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 injestion 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 injested 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, injestion or incident reports.

III. 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.

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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.

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

1. Have the carrier place the package on a cart or wheelchair.
2. 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.
3. 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

   Radiopharmaceutical 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:

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All information on this notice will be completed prior to posting

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 contiamination.
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 shoulb 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) Revove 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 paterial "in" on the correct Radioisotope Distribution Record.
8) Finish the Radioactive Material Package Order and Receipt Record as frovided on the next page of this section.

PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL-
RADIOACTIVE MATERIAL PACKAGE ORDER AND RECEIPT FORM

These records will be maintained on the following record form shown smaller that the actual record.

RADIOACTIVE MATERIAL PACKAGE ORDER AND RECEIPT RECORD

Order		Receipt		Packing Slip #	Radioactive Material			Supplier	Package Condition	Exposure		Contamination	Notes	By
Date	By	Date	Time		Isotope	Activity	Form			1 m	Surface			

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RADIOPHARMACEUTICAL RECORDS

Records of the radiopharmaceutical, supplier, date, time, activity, patient, pre-administration dose calibrator assay and person administering the material will be maintained by the facility. These records will be completed on the forms shown below, or on a form supplied by the radiopharmacy containing all of the same information.

UNIDOSE RECORD — RADIOPHARMACY RADIOPHARMACEUTICAL UNIDOSE RECORD

Radiopharmacy: _____

PACKAGE RECEIPT AND MONITOR RECORD

Receipt: Date: _____ Time: _____ am/pm By: _____ Confirmation With Order: _____

Package Condition: _____ Surface Exposure Rate: _____ mR/hr Contamination: _____

Notes: _____

PRESCRIPTION RECORD

Prescription Record					
Activity _____ Isotope _____ Form _____	Dose Calibrator		Disposal Record		
Patient _____ Time _____ By _____	Pre-Administration		Disposal Route: _____ Date: _____		
	Activity Check _____		Returned To Radiopharmacy _____		
Prescription Record	Dose Calibrator		Disposal Record		
Activity _____ Isotope _____ Form _____	Pre-Administration		Disposal Route: _____ Date: _____		
Patient _____ Time _____ By _____	Activity Check _____		Returned To Radiopharmacy _____		
Prescription Record	Dose Calibrator		Disposal Record		
Activity _____ Isotope _____ Form _____	Pre-Administration		Disposal Route: _____ Date: _____		
Patient _____ Time _____ By _____	Activity Check _____		Returned To Radiopharmacy _____		
Prescription Record	Dose Calibrator		Disposal Record		
Activity _____ Isotope _____ Form _____	Pre-Administration		Disposal Route: _____ Date: _____		
Patient _____ Time _____ By _____	Activity Check _____		Returned To Radiopharmacy _____		
Prescription Record	Dose Calibrator		Disposal Record		
Activity _____ Isotope _____ Form _____	Pre-Administration		Disposal Route: _____ Date: _____		
Patient _____ Time _____ By _____	Activity Check _____		Returned To Radiopharmacy _____		

UNIDOSE RECORD — _____ ISOTOPE _____ FORM _____

Note: Complete the Order and Receipt Record prior to entering any information on this record form.

Date Received	Supplier	Lot #	Calibration			Administration			Dose Calibrator Activity Check	Patient		By	Disposal	
			Activity	Date	Time	Date	Time			Name	Number		Date	Route

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 radipharmaceutical 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 misadminstrations, adverse reactions, or any discrepancies will be immediately reported to the RSO for immediate investigation.

***

Multidose Distribution Records

Multidose Distribution Records

Procedure

For each multidose vial received from a supplier or prepared, record:

1. Radionuclide;
2. Generic name or its abbreviation or trade name;
3. Date of receipt or preparation;
4. Date and time of initial assay and amount in both millicuries and cubic centimeters (cc) or millimeters (ml);
5. Supplier or kit manufacturer;
6. If administered,
   a. Prescribed dosage (unless already recorded in clinical procedure manual),
   b. Date and time dosage was drawn and measured,
   c. Calculated volume that is needed for the prescribed dosage,
   d. Measured activity in millicuries or microcuries,
   e. Patient name and identification number if one has been assigned;
7. If discarded, the method of disposal and date; and
8. Initials of the individual who made the record.

RADIOACTIVE MATERIAL PACKAGE ORDER AND RECEIPT RECORD

Order		Receipt		Packing	Radioactive Material			Supplier	Package	Surface	Contamination	Notes	By
Date	By	Date	Time	Slip #	Isotope	Act.	Form		Condition	Exposure			

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NUCLEAR RECORD SYSTEM
NUCLIDE:_____
FORM:_____

UNIDOSE DISTRIBUTION RECORD

Note: Complete the Order and Receipt Record prior to entering any information on this record.

Date Received	Supplier	Lot Number	Supplier Assay			Patient		Patient ID	Referral	Prescription	Clinical Proc.	Pres. Activity	Dose Cal.	Administration		By	Disposal	
			Activity	Date	Time	Name	Number							Date	Time		Date	Route

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NUCLEAR RECORD SYSTEM
NUCLEIDE:_____
FORM:_____

MULTIDOSE DISTRIBUTION RECORD

Manufacturer: Date Received: _____ Supplier: _____ Lot Number: _____

Assay – Date: _____ Time: _____ Activity(mCi): _____

Volume(cc): _____ Concentration(mCi/cc): _____

Disposal – Date: _____ Route: _____ By: _____

Note: Complete the Order and Receipt Record prior to entering any information on this record form.

Date Administered	Time	Decay Factor	Current Concentration (mCi/cc)	Prescribed Activity (mCi)	Dose Volume (cc)	Patient		Patient ID	Referral	Prescription	Clinical Pres.	Pres. Activity	Dose Cal.	By
						Name	Number							

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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^2 of 57Co, 99mTc, or of 201 Tl is found or if 100dpm/100cm^2 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^2 of 57Co, 99mTc or 201Tl and 200 dpm/100cm^2 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.

Comtamination Action Levels:(dpm/100cm^{2}of surfact contamination)

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

CONTAMINATION SURVEY RECORD FORM

The form used for this survey is found, reduced in size, below. The floor plan of the facility will be reporduced on the form and the locations of the "swipes" will be indicated on the floor plan, by numbers. The type of "swipe" that will be used is found on the bottom of the page

CONTAMINATION SURVEY RECORD

(Survey For Removable Contamination)

Survey: Date _____ Time _____ By _____ Assay: Date _____ Time _____ By _____

Instrument: _____ PHA/E _____ Kev to _____ Kev

Standard: Radionuclide _____ Assay: Activity _____ Date _____

I. SURVEY AREA

II. SAMPLE ANALYSIS

Swipe #	Gross cpm	−	Bkg cpm	=	Net cpm	x	dpm* / cpm	=	dpm	Action Taken**

*From "Standard Analysis" below

**See "Contamination 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 x 10^6 dpm/uCi = dpm _____

D. Calibration Factor A/C = Net cpm/dpm = _____ / _____ = cpm/dpm _____

IV. CONTAMINATION ACTION LEVELS (dpm/100cm² of surfact contamination)

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

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"SWIPE"

Directions:

1. Complete the lower panel
2. Place this panel on the dry surface to be surveyed
3. Using the index finger, lightly press the swipe on the surface (1cm²)
4. Wipe a distance of 100cm for a sample area of 100cm²
5. Fold the swipe with the sample area on the inside

Note: Avoid touching the surface or swipe with your finger
Do not spread known contamination
Do not cross-contaminate the swipes

Radioactive Contamination Wipe

Sample # _____

Location: _____

_____

Date: _____ Time: _____

Analysis (dpm) _____ _____

Suspect Radionuclide(s): _____

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AMBIENT EXPOSURE SURVEY RECORD FORM

The form used for this survey is found, reduced in size, below. The floor plan of the facility will be reproduced on the form and the locations of the measurements indicated, by numbers, on the floor plan.

AMBIENT EXPOSURE SURVEY
(Survey For Source Exposure and Contamination)

Instrument: _____ Probe _____

Date of Calibration: _____ Reference Check _____ mR/hr

I. SURVEY AREA

II. SURVEY

Date	Identification of Location and Exposure in mR/hr												Operator Action*
	1	2	3	4	5	6	7	8	9	10	11	12	

*See "Exposure Action Levels" below

III. EXPOSURE ACTION LEVELS (mR/hr of ambient exposure)

1. All areas	Any unexpectedly high or low levels
2. All areas	Any exposure where radionuclides should not be present
3. Unrestricted areas	2.0 mR/hr or higher
4. Restricted areas	5.0 mR/hr or higher

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