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

L&L 28247

030-30699

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

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)*

JohnFornace, D.O.
309 Medical Arts Pavilion
2705 DeKalb Pike
Norristown, PA 19401

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

same as 2. above

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

John Fornace, DO

TELEPHONE NUMBER: 215-278-2000

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.

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

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

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*

FEE CATEGORY

AMOUNT ENCLOSED $ 580.00

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

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

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE–CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
John Fornace DO	John Fornace, DO	Physician/Applicant	7/11/88

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
APP	Jul. 15	7C		S. Kimberly
AMOUNT RECEIVED	CHECK NUMBER			DATE
580	124			7/21/88

"OFFICIAL RECORD COPY" ML18

7-13-88

DOCUMENTATION OF ATTACHMENTS TO THIS APPLICATION

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

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

DESCRIPTION OF THE SCOPE OF THE OPERATION

This license application is for nuclear cardiology procedures only. The procedures will be implemented in a private practice facility. The materials used will be obtained from a radiopharmacy. The applicant will not obtain a 99mTc/99Mo generator. There is no intent to purchase any materials in "bulk" form, and all sources will be obtained in unidose from form the radiopharmacy.

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

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

RADIOACTIVE MATERIALS REQUESTED IN THIS APPLICATION

Radiopharmaceuticals

The applicant wiches 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
201 Tl*	Chloride	60.00	Human Use
99m Tc*	Pertechnetate	5.00	Quality Control & Calibration
201 Tl*	Chloride	1.00	Quality Control & Calibration

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

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

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

APPLICATION FOR MATERIAL LICENSE

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	062-295

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

Isotope Calibrator Reference Sources

• For checking calibrator accuracy, performance and consistency.

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

(a) A long-lived source, such as ^{137}Cs ($T\frac{1}{2}$ = 30 yrs.), to avoid the tedium of constant decay corrections.

(b) A ^{57}Co source ($T\frac{1}{2}$ = 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 attached documents document the training and experience of the physician applicant. The documents show the Basics of Radioisotope Handling training as 200+ hours and Preceptored Clinical Experience. There is additional Clinical Experience but additional documentation should not be required of the applicant.

A description of the training program provided by the Institute For Nuclear Medical Education is on file with your agency. This training program has been reviewed by all NRC Regions and by most Agreement States and has also been reviewed by the State of Colorado, Radiological Health Section, Charles Mattson. The program has been submitted by several agencies including the State of Colorado, for inclusion in the NRC list of Service and Training Programs. If additional information of this program is required, please contact:

Charles H. Rose, MA,MSPH,D(ABSNM)
Program Director
Institute For Nuclear Medical Education
3011 Broadway
Boulder, Colorado 80302
303-444-1943

SUBSTITUTE NRC 313 M
SUPPLEMENT A

TRAINING OF AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER

JOHN W. FORNACE

ADDRESS

2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE

NJ

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION			
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MANAGEMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

The description of these programs is on file with the NRC and Agreement States. The dates of the programs are given on the Certificates of completion.

Subject Category	Principles of Radiation	Medical Radiation Instrumentation	Medical Radiation Protection	Radiopharmaceuticals and Chemistry	Total Hours of Subject
Radiation Physics and Instrumentation	39	31	8	22	100
Radiation Protection	2	4	20	4	30
Mathematics Pertaining to The Use and Measurement Of Radioactivity	5	6	6	3	20
Radiation Biology	2	3	12	3	20
Radiopharmaceutical Chemistry	2	6	4	18	30
Total Hours (Actual Hours May Exceed This Number)					200

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
		SEE THE ATTACHED DOCUMENTATION		

6. TRAINING WAS COMPLETED UNDER THE DIRECT SUPERVISION OF:

NAME: Institute For Nuclear Medical Education, Attention: C.H. Rose

ADDRESS: 3011 Broadway

CITY: Boulder STATE: CO ZIP: 80302

TELEPHONE: 303-444-1943

Authorized Signature

Charles H. Rose, MA, MSPH, D(ABSNM) Program Director

NUCLEAR MEDICAL EDUCATION PROGRAM

AFFIDAVIT OF ACADEMIC COMPLETION

This document is to attest that

JOHN W. FORNANCE

has successfully completed the didactic program

RADIOPHARMACEUTICALS

and has provided evidence of achieving the objectives of this program

The program provides the following levels of accomplishment

50 *didactic instructional hours (DIH)*

5 *continuing education units (CEU)*

50 *continuing medical education units (CME)*

21 MARCH 1988

Date C

Authorized signature

Affidavit

INSTITUTE FOR NUCLEAR MEDICAL EDUCATION

NUCLEAR MEDICAL EDUCATION PROGRAM

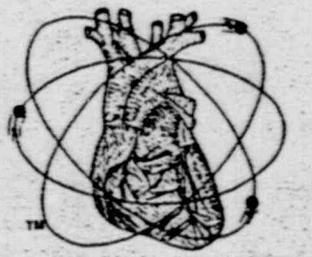
AFFIDAVIT OF ACADEMIC COMPLETION

This document is to attest that

JOHN W. FORNACE

has successfully completed the didactic program

THE PRINCIPLES OF RADIATION PHYSICS



and has provided evidence of achieving the objectives of this program

The program provides the following levels of accomplishment

50 *didactic instructional hours (DIH)*

5 *continuing education units (CEU)*

50 *continuing medical education units (CME)*

9 FEBRUARY 1988

Date Commenced

Authorized signature

Affidavit

INSTITUTE FOR NUCLEAR MEDICAL EDUCATION

NUCLEAR MEDICAL EDUCATION PROGRAM

AFFIDAVIT OF ACADEMIC COMPLETION

This document is to attest that

JOHN W. FORNACE

has successfully completed the didactic program

MEDICAL RADIATION INSTRUMENTATION

and has provided evidence of achieving the objectives of this program

The program provides the following levels of accomplishment

50 *didactic instructional hours (DIH)*

5 *continuing education units (CEU)*

50 *continuing medical education units (CME)*

13 FEBRUARY 1988

Date Commenced

Authorized signature

Affidavit

INSTITUTE FOR NUCLEAR MEDICAL EDUCATION

NUCLEAR MEDICAL EDUCATION PROGRAM

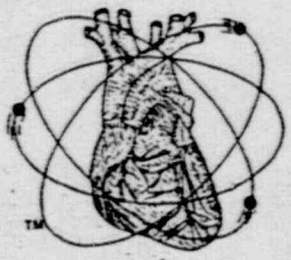
AFFIDAVIT OF ACADEMIC COMPLETION

This document is to attest that

JOHN W. FORNANCE

has successfully completed the didactic program

MEDICAL RADIATION PROTECTION



and has provided evidence of achieving the objectives of this program
The program provides the following levels of accomplishment

50 *didactic instructional hours (DIH)*
5 *continuing education units (CEU)*
50 *continuing medical education units (CME)*

17 MARCH 1988
Date Conferred

Authorized signature

Affidavit

INSTITUTE FOR NUCLEAR MEDICAL EDUCATION

Osteopathic Medical Center of Philadelphia
4150 City Avenue, Philadelphia, Pennsylvania 19131-1696

(215) 581-6148

Michael Kirschbaum, D.O., Chairman
Wayne Arnold, D.O.
Eva Placentra-Sesso, D.O.
Division of Cardiology

Osteopathic

April 4,1988

Regarding: preceptorship, John Fornace D.O.

From the time period July 1, 1984 to June 30, 1985 John Fornace, D.O. was under my supervision in an approved Cardiology Fellowship. During that time period he completed the following procedures:

First-pass radionuclide angiograms Technitium	230
Equilibrium radionuclide angiograms (MUGA) Technitium	100
Thallium perfusion scans	140

Sincerely,

M Kirschbaum DO

Michael Kirschbaum, D.O.
Chairman of Cardiology

PERSONNEL QUALIFICATIONS AND TRAINING

Technologist Qualifications

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

In addition to the above, the physician applicant will interview the technologist and obtain a resume of his/her experience and will evaluate the technologist through close observation of the nuclear medical techniquies 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 vacinity 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:
Insturction will include but not be linited to the following subjects:

a) Applicable regualtions and license conditions
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) Easch individual's obligation to report unsafe conditions to the RSO
g) Appropriate response to emergencies or unsafe conditions
h) Personnel who work with the materials will also receive copies of- the procedures for- monitoring the performance of imaging equipment, ordering and receiving radioactive material, opening packages, records of byproduct material use, radiation area surveys, safe use of radiopharmaceuticals, waste disposal and emergency procedures

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

Method of Evaluation:

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

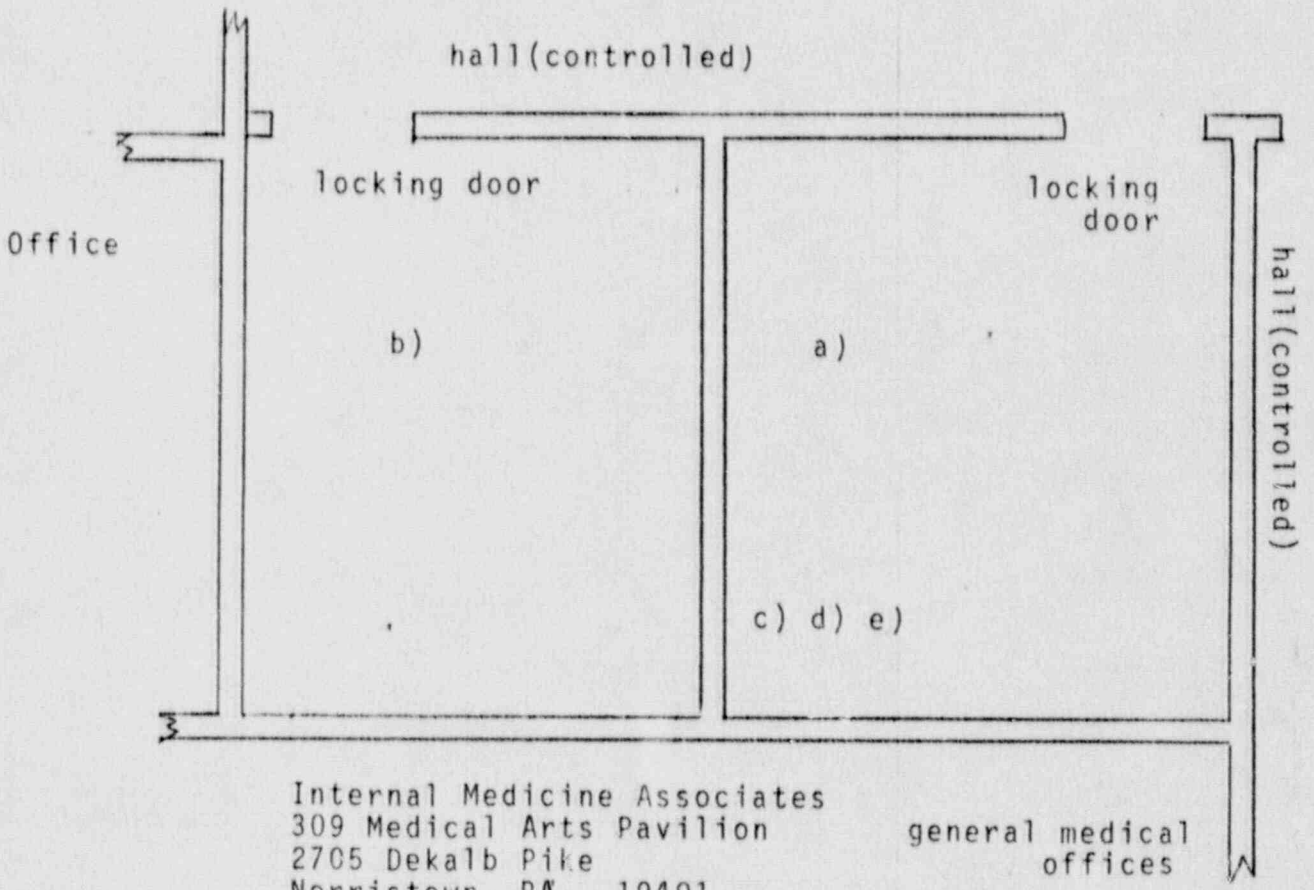
FACILITIES-ANNOTATED DRAWING OF THE RADIOISOTOPE FACILITY

Scale: ¼"= 1'-0"

Direction of North

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

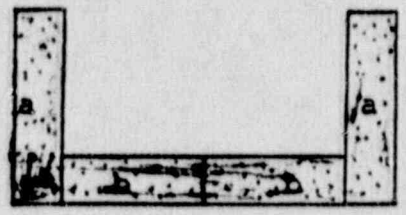
Identification of Areas
a) nuclear imaging area
b) computer area
c) radioisotope receipt
d) radioisotope storage
e) radioisotope waste



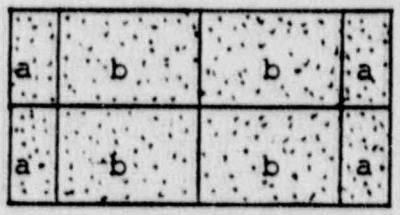
APPLICATION FOR MATERIAL LICENSE

FACILITIES- SHIELDING OF THE RADIOISOTOPE STORAGE AREA

Lead Brick Storage Shield



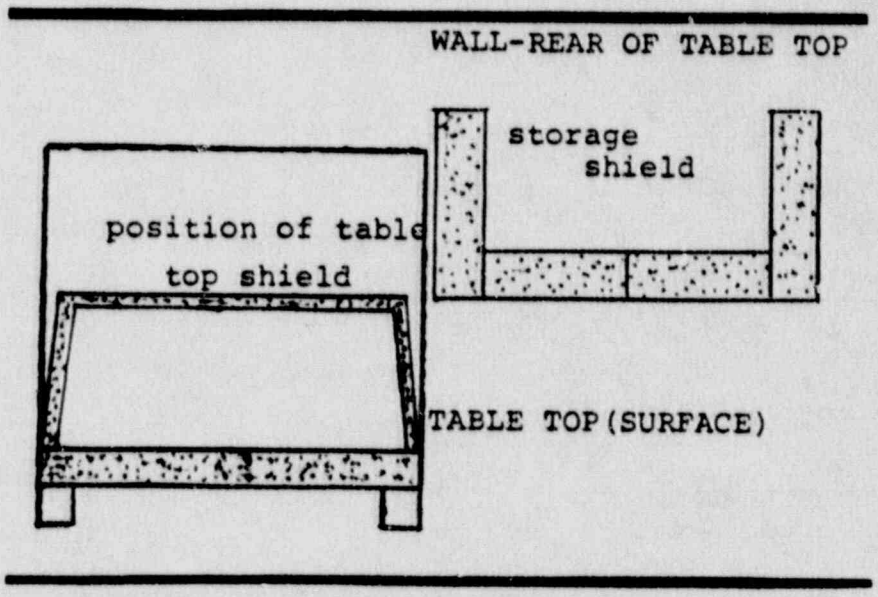
Top View of Configuration



Front View of Configuration

Bricks Used: 4- 2x4x8 (a)
4- 2x4x6 (b)

Location of Table Top Shield and Lead Brick Storage Shield on Table

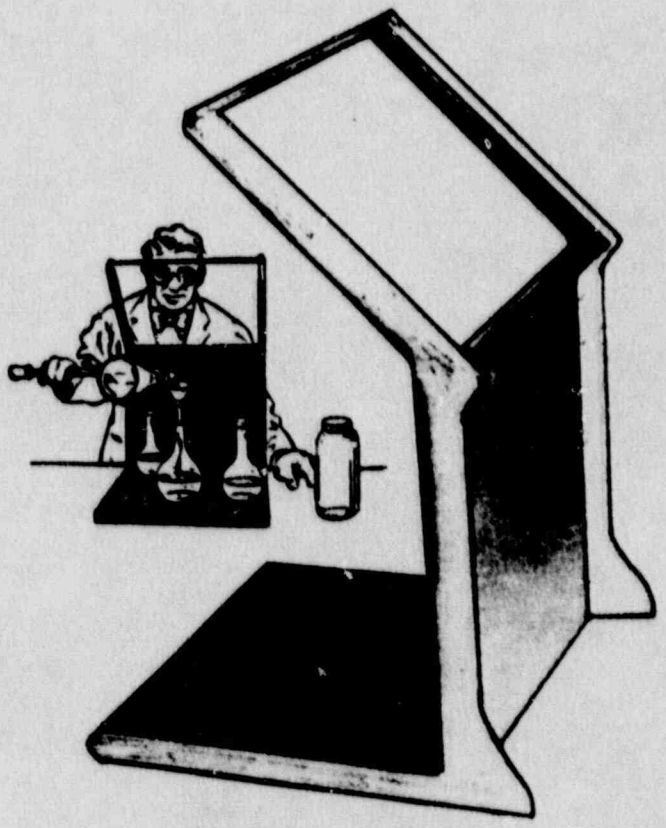


Note: Very low level waste of short lived radiopharmaceuticals will be stored below the table, under the shield. Current waste, ie unused 99mTc and 201 Tl, will be stored in the lead storage container on the table, behind the shield.

FACILITIES-TABLE TOP BARRIER SHIELD

Table Top Lead Barrier Shield

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



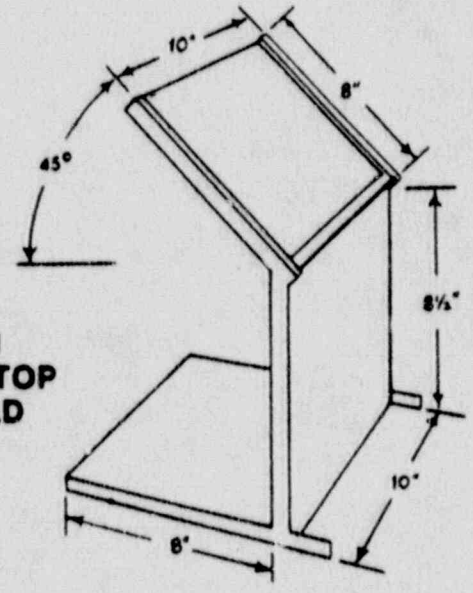
MINI TABLE TOP SHIELD for small jobs in limited working areas.

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

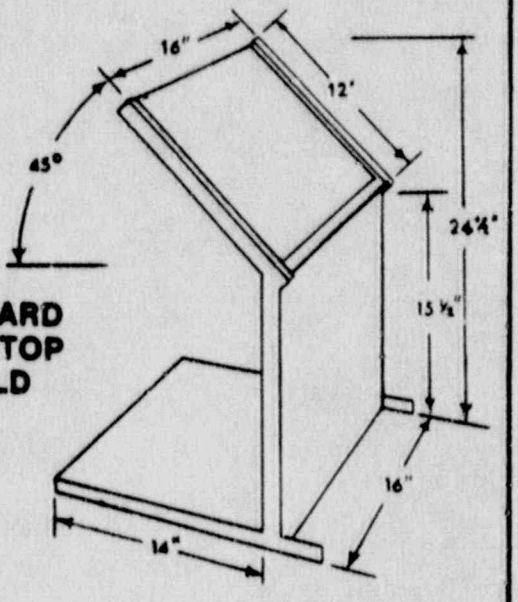
Select the shield most suited to your workload. Both units provide exceptional protection to the clinician when setting up technetium generators, filing syringes, performing radium loading procedures, etc.

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

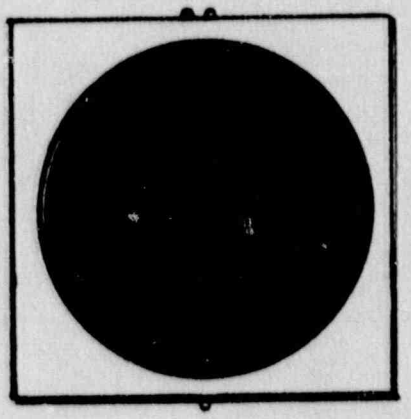


STANDARD TABLE TOP SHIELD

EQUIPMENT QUALITY CONTROL PHANTOMS

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

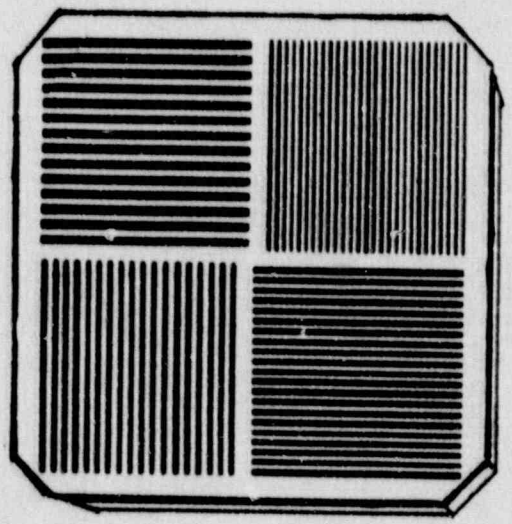
EMISSION PHANTOM



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	NCSystems-GE/Siemens*	Nuclear Cardiology Image and Function
Nuclear Medical Computer	NCSystems-ADAC/GE/Siemens*	Data Analysis and Presentation
Dose Calibrator	Capintec CRC-7 or AccuCal* 2002	Calibration and Quality Control
Survey Meter	PUG-1 or Ludlum Model 14C	Surveys and Spill control as well as personnel contamination monitoring
Film Badges-Body	Landauer**	Whole Body Personnel monitoring of all individuals who work with or arround sources or patients who contain radiopharmaceuticals
Finger TLD Dosimeters	Landauer**	Personnel monitoring of all personnel who handle sources or patients containing radiopharmaceuticals.

* The specific system has not been determined but the use of the system will not change this application or the operational contitions of the resulting license granted.

Note: See the following pages for descriptions of the equipment described above.

**These are described in the "Personnel Monitoring Program and ALARA section of this application and they will be changed on a monthly basis, at the start of each month.

RADIATION DETECTION INSTRUMENTATION-SURVEY METERS

Universal Portable Monitor and Survey Meter

FOR ALPHA-BETA-GAMMA LEVELS

- 3 ranges
- Selection of Geiger and scintillation probes
- Aural and meter radiation indicators
- Battery operated ("D" cells only)
- One-hand operation

The PUG-1 is a portable universal Geiger/Scintillation Survey meter for alpha, beta, gamma and neutron survey and monitoring. A selection of probes offers virtually unlimited versatility in measuring radiation levels. A convenient probe mount on the side of the unit permits attachment of the probe to the instrument body for single-hand operation.

The bold-numbered 4" meter offers excellent readability. Readout is in cpm, however transparent mR/hr cards are supplied to clip over the meter face so that radiation levels may be read simultaneously with any probe. The aural indicator is controlled manually by an off-on switch and responds to radiation intensity. Pulse input is zener diode protected so that the probes may be interchanged without shutting off the instrument. All probes are interchangeable. Each has its own meter face card.

PUG-1 Monitor

A panel switch permits rapid change of ranges (0-500, 0-5000, 0-50,000 cpm plus battery check). Calibration is a simple screwdriver adjustment.

SPECIFICATIONS

Ranges: Fixed meter face 0-500, 0-5000, 0-50,000 cpm. Calibrated clip-on face card in mR/hr is supplied with each probe

Controls: On-off range selector, battery check, calibrate, speaker on-off

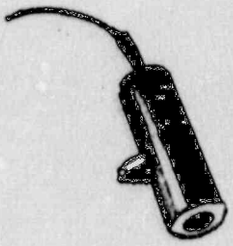
Speaker: Volume controlled

Probe Connections: BNC low noise teflon insulated

Batteries: Three "D" cells

032-100 PUG-1 Portable Monitor

GEIGER PROBES



032-170 ALPHA/BETA/GAMMA "End-Window" Geiger Probe.

Most popular probe for general use.

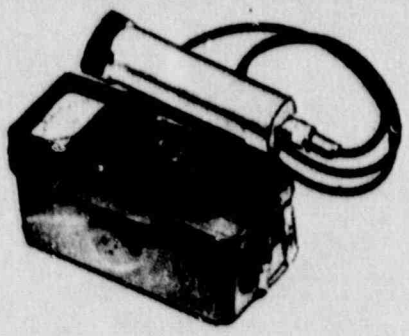
This probe, which incorporates a 1.4 mg/cm² end window GM tube, is ideal for detecting alpha and soft beta radiation not detectable with side-window probe. Includes extra meter face P-6

Range: 0 to .3 mR/hr
On low range

RADIATION DETECTION INSTRUMENTATION-SURVEY METERS

Ludlum Model 14C Geiger Counter

- **Alpha/Beta/Gamma Geiger Counter**
- **One Internal Range: 0-2,000 mR/hr**
- **Four External Ranges: 0-200 mR/hr**
- **Includes External & Internal Probe**



The Model 054-014 Geiger Counter is a portable, self-contained instrument with five counting scales. The first four counting scales are connected to an external detector and the fifth scale (X-1,000) is connected to an internal detector. Two "D" cell flashlight batteries will operate the unit, including the speaker, for 2,000 hours. The meter is housed in a rugged, cast aluminum bezel, sealed with "O" rings. Any GM probe offered will operate as well as any scintillator probes offered. Adjustable high voltage is provided.

SPECIFICATIONS:

Audio: Built in unimorph speaker with ON/OFF switch.

Response: Toggle switch for FAST (3 seconds) or SLOW (11 seconds) for 67% of final reading.

Reset: Push button to zero meter after over range exposure.

Meter: 0-2 mR/hr linear, 0-2 mR/hr non-linear for 2,000 mR/hr scale, and BAT OK.

¼ Multiplier Ranges: x0.1; x1; x10; x100 for external detector; x1,000 for internal detector.

Batteries: 2 each, "D" cell with 200 hours typical life.

Detector:
Internal - For high range Gamma detection only; 200 mR/rh
External - Model 44-7; 1.7 ± 0.3 mg/cm² mica end window, 6.4 cm² active window area.
Alpha Efficiency - 30%
Beta Efficiency - 10% for C-14, 45% for Sr-90
Gamma Efficiency - 1700 CPM/mR/hr for Cs-137

Construction: Cast and drawn aluminum with beige polyurethane paint finish.

Size: 3.4" W x 6" H x 7" L. (8.6 cm x 15.5 cm x 17.8 cm)

Weight: 3.6 lbs. (1.6 kg.)

Gamma Check Source

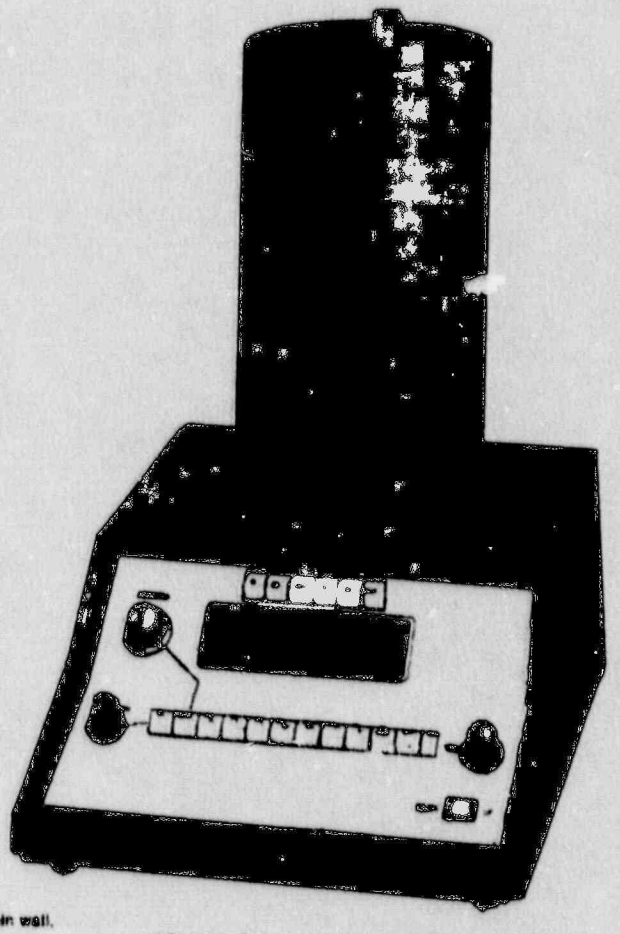
This disc type is preferable with standard flat faced crystals. (No License Necessary)

101-103 Uncalibrated ^{137}Cs Disc Source, 10μCi. 1" D x ¼" thick.

RADIATION DETECTION INSTRUMENTATION-DOSE CALIBRATOR

CRC-7 Dose Calibrator

- Pushbutton isotope selector
- Fully shielded chamber
- Four-digit LED readout
- ± 1% repeatability
- Easy-to operate
- Totally dependable



INCLUDES:

022-340	Vial Dipper
022-341	Well Insert
022-423	Moly Shield

SPECIFICATIONS:

Ionization Chamber Design: Integrated deep well, thin wall, high pressure, argon gas filled chamber.

Activity Range: .01uCi to 7999 mCi.

Ionization Well Dimensions: 10" H x 2.5" D (25 cm x 6 cm).

Digital Readout: Four digit, seven segment LED display with floating decimal point. Readout accuracy ± 0.1% of reading, ± 0.02% of full scale, ± 1 on last digit.

Detector Linearity: ± 1% for 2 Ci of Tc-99m.

Electrometer Linearity: ± 1%

Electrometer Accuracy: ± 2%, except ± 3% on the 0uCi to 300 uCi range.

Response Time: Typically less than 10 seconds to 99% of the final reading. When the "Averaging Period" switch is in the "long" position, 99% of the final reading is reached in less than 30 seconds.

Overall Accuracy: Overall accuracy of the calibrator is determined by the accuracy of the specific source, calibration accuracy, detector linearity, electrometer accuracy and readout accuracy.

Repeatability: Within the specified six month calibration interval, all measurements will fall within the tolerances listed above. Measurements will repeat to within ± 1% for a period of 24 hours during which time the calibrator is maintained under constant temperature, humidity, and radiation background conditions and is powered at all times.

Power Requirements: 120 VAC @ 0.05A (50-120) or 240 VAC @ 0.03A (180-260)

Frequency: 50 or 60 Hz.

Dimensions: 17" H (with chamber) x 12¼" W x 18" D (43 cm x 32 cm x 46 cm)

Weight: 48 lbs. (21.8 kg).

RADIATION DETECTION INSTRUMENTATION-DOSE CALIBRATOR

AccuCal 2002 Specifications

Dimensions

Console: 10.3" (25.3 cm) length; 8.2" (20.7 cm) width; 4.3" (10.8 cm) height.

Ion Chamber: 17" (43.2 cm) height; 8.8" (21.9 cm) outside diameter; 2.5" (6.6 cm) well diameter; 10.4" (26 cm) well depth. Replaceable plastic well liner included.

Shielding: One-piece ⅛" (0.3 cm) steel outer shell with ¼" (0.6 cm) lead lining; additional external lead shielding will not affect calibration.

Weight: Console: 1.5 lbs (3.3 Kg) Ion Chamber and Shield: 59.4 lbs (27 Kg)

Location: Remote, up to 9' (3 m)

Ion Chamber Bias: 300v battery (EVEREADY #493 or NEDA #722)

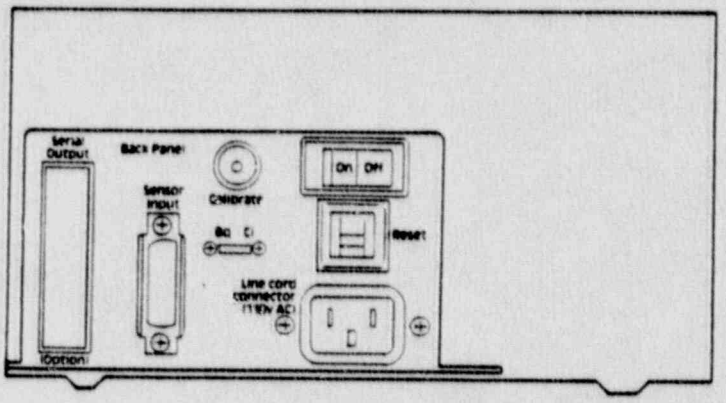
Power: 115v AC ± 10v AC; 230v AC ± 20v AC; 50/60 Hz, 25W (max.)

Response Time: Less than 3 seconds for activities above 800μCi (29.6 MBq); Less than 5 seconds for activities between 200μCi (7.4 MBq) and 800μCi (29.6 MBq); Less than 10 seconds for activities below 200μCi (7.4 MBq).

Ion Chamber: Hermetically sealed, pressurized argon gas, well-type.

Accuracy: Response normalized at Co^{60} and Cs^{137} to within ± 1% NBS-calibrated sources (excluding uncertainty quoted by NBS).

Linearity: Less than ± 1% non-linearity due to recombination effects up to 2000 mCi (74 GBq) for Tc ^{99m}; Less than ± 2% between 2000 mCi (74 GBq) and 5000 mCi (185 GBq).



Ion Chamber:

Noise: rms ≤ 0.2μCi (0.01 MBq) for Tc^{99m} when determined over 10 separate measurements (excluding radiation statistical fluctuations).

Stability: Less than ± 1% long-term (excluding radiation statistical fluctuations or background changes).

Resolution: 0.1μCi on 200μCi (7.4 MBq) range.

Charge Conversion (exclusive of Ion Chamber):

Accuracy: ± 0.5% plus 1 digit, full range.

Linearity: ± 0.5%, full scale.

Noise: rms ≤ 1 digit, full scale.

Stability: (short term) ± 0.1% above 2000μCi (74 MBq) for Tc ^{99m}; (long term) ± 0.5% full scale; ± 0.5% for activities below 2000μCi (74MBq) plus 3 digits on the 200μCi (7.4 MBq) range.

Display: Custom 4 digit, 7 segment liquid crystal.

Control Unit: Z-80 microprocessor Memory: 2K RAM; 32 BYTE EAROM; 20K PROM.

Data Output: RS 232 Serial Port; diagnostic and remote modes. (Optional)

Standard Accessories: Well Liner; Sample Holder; Molybdenum Breakthrough Shield

Optional Accessories: 300v DC Bias Supply; RS 232 Serial Port

- SYSTEM SELF-TEST
- REMOTE WELL-TYPE ION CHAMBER
- LED FUNCTION IDENTIFICATION
- DISPLAY RANGE: 0.1uCi - 4999mCi
- USER PROGRAMMABLE RADIONUCLIDE SELECTION KEYS
- AUTORANGING
- MEASUREMENT ON CURIE OR BECQUEREL SCALE

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 will 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-C1.

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.

PROCEDURE FOR CALIBRATION AND QUALITY CONTROL OF THE DOSE CALIBRATOR

The applicant will implement the following procedures on the dose calibrator.

1) Geometry Dependence- Geometry dependence will be determined at the time of installation and will be no greater than +/- 5% with the types of containers used by the applicant. The procedure for measurement of geometry dependence is:
   a) A syringe of the type used for routine procedures will be filled with.5cc of 99mTc containing 1-10mCi of 99mTc.
   b) The syringe will be "counted" in the dose calibrator in the same way that patient dose's are measured.
   c) An additional .5cc of water will be drawn into the syringe and it will again be "counted" as in b) above.
   d) The procedure will be repeated untill there is no less than 2.0cc in the syringe
   e) Selecting the volume closest to that normally used for patients as the "standard", 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, it will be necessary to make a correction table for the calibrator showing indicated activity at that volume vs true activity at that volume.

Geometry Dependence

Date:_____ Calibrator:Model:_____ Serial #_____
Activity Used:_____mCi Measurement By:_____

Volume, cc	Activity Indicated, mCi	Correction Factor

2) Accuracy- Accuracy will be determined at the time of installation and not less than annually thereafter and the accuracy must be within +/- 5%. The procedure to measure the accuracy is:
   a) The calibrated reference sources of 57Co, 133Ba and 137Cs as authorized under this license will be used for this procedure (see "sealed sources"). These sources are to be obtained with calibration certificates that are traced to the NBS by the source supplier.
   b) Each source will be "counted" at its correct setting on the calibrator, background on that setting subtracted, and the activity recorded. This procedure will be repeated for three measurements of each of the trhee sources.
   c) The average of the three readings, of each source, will be made and divided into certified activity of the source after corrected for decay.

d) The results of the caluclations, section c) must fall within the range of 1.05 and 0.95 (to fit within +/-5%. It it does not fall within this range, repair or recalibration should be considered however, if it exceeds 1.10 and .90 (a +/-10% range) repair, recalibration or repalcement must be made.
e) Because these same sources will be used for the daily constancy tests, the 57Co source will also be used to measure the reading on both the 57Co setting and the 201Tl setting during the accuracy measurement.
f) A Sticker will be placed on the Dose Calibrator indicating when the next accuracy test is due.

Accuracy

Date:_____ Calibrator:Model:_____Serial #____

Source	Accuracy	Deviation	Notes
_____mCi of _____	_____mCi		
SN#:_____	_____mCi	____/_____	
Calibration date:	_____mCi		
_____	Av:_____mCi	_____	
_____mCi of _____	_____mCi		
SN#:_____	_____mCi	____/_____	
Calibration date:	_____mCi		
_____	Av:_____mCi	_____	
_____mCi of _____	_____mCi		
SN#:_____	_____mCi	____/_____	
Calibration date:	_____mCi		
_____	Av:_____mCi	_____	

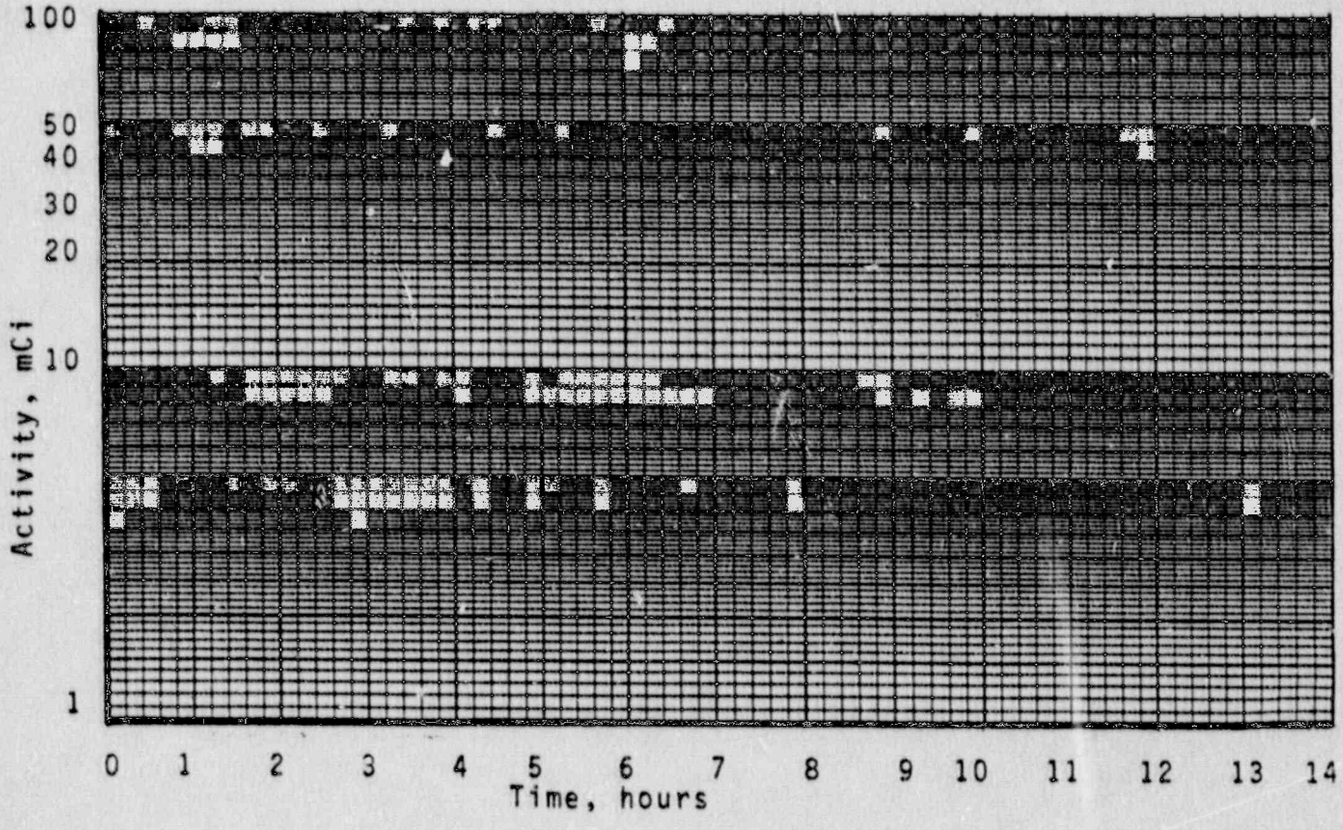
3) Linearity- Linearity will be determined at the time of installation and not less than quarterly thereafter and the linearity must be within +/- 5%. The procedure to measure linearity is:
a) A syringe containing not less than 50mCi of 99mTc will be obtained from the radiopharmacy.
b) The syringe will be "counted" in the dose calibrator at the earliest time in the morning, i.e. 8:00 am and the mCi indicated, minus background, will be recorded.
c) The syringe will be counted again at not less than three times during the day during a 9hour period of time. The readings will be recorded, minus background.
d) The values obtained will be indicated on semi-log graph paper and the best-fit line drawn through the values. A second line will be drawn through the expected points as calculated using decay factors of the expired time.
e) The maximum deviation of the observed line from the calculated line will be determined. If the deviation is more than +/- 5% (0.05) the instrument will be adjucted 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.

APPLICATION FOR MATERIAL LICENSE

Linearity

Date:_____ Calibrator:Model:_____ Serial #_____
Source:_____mCi of 99mTc in _____cc @ _____am

Time Hour Elapsed	Assay	Bkg	Activity Observed	Activity Expected
_____	_____	_____	_____ mCi	_____ mCi
_____	_____	_____	_____ mCi	_____ mCi
_____	_____	_____	_____ mCi	_____ mCi
_____	_____	_____	_____ mCi	_____ mCi
_____	_____	_____	_____ mCi	_____ mCi



4) Constancy- The constancy of the readings from the dose calibrator will be measured at least once each day of radionuclide operation. If no radioisotopes are received or used during the day, no operations take place, then constancy will not be checked on that day. The constancy must be within +/- 5% of the anticipated value. The procedure to measure constancy will be:
   a) The 57Co sealed, dose calibrator source will be measured on both the 201Tl and 57Co settings .
   b) The background at the same settings will be recorded
   c) The acitivity indicated, at both settings, will be determined by subtracting the background, b), from the readings determined in a) and this value will be recorded.
   d) Action levels will be determined for the reading at each setting reflecting the range of +/- 5% of the anticipated reading. If the value is greater than +/- 5%, the RSO will be notified and if it is 10% or greater from the expected value, the instrument will be repaired or replaced.
   e) Records will made of the above constancy measurement using the form shown below.

DOSE CALIBRATOR QUALITY CONTROL AND PERFORMANCE RECORD

Dose Calibrator Identification: _____ Sealed QC Sources Isotope Cal. Activity

Geometry Dependence: Date _____, +/- _____% (+/- 2% limit)*
Annual Accuracy Test: Date _____, +/- _____% (+/- 5% limit)*
Quarterly Linearity: Date _____, +/- _____% (+/- 5% limit)*

_____ _____ mCi
_____ _____ mCi
_____ _____ mCi

Quality Control		Background	Constancy Check			Other Test	Notes	By
Date	Time	Activity	57 Co	137 Cs	133 Ba			

*See the records of these tests and be sure they are not coming due in the near future.

5) After repair, adjustment or relocation of the dose calibrator, the tests established in 1)-4) will be repeated as may be appropriate.

6) 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 instructions.

7) The RSO will review and sign the records of all geometry, linearity and accuracy tests.

8) Records of all activities performed on the dose calibrator will be make and maintained by the applicant.

9) The records, in addition to the records indicated in this application, will be recorded on the "Dose Calibrator Quality Control And Performance Record Form". This form has room for the optional constancy check with sources other than 57Co which may also be done in the constancy check by the applicant but because only 99mTc and 201 Tl are to be used, the basic check will be done with 57Co.

PROCEDURE FOR QUALITY CONTROL OF THE GAMMA CAMERA

The following procedure will be followed for quality control of the gamma camera system. The individual procedures may be modified as the clinical procedures evolve and experience with the system is acheived. Any such changes will be made only to establish evidence of the quality of the clinical results and to enhance the reproduction of accurate images and functional information.

1) Prior to the use of the system for clinical studies the system will be deemed to meet the specifications of the manufacturer including the uniformity, resolution, linearity(spacial) and its switches and interlocks are all operational as well as acceptable maximum count rate capacity and sufficient count rate linearity at 20% count rate loss.

2) Daily, the PHA will be adjusted, the spatial resolution determined and image quality evaluated.

3) Weekly, the maximum count rate capacity and flood field uniformity will be determined on the system.

4) Quarterly, a background flood, count rate linearity at 20% count rate loss and all interlocks and switches will be examined.

5) The operator of the system will be instructed to be aware, with each use of the system, of any changes in the electrical, mechanical or radiation detection performance of the system. If any events are noted that are not expected, the operator will remove the patient from the machine and notify the RSO prior to continuing operation.

6) The "Gamma Camera Quality Control and Performance Record" and the "Gamma Camera Incident and Service Record" will be used to document activities on the system. These documents are found on the next two (2) pages of this application.

Procedure For Quality Control Of The Gamma Camera-Continued

GAMMA CAMERA INCIDENT AND SERVICE RECORD

Gamma Camera Identification: _____ Service Agent: _____

Telephone Number: _____

Incident		Description of Incident	Request		Action(s) Taken				Notes
Date	Time		Date	Time	Date	Time	By	Description	

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 ocrasional basis such as security personnel who deliver packages, secrecarial 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 36.23 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 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							upon any incident
daily use areas	X						
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.

ALARA PROGRAM-POSTING OF NOTICE AND EVALUATION OF DOSIMETERS

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

A L A R A

As Low As Reasonably Achievable
Can You Lower Your Exposure?

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

NOTICE TO ALL RADIATION WORKERS

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

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

Acceptable Levels of Radiation Exposure (mRems)

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

*From Title 10, Part 20.101(a)

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

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

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

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

ALARA PROGRAM/EMERGENCY NOTIFICATION-POSTING OF NOTICES

The following notices will be posted, larger than indicated below and complete with the required information which can not be obtained until a license is issued and the facility is implemented, at the entrance to the room where radioactive materials are used and in the 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: _____

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: _____

LEAK TESTING OF SEALED SOURCES

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

1) A list of all sources to be leak tested will be made. It will include the following information:
   a) radioisotope b)activity at a specific date c) the physical form
2) Each source will be wiped, "swiped" with a cotton swab using caution to not touch the source except with the swab and keeping the source shielded as much of the time as possible. Each swab will be identified to know which source was tested and caution will be used to assure that the operator will not become contaminated with the swab or source and that the swabs will not be cross contaminated.
3) Count the "swipe swabs" with the GM survey meter to determine if any counts, activity indication, is present after counting a gamma reference source of 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 mCi present using the cpm/mCi 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 0.005mCi 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		$\frac{uCi}{cpm}$		uCi	Action Taken
Isotope	Activity	Form	#	cpm	−	cpm	=	cpm	×		=		
137 Cs													
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 $A/C = \_\_\_\_ \frac{uCi}{cpm}$

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 GM survey detector system, more than 2,220 cpm per 0.1uCi or 111 cpm/0.005uCi, even if the efficiency of the system is only 1%. This 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:

Wipe Testing Completed

Date_____Operator_____
This source was wipe tested on the above date and analysis of the sample indicated _____uCi of removable contamination which meets the requirements as 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 scurce will be removed from service and labeled with the following information:

Leaking Source-Do Not Use

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

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.

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

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.

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

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

Note: The survey will be done with the GM survey detector system

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:

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 the surface and at 1 meter distance from the surface. If it is higher than expected, stop and notify the RSO.
   Note: The surface exposure rate of packages with the Yellow II and Yellow III labels should not exceed 200mR/hr and the surface rate of exposure for the White I labels should not exceed 0.5 mR/hr. None of the rates should exceed the posted rate on the box or the expected rate for a shipment of this type and quantity.
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	Surface Exposure	Contamination	Notes	By
Date	By	Date	Time		Isotope	Activity	Form						

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

PACKAGE RECEIPT AND MONITOR RECORD

Receipt: Date: ______ Time: ______ am/pm By: ______ Radiopharmacy: ______

Confirmation With Order: ______

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

Notes: ______

PRESCRIPTION RECORD

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

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

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

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

Prescription Record
Activity ______ Isotope ______ Form ______
Patient ______ Time ______ By ______
Dose Calibrator Pre-Administration Activity Check ______
Disposal Record
Disposal Route: ______ Date: ______
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

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 cpm/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.

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

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

"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): _____

II. SAMPLE ANALYSIS

Swipe #	Gross cpm	–	Bkg cpm	=	Net cpm	×	$\frac{dpm^*}{cpm}$	=	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 surface contamination)

Area	Contaminant Radionuclide	
	^{57}Co, ^{99m}Tc, ^{201}Tl	All Others
Unrestricted Areas & Personnel Clothing	2,000	200
Restricted Areas, Protective Clothing, Skin	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 reproduced 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

APPLICATION FOR MATERIAL LICENSE

RADIOISOTOPE WASTE DISPOSAL PROCEDURE

Disposal By Transfer

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

Disposal By Decay-In-Storage(DIS)

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

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

DISPOSAL BY DECAY-IN-STORAGE RECORD

Storage Container	Input			Survey Prior To Disposal				Disposal				
	Date	Isotope	Activity	Date	Instrument	Bkg*	Container**	By	Date	Route	By	Notes

* Must be less than 0.05 mR/hr

**Must be the same as background, at the surface of the container, all shielding removed

Note: • All radionuclides must have half-lives of less than 65 days.
• Place the material in the Decay-In-Storage container only after substantial decay in the shielded container (at least 5-10 half lives) and
• Remove or violate all radiation symbols and radioactive material signs prior to placing the radioisotope in the bag and container which must be marked.
• Separate needles and other BioHazards from the radioactive materials for proper disposal as stipulated by State and OSHA regulations.

APPLICATION FOR MATERIAL LICENSE

"OFFICIAL RECORD COPY" ML10

10 3223

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: _____
STATUS CODE: 3
FEE CATEGORY: _____
EXP. DATE: 0
FEE COMMENTS: _____

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: FORNACE, D.O., JOHN
RECEIVED DATE: 880713
DOCKET NO: 3030699
CONTROL NO.: 109223
LICENSE NO.:
ACTION TYPE: NEW LICENSEE

2. FEE ATTACHED
AMOUNT: 580.00
CHECK NO.: 1341

3. COMMENTS

SIGNED BP
DATE 7/13/88

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED / ~~_~~)

1. FEE CATEGORY AND AMOUNT: 2C $580

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT _____
RENEWAL _____
LICENSE ~~_____~~

3. OTHER _____
_____

SIGNED S. Kimberley
DATE 7/13/88