NRC FORM 313M (9-81) 10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE – MEDICAL

Approved by OMB 3150-0041

INSTRUCTIONS – *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to : Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

Veterans Administration Medical Center
1201 N.W. 16th Street
Miami, Florida 33125

TELEPHONE NO.: AREA CODE (305) 324 4455

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

Same as 1 (a).

84 AUG -7 A11:20

2. PERSON TO CONTACT REGARDING THIS APPLICATION

S.K.C. Chandarlapaty, M.D.
Chief, Nuclear Medicine Service
TELEPHONE NO.: AREA CODE (305) 324 4455

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. XX RENEWAL OF LICENSE NO. 09-00239-06

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)* S.K.C. Chandarlapaty, M.D.
Frank Gollan, M.D.
Stephen P. Rosenthal, M.D.
Komanduri K.N. Charyulu, M.D.

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

Robert M. Cobb

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
10 CFR 31.11 FOR IN VITRO STUDIES	X	As Needed
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III	X	2 Ci
10 CFR 35.100,SCHEDULE A, GROUP IV	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI	X	300 mCi

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	50 mCi
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	X	30 mCi
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	200 mCi
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	X	200 mCi
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	2 Ci

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35 , and NEED NOT BE LISTED.)*

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
Calcium 45	Any	11 mCi	Experimental Research
Carbon 14	Any	35 mCi	Experimental Research
Cesium 137	Any	1 mCi	Reference Standards
Cesium 137	Sealed Source	1 mCi	Calibration Sources
Chromium 51	Any	35 mCi	Experimental Research
Cobalt 60	Any	10 mCi	Calibration Sources
Hydrogen 3	Any	500 mCi	Experimental Research
Iodine 125 or Iodine 131	Any	50 mCi	In Vitro Studies

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INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. _____ Date: _____

7. MEDICAL ISOTOPES COMMITTEE

- ☐ Names and Specialties Attached; and
- ☐ Duties as in Appendix B; or _____ *(Check One)*
- ☐ Equivalent Duties Attached

8. TRAINING AND EXPERIENCE

- ☐ Supplements A & B Attached for Each Individual User; and
- ☐ Supplement A Attached for RSO.

9. INSTRUMENTATION *(Check One)*

- ☐ Appendix C Form Attached; or
- ☐ List by Name and Model Number

10. CALIBRATION OF INSTRUMENTS

- ☐ Appendix D Procedures Followed for Survey Instruments; or _____ *(Check One)*
- ☐ Equivalent Procedures Attached; and
- ☐ Appendix D Procedures Followed for Dose Calibrator; or _____ *(Check One)*
- ☐ Equivalent Procedures Attached

11. FACILITIES AND EQUIPMENT

- ☐ Description and Diagram Attached

12. PERSONNEL TRAINING PROGRAM

- ☐ Description of Training Attached

13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

- ☐ Detailed Information Attached

14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*

- ☐ Appendix F Procedures Followed; or
- ☐ Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*

- ☐ Appendix G Rules Followed; or
- ☐ Equivalent Rules Attached

16. EMERGENCY PROCEDURES *(Check One)*

- ☐ Appendix H Procedures Followed; or
- ☐ Equivalent Procedures Attached

17. AREA SURVEY PROCEDURES *(Check One)*

- ☐ Appendix I Procedures Followed; or
- ☐ Equivalent Procedures Attached

18. WASTE DISPOSAL *(Check One)*

- ☐ Appendix J Form Attached; or
- ☐ Equivalent Information Attached

19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*

- ☐ Appendix K Procedures Followed; or
- ☐ Equivalent Procedures Attached

20. THERAPEUTIC USE OF SEALED SOURCES

- ☐ Detailed Information Attached; and
- ☐ Appendix L Procedures Followed; or _____ *(Check One)*
- ☐ Equivalent Procedures Attached

21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)

- ☐ Detailed Information Attached

22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS

- ☐ Detailed Information Attached

23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b

- ☐ Detailed Information Attached

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM POSSESSION LIMIT (mCi)	DESIRED PURPOSE FOR USE
Krypton 85	Any	10 mCi	Experimental Research
Phosphorus 32	Any	25 mCi	Experimental Research
Potassium 42	Any	25 mCi	Experimental Research
Rubidium 86	Any	5 mCi	Experimental Research
Sulfur 35	Any	10 mCi	Experimental Research

EMERGENCY PROCEDURES

Minor Spills

1. NOTIFY: Notify all persons in the area that a spill has occurred.

2. PREVENT THE SPREAD: Prevent the spread of the spill by covering it with absorbent paper.

3. CLEAN UP: Clean up the spill by donning disposable gloves and using remote handling tongs. Carefully fold the contaminated paper or pads, insert into plastic bags, and dispose of material in the radioactive waste container including the gloves.

4. SURVEY: Survey the area around the spill, hands, and clothing with a low-range, thin-window G-M survey meter.

5. REPORT: Report the incident to the Radiation Safety Officer.

Major Spills

1. CLESR THE AREA: Notify all persons in the area not involved in the spill to vacate the room.

2. PREVENT THE SPREAD : Cover the spill with absorbent paper or pads, but do not attempt to clean it up. Confine the movement of all persons potentially contaminated to prevent the spread.

3. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if this can be safely done without further contaminating the area or significantly increasing your radiation exposure.

4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.

5. CALL FOR HELP: Notify the Radiation Safety Officer immediately.

6. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mils soap and lukewarm water.

RADIATION SAFETY OFFICER: Robert M. Cobb

OFFICE PHONE: 324-4455 ext. 3496 3268 3269

HOME PHONE: 251-1751

AREA SURVEY PROCEDURES

1. Surveys are made daily in all areas where radiopharmaceuticals are prepared and injected with an appropriately low-range survey meter and these areas are decontaminated if necessary.

2. Laboratory areas where only small quantities of radioactive materials are used (less than 200 μCu) are surveyed monthly.

3. Nuclear Medicine Service, where large quantities of radiopharmaceuticals are received daily, surveys are made on a daily basis.

4. The weekly and monthly, as well as, daily surveys consist of:

   a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.

   b. A series of wipe test to measure contamination levels. The method for performing wipe tests consists of using radi-wipe smears moisted with radiacwash and counted with a meter sufficiently sensitive to detect 200 dpm per 100 cm^2 for the contaminant involved. Wipes of the areas are removed to a low back-ground area for measurement.

5. Permanent records of all surveys, including negative results, are maintained by the Radiation Safety Officer and include:

   a. Location, date, and identification of equipment used, including the serial number and pertinent counting efficiencies.

   b. Name of the person conducting the survey.

   c. Drawing of the area surveyed, identifying the relevent features such as active storage areas, active waste areas, etc.

   d. Measured exposure rates, keyed to location on the drawing.

   e. Detected contamination levels, keyed to location on drawing.

   f. Corrective action taken in the case of contamination or excessive exposure rates, the results of decontamination, exposure rates after corrective action and any appropriate comments.

6. All areas where the contamination level exceeds 200 dpm/100 cm^2 will be immediatley decontaminated

BKGD. _____ CPM

EFF. _____ %

ALLW'D DPM/100 CM^2: _____

TEST FOR: a b y ^{3}H ^{14}C

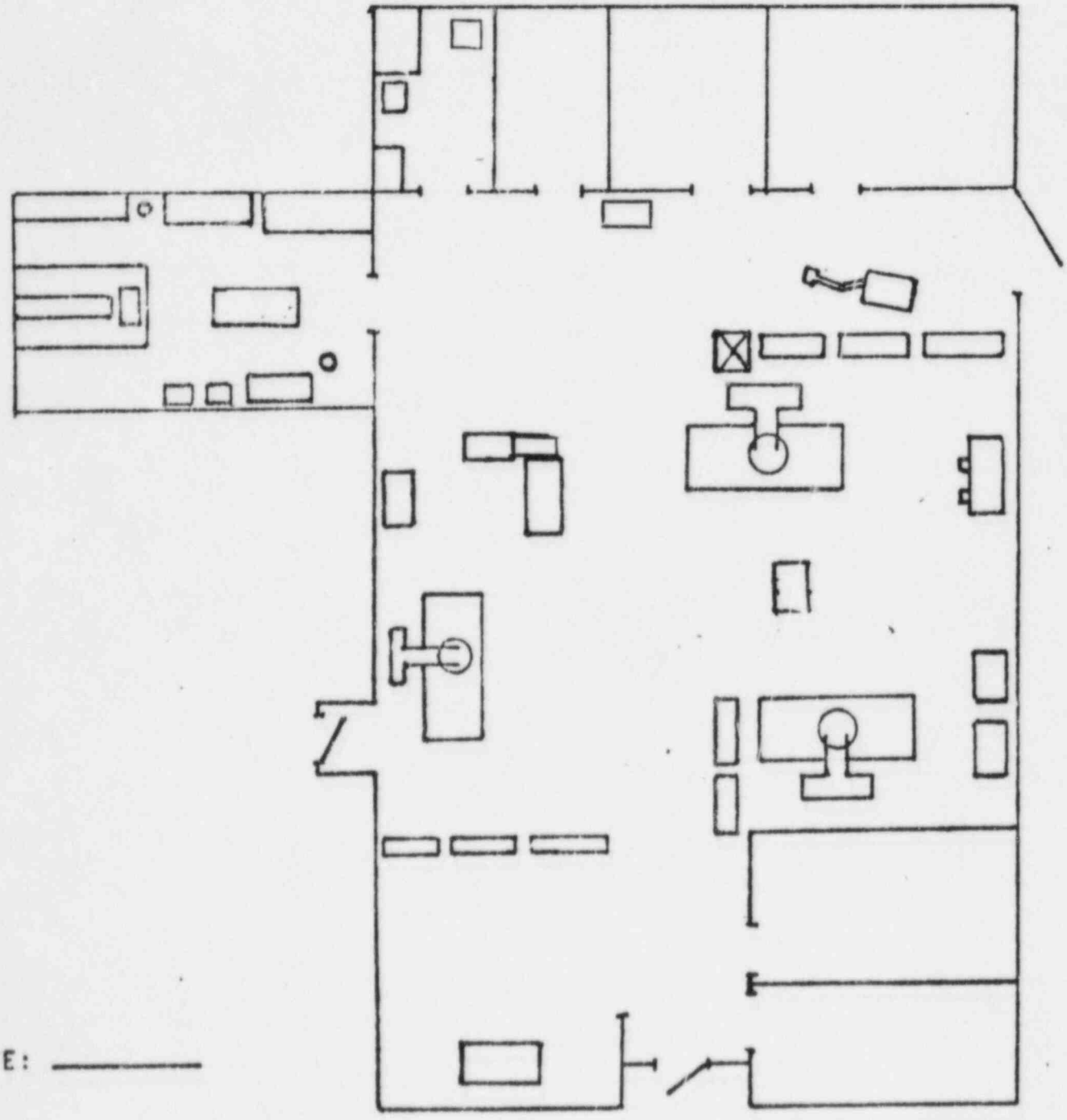
FACILITY: V.A. MEDICAL CENTER
1201 N.W. 16th Street
Miami, Florida 33125

DATE: _____

#	LOCATION OF WIPE SAMPLE	GROSS CPM	NET CPM	NET DPM	EXCESS DPM	COMMENTS

VETERANS ADMINISTRATION HOSPITAL

Miami, Florida



DATE: _____

10/79 Wipe Test Locations scale: 3/32" = 1'

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WASTE DISPOSAL

1. Liquid waste will be disposed of (check as appropriate)

__X__ In the sanitary sewer system in accordance with Section 20.303 of 10 CFR Part 20.

__X__ By commercial waste disposal service (see Item 4 below).

__X__ Other (specify): Liquid scintillation waste containing minute amounts of tritiated compounds and carbon 14 are sealed in 55 gallon DOT-17H drums as limited quantity radioactive materials (UN 2910) and shipped QUADREX-HEALTH PHYSICS SYSTEMS, INC., Gainesville, Fla. for disposal.

2. Mo-99/Tc-99m generators are no longer used in Nuclear Medicine Service. Unit doses of Tc-99m are:

__X__ Returned to the supplier for disposal.

__X__ Held for decay in a decay storage room until the level of activity,as measured with a low-level survey meter, is low enough to be disposed of as normal trash. All radiation labels are removed or obliterated and the contents of each vial is flushed down the sanitary sewre system.

__X__ Other The contents of all short-lived radioactive material vials are held in decay until the level of activity is within the limits specified in Section 20.303 of 10 CFR Part 20. Long-lived radioactive materials are stored in a special cabinet.

3. Other solid waste will be (check as appropriate)

__X__ Held for decay intil radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the waste will be disposed of in the normal trash.

__X__ Disposed of by commercial waste disposal service.

__X__ Other Animal tissue and carcasses will be disposed of through the services of a commercial waste disposal company in accordance with the guideline under Section 20.306 of 10 CFR Part 20.

4. The commercial waste disposal service used will be

For Animal Carcasses and Tissue: ACME SEFVICES UNLIMITED (Name) Miami, Fla. (City, State)

FOR Solid Waste: WORLD SANITATION, INC (Name) Miami, Fla. (City, State)

NRC/Agreement State License No. 09-00239-06

VETERANS ADMINISTRATION HOSPITAL
1201 N.W. 16th Street
MIAMI, FLORIDA 33125

NURSING PROCEDURES FOR RADIOISOTOPE THERAPY

It is the responsibility of all personnel involved in radiation therapy procedures to minimize his or her exposure to external radiation as much as possible. This may be accomplished by performing only the minimum nursing procedures consistent with adequate care for the patient and by keeping as much distance as possible between the patient and attending personnel.

Not all radioactive procedures involve the same hazard. At low levels (diagnostic procedures) and with some isotopes like phosphorus 32 and other beta emmiting radionuclides, the hazard may be very small whereas, in others it may be quite considerable. Amounts of radioisotopes less than certain "prescribed levels" require no special precautions other than general principles of radiation safety. However, special precautionary measures are warranted in procedures where the dose exceeds the prescribed level for that isotope. The prescribed level is based on an amount of isotope delivering approximately 0.75 mr/hr (30 mr in a 40-week) at 1 meter from the source.

SPECIAL RULES

1. Read thoroughly and observe all general rules.

2. Contamination with radioactive fluids should always be avoided by wearing rubber or disposable gloves and suitable protective clothing.

3. Wash hands immediately after treating or handling patients where contamination might occur from radioactive fluids or urine.

4. Deposit used gloves and clothing in the container provided by the Radiation Safety Officer.

5. Waste containers provided by the Radiation Safety Officer should not be removed from the room until surveyed for radioactive contamination.

6. Bed linen and clothing will be surveyed for contamination before removal from the room.

7. No general rules are made regarding the disposal of radioactive excreta. In cases where this is important, special instructions will be given by the Radiation Safety Officer, otherwise the patient will be permitted to use the bathroom as usual. Spillages should be immediately reported so that decontamination can be initiated.

8. Visitors must obtain permission before entering the patient's room and should not be permitted to remain more than 30 minutes per day with patients containing radioactivity above the prescribed level.

9. Warning signs will be placed on the door by the Radiation Safety Officer and must not be removed.

10. In the event of an emergency or for additional information contact the Radiation Safety Officer, Nuclear Medicine Service, extensions 3451, 3268 or 3269.

PROCEDURES FOR USE OF GROUPS IV AND V RADIOPHARMACEUTICALS
FOR TREATMENT OF PATIENTS

1. All patients treated with Iodine-131 or Gold-198 will be placed in a private room with a toilet.

2. The patient's room will be posted with warning signs in accordance with section 20.203 of 10 CFR Part 20.

3. Surveys of the patient's room and surrounding areas will be conducted immediately after administration of the treatment dose. Exposure rates will be measured at the patient's bedside, three feet away and at the entrance to the room. The Radiation Safety Officer will then determine how long a person may remain at these positions and will post these times in the patient's chart and on the door. The results of daily surveys will be used to recalculate permitted times which will be posted in the patient's chart and again on the door.

4. The form, "Nursing Instructions for Patients Treated with Phosphorus-32, Gold-198, or Iodine-131," will be completed immediately after administration of the patient's dose. A copy will be posted in the patient's chart.

5. Radiation levels in unrestricted areas will be maintained less than the limits specified in Section 20.105(b) of CFR 10 Part 20.

6. All bed linen, wash cloths and towels will be surveyed for contamination before being removed from the patient's room and will, if necessary, be held in decay until a safe level has been achieved.

7. Disposable plates, cups, eating utensils, tissues, surgical dressings, and other similar waste items will be placed in a specially designated container. The waste will be collected daily by the Radiation Safety Officer, surveyed for radioactive contamination, and disposed of as normal or radioactive, as appropriate.

8. Non-disposable items used for these patients will be held in plastic bags in the patient's room, and checked for contamination by the Radiation Safety Officer. Items may be returned to normal use, held in decay or decontaminated, as appropriate.

9. Urine and vomitus from Iodine-131 patients will be stored in the decay area for storage of radioactive waste. When it has reached background level as measured with a low-level survey meter, it will be released into the sanitary sewer system.

10. Before a therapy patient's room is reassigned to another patient, the room will be surveyed for contamination (and decontaminated if necessaty) and all radioactive waste and waste containers will be removed.

11. Nursing Instructions

    a. Nurses should spend only that amount of time near the patient required

for ordinary nursing care. Special restrictions may be noted on the precaution sheet in the patient's chart. Nurses should read these instructions before administering to the patient. Call the Department of Nuclear Medicine or the Radiation Safety Officer if there are any further questions regarding care of the patient.

b. Visitors will be limited to those 18 years of age or older, unless other instructions are noted on theprecaution sheet in the patient's chart.

c. Patients must remain in the bed while visitors are in the room and visitors should remain at least three feet from the patient.

d. Radioactive patients are to be confined to their rooms except for special medical and nursing purposes approved by Nuclear Medicine.

e. No nurse, visitor or attendant who is pregnant should be permitted in the room of a patient who has received a therapeutic dose of a radiopharmaceutical until the patient no longer presents a radiation hazard. Female visitors should be asked whether or not they are pregnant.

f. Attending personnel must wear rubber or disposable gloves and protective clothing when handling urinals, bedpans, emesis basins or other containers having any material obtained from the body of the patient. Wash gloved hands and remove gloves, wash hands. The gloves must be left in the patient's room in the designated waste container.

g. Disposable items should be used in the care of these patients, whenever possible. These items should be placed in the designated waste container. Contact the Radiation Safety Officer of the Department of Nuclear Medicine for proper disposal of the contents of the waste container.

h. All clothes and bed linen used by the patient should be placed in the laundry bag provided for this purpose and left in the patient's room to be checked by the Radiation Safety Officer.

i. All disposable and non-disposable items should be placed in the plastic bags provided and left in the room to be checked by the Radiation Safety Officer.

j. Surgical dressings should be changed only as directed by the physician. Colloidal Gold-198 leaking from a puncture wound will stain the dressing dark red or purple. Such dressings should not be discarded but should be collected in plastic bags and turned over to the Radiation Safety Officer. Handle these dressings with tongs or forceps. Wear disposable gloves.

k. For Iodine-131 Patients

(1) When necessary, urine from iodine-131 patients will be collected in special contianers provided by Nuclear Medicine Service. The

patient should be encouraged to collect his own urine in the container in these instances. If the patient is bedridden, a separate urinal or bed pan should be provided. The urinal or bed pan should be flushed several times with hot soapy water after use.

(2) If the nurse helps with the collection of excreta, she should wear disposable gloves. Afterwards she should wash her hands with the gloves on, again after removing the gloves and the gloves placed in the waste container provided.

(3) Disposable plates, cups, eating utensils,etc., will be used by patients who are treated with therapeutic ipdine-131.

(4) Vomiting within 24 hours after oral administration of the dose, urinary incontinence, or excessive sweating within the first 48 hours may result in contamination of linen and/or floor. In such situations or if radioactive urine and/or feces is spilled during collection, call the Radiation Safety Officer or the Department of Nuclear Medicine . Meanwhile, handle all contaminated material with disposable gloves and avoid spreading the contamination.

(5) All vomitus must be kept in the patient's room for disposal by the Nuclear Medicine Department. Feces need not be routinely saved unless ordered on the chart. The same toilet should be used by the patient at all times and it should be well flushed.

l. Utmost precautions must be taken to assure that no urine or vomitus is spilled on the floor or on the bed. If any part of the patient's room is suspected to be contaminated, notify the Radiation Safety Officer.

m. If a nurse, attendant or anyone else knows or suspects that his skin or clothing, including shoes, is contaminated, notify the Radiation Safety Officer immediately. This person should remain in the patient's room and not walk about the hospital. If the hands become contaminated, wash immediately with soap and water.

n. If a therapy patient should need emergency surgery or should die, notify the Radiation Safety Officer and Department of Nuclear Medicine immediately.

o. When the patien is discharged call the Radiation Safety Officer and request that the room be surveyed for contamination before remaking the room for occupancy.

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH PHOSPHOUS-32, GOLD-198, or IODINE-131

Patient's Name: _____

Room No.: _____ Physician's Name: _____

Radioisotope Administered: _____

Date and Time of Administration: _____

Dose Received: _____ Method of Administration: _____

Exposure Rates in MR/hr

Date	3 feet from bed	10 feet from bed

(Comply with all Check Items)

_____1. Visting time permitted: _____

_____2. Vistors must remain _____ from patient.

_____3. Patient may not leave room

_____4. Vistors under 18 not permmitted.

_____5. Pregnant visitors not permitted.

_____6. Film badges must be worn.

_____7. Use and complete the following tags:

_____door

_____bed

_____chart

_____wrist

_____8. Gloves must be worn while attending patient.

_____9. Patient must use disposable utensils.

_____10. All items must remain in romm until OK'd by Radiation Safety.

_____11. Smoking is <u>not</u> permitted.

_____12. Do not release room to admitting until OK'd by Radiation Safety.

_____13. Other instructions

In case of an emergency contact:

RSO _____ / _____

name on/off duty telephone no.

PROCEDURES FOR USE OF GROUP VI SOURCES FOR
TREATMENT OF PATIENTS

1. All patients treated with brachytherapy sources will be placed in a private room with a toilet.

2. The patient's room will be properly posted with warning signs in accordance with Section 20.203 of 10 CFR Part 20.

3. Surveys of the patient's room and surrounding areas will be conducted immediately after the sources have been implanted. Exposure rate measurements will be taken at the patient's bedside, three feet away and at the entrance to the room. The Radiation Safety Officer or his designate will then determine how long a person may remain at these positions and will post these times in the patient's chart.

4. The form, "Nursing Instructions for Patients Treated with Brachytherapy Sources", will be completed immediately after the sources are implanted and placed in the patient's chart.

5. Radiation levels in unrestricted areas will be maintained less than the limits specified in Section 20.105 (b) of 10 CFR Part 20.

6. Nurses caring for brachytherapy patients will be assigned film badges. TLD finger badges will also be assigned to nurses who must provide extended care to the patient.

7. At the conclusion of treatment, a survey will be performed to ensure that all sources have been removed from the patient and that no sources remain in the patient's room or any other area occupied by the patient. At the same time all radiation warning signs will be removed and all film badges and TLD badges assigned to nurses will be collected.

8. Instruction to Nurses

   a. Special restrictions may be noted on the precaution sheet in the patient's chart. Nurses should read these instructions before administering to the patient. Contact the Radiation Safety Officer or the Department of Nuclear Medicine if there are futher questions regarding the care of the patient.

   b. Nurses should spend only the minimum necessary time near a patient for routine nursing care, but must obtain and wear a film badge.

   c. When a nurse receives an assignment to a therapy patient, a film badge or finger badge should be obtained immediately from the Radiation Safety Officer. The badge shall be worn only bt the person to whom it is assigned and shall not be interchanged between personnel.

   d. Pregnant nurses should not be assigned to the personal care of these patients.

e. Never touch needles, capsules or containers holding brachytherapy sources. If a source becomes dislodged use long forceps and put it in the corner of the room or in the shielded container provided; contact the Department of Nuclear Medicine.

f. Bed baths given by the nurse or nursing personnel should be omitted while the sources are in place.

g. Perineal care is not given during gynecologic treatment; the perineal pad may be changed when necessary, unless orders to the contrary have been written.

h. Surgical dressings and bandages used to cover areas of needle insertion may be changed only by the attending physician or a Radiologist, and May Not Be Discarded until directed by the Radiologist. Dressings should be kept in the basin until checked by the Radiologist or the Radiation Safety Officer. Special orders will be written for oral hygiene for patients with oral implants.

i. No special precautions are needed for sputum, urine, vomitus stools, eating utensils, instruments, or bedding unless special orders are given.

j. These patients must stay in bed unless orders to the contrary are written.

k. Visitors will be limited to those 18 years of age or over, unless other instructions are noted in the patient's chart.

l. Visitors should not sit at least within three feet of the patient and should remain no longer than the times specified on the form posted on the patient's door and in the patient's chart.

m. No nurse, visitor or attendant who is pregnant should be permitted in the room of a patient while brachytherapy sources are implanted. Female visitors should be asked whether or not they are pregnant.

n. Emergency Procedures

(1) If an implanted source becomes loose or separated from the patient or,

(2) If the patient dies, or

(3) If the patient requires emergency surgery, immediately call the Radiation Safety Officer _____, phone No._____ _____(days) _____(nights).

o. At the conclusion of the treatment, cal the Radiation Safety Officer and request that the patient and the room be surveyed to assure that all radioactive sources have been removed.

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH BRACHYTHERAPY SOURCES

Patient's Name: _____

Room Number: _____ Physician's Name: _____

Isotope Activity: _____

Date and Time of Administration: _____ _____

Date and Time Sources are to be removed: _____ Isotope _____

Is Source Permanent Inplant: _____ Yes _____ No _____

Exposure Rates in mR/hr

Bedside _____ 3 feet from bed _____ 10 feet from bed _____

_____

_____

(Complete checked items)

____1. Wear film badge or issued radiation detection device.

____2. Wear rubber or disposable gloves.

____3. Place laundry in linen bag and leave in room.

____4. Housekeeping may not enter the room.

____5. Patient may not have visitors.

____6. No pregnant visitors.

____7. No visitors under 18 years of age.

____8. A dismissal survey must be performed before patient is discharged.

____9. Patient must have a private room.

___10. Other instructions.

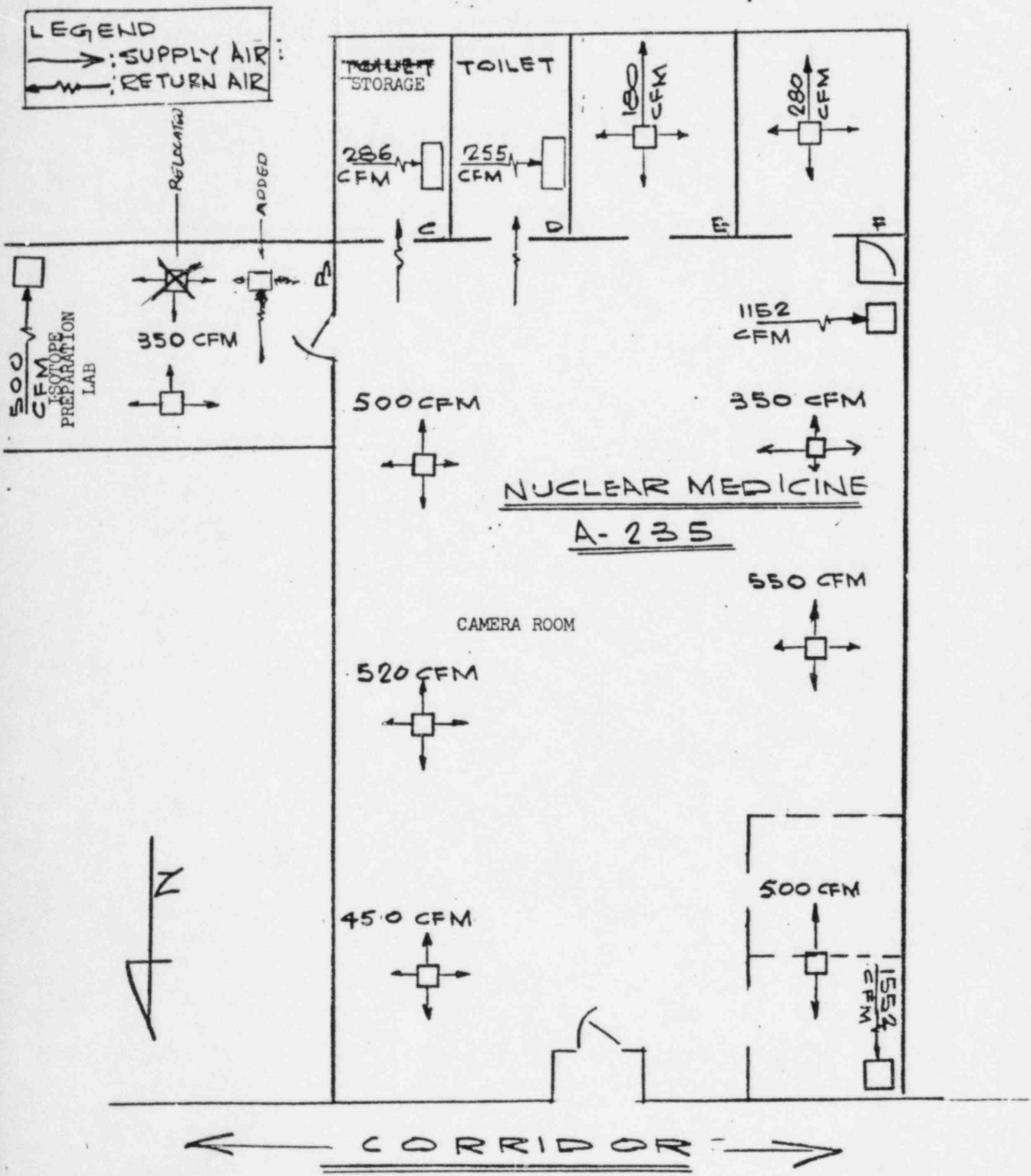
RSO _____, _____

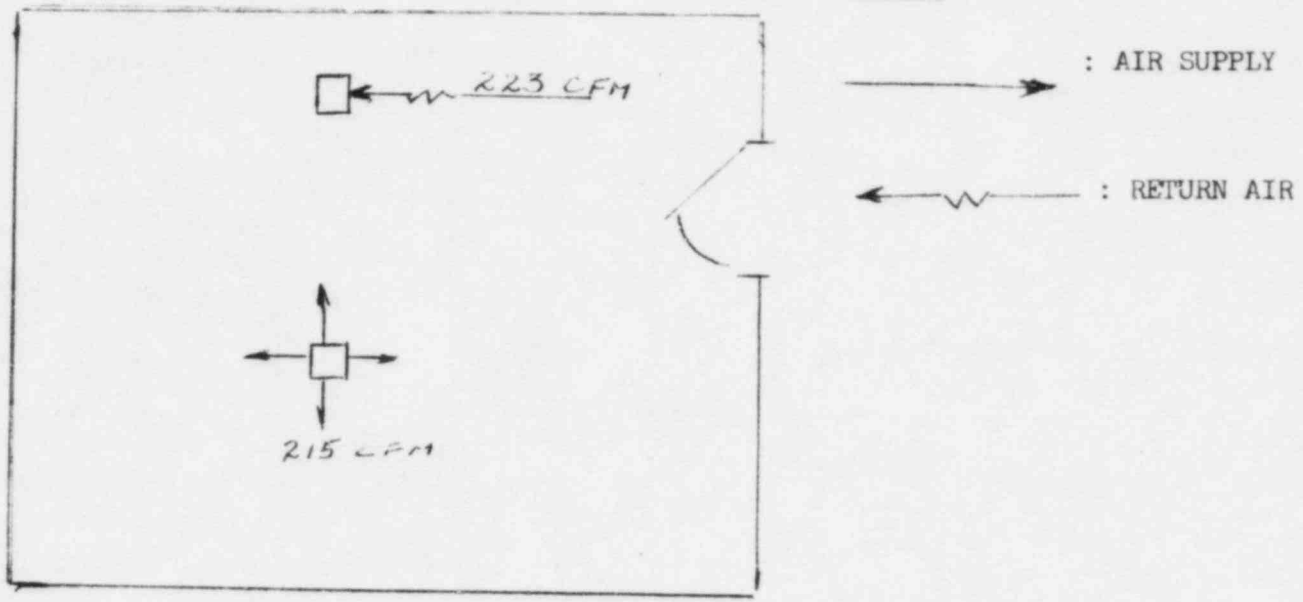
Name on duty/off duty telephone number

BY F. DAWKINS DATE 3/23/81 SUBJECT AIR DISTRIBUTION SHEET NO. 1 OF 1

CHKD. BY FD DATE NUCLEAR MEDICIN JOB NO.

SUPPLY AIR : 3680 CFM
RETURN AIR : 3745 CFM





DECAY STORAGE AREA

RADIATION SAFETY PRECAUTIONS

Use of Radionuclides in Animals

1. Only the animal room designated as "active" will be used for housing radioactive animals.

2. No uncontrolled exchange of animals, instruments, cages, or other items between "active" and inactive laboratories will be made.

3. Excreta, body constituents from biopsies and autopsies and animal cadavers will be considered as radioactive waste.

4. Animal parts and cadavers will be placed in plastic bags, labeled as to their contents and stored in the designated location as prescribed by the Radiation Safety Officer.

5. Liquid waste shall be collected and retained for proper disposal by the Radiation Safety Officer.

6. No eating, drinking, smoking or use of cosmetics must occur when working with radioactive materials or animals. Appropriate wearing apparel must be worn when working within "active" areas.

7. The radioactive animals or their cages must be marked with labels indicating the nature and amount of radionuclide used, time of administration and the Principle Investigator for the experiment.

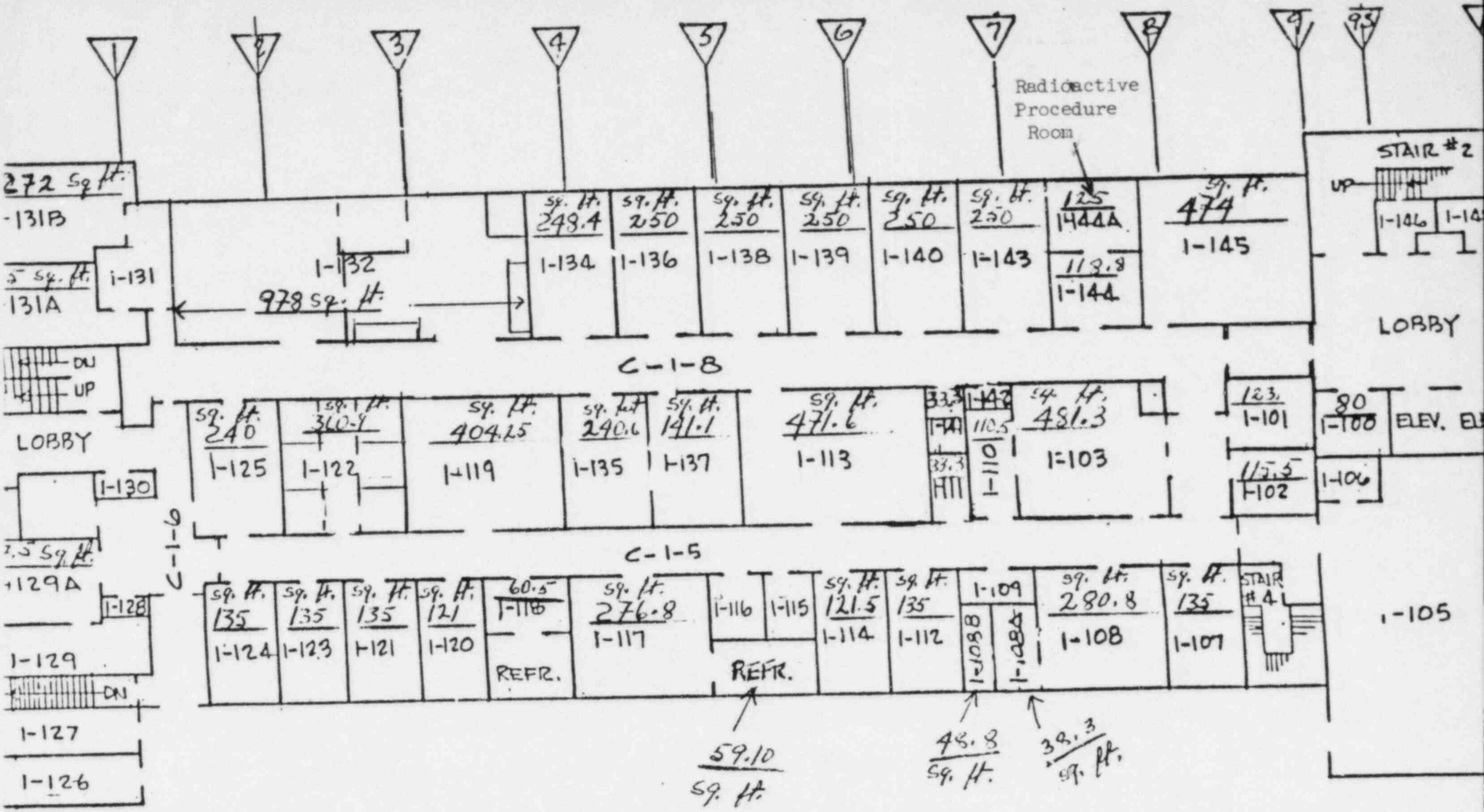
8. Precautions shall be taken to prevent the possibility of contaminated wounds in the course of handling the animals and of contamination from radioactive aerosols or splashings produced by animals' movements, coughing, etc.

9. Presence of vermin as potential vectors of contamination shall always be considered.

10. Report any accident involving radioactive materials or animals immediately to the Radiation Safety Officer.

The Radiation Safety Officer may be phoned at: 3496

!!!POST THIS NOTICE!!!



RESEARCH AND EDUCATION
FIRST FLOOR PLAN

N

VETERANS ADMINISTRATION MEDICAL CENTER
MIAMI, FLORIDA 33125

THE ADMINISTRATION OF RADIOPHARMACEUTICALS IN HUMAN USE

1. Radiopharmaceuticals will be ordered from suppliers by the Chief, Nuclear Medicine Service, on a prescription form indicating the name of the patient, the radioactive drug and desired activity.

2. A list of the suppliers's tradenames, as well as, the chemical names of desired radioactive drugs will be expanded as they are approved by the Nuclear Regulatory Commission.

3. When packages containing radioactive materials are received they are visually inspected for any sign of damage (e.g., wetness, crushed). The exposure rate is measured at the surface of the package and at 3 feet. Wipe tests are performed on packages in compliance with Part 20.205 of Title 10, Chapter 1, of the Code of Federal Regulations. The outer package is opened if no physical damage is observed. The packing slip is removed and checked to verify the contents according to requisition, label on the container, damage to the container, loss of contents and discoloration of packing material. Upon verification of correctness of order, receipt of the material is entered in the appropriate logs indicating date of receipt, assay activity and chemical form.

4. Patient doses are requested in writing on Clinical Record Consultation Sheet, Standard Form 513, and signed by the requesting physician.

5. Patient doses are labeled with regard to radionuclide, chemical form, activity, time and date of assay. In addition therapeutic doses are recorded on Medical Record Authorization Sheet, Standard Form 522, indicating the treatment or procedure and identifying the patient by name and Social Security number. This information is cross-referenced in a therapy log.

6. Radiopharmaceuticals will be clearly labeled with respect to route of administration: <u>CAUTION-- FOR ORAL USE ONLY</u> or <u>CAUTION-- FOR I.V. INJECTION</u>.

/SKC Chandarlapaty, M.D.
Chief, Nuclear Medicine Service

BIOASSAY PROGRAM

Except in cases involving therapeutic doses of Iodine-131 in a volatile or dispensable form above bioassay activity levels gelatin capsules are used in diagnostic procedures.

1. Procedures requiring the use of Iodine-125 or Iodine-131 in a volatile and/or dispensable form or bound to a non-volatile agent above the following levels of activity will necessitate personnel bioassays:

	Volatile or Dispensable	Bound to non-volatile Agents
(a) Open room or bench	0.1 mCi	1 mCi
(b) Within a fume hood	1 mCi	10 mCi
(c) Within glove boxes	10 mCi	100 mCi

2. Participation in personnel bioassay shall be required of all workers handling radioactive materials as radioactive iodine or in close proximity to its use as described in the above.

3. Personnel bioassays shall consist of the following: Thyroid counts, urine counts, and in instances where merited whole body counts will be performed.

4. Criteria frequency in performing bioassay will depend upon the use of these radionuclides. A baseline will be established for persons handling radioiodine in sufficient quantity that require bioassay as specified in item No. 1 above. Routine bioassays will then be performed periodically.

5. When positive results are obtained after an initial bioassay, a diagnostic follow-up will be performed every two weeks in accordance with regulatory positions. Periodic follow-ups will be performed on selected frequency basis.

6. The above criteria for bioassay in the use of tritium shall apply when:

Procedure	HT Form	HT or T_2 Gas (Sealed vessel)	Nuclide Precursors	HTO mixed with more than 10 Kg of Inert H_2O or other substitute
Open room, bench	0.1 Ci	100 Ci	0.01 Ci	0.01 Ci/Kg
Fume hood	1 Ci	1000 Ci	0.1 Ci	0.1 Ci/Kg
Glove box	10 Ci	10,000 Ci	1 Ci	1 Ci/Kg

Program for Maintaining Occupational
Radiation Exposures at Medical Institutions ALARA

VETERANS ADMINISTRATION MEDICAL CENTER
(Licensee's Name)

June 9, 1982
(Date)

I. Management Commitment

a. We, the management of this medical facility are committed to the program described in this paper for keeping exposures (individual and collective) as low as reasonably achievable (ALARA). In accord with this commitment, we hereby establish an administrative organization for radiation safety and develop the necessary written policy procedures and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC), and a Radiation Safety Officer (RSO). We are also committed to following the guidance provided by U.S. Nuclear Regulatory Guides 8.10 and 8.18.

b. We will perform a formal audit annually to determine how exposures might be lowered. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants. A brief summary of the audit will be prepared covering the scope of the review and the conclusions reached.

c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will significantly reduce exposures at reasonable costs. We will be able to demonstrate that improvements have been sought, that modifications have been considered, and that they have been implemented where practicable. Where modifications have been considered but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

II. Radiation Safety Committee (RSC)

a. Review of Proposed Users and Uses

1. The RSC will thoroughly review the qualifications of each potential authorized user with respect to the types and quantities of materials and uses for which he has applied to assure that the user will be able to take appropriate measures to maintain exposure ALARA.

2. When considering a new use of byproduct material, the RSC will review the efforts of the authorized user to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA, and should have considered the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.

3. The RSC will ensure that the user justifies his procedures and that they will result in ALARA doses (individual and collective).

b. Delegation of Authority

1. The RSC will delegate sufficient authority to the RSO for enforcement of the ALARA concept.

2. The RSC will support the RSO in those instances where it is necessary for the RSO to assert his authority. Where the RSO has been overruled, the Committee will record the basis for its action.

c. Review of ALARA Program

The RSC of our medical facility will perform an annual review of all radiation safety programs. This review will be performed independently of that performed by management.

1. The RSC will encourage all users to review current procedures and develop new procedures as appropriate for ways to implement the ALARA concept.

2. The RSC will review all instances of deviations from the ALARA philosophy. Information in support of the review will normally be supplied by the RSO.

3. The RSC will evaluate our institution's overall efforts for maintaining exposures ALARA. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

d. Public Statement of Commitment by the RSC to ALARA

All elements of our institution will be informed of the RSC's commitment to the ALARA concept.

1. The RSC will ensure that employees are aware of the RSC's commitment to the ALARA philosophy.

2. The RSC will demonstrate its commitment to the ALARA concept through the methods employed in its review of proposed users and uses.

III. Radiation Safety Officer (RSO)

a. Annual and Quarterly Review

1. Annual review of the Radiation Safety Program. The RSO will perform an annual review of the Radiation Safety Program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.

2. Quarterly review of Occupational Exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of paragraph VI of this program.

3. Quarterly review of records of Radiation Level Surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

b. Education Responsibilities for an ALARA Program

1. The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

2. The RSO will assure that authorized users, workers and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

1. The RSO will maintain close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

2. The RSO will establish procedures for encouraging, receiving, and evaluating the suggestions of individual workers for improving health physics practices.

d. Reporting and Reviewing Instances of Deviation from Good ALARA Practices

1. The RSO will investigate all instances of deviation from good ALARA practices; and, if possible, determine the causes. When the cause is known, the RSO will propose changes in the program to maintain exposures ALARA.

2. The RSO will report all significant instances of deviation from ALARA concepts to the RSC for review.

IV. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

1. The authorized user will consult the RSO and RSC before using radioactive materials for a new procedure.

2. The authorized user will consider all procedures thoroughly before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsibility of the Authorized User to Those He Supervises

1. The authorized user will thoroughly explain the ALARA concept and his commitment to maintain exposures ALARA to all of those he supervises.

2. The authorized user will ensure that his occupational workers are trained and educated in good health physics practices and in maintaining exposures ALARA.

V. Occupational Worker

a. What the Occupational Worker Must Consider about ALARA

1. The worker will implement ALARA procedures developed by the authorized user and the RSO.

2. The occupational worker will know what recourses are available if he feels that ALARA is not being promoted on the job.

3. The occupational worker will understand that ALARA concept and will review his own working conditions and those of his fellow workers for the implementation of ALARA principles.

VI. Establishment of Action Levels in Order to Achieve Reductions in Individual Occupational Exposures

This institution hereby establishes exposure action levels for specific kinds or classes of operations which, when exceeded, will trigger investigation by the Radiation Safety Committee and/or the Radiation Safety Officer. The exposure action levels that we have established are listed in Section VII below. These levels apply to the exposure of individual workers. The exact levels have been determined based on our institution's radiation exposure history and a thorough analysis of our current program. We will maintain on file at our institution an account of the considerations used in establishing action levels.

Written justification is appended to this program for any exposure action levels that exceed 10% of MPD (10 CFR 20.201). This justification includes details of the past exposure history at this institution for the particular kind or class of operation, a summary of efforts taken to reduce this exposure, and an explanation of why further dose reductions are not feasible.

Table 1

		Investigational Levels - (mrems per calendar quarter)	
		LEVEL I	LEVEL II
1.	Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2.	Hands and forearms; feet and ankles	1875	5625
3.	Skin of whole body*	750	2250

* Not normally applicable to nuclear medicine operations except those using significant quantities of beta emitting isotopes.

The Radiation Safety Officer will review and record on Form NRC-5, Current Occupational External Radiation Exposures, or an equivalent form (e.g. dosimeter processor's report), results of personnel monitoring, not less than once in any calendar quarter, as is required by 10 CFR 20, §20.401. The following actions will be taken at the Investigational Levels as stated in Table 1:

a. Quarterly exposure of individuals to less than Investigational Level I.

   Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table I values for the Investigational Level I.

b. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

   The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I. He will report the results of his reviews at the first RSC meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Exposure equal to or greater than Investigational Level II.

   The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the Committee minutes. Committee minutes will be sent to the management of this institution for review. The minutes, containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection.

d. Re-establishment of an individual occupational worker's Investigational Level II Above That Listed In Table I.

In cases where a worker's or a group of worker's exposures need to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

The Radiation Safety Committee will review the justification for, and will approve, all revisions of Investigational Levels II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed in paragraph c above will be followed.

VII. Action Levels

The specific action levels established by this institution are as follows:

Kind or Class of Operation	Action Level
1. Diagnostic Nuclear Medicine	375 mrems
2. Radioimmusioassay Procedures	375 mrems
3. Research Procedures	375 mrems
4. Radiology Procedures	750 mrems
5. Dental Radiographic Procedures	375 mrems
6. Radiation Therapy Procedures	375 mrems
7. Cardiopulmonary Procedures	750 mrems

VIII Signature of Certifying Official

I hereby certify that this institution (or private practice), is committed to the ALARA Program set forth above.

T.C. Doherty

Signature

T.C. DOHERTY

Name (print or type)

Director

Title

Institution: VETERANS ADMINISTRATION MEDICAL CENTER
1201 Northwest 16th Street
Miami, Florida 33125

APPENDIX

VI. Establishment of Investigational Levels in Order to Monitor Individual Occupationa External Radiation Exposures

d. Re-establishment of an individual occupational worker's Investigational Level II above that listed in Table I.

Based on recorded exposure levels over the past 2 years at the Miami V.A. Medical Center for personnel in Radiology Service and Cardiopulmonary Laboratory Unit, a higher Investigative Level II (750 mrems/quarter) is established. It is consistent with good ALARA practice for these groups in view of their nature of work.

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	Radiation Detection Company	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER	X	FILM	Radiation Detection Company	Monthly
		TLD		
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

Self-Reading Pocket Dosimeters are utilized for immediate assessment of radiation exposures on special occasions.

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED
(See Section 170.31, 10 CFR 170)

(1) LICENSE FEE CATEGORY:

(2) LICENSE FEE ENCLOSED: $ _____

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

T.C. Doherty

(1) NAME *(Type or Print)*
T.C. DOHERTY

(2) TITLE
DIRECTOR

c. DATE
July 27, 1984

NRC FORM 313M (9-81)

1794

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.

5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

VETERANS ADMINISTRATION MEDICAL CENTER

MIAMI, FLORIDA

MEDICAL CENTER POLICY MEMORANDUM
NO. 115-2-83 JUNE 17, 1983

RADIATION SAFETY COMMITTEE

I. PURPOSE

To establish policies and procedures for coordinating the use of by-product materials in the Medical Center.

II. POLICY

Nuclear Medicine diagnostic and therapeutic services shall be performed only upon written request of a physician on staff at the VAMC. Radionuclides shall be administered to patients under the supervision of a physician designated as a "user". House staff physicians are authorized to request all diagnostic studies. Therapeutic services can be requested by staff physicians in the respective sub-specialities.

III. DEFINITIONS

A. A "user" is a member of the medical staff designated by the U.S. Nuclear Regulatory Commission to procure and use specific radionuclides for diagnostic and therapeutic purposes.

B. Physicians

C. House Staff

D. Physicians in Sub-specialities.

IV. RESPONSIBILITIES

A. The Chief of Nuclear Medicine Service serves as Chairman of the Radiation Safety Committee and supervises all human use of isotopes.

B. The Radiation Safety Committee will be composed of the following membership as the local committee to implement the regulations of the U.S. Nuclear Regulatory Commission which is the license granting Federal Agency.

Chairman	Chief, Nuclear Medicine Service
Recorder	Radiation Safety Office
Members:	
Staff Physician	Nuclear Medicine Service
Staff Physician	Nuclear Medicine Service
Staff Physician	Dermatology Service
Chief, Radiology Service	Radiology Service
Richard Cowman, Ph. D.	Dental Research Service
Radiopharmacist	Pharmacy Service
Admin. Asst/COS	Chief of Staff Office
Head Nurse(6AB)	Nursing Service
Supervisory Technologist	Nuclear Medicine Service

17941

1. Reviews and evaluates the implementation of the hospital radiation safety plan, including the receipt, custody, accountability and disposal of all radioactive materials approved for institutional use by the U.S. Nuclear Regulatory Commission. The hospital radiation safety plan outlines the measures to be taken to protect personnel from the hazards of ionizing radiation which may arise from the NRC reactor produced by-product material. This excludes the prescribing and administration of those radiation safety measures required to protect personnel from sources of ionizing radiation normal to radiology and which include X-ray tubes, flouroscopes, teletherapy devices and particle accelerators.

2. Initiates, develops and reviews working relations with the VA Medical Center Research and Development Staff and the affiliated VA stations.

3. Reviews the efforts of the Nuclear Medicine Service to provide all possible support for research activities in the Medical Center and affiliated institutions.

4. Reviews the efforts of the Nuclear Medicine Service to integrate with the teaching programs of both medical and paramedical personnel.

5. Will serve in an advisory capacity to the Medical Center Director, through the Chief of Staff, in the implementation of Veterans Administration Policy. The Radiation Safety Committee will review all proposed uses of radionuclides in the Medical Center.

V. PROCEDURES

The Radiation Safety Committee will meet quarterly and will forward minutes through the office of the Chief of Staff, to Chiefs of Professional Services, and Associate Chief of Staff for Research, to the Medical Center Director.

VI. OTHER

None

VII. REFERENCES

10 CFR Part 35, October 12, 1982

VIII. RECISSIONS

Medical Center Policy Memorandum 115-2-82

IX. FOLLOW-UP RESPONSIBILITY

Chief, Nuclear Medicine Service

X. This Medical Center Policy Memorandum will remain in effect until rescinded.

T.C. DOHERTY
Director

VETERANS ADMINISTRATION MEDICAL CENTER

MIAMI, FLORIDA

MEDICAL CENTER POLICY MEMORANDUM
NO. 115-2-83
CHANGE # 1.

June 28, 1984

RADIATION SAFETY COMMITTEE

Please make the following changes to Medical Center Policy Memorandum 115-2-83, dated June 17, 1983.

I. Paragraph IV RESPONSIBILITIES

B. MEMBERS: Delete Listing

II. Paragraph IV RESPONSIBILITIES

B. MEMBERS: Add:

Staff Physician	Dermatology Service
Admin. Asst/COS	Chief of Staff Office
Surgical Nurse Supervisor	Nursing Service
Chief, Radiology Service	Radiology Service
Research Safety Officer	Research Service
Asst. Chief, Radiation Therapy	Radiation Therapy Service

T. C. DOHERTY,
Director

Distribution: A& X (X=20 to 115)

RADIATION SAFETY COMMITTEE

a. Committee's Duties and Responsibilities

RESPONSIBILITY:

The Committee is responsible for:

1. Ensuring that all individuals who work with or in the vicinity of radioactive material have sufficient training and experience to enable them to perform their duties safely and in accordance with NRC rules and regulations and the conditions of the license.

2. Ensuring that all use of radioactive material is conducted in a safe manner and in accordance with NRC rules and regulations and the conditions of the license.

DUTIES:

The committee shall:

1. Be familiar with all pertinent regulations, the terms of the license, and information submitted in support of the request for the license and amendments thereto.

2. Review the training and experience of any individual who uses radioactive materials (including physicians, technologists, physicists, and pharmacists) and determine that the qualifications are sufficient to enable them to perform their duties safely and in accordance with NRC regualtions and the conditions of the license.

3. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive material (e.g., nursing, security and housekeeping personnel) are properly instructed as required by Section 19.12, 10 CFR Part 19.

4. Review and approve the acquisition and use of radioactive materials within the institution.

5. Prescribe special conditions that will be required during a proposed use of radioactive material such as requirements for bioassays, physical examinations of users ans special monitoring procedures.

6. Review the entire radiation safety program at least annually to determine that it meets all its goals and that all activities are being conducted safely and in accordance with NRC regulations and the conditions of the license. The review shall include an examination of all records, reports from the Radiation Safety Officer, results of NRC inspection, and written safety procedures to determine whether current procedures are maintaining exposures as low as reasonably achievable.

7. Recommend remedial action to correct any deficiencies identified in the radiation safety program.

8. Maintain written records of all Committee meetings, actions, recommendations, and decisions.

9. Ensure that the byproduct material license in amended, when necessaty to include any changes in facilities, equipment, policies, procedures, and personnel.

b. MEETING FREQUENCY

The Radiation Safety Committee will meet quarterly or as often as necessary to conduct its business and will forward minutes of the meetings through the office of the Chief of Staff, to the Medical Center Director, to Chiefs of Professional Services, and Associate Chief of Staff for Research.

c. Name and Specialty of Committee Members:

1. S.K.C. Chandarlapaty, M.D., Chief, Nuclear Medicine Service
Florida Board - Certified in Nuclear Medicine

2. Robert M. Cobb, Radiation Safety Officer
Training and experience listed in Item 8.

3. J. Richard Taylor, M.D., Assist. Chief, Dermatology Service
Experience in the use of labelled compounds in research studies in the diagnosis and treatment of skin conditions.

4. Bernard Lieberman, M.D., Chief, Radiology Service
Florida Board - Certified Radiologist

5. Ramish K. Rao, M.D., Assist. Chief, Radiation Therapy Service
Florida Board - Certified Radiologist

6. Richard A. Cowman, Ph.D., Medical Research Service
Experience in the use of labelled compounds in research studies in the diagnosis and treatment of dental streptococci.

7. Janet Fierro, R.N., Nursing Service
Registered Nurse

8. Debbie Berngard, Administrative Assist./COS
Management

9. Gonzalo Vuelta, Nuclear Medicine Technologist
Supervisory Technician, Nuclear Medicine Service

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

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
S.K.C. CHANDARLAPATY, M.D.	Florida & New York

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Internal Medicine	American Board of Internal Medicine	Aug. 1971
Nuclear Medicine	American Board of Nuclear Medicine	June 1972

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	V.A. Hospital, Hines, Ill. V.A. Medical Center, Miami, Fl.	7-1-71 to 6-30-72 11-'72 to 11 --	
b. RADIATION PROTECTION	V.A. Hospital , Hines, Ill. V.A. Medical Center, Miami, Fl.	7-1-71 to 6-30-72 11-'72 to 11 --	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	V.A. Hospital, Hines, Ill. V.A. Medical Center, Miami, Fl..	7-1-71 to 6-30-72 11-'72 to 11 --	
d. RADIATION BIOLOGY	V.A. Hospital, Hines, Ill. V.A. Medical Center, Miami, Fl.	7-1-71 to 6-30-72 11-'72 to 11 ---	
e. RADIOPHARMACEUTICAL CHEMISTRY	V.A. Hospital, Hines, Ill. V.A. Medical Center, Miami, Fl.	7-1-71 to 6-30-72 11-'72 to 11 --	

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
I-131	100 mCi	VAH, HINES, Ill.	1 year	Diagnostic & Therapeutic
		VAH, Miami, Fla.	12 years	Same as above
P-32	10 mCi	Above locations	Above duration	" " "
Au-198	10 mCi	" "	" "	" " "
Cr-51	10 mCi	" "	" "	" " "

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION	TYPE OF USE
Tc-99m	1 Ci	VAH, Hines, Ill. VAH, Miami, Fl.	1 year 12 years	Diagnostic Diagnostic
Hg-203	1 mCi	Above locations	As above	Diagnostic
Hg-197	5 mCi	" "	" "	Diagnostic
I-125	40 mCi	VAH, Miami, Fl.	12 years	Therapeutic
In-111	5 mCi	Above locations	As above	Diagnostic
Sr-85	2 mCi	Above locations	As above	Diagnostic
F-18	10 mCi	VAH, Hines, Ill.	1 year	Diagnostic
Ga-67	20 mCi	Above locations	As above	Diagnostic
Xe-133	2 Ci	" "	" "	"
Se-75	1 mCi	" "	" "	"
Co-57	1 mCi	" "	" "	"
Co-58	1 mCi	" "	" "	"
Tl-201	10 mCi	VAH, Miami, Fl.	3 years	Diagnostic

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

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

ADDENDUM TO ORIGINAL ____ UP DATED

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

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

S.K.C. CHANDARLAPATY, M. D.

STREET ADDRESS

VA Medical Center, Nuclear Medicine Svc.

CITY | STATE | ZIP CODE

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

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

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

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

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION	147	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME	115	
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES	415	
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS	197	
I-131	THYROID IMAGING	83	
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	128	
OTHER			
Tc-99m	BRAIN IMAGING	34	
	CARDIAC IMAGING	131	
	THYROID IMAGING	49	
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING	1897	
	LUNG IMAGING	223	
	BONE IMAGING	1560	
OTHER			

PRECEPTOR STATEMENT *(Continued)*

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

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	21	
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM	63	
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS	87	
Other			

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

Oversees all diagnostic and therapeutic studies as chief of Nuclear Medicine Service.

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

a. NAME OF SUPERVISOR

b. NAME OF INSTITUTION

c. MAILING ADDRESS

d. CITY

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE

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

8. DATE

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

Form AEC-313a
(11/63)
Page 3

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE - MEDICAL

SUPPLEMENT A -- PRECEPTOR STATEMENT

This page is to be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each. Back of page may be used for comments.

9. NAME AND ADDRESS OF APPLICANT PHYSICIAN (Include ZIP Code)

S.K.C. Chandarlapaty, M.D.
Veterans Administration Hospital (172)
Miami, Florida 33125

10. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN NAMED IN ITEM 9 ABOVE

(A) ISOTOPE	(B) CONDITIONS DIAGNOSED OR TREATED	(C) No. Cases Observed (See 1 in key below)	(D) No. Cases Involving Personal Participation (See 2 in key below)
I-131	Diagnosis of thyroid function	929	
	Dilution studies		
	Excretion studies	180	
	Brain tumor localization		
	Scanning studies	702	
	Treatment of hyperthyroidism	8	
	Treatment of cardiac conditions		
	Treatment of thyroid carcinoma	1	
P-32 Soluble	Treatment of polycythemia		
	Treatment of leukemia		
	Treatment of bone metastases		
	Tumor localization		
	Intracavitary treatment		
	Interstitial treatment		
Au-198	Intracavitary treatment		
	Interstitial treatment		
	Scanning studies	260	
Cr-51	Blood determinations	36	
	Scanning studies Liver & spleen ratio	36	
Co-58 or Co-60	Diagnosis of pernicious anemia		
Co-60 I-192	Interstitial treatment		
	Intracavitary treatment		
Co-60 or Cs-137	Teletherapy treatment		
Sr-90	Treatment of superficial diseases of the eye		
Other Isotopes Use back of page	OVER		

Key to Column (C) and (D) above

1. Observation should consist of observing radioisotope administration techniques and discussion with preceptor the case histories to establish most appropriate diagnostic and/or therapeutic procedure, limitation, contraindications, etc.

2. Personal participation should consist of (a) supervised examination of patient, to determine the suitability for radioisotope diagnosis and/or treatment and recommendation on dosage to be prescribed, (b) collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurements, and plotting of data; and (c) adequate period of training to enable the physician to manage radioactive patients and to follow patients through diagnosis and/or the course of treatment.

11. DATES AND TOTAL NUMBER OF HOURS OF CLINICAL RADIOISOTOPE TRAINING 7/1/71 - 6/30/72

12. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF ERVIN KAPLAN, M.D.

AT VA Hospital, Hines, Il 60141 (Institution Name and Address) AEC #12-1007-7 (Byproduct Material License Number)

(Signature of Preceptor)

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE - MEDICAL

SUPPLEMENT A—HUMAN USE

This page may be used for providing additional information.

^{99m}Tc	Brain	1004	^{133}Xe	Lung	15
	Liver	546			
	Spleen	12	^{75}Se & ^{198}Au	Pancreas	262
	Liver & Lung	6			
^{203}Hg	Localize kidneys	180	^{57}Co	Serum B_{12}	2016
^{197}Hg	Renal scan	98	^{58}Co	Whole Body Schillings	68
^{125}I	In vitro	1220			
^{111}In	Cisternals	6			
^{85}Sr	Bone scan	30			
^{18}F	Bone scan	30			
	Whole body scan	40			
^{67}Ga		3			

***

Dr. Chandarlapaty is a skilled internist and specialist in nuclear medicine. He is board certified in both specialties. He has completed a year of advanced training in nuclear medicine at our laboratories.

He is of excellent moral character, has broad experience in the field of nuclear medicine. He has been exposed to and participated in many procedures. His qualifications are excellent for being granted a byproducts material license.

* U.S. GOVERNMENT PRINTING OFFICE : 1974 O—522-213

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

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF ~~AUTHORIZED USER~~ OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Robert M. Cobb	

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	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	V.A. Hospital, Coral Gables V.A. Medical Center Miami, Florida	1955 -	1955 -
b. RADIATION PROTECTION	Same as above	1955 -	1955 -
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Same as above	1955 -	1955 -
d. RADIATION BIOLOGY	Same as above	1955	1955 -
e. RADIOPHARMACEUTICAL CHEMISTRY			

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
I-131	110 mCi	VAH, Little Rock, Ark.	80 hrs	Radiation Safety & Diagnosis
		NBS, Bethesda, Md.	40 hrs	"
		VAH, Coral Gables, Fla.	13 yrs	Rad. Safety, Diagnosis & Treatment
		VAMC, Miami, Fla.	16 yrs	

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPER.	TYPE OF USE
Co-57	5 mCi	VAH, Miami, Fla.	13 yrs.	Calibration
		VAMC, Miami, Fla.	16 yrs	"
Co-60	900 R/hr	JMH, Miami, Fla.	3 yrs.	Research
	10 mCi	VAMC, Miami, Fla.	10 yrs.	Calibration
Na-22	10 mCi	VAH, Coral Gables, Fl.	13 yrs.	Diagnosis
Na-24	5 mCi	VAH, Coral Gables, Fl.	13 yrs.	"
K-42	5 mCi	" " " "	13 yrs.	"
P-32	10 mCi	" " " "	13 yrs.	Therapeutic
		VAMC, Miami, Fla.	16 yrs.	"
Hg-203	5 mCi	VAH, Coral Gables, Fl.	13 yrs.	Diagnosis
		VAMC, Miami, Fl.	11 yrs.	"
Hg-197	5 mCi	VAH, Coral Gables, Fl.	13 yrs.	"
		VAMC, Miami, Fl.	11 yrs.	"
Se-75	3 mCi	VAH, Coral Gables, Fl.	6 yrs.	"
		VAMC, Miami, Fl.	6 yrs.	"
Cr-51	25 mCi	VAH, CORAL Gables, Fl.	13 yrs.	Diagnosis &
		VAMC, Miami, Fl.	16 yrs.	Research
Fe-59	2 mCi	VAH, Coral Gables, Fl.	13 yrs.	Diagnosis
		VAMC, Miami, Fl.	16 yrs.	"
C-14	20 mCi	VAH, Coral Gables, Fl.	13 yrs.	Research
		VAMC, Miami, Fl.	16 yrs.	"
Y-90	20 mCi	VAMC, Miami, Fl.	13 yrs.	"
		VAH, Coral Gables, Fl.	8 yrs.	"
Sr-90 Med. Applicator	100 mCi	VAH, Coral Gables, Fl.	6 yrs.	Wipe Test
		VAMC, Miami, Fl.	23 yrs.	" "
S-35	1 mCi	VAH, Coral Gables, Fl.	13 yrs.	Research
		VAMC, Miami, Fl.	16 yrs.	"
Au-198	50 mCi	VAH, Coral Gables, Fl.	13 yrs.	Therapeutic
		VAMC, Miami, Fl.	10 yrs.	"
Au-198 Seeds	875 mCi	VAMC, Miami, Fl.	3 yrs.	"
I-125 Seeds	60 mCi	VAMC, Miami, Fl.	5 yrs.	"
Xe-133	1 Ci	VAMC, Miami, Fl.	16 yrs.	Diagnosis
Cs-137	.5 mCi	VAMC, Miami, Fl.	16 yrs.	Calibration
In-111	3 mCi	VAMC, Miami, Fl.	12 yrs.	Diagnosis
Ga-67	24 mCi	VAMC, Miami, Fl.	12 yrs.	"
Tc-99m	600 mCi	VAMC, Miami, Fl.	15 yrs.	"
H-3	500 mCi	VAMC, Miam, Fl.	16 yrs.	Research

Except for some diagnostic studies performed in the past as a laboratory technician the above type of use is primarily confined to disposal, storage and receipt of all radionuclides received and used in the Medical Center. This includes some research studies using X-ray and Cobalt machines. Other use of radionuclides includes wipe tests on sealed sources, instrument calibration, and monitoring surgical procedures,etc.

Form AEC-313a
(2-73)
PAGE 3

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—PRECEPTOR STATEMENT

This page is to be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each. Page 2 may be used for comments and additional information.

10. NAME AND ADDRESS OF APPLICANT PHYSICIAN (*Include ZIP Code.*)

Stephen P. Rosenthal, M.D.
Nuclear Medicine Service

V. A. Hospital
1201 N.W. 16 Street, Miami, Fla. 33136

11. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN NAMED IN ITEM 10 ABOVE

(A) ISOTOPE	(B) CONDITIONS DIAGNOSED OR TREATED	(C) No. Cases Observed (See 1 in key below)	(D) No. Cases Involving Personal Participation (See 2 in key below)
I-131 or I-125	Diagnosis of thyroid function	20	50
	Determination of blood and blood plasma volume	10	5
	Liver function studies	5	40
	~~Adrenocortical studies~~ Iodocholesterol Adrenal	--	2
	Kidney function studies	--	50
	In vitro studies	--	50
Cr-51	Gastrointestinal protein loss studies	6	--
	Determination of red blood cell volume and studies of red blood cell survival	10	5
Fe-59	Iron turn over studies	4	--
Co-58or Co-60	Intestinal absorption studies	1	1
~~K-42~~ K-43	Potassium ~~space determinations~~ myocardial imaging	2	--
I-131	Thyroid imaging	--	30
	Brain tumor localization and cardiac imaging	--	1
	Cisternography	--	20
	Lung imaging	--	20
	Liver imaging	--	40
	Kidney imaging	--	50
	Placenta localization	--	--
Cr-51	Placenta localization	--	--
	Spleen imaging	--	--
Au-198	Liver imaging	--	--
Hg-197	Brain imaging	--	--
	Kidney imaging	20	50
Hg-203	Brain imaging	--	--
Sr-85	Bone imaging	--	--
Tc-99m	Brain imaging	--	150
	Thyroid imaging	--	50
	~~Salivary gland imaging~~	--	--
	Blood pool imaging & Cardiac with Tc, Tc albumen microspheres	5	30

APPLICATIO' FOR BYPRODUCT MATERIAL LICENS" -MEDICAL

SUPPLEMENT A—HUMAN USE

(A) ISOTOPE	(B) CONDITIONS DIAGNOSED OR TREATED	(C) No. Cases Observed (See 1 in key below)	(D) No. Cases Involving Personal Participation (See 2 in key below)
Tc-99m	Placenta localization	1	10
	Liver and spleen imaging	--	150
	Lung imaging	--	150
	Bone imaging Pyrophosphate, Polyphos, Diphosphonate	--	100
Xe-133	Blood flow studies and pulmonary function studies	5	30
Se-75	Pancreas imaging	5	30
P-32	Treatment of polycythemia, leukemia, and Bone metastases	--	5
	Intracavitary treatment	3	10
I-131	Treatment of thyroid carcinoma	1	4
	Treatment of hyperthyroidism and cardiac condition	--	40
Au-198	Intracavitary treatment	--	
In-111 DTPA Co-60 or CO-137	~~Interstitial treatment~~ Cisternogram	--	15 2
	Intracavitary treatment	--	--
Ir-192	Interstitial treatment	--	--
Co-60x ~~CO-137~~	GA-67 Scanning for neoplasm and abscesses ~~Intracavitary treatment~~	--	50
Tl-201 ~~Sr-90~~	~~Treatment of eye disease~~ Myocardial Imaging	5	10

Key to Column (C) and (D) above

1. Observation should consist of observing radioisotope administration techniques and discussion with preceptor the case histories to establish most appropriate diagnostic and/or therapeutic procedure, limitation, contraindications, etc.

2. Personal participation should consist of (a) supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation on dosage to be prescribed; (b) collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurements, and plotting of data; and (c) adequate period of training to enable the physician to manage radioactive patients and to follow patients through diagnosis and/or the course of treatment.

12. DATES AND TOTAL NUMBER OF HOURS OF CLINICAL RADIOISOTOPE TRAINING 7/1/73 - 6/31/75 10,400

13. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF August Miale, Jr., M.D.

AT Jackson Memorial Hospital, Miami, Florida (Institution) Name and Address

59-3 (G79) (Byproduct Material License Number)

Above (Signature of Preceptor)

Form AEC-313 a (3-56)
PAGE 3

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A—HUMAN USE

Form approved.
Budget Bureau No. 38-R080.1

This page may be completed by the physician's preceptor (if any) in the medical use of radioisotopes. When the information is not furnished by the preceptor, the name and present address of the preceptor (if any) should be shown in item 12 below.

9. (a) USING PHYSICIAN'S NAME	(b) NAME AND ADDRESS OF APPLICANT (If different from 9(a))
Frank Gollan, M.D.	Veterans Administration Hospital 90 White Bridge Rd., Nashville 5, Tennessee

10. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN WHO WILL USE BYPRODUCT MATERIAL

(A) ISOTOPE	(B) CONDITION(S) DIAGNOSED OR TREATED	(C) NUMBER OF CASES	(D) TYPE OF PARTICIPATION FOR ALL CASES IN COLUMN D (circle applicable numbers of items in accordance with key set forth below)
I-131	Diagnosis of thyroid function	48	(1)(2)(3)(4)
	Treatment of hyperthyroidism	46	(1)(2)(3)(4)
	Treatment of thyroid cancer	3	(1)(2)(3)(4)
	Treatment of cardiac conditions	10	(1)(2)(3)(4)
	Brain tumor localization	22	(1)(2)(3)(4)
	Blood determinations	38	(1)(2)(3)(4)
	Others:		1 2 3 4
			1 2 3 4
P-32 Soluble	Treatment of polycythemia and leukemia	10	(1) 2 (3)(4)
	Brain tumor localization	4	(1)(2)(3)(4)
	Treatment of bone metastases		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
P-32 $CrPO_4$	Treatment of prostatic cancer	4	( )(2)(3)(4)
	Treatment of cervical cancer		1 2 3 4
	Treatment of pleural effusions and/or ascites	10	(1)(2)(3)(4)
	Others:		1 2 3 4
			1 2 3 4
Au-198 Colloid	Treatment of prostatic cancer	14	1 (2) 3 (4)
	Treatment of cervical cancer		1 2 3 4
	Treatment of pleural effusions and/or ascites	18	1 (2) 3 (4)
	Others:		1 2 3 4
			1 2 3 4
Cr-51	Blood determinations		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
Other Isotopes			1 2 3 4
			1 2 3 4
			1 2 3 4

Key to above numbers (column D) Active Participation and Discussion

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

11. TOTAL NUMBER OF HOURS OF PARTICIPATION IN CLINICAL TRAINING 3 years hours

12. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OR GUIDANCE OF

W.L. Alsobrook, M.D. (Name of physician (preceptor)) AT VAH, Nashville 5, Tenn. (Institution) _____ (Signature)

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A—HUMAN USE

Form approved.
Budget Bureau No. 38-R080.1

This page may be used for providing additional information.

In addition to formal training in the use of radioisotopes clinically and therapeutically, Dr. Frank Gollan has completed a two week advanced course in Radioisotopes in Medicine at the Oak Ridge Institute of Nuclear Studies.

U.S. GOVERNMENT PRINTING OFFICE: 1960 O - 568572

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

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Komanduri K.N. Charyulu, M.D. (UPDATED TO PRESENT)	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Osmania University, India	Medical Radiology	Feb. 1959 (DMR)
Royal College of Physicians and Surgeons, England	Medical Radiotherapy	Mar. 1960 (MMRT)
Royal College of Radiologists	Radiation Therapy	Mar. 1961 (FRCR)
American Board of Radiology	Therapeutic Radiology	1970 (DABR)

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	1. Radium Institute, Hyderabad, India, 1955 1957	200	125
	2. London Hospital, London 1959 - 1961	180	130
b. RADIATION PROTECTION	1. Same as above	20	18
	2. " " "	22	14
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	1. " " "	180	320
	2. " " "	60	150
d. RADIATION BIOLOGY	1. " " "	58	26
	2. " " "	62	32
e. RADIOPHARMACEUTICAL CHEMISTRY			

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Radium	600 mg.	Radium Institute, Hyderabad, India	1955 - 1959	Intercavitary Interstitial
Radium	1,000 mg.	London Hospital, London	1959 - 1961	"
Radon	40 mCi	" " "		"
Radon	30 mCi	University Of Minnesota Hospital, Minneapolis, MN.	7 years (1964 - 1970)	" Intercavitary
Radon	30 mCi	Jackson Memorial Hospital Miami, Fla.	9 1/2 years (1970 - 1980)	Interstitial Intercavitary

5. EXPERIENCE WITH RADIATION

Isotope	Maximum Amount	Where Experience Was Gained	Duration	Type of Use
Radon	30 mCi	VA Medical Center, Miami	1980 -	Intercavitary
Radium	500 mg.	University of Minnesota Hospital, Minneapolis, MN	1964- 1970	"
Radium	600 mg	Jackson Memorial Hospital Miami, Fla.	1970 1980	Interstitial
A Gold 198	87 mCi	V A Medical Center Miami, Fla.	1980 -	"
Iodine 125	30 mCi	V A Medical Center	1980 -	"
Radon	30 mCi	V A Medical	1980 -	"

PRECEPTOR STATEMENT *(Continued)*

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

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	25	
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT	10	
I-131	TREATMENT OF THYROID CARCINOMA	10	
	TREATMENT OF HYPERTHYROIDISM	25	
Au-198	INTRACAVITARY TREATMENT	30	
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT	100	
Co-60 or Cs-137	TELETHERAPY TREATMENT	> 10,000 new patients	
Sr-90	TREATMENT OF EYE DISEASE	250	
Yb-169	RADIOPHARMACEUTICAL PREPARATION	35	
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other Rn-222 Ra-226 Au-198	 Interstitial Treatment Interstitial Treatment Interstitial Treatment	 120 3100 30	

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

1955 to 1961 280 hours

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

a. NAME OF SUPERVISOR
H. Syed Ali & Walter Shanks

b. NAME OF INSTITUTION
Red Hills, Hyderabad, India
White Chapel, London, England

c. MAILING ADDRESS
Hyderabad, India Radium Institute
London Hospital London, England

d. CITY
Hyderabad, India
London, England

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE
Not Available

7. PRECEPTOR'S NAME *(Please type or print)*
H. Syed Ali
Walter Shanks

8. DATE

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

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

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

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

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME
Komanduri K.N. Charyulu, M.D.

STREET ADDRESS
V.A. Medical Center
1201 N.W. 16th Street

CITY | STATE | ZIP CODE
Miami | Fla. | 33125

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

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

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

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

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

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

INSTRUMENTATION

1. Survey Meters

a. Manufacturer's name: Eberline Instrument Corporation

Manufacturer's model number: E500B

Number of instruments: 1

Minimum range: .01 mr/hr to .20 mr/hr

Maximum range: 200 mr/hr to 2000 mr/hr

b. Manufacturer's name: Eberline Instrument Corporation

Manufacturer's model number : Digital Ion Chamber RO-4B

Number of instruments available: 1

Minimum range: 0.1 mr/hr to 1999 mr/hr (low rate)

Maximum range: 0.01 mr/hr to 199.9 mr/hr (high rate)

c. Manufacturer's Name : Eberline Instrument Corporation

Manufacturer's model number: E-120E

Number of instruments available: 1

Minimum range: 500 CPM to

Maximum range: 50K CPM

d. Manufacturer's Name: Nuclear Associates

Manufacturer's model number: 05-571

Number of instruments available: 1

Minimum range: 0 mr/hr to 10 mr/hr

Maximum range: 0 mr/hr to 1000 mr/hr

e. Manufacturer's Name: Victoreen, Inc.

Manufacturer's model number: 740F "Cutie Pie"

Number of instruments: 1

Minimum range: 0 mr/hr to 25 mr/hr

Maximum range: 0 mr/hr to 25K mr/hr

f. Manufacturer's name: Nuclear Chicago Corporation

Manufacturer's model number: 2650

Number of instruments available: 1

Minimum range: 0.1 mr/hr to 10 mr/hr

Maximum range: 1000 mr/hr to 10000 mr/hr

g. Manufacturer's name: Victoreen Instrument Division

Manufacturer's model number Radocon II 555

Number of instruments available: 1

Minimum range: 3 mr/minto 300 mr/min

Maximum range: 1 R/min to 10 R/min

h. Manufacturer's name: International Crystal Mfg. Co. Inc.

Manufacturer's model number; Microdek 310 Leakage Meter

Number of instruments available: 1

Minimum range: 1 MW/Cm^2 to 6 MW/Cm^2

Maximum range: 1 MW/Cm^2 to _____ MW/Cm^2

2. Dose Calibrator

Manufacturer's name: Capintec, Inc.

Manufacturer's model number: CRC 10

Number of instruments available: 1

3. Instruments used for diagnostic procedures:

Type of Instrument	Manufacturer's Name	Model No.
Dyna-Camera System	Picker Internatinnal	Series 5
Scintillation Camera System	Ohio-Nuclear	Series 100
Scintillation Camera System	Searle	Pho/Gamma
^{133}Xe Ventil-Con	Radx	
Ultrasonic System	Picker-Nuclear	
Ultrasonic System	Technicare	

Stress Table with Ergometer

4. Other

Spectroscaler Counting System	Picker	4R
Analytic Counting System	Tracor	Gamma Trac 1191
Multi-Prias 4 Counting System	Packard	
PrimeAlert 35 Area Monitor	Nuclear Asscoiates	Mdl. 05-437
Apple Computer System		
Medical Data Computer	MDS	
Lamniflow Hood		

Assosted remote handling devices, lead-lined gloves, shielded syringes, storage containers, etc.

CALIBRATION OF INSTRUMENTS

Section 1

METHODS FOR CALIBRATION OF (X- AND GAMMA-RAY) SURVEY METERS, INCLUDING PROCEDURES, STANDARDS, AND FREQUENCY

A. Calibration of survey meters will be performed with radionuclide sources.

1. The sources will be approximate point sources.

2. The source activities or exposure rates at given distances shall be traceable by documented measurements to a standard source certified within 5 percent accuracy to the U.S. National Bureau of Standards (NBS) calibrations.

3. The frequency will be at least annually and after each servicing.

4. Each scale of the instrument will be calibrated at least at two points located at approximately 1/3 and 2/3 of full scale.

5. The exposure rate measured by the instrument will differ from the true exposure rate by less than 10 percent at the two points on each scale. Readings within ± 20 percent will be considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret meter reading to within 10 percent for radiation protection purposes.

B. A reference check source of long half-life, e.g, Cs-137 or Ra D and E, will also be read at the time of the above calibration or as soon as the instrument is received from a calibration laboratory. The readings will be taken with the check source placed in specific geometry relative to the detector. A reading of this reference check source will be taken:

1. Before each use and also after each survey to ensure that the instrument was operational during the survey.

2. After each maintenance and/or battery change, and as required.

3. At least quarterly.

Any reading with the same geometry not within ± 20 percent of the reading measured immediately after calibration will necessitate recalibration of the instrument.

C. Instruments used for lower energies will be calibrated to the need.

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

X 1. Survey instruments will be calibrated at least annually and following repair.

X 2. Calibration will be performed at two points on each scale used for radiation protection purposes, i.e., at least up to 1 R/hr.

The two points will be approxomately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ± 10 percent of the calculated or known values for each point checked. Readings within ± 20 percent are considered acceptable if a calibrated chart, graph, or response factor is prepared, attached to the instrument, and used to interpret readings within ± 10 percent. Also when higher scales are not checked or calibrated, an appropriate precautionary note will be posted on the instrument.

3. Survey instruments will be calibrated

____ a. By the manufacturer

X b. At the licensee's facility

(1) Calibration source

Manufacturer's name Eberline Ins. Corp. Nuclear Associates Victoreen Inc. Nuclear-Chicago inc.

Model no. CS7A CS10 2650 ICN-Sr90

Activity in millicuries (CS7A)= .008 Cs-137 (CS10)= .01 Cs-137 (2650)= .06 Ra-226 (ICN Sr90)= .005 Sr-90

Accuracy Eberline #E120E Sr-90 Approx. 45 %; Tc-99 Approx. 30 % & C-14 Approx. 10 % RO-4 Approx. 90 % 740F Approx. 10 % Others at Approx. 10 %

Traceability to primary standard 100 %

X (2) The calibration procedures in Section I of Appendix D will be used.

X c. By a consultant or outside firm

(1) Name Gary Beck, Physicist , REM Enterprises

(2) Location 8001 S.W. 163 St. Miami, Fla. 33157

(3) Procedures and sources

-- X -- have been approved by NRC and are on file in License No. 09-00239-06 Amendment NO. 62

(4) Certificates of Instrument Calibration are maintained in the files of the Radiation Safety Officer.

Section 2

METHODS FOR CALIBRATION OF DOSE CALIBRATOR

All radiopharmaceuticals must be assayed for activity to an accuracy of 10 percent. We accomplish this by use of an ionization type dose calibrator. The instrument must be periodically checked for accurate operation as follows:

A. Test for the following:

1. Instrument constancy (daily)

2. Instrument accuracy (at installation and at least annually)

3. Instrument linearity (at installation and at least annually)

4. Geometrical variation (at installation)

B. After repair or adjustment of the dose calibrator, all of the appropriate tests listed above will be repeated (dependent upon the nature of the repairs.

C. Daily

1. Measure and record the activity of at least one reference source (Co-57 or Cs-137). This check will be repeated during the day whenever sample readings are not within 10 percent of the anticipated assay. Variation greater than 5 percent in this test will indicate the need for instrument repair, adjustment or recalibration.

D. Weekly

1. Measure and record the apparent activity of a long-lived standard radionuclide (Cs-137) at all of the commonly used radionuclide settings (when the unit was first calibrated against NBS-traceable standards).

E. Quarterly

1. Inspect the instrument to ascertain that the measurement chamber liner is in place and that instrument zero is properly set.

9. Replace yellow tube with green tube. Record.
10. Replace green tube with blue tube. Record.
11. Replace blue tube with purple tube. Record.
12. Remove the Calicheck assembly and place source in a shielded container. Place Calicheck in storage container provided.

DATA TREATMENT OF DATA SHEET #1:

1. Divide the numerator by the denominator in Column B to determine the Calibration Factor, and record in Column C. **Retain these values for future reference.** These factors will be used for all future activity linearity tests provided **all** conditions of the test are met (i.e., **same** dose calibrator, **same** kit, **same** radionuclide, **same** source configuration). Recalculation will be required following repair of dose calibrator or Calicheck.
2. Compare results to chart of "Typical Calibration Factors" on page 9. Differing values may be due to variations in geometry, in the response of the dose calibrator and/or in the kit manufacturing process itself.
3. Transfer determined Calibration Factors from Data Sheet #1 to appropriate place in Column C of Data Sheet #2. (See example on page 13.) To confirm the accuracy of the determined factors, complete Data Sheet #2. If no error has been made, all values in Column D (product of B x C) should be the same. If values differ, repeat the determination.

DATA SHEET #1: *(To be completed only ONCE)**

Kit Calibration

All readings must be taken at lowest range setting available and converted to mCi units.

TUBES		DISPLAYED ACTIVITY		CALIBRATION FACTORS
A		B		C
Black Only / Black Only	=	mCi / mCi	=	1.00
Black Only / Black & Red	=	mCi / mCi	=	
Black Only / Black & Orange	=	mCi / mCi	=	
Black Only / Black & Yellow	=	mCi / mCi	=	
Black Only / Black & Green	=	mCi / mCi	=	
Black Only / Black & Blue	=	mCi / mCi	=	
Black Only / Black & Purple	=	mCi / mCi	=	

SOURCE CONFIGURATION

_____ Syringe

_____ Vial

*Or following repair of dose calibrator or Calicheck Kit. In all instances these factors can only be determined following proof of activity linearity by standard techniques. **KEEP THIS FORM FOR FUTURE REFERENCE!**

DATA SHEET #2 *(to be completed each quarter)*

Dose Calibrator Activity Linearity Check

Dose Calibrator _____ Date _____

Model _____ Technologist _____

Source Configuration _____ *(must be same as on Data Sheet #1)*

All readings must be taken at lowest range setting available and converted to mCi units.

A	B		C		D
TUBE COLOR	**DISPLAYED ACTIVITY**		**CALIBRATION FACTOR**		**PRODUCT OF B X C**
Black Only:	_____ mCi	X	1.00	=	_____
Black & Red:	_____ mCi	X	_____	=	_____
Black & Orange:	_____ mCi	X	_____	=	_____
Black & Yellow:	_____ mCi	X	_____	=	_____
Black & Green:	_____ mCi	X	_____	=	_____
Black & Blue:	_____ mCi	X	_____	=	_____
Black & Purple:	_____ mCi	X	_____	=	_____
			SUM	=	_____

$$\text{MEAN} = \frac{\text{SUM}}{7} = \text{_____}$$

MEAN X 1.05 = _____ = UPPER LIMIT*

MEAN X 0.95 = _____ = LOWER LIMIT*

Compare Column D data to upper and lower limits to confirm linearity.

*Instead of a variation in the Column D data of ±5%, your radioactive material license may allow a difference of ± 10% in the test results. If so, multipliers of 1.10 and 0.90 can be used to determine the upper and lower limits.

Example

A Mo/Tc generator is eluted and yields 342 mCi. The entire elution is placed in the dose calibrator inside the black tube. Subsequent readings generated the following data.

Dose Calibrator Activity Linearity Check

All readings were taken at lowest range setting available and converted to mCi units.

A	B		C		D
TUBE COLOR	**DISPLAYED ACTIVITY**		**CALIBRATION FACTOR**		**PRODUCT OF B X C**
Black Only:	342 mCi	X	1.00	=	342
Black & Red:	201 mCi	X	1.72	=	346
Black & Orange:	106 mCi	X	3.23	=	342
Black & Yellow:	34.1 mCi	X	9.53	=	325
Black & Green:	10.2 mCi	X	29.5	=	301
Black & Blue:	3.54 mCi	X	96.6	=	342
Black & Purple:	1.19 mCi	X	305	=	363
			SUM	=	2361

$$\text{MEAN} = \frac{2361}{7} = 337$$

MEAN X 1.05 = 354 = UPPER LIMIT*

MEAN X 0.95 = 320 = LOWER LIMIT*

The readings for the **green** and **purple** tubes are outside the limits. The procedure should be repeated to confirm the data. Repair may be indicated. Failure to account for a re-zeroing problem between ranges *(see Procedure Step #3)* or an unstable background may also have produced this apparent non-linearity.

F. Test of Instrument Linearity

The linearity of the dose calibrator will be ascertained over the entire range of activities employed. This test will utilize a vial of Tc-99m whose activity is equivalent to the maximum anticipated activity to be assayed.

A Calicheck kit, designed to perform the activity linearity on a dose calibrator quickly and accurately, will be utilized. The kit consists of seven tubes, six of which are lead-lined to attentuate gamma radiation from radioactive sources, and a seventh, unlined tube. Each lead-lined tube varies in the thickness of lead so as to simulate various stages of radioactive decay, representing values that would have been obtained at approximately 0, 6, 12, 20, 30, 40, and 50 hours after the initial assay of Tc-99m.

Procedure

1. Remove any syringe hanger or chamber liner, if necessary, from the dose calibrator.

2. Set dose calibrator to measure Tc-99m.

3. Adjust zero, background, etc., if applicable. Check zero on each range. If background is not zero on all ranges, zero on one range and record values on all other ranges to add or subtract from final results when those ranges are used.

4. Place source to be used for the linearity procedure into the black tube and insert tube into the dose calibrator CAREFULLY with the open end in the upward position.

5. Record "displayed activity" on "BLACK ONLY" on Data Sheet #2 "Dose Activity (Calibrator) Linearity Check", (attached).

6. Carefully ensure that, in the following steps, each tube is firmly seated against the lead at the base of the black tube.

7. Place red tube in the dose calibrator over the balck tube. Record "displayed activity" on "Black & Red" blank on Data Sheet #2.

8. Replace red tube with orange tube. Record on "Black & Orange" blank.

9. Replace orange tube with yellow tube. Record on "Black & Yellow" blank.

10. Replace yellow tube with green tube. Record on Black & Green" blank.

11. Replace green tube with blue tube. Record on "Black & Blue" blank.

12. Replace blue tube with purple tube. Record on "Black & Purple" blank.

13. Remove C[illegible]ck assembly and place source in shielded container.

Data Treatment of Data Sheet #2

1. Enter appropriate Calibration Factors from Data Sheet #1 for your dose calibrator in Column C. (attached)

2. Multiply the value in Column B by the corresponding value in Column C to determine product of each entry for Column D. Record values. (Ideally, these values will be the same.)

3. Add all products in Column D and divide by 7 to determine the mean value. Multiply the mean by 1.05 and 0.95 as indicated. These define the upper and lower limits of $\pm$ 5 % variation.

If all values in Column D fall between these two limits, your dose calibrator has acceptable activity linearity.

G. Test for Geometrical Variation

There may be significant geometrical variation in activity measured as a function of sample volume or configuration, depending on the volume and size of the ionization chamber used in the dose calibrator. The extent of geometrical variation will be ascertained for commonly used radionuclides and appropriate correction factors computed if variations are significant, i.e., greater than $\pm$ 2 % (even though correction factors may be provided by the manufacturer, the accuracy of these should be checked).

To measure variation with volume of liquid, an appropriate radionuclide in a volume of 0.5 ml will be used. (This procedure will be performed on all commonly used radionuclides.)

1. Assay vial at the appropriate instrument setting and subtract background level to obtain net activity.

2. Increase the volume of liquid in the vial in steps to 1, 2, 4, 8, 10, 20, and 25 ml by adding the appropriate amount of water or saline. After each addition, gently shake vial to mix contents and assay as in step one. Make decay calculations if applicable.

3. Use 2 ml as the reference volume activity and calculate the ratio of measured activities for each volume to the reference volume activity. This represents the volume correction factor.

   Example: If activities of 2.00, 2.04, and 2.02 mCi are measured for 2, 4, and 8 ml volumes and 2 ml is the reference volume, then

$$4 \text{ ml Volume CF} = \frac{2.00}{2.04} = 0.98$$

4. Plot the correction factors against the volume on linear graph paper. Use this graph to select the proper volume correction factors for routine assay of that radionuclide.

5. The true activity of a sample is calculated as follows:
   True Activity = Measured Activity x CF
   Where the CF used is for the same volume and geometrical configuration as the sample measured.

The stock vial for lower energy radionuclides such as I-125 will be assayed before and after filling the syringe. The activity in the syringe is then the difference in the two readings (with a volume correction if significant). This is an alternate to providing syringe correction factors.

H. Test for Instrument Accuracy

The accuracy of the dose calibrator will be checked with several radionuclides, such as Cs-137 and Co-57 reference standards, whose activities are traceable to NBS. The activity levels of the reference sources used will approximate those levels normally encountered, giving adequate attention to source configuration.

1. Assay the reference standard in the dose calibrator at the appropriate setting and subtract the background level to obtain the net activity.

2. Repeat step 1 for a total of 5 determinations and average results.

3. The average activity determined in step 2 should agree with the certified activity of the reference source within $\pm$ 5 % after decay corrections.

4. Repeat the above steps for other commonly used radionuclides for which adequate reference standards are available.

5. Keep a log of these calibration checks.

6. Calibration checks which do not agree within $\pm$ 5 % indicate that the instrument should be repaired or adjusted. If this is not possible, a calibration factor should be calculated for use during routine assays of radionuclides.

7. At the same time the instrument is being initially calibrated with the NBS-traceable standards, place a long-lived source in the calibrator, set the instrument, in turn, at the various radionuclide settings used (Cs-137, I-131, Tc-99m, I-125, etc.) and record the readings. These values may later be used to check instrument calibration at each setting (after correcting for decay of the long-lived source), without requiring more NBS-traceable standards. Keep a log of these initial and subsequent readings.

I. Test for Instrument Constancy

A reference source such as Co-57 will be assayed using a reproducible geometry before each daily use of the instrument. This procedure will be repeated weekly with a long-lived source such as Cs-137 for all of the commonly used radionuclide settings.

1. Assay the reference source using the appropriate instrument setting.

2. Measure background level at the same instrument setting.

3. Calculate net activity of each source subtracting the background level.

4. Log the background levels.

5. Calculate the percent difference from assayed activity vs. calculated activity.

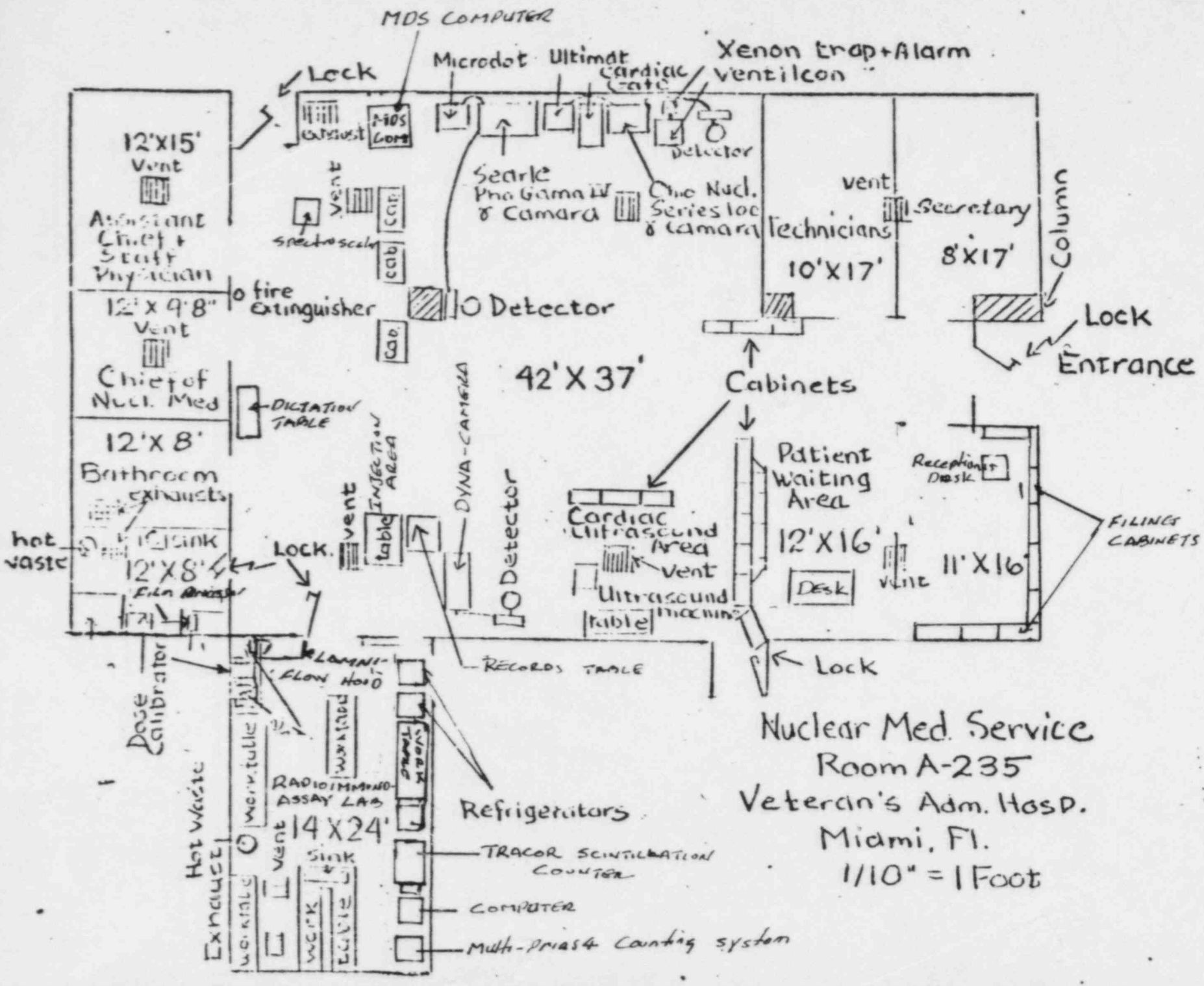
   Example: If the activity of the assayed source is 2.02 mCi, and the calculated activity of the source is 2.04 mCi, the,

$$\% \text{ Difference} = \frac{2.04 - 2.02}{.02} \quad \frac{.02}{2.04} \times 100 = 1.0\ \%$$

6. Assayed activity must be within $\pm$ 5 % of calculated source activity.

7. Variations greater than $\pm$ 5 % from the predicted activity indicate the need for instrument repair or adjustment.

8. Higher than normal background levels should be investigated to determine their origin and eliminated if possible by decontamination, relocation, etc.


MDS COMPUTER
Lock
Microdot
Ultimat
Cardiac Cath
Xenon trap+Alarm
Ventilcon
12'X15'
Vent
Assistant Chief + Staff Physician
12' x 9'8"
Vent
Chief of Nucl. Med
12'X8'
Bathroom exhausts
hot waste
sink
12'X8'
Lock
Fan
Dose Calibrator
Hot Waste
Exhaust
Vent
Sink
Work table
Fan
Work table
RADIOIMMUNO-ASSAY LAB
14'X24'
Refrigerators
TRACOR SCINTILLATION COUNTER
COMPUTER
Multi-Prism 4 Counting system
LAMINI-FLOW HOOD
RECORDS TABLE
Searle Pho Gamma IV & Camara
Ohio Nucl. Series 100 & Camara
Detector
fire extinguisher
Detector
Vent
Spectroscaler
Cab
Cab
Cab
42'X37'
DICTATION TABLE
Vent
Table
INJECTION AREA
DYNA-CAMERA
Detector
Cardiac Ultrasound Area
Vent
Ultrasound machine
Table
Cabinets
Patient Waiting Area
12'X16'
Desk
Vent
Technicians
10'X17'
Vent
Secretary
8'X17'
Column
Lock
Entrance
Reception Desk
11'X16'
FILING CABINETS
Lock
Nuclear Med. Service
Room A-235
Veteran's Adm. Hosp.
Miami, Fl.
1/10" = 1 Foot

PERSONNEL TRAINING PROGRAM

The personnel radiation training program includes all the employees in Nuclear Medicine Service, the Research Service, Nursing Service, Physicians, and other ancillary personnel who may on occasions be exposed to sources of radiation.

The Chief of Nuclear Medicine Service conducts bi-weekly orientation tours involving human uses of radiopharmaceuticals and brachytherapy sources to all new employees. The main focus of these classes is to present:

1. An overview of the human use of radiopharmaceuticals in the Medical Center and the licenses and regulations governing their use

2. Instructions in biological effects of radiation and the associated risks in work areas

3. Instruction in radiation safety measures to minimize radiation exposure

4. Managements commitment to ALARA and

5. Constant reviews of instrumentation and methodology in Nuclear Medicine on a continuing basis.

The Radiation Safety Officer conducts monthly orientation classes for new employees, periodic refresher classes, and in-house lectures to all employees in groups.

The primary focus of these classes is an introduction to radiation safety, radiation exposure, the risks and hazards associated with exposure to sources of radiation, and for the most part is broad based to include personnel actively engaged in work involving the use of radioactive materials and radiation sources, and the need for film badges, isolation of patients when they are hospitalized for infectious disease.

The objective of the program is:

1. To provide instructions in instrumentation, with demonstrations of the various types of radiation detecting instruments and their use

2. To provide instructions about the various types of radiation and the biological effects of occupational exposure to each

3. To provide instructions in the use of protective measures to reduce exposure to harmful radiation, e.g., the use of shielding, protective clothing, and adherence to time and distance instructions

4. To provide instructions in safe handling and disposal of radioactive materials.

5. To provide instructions in patient care during radiation therapy

6. To acquaint personnel with license regulations and guidelines governing the use of radioactive materials, and

7. To inform all personnel of managements commitment to ALARA

8. To inform of the proper need for wearing various film and finger badges.

17941

PROCEDURES FOR ORDERING AND ACCEPTING DELIVERY OF RADIOACTIVE MATERIAL

1. Nuclear Medicine Service Technologists and the Radiation Safety Officer will place all orders for radioactive materials and assure that the requested materials, chemical form and quantities are authorized by license and that posession limits are not exceeded.

2. Routinely used materials on a standing order basis are delivered to the Nuclear Medicine Service in prepared unit doses periodically during the day. Written records identifying the radiopharmaceutical, activity, supplier, etc., are maintained in duplicate.

3. Therapeutic doses of radiopharmaceuticals are ordered only by instructions from the Chief, Nuclear Medicine Service, on a signed prescription which identifies the patient by name and social security number, the chemical form and activity.

4. Orders for radioactive materials to be used in laboratory research and in vitro studies are approved by the Radiation Safety Officer to assure license compliance and then placed through the normal procedures of ordering supplies.

5. During normal working hours carriers deliver packages containing radioactive materials to the Supply Service where they are received then delivered directly to the Nuclear Medicine Service or the Radiation Safety Officer.

6. During off-duty hours security personnel will accept delivery of radioactive material packages in accordance with the procedures outlined in the attached memorandums.

VETERANS ADMINISTRATION MEDICAL CENTER
MIAMI, FLORIDA

MEDICAL CENTER POLICY MEMORANDUM August 5, 1982

NO.----------115-6-82

DELIVERY OF RADIOACTIVE MATERIALS

I. PURPOSE

To establish procedures for accepting delivery of packages containing radioactive materials in accordance with NRC regulations.

II. POLICY

The Chief, Police Section, Chief, Supply Service and Chief, Medical Administration Service will assure that the procedures set forth in this memorandum will be followed by all personnel under their jurisdiction.

III. DEFINITIONS

This memorandum applies to all personnel involved in the receipt of packages containing radioactive materials delivered to the Medical Center.

IV. RESPONSIBILITIES

a. During the normal tour of duty (8:00 a.m. to 4:30 p.m. Monday thru Friday) all packages containing radioactive materials will be delivered by the vendor to the Receiving Section of Supply Service. Upon receipt of the shipment, Supply Service will deliver the materials to the Radiation Safety Officer in Room C-238 or to Nuclear Medicine Service, Room A - 235, according to the delivery instructions on the purchase order (VAF-2237).

b. Packages containing radioactive materials that arrive between the hours of 4:30p.m. and 8:00 a.m. daily and on Saturdays, Sundays, and holidays shall be signed for by the Medical Administration Assistant on duty; the MAA shall notify the Police of the arrival of the package. The Police only will deliver packages that need refrigeration to Room A 235 B. All other packages are stored in Room D 150. Nuclear Medicine personnel will pick up packages on the next duty day.

c. Packages requiring refrigeration, upon receipt by the Police, will be placed in the refrigerator in Room A 235 B, adjacent to the work bench. In each such instance, Nuclear Medicine will advise the Chief, Storage and Distribution Section, Supply Service of such deliveries on or before 10:00 a.m. of the first work day following delivery, so that the proper receipts and paperwork can be processed by Supply Service for vendor payment.

d. No radioactive packages will be placed in the Laboratory Service refrigerator or any other refrigerator than the one specified.

V. PROCEDURES

Adequately covered under Responsibilities.

VI. OTHER

None

VII. REFERENCES

1. Code of Federal Regulations, Title 10. Part 20.

2. NRC Regulatory Guide No. 10.8.

3. VAMC Handbook of Radiation Safety

VIII. RECISSIONS

None

IX. FOLLOW-UP RESPONSIBILITY

Chief, Police Section, Medical Administration Service, Chief, Nuclear Medicine Service and Radiation Safety Officer.

X. This Medical Center Policy Memorandum will remain in effect until rescinded.

T. C. DOHERTY
Director

Distribution: A & X
X=10 to (115)

VETERANS ADMINISTRATION MEDICAL CENTER
Miami, Florida 33125
NUCLEAR MEDICINE SERVICE

RECEIPT OF RADIOACTIVE MATERIALS
(Research Service)

1. During regular duty hours (8:00 A.M. - 4:30 P.M.) all radioactive materials for Research Service will be delivered to the Radiation Safety Officer, Robert Cobb, in Room C-238 for initialling of 2237 as having been received.

2. Packages will be visually checked for spillage or damage.

3. Packages will be opened and checked for accuracy of contents, radionuclide, activity and chemical form, making certain that packing slip agrees with contents. Retain packing slip for records.

4. Package will then be delivered to ordering department.

5. In the event the R.S.O. is absent from duty (annual or sick leave) all packages will be delivered to Nuclear Medicine Service (Room A-235) for initialling by Gonzalo Vuelta or Dr. Chandarlapaty. If neither is available shipment may be received by someone in the department who is authorized to sign for purchases.

6. Steps 2 and 3 will be followed at all times.

7. Record shipment into record book, "Research Radionuclide Receipt". Investigator will be found on purchase order (2377) next to delivery location (C238).

8. Inform Mrs. Drugash in the Research Office, phone 3446, that a shipment has been received and ask for information regarding pickup.

9. Packages received after regular duty hours (4:30 P.M. - 8:00 A.M.), on weekends, and holidays will be checked as soon as possible on the next duty day, shipment of receipt recorded and Mrs. Drugash contacted.

10. SHIPMENT PACKED IN DRY ICE WILL BE CHECKED AND RETURNED TO DRY ICE AS SHIPPED.

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Special requirements will be followed for packages containing quantities of radioactive material in excess of the type A quantity limits as specified in paragraphs 20.205(a)(1) and (c)(1) of 10 CFR Part 20. They will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during normal working hours or within 18 hours if received after normal working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). All shipments of liquids greater than exempt quanitities will be tested for leakage. The NRC Regional Office will ne notified in accordance with the regulations if removable contamination exceeds 0.01 $\mu Ci/100\ cm^2$ of if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 feet (or 1 m).

2. For all packages, the following additional procedures will be followed for opening packages:

   a. Put on disposable gloves to prevent hand contamination.

   b. Visually inspect the package for any sign of damage (e.g., wetness, crushed, etc.). If damage is noted, stop procedure and notify the Radiation Safety Officer.

   c. Measure the exposure rate at 3 feet from the surface of the package and record. Stop the procedure and notify the Radiation Safety Officer if the rate is > 10 mR/hr.

   d. Measure the surface exposure rate and record. Stop the procedure and notify the Radiation Safety Officer if the rate is > 200 mR/hr.

   e. Remove packing slip from outer envelop. Open the outer package and inspect. Open inner package to verify contents (compare requisition, packing slip, and label on container.

   f. Check integrity of final source container (i.e., inspect for breakage of seals or container, loss of liquid, discoloration of packing material).

   g. Check to assure possession limits are covered in license.

   h. Wipe external surface of final source container and remove wipe to a low background area. Assay the wipe and record the amount of removable radioactivity. Count wipes in scintillation counter and record results.

   i. Monitor the packing material and packages before discarding, and handle as either radioactive or non-radioactive. Obliterate radiation labe.

3. Maintain records of the results of checking each package, using "Radioactive Shipment Receipt Record".

RADIOACTIVE SHIPMENT RECEIPT REPORT

1. P.O. # _____ SURVEY DATE _____ TIME _____

   SURVEYER _____

2. CONDITION OF PACKAGE:

   _____ O.K. _____ PUNCTURED _____ STATUS _____ WET

   _____ CRUSHED _____ OTHER _____

3. RADIATION UNITS OF LABEL: _____ UNITS (mr/hr)

4. MEASURED RADIATION LEVELS: a. Package Surface _____ mr/hr

   b. 3 ft from Surface _____ mr/hr

5. DO PACKING SLIP and VIAL CONTENTS AGREE?

   a. Radionuclide _____ Yes _____ No _____ No Difference

   b. Amount _____ Yes _____ No _____ No Difference

   c. Chem Form _____ Yes _____ No _____ No Difference

6. WIPE RESULTS FROM: a. Outer $\frac{\text{\_\_\_\_\_ CPM}}{\text{eff} = (\quad)}$ = _____ DPM

   b. Final source container $\frac{\text{\_\_\_\_\_ CPM}}{\text{eff} (\quad)}$ = _____ DPM

7. WIPE RESULTS: μCi wipe ($0.01\ \mu Ci/100\ cm^2$) = $\frac{\mu Ci \text{ of std} \times \text{cpm of wipe}}{\text{cpm of std}} = \frac{(\quad \mu Ci) \times (\quad)}{(\quad)}$

   =

8. SURVEY RESULTS OF PACKING MATERIAL AND CARTONS _____ mr/hr

   _____ CPM

9. DISPOSITION OF PACKING AND PACKAGE AFTER INSPECTION _____

10. IF NRC/CARRIER NOTIFICATION REQUIRED, GIVE TIME, DATE AND PERSONS NOTIFIED

    _____ _____

GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

1. Wear laboratory coats, or protective clothing at all times in areas where radioactive materials are used.

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

3. Monitor hands and clothing for contamination after each procedure or before leaving the area.

4. Use syringe shields for preparation of patient doses and administration to patients except in circumstances, such as pediatric cases, where their use would compromise the patient's well-being.

5. Do not eat, drink, smoke or apply cosmetics in any area where radioactive materials are stored and used.

6. Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10 %.

7. Wear personnel monitoring devices (film badges, dosimeters, etc.) at all times while in areas where radioactive materials are used or stored.

8. Wear TLD finger badges during elution of generators and preparation, assay and the injection of radiopharmaceuticals.

9. Never pipette by mouth.

10. Dispose of radioactive waste only in specially designated receptacles.

11. Survey generators, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.

12. Confine radioactive solutions in covered containers plainly identified and labeled with the name of the compound, radionuclide, date, activity, and radiation level if applicable.

13. Always transport radioactive materials in well shielded containers.

14. WHEN ADMINISTERING THERAPEUTIC DOSES OF RADIOPHARMACEUTICALS always check the patient's name, social security number, the radionuclide, the chemical form and the activity, and have this information verified by the chief of Nuclear Medicine or his designate.