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

Newcomb Medical Center (formerly Newcomb Hospital)
65 South State Street
Vineland, New Jersey 08360

TELEPHONE NO.: AREA CODE (609) 691 - 9000

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

Same

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Julie George

TELEPHONE NO.: AREA CODE ( ) Same

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. ☒ RENEWAL OF LICENSE NO. 29-03438-01

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*

Refer to Item 8, attached

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.)*

Ernest B. Go, M.D.

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		
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 Curies
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		

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

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

RECEIVED BY LFMB
Date 3/21/85
Log Mar-15
By
Orig. To

Applicant
Check No. 114200
Amount/Fee Category 150A-7C
Type of Fee Renewal
Date Check Rec'd 3/21/85
Received By

"OFFICIAL RECORD COPY"
ML10 03537

NRC FORM 313M (9-81)

Amdt. Complete 3/21/85

8507030640 850611
REG1 LIC30
29-03438-01 PDR

MAR 15 1985

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	**15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL** *(Check One)*
☐ Names and Specialties Attached; and	☐ Appendix G Rules Followed; or
☐ Duties as in Appendix B; or *(Check One)*	X Equivalent Rules Attached
X Equivalent Duties Attached	**16. EMERGENCY PROCEDURES** *(Check One)*
8. TRAINING AND EXPERIENCE Refer to Item 8, attached	☐ Appendix H Procedures Followed; or
☐ Supplements A & B Attached for Each Individual User; and	X Equivalent Procedures Attached
☐ Supplement A Attached for RSO.	**17. AREA SURVEY PROCEDURES** *(Check One)*
9. INSTRUMENTATION *(Check One)*	☐ Appendix I Procedures Followed; or
☐ Appendix C Form Attached; or	X Equivalent Procedures Attached
X List by Name and Model Number	**18. WASTE DISPOSAL** *(Check One)*
10. CALIBRATION OF INSTRUMENTS	☐ Appendix J Form Attached; or
☐ Appendix D Procedures Followed for Survey Instruments; or *(Check One)*	X Equivalent Information Attached
X Equivalent Procedures Attached; and	**19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS** *(Check One)*
☐ Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*	☐ Appendix K Procedures Followed; or
X Equivalent Procedures Attached	X Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	**20. THERAPEUTIC USE OF SEALED SOURCES**
X Description and Diagram Attached	☐ Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM	☐ Appendix L Procedures Followed; or *(Check One)*
X Description of Training Attached	☐ Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	**21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)**
X Detailed Information Attached	X Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	**22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS**
	☐ Detailed Information Attached
☐ Appendix F Procedures Followed; or	**23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b**
X Equivalent Procedures Attached	☐ Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	R.S. Landauer & Co., Glenwood, IL	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	Same	Same
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

Refer to the attached ALARA Program

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: $ 580.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

X Dan L. Rex

(1) NAME *(Type or Print)*
Dan L. Rex

(2) TITLE
President & Chief Exec. Officer

c. DATE
3/12/85

NOTICE TO LICENSEES

Both management and involved employees of medical facilities must be aware of, and comply with all license conditions. The following actions are recommended:

1. Assure that a representative of management understands the commitments being made in the application and contained in the license as finally issued.*

2. Assure that existing and new employees are instructed in and are familiar with all applicable conditions of the license, including the details of applicable documents, such as procedures that are incorporated by condition of the license.

3. Assure that all employees are instructed in application changes each time the license is amended.

4. Assure that copies of the current regulations and copies of the license, as well as documents incorporated into the license by reference, are posted and/or made available to employees in accordance federal and/or state regulations.

* Upon issuance of the license, your facility will be required to comply with all statements and representations made in the application.

RADIATION SAFETY COMMITTEE

Meeting Frequency
The medical isotopes committee shall meet as often as necesary to conduct its business but not less than once in each calendar quarter.

Responsibilities

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 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 regulations and the conditions of the license.

Duties
The committee shall
1. Be familiar with all pertinent NRC regulations, the terms of the license, and information submitted in support of the request for the license and its amendments.
2. Review the training and experience of any individual who uses radioactive material (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 regulations 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 19.2 of 10 CFR part 19.
4. Review and approve all requests for use of radioactive material 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, and special monitoring procedures.
6. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with NRC regulations and the conditions of the license, to include the ALARA Program. The review shall include an examination of all records, reports from the radiation safety officer, results of NRC instpections, written safety procedures, and management control system.
7. Recommend remedial action to correct any deficiencies identified in the radiation safety program.

RADIAITON SAFETY COMMITTEE

Duties (continued)

8. Maintain written records of all committee meetings, actions, recommendations, and decisions.
9. Ensure that the byproduct material license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures, and personnel.

Members

The membership of this committee will consist of at least three members and will include:

1. the radiation safety officer;

2. the hospital administrator, or other administrative official directly responsible to the hospital administrator in the hospital's internal chain of command;

3. a physician specialist from each department where radioactive materials are used; and

4. a representative of the hospital's nursing staff.

The names and qualifications of the committee members will be documented in the committee's records, will be updated as necessary, and will be available for inspection by the NRC.

ITEM 7

AUTHORIZED INDIVIDUAL USERS

Ernesto B. Go, M.D.

Satish P. Shah, M.D.

Fazlollah Golestaneh, M.D.

Ramaa B. Athreya, M.D.

All of the above are currently authorized under the present license (29-03438-01)

RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER

The specific duties of the Radiation Safety Officer include:

1. Establishing and maintaining operations procedures so that the radiation exposure of each worker is kept as far below the maximum permissible exposure as is practicable.

2. Instructing personnel in safe working practices and in the nature of injuries resulting from overexposure to radiation.

3. Assuring that personnel monitoring devices are used where indicated and that records are kept of the results of such monitoring.

4. Investigating any case of excessive or abnormal exposure to determine the cause and taking steps to prevent its recurrence.

5. Advise radiation workers of any unusual procedures which they must employ in order to reduce unnecessary exposure.

6. See that all license commitments and regulatory requirements have been met. To this end, Health Physics Services, Inc., Potomac, Maryland, will assist the Radiation Safety Officer in managing the overall radiation protection program.

7. Review the radiation survey reports furnished by Health Physics Services, Inc. The surveys will include the following:

   A. Smears for spreadable contamination
   B Survey meter measurements in those areas where radioactive materials are used or stored
   C. A review of all personnel dosimetry reports
   D. A review of the records of inventory, isotope receipt, isotope disposal, and other health physics records for completeness and accuracy
   E. Required dose calibrator instrumentation tests (e.g. accuracy and linearity)
   F. Sealed source leak testing
   G. Survey meter calibration results
   H. Any other health physics records pertinent to license compliance

8. Be available to respond to any radiation emergency.

INSTRUMENTATION

1. Survey Meters

   Victoreen Model 493, 0-50 mR/hr, surveying/monitoring

   Victoreen Model 740F, 0-25,000 mR/hr, surveying/monitoring

   Eberline E-520, 0-2,000 mR/hr, surveying/monitoring

2. Dose Calibrator

   CRC-10M

3. Diagnostic Instrumentation

   Siemens Pho/Gamma 37GP

   ADC Medical Xenon Unit

   Siemens 750 CLC

   Medical Data Systems A3

   Medical Data Systems A2

   ADC Medical Model 300
   Nuclear Spectrometer

CALIBRATION OF SURVEY METER INSTRUMENTATION

Survey meter calibrations will be conducted at intervals not to exceed six (6) months by Health Physics Services, Inc., Potomac, Maryland, using sealed a Cesium-137 source of approximately 500 mCi, authorized by the State of Maryland under License Number MD-31-035-01. The calibration procedures are on file with the NRC, Under License No. 19-19791-01.

For instruments used to monitor lower energy radionuclides such as Tc-99m, etc., a correction factor is determined. After calibration with Cesium-137, a Tc-99m factor is determined by measuring the response of the instrument to a calibrated source of Cobalt-57. The exposure rate at an arbitrary distance for the Cobalt-57 source is determined using the inverse square law and verified with a calibrated dose rate meter.

DOSE CALIBRATOR CALIBRATION AND LINEARITY PROCEDURES

1. On a daily basis, the constancy of the dose calibrator will be determined with two sources: 200uCi of Cesium-137, and greater than one millicurie of Cobalt-57. These sources are NBS traceable with an accuracy of ±5%. Should the error of the constancy measurement be greater than ±5%, appropriate adjustment or instrument repair will be affected.
2. At intervals not to exceed six (6) months, Health Physics Services, Inc., Potomac, Maryland, will conduct the dose calibrator accuracy test under Maryland License No. MD-31-035-01. A Cobalt-57 source of approximately 10 millicuries will be used to insure the dose calibrator accuracy. Should the calibration deviate by greater than ±5%, appropriate adjustment or instrument repair will be conducted. This semi-annual procedure will be repeated using a Cesium-137 and a Barium-133 source of approximately 0.2 millicuries each. The three calibration sources are NBS traceable with an accuracy of ±5%.
3. The linearity of the dose calibrator will be determined quarterly, by Health Physics Services, Inc., in accordance with the NRC Medical Licensing Guide, Appendix D, Section 2.E., over the full range of activities of Technetium used. Should the linearity (measured versus calculated) vary by greater than ±5%, appropriate corrective action will be conducted.
4. Test for geometrical variation will be conducted in accordance with Appendix D, Section 2, Item F., of the NRC Medical Licensing Guide, unless certified data is supplied by the dose calibrator manufacturer.

CALIBRATION OF DIAGNOSTIC INSTRUMENTATION

Calibrations of diagnostic instrumentation, to include gamma cameras and associated instrumentation will be conducted in accordance with the manufacturers' instructions.

Daily floods will be conducted to insure integrity of the camera.

LEAK TESTING OF SEALED SOURCES

At intervals not to exceed six (6) months, all sealed sources of radioactive material will be leak tested by Health Physics Services, Inc., in accordance with their Maryland license, No. MD-31-035-01.

Health Physics Services, Inc.

7825 Tuckerman Lane, Suite 214
Potomac, Maryland 20854
Phone: (301) 299-2700 Toll Free: 800-638-8488

CALIBRATION CERTIFICATE

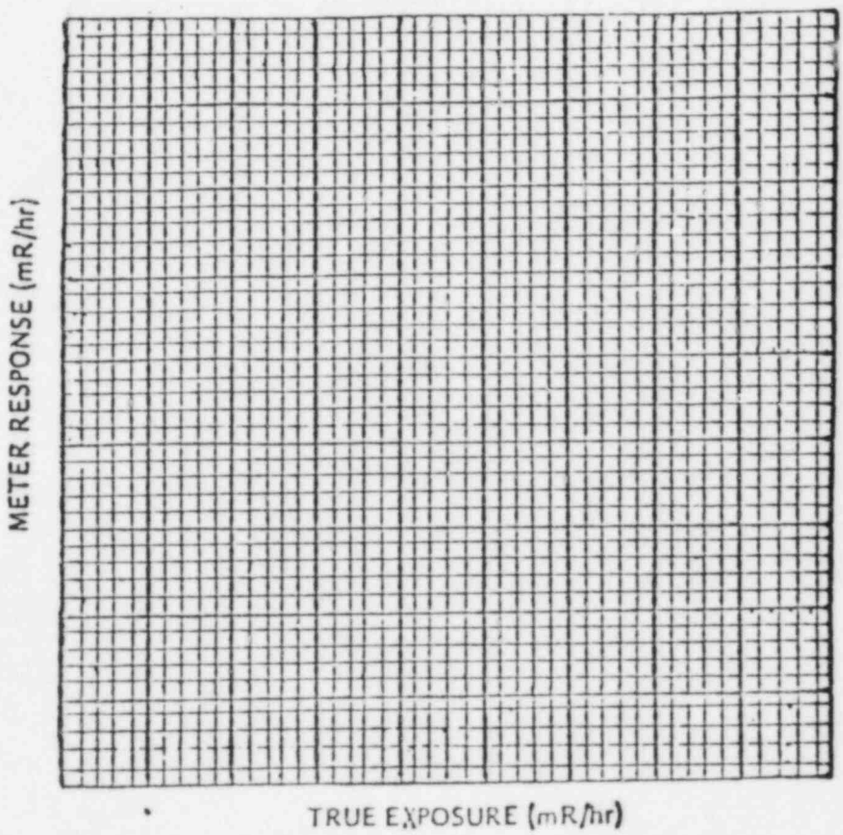
OWNER _____ CALIBRATION DATE _____ NEXT DUE _____

MANUFACTURER _____ MODEL NUMBER _____ SERIAL NUMBER _____

BATTERIES CHANGED: ___YES ___NO INTERNAL ADJUSTMENT: ___YES ___NO

The instrument was calibrated with the sensitive chamber positioned parallel/perpendicular to the radiation field.

METER RESPONSE (mR/hr)	SCALE	TRUE EXPOSURE (mR/hr)



After calibration with Cesium-137, a Tc-99m factor was determined by measuring the reponse of this instrument to a calibrated source of Cobalt-57. The exposure rate at an arbitrary distance for the Cobalt-57 source is determined using the inverse square law and verified with a calibrated dose rate meter.

TRUE EXPOSURE	MEASURED EXPOSURE

THIS CERTIFIES that the instrument described above was calibrated with Cesium-137. Exposure rates for this source have been verified with instrumentation whose calibration is traceable to the National Bureau of Standards.

_____
Health Physics Technican

FACILITIES AND EQUIPMENT

Radiation Handling Equipment

To enable personnel to work safely with unsealed radioactive materials, the Nuclear Medicine laboratory will have the proper radiation handling equipment. The following is a list of basic radiation handling equipment which is available in the Nuclear Medicine Departments.

Shielding/Handling Equipment

Lead bricks (e.g., 2" x 4" x 8")

Lead syringe holders for transporting syringes containing radioactivity

Lead syringe shields for reducing exposure during injection of radiopharmaceuticals

Lead vial and container shields (pigs) for reducing exposure during transport and storage of vials, etc., that contain radioactive material

Remote handling devices (tongs)

If applicable, generators will be maintained in the manufacturer's lead shielding or addition lead shielding, e.g. bricks, will be utilized

Contamination Control

Laboratory coats or uniforms

Absorbent pads (absorbent layer backed by non-absorbent plastic material) for covering work surfaces

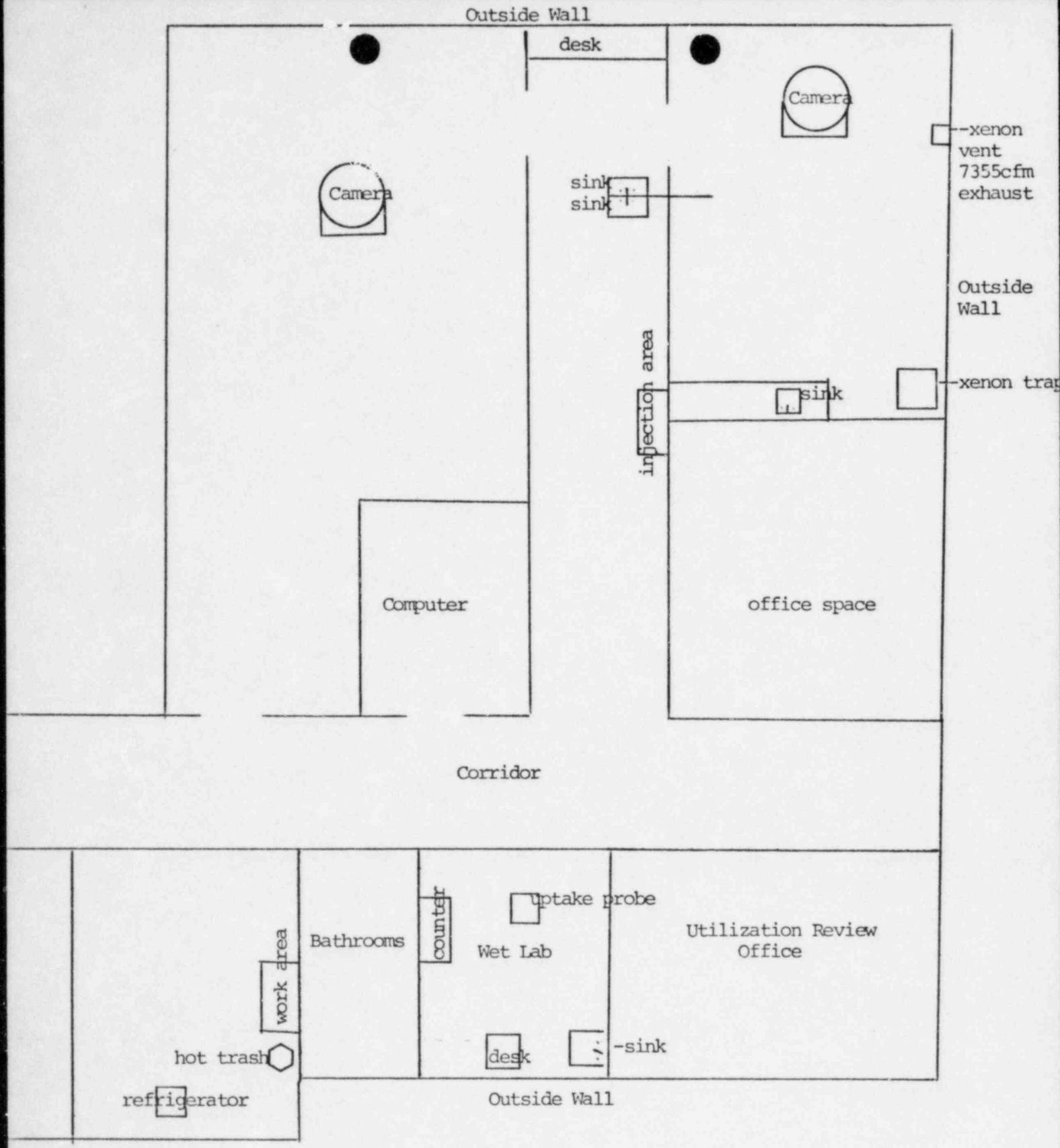
Disposal gloves

Decontaminating agents for decontaminating hands, utensils, work areas, etc.

Signs and labels indicating the presence of radioactive materials in areas or rooms where they are being used or stored. Labels on containers indicating radionuclide, activity, and date.

Monitoring

Appropriate survey instrumentation relative to the types and quantities of radioactive materials requested. Refer to the equipment/instrumentation listing.


Outside Wall
desk
Camera
--xenon
vent
7355cfm
exhaust
Camera
sink
sink
Outside
Wall
injection area
sink
--xenon trap
Computer
office space
Corridor
work area
Bathrooms
counter
uptake probe
Wet Lab
Utilization Review
Office
hot trash
desk
-sink
refrigerator
Outside Wall

PERSONNEL TRAINING PROGRAM

The personnel training program will be given to all personnel who work with or in the vicinity of radioactive materials. The training will be in the form of lectures and the duration of each session will depend on the extent of applicability to the employees involved. The training program will be of sufficient scope to ensure that all personnel, including technical, clerical, nursing, housekeeping, and security personnel receive proper instruction in the items specified in 19.12 of 10 CFR Part 19, to include:

A. Areas where radioactive materials are used or stored.
B. Potential hazards associated with radioactive material
C. Radiological safety procedures appropriate to their respective duties.
D. Pertinent NRC regulations.
E. Rules and regulations of the licensee.
F. Pertinent terms of the license.
G. Their obligation to report unsafe conditions.
H. Appropriate response to emergencies or unsafe conditions.
I. Their right to be informed of their radiation exposure and bioassay results.
J. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.

Personnel will be properly instructed as follows:

1. Before assuming duties with or in the vicinity of radioactive materials.

2. During annual refresher training.

3. Whenever there is a significant change in duties, regulations, or the terms of the license.

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. The Chief Nuclear Medicine Technologist, or his designee, will place all orders for radioactive material, ensure that the requested materials and quantities are authorized by the license, and that possession limits are not exceeded.

2. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.

3. During off-duty hours security personnel will accept delivery of radioactive packages in accordance with the procedures outlined in the enclosed memorandum.

4. A system for ordering and receiving radioactive materials will be established and maintained. The system will consist minimally of the following:

   A. Ordering of routinely used materials

      1. Written records that identify the isotope, compound, activity levels, and supplier, etc., will be used.
      2. The written records will be referenced when opening or storing radioactive shipments.

   B. Ordering of specially used materials (e.g., therapeutic uses)

      1. A written request* will be obtained from the physician who will perform the procedure.
      2. Persons ordering the materials will reference the physician's written request when placing the order. The physician's request will indicate isotope, compound, activity level, etc.
      3. The physician's written request will be referenced when receiving, opening, or storing the radioactive material.

   C. It is essential that written records* be maintained for all ordering and receipt procedures.

* In the case of special orders, the physician's written request and appropriate shipping/receipt records will be referenced and the dose assayed prior to its administration.

TO BE TYPED ON HOSPITAL LETTERHEAD, SIGNED BY THE ADMINISTRATOR, AND GIVEN TO THE ADDRESSEE. (ALSO TO BE INCLUDED IN THE LICENSE APPLICATION)

SAMPLE MEMORANDUM

TO: Security Personnel

FROM: _____, Administrator

RE: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

Any packages containing radioactive material that arrive between 4:30 p.m. and 7 a.m. or on Sundays, will be signed for by the Security guard on duty and taken immediately to the Nuclear Medicine Department's Hot Lab.

Unlock the door, place the package on the floor in the middle of the room, and relock the door upon leaving.

If the package is wet or appears to be damaged, immediately contact the hospital Radiation Safety Officer and/or the chief technologist of the department.

Ask the carrier to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

RADIATION SAFETY OFFICER: _____

OFFICE PHONE: _____

HOME PHONE: _____

CHIEF TECHNOLOGIST: _____

OFFICE PHONE: _____

HOME PHONE: _____

PROCEDURES FOR SAFELY OPENING PACKAGES
CONTAINING RADIOACTIVE MATERIAL

For safely opening packages containing radioactive material, the technologist will:

1. Put on gloves to prevent hand contamination.
2. Visually inspect packages for any sign of damage (wetness, crushed, etc.). If damage is noted, the procedure will be stopped and the radiation safety officer notified.
3. Measure exposure rate at 3 feet from package surface and record. If greater than 10 mR per hour, the procedure will be stopped and the radiation safety officer notified.
4. Measure surface exposure rate and record. If greater than 200 mR per hour, the procedure will be stopped and the radiation safety officer notified.
5. Wipe external surface of shipping container and remove wipe to low background area. Assay the wipe and record amount of removable radioactivity (e.g., dpm/100 sq. cm., etc.). Check wipes with a thin end window GM survey meter. The procedure will be stopped if removable contamination is greater than 22,000 dpm/100 sq. cm. above background. The radiation safety officer and health physics consultant shall be notified to determine the "exempt" status of the package with respect to wipe testing. If the package is not exempt, then appropriate notification of regulatory offices will be made.
6. Open the package with the following precautionary steps:

   A. Open the outer package following manufacturer's instructions, if supplied, and remove packing slip.
   B. Open inner package and verify that contents agree with those on packing slip. Compare requisition, packing slip, and label on bottle.
   C. Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).
   D. Check also that shipment does not exceed possession limits.

7. Wipe external surface of final source container and remove wipe to low background area. Assay the wipe and record amount of removable radioactivity (e.g., dpm/100 cu. cm., etc.). Check wipes with a well counter/scintillation detector or thin end window GM survey meter, and take precautions against the spread of contamination as necessary. The acceptable level of removable contamination will be 200 dpm/ 100 sq. cm. above background. The procedure will be stopped and the radiation safety officer notified if this level is exceeded.
8. Monitor the packing material and packages for contamination before discarding. If contaminated, treat as radioactive waste. If not contaminated, radiation labels will be obliterated before discarding in regular trash.

Records will be maintained of the results of checking each package (see following sample).

RADIOACTIVE SHIPMENT RECEIPT REPORT

1. P. O. #_____ Survey Date _____ Time _____
(if applicable)
Surveyor _____

2. CONDITION OF PACKAGE:
_____O. K. _____Punctured _____Status _____Wet
_____Crushed _____Other

RADIOACTIVE MATERIAL PACKAGES LABEL CRITERIA
(173.399)
DOSE RATE LIMITS

LABEL	AT ANY POINT ON ACCESSIBLE SURFACE OF PACKAGE	AT THREE FEET FROM EXTERNAL SURFACE OF PACKAGE (TRANSPORT INDEX)
"RADIOACTIVE-WHITE I"	Ø.5mR/hr	Ø
"RADIOACTIVE-YELLOW II"	5Ø mR/hr	1.Ø mR/hr
"RADIOACTIVE-YELLOW III"	2ØØ mR/hr	1Ø mR/hr

3. Radiation Label number _____

4. MEASURED RADIATION LEVELS:

a) Bkg = _____mRem/hr.

b) Package surface _____mRem/hr.

c) 3 feet or 1 meter from surface _____mRem/hr.

5. Notification to the NRC or Agreement state is voluntary if mR/hr levels exceed those indicated for applicable Labels I & II. Notification of the RSO, health physics consultant, carrier, and NRC/ Agreement state is mandatory if levels of exposure exceed either 1ØmR/hr at three feet or 2ØØmR at the surface of the package.

6. DO PACKING SLIP AND VIAL CONTENTS AGREE?

a. Radionuclide _____yes _____no, difference _____

b. Amount _____yes _____no, difference _____

c. Chem form _____yes _____no, difference _____

(Rev. 3, January 1984)

7. WIPE RESULTS

a. Bkg _____CPM (Eff.= ____%) -> CPM x $\frac{100}{\text{eff.}}$ = _____bkg. DPM

b. Outer _____CPM (Eff.=____%) -> CPM x $\frac{100}{\text{eff.}}$ = _____ DPM

c. Final source container _____CPM (Eff.= ____%)

-> CPM X $\frac{100}{\text{eff.}}$ = _____DPM

8. SURVEY RESULTS OF PACKING MATERIAL AND CARTONS _____mRem/hr, CPM

9. DISPOSITION OF PACKAGE AFTER INSPECTION_____

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

_____

GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL

1. Laboratory coats and other protective clothing will be worn at all times in areas where radioactive materials are used.

2. Disposable gloves will be worn at all times while handling radioactive materials.

3. Hands and clothing will be monitored for contamination at the end of each working day.

4. Syringe shields for preparation of patient doses and administration to patients will be used except in circumstances such as pediatric cases when their use would compromise the patient's well-being.

5. There will be no eating, drinking, smoking, or application of cosmetics in any area where radioactive material is stored or used.

6. Each patient dose will be assayed in the dose calibrator just prior to administration. Any doses that differ from the prescribed dose by more than 10% will not be used.

7. Personnel monitoring devices (film badge or TLD) will be worn at all times while in areas where radioactive materials are used or stored.*

8. TLD finger badges will be worn during elution of generator and preparation, assay, and injection of radiopharmaceuticals.

9. Radioactive waste will be disposed of only in specially designated receptacles.

10. There will be no pipetting by mouth.

11. Generator, kit preparation, and injection areas will be surveyed for contamination after each procedure or at the end of the day and will be decontaminated if necessary.

12. Radioactive solutions will be confined in covered containers, plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.

13. Radioactive material will always be transported and maintained in shielded containers.

* Personnel monitoring devices will be stored in a designated low background area when not being worn.

GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (cont'd)

14. The laboratory will be locked when personnel are not present.

15. Emergency notification home telephone numbers will be posted on the door.

16. There will be no storage of food, drink, or personal effects with radioactive material.

17. If therapeutic doses are authorized, the following will be verified with the order written by the physician who will perform the procedure:

    A. Patient's name
    B. Radionuclide
    C. Chemical form
    D. Activity

USE OF MOLY/TECH GENERATORS, PREPARATION OF REAGENT KITS AND DOSE ADMINISTRATION

1. In all cases, all instructions supplied by the manufacturers of the generators and radiopharmaceutical kits will be followed precisely, including procedures for elution, assay, kit preparation, radiation precautions and the use of special equipment such as syringe shields, and other accessories.

2. Areas used for elution of Mo-99/Tc-99m generators, for preparation of radiopharmaceuticals from reagent kits, and for preparation of individual patient doses will be surveyed for contamination after each procedure or at the end of each work day.

3. Every elution of generators will be assayed by use of the dose calibrator for technetium-99m activity and molybdenum-99 breakthrough contamination. The eluates will not be used if there is more than one (1) microcurie of Moly-99 per millicurie of technetium-99m or more than five (5) microcuries of Moly-99 per administered dose of technetium-99m.

   NOTE: Molybdenum breakthrough tests will be performed in accordance with the instructions provided in the Operating/Instruction Manual for the dose calibrator.

4. Individuals who elute Mo-99/Tc-99m generators, prepare radiopharmaceuticals from reagent kits, and all personnel who prepare patient doses or work in areas used for elution of generators, preparation of radiopharmaceuticals or preparation of individual patient doses will monitor their hands and clothing for contamination before leaving those areas.

5. The activity of all radionuclides or radiopharmaceutical doses to be administered to patients will first be determined by mathematical calculations. Once drawn, the total activity contained in the syringe will be double checked by use of the dose calibrator. Except for this determination, the syringe will be kept in the syringe shield and/or pig. All radiopharmaceuticals will be assayed just prior to administration to the patient.

6. Patient dose information of administered technetium-99 and all other administered radioactive materials will be recorded in the patient dose log.

EMERGENCY PROCEDURES

Minor Spills

1. All persons in the area will be notified when a spill has occurred.

2. The spill will be covered with absorbent paper to prevent its spread.

3. Disposable gloves and remote handling tongs will be used to clean up the spill. The absorbent paper and pad will be carefully folded, inserted into a plastic bag and disposed of in the radioactive waste container. All other contaminated materials such as disposable gloves will also be inserted into the plastic bag.

4. The survey will be conducted using a low-range, G-M survey meter. The area around the spill, hands, and clothing will be checked for contamination.

5. The incident will be reported to the radiation safety officer.

Major Spills

1. All persons not involved in the spill will be notified to vacate the room.

2. The spill will be covered with absorbent pads, but no attempt to clean it up will be made. The movement of all personnel potentially contaminated will be confined to prevent the spread.

3. If possible, the spill will be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.

4. The room will be vacated, and the door(s) locked to prevent entry.

5. The radiation safety officer will be notified immediately.

6. Contaminated clothing will be removed and stored for further evaluation by the radiation safety officer. If the spill is on the skin, the area will be flushed thoroughly and washed with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: Ernesto B. Go, M. D.

OFFICE PHONE: 609/691-9000

HOME PHONE: 609/696-1368

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER: Fazlollah Golestaneh, M. D. 692-6356

Julie George 696-4357

AREA SURVEY PROCEDURES

The following area survey procedures will be conducted by the Chief Technologist of the department or his designee, in each area where radioactive material is used or stored:

1. Preparation and injection areas will be surveyed on a daily basis with an appropriately low range G-M survey meter and decontaminated if necessary.

2. All other laboratory areas will be surveyed weekly.

3. The weekly survey will consist of:

   A. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mRem per hour.

   B. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 200 dpm per 100 sq. cm. for the contamination involved.

4. A permanent record will be kept of all survey results, including negative results. The record will include:

   A. Location, date, and type of equipment used.

   B. Name of person conducting the survey.

   C. A drawing of the area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.

   D. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).

   E. Detected contamination levels, keyed to locations on drawing.

   F. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

5. The area will be cleaned if the contamination level exceeds 200 dpm per 100 sq. cm.

NOTE: For daily surveys where no abnormal exposures are found, only the date, identification of the person performing the survey and the survey results will be recorded.

DAY	DAILY CONSTANCY MEASUREMENTS*		DAILY LABORATORY SURVEY**						WEEKLY WIPE TEST SURVEY***							
	Co-57	Cs-137	A	B	C	D	E	F	G	H	I	J	K	L	M	N**
1																
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A. Eye level in front of isotope prep. area
B. Waist level in front of storage area
C. Injection area
D. Non-radioactive waste container
E. Background mR/hr
F. Surveyor's initials

G. Hot lab middle of floor
H. Scanning Area I, floor
I. Scanning Area II, floor
J. Scanning Area III, floor
K. Bench top, storage area
L. Background dpm
M. Surveyor's initials

N. Xenon-133 Gas Trap

*Units in mCi
**Units in mR/hr.
***Units in dpm

MONTH OF _____

(Revised 4/84)

WASTE DISPOSAL PROCEDURES

Solid radioactive waste will be divided into three groups: short-lived, medium-lived, and long-lived.

A. Short-lived - Waste material with a half-life less than 1 day (24 hours) (i.e., Tc-99, I-123)

B. Medium-lived - Waste material with a half-life between 1 - 15 days (i.e., Ga-67, Tl-201, Xe-133, I-131, P-32)

C. Long-lived - Material with a half-life greater than 15 days

Adequate lead or other suitable shielding will be provided as necessary to reduce the radiation exposure levels to the lowest reasonable level while radioactive waste is in temporary storage.

All solid radioactive waste will be held for decay until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. Once this has been achieved, all radiation labels will be removed or obliterated, and the waste will be disposed of in normal trash. Appropriate documentation will be maintained.

Liquid radioactive waste will be disposed of in the sanitary sewage system in accordance with 10 CFR, Part 20.303, Code of Federal Regulations.

If generators are authorized, they will be disposed of by either of the following methods:

1. Returned to the manufacturer in accordance with applicable DOT, NRC, and/or State regulations governing the transport of radioactive materials.

2. Generators will be disassembled after a minimum of 10 half-lives from the original assay date. The core will be placed in the medium-lived waste container for subsequent storage and monitoring as described above. The lead will be surveyed as above and disposed of accordingly.

NOTE: The radioactive waste area is located within the hot lab/scan room, which is locked when staff personnel are not present. Radiation surveys are conducted at least weekly.

Records are maintained for each of the described disposal methods. Such records include the date of storage, amount of radioactivity, radionuclides, date of disposal, disposition of materials, and initials of the disposing individual.

Xenon-133 Handling Procedures

Quantity to be Used

1. A maximum of 520 patients per year will be studied with an average activity of 10 millicuries per patient.
2. Desired possession limit: 200 millicuries

Use and Storage Areas

The Xe-133 will be used and stored in the Nuclear Medicine Department. Storage of the individual Xe-133 doses will be in a lead container surrounded by lead bricks in the Camera Room. Patient doses will be administered in the Camera Room.

Description of Ventilation System

1. The total area of the Camera Room is approximately 2856 ft, with a 12 foot ceiling, for a total volume of 2856 cubic feet. The room will be under negative pressure with the normal air return system exhausted directly to the outside atmosphere.

Procedures for Routine Use

1. Xe-133 will be procured in precalibrated doses and delivered directly to the Nuclear Medicine Lab. It will be stored in its shipping container in the isotope storage area until ready for patient administration. Upon receipt, the package will be inspected in accordance with the Procedures for Safely Opening Packages Containing Radioactive Material.
2. Immediately prior to administration, the dose will be measured in the dose calibrator. The patient will be positioned with a self-contained breathing bag and/or nose clamp. All valve positions will be checked for proper settings. The dose will then be injected into the mouthpiece and the scan started. After the scan is completed, the exhaled Xe-133 gas will be collected in the integrated gas trap system and allowed to decay to background. No Xe-133 gas will be exhausted into the atmosphere.

Emergency Procedures

1. If, during the patient study, an accidental release of Xe-133 occurs, the rooms will be evacuated immediately and the doors closed.
2. Based on actual exhaust rates of 356 cfm, the room will remain vacated for a minimum of 24 minutes, which will allow for at least 3 air exchanges in the Camera Room.

Emergency Procedures (Continued)

3. At the end of 24 minutes, the floor will be monitored with a low-range GM survey meter to check for any residual Xe-133 gas. If the resulting measurements are greater than background, the room will be vacated for another 24 minutes and then monitored again to assure that no Xe-133 is present.

Air Concentrations of Xe-133 in Restricted Areas

MPC for restricted areas is 1×10^{-5} uCi/ml

1. Camera Room - (storage and use area)

   A. A_1 = maximum activity used per week

   $A_1 = (10 \text{ mCi/pt})(10 \text{ pt/week})(1 \times 10^3 \text{ uCi/mCi}) = 1 \times 10^5 \text{ uCi/wk}$

   Assume a loss rate of 20% during use, $f_1 = .2$

   A_2 = Maximum activity on hand per week

   $A_2 = 200 \text{ mCi} = 2 \times 10^5 \text{ uCi}$

   Assume a loss rate of 5% during storage, $f_2 = .05$

   B. V = required ventilation to maintain airborne concentrations of Xe-133 below MPC in a restricted area, when averaged over a 40 hour week.

$$V = \frac{A_1 f_1 + A_2 f_2}{MPC} \left(\frac{ft^3/min}{6.8 \times 10^7 \text{ ml/40hr wk}} \right)$$

$$V = \left(\frac{(1 \times 10^5 \text{ uCi/wk})(.2) + (2 \times 10^5)(0.5)}{1 \times 10^{-5} \text{ uCi/ml}} \right) \left(\frac{ft^3/min}{6.8 \times 10^7 \text{ ml/40hr wk}} \right)$$

$$V = 44 \text{ ft}^3/\text{min}$$

Method of Disposal

1. The Xe-133 expired air will be vented through the exit port in the integrated gas trap system. To insure proper operation of the Xenon-133 trap, the exhaust from the exit port of the trap will be monitored weekly with an end-window GM survey meter. The monitoring will be performed either during a Xenon study or with all of the expired gas from a study. Any increase above 2 times background level readings will be cause for appropriate replacement of exhaust duct, etc.
2. If there should be leakage in the gas trap system, the Xe-133 gas will be exhausted directly to the outside, or unrestricted area, through the ventilation ducts. There is no recirculation of exhausted air within the facility and the point of exit for the exhaust duct is at least 25 feet from the closest point of air intake.
3. The air from the outlet port of the trap system will be collected into a clean unused bag, which will be monitored weekly with a GM survey meter to check on system performance, and to determine when the filters approach saturation point. Readings of twice above background indicate the need to replace the charcoal cartridge. Saturated filters will be removed from the system and stored within the hot lab in airtight shielded containers until the Xe-133 activity decays to background (meter readings less than 0.05 mR/hr).
4. A velometer will be used to assure the ventilation rate is adequate. This will be conducted prior to the initial use of Xe-133 studies, after any repairs which may alter the flow rate, and quarterly thereafter.
5. Weekly surveys will be made of the storage area and xenon delivery system to insure radiation levels are within allowable limits, and as low as reasonably achievable.
6. Records will be maintained of all monitoring and disposal.

Concentrations of Effluents to Unrestricted Areas

MPC for unrestricted area is 3×10^{-7} uCi per ml.

1. Camera Room Exhaust

   A. A_1 = Maximum amount to be used per year

   A_1 = (10 mCi/pt)(10 pt/wk)(1×10^3 uCi/mCi)(52 wks/yr) = 5.2×10^5 uCi/yr

   Assume a loss rate of 20% during use (f_1), f_1 = .2

   A_2 = Maximum amount to be released per year

   A_2 = (200 mCi/wk)(52 wk/yr)(10^3 uCi/mCi) = 1.0×10^7 uCi/yr

   Assume a loss rate of 5% during storage (f_2), f_2 = .05

Summary

The minimum ventilation rates required to maintain concentrations of Xe-133 in a restricted area below $1x10^{-5}$ uCi/ml are 44 ft^3/min in the Camera Room. The minimum ventilation rates to maintain airborne concentrations of Xe-133 in an unrestricted area below $3x10^{-7}$ uCi/ml are 135 ft^3/min in the Camera Room.

The ventilation rates in the Camera Room will be no less than 135 ft^3/min. This will insure airborne concentrations in restricted and unrestricted areas are less than permissible concentrations of $1x10^{-5}$ uCi/ml and $3x10^{-7}$ uCi/ml, respectively.

NEWCOMB HOSPITAL

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VINELAND, NEW JERSEY 08360-9979

(609) 691-9000

DAN L. REX
President and Chief Executive Officer

FOREWORD

Ionizing radiation is among the most versatile and useful tools of modern medicine and biomedical research. Like many other instrumentalities of medicine, ionizing radiation is potentially hazardous unless used with strict adherence to safety rules and procedures. Thus, the safety rules which govern the uses of radiation are concerned with preventing genetic damage as well as with protecting the health of the exposed individual.

The rules and procedures set forth here have one single, straightforward purpose: to protect the patients, employees and visitors from unnecessary and potentially harmful radiation.

The existing radiation safety program has many facets designed to keep the levels of exposure to personnel at a minimum. This program has three main phases:

PHASE I

Achieve the objective of maintaining radiation exposure to "As Low As Reasonably Achievable" (ALARA) to employees, visitors, students and patients who are not under medical supervision for the administration of radiation or radioactive materials for diagnostic or therapeutic purposes.

PHASE II

Control operational procedures by the user of radiation sources.

PHASE III

Evaluate the radiation safety program performed by the Radiation Safety Officer, health physics consultant and the Radiation Safety Committee.

We, the management of this hospital, are committed to the program procedures and develop new procedures as appropriate to implement the ALARA concept.

Dan L. Rex

President and Chief Executive Officer

3/12/85

Date

RADIATION SAFETY PROGRAM (ALARA)

1. INTRODUCTION

A. Purpose

This program sets forth the philosophy and general management policies that are established by this hospital to achieve the objective of maintaining radiation exposures to "as low as reasonably achievable" (ALARA), for employees, visitors, students, and patients not under medical supervision for the administration of radiation or radioactive materials for diagnostic or therapeutic purposes.

B. Policy

In addition to complying with the limits set forth in pertinent regulations, guides, and standards, users and supervisors of radiation sources shall make every reasonable effort to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas to as low as reasonably achievable.

II. MANAGEMENT COMMITMENT

A. The management and the entire staff of this hospital are committed to the program described herein for keeping radiation exposures, individual and collective, to as low as reasonably achievable.

B. We will perform a formal annual review of the radiation safety program including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.

C. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended 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.

E. The services of Health Physics Services, Inc., have been contracted to assist in the program management to insure that all pertinent hospital staff and employees receive appropriate briefings and training in radiation safety including ALARA concepts.

III. RADIATION SAFETY COMMITTEE

In addition to other responsibilities delineated in pertinent radiation control standards, the Radiation Safety Committee (RSC) shall:

A. Determine whether current procedures are, in fact, maintaining radiation exposures to ALARA. The efforts of the radiation safety officer (RSO), health physics consultant, users and supervisors of radiation sources will be reviewed during the committee meeting.

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

C. Perform an annual audit of all aspects of the radiation safety program to insure that the overall philosophy and policies of the ALARA program are being accomplished.

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

E. Delegation of Authority

1. The RSC will delegate authority to the RSO and his consultant staff 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 in the minutes of the Committee's quarterly meeting.

F. Review of the ALARA program

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

2. The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table 1 below are exceeded. The principle purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded.

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

IV. RADIATION SAFETY OFFICER, AND HIS CONSULTANT STAFF ARE RESPONSIBLE FOR THE FOLLOWING:

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 VII of this program.

3. Quarterly review of records of Radiation Level Surveys. The RSO will review radiation levels in unrestricted andf 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 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 the formulation of the procedures that they will be required to follow.

1. The RSO will be in 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 receiving and evaluating the suggestion of individual workers for improving health physics practices and encourage the use of those procedures.

D. Reviewing Instances of Deviation from Good ALARA Practices

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

V. AUTHORIZED USERS

A. New Procedures Involving Potential Radiation Exposures

1. The authorized user will consult with, and receive the approval of, the RSO and/or RSC during the planning stage before using radiation sources for a new procedure.

2. The authorized user will evaluate all procedures before using radiation sources 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 explain the ALARA concept and his commitment to maintain exposures ALARA to all of those he supervises.

2. The authorized user will ensure that those under his supervision who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

VI. PERSONS WHO RECEIVE OCCUPATIONAL RADIATION EXPOSURE

A. The worker will be instructed in the ALARA concept and its relationship to his working procedures and work conditions.

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

VII. ESTABLISHMENT OF INVESTIGATIONAL LEVELS IN ORDER TO MONITOR INDIVIDUAL OCCUPATIONAL EXTERNAL RADIATION EXPOSURES

This institution hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the Radiation Safety Officer or consultant staff. The Investigational Levels that we have adopted are listed in Table 1 below. These levels apply to the exposure of individual workers.

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 medical facilities except those using significant quantities of beta emitting isotopes.

The Radiation Safety Officer will review the results of personnel monitoring, film badge report, 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 1 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 film badge record 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 Invewstigational Level II above that listed in Table 1.

In cases where a worker's or a group of workers' exposure needs 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 Levewl II will be documented.

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

VIII. SIGNATURE OF CERTIFYING OFFICIAL

I hereby certify that this institution has implemented the ALARA Program set forth above.

X _____
Signature of Administrator

Dan L. Rex
Name (type or print)

President & Chief Exec. Officer
Title

HEALTH PHYSICS ASPECTS OF THE THERAPEUTIC USE OF RADIOACTIVE MATERIAL

Iodine-131

GENERAL

The physician will determine which radioisotope and proper activity is to be administered to the patient.

Because of the relatively high energy and activity used in radiation therapy, the staff will take advantage of time, distance, and shielding to reduce unnecessary exposure to radiation. This is important in the initial preparation stage as well as the hospitalization period.

OUTPATIENT THERAPY

Outpatients may be administered up to 30 millicuries of radioactive material. Radiation safety instructions should be given to the patients, depending on their condition and age of other members in their household.

For levels administered greater than 30 millicuries, the patients must be admitted to the hospital.

INPATIENT THERAPY

Inpatients may be administered radioactive materials as limited by the facility license.

Because of the significant potential for contamination by the patient during hospitalization, it is important that proper radiation controls be strictly enforced.

Radiation safety procedures and related nursing procedures for inpatients undergoing therapeutic use of radiopharmaceuticals will be those set forth in Appendix K (enclosed).

The patient may be discharged from the hospital when the residual activity is less than thirty (30) millicuries. After vacating the room, a thorough radiation protection survey should be conducted to insure the absence of radioactivity, radiation signs, etc. Special attention should be given to the monitoring of the bed linen, waste containers, and bathroom.

IODINE-131 HANDLING PROCEDURES

1. In order to minimize the potential volatilization and contamination during patient dose preparation, the use of radioiodine will mainly be in the physical form of capsules.

2. When uncontained high specific activity is used, such as in treatment of thyroid carcinoma, the following additional procedures will be followed:

   a. The vial containing the radioiodine will remain unopened and stored in the lead shipping container in the isotope storage area until just prior to patient administration.

   b. When ready for patient administration, while wearing a laboratory coat and rubber gloves and using forceps, the vial will be opened in a fume hood (if present) to allow any volatized buildup of Iodine to escape. Should a fume hood not be avialable, the vial will be opened at an arms length in an area of relatively low air circulation, such as the corner of the room. The vial will then be closed, and the surface of the unshielded container will be wiped with an alcohol sponge pad to remove any possible contamination. It will then be assayed in the dose calibrator and replaced in its shield. Smears will be taken to assure that no contamination has occurred in the work area.

   c. The unopened vial will be taken, in its shield, to the patient administration area. While using rubber gloves, the vial will be opened and a straw inserted. The patient will be draped across the shoulders with an absorbent pad such as a chux, etc. The shielded container will be given to the patient to drink.

   d. When the dose has been administered, the shielded vial will be placed in a plastic bag, sealed, and returned to the isotope storage area for decay and disposal.

   e. Several smears of the patient administration area will be taken to check for contamination.

   f. Individuals involved with dose administration will wash their hands thoroughly with soap and water and will have their thyroid checked for possible uptake as described in the Bioassay Procedures.

   g. Hoods used for opening therapeutic quantities of Iodine will be evaluated at least semi-annually to verify adequate exhaust ventilation rates.

IODINE-131 HANDLING PROCEDURES (Continued)

h. Film badges and extremity monitoring devises (TLD's) will be worn by individuals handling therapeutic quantities of radioactive Iodine.

i. Thyroid bioassays will be performed on individuals handling therapeutic quantities of Iodine in accordance with the following.

THYROID BIOASSAYS

1. Thyroid bioassays will be conducted on radiation workers initially upon employment to establish base line data. Such analyses will be performed on only those individuals who might subsequently handle therapeutic quantities of Iodine or be sufficiently close to the process that intake is possible (e.g. within a few meters in the same room).

2. Bioassay studies of occupationally exposed personnel will be performed when there is believed to be a reasonable risk of significant internal radioactive exposure. As a minimum, the type of bioassay, frequency of administration, and action levels are as follows:

*Activity Handled at Any One Time in Unsealed Form Making Bioassay Necessary.

Types of Operation	Volatile or *Dispersible	Bound to Nonvolatile *Agent
Processes in open room or bench, with possible escape of iodine from process vessels	0.1 mCi	1 mCi
Processes with possible escape of iodine carried out within a fume hood of adequate design, face velocity, and performance reliability	1 mCi	5 mCi
Processes carried out within gloveboxes, ordinarily closed, but with possible release of iodine from process and occasional exposure to contaminated box and box leakage	10 mCi	100 mCi

A total thyroid radioactive iodine content equal to or greater than 0.12 microcuries of I-125 or 0.04 microcuries of I-131 will result in the individual being removed from duties involving radioactive iodine

THYROID BIOASSAYS (Continued)

exposure until the thyroid content has dropped to less than the stated levels.

Additional bioassay procedures and related actions will be conducted in accordance with NRC Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131," April 1978 (enclosed). Records of bioassay studies will be maintained for review by appropriate officials.

HEALTH PHYSICS ASPECTS OF THE THERAPEUTIC USE OF RADIOACTIVE MATERIAL PHOSPHORUS-32

1. The vial containing Phosphorus-32 will not be opened until the time of patient administration. Personnel will wear laboratory coats and rubber gloves when handling and opening this material.

2. Phosphorus-32 will be handled behind low Z number shielding, such as plexiglass, in order to keep bremstrahlung radiation at a minimum.

3. Several smears of the patient administration area will be taken to check for contamination.

4. Individuals involved with dose administration will wash their hands thoroughly with soap and water and then carefully monitor their hands and clothing to detect any contamination.

5. Whole body and extremity monitoring devices will be worn by all personnel handling Phosphorus-32.

6. After administration of the patient dose, the empty vial will be placed in a plastic bag, sealed, and returned to the storage area for decay and disposal.

7. Eye protection, i.e. plexiglass goggles, will be used for procedures involving 10 millicuries or more of Phosphorus-32.

8. A dry run will be performed prior to performance of unfamiliar procedures in order to preclude unexpected complication.

9. If patients undergoing Phosphorus-32 therapy require hospitalization, the patient will be placed in a private room. The radiation safety procedures and related nursing procedures set forth in Appendix K, with attachments, (enclosed) will be followed.

APPENDIX K

RADIATION SAFETY PROCEDURES FOR THERAPEUTIC USE OF RADIOPHARMACEUTICALS*

1. All patients treated with I-131 or Au-198 will be placed in a private room that has a toilet. The large surfaces in the room and toilet areas that are more likely to be contaminated will be covered with absorbent pads or protective material as appropriate to the amounts of contamination to be expected. Attention should be given to objects likely to be touched by the patient, e.g., telephones, doorknobs, and other items that would be difficult to decontaminate. Plastic bags or wrappings that are waterproof and easily disposable should be used on the smaller items.

2. The patient's room will be properly posted or attended in accordance with §§20.203 or 20.204 of 10 CFR Part 20.

3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after administration of the treatment dose. Exposure rates will be measured at the patient's bedside and 3 feet (or 1 m) from the patient after administration and at the entrance to the room. The Radiation Safety Officer or his designee will then determine how long a person may remain at these positions and will post these times on the patient's chart and on his door. The results of daily surveys will be used to recalculate permitted times, which will be posted on the patient's chart and on his door.

4. The form, Nursing Instructions for Patients Treated with Phosphorus-32, Gold-198, or Iodine-131 (or a similar form containing all the requested information), will be completed immediately after administration of the treatment dose. A copy will be posted on the patient's chart.

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

6. All linens will be surveyed for contamination before being removed from the patient's room and, if necessary, will be held for decay.

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

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

9. If urine and vomitus from I-131 therapy patients are collected, they will be stored for decay in the radioactive waste storage area. Such stored wastes will be retained until they have reached background levels, as measured with a low-level survey meter. They will then be released to 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 necessary, 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 on the patient's chart. Nurses should read these restrictions before administering to the patients. Call the Nuclear Medicine Department or the Radiation Safety Officer with any questions about the care of these patients. Nursing personnel who attend the patient will wear personnel monitoring devices as advised by the Radiation Safety Office.

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

    c. Patients must remain in bed while visitors are in the room and visitors should remain at least 3 feet (or 1 m) from the patient.

    d. Patients containing radioactive materials are to be confined to their rooms except for special medical or nursing purposes approved by the Nuclear Medicine Department.

    e. No nurse, visitor, or attendant who is pregnant should be permitted in the room of a patient who has received a therapeutic amount of radioactivity until the patient no longer presents a radiation hazard. Female visitors should be asked whether they are pregnant.

    f. Attending personnel should wear rubber or disposable plastic gloves when handling urinals,

* Be sure to submit a complete response to Item 19b in addition to referencing procedures in Appendix K.

bedpans, emesis basins, or other containers having any material obtained from the body of the patient. Wash gloves before removing and then wash hands. The gloves should be left in the patient's room in the designated waste container. These gloves need not be sterile or surgical in type.

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 or his designee for proper disposal of the contents of the designated waste container.

h. All clothes and bed linens used by the patient should be placed in the laundry bag provided and should be left in the patient's room to be checked by the Radiation Safety Officer or his designee.

i. All nondisposable items should be placed in a plastic bag and should be left in the patient's room to be checked by the Radiation Safety Officer or his designee.

j. Surgical dressings should be changed only as directed by the physician. Au-198 leaking from a puncture wound may stain the dressings 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 or his designee. Handle these dressings only with tongs or tweezers. Wear disposable gloves.

k. For I-131 patients:

(1) To the degree possible with cooperative patients, urine will be collected in special containers provided by the Radiation Safety Officer or his designee. The patient should be encouraged to collect his own urine in the container. 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 to collect the excreta, disposable gloves should be worn. Afterward, hands should be washed with the gloves on and again after the gloves are removed. The gloves should be placed in the designated waste container for disposal by the Radiation Safety Officer or his designee.

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

(4) Vomiting within 24 hours after oral administration, urinary incontinence, or excessive sweating within the first 48 hours may result in contamination of linen and floor. In any situation where the patient's room may be contaminated or if radioactive urine and/or feces is spilled during collection, call the Radiation Safety Officer or his designee, Ext. _____. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.

(5) Keep all contaminated wastes and vomitus in plastic bags in the patient's room for disposal by the Radiation Safety Officer or his designee. 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 (3 times). The Radiation Safety Officer will establish procedures for disposal of wastes (see Item 12 below).

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

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

n. When the patient is discharged, call the Radiation Safety Officer or his designee or the Nuclear Medicine Department and request that the room be surveyed for contamination before remaking the room.

12. Waste Disposal

When contaminated wastes are transported to the Waste Storage/Disposal area, precautions will be taken to minimize external irradiation of personnel. Stored wastes will be shielded to maintain exposure to personnel in restricted and unrestricted areas ALARA.

Date _____

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH PHOSPHORUS-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 checked items)

_____ 1. Visiting time permitted: _____

_____ 2. Visitors must remain _____ from patient.

_____ 3. Patient may not leave room.

_____ 4. Visitors under 18 are not permitted.

_____ 5. Pregnant visitors are not permitted.

_____ 6. Film or TLD badges must be worn.

_____ 7. Pocket chambers will be worn for supplementary personnel monitoring of individual tasks.

_____ 8. Tag the following objects and fill out the tag:

_____ door _____ chart

_____ bed _____ wrist

_____ 9. Disposable gloves must be worn while attending patient.

_____ 10. Patient must use disposable utensils.

_____ 11. All items must remain in room until approved for removal by the Radiation Safety Officer or his designee.

_____ 12. Smoking is not permitted.

_____ 13. Room is not to be released to Admitting Office until approved by the Radiation Safety Officer or his designee.

_____ 14. Other instructions.

In case of an emergency contact:

RSO _____

Name On-duty/Off-duty Telephone Numbers

TIENT RADIATION SURVEY SHEET
(Unsealed Sources)

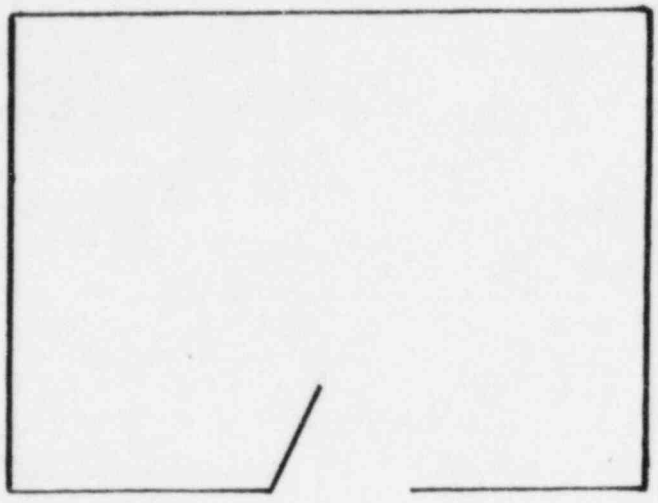
ATIENT'S NAME: _____ Room No. _____ Therapy Start Date _____

sotope: _____ Activity _____(millicuries)

KETCH OF PATIENT'S ROOM/BED LOCATION (be specific)

Adjacent Room?

Yes____
No ____



Adjacent Room?

Yes____
No ____

urvey Meter Measurements: At Bedside: _____mR/hr.

Doorway: _____mR/hr.

Occupied adjacent room(s): _____mR/hr.

1 meter from source: _____mR/hr.

ENERAL

ave nurses been given film badges or dosimeters and log? YES____ NO____

as the 5 mR/hr. tape been placed on the floor? YES____ NO____

as the patient been positioned so exposure to others is minimal? YES____ NO____

ave the nurses received a copy of the protocol for Nursing Care of Radiation Therapy Patients? YES____ NO____ (Supply with protocol if answer is NO)

as the patient's room been properly posted? YES____ NO____ (Supply posting if NO)

erapy Termination Date: _____ Termination Survey Conducted By:_____

diation survey of patient and room confirmed removal of all radioactive materials: YES / NO (Circle One)

L radiation caution signs removed? YES____ NO____

lm badges or dosimeters collected? YES____ NO____

NOTE: If radiation levels are detected above natural background levels, IMMEDIATELY NOTIFY RADIATION SAFETY OFFICER AND THERAPIST.

U.S. NUCLEAR REGULATORY COMMISSION

April 1978

REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

REGULATORY GUIDE 8.20
APPLICATIONS OF BIOASSAY FOR I-125 AND I-131

A. INTRODUCTION

Section 20.108, "Orders Requiring Furnishing of Bioassay Services," of 10 CFR Part 20, "Standards for Protection Against Radiation," indicates that the Nuclear Regulatory Commission (NRC) may incorporate into a license provisions requiring a specific program of bioassay measurements as necessary or desirable to aid in determining the extent of an individual's exposure to concentrations of radioactive material. In certain cases, the requirement for bioassay may also be included in the license by reference to procedures specifying in vivo measurements, measurements of radioactive material in excreta, or both.

This guide provides criteria acceptable to the NRC staff for the development and implementation of a bioassay program for any licensee handling or processing I-125 or I-131. It further provides guidance to such licensees regarding the selection of workers who should participate in a program to detect and/or measure possible internal radiation exposure. The guide is programmatic in nature and does not deal with measurement techniques and procedures.

B. DISCUSSION

The topics treated in this guide include determinations of (1) whether bioassay should be performed, (2) frequencies of bioassay, (3) who should participate, (4) the actions to take based on bioassay results, and (5) the particular results that should initiate such actions.

For the user's convenience, the following terms are presented with their definitions as used in this guide:

Bioassay—The determination of the kind, quantity or concentration, and location of radioactive material in the human body by direct (in vivo) measurement or by analysis in vitro of materials excreted or removed from the body.

Intake—The total quantity of radioactive material entering the body.

In vivo measurements—Measurement of gamma- or x-radiation emitted from radioactive material located within the body for the purpose of detecting or estimating the quantity of radioactive material present.

In vitro measurements—Measurement of radioactivity in samples of material excreted from the human body.

C. REGULATORY POSITION

1. Conditions Under Which Bioassay Is Necessary

a. Routine[1] bioassay is necessary when an individual handles, at any one time, unsealed[2] quantities of radioactive iodine that exceed those shown in Table 1 of this guide.

b. When quantities handled in unsealed form are greater than 10% of, but less than, Table 1 values, routine bioassay may still be necessary under certain circumstances. A written justification for not performing such measurements should be prepared and recorded for subsequent review during NRC inspections whenever bioassay is not performed and the quantities handled exceed 10% of the levels in Table 1.

c. Except as stated in regulatory position 1.d, bioassay is not required when process quantities handled by a worker are less than 10% of those in Table 1.

d. Special bioassay measurements should be performed to verify the effectiveness of respiratory protection devices and other protective clothing. If an

[1] *Routine* means here that an individual is assigned on a scheduled and repeatable basis to submit specimens for bioassay or to report for in vivo measurements. Either radiochemical bioassay of urine or in vivo counting is acceptable to the NRC staff for estimating internal radioactivity burdens or intakes. In some cases, however, a licensee may wish to corroborate estimates from urinalysis data with in vivo determinations.

[2] See discussion in the footnote to Table 1.

Table 1

ACTIVITY LEVELS ABOVE WHICH BIOASSAY FOR I-125 OR I-131 IS NECESSARY

Types of Operation	Activity Handled at Any One Time in Unsealed Form Making Bioassay Necessary* Volatile or Dispersible*	Bound to Nonvolatile Agent*
Processes in open room or bench, with possible escape of iodine from process vessels	0.1 mCi	1 mCi
Processes with possible escape of iodine carried out within a fume hood of adequate design, face velocity, and performance reliability	1 mCi	10 mCi
Processes carried out within gloveboxes, ordinarily closed, but with possible release of iodine from process and occasional exposure to contaminated box and box leakage	10 mCi	100 mCi

* Quantities present may be considered the amount in process by a worker at one time. Quantities in the right-hand column may be used when it can be shown that activity in process is always chemically bound and processed in such a manner that I-125 or I-131 will remain in nonvolatile form and diluted to concentrations less than 0.1 μCi/mg of nonvolatile agent. Capsules (such as gelatin capsules given to patients for diagnostic tests) may be considered to contain the radioiodine in nonfree form, and bioassay would not be necessary unless a capsule were inadvertently opened (e.g., dropped and crushed). On the other hand, certain compounds where radioiodine is normally bound are known to release radioiodine when the material is in process, and the left-hand column may then be applicable. In those laboratories working only with I-125 in radioimmunassay (RIA) kits, the quantities of I-125 are very small and in less volatile forms; thus, bioassay requirements may be judged from the right-hand column.

individual wearing a respiratory protective device or protective clothing is subjected to a concentration of I-125 or I-131 (in any form) in air such that his or her intake with no protection would have exceeded the limits specified in paragraph 20.103(a)(1) of 10 CFR Part 20,[3] bioassays should be performed to determine the resulting actual I-125 or I-131 intake. These special bioassay procedures should also be conducted for personnel wearing respirators if for any reason the I-125 or I-131 concentration in air and the duration of exposure are unknown.

2. Participation

All workers handling radioactive iodine or sufficiently close to the process that intake is possible (e.g., within a few meters and in the same room as the worker handling the material) should participate in bioassay programs described in regulatory position 1.

3. Types of Bioassays That Should Be Performed

a. *Baseline (preemployment or preoperational).* Within 2 weeks prior to beginning work with radioactive iodine in sufficient quantity that bioassay is specified in regulatory position 1.

b. *Routine.* At the frequencies specified in regulatory position 4.

c. *Postoperational and with Separation Physical.* A bioassay should be performed within 2 weeks of the last possible exposure to I-125 or I-131 when operations are being discontinued or when the worker is terminating activities with potential exposure to these radionuclides.

d. *Diagnostic.* Followup bioassay should be performed within 2 weeks of any measurement exceeding levels given as action points in regulatory position 5 in order to confirm the initial result and, in the case of a single intake, to allow an estimate of the effective half-life of radioiodine in the thyroid.

4. Frequency

a. *Initial Routine.* Within 72 hours following entry of an individual into an area where bioassay is speci-

[3] Multiplying the concentrations given in Appendix B, Table I, Column I, 10 CFR Part 20, 5×10^{-8} μCi/ml for I-125 (soluble) and 9×10^{-8} μCi/ml for I-131 (soluble), by 6.3×10^{8} ml gives the corresponding quarterly intake of the respective iodines by inhalation. These quarterly intakes would be about 3.2 μCi for I-125 and 5.7 μCi for I-131, which would give a thyroid dose commitment of about 7.5 rems to a 20-gram thyroid integrated over all future time, using effective half-lives of 41.8 days for I-125 and 7.6 days for I-131 and using a quality factor (QF) of 1.7 to calculate effective disintegration energy in the case of I-125. (This QF of 1.7 is used for conservatism, even though the International Commission on Radiological Protection (1969) and the National Council on Radiation Protection (1971) have published a QF of 1, because some calculations in more recent scientific literature have suggested the use of QF values higher than 1 for electron or beta energies of 0.03 MeV or less.)

fied in accordance with regulatory positions 1 and 2 (but waiting at least 6 hours for distribution of a major part of the iodine to the thyroid[4]) and every 2 weeks or more frequently thereafter as long as the conditions described in regulatory positions 1 and 2 exist. When work with radioactive iodine is on an infrequent basis (less frequently than every 2 weeks), bioassay should be performed within 72 hours of the end of the work period during which radioactive iodine was handled (but not sooner than 6 hours).

b. *After 3 Months.* When a periodic measurement frequency has been selected in accordance with regulatory position 4.a, it may be changed to quarterly if, after 3 months, all the following conditions are met:

(1) The average thyroid burden for each individual working in a given area was less than 0.12 μCi of I-125, less than 0.04 μCi of I-131, and less than the corresponding proportionate amount[5] of a mixture of these nuclides during the initial 3-month period;

(2) The quarterly average radioiodine concentration (μCi/ml) in air breathed by any worker (as obtained when measurements of radioiodine concentrations in air are required) does not exceed 25% of the concentration values for "soluble" (s) iodine given in Appendix B, Table I, Column 1, 10 CFR Part 20 (5×10^{-9} μCi/ml for I-125 and 9×10^{-9} μCi/ml for I-131), i.e., 25% of these concentrations multiplied by the total air breathed by an employee at work during one calendar quarter, 6.3×10^{8} ml, does not exceed 0.8 μCi of I-125 or 1.4 μCi of I-131. The appropriate proportionate amount[5] of a mixture of these nuclides should be used as a guide when both I-125 and I-131 are present; and

(3) The working conditions during the 3-month period, with respect to the potential for exposure, are representative of working conditions during the period in which the quarterly bioassay frequency will be employed, and there is no reasonable expectation that the criteria in regulatory positions 4.b(1) and 4.b(2) above will be exceeded.

c. Between 10 and 48 hours after respiratory protective devices, suits, hoods, or gloves are used to limit exposure as stated in regulatory position 1.d.

5. Action Points and Corresponding Actions

a. *Biweekly or More Frequent Measurements*

(1) Whenever the thyroid burden at the time of measurement exceeds 0.12 μCi of I-125 or 0.04 μCi of I-131, the following actions should be taken:

(a) An investigation of the operations involved, including air and other in-plant surveys, should be carried out to determine the causes of exposure and to evaluate the potential for further exposures.

(b) If the investigation indicates that further work in the area might result in exposure of a worker to concentrations that would cause the limiting intakes established in §20.103 of 10 CFR Part 20 to be exceeded, the licensee should restrict the worker from further exposure until the source of exposure is discovered and corrected.

(c) Corrective actions should be implemented that will eliminate or lower the potential for further exposures.

(d) A repeat bioassay should be taken within 2 weeks of the previous measurement and should be evaluated within 24 hours after measurement in order to confirm the presence of internal radioiodine and to obtain an estimate of its effective half-life for use in estimating dose commitment.

(e) Reports or notification must be provided as required by §§20.405, 20.408, and 20.409 of 10 CFR Part 20 or as required by conditions of the license pursuant to §20.108 of 10 CFR Part 20.

(2) If the thyroid burden at any time exceeds 0.5 μCi of I-125 or 0.14 μCi of I-131, the following actions should be taken:

(a) Carry out all steps described in regulatory position 5.a(1).

(b) Refer the case to appropriate medical/health physics consultation for recommendations regarding therapeutic procedures that may be carried out to accelerate removal of radioactive iodine from the body.

(c) Carry out repeated measurements at approximately 1-week intervals at least until the thyroid burden is less than 0.12 μCi of I-125 or 0.04 μCi of I-131. If there is a possibility of longer-term compartments containing I-125 or I-131 that require evaluation, continue measurements as long as necessary to ensure that appreciable exposures to these other compartments do not go undetected.

b. *Quarterly Measurements.* Carry out actions at levels as indicated under regulatory position 5.a(1). If measurements and surveys indicate an appreciable likelihood that a worker will receive further exposures exceeding the criteria of regulatory positions 4.b(1) and 4.b(2), reinstitute biweekly or more frequent bioassays.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC staff's plans for using this regulatory guide.

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[4] NCRP Report No. 55, "Protection of the Thyroid Gland in the Event of Releases of Radioiodine," National Council on Radiation Protection and Measurements, Washington, D.C., August 1, 1977, p. 21.

[5] See the appendix for a description and example of using this condition for mixtures.

Except in those cases in which the applicant or licensee proposes an acceptable alternative method, the staff will use the methods described herein after December 15, 1978, in evaluating the radiation protection programs of licensees who have bioassay requirements incorporated in their licenses in accordance with § 20.108 of 10 CFR Part 20.

If an applicant or licensee wishes to use the method described in this regulatory guide on or before December 15, 1978, the pertinent portions of the application or the licensee's performance will be evaluated on the basis of this guide.

Appendix
CALCULATION OF ACTION LEVELS FOR MIXTURES OF I-125 AND I-131

A.1 Controlling Instantaneous Thyroid Burdens

Regulatory position 4.b(1) is based on controlling the instantaneous amount in the thyroid and is taken as 25% of the maximum permissible organ burden (MPOB) of I-125 or I-131, respectively, that would give a dose rate of 0.6 rem/week if continuously present in the thyroid. If a mixture of both nuclides is present in the thyroid and X is the fractional activity that is I-125, a 3-month interval may be resumed when the total activity of I-125 and I-131 is below

$$0.12X + 0.04(1 - X)$$

Example

If the measurements of I-125 and I-131 in a worker's thyroid are 0.10 μCi of I-125 and 0.05 μCi of I-131, the fractional I-125 activity is

$$X = 0.10/(0.10 + 0.05)$$
$$= 0.667$$

Then

$$0.12X + 0.04(1 - X) = 0.12(0.667) + 0.04(0.33)$$
$$= 0.0932$$

$$\text{Total} = 0.10 + 0.05 = 0.15\ \mu\text{Ci}$$

Thus, in this case, the worker involved should remain on the biweekly (or more frequent) schedule and should not be put on the quarterly frequency.

A.2 Controlling Total Intakes

Regulatory position 4.b(2) is based on controlling total intakes[6] during a quarterly period when air concentration data are available to assess the potential exposure of the worker, either to random single intakes or to variable or constant continuous exposures. The quantities of 0.8 μCi of I-125 and 1.4 μCi of I-131 were obtained by calculating 25% of the respective total quarterly intakes of 3.2 μCi of I-125 or 5.7 μCi of I-131 (see footnote 3) that would be inhaled when breathing a total of 6.3×10^8 ml per quarter working at the standard man breathing rate for 40 hours per week for 13 weeks.

Example

Should the average quarterly concentrations estimated from air sampled in a worker's breathing zone be 3×10^{-9} μCi/ml for I-125 and 5×10^{-9} μCi/ml for I-131, the total quarterly intakes are:

$$3 \times 10^{-9} \times 6.3 \times 10^8 = 1.89\ \mu\text{Ci I-125}$$

$$5 \times 10^{-9} \times 6.3 \times 10^8 = 3.15\ \mu\text{Ci I-131}$$

$$\text{Total} = 5.04\ \mu\text{Ci}$$

Also, X, the proportion of I-125, is 1.89/5.04 = 0.375

Thus the control level for maintaining biweekly or more frequent bioassay checks would be:

$$0.8X + 1.4(1 - X) = 0.8(0.375) + 1.4(1 - 0.375)$$

$$\text{Total} = 1.18\ \mu\text{Ci for this mixture.}$$

Since the intake of 5.04 μCi is greater than 1.18, this employee should stay on the more frequent bioassay schedule.

Note: The numbers of significant digits carried in the above calculations do not imply any given degree of accuracy of measurement. Enough digits are carried to allow following the arithmetic for purposes of the examples.

[6] The limiting total quarterly intakes are in different proportions for I-125 and I-131 than are the MPOBs. This difference is a result of the fact that permissible concentrations are inversely proportional to effective half-lives; whereas an MPOB is calculated assuming a constant burden in the organ of concern, which is maintained by continuous intake of activity balanced by an equal rate of elimination from the organ.