NRC FORM 313
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires 8-31-89

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS. IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

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

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
NUCLEAR MATERIALS SAFETY SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

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

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

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

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

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
NUCLEAR MATERIALS SAFETY SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

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

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [X] C. RENEWAL OF LICENSE NUMBER 45-18332-01

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

Stuart Circle Hospital
413 Stuart Circle
Richmond, Virginia 23220

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

413 Stuart Circle
Richmond, Virginia 23220

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION | TELEPHONE NUMBER

Becky Stevens, Nuclear Medicine Department | 804-358-7051

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

5. RADIOACTIVE MATERIAL
a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

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

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

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)
FEE CATEGORY | AMOUNT ENCLOSED $ 580.00

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

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

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

SIGNATURE-CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
[signature]	Chris Darling,	Acting Administrator	1-17-89

9002090230 890430
REG2 LIC30
45-18332-01 PDR

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
A	Jan 5-II	7C		[signature]
AMOUNT RECEIVED	CHECK NUMBER			DATE
$580	087439			1/25/89

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 with 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.

RADIOACTIVE MATERIAL

	Byproduct Material	Amount	Purpose
5.a	Material in 35.100	As needed	6.a Medical Use
5.b	Material in 35.200	As needed	6.b Medical Use
5.c	Material in 35.300	As needed	6.c Medical Use
5.d	Material in 35.500*	As needed	5.d Medical Use
5.e	Material in 31.11	As needed	6.e In Vitro

*Devices to be used with this material are as follows:

1. Lixiscope Models LSM-80-X (Series) or LSM-82-X (Series) portable fluoroscopes.

2. Lunar Radiation Corporation Model DP3 bone scanner.

Item 7

AUTHORIZED USERS

Radioactive material will be used by or under the supervision of the following:

1. Patrick K. Burke, M.D. - ALL
2. Timothy S. Burke, M.D. - 35.100, 35.200, Gd-153, In Vitro, Lixiscope Device
3. Howard F. Duke, D.P.M. - Lixiscope Device
4. Wyndell H. Merritt, M.D. - Lixiscope Device
5. Dale E. Siegel, M.D. - Lixiscope Device
6. J. B. Dalton, M.D. - Lixiscope Device
7. Steven H. Jones, M.D. - Lixiscope Device
8. Douglas Jessup, M.D. - Lixiscope Device
9. Arthur C. Ernst, M.D. - Lixiscope Device
10. Thomas J. Carrico, M.D. - Lixiscope Device
11. Scott B. Anthony, M.D. - Lixiscope Device

Training and experience documentation for the above is already on file under this license.

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 applicable 19.12 of 10 CFR Part 19, to include:

A. Areas where radioactive materials are used or stored.

B. Potential hazards associated with radioactive materials.

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:

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

B. During annual refresher training.

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

Item 9

FACILITIES AND EQUIPMENT

9.1 Annotated Drawing

9.2 Survey Instrument Calibration Procedures

We have developed a survey instrument calibration procedure for your review that is appended as ATT 9.2

9.3 Dose Calibrator Calibration Procedures

We have developed a dose calibrator calibration procedure for your review that is appended as ATT 9.3

9.4 External Monitoring Program

We have developed an external monitoring program for your review that is appended as ATT 9.4

FACILITIES AND EQUIPMENT

Radiation Handling Equipment

To enable personnel to work safely with unsealed radioactive material, the Nuclear Medicine Department 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 Department. The following survey instrumentation is utilized by the department in compliance with 10 CFR 35.220 and 35.315(a)(7).

(1) Eberline E-130A
(1) Dosimeter Corporation 3700
(1) Eberline E-520
(2) Picker Dose Calibrators

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 additional 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

Disposable gloves

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

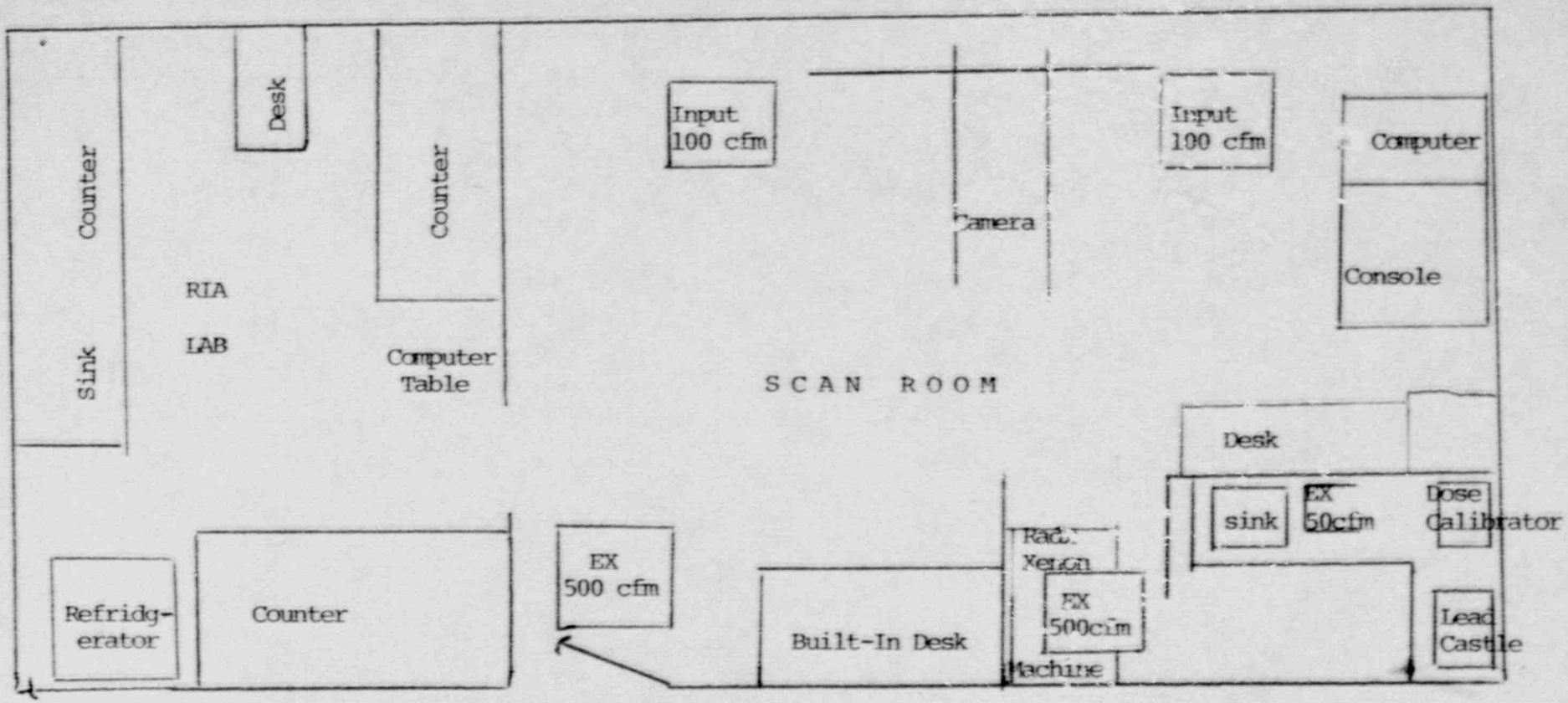
Signs and labels indicating the presence of radioactive materials in areas or rooms where they are being used or stored. Labels on containers indicating radionuclide, activity, and date.

Monitoring

Appropriate survey instrumentation relative to the types and quantities of radioactive materials requested.

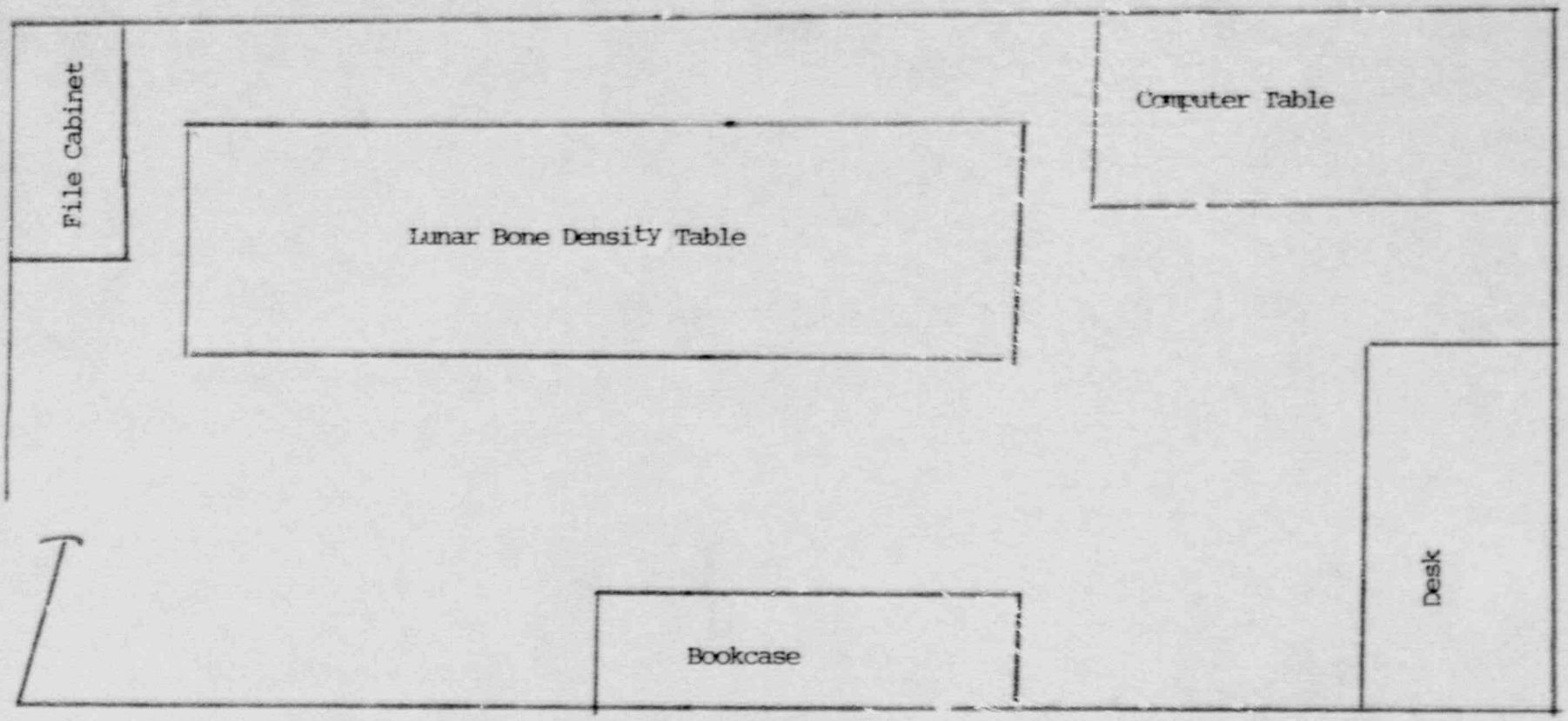
A diagram of the facilities is also enclosed herewith.

STUART CIRCLE HOSPITAL



Nuclear Medicine Department (Room 519)

STUART CIRCLE HOSPITAL



Osteoporosis Center (Room 522)

CALIBRATION OF SURVEY METER INSTRUMENTATION

Survey meter calibrations will be conducted at intervals not to exceed six (6) months by Health Physics Services, Inc., Rockville, Maryland, using a sealed 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 Number 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 from the Cobalt-57 source is determined using the inverse square law and verified with a calibrated dose rate meter.

In addition to the above outlined calibration procedures, the apparent dose rate from an owner supplied or built in check source will be determined. The apparent dose rate will be indicated on the meter at the point of measurement.

DAILY SURVEY METER CHECK

On a daily basis, survey meter response will be checked using the owner supplied or built-in check source that is used for calibration purposes.

HEALTH PHYSICS SERVICES, INC.
4 RESEARCH PLACE, SUITE 140
ROCKVILLE, MARYLAND 20850
(301) 670-1818 OR 800 - 638-8488

CALIBRATION CERTIFICATE

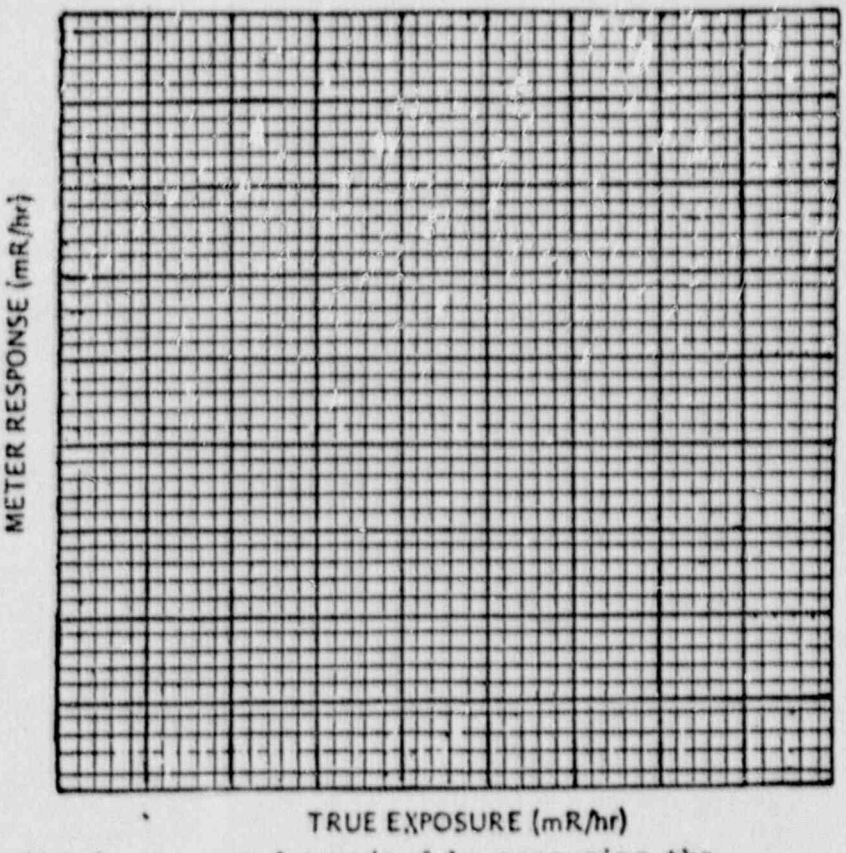
OWNER _____ CALIBRATION DATE _____ NEXT DUE _____

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

DOSE CALIBRATOR CALIBRATION AND LINEARITY PROCEDURES

1. On a daily basis, the constancy of the dose calibrator will be determined with two sources: 200 uCi of Cesium-137 will be used on all commonly used radionuclide settings, and greater than 50 microcuries of Cobalt-57 will be used on the Co-57 and Tc-99m settings. 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 conducted.
2. At intervals not to exceed six (6) months, Health Physics Services, Inc., Rockville, Maryland, will conduct the dose calibrator accuracy test under Maryland License No. MD-31-035-01. A Cobalt-57 source of greater than 50 microcuries 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 semiannual procedure will be repeated using a Cesium-137 source of greater than 50 microcuries. The 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 Proposed Revision 2 to Regulatory Guide 10.8, Guide for the preparation of Applications for Medical Programs, Appendix C, Item 5 over the full range of activities of Technetium used from the highest dose administered to a patient to 10 uCi. 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 the Proposed Revision 2 to Regulatory Guide 10.8, Guide for the preparation of Applications for Medical Programs, Appendix C, Item 6, unless certified data is supplied by the dose calibrator manufacturer.
5. The RSO will review and sign the records of all geometry, linearity, and accuracy tests.
6. Accuracy, linearity, and geometry testing of the dose calibrator will also be performed upon installation and after repair.

DOSE CALIBRATOR CONSTANCY

Dose calibrator constancy will be evaluated on days of dose calibrator use prior to patient dose assay with at least one source using a reproducibility geometry. The source will have an activity of not less than 10 microcuries of Ra-226 or 50 microcuries of any other photon emitting radionuclide.

Procedure:

1. The source will be assayed using the appropriate dose calibrator setting. The result will be recorded.

2. The background at the same setting should be measured to confirm proper operation of the automatic background subtract circuit if it used.

3. The source used for constancy should be decayed so that the activity of the source on the day of measurement is known. This will be done either using graph paper or maintained numerically in a log book.

4. The source will then be assayed on all commonly used radioisotope settings. The results will be recorded.

5. Action levels will be established and maintained on file for each setting. Values obtained during constancy checks will be evaluated against these action levels.

6. If activities measured under Item 1 exceed 10% of the predicted activity, the RSO or Chief Technologist will be notified as required in 10 CFR, Part 35.50.d and will insure that the dose calibrator is repaired or replaced.

7. If activities measured under Item 4 exceed the trigger levels established under Item 5, the RSO or Chief technologist will be notified to take appropriate action as required in 10 CFR, Part 35.

DOSE CALIBRATOR ACCURACY

Accuracy will be evaluated semiannually by Health Physics Services, Inc., with sources traceable to NBS.

Procedure:

1. At least two sources with different principle photon energies will be used. One source will have a principle photon energy between 100 kev and 500 kev. Typically, a Cs-137 and Co-57 source will be used for accuracy.

2. Assay the sources on the appropriate setting.

3. The assayed value should be within 10% of the certified activity of the referenced source mathematically corrected for decay. If it exceeds 10%, the dose calibrator will be repaired or replaced.

PERSONNEL MONITORING PROGRAM

1. The RSO will promptly review all exposure records to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records, for example, pocket ionization chambers, when the monitor of record is a film or TLD.

2. Personnel dosimetry devices will be issued to employees pursuant to 10 CFR 20.202.

3. Personnel dosimetry devices supplied by a contract services such as R.S. Landauer or Siemens Gammasonics will be issued on a monthly basis.

RADIATION SAFETY PROGRAM

10.1 Radiation Safety Committee/Radiation Safety Officer

We have developed a procedure for establishing a Radiation Safety Committee that is appended as ATT 10.1

10.2 ALARA Program

We have developed an ALARA program for your review that is appended as ATT 10.2

10.3 Leak Test Procedures

We have developed leak testing procedures for your review that is appended as ATT 10.3

10.4 Safe Use of Radiopharmaceuticals

We have developed rules for the safe use of radiopharmaceuticals for your review that are appended as ATT 10.4

10.5 Emergency Procedures

We have developed spill procedures for your review that are appended as ATT 10.5

10.6 Ordering and Receiving Radioactive Material

We have developed a procedure for ordering and receiving radioactive material for your review that is appended as ATT 10.6

10.7 Procedures for Safely Opening Packages Containing Radioactive Material

We have developed a package opening procedure for your review that is appended as ATT 10.7

10.8 Unit Dosage Records

We have developed a procedure for a unit dosage record system for your review that is appended as ATT 10.8

10.9 Multidose Vial Records

We have developed a procedure for a multidose vial record system for your review that is appended as ATT 10.9

10.10 Molybdenum Concentration Records

We have developed a procedure for measuring and recording molybdenum concentration for your review that is appended as ATT 10.10

10.11 Implant Source Inventory

N/A

10.12 Area Survey Procedures

We have developed survey procedures for your review that are appended as ATT 10.12

10.13 Xenon Handling Procedures

We have developed a procedure for monitoring worker dose due to submersion in noble gases that is appended as ATT 10.13

10.14 Iodine-131 Handling Procedures

We have developed a procedure for radiation safety during therapeutic use of radiopharmaceuticals for your review that is appended as ATT 10.14

10.15 Procedure for Radiation Safety During Implant Therapy

N/A

RADIATION SAFETY COMMITTEE

Meeting Frequency

The radiation safety committee shall meet as often as necessary to conduct its business but not less than once in each calendar quarter.

Charge

The committee shall:

1. Ensure that licensed material will be used safely. This includes review as necessary of training programs, equipment, facility, supplies, and procedures;

2. Ensure that licensed material is used in compliance with NRC regulations and the institutional license;

3. Ensure that the use of licensed material is consistent with the ALARA philosophy and program;

4. Establish a table of investigational levels for individual occupational radiation exposures; and

5. Identify program problems and solutions.

Responsibilities

The committee shall:

1. Be familiar with all pertinent NRC regulations, the license application, the license, and amendments;

2. Review the training and experience of authorized users and the Radiation Safety Officer (RSO) to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the regulations and the license;

3. Review on the basis of safety and approve or deny, consistent with the limitations of the regulations, the license, and the ALARA philosophy all requests for authorization to use radioactive material within the institution;

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

5. Review quarterly the RSO's summary report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive;

6. Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used (e.g., nursing, security, housekeeping, physical plant) are appropriately instructed as required in 19.12 of 10 CFR Part 19;

7. Review at least annually the RSO's summary report of the entire radiation safety program to determine that all activities are being conducted safely, in accordance with NRC regulations and the conditions of the license, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the RSO, results of NRC inspections, written safety procedures, and the adequacy of the management control system;

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

9. Maintain written minutes of all committee meetings, including members in attendance and members absent, discussions, actions, recommendations, decisions, and numerical results of all votes taken; and

10. Ensure that the byproduct material license is amended if required prior to any changes in facilities, equipment, policies, procedures, and personnel.

Administrative Information

1. Membership must include one authorized user for each type of use authorized by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor an RSO. Management may appoint alternate members to participate in meetings in the case of absence or principal members and should consider appointing as adjunct members representatives from security, physical plant, housekeeping, and other departments. (Adjunct members should abstain from balloting on radiation safety technical questions such as Items 2 through 5 in the "Responsibilities" section above.)

2. To establish a quorum, one-half of the Committee's membership, including the RSO and the management representative, must be present.

3. To the extent that they do not interfere with the mission of the Committee, management may assign other responsibilities such as x-ray radiation safety, quality assurance oversight, and research project review and approval.

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. Written policies will be evaluated and implemented for the following items:

   a. Authorizing the purchase of byproduct material.
   b. Receiving and opening packages.
   c. Storing byproduct material.
   d. Keeping an inventory.
   e. Using byproduct material.
   f. Taking emergency action if material is lost.
   g. Disposing of byproduct material
   h. Training of personnel subjected to a radiation environment.

2. Instructing personnel in safety 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. Establishing investigational levels and promptly investigating any case of excessive or abnormal exposure to determine the cause and taking steps to prevent its recurrence. This includes overexposures, accidents, spills, transfers, and any other deviation from approved radiation safety practice.

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., Rockville, 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 survey 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 accuracy and completeness.
   e. Required dose calibrator instrumentation tests (e.g., accuracy and linearity).

7. Continued

   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.

9. The RSO will brief facility administration once each year on the byproduct material program.

10. The RSO will assist the Radiation Safety Committee in the performance of its duties.

Stuart Circle Hospital

TO: All Employees

FROM: Chief Executive Officer

DATE: January 17, 1989

SUBJECT: DELEGATION OF AUTHORITY

Dr. Patrick K. Burke has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radiation. The Radiation Safety Officer is responsible for managing the radiation safety program, identifying radiation safety problems, initiating, recommending, or providing corrective actions, verifying implementation of corrective actions, and ensuring compliance with regulations. The Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities.

The Radiation Safety Officer is also responsible for assisting the Radiation Safety Committee in the performance of its duties, and for serving as its secretary.

CEO:vk

Stuart Circle Hospital

ATT 10.2

FOREWARD

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 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 exposures to "As Low As Reasonably Achievable" (ALARA) to employees, visitors, students, and patients who are not under medical supervision of the administration of radiation or radioactive material 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.

Administrator Interim

1/17/88
Date

CD:vk

413 Stuart Circle • Richmond, Virginia 23220 • (804) 358-7051
Charter Medical Corporation

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 "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 and unrestricted 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 Effort 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 EXPOSURES

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. The minutes, containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection.

D. Reestablishment of an individual occupational worker's Investigational 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 wit good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

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

VIII. SIGNATURE OF CERTIFYING OFFICIAL

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

Signature of Administrator

Chris Darling

Name (type or print)

Acting Administrator

Title

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 Number MD-31-035-1.

GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIALS

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 specifically designated receptacles.

10. The will be no pipetting by mouth.

11. 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.

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

18. Confine radioactive solutions in shielded containers that are clearly labeled. Radiopharmaceutical multidose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. A log book should be used to record the preceding information and total prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, total volume remaining, the measured activity of each patient dosage, and any other appropriate information. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study, or patient's name and identification number.

19. Assay each patient dosage in the dose calibrator before administering it. Do not use a dosage if it is more than 10 percent off from the prescribed dosage, except for prescriptions of less than 10 microcuries. Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering.

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 be also inserted into the plastic bag.

4. The survey will be conducted using a low-range, GM 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: Patrick K. Burke

OFFICE PHONE: (804) 358-7051 x 430

HOME PHONE: (804) 740-4119

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER:

Rebecca H. Stevens (804) 276-3703

R. Sherman Pillis (804) 746-4285

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIALS

1. The RSO or a designate must authorize each order for radioactive materials.

2. The supervising nuclear medicine technologist or his designee will place all orders for radioactive material, and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

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

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

5. 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, 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 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.

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

For safely opening packages containing radioactive materials, 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 the 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 as well as the final delivering carrier and the appropriate regulatory offices.
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 sq. 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.

Procedures for Safely Opening
Packages Containing Radioactive Material

Note, package containing quantities of radioactive material in excess of Type A quantity limits specified in 10 CFR 20.205(b) will be monitored for external radiation levels and surface contamination within 3 hours after receipt if received during working hours or within 18 hours if received after working hours.

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
(172.403)
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"	0.5mR/hr	0
"RADIOACTIVE-YELLOW II"	50 mR/hr	1.0 mR/hr
"RADIOACTIVE-YELLOW III"	200 mR/hr	10 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 10mR/hr at three feet or 200mR 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.

_____

Stuart Circle Hospital

TO: Security Personnel

FROM: Chris Darling, Administrator

DATE: January 17, 1989

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

Any packages containing radioactive material that arrive between 4:00 p.m. and 7:30 a.m., or on Saturday or Sunday, 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: Patrick K. Burke, M.D.

OFFICE PHONE: (804) 358-7051 x 430

HOME PHONE: (804) 740-4119

CHIEF TECHNOLOGIST: Rebecca H. Stevens

OFFICE PHONE: (804) 358-7051 x 468

HOME PHONE: (804) 276-3703

SRP:vk

PROCEDURES FOR MAINTAINING RECORDS OF UNIT DOSE VIAL USE

For each unit dosage received from a supplier, make a record of the:

1. Radionuclide:
2. Generic name or its abbreviation or trade name;
3. Date of receipt;
4. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time;
5. Supplier;
6. Lot number or control number if assigned and expiration date;
7. Date of administration or disposal;
8. If administered,
   a. Prescribed dosage (unless already recorded in clinical procedure manual),
   b. Measured activity in millicuries or microcuries and date and time of measurement,
   c. Patient name and identification number if one has been assigned;
9. If discarded, the date and method of disposal; and
10. Initials of the individual who made the record.

PROCEDURES FOR MAINTAINING RECORDS OF MULTIDOSE VIAL USE

For each multidose vial that you receive from a supplier or that you prepare, make a record of the:

1. Radionuclide;
2. Chemical form or its abbreviation or trade name;
3. Date of receipt or preparation;
4. Date and time of initial activity assay and activity in millicuries and volume;
5. supplier or kit manufacturer;
6. If administered,
   a. Date and time dosage was drawn,
   b. Prescribed dosage,
   c. Measured activity in millicuries,
   d. Patient name and identification number if one has been assigned;
7. If discarded, the method of disposal and date; and
8. Initials of the individual who made the record.

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 for molybdenum-99 breakthrough contamination. The eluates will not be used if the concentration of molybdenum to technetium is greater than 0.15 uCi moly/1 mCi of technetium.

   NOTE: Molybdenum breakthrough tests will be performed in accordance with 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 the 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 in accordance with Regulatory Guide 10.8.

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 GM survey meter and decontaminated if radiation levels measured are in excess of established trigger levels. Trigger levels will not exceed 0.5 mR/hr in unrestricted areas or 5 mR/hr in restricted areas.

2. Radiopharmaceutical storage and waste storage areas will be surveyed weekly.

3. All other laboratory areas will be surveyed weekly.

4. The weekly survey will consist of:

   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.

5. 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 to conduct the survey or analyze the results.

   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 (mR/hr), keyed to location of the drawing (point out rates that require corrective action).

   e. Detected contamination levels (dpm/100 cm^2), keyed to locations on drawing.

   f. Trigger levels established for each, and decontamination results when necessary.

6. The area will be cleaned if the contamination level exceeds 200 dpm per 100 sq. cm. in an unrestricted area or 2000 dpm per 100 sq. cm. in a restricted area.

7. The Radiation Safety Officer will be notified immediately if survey results exceed the trigger levels.

FACILITY_____ MONTH/YEAR_____

	DAILY AREA SURVEYS - mR/hr TRIGGER LEVELS													WEEKLY WIPE TESTS - TRIGGER LEVEL =									
DAY	A	B	C	D	E	F	G	H	I	J	K	Init	L	M	N	O	P	Q	R	S	T	Init
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SURVEY METER -_____
SERIAL NUMBER -_____

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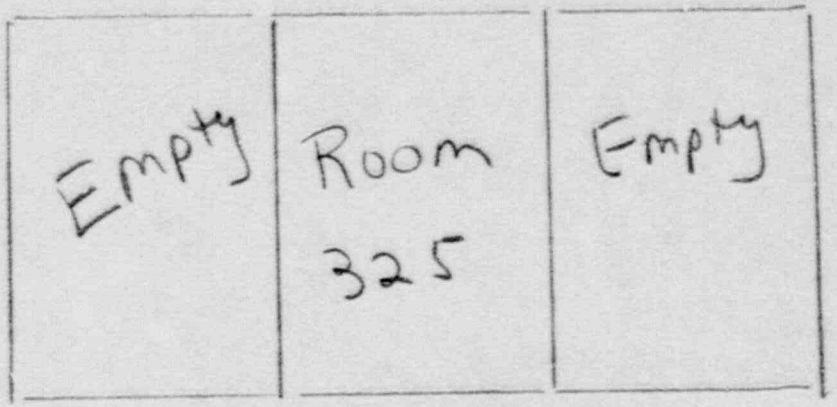
CPM - DPM
CONVERSION

STUART CIRCLE HOSPITAL

Empty



Storage Room for waste located in Laural Hill House. (Building behind hospital)

This entire floor is vacant of personnel.

Xenon-133 Handling Procedures

Quantity to be Used

1. A maximum of 100 patients per year will be studied with an average activity of 10 millicuries per patient.
2. Desired possession limit: 500 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 in the isotope storage areas surrounded by lead bricks in the Hot Lab. Patient doses will be administered in the Camera Room.

Description of Ventilation System

1. The total area of the Camera Room is approximately 320 square feet, with an 8 foot ceiling, for a total volume of 2560 cubic feet. The room will be under negative pressure with the normal air return system exhausted directly to the outside atmosphere.
2. The Hot Lab, where radioactive material is stored and prepared for dosing, is approximately 15 square feet, with an 8 foot ceiling, for a total volume of 120 cubic feet. Room air is exhausted to the outside atmosphere by a dedicated ventilation system.

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

If, during the patient study or handling of xenon, an accidental release of Xe-133 occurs, the rooms will be evacuated immediately and the doors closed. The room will be closed in accordance with the established gas clearance times. Clearance times will be posted in the rooms.

Air Concentrations of Xe-133 in Restricted Areas

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

1. Camera Room

   A. A = maximum activity used per week

      $A = (10 \text{ mCi/pt})(3 \text{ pt/week})(1 \times 10^{3} \text{ uCi/mCi}) = 3.0 \times 10^{4} \text{ uCi/wk}$

   B. Assume a loss rate of 20%, f = .2

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

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

      $$V = \frac{(3.0 \times 10^{4} \text{ uCi/wk} \times .2)}{1 \times 10^{-5} \text{ uCi/ml}} \left(\frac{\text{ft}^3/\text{min}}{6.8 \times 10^{7} \text{ ml/40hr wk}} \right)$$

      $= 9.0 \text{ ft}^3/\text{min}$

2. Hot Lab

   A. A = Maximum activity on hand per week

      $A = 80 \text{ mCi} = 8.0 \times 10^{4} \text{ uCi}$

   B. Assume a loss rate of 5%, f = .05

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

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

      $$V = \frac{(8.0 \times 10^{4} \text{ uCi/wk} \times .05)}{1 \times 10^{-5} \text{ uCi/ml}} \left(\frac{\text{ft}^3/\text{min}}{6.8 \times 10^{7} \text{ ml/40hr wk}} \right) = 6 \text{ cfm}$$

      assuming 5% loss CAC

      $= 23.5 \text{ ft}^3/\text{min}$ → if assuming 20% loss CAC

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.

CHARCOAL TRAP
(SEE NEXT PAGE) CAC

Method of Disposal (continued)

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 room exhaust vents. There is no recirculation of exhausted air within the facility and the point of exit for the exhaust duct is at least 50 feet from the closest point of air intake.
3. If there should be an accidental release of Xe-133 in the Camera Room, the gas will be exhausted to the outside or unrestricted area through the emergency exhaust vent.
4. 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).
5. 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.
6. 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.
7. 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 = Maximum amount to be used per year

   $$A = (10 \text{ mCi/pt})(3 \text{ pt/wk})(1 \times 10^{3} \text{ uCi/mCi})(52 \text{ wks/yr}) =$$

   $$1.56 \times 10^{6} \text{ uCi/yr}$$

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

   C. V = The required ventilation to maintain airborne concentrations of Xe-133 below MPC in an unrestricted area.

   $$V = \frac{Axf}{3.0 \times 10^{-7} \text{ uCi/ml}}$$

   $$V = \frac{1.56 \times 10^{6} \text{ uCi/yr} \times .2}{3.0 \times 10^{-7} \text{ uCi/ml}} \left(\frac{\text{ft}^3/\text{min}}{1.49 \times 10^{10} \text{ ml/yr}} \right)$$

   $$V = 70 \text{ ft}^3/\text{min}$$

Concentrations of Effluents to Unrestricted Areas (Continued)

2. Hot Lab Exhaust

A. A = Maximum amount to be released per year

$A = (80\ mCi/wk)(52\ wk/yr)(10^3 uCi/mCi) = 4.2 \times 10^6 uCi/yr$

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

C. V = The required ventilation to maintain airborne concentrations of Xe-133 below MPC in an unrestricted area.

$$V = \frac{Axf}{3.0\times10^{-7} uCi/ml} \left(\frac{ft^3}{1.49\times10^{10}\ ml/yr} \right)$$

$$V = \frac{4.2\times10^6 uCi/yr\ (.05)}{3\times10^{-7}\ uCi/ml} \left(\frac{ft^3/min}{1.49\times10^{10}\ ml/yr} \right)$$

$V = 47\ ft^3/min$

Summary

The minimum ventilation rates required to maintain concentrations of Xe-133 in a restricted area below 1×10^{-5}uCi/ml are 23.5 ft^3/min in the hot lab and 9.0 ft^3/min in the camera room. The minimum ventilation rates to maintain airborne concentrations of Xe-133 in an unrestricted area below 3×10^{-7}uCi/ml are 47 ft^3/min in the hot lab and 70 ft^3/min in the camera room.

The ventilation rates will be no less than 47 ft^3/min in the hot lab and no less than 70 ft^3/min in the camera room. This will insure airborne concentrations in restricted and unrestricted areas are less than permissible concentrations of 1×10^{-5} uCi/ml and 3×10^{-7} uCi/ml, respectively.

Spilled gas clearance time will be calculated using the procedures and calculations outlined in USNRC Regulatory Guide 10.8 Appendix O.4. The results of this determination will be posted in the Hot Lab and Scan Room (see attached form). Calculations will be revised if there is a change in air flow or activity of isotope used.

SPILLED GAS CLEARANCE TIMES

V = Room volume in ft^3
Q = Air exhaust rate in ft^3/min
A = Highest activity in a single container (Xenon-133) or used during a study (Tc-99m)
C = Maximum Permissible Concentration

$$\left(\frac{-V(2.83 \times 10^4\ ml/ft^3)}{Q(2.82 \times 10^4\ ml/ft^3)}\right) \ln\left(MPC \times \frac{V(2.83 \times 10^4\ ml/ft^3)}{A\ uCi}\right)$$

1. Xe-133 - Assuming Uniform Distribution of Xe-133 in Room:

   $C = 1 \times 10^{-5}$ uCi/ml
   $A = 80$ mCi or 8×10^4 uCi
   $V = 2560\ ft^3$
   $Q = 787\ ft^3/min$

$$\left(\frac{-(2560\ ft^3)(2.83 \times 10^4\ ml/ft^3)}{(787\ ft^3/min)(2.83 \times 10^4\ ml/ft^3)}\right) \ln\left(\frac{(1 \times 10^{-5}\ uCi/ml)(2560\ ft^3)(2.83 \times 10^4\ ml/ft^3)}{8.0 \times 10^4\ uCi}\right)$$

Clearance Time = 15.3 minutes

Comments: These are sample calculations based on measured room exhaust rates. The room exhaust rates will be periodically measured and if necessary, appropriate changes will be made in the calculations to reflect the changes. Room clearance times will be posted in the rooms.

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 P of the NRC Licensing Guide (enclosed).

The patient may be discharged from the hospital when the exposure rate from the patient is less than 5 mR/hr at 1 meter distance or the retained radioactivity is less than 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.

..ODINE-131 HANDLING PROCEDUR.

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 available, 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. If hoods are used for opening therapeutic quantities of iodine, they will be evaluated at least semiannually to verify adequate exhaust ventilation rates.

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

3. 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 baseline 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 glove-boxes, 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 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.

APPENDIX P

Model Procedure for Radiation Safety During Iodine Therapy Over 30 Millicuries (See §§ 35.300, 35.75, and 20.105.)

You may use the following procedure for reducing worker and public dose during radiopharmaceutical therapy. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for radiation safety during radiopharmaceutical therapy that was published in Appendix P to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of §§ 19.12, 20.105, 35.75, and 35.300. Say on your application, "We have developed a procedure for radiation safety during therapeutic use of radiopharmaceuticals for your review that is appended as ATT 10.14," and append your procedure.

MODEL PROCEDURE

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room with private sanitary facilities and should be without carpet.

2. Prepare the room for the procedure as follows:

   a. Use leak-proof absorbent paper to cover large surfaces (the bed, chairs, and the floor around the toilet) that are likely to be contaminated. Small items (telephone, door knobs, bed remote control, television control, and nurse call cord) may be covered with absorbent paper or plastic bags.

   b. Prepare separate boxes for linen, disposable waste, and nondisposable contaminated items. Place a single large reclosable plastic bag in each box, or supply several small plastic bags.

   c. Determine whether urine will be discarded by release to the sanitary sewer or collected. If urine will be collected, prepare collection containers.

      (1) Containers should be unbreakable and closable.

      (2) If there is no need for assay or volumetric determination and urine will be decayed in storage, add to each container an absorbent such as vermiculite.

      (3) To avoid room contamination in the case of a spill, place containers in a box or deep tray that has been lined with a plastic bag and absorbent paper or vermiculite.

      (4) Supply a few half-value layers of shielding for each container. (For I-131, one half-value layer is approximately 3 mm of lead.)

      (5) Supply a wide-mouth antisplash funnel.

d. Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use as necessary by nursing, nuclear medicine, and radiation safety personnel.

3. Order disposable table service for the duration of the patient's stay. Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.

4. Supply the nurses with film badges, TLDs, or pocket ionization chambers.

5. Brief the nurses on radiation safety precautions. Use the sample form, "Nursing Instructions for Patients Treated with Iodine-131, Phosphorus-32, or Gold-198" (Exhibit 17), or your own nursing instruction form as an outline. Allow time for questions and answers during the briefing. Leave a written copy of the radiation safety precautions in the patient's chart or at the nurses' station.

6. Brief the patient on radiation safety procedures for the dosage administration, visitor control, urine collection, radioactive waste, and other items as applicable.

7. Only those persons needed for medical, safety, or training purposes should be present during the administration.

8. Mark a visitors' "safe line" on the floor with tape as far from the patient as possible.

9. Following administration of the dosage, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the visitors' "safe line," and in the surrounding hallways and rooms (the last rates must conform to requirements in paragraph 20.105(b)). Record this and any other necessary information on the nursing instructions form or the nurses' dosimeter signout form. Post the room with a "Radioactive Materials" sign.

10. For patients treated with liquid or gelatin-capsuled I-131, 1 day after the dosage administration, measure the thyroid burden of all personnel who were present for the administration. Also consider a thyroid burden assay for patient care personnel 2 days after the administration. Make a record of the worker's name, amount of I-131 activity in a thyroid phantom in microcuries and associated counts per minute, the counts per minute from the worker's thyroid, the calculated thyroid burden, and date.

11. As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area.

12. Do not release any patient until either the exposure rate from the patient is less than 5 millirem per hour at 1 meter or the retained radioactivity is less than 30 millicuries (see § 35.75). If you use the exposure rate standard as the release criterion, measure it with a radiation measurement survey meter at a distance of 1 meter from the umbilicus while the patient is standing or, if the patient is not ambulatory, 1 meter from the bedside with the patient supine.

13. Before using the room for general occupancy, it must be decontaminated and released to the Admitting Office.

    a. Remove all absorbent paper, and place it in the appropriate container.

    b. Transfer all containers to a decay-in-storage or decontamination area.

    c. Use a radiation detection survey meter to check for room contamination. Clean contaminated areas until removable contamination is less than 200 dpm/100 cm^2.

    d. Call the Housekeeping Office to remove the cleaning restriction and call the Admitting Office to return the room to the vacant list.

Exhibit 18, "Radiation Safety Checklist for Iodine Therapy over 30 Millicuries," may also be helpful to you.

EXHIBIT 17

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH IODINE-131, PHOSPHORUS-32, OR GOLD-198

Patient Name:_____ Patient Number:_____
Attending:_____Phone:___ Pager:_____ Patient Room:_____

Dose:_____mCi of _____ as _____ was administered at __:__ [redacted]
Signature:_____ Date:___-___-___

RADIATION EXPOSURE RATES

Unrestricted areas: door-___ ___mR/hr; ra___-____mR/hr; ra___-____mR/hr
Patient supine in bed or _____

Date	Time	Bedside	3 ft from bed	Door	_____
___-___-___	__:__ am/pm	_____mR/hr	_____mR/h	_____mR/hr	_____mR/hr
___-___-___	__:__ am/pm	_____mR/hr	_____mR/h	_____mR/hr	_____mR/hr
___-___-___	__:__ am/pm	_____mR/hr	_____mR/h	_____mR/hr	_____mR/hr
___-___-___	__:__ am/pm	_____mR/hr	_____mR/h	_____mR/hr	_____mR/hr
___-___-___	__:__ am/pm	_____mR/hr	_____mR/h	_____mR/hr	_____mR/hr
___-___-___	__:__ am/pm		_____mR/h		

INSTRUCTIONS

Vistor Restrictions:
- ☐ No visitors.
- ☐ No visitors under 18 or pregnant.
- ☐ ___ minutes each day maximum for each visitor.
- ☐ Visitors must stay behind line on floor at all times.

Nursing Restrictions:
- ☐ Patient is restricted to room.
- ☐ No nurses who are pregnant may render care.
- ☐ ___ minutes each day per nurse in the room.

Patient Care:
- ☐ Wear disposable gloves. Wash your hands after caring for patient.
- ☐ Discard linen, bedclothes, plates, utensils, dressings, etc., in boxes in room.
- ☐ Collect urine in containers provided. Discard feces in toilet.
- ☐ Discard urine and feces in toilet. Flush three times.
- ☐ Housekeeping personnel are not permitted in the room.
- ☐ Only RSO may release room to admitting office.
- ☐ Wear your radiation monitor when caring for patient. Leave at nursing station at the end of your shift. You may use the same monitor on your next shift. Do not share. Call RSO for additional monitors if needed.
- ☐ _____
- ☐ _____

In case of emergency, or if you have a question, call:
RSO:_____ Work:_____ Home:___-____ Pager:____
MD:_____ Work:_____ Home:___-____ Pager:____

RADIATION SAFETY CHECKLIST
IODINE THERAPY OVER 30 MILLICURIES

Patient:_____ Room:_____ Date:_____

PREPARATION

- ☐ Schedule a private room, with private sanitary facilities and without carpet, in a low traffic area.
- ☐ Cover large room surfaces with absorbent paper and small surfaces with absorbent paper or plastic bags.
- ☐ Prepare labeled boxes for used linen, disposable waste, and nondisposable contaminanted items.
- ☐ Prepare urine collection containers if urine will be collected.
- ☐ Stock room with disposable gloves, absorbent paper, and "radioactive waste" labels.
- ☐ Mark a visitors' "safe line" on the floor.
- ☐ Order disposable table service.
- ☐ Notify housekeeping to not clean the room until further notice.
- ☐ Brief the nursing staff on radiation safety measures.
- ☐ Supply the nursing staff with personnel radiation dosimeters.

ADMINISTRATION

- ☐ Clear the room of unneeded personnel.
- ☐ Brief the patient on the clinical procedure.
- ☐ Administer the dosage.
- ☐ Measure dose rates at bedside, 1 meter from bedside, visitors' "safe line," and surrounding hallways and rooms.
- ☐ Post the room with a "Radioactive Materials" sign.

FOLLOWUP

- ☐ Measure the thyroid burden of all personnel who were present for the administration.
- ☐ Pick up waste for decay-in-storage or decontamination.
- ☐ Release the patient.
- ☐ Decontaminate and survey the room. Remove the "Radioactive Materials" sign.
- ☐ Call the Housekeeping Office to clean the room.

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.

U.S. . CLEAR REGULATORY COMMISS) 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 radioimmunoassay (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 1, Column 1, 10 CFR Part 20, 5×10^{-9} μCi/ml for I-125 (soluble) and 9×10^{-9} μCi/ml for I-131 (soluble), by 6.3×10^{9} 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 an 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.

WASTE DISPOSAL

Item 11

We have developed a procedure for waste disposal for your review that is appended as ATT 11.1.

WASTE DISPOSAL PROCEDURES

Solid radioactive waste will be divided into three groups:

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 less than 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.

Radioactive waste will be stored on site or returned to the commercial/radiopharmacy. Solid radioactive waste not returned to the commercial/radiopharmacy will be held for decay for a minimum of 10 half lives and 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.

Packages containing radioactive material that are returned to Syncor will be transported in accordance with the regulations set forth in 49 CFR.

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 material.

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:

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

WASTE DISPOSAL

General Rules

1. Shield radioactive waste when in storage.
2. Remove or obliterate all radioactive material labels before disposal.
3. Maintain waste records for the duration of the license.

Date Waste Placed In Storage	Type of Radioactive Material	Disposal Date	mR/hr Surface	mR/hr Background	Survey Meter Model/ Serial No.	Initials