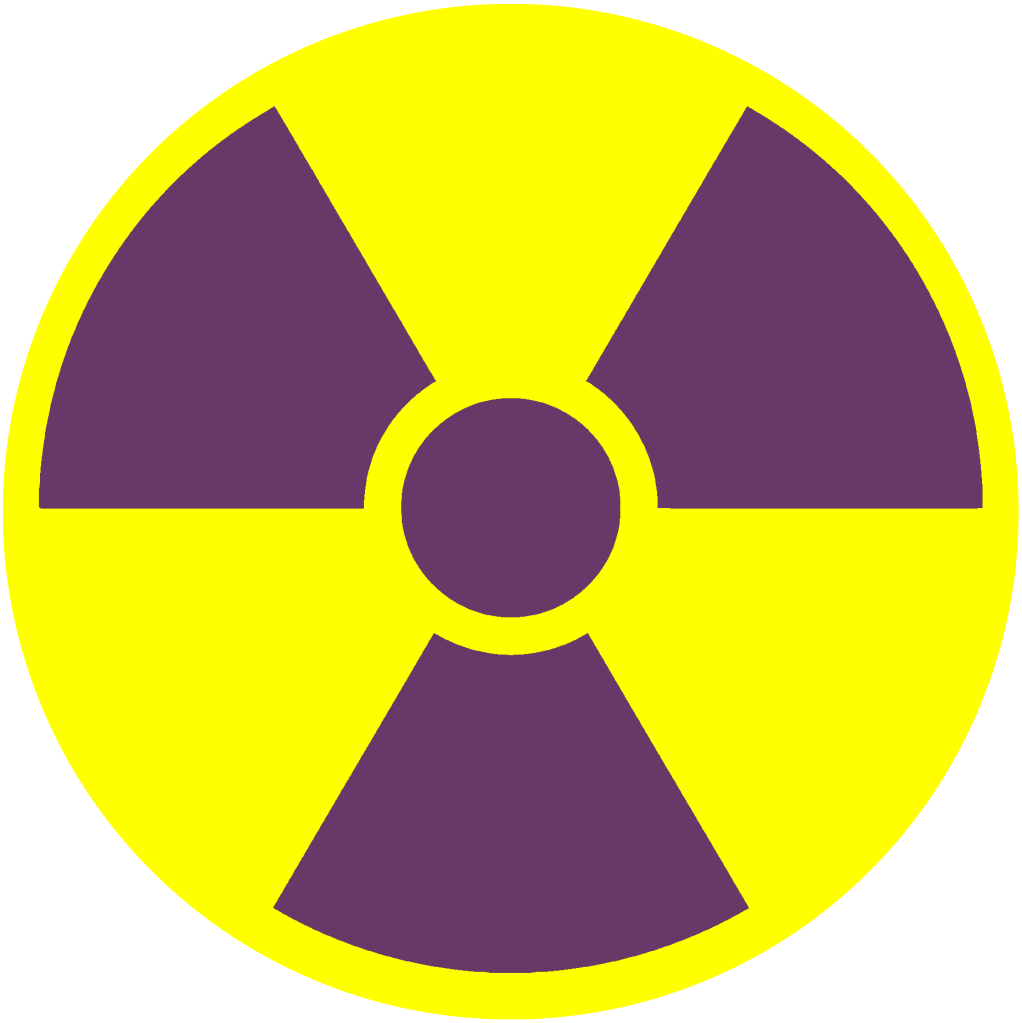
Vanderbilt University Medical Center
Radiation Safety Manual



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Introduction

This manual contains the radiation safety policies established by the Vanderbilt University Medical Center (VUMC) Radiation Safety Committee (RSC). Activities involving radiation sources are conducted under licenses and registrations issued by the Tennessee Department of Environment and Conservation, Division of Radiological Health, for the VUMC main campus. The Office of Clinical and Research Safety (OCRS) administers the Vanderbilt radiation safety program. Although the RSC approves Authorized User physicians, the Radioactive Drug Research Committee (RDRC) must approve all research uses of ionizing radiation administered to human research subjects (HRS).

All radiation users must know and comply with the applicable rules set forth in this manual and have access to the current version posted on the OCRS website. No one may use, bring on site, or remove from Vanderbilt facilities any regulated radioactive material, including generally licensed devices (any detectors or devices containing radioactive material sources, such as liquid scintillation counters, static eliminators, etc.) or radiation-emitting devices (e.g., X-ray tubes, accelerators) without obtaining written authorization from OCRS.

Section 1: Roles and Responsibilities

A. VUMC Radiation Safety Committee (RSC)

The VUMC RSC oversees the Radiation Safety Program and is responsible for the safe use of ionizing radiation. Members of the RSC are selected to include individuals with expertise in medical use areas, technical expertise, and management.

The RSC will also serve as the *Medical Committee* specified in the Tennessee regulations to evaluate all proposals for research, diagnostic, and therapeutic use of medical accelerators within this institution; as such, the RSC will include physician experts in internal medicine, hematology, therapeutic radiology, and an individual experienced in particle depth dose calculations and protection against radiation.

The RSC's responsibilities are to:

1. Ensure that ionizing radiation-emitting equipment and licensed radioactive material are managed safely and in compliance with applicable Tennessee and federal regulations.
2. Review recommendations on ways to maintain individual and collective doses as low as reasonably achievable (ALARA).
3. Review quarterly all incidents involving licensed materials with respect to cause and subsequent actions taken.
4. Be familiar with pertinent state regulations, certified registrations, the license application, the license, and amendments.
5. Review the training and experience of the proposed Principal Investigators, Authorized Users and the RSO to ensure their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the regulations, registrations, and the license.
6. Review, approve or deny all requests for authorization to use radioactive material, or ionizing radiation-emitting equipment requiring a certified registration, within the institution. The review must be based on safety and approved requests must be consistent with the limitations of the regulations, registrations, VUMC license and the ALARA philosophy.
7. Prescribe special conditions that will be required during a proposed method of use of radioactive material such as requirements for bioassays and special monitoring procedures.
8. Review quarterly the RSO's summary report of the occupational radiation exposure records of all VUMC personnel, giving attention to individuals, or groups of workers, whose occupational exposure appears excessive.
9. Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used (i.e., nursing, security, housekeeping, physical plant) are appropriately instructed as required by the applicable regulations.
10. Review at least annually the RSO's summary report of the VUMC radiation safety program to determine that all activities are being conducted safely, in accordance with state regulations, registrations, 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 state inspections, written safety procedures, and the adequacy of the management control system.
11. Recommend remedial action to correct any deficiencies identified in the radiation safety program.
12. 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.

B. The Radioactive Drug Research Committee (RDRC)

1. The RDRC is a local committee directly sanctioned and governed by the Food and Drug Administration (FDA) for the purpose of reviewing the investigational use of radioactive compounds / radiopharmaceuticals used in humans. The RDRC will only review proposals for metabolic studies of compounds of previously used in humans that exhibit no pharmacological effect at the proposed dose levels and adhere to dosimetry guidelines.

2. The operation of the RDRC is detailed in the IRB's written policy documents.

C. Office of Clinical and Research Safety (OCRS)

1. Order, receive and deliver radioactive materials, except for those items managed by the Radiopharmacy.
2. Manage radioactive waste.
3. Perform laboratory audits and surveys.
4. Perform instrument calibration/performance checks.
5. Provide personnel monitoring/bioassay services.
6. Provide radiation safety support for therapeutic applications.
7. Perform inventory/leak test/survey requirements for sealed sources.
8. Provide Radiation Safety Training.
9. Maintain emergency preparedness.
10. Maintain records.
11. Provide advice and consultation to faculty on matters related to radiation safety.
12. Monitor radiation users for compliance with State and Federal regulations, license conditions, and policies of the Radiation Safety Committees.
13. Monitor radiation-emitting equipment requiring a certified registration for compliance with State regulations.
14. Provide administrative support for the RSC.
15. Provide initial review of proposals submitted to the RSC.
16. Prepare and ship all radioactive materials sent from Vanderbilt, except for those items managed by the Radiopharmacy.

D. Radiation Safety Officer (RSO)

1. Implement and manage the radiation safety program.
2. Identify radiation safety problems.
3. Initiate, recommend, or provide corrective actions.
4. Verify implementation of corrective actions.
5. Ensure compliance with regulations.
6. Assist the RSC in the performance of its duties.
7. Suspend any operation that is found to be a serious threat to health or property.
8. Submit plans for new buildings and modifications of existing structures where radioactive material or radiation-emitting equipment requiring a certified registration is to be used to the RSC for approval prior to construction or modification.
9. Serve as a liaison between Vanderbilt and the state Division of Radiological Health; maintain Vanderbilt's radioactive material licenses and certified registrations.

E. Principal Investigator (PI) [Nonclinical Use of Radioactive Material]

1. Maintain occupational radiation exposures in the PI's lab ALARA.
2. Notify OCRS of all changes (nuclides, possession limits, locations, personnel, etc.) in the PI's radioactive material permit.
3. Ensure proper receipt, storage, use and security of the PI's radioactive material.
4. Ensure radiation workers listed on the PI's radioactive material permit:
    a. have completed the radiation safety training specified by OCRS;

b. comply with all applicable policies and regulatory requirements;

c. are familiar with the requirements of the PI's permit and any other specific hazards, precautions, control measures, and procedures associated with the PI's lab;

d. are knowledgeable of the characteristics of all radioactive material used in the laboratory; and

5. ensure employees have been instructed in radiation safety aspects of the specific operations in their laboratory or workplace, including on-the-job training. Do not allow use of the PI's radioactive material by anyone not listed on the PI's permit.
6. Ensure appropriate personnel and area monitoring, as required by OCRS.
7. Ensure proper disposal of radioactive waste.
8. Ensure all records of inventory, use, disposal, and surveys are maintained.
9. Notify OCRS when terminating the use of radioactive material.
10. Notify OCRS in advance prior to a laboratory move.
11. Upon leaving VUMC, account for and dispose of all radioactive material and complete any necessary decontamination of laboratory facilities. The PI's department must assume these responsibilities if the PI leaves before resolving these matters.
12. Notify OCRS in writing of any staff to whom the PI has delegated authority for management (i.e. ordering radioactive material, revising the PI's permit) of the PI's radiation safety program. A PI is not required to delegate such authority, but should a PI decide to do so, the PI remains ultimately responsible for any actions taken on their behalf by their personnel.

F. Authorized User Physician, Nuclear Pharmacist, and Medical Physicist [Clinical Use of Radioactive Material, or therapeutic administration of ionizing radiation from devices (in Patients or Human Research Subjects [HRS])]

1. An Authorized User Physician (AU) must meet the following criteria:
   a. The AU must be a physician, dentist, or podiatrist licensed to practice medicine in the State of Tennessee.
   b. Each AU who administers or supervises the administration of radioactive materials, or ionizing radiation from radioactive materials or radiation emitting machines, to humans must be approved by the RSC for the type of use they are administering or supervising., Training and experience requirements outlined in the applicable TN Rule for the types of uses administered by the AU must be satisfied.
   c. AUs wanting to perform research uses of diagnostic or therapeutic administrations of radioactive materials in HRS must also obtain approval from the RDRC subcommittee~~s~~ of the IRB for each protocol. Human research includes phase I, II, or III clinical trials, off label use of FDA approved radiopharmaceuticals, research protocol in which HRS are exposed to radiation sources, or HRS receive radiation from a procedure that is not part of standard care.
2. An Authorized Nuclear Pharmacist (ANP) must meet the following criteria:
   a. The ANP must be a pharmacist licensed to practice pharmacy in the State of Tennessee.
   b. The ANP must meet the training and experience requirements outlined in the applicable TN Rule.
   c. Each ANP must be approved by the RSC.
3. Authorized Medical Physicist (AMP)
   a. An AMP must meet the training and experience requirements outlined in the applicable TN Rule.
   b. Each AMP must be approved by the RSC.

G. Radiation Worker

1. Work in a manner that maintains occupational radiation exposures to themselves, fellow workers, and the general public ALARA.
2. Know and adhere to the requirements of the VUMC Radiation Safety Manual and any specific radiation safety procedures applicable to their work.

3. Complete all radiation safety training specified by OCRS.
4. Immediately report to OCRS incidents involving contamination of personnel, unconfined spills, theft or loss of radioactive material, suspected overexposures, or failure to comply with the VUMC Radiation Safety Manual or other regulatory requirements.
5. Clearly delineate radiation work areas; properly identify radioactive material and any potentially contaminated equipment.
6. Be familiar with the characteristics of the radioactive material they are using.
7. Ensure the security of all radioactive material; all radioactive material must be locked up unless constantly attended.
8. Understand how survey meters work and which survey meters will detect the radiation they are using.
9. Be familiar with radiation survey procedures and routinely survey work areas, hands, body, and clothing for contamination during and after each radioisotope procedure. In case of personnel (skin) contamination contact OCRS at 615-322-2057 or 615-875-3779 and confine the contaminated workers.
10. Be familiar with decontamination procedures and cleanup any contamination discovered.
11. Wear and handle any assigned personnel monitoring badges properly, furnish any required bioassay samples to OCRS when requested, and perform periodic thyroid uptake measurements if required when working with radioiodine.
12. Ensure the proper disposal of radioactive waste and maintain records of all disposals.

Section 2: Non-Clinical Radioactive Material Use

A. Principal Investigator (PI) Permit to Use Radioactive Material

1. Application Process:

   Permit application forms and instructions may be obtained from OCRS or downloaded from the OCRS website. OCRS staff review all applications prior to submittal to the VUMC RSC subcommittee for review and approval, except for permits with the "Slight" hazard rating (see section 2.D for explanation of lab hazard classification), which may be administratively approved by the RSO. New permits approved since the last RSC meeting will be reviewed at the next RSC meeting.

2. Principal Investigator Qualifications; the PI must:

   a. have training and experience in the safe handling of radioactive materials, and in the characteristics of ionization radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive materials to be used;

   b. be physically present at least half of the year;

   c. be at least half time employed by VUMC, and cannot be a resident, or fellow, student, or visiting faculty; and

   d. be a full time VUMC faculty member, unless the RSC approves an exception.

3. Permit Status

   a. Active: the RSC has approved the PI's permit to obtain, possess, and use radioactive material. A PI must have an active status permit if they possess any regulated quantity of radioactive material in sealed or unsealed form.

   b. Inactive: the PI remains authorized to obtain, possess, and use radioactive material, but has chosen not to use radioactive material for an extended period. A PI may change their permit to inactive status by removing all radioactive material from their lab (by disposal or transfer to an active status PI) and sending the RSO a written request for inactive status. Inactive status will be granted upon completion of a lab closeout by OCRS except for space shared with an active PI. While inactive, the PI is exempt from all training, survey meter calibration, and record keeping requirements associated with their permit. A PI may change back to active status at any time by sending a written request to the RSO and completing any active permit requirements (e.g. training, survey meter calibration) that may have lapsed during their inactive status.

   c. Terminated: The PI is no longer authorized to obtain, possess, and use radioactive material. The disposition of their radioactive material will be resolved by disposal or transfer to a PI with an active permit, and their lab space will undergo a formal OCRS radioactive material close out procedure unless that space has been transferred to an active PI.

   d. Leave of Absence: If a PI takes a leave of absence, their permit becomes inactive, unless, for the duration of the PI's absence another suitably qualified PI agrees in writing to assume responsibility for the permit. An absent PI's inactive permit reverts to active status upon the PI's return and concurrence.

4. Amendments

   a. RSC subcommittee review and approval are required for any permit changes if:

      i. a possession limit increases by more than 20% of the current possession limit, unless the requested increase maintains a "Slight" hazard rating (see section 2.D below for explanation of lab hazard rating);

      ii. radionuclides are added;

      iii. radioactive material use procedures change; or

      iv. any change for which the RSO deems RSC review appropriate.

b. Minor permit changes meeting the following criteria can be administratively approved by the RSO or designated approver:
    i. any possession limit decrease;
    ii. any possession limit increase of 20% or less of the current possession limit;
    iii. any changes to a permit with a “Slight” hazard rating;
    iv. changes in locations (rooms); or
    v. changes to personnel authorized under the permit.

5. Permit Audit & Renewal
    a. All active status permits will be audited at a frequency determined by the RSO based on the amount of radioactive material the lab is approved for, usage, and any other pertinent factors.
    b. The audit will include a consolidation of the PI’s radioactive material inventory, a physical inspection of the PI’s radiation enabled laboratories, an evaluation of radiation safety practices of the PI’s authorized radiation workers, a review of the accuracy of information on the permit, and overall compliance with this manual.
    c. The permit will be renewed upon completion of the audit if:
        i. No radiation safety deficiencies are identified; or
        ii. All radiation safety deficiencies identified during the permit audit are addressed and corrected.
    d. Failure to renew the permit will result in an immediate suspension of radioactive materials ordering.

B. General Radiation Safety Enforcement Policy

For serious or flagrant radiation safety violations, the Principal Investigator's (PI) authorization to use radioactive material will be immediately suspended. Following a suspension, the PI must appear before the RSC and present an acceptable plan for corrective actions before authorization can be reinstated.

Serious incidents or flagrant radiation safety violations can include, but are not limited to:

1. Activities that result in radioactive contamination in public areas
2. Radiation exposure to a member of the general public in excess of the legal limits
3. Overexposure of an individual to radiation
4. Releases of radioactive material to the environment in excess of legal limits
5. Leaving unattended licensed radioactive material unsecured
6. Allowing an individual to work with radiation sources without meeting radiation safety training requirements

For less serious violations, or a pattern that indicates an overall laxity in the radiation safety program, the PI will be given one written warning before a suspension is imposed. Less serious violations can include, but are not limited to:

1. Food and/or beverage in inappropriate locations
2. Failure to perform required surveys
3. Failing to provide and require the use of radiation monitoring badges when required
4. Failure to promptly decontaminate when radioactive contamination is detected

C. Radiation Safety Training Requirements

Unless specifically exempted in writing by the RSO, each person working with radioactive material must satisfy the following training requirements:

1. Initial Training (prior to handling radioactive material at VUMC):
    a. Basic Radiation Safety; all radioactive material users must satisfy one of the following:
        i. attend the Radiation Safety Course provided by OCRS;
        ii. furnish evidence of previous attendance of a radiation safety course;

iii. pass an exam administered by OCRS; or

iv. for clinical radioactive material use, hold an applicable professional board certification (e.g. CNMT, ABR, etc.).

b. Vanderbilt Radioactive Material Safety Orientation:

All personnel handling radioactive material, including the PI, are required to complete the provided training which covers Vanderbilt University Medical Center Radiation Safety policies and procedures; this training is mandatory, regardless of prior experience or training.

c. Job-Specific Training:

The PI shall instruct employees in radiation safety aspects of the specific operations in their laboratory or workplace, including on-the-job training.

2. Annual Training

All active radiation workers listed on a radioactive materials permit must have completed the appropriate digital radiation safety refresher training provided by OCRS at least annually following completion of the initial training requirements

D. Laboratory Hazard Classification Scheme

1. Radioactive material permits are classified on the basis of the PI's possession limit for each radionuclide as it relates to the annual limit on intake (ALI) for that radionuclide. The permit hazard rating is determined by expressing each radionuclide possession limit in terms of the number of ALI for that radionuclide and summing the number of ALI of all nuclides for which the PI has possession limits.

Table 1: Laboratory Hazard Classification Scheme

Lab Hazard Rating	Approved No. of ALIs
Slight	≤ 1
Low	1-150
Medium	150-100,000
High	> 100,000

2. Possession limits for radioactive material in the form of sealed sources do not contribute to the total number of ALI, for purposes of permit hazard rating.

3. If a PI has more than one laboratory room, at least one of the rooms will be rated at the calculated level, although OCRS may choose to classify other rooms at a lower level if the quantity of radioactive material present in that room will never exceed to corresponding number of ALI for the requested hazard rating.

E. Facilities and Equipment

1. Radioactive Material Storage and Use Areas

a. Radioactive material may only be used or stored in areas listed on an active-status PI's radioactive material permit.

b. Radioactive material use and storage should be confined to the minimum area necessary. One area should be designated as a "hot" work area for higher activities and other areas designated as "low level" work areas.

c. Radioactive material presenting an external exposure hazard must be shielded to maintain radiation exposure to laboratory personnel As Low As Reasonably Achievable (ALARA), and sufficient shielding must be provided to reduce radiation levels to below 2 mrem/hr (0.02 mSv) at 30 cm from the material.

d. Radioactive materials should be stored separately from non-radioactive material, where feasible.

e. Radioactive material should be returned to the storage location immediately after use.

f. All storage and use areas must be secured against unauthorized access and removal of radioactive material.

g. Unsealed radioactive material must be stored in secondary containment, e.g. stock vials must be stored inside plastic bags or other sealed container, liquid radioactive waste must be stored in tubs, etc.

2. Work Surfaces

   a. Work surfaces in unsealed radioactive material use areas must be constructed of non-porous materials and covered with absorbent paper that has a plastic backing. The absorbent paper should be replaced at frequent intervals.

   b. All unsealed radioactive material should be handled in spill trays covered with absorbent paper that has a plastic backing; the absorbent paper should be replaced at frequent intervals.

3. Fume Hoods

   a. Procedures involving aerosols, dusts, or gaseous products that might produce airborne contamination shall be conducted in a hood or glove box. Requirements to use a fume hood when working with radioactive materials are given in Table 2. The average airflow at the face of the hood must be at least 0.5 m/sec (100 linear feet per minute). Hood exhaust fans must be "on" whenever the hood is in use.

   b. Releases to the atmosphere shall not exceed the maximum permissible concentrations in air specified in TN State regulations. Traps or filters may be required to ensure that environmental releases are within acceptable limits. Should either activated charcoal filter or a HEPA filter need to be used, the filters must be incorporated into the fume hood system. As an alternative to installing a filter in an existing hood, a tabletop hood equipped with one of these filters can be placed inside of an existing fume hood.

   c. The RSO reserves the right to waive the fume hood requirement in situations where the dose to an individual worker is potentially increased by requiring storage in a fume hood as required by Table 2. These exemptions will be reviewed on a case-by-case basis and approved by the RSC Subcommittee.

Table 2: Fume Hood Requirements for Radioactive Material.

Physical Form	Number of ALI's* Used	Hood Requirement
Volatile Radioisotopes	< 1	No Hood Required
	1 - 10	Standard Chemical Fume Hood
	> 10	Activated Charcoal Filter** Required
Volatile Radioiodines	< 1	Standard Chemical Fume Hood
	> 1	Activated Charcoal Filter** Required
Non-Volatile Radioisotopes	< 10	No Hood Required
	10 - 100	Standard Chemical Fume Hood
	> 100	HEPA Filter*** Required

**The Annual Limit of Intake (ALI) can be found in in Table 1 of TN Rule 0400-20-05-.161.*
***Activated charcoal filter for gaseous contamination*
****High Efficiency Particulate Air (HEPA) filter for particulate airborne contamination*

F. Posting and Labeling Requirements

1. Areas authorized for radioactive materials use or storage

   The PI is responsible for ensuring that each room for which they are authorized for radioactive material use, or storage, is posted with:

   a. a "Caution, Radioactive Materials" sign at each entrance; and

   b. up-to-date copies of the TN Notice to Employees, TN Notice to Pregnant Workers, and OCRS' "Emergencies Involving Radioactive Materials" in a conspicuous location. Copies of these posting are available online from the OCRS website.

2. Containers and equipment used for radioactive material

    a. All containers of radioactive material must be labeled with a "Caution, Radioactive Material" label. The label must provide the radionuclide(s) present, an estimate of the activity, the date for which the activity is estimated, and kinds of material. Any hazardous chemicals should also be identified on the label.

    b. Any refrigerator, fume hood, incubator, or other equipment where radioactive materials are stored must be labeled. A refrigerator where radioactive materials are stored must be labeled with a "Caution, Radioactive Materials" or a "Caution Radioactive Materials No Food or Beverage May Be Stored in This Unit" sign. An incubator, fume hood, or other equipment must be posted with a "Caution, Radioactive Materials" sign.

    c. If any radioactive labeled equipment will no longer be used with radioactive material, or maintenance will be performed on the equipment, call OCRS to schedule an equipment check to survey the equipment for contamination and removal of the labels prior to repairs or disposal. Any equipment used with radioactive material should be posted with a "Caution, Radioactive Materials" label.

3. Sinks for disposal of liquid radioactive waste

    If a PI wishes to dispose of radioactive material via the sanitary sewer, the radioactive material must be readily soluble or readily biologically dispersible material in water. The sink designated for sanitary sewer disposal must be posted with a “Radioactive Hot Sink” label and, unless the sink is in a medical use area, it must also be posted with the “Radioactive Material Sink Disposal Log”. If any repairs are to be made to the posted sink, contact OCRS to schedule a sink check to survey for contamination prior to repairs.

4. Radioactive waste containers

    All radioactive waste containers must be posted with a "Caution, Radioactive Materials" sign. All full waste bags must be tagged with a radioactive waste tag. The waste tag must have the radionuclide, the estimated activity, the date of the estimated activity, the name of the PI, and a signature. If a radioactive waste container has been emptied by Environmental Services, contact OCRS immediately (2-2057). See Appendix F for additional information.

G. General Safety Rules for Working with Radioactive Material

1. Prior to using Radioactive Material

    a. Be familiar with the procedure being performed; perform a "dry" run to identify any potential problems; seek supervision for an initial run from an investigator experienced with that particular procedure.

    b. Ensure all needed equipment is available and functioning properly.

    c. Prepare the work area with absorbent paper (absorbent side up); use absorbent lined trays when possible.

    d. Prepare for spills. Familiarize yourself with decontamination procedures. You are responsible for decontaminating your own spills.

    e. Have decontamination supplies available.

    f. Post radiation work areas, laboratories, and containers of radioactive materials with appropriate warning signs.

    g. Volatile radioactive materials or operations where significant gases or vapor could be released must be conducted in a fume hood.

2. When Working with Radioactive Material

    a. Wear a lab coat or other protective clothing. Potentially contaminated laboratory coats should not be worn outside the laboratory.

    b. If assigned, wear appropriate personnel monitoring devices.

    c. Wear gloves whenever handling unsealed radioactive material.

    d. Use remote handling tools and appropriate shielding as indicated: Plexiglas for 32P; lead for 125I; etc.

    e. Volatile materials must be used under a fume hood.

f. Do not eat, drink, smoke, or apply cosmetics in areas where radioactive material is used or stored.

g. Do not pipette by mouth.

h. Do not store food or beverages in a refrigerator designated as a radioactive materials storage area.

i. Use disposable absorbent pads or lipped trays to protect work surfaces and to confine spills.

j. Hands should be checked often for contamination while working with radioactive material. If contamination is discovered, remove gloves and check hands.

k. Limit as much as possible the amount of time spent handling radioactive material.

l. Work with radioactive material must be confined to designated work area.

m. Radioactive materials should not be left in uncovered containers.

n. All radioactive material containers should have the contents clearly labeled.

o. Liquid radioactive material must be in a secondary container.

3. Security of Radioactive Material

   a. Licensed radioactive material must be secured against unauthorized access or removal by either:

      i. storage in a locked cabinet, refrigerator/freezer, lock box, or other locking enclosure or mechanism; or

      ii. being constantly attended or secured in a locked room when unattended.

         1. If access to the room is shared, a secondary means of security must be utilized.

   b. Authorized radioactive material users shall not permit unauthorized personnel in radioactive material use areas, unless escorted.

   These security requirements do not apply to license-exempt radioactive material (e.g. exempt check sources, liquid scintillation counting waste, unconcentrated naturally-occurring radioactive material, etc.).

H. Receipt, Transfer, and Disposal of Radioactive Material

1. Ordering Radioactive Material

   a. With the exception of radioactive material ordered by the Radiopharmacy, PIs must place all radioactive material orders, including those for which there is no charge, through OCRS. Radiopharmacy staff may order radioactive material for use in patients or human research subjects (HRS) directly from the supplier but must order radioactive material for non-human use through OCRS. Any other exceptions must be approved by the RSO.

   b. Only a PI who has been approved by the RSC may order and/or receive radioactive material.

   c. Radioactive material may only be ordered by a PI or the PI's designee. The PI must submit in writing to OCRS the names of any individuals who the PI has authorized to place radioactive material orders on the PI's behalf.

   d. Radioactive material possession limits are established by the RSC for each PI. OCRS must verify that the receipt of an order will not cause a PI to exceed the authorized possession limit.

   e. The PI who orders radioactive material is responsible for the safe use and disposal of that material. This responsibility is not transferred to another individual who uses the radioactive material unless an official transfer has been accepted through OCRS.

   f. If training requirements specified in Section 2.C. are not met by PI and staff, ordering of radioactive material will be suspended until all staff (including the PI) has met all training requirements specified in Section 2.C.

2. License Exempt Purchases

   a. Small "license exempt" (unregulated) quantities of radioactive material may be purchased by any PI who has been authorized by the RSC to use those radionuclides as license exempt.

b. License-exempt purchases must be ordered in the same manner as non-exempt radioactive material. An accountability record will not be issued for an exempt radiation source.

c. Materials received as licensed exempt may not be administered to humans.

d. Exempt quantities of naturally-occurring radioactive material (NORM, e.g. thorium nitrate, uranyl, nitrate, uranyl acetate) may be ordered directly by any Vanderbilt staff.

e. Exempt quantities of radioactive material, including NORM, may not be transferred to any other PI or institution, nor disposed of, except as approved by OCRS.

3. Receipt of Radioactive Material Packages

a. All radioactive material must be received by OCRS, except for human use radioactive material, which may be received by the Radiopharmacy. Any other exceptions must be approved by the RSO.

b. OCRS receives, surveys, inventories, and delivers radioactive material directly to the laboratory.

c. OCRS will only release radioactive material to trained radiation workers who have been added and approved as a radiation worker on a PI's radioactive materials use permit.

d. If the PI is not authorized for the type or the amount of radioactive material, then OCRS will hold the radioactive material until the problem is resolved.

4. Receipt and Disposal Records

a. The PI is responsible for maintaining receipt, use, and disposal records for all radioactive material in their inventory, using the inventory tracking method provided by OCRS.

b. OCRS maintains the total site inventory records for inspection by regulatory agencies.

5. Transfer of Radioactive Material

a. PIs must obtain prior OCRS approval for any radioactive material transfers between PIs, or between a PI and an outside facility (including transfers between a PI's VUMC lab, the same PI's Vanderbilt University lab, and the same PI's VA Medical Center lab).

b. OCRS must verify that the PI in question is authorized to receive the radionuclide and will not exceed authorized limits.

c. If training requirements specified in Section 2.C. are not met by PI and staff, transferring of radioactive material will be suspended until all staff (including the PI) has met all training requirements specified in Section 2.C.

6. Shipping Radioactive Material

All shipment or transfer of radioactive material from Vanderbilt University Medical Center, whether between VUMC sites or to non-VUMC sites, must be coordinated through OCRS.

7. Radioactive Waste Disposal

See Appendix F: Radioactive Waste Disposal

I. Radiation and Radioactive Contamination Surveys

1. Unless otherwise approved by the RSC in the PI's radioactive material permit, each PI must ensure that:

a. radiation workers listed on the PI's permit are adequately trained in performing surveys (measurements with appropriate radiation detection equipment); and

b. all areas for which the PI is responsible, sufficient surveys are performed and corrective actions taken to ensure that:

i. radiation levels are kept:

1. ALARA;
2. < 2 mrem/hour at 30 cm from any accessible surface; and
3. low enough such that no member of the general public could receive >100 mrem/year.

ii. Radioactive contamination levels are kept below the values specified in Table 3.

2. Each PI may express wipe test results from liquid scintillation counters in net counts per minute (CPM) or disintegrations per minutes (DPM), as they deem appropriate.
    a. Expressing results in CPM and decontaminating areas producing greater than 100 net CPM per wipe will ensure compliance with the Table 3 limits (see Appendix C).
    b. Results expressed in DPM, using an appropriate conversion factor, may be compared directly to the Table 3 limits.
3. Each PI whose possession limits establish 'Medium' or 'High' hazard labs (see Section 2.D) must document weekly contamination surveys in any areas where such quantities of radioactive material are used or stored. During weeks when no radioactive material was handled, labs may instead insert a weekly statement indicating that no radioactive material was used instead of a contamination survey, so long as a contamination survey was performed and documented since the last time radioactive material was handled.
4. Unless otherwise authorized by OCRS, potentially contaminated items may not be removed from a PI's permitted radioactive material use or storage area, unless contamination levels do not exceed the levels in Table 3.

Table 3: Contamination Limits

Type of Contamination	Low[a] Toxicity Radionuclide (dpm/100 cm²)	Moderate[b] and High[c] Toxicity Radionuclide (dpm/100 cm²)	Very High[d] Toxicity Radionuclide (dpm/100 cm²)
Unrestricted areas and personal clothing	2,000	200	20
Restricted areas	10,000	1,000	200
Fixed contamination	10,000	1,000	200

"Removable contamination" is any radioactivity that can be removed from the surface using moderate pressure, i.e. is not fixed.
The Toxicity class is based on the Annual Limit on Intake (ALI)
a. Low: ALI >5,000 µCi
b. Moderate: ALI between 500 and 5,000 µCi
c. High: ALI between 5 and 500 µCi
d. Very High: ALI < 5 µCi

5. Radioactive material use or storage areas may not be released for unrestricted use until contamination survey results show that contamination levels do not exceed those in Table 3.
6. Fixed contamination levels may be measured with a survey meter calibrated to read in mR/hr. The average and maximum radiation levels associated with surface contamination by beta-gamma emitters should not exceed 0.2 mR/hr with the detector 1 cm from the surface and 1.0 mR/hr with the detector 1 cm from the surface, respectively, as measured through not more than 7 mg/cm^2 of total absorber.
7. OCRS will conduct periodic inspections and surveys at a frequency commensurate with the hazard of the laboratory and alert the responsible PI of any radiological issues observed during those surveys.
    a. The surveys performed by OCRS do not replace the radiation survey requirements in Section 2.I.

J. Use of Radioactive Material in Animals

1. Protocols and Housing Locations for Animals Containing Radioactive Material
    a. All radioactive material usage in animals must be in an approved protocol by the Institutional Animal Care and Use Committee (IACUC).
        i. All radioactive material uses in animal protocols must be linked to a core protocol or each radionuclide will need to be added and correctly classified as radioactive material.
        ii. OCRS will review animal protocols and ensure the responsible PI for the radiation uses are approved for the procedures on their radioactive materials permit for each radioactive substance as part of the study; the animal study will not be approved until all discrepancies are corrected.

b. All housing locations for animals administered radioactive materials must be approved by Division of Animal Care (DAC) and the RSC.

2. Management of Animals Containing Radioactive Material

   a. All cages housing animals containing radioactive materials shall be labeled with a "Caution, Radioactive Materials" label. The label must remain on the cage until the animal has been removed and the cage has been decontaminated.

   b. Any excreta or litter that is radioactive must be disposed in the same manner as biological radioactive waste.

   c. Adequate ventilation must be provided for animals administered radioactive materials that may be volatized.

   d. Experimental animals administered radioactive materials may not be used for human or animal consumption.

3. Use of Division of Animal Care (DAC) Facilities

   PIs using these facilities are approved through protocols that are reviewed by OCRS. The PI must ensure that:

   a. radioactive animals are isolated from other animals where appropriate;

   b. radioactive litter is changed and collected, and personnel wear appropriate disposable gloves and a lab coat when changing litter or cleaning the cages;

   c. all locations where radioactive animals were injected, housed, or sacrificed are monitored for contamination, and all cages are monitored for radioactive contamination after the animals are removed and decontaminated to below the criteria stated in section 4 of this manual before being returned to DAC;

   d. personnel avoid petting or grooming radioactive animals;

   e. personnel monitor themselves after any work with radioactive animals; and

   f. precautions are taken to minimize dust production.

K. Use of Sealed Sources of Radioactive Material

1. The PI responsible for each sealed source must ensure that it is:

   a. secured at all times against unauthorized access;

   b. used only by appropriately trained and authorized personnel;

   c. never deliberately removed from its encapsulation; and

   d. made available to OCRS staff as needed for inspection, physical inventory, leak testing, etc.

2. The PI must notify OCRS if any of their sealed sources are lost or damaged, and prior to any transfer or disposal.

3. Unless a sealed source is exempt by regulation, OCRS will conduct a physical inventory at intervals not to exceed six months, except for generally-licensed sources, which will undergo an annual physical inventory.

4. Leak Testing:

   a. OCRS will conduct leak tests at intervals not to exceed six months on sealed sources meeting the following criteria:

      i. Half-life greater than 30 days;

      ii. Nongaseous form;

      iii. Activity greater than 100 μCi (3.7 MBq) for a beta or gamma emitter, or 10 μCi (370 kBq) for an alpha emitter; and

      iv. any radionuclide other than tritium.

   b. If the source is stored and no longer in use, a leak test will not be required until transfer or later use.

c. If the leak test indicates 0.005 μCi (185 Bq) or more of removable contamination, the source will be removed from use.

5. Any safety and handling precautions furnished by the manufacturer shall be maintained in a location that is readily available to all workers and followed.
6. Brachytherapy source users must comply with the additional requirements in Section 3.E.

Section 3: Additional Requirements for Medical Radiation Use

A. Medical Use of Radiation Producing Machines

1. Diagnostic and Medical Imaging: The use of X-ray equipment for medical diagnostic and medical imaging purposes must be in compliance with the applicable VUMC policies.
2. Therapeutic:
    a. The RSC will serve as the medical committee to evaluate all proposals for research, diagnostic, or therapeutic use of linear accelerators [LINAC].
    b. Therapeutic administration of machine-produced ionizing radiation (e.g. LINAC, orthovoltage machine) to humans may only occur under the direction of an Authorized User Physician (AU) approved by the RSC for that type of therapeutic administration.
    c. No one, except the patient, may be present in the LINAC room during an irradiation.
    d. Operating and emergency procedures must be available at each LINAC control console.

B. Diagnostic Use of Radioactive Materials

1. Diagnostic administration of radioactive material may only be performed by, or under the supervision of, an AU authorized for that type of use.
2. Individuals administered radioactive material for diagnostic purposes may be released immediately with no restrictions on their activities or contacts with other patients or visitors, unless otherwise advised by the physician or OCRS. Special precautions are not required for any furniture, dishes, instruments, or linen the patient may have come in contact with.
3. Radiation warning signs are not required for rooms housing these patients.
4. Standard precautions will protect staff working with these patients, and radiation monitoring badges are not required.

C. Therapeutic Use of Radioactive Material – General Requirements

1. The administering AU physician's department must notify OCRS of all therapeutic radiopharmaceutical or brachytherapy administrations requiring release documentation.
2. The administration of radioactive material in either unsealed form (radiopharmaceuticals) or as sealed sources (brachytherapy) for therapeutic purposes may be performed only by, or under the supervision of, AUs approved by the RSC for that type of use.
3. For every therapeutic administration, an AU approved for that type of use must prepare, sign, and date a Written Directive (kept on file for three years after the date of administration). The Written Directive must contain the individual's name and the following information:
    a. For any administration of a therapeutic dosage of radioactive drug containing radioactive material: The radioactive drug, the dosage, and route of administration;
    b. For high dose-rate remote afterloading brachytherapy: The radionuclide, the treatment site, dose per fraction, number of fractions, and total dose;
    c. For permanent implant brachytherapy:
        i. Before implantation: The radionuclide, the treatment site, and the total source strength; and
        ii. After implantation but before the patient leaves post-treatment recovery area: The treatment site, the number of sources implanted, and the total source strength implanted; or
    d. For all other brachytherapy, including, low, medium, and pulsed dose rate remote afterloaders:
        i. Before implantation: Treatment site, the radionuclide, and dose; and

ii. After implantation but before the completion of the procedure: The radionuclide, treatment site, number of sources, and the total dose.

4. Individuals who have been administered therapeutic radioactive material must meet the applicable radiation release criteria, prior to discharge. OCRS, Nuclear Medicine, or Radiation Oncology, as appropriate, must document the basis for release, signed by an AU approved for that type of therapy, unless the type of therapy has been specifically exempted from this requirement (See Appendix D).
5. Nuclear Medicine, Radiation Oncology, or OCRS as appropriate, must provide instructions, including written instructions, to individuals administered radioactive materials on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 0.1 rem (See Appendix D).
6. Radiation monitoring badges will be issued to healthcare workers providing care to radioactive material therapy patients, unless OCRS determines dosimetry monitoring is not required.
7. Pregnant staff should not be responsible for routine care of patients undergoing radioactive material therapy.

D. Therapeutic Use of Unsealed Radioactive Material [Radiopharmaceuticals]

1. Specimens should be taken before administration of therapeutic radiopharmaceuticals.
2. Any specimens of tissue, blood, ascetic fluid, or excreta taken from patients *after* administration of therapeutic radioactive material, prior to discharge, must be evaluated by OCRS.
    a. OCRS will determine if special handling or labeling is required and will instruct staff on proper handling of samples.
3. *Radiation Precautions* for hospitalized radiopharmaceutical therapy patients will include:
    a. Notifying Inpatient admitting when a patient is to receive therapeutic quantities of radioactive material.
    b. A private assigned room, with a private bathroom, which has been approved by the RSC for this purpose.
    c. Room preparation, prior to administration, to facilitate subsequent decontamination by adequately covering surfaces likely to be contaminated with protective material, such as a waterproof mattress cover should be placed on the bed.
    d. Administration of radiopharmaceuticals within the prepared patient room, whenever feasible.
    e. Upon administration, OCRS will perform sufficient area radiation surveys to ensure that exposure rates in unrestricted areas (hallway and adjacent patient rooms) do not exceed 2 mR/hour. If higher exposure rates in unrestricted areas cannot be sufficiently reduced by the application of temporary shielding, access to those areas will be restricted.
    f. Once radiopharmaceuticals have been administered, the following procedures remain in effect until Radiation Precautions are discontinued by OCRS:
        i. Anyone entering the room must wear disposable personal protective equipment (PPE; gloves, shoe covers, and gown) before entering, and remove PPE before leaving the room.
        ii. All items within the room must be surveyed for contamination by OCRS staff before being removed from the room.
        iii. Disposable food service should be ordered and discarded after use in designated waste containers located in the room.
        iv. Patient garments, towels, and bed linens that have come into contact with the patient should be placed in a laundry bag and left in the patient's room until surveyed for contamination by OCRS.
        v. Bags of radioactive waste generated by radiotherapy patients will be collected and disposed by OCRS.
        vi. Healthcare providers should minimize time spent in the room and near the patient, consistent with the provision of all necessary care.

vii. Nursing staff should not provide assistance in bathing the patient for the first 48 hours, unless specifically approved by the physician. However, the patient should be encouraged to bathe daily.

viii. The patient will remain in the room until OCRS determines that release criteria have been met. If emergent conditions require moving the patient from the room before release criteria have been met, Patient Transport staff will not be used to transport the patient unless approved by the RSO.

g. OCRS will post Radiation warning signs whenever the administered activity exceeds release criteria. These signs may only be removed by OCRS. If there are any special instructions for a particular patient, they will be noted on the therapy form provided by OCRS for the patient or on the posted signs. *Radiation Precautions* will be in effect during the entire period that the radiation warning signs are posted.

h. Healthcare providers caring for the patient must instruct the patient that while *Radiation Precautions* are in effect, the patient:

i. is restricted to their assigned room;

ii. should use disposable food service, and discarded after use in the specified waste container in the room;

iii. should be advised to minimize the number of personal items they bring into the room, and wear disposable gloves when handling items that are not protected by coverings, such as personal items the patient may wish to take home;

iv. should flush the toilet two or three times after each use to help ensure that all radioactive urine is washed from the toilet bowl; and

v. should avoid physical contact with visitors.

i. Visitors of inpatients must:

i. limit visits to 1 hour per day;

ii. if pregnant or under age 18, obtain permission from OCRS before visiting;

iii. remain at least 6 feet from the patient;

iv. if entering the room, wear disposable gowns, shoe covers, and gloves, and should not handle any items in the room or bring any of their personal items into the room; and

v. not smoke, eat, or drink while in the patient's room.

j. Upon discharge of the patient or cessation of radiation precautions by OCRS, OCRS will survey the room and decontaminate as needed to ensure that radiation and contamination levels meet requirements for unrestricted use. OCRS will maintain all survey records for inspection by the State regulatory agency. Removal of the Radiation sign signifies that another patient may occupy the room.

E. Therapeutic Use of Sealed Radioactive Material [Brachytherapy]

1. When radiation sources are implanted in surgery, the radiation oncologist is responsible for instructing other participating personnel in radiation precautions. Personnel caring for hospitalized brachytherapy implant patients must complete appropriate radiation safety training initially and at least annually, to include:

a. the size and appearance of the brachytherapy sources;

b. safe handling and shielding instructions;

c. patient and visitor restrictions; and

d. the requirement to notify OCRS and an Authorized User physician if the patient has a medical emergency or dies.

2. Radiation Oncology must maintain accountability at all times for all brachytherapy sources in storage and in use,and shall return brachytherapy sources to secure storage immediately after each use. Source accountability records must be maintained for three years and include:

a. for temporary implants,

i. the number and activity of sources removed from storage, time and date they were removed from storage, the name of the person who removed them from storage, and the location of use; and

ii. the number and activity of sources returned to storage, time and date they were returned to storage, and the name of the person who returned them to storage.

b. for permanent implants:

i. the number and activity of sources removed from storage, time and date they were removed from storage, the name of the person who removed them from storage;

ii. the number and activity of sources not implanted, time and date they were returned to storage, and the name of the person who returned them to storage; and

iii. the number and activity of sources permanently implanted.

3. Radiation Oncology or OCRS, as appropriate, must make and record a survey, to include date, survey results, instrument used, and surveyors name:

a. after each brachytherapy implant, and account for all sources that have not been implanted; and

b. immediately after the removal of the last temporary implant, Radiation Oncology or OCRS must make and record a survey to confirm that all sources have been removed.

c. Each survey record must be retained on file and available for inspection for three years.

4. Radiation Precautions for hospitalized brachytherapy implant patients:

a. The patient must be placed in a private room approved for this purpose by the RSC.

b. OCRS will post warning signs and make the required radiation measurements as necessary.

c. Equipment as needed to respond to a source dislodged from the patient or lodged in the patient after removal of the source applicators, must be available near each treatment room.

F. Misadministration

1. A misadministration is defined as any event in which radioactive material or radiation from a radiation production machine results in:

a. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sievert (5 rem) effective dose equivalent, 0.5 Sievert (50 rem) to an organ or tissue, or 0.5 Sievert (50 rem) shallow dose equivalent to the skin; and

i. The total dose delivered differs from the prescribed dose by 20 percent or more;

ii. The total dosage delivered differs from the prescribed dosage range; or

iii. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

b. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 (50 rem) shallow dose equivalent to the skin from any of the following:

i. An administration of a wrong radioactive drug;

ii. An administration of a radioactive drug containing radioactive material by the wrong route of administration;

iii. An administration of a dose or dosage to the wrong individuals or human research subject;

iv. An administration of a dose or dosage delivered by the wrong mode of treatment; or

v. A leaking sealed source.

c. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

d. A therapeutic radiation machine dose:

i. Involving the wrong individual, wrong mode of treatment or wrong treatment site;

ii. When the treatment consists of 3 or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

iii. When the calculated weekly administered dose exceeds the weekly prescribed dose by 30 percent or more of the weekly prescribed dose; or

iv. When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

2. Upon discovery of a misadministration, OCRS must be notified immediately.
   Normal Business Hours: 615-322-2057; Afterhours 615-875-3779

Section 4: Personnel Monitoring

A. Occupational Dose Limits

Vanderbilt will maintain a radiation protection program designed to ensure that occupational doses remain ALARA and that no occupational dose limit is exceeded.

Table 4: Annual Occupational Dose Limits for Adults		
Description	**Dose Limit (mSv)**	**Dose Limit (mrem)**
Whole Body	50	5,000
Skin	500	50,000
Extremity	500	50,000
Any organ other than the lens of the eye	500	50,000
Lens of the eye	150	15,000
Fetal Dose of declared pregnant workers*	5	500

** fetal dose is based on the entire gestation period (a 10-month period) and is not limited to one calendar year.*

1. The annual occupational dose limits for minors are 10% of the limits for adult radiation workers.
2. A declared pregnant worker (DPW) is a radiation worker who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception. The regulatory dose limit for an embryo/fetus of a DPW is 500 mrem (5 mSv) for the entire gestation period and should not exceed 50 mrem/month (0.5 mSv/month).

   These limits only apply if the pregnancy is declared. Declaration forms are available from OCRS or Occupational Health Clinic (OHC). See Section 5 for more information.
3. Any staff whose occupational radiation monitoring results for the calendar year exceed 80% of an occupational dose limit must either:
   a. cease working around ionizing radiation sources for the remainder of the calendar year; or
   b. wear instantly readable dosimetry devices in addition to their assigned dosimetry badges, and coordinate with OCRS to have the instantly readable dosimeter results reviewed at a frequency sufficient to allow timely assessment of the worker's current accumulated dose for the calendar year.
4. Any staff whose occupational radiation monitoring results for the calendar year exceeds 90% of an occupational dose limit must cease working around ionizing radiation sources for the remainder of the calendar year.

B. Personal Dosimeters ["Radiation Badges"]

2. State regulations require radiation dosimetry monitoring of individuals expected to receive an occupational dose exceeding 10% of a regulatory occupational dose limit. OCRS will determine whether to issue personal dosimeters (radiation badges) based on each radiation worker's ionizing radiation use. Badge applications may be obtained from the OCRS website, or the departmental badge representative.
3. Workers issued personal dosimetry badges must:
   a. wear only their own assigned badge;
   b. wear badges appropriately on the chest, collar, or waist, as directed by OCRS to indicate "whole body" exposure;
   c. wear their badge at all times when working with sources of ionizing radiation;
   d. never tamper with, experimentally irradiate, or use the badge to measure any radiation exposure received as a medical patient;
   e. exchange badges on time with their departmental badge representative;
   f. wear ring badges, if assigned, as close to the point of maximum exposure as possible under the gloves to prevent contamination, with the sensitive portion of the detector facing toward the source of exposure;

g. regularly review their own radiation dose reports to ensure doses are ALARA;

h. notify OCRS of their radiation monitoring by any other institution, if applicable.

4. The RSO will review occupational dosimetry records and investigate unusual results as indicated in the ALARA policy (see Appendix A).

5. Dosimetry records will be made available to all monitored personnel.

   a. Departmental badge representatives receive dosimetry reports at the specified exchange interval (i.e., quarterly or monthly).

   b. Badged radiation workers may receive their dosimetry records from OCRS upon request.

   c. Badged radiation workers may also view their own dosimetry results online through the dosimetry vendor's website, instructions are posted on the OCRS website.

6. Formerly badged radiation workers may obtain their previous occupational dose history from VUMC by submitting a signed written request to OCRS Radiation Safety. VUMC must have the signature of the radiation worker on the request in order to release radiation exposure history records.

C. Bioassays

1. Thyroid Monitoring Requirements for Unsealed Sources of Radioiodine.

   a. Before handling quantities of radioiodine exceeding 10% of the values given in Table 5, an individual must have a baseline thyroid bioassay.

   b. A thyroid bioassay is required when an individual handles unsealed quantities of radioiodine exceeding the limits in Table 5. The thyroid bioassay must be performed within the interval specified in Table 6.

   c. All personnel directly involved in unsealed therapeutic radioiodine administrations must conduct a thyroid bioassay within ten days of the administration.

   d. The RSO will investigate thyroid bioassay results (action levels) indicating thyroid content at the time of measurement in excess of the quantities indicated in Table 6. Repeat thyroid bioassays will be required for individuals with thyroid bioassay results indicating uptakes in excess of these action levels.

Table 5: Thyroid Bioassay Requirements*

Type of Operation	Volatile Form (mCi)	Bound to Nonvolatile Agent (mCi)
Processes on open bench, with possible escape of iodine from process vessels	1	10
Processes carried out in appropriate fume hood	10	100

**Quantities are considered to be the cumulative amount in processes handled by a worker during a 3-month period.*

Table 6: Bioassay Thyroid Action Levels*

Nuclide	Thyroid Action Level (µCi)	Maximum Interval Between Handling Radioiodine and Conducting Bioassay (days)
^{123}I	0.1	3
^{124}I	0.1	7
^{125}I	0.1	10
^{131}I	0.1	10

** See Appendix B for additional information.*

2. Tritium Bioassay Requirements

   Individuals involved in operations that utilize, at any one time, more than 100 mCi (3.7 GBq) of 3H in a non-contained form, other than metallic foil, shall have urine bioassays performed within one week following a single operation and at weekly intervals for continuing operations. The assay frequency for continuing operations may be reduced to monthly after the first calendar quarter, dependent upon initial results.

3. Accidents

   Bioassays may be required if a person has been involved in a spill or other incident in which there may have been a significant intake of radioactive material. Bioassays may include urinalysis, analysis of other excreta such as fecal samples, nose wipes, whole body or thyroid counts.

4. Obtaining Bioassay Measurements

   Contact OCRS Radiation Safety for further information on how to obtain a bioassay.

5. Bioassay Records

   Monitored radiation workers may receive their bioassay records from OCRS upon request.

Section 5: Declared Pregnant Workers (DPW)

A. Declaration

1. Radiation protection regulations allow a pregnant radiation worker to decide whether she wants to formally declare her pregnancy to her employer, thereby taking advantage of the reduced radiation exposure limits established to protect the developing embryo/fetus.
2. A woman cannot be required by her employer to make a declaration of pregnancy, and a woman may withdraw her declaration of pregnancy at any time.
3. If a woman chooses to declare her pregnancy, lower radiation dose limits will be applied (see Section 4).

B. Confidentiality

1. Declaring a pregnancy is confidential; a radiation worker's pregnancy status will not be shared with the worker's supervisor or anyone outside of the Vanderbilt Occupational Health Clinic (OHC) and OCRS-Radiation Safety program without the worker's consent.
2. If a DPW wishes to disclose her pregnancy and declaration to her supervisor, she must be the one to communicate the information.

C. How to Declare

1. Declaration forms are available to complete and submit on both the OCRS Radiation Safety and Occupational Health websites; DPW declaration and all associated information regarding DPW declaration will be on record with both departments.
2. Upon receiving the declaration form, the DPW will be contacted by OCRS Radiation Safety to begin fetal monitoring, if appropriate, and will be presented with the option to have an informal counseling session.

Section 6: Emergency Procedures

For Assistance Contact OCRS

During normal business hours: 615-322-2057

After normal business hours: 615-875-3779

A. Accidents or Injuries Involving Radioisotopes

1. For serious injuries - call 911 to arrange transport to the Emergency Department.
2. For minor injuries:
    a. Wash minor wounds thoroughly under tepid water to flush out radioactive material.
    b. Seek appropriate medical care:
        i. During normal business hours, send faculty or staff to the Occupational Health Clinic and students to the Student Health Center.
        ii. After normal business hours, send injured personnel to the Emergency Department.
    c. Complete a Tennessee First Report of Injury.
3. If anyone accidentally ingests, inhales, absorbs, has bare skin contaminated with any quantity of radioactive material, or presents at the Emergency Department with these symptoms, notify the OCRS immediately.

B. Major Spills of Radioactive Material

1. Notify other persons in the area of the spill.
2. Evacuate if spill is of a volatile material.
3. Immediately remove contaminated shoes or clothing.
4. Cordon off the spill area and limit access to avoid the inadvertent spread of contamination.
5. Rinse contaminated skin thoroughly with tepid water.
6. Notify OCRS.

C. Fires Involving Radioisotopes

1. Follow the site-specific fire plan for your area.
2. If you discover a fire, follow the RACE procedures: Remove all persons in immediate danger to safety, activate manual pull station and notify 911, close doors and fire shutters and extinguish the fire, if you are able to do so safely.

D. Exposures Exceeding the Maximum Permissible Dose

Individuals suspected to have been overexposed will be suspended from further work with radiation sources pending the outcome of an investigation by OCRS.

E. Posting of Radiation Emergency Procedures

State regulations require that radiation emergency procedures be posted in areas where radioactive material is used or stored.

Section 7: Research Use of Non-Clinical Radiation-Producing Machines

See Appendix G: Research Use of Non-Clinical Radiation-Producing Machines

Appendix A: VU & VUMC ALARA Policy - Dosimetry Badge Monitoring Program

Purpose: This Policy establishes criteria for monitoring, assessing, and responding to occupational radiation dosimetry badge results in support of efforts to keep occupational radiation exposure as low as reasonably achievable (ALARA).

Scope: This policy is limited to occupational dosimetry results and does not apply to monitoring for other purposes.

Policy: OCRS will conduct a quarterly review of dosimetry results and compile a summary report based on the investigational level framework below. The RSO will investigate doses exceeding Level III, and unexpected doses exceeding Level II. The VU RSC will review biannually a summary of radiation dose records (ALARA report) as specified by the VU Radiation Safety Manual. The VUMC RSC will review quarterly a summary of radiation dose records (ALARA report) as specified by the VUMC Radiation Safety Manual.

Quarterly Investigational Levels:

Level I (10% of Quarterly Dose Limit): occupational dose for which regulations require personnel monitoring[1]; the number of workers exceeding level 1 indicates roughly the number of people Vanderbilt is required to monitor.

Level II (25% of Quarterly Dose Limit): occupational dose for which scientific consensus guidance[2] requires personnel monitoring; also, NRC guidance[3] recommends applying correction factors to doses of those workers whose only exposure is from diagnostic X-ray machines, and who wear leaded personal protective equipment (Pb PPE). Measured doses exceeding Level II should be corrected to account for Pb PPE in such cases.

Level III (80% of Quarterly Dose Limit): occupational dose for which the worker may potentially exceed a regulatory dose limit if exposure patterns are allowed to persist; such cases will be investigated by the RSO when feasible.

Quarterly Investigational Level	Quarterly Investigational Levels			
	DDE mSv (mrem)	LDE mSv (mrem)	SDE mSv (mrem)	DPW mSv (mrem)
I	1.25 (125)	3.75 (375)	12.5 (1,250)	0.15 (15)
II	3.12 (312)	9.37 (937)	31.2 (3,120)	0.4 (40)
III	10 (1,000)	30 (3,000)	100 (10,000)	1.2 (120)
Quarterly Dose Limit*	12.5 (1,250)	37.5 (3,751)	125 (12,500)	1.5 (150)

Occupational Exposure Categories: DDE = deep dose equivalent; LDE = lens of the eye dose equivalent; SDE = shallow dose equivalent, whole body (skin) or maximally exposed extremity (hand); DPW = declared pregnant worker (fetal dose).
***Quarterly Dose Limits** are defined as one fourth of the regulatory annual occupational dose limits; exceeding this value within a calendar quarter does not by itself constitute noncompliance.

Annual Action Levels:

Level I (80% of Annual Dose Limit): any worker exceeding this limit must *either* cease working around ionizing radiation sources for the remainder of the calendar year, or wear instantly readable dosimetry devices in addition to their assigned dosimetry badges, and coordinate with OCRS to have the instantly readable dosimeter results reviewed at a frequency sufficient to allow timely assessment of the worker's current accumulated dose for the calendar year.

Level II (90% of Annual Dose Limit): any worker exceeding this limit must immediately cease working around ionizing radiation sources for the remainder of the calendar year.

Action Level	Annual Action Levels			DPW Full Term
	DDE mSv (mrem)	LDE mSv (mrem)	SDE mSv (mrem)	DPW mSv (mrem)
I	40 (4,000)	120 (12,000)	400 (40,000)	4 (400)
II	45 (4,500)	135 (13,500)	450 (45,000)	4.5 (450)
Annual Dose Limit[4]	50 (5,000)	150 (15,000)	500 (50,000)	5 (500)*

*DPW full term Dose limit is based off of a 10 month gestation period and is not restricted to one calendar year.

Modification of Measured Dose to Account for Leaded (Pb) Personal Protective Equipment (PPE)

For radiation workers whose only occupational exposure comes from diagnostic X-ray devices, and who wear Pb PPE during the X-ray procedures, dosimetry badges worn outside the Pb PPE provide a significant overestimation of occupational dose. Several recognized methods[5] exist for correcting these measured DDE doses to more accurately reflect the worker's actual occupation dose, but the two recognized by the NRC[2] are:

- Single Badge (worn outside Pb PPE at collar): $Dose_{reported} = 0.3\ Dose_{measured}$
- Double Badge (one worn outside Pb PPE at collar, one under PPE at waist): $Dose_{reported} = 0.04\ Dose_{collar} + 1.5\ Dose_{waist}$

The State has approved Vanderbilt's use of a LDE correction factor for radiation workers who also wear leaded eye protection:

- LDE $Dose_{reported} = 0.5$ LDE $Dose_{measured(collar)}$

Radiation workers whose exposures meet these criteria should have these correction factors applied if their dose exceeds 25% of the regulatory limit for a monitoring period.

[1] TN: 0400-20-05-.71; NRC: 10cfr20.1502
[2] Se e.g. NRCP Report 105 (1989), p. 19
[3] See e.g. C.3 of NRC RegGuide 8.40; CRCPD SPAR Part D, vol. 1 (1995); NRC Reg. Issue Summary 2002-06 (2002)
[4] TN: 0400-02-05-.50 [workers], 0400-02-05-.56 [DPW] ; NRC: 10cfr20.1201 [workers], 10cfr20.1208 [DPW]
[5] See e.g. Table 1 of Jarvinen et al (2008), NCRP Report 122 (1995)

Appendix B: VU & VUMC Thyroid Bioassay Program – Technical Basis Document

I. Radionuclides

The radioiodine isotopes used at Vanderbilt include: ^{123}I, ^{124}I, ^{125}I, and ^{131}I

II. Assumptions

a. Most radioiodine compounds used at Vanderbilt have a stable (non-volatile) chemical form; exceptions (use for iodination procedures, etc.) will be clearly identified by the site's radioactive procedural review process and handled in approved fume hoods. Therefore, unless otherwise specified or under accident conditions likely to produce volatile forms, relatively nonvolatile radioiodine compounds can be assumed.

b. Actual measureable radioiodine intakes will continue to be rare.

c. Any intakes that do occur will be by inhalation. Intake by ingestion will be prevented by strict observance of standard precautions and the prohibition on eating, drinking, or applying cosmetics in radioiodine use areas, etc.

d. Per Vanderbilt policies, *in vivo* thyroid measurement ("bioassay") will be conducted within the duration specified in section III after handling radioiodine in amounts exceeding those indicated in the Personnel Monitoring Section in the VU &VUMC Radiation Safety Manuals.

e. About 0.3 of radioiodine intake will appear as thyroid uptake (i.e. assume individuals with normally functioning endocrine systems and no thyroid blocking agents). Hence thyroid *uptake* = 0.3 × body *intake*.

III. Annual Limits on Intake (ALI) and Thyroid Action Level

The "Thyroid Action Level" (thyroid content at time of measurement requiring investigation of operations, corrective actions, and repeat thyroid measurements) specified in the Personnel Monitoring Section in the VU &VUMC Radiation Safety Manuals shall be:

Nuclide	ALI (µCi)*	Thyroid Action Level (µCi)	Maximum interval between handling radioiodine and conducting bioassay (days)
^{123}I	6,000	0.1	3
^{124}I	80	0.1	7
^{125}I	60	0.1	10
^{131}I	50	0.1	10

** The Annual Limit of Intake (ALI) can be found in in Table 1 of TN Rule 0400-20-05-.161*

Rationale:

The NRC's Regulatory Guide 8.20 (2014) defines a Predetermined Action Level (PAL) as an intake activity that should be investigated, and sets this level at 1µCi iodine content in the thyroid at time of measurement for any radioiodine. The PAL is based on 131I and the product of the 10 percent of ALI (stochastic) and the intake retention fraction of 0.07 as iodine in the thyroid 8-hours post-intake. This is the lowest intake for which that Guide indicates any action is warranted. Therefore adopting a thyroid action level of 0.1 µCi thyroid content at time of measurement for any radioiodine as Vanderbilt's Action Limit (for which an investigation, corrective action, and repeat bioassay measurement is required) is conservative, i.e. errs on the side of safety by prompting these actions at a lower intake activity than that specified in the NRC guidance.

IV. References

ICRP 30: Limits for Intakes of Radionuclides by Workers (1978)
U.S. NRC. Regulatory guide 8.20: Applications of Bioassay for Radioiodine (2014)
U.S. NRC. Regulatory guide 8.9: acceptable concepts, models, equations, and assumptions for a bioassay program (1993)

Appendix C: Technical Basis for Expressing Wipe Test Results in CPM

Purpose: To provide the technical basis demonstrating that use of a "100 CPM above background" decision limit for removable contamination surveys ("wipe tests") approximately satisfies, in every case, the DPM based limits specified in the Radiation Safety Manual.

Technical Basis: The counting efficiency for wipe test samples counted in a liquid scintillation counter (LSC) varies depending on the radionuclide(s) in the sample, the wipe collection media (e.g. filter paper, cotton swab), and for low-energy beta emitters, the amount of self-absorption due to dirt, etc. in the sample. Klein et al (1992)* documented this variation in counting efficiency for several commonly used radionuclides, as summarized in the table below:

Table 1: Counting efficiencies for commonly used radionuclides

Media	^{3}H (%)	^{14}C (%)	^{32}P (%)
None	43.1±1.8	97.5±1.6	101.3±1.4
Clean Glass Fiber Filter	29.1±5.6	94.2±4.8	94.6±0.6
Dirty Glass Fiber Filter	7.6±0.2	84.8±4.8	93.2±0.5
Clean Swab	5.8±0.8	83.7±0.8	87.7±1.3
Dirty Swab	2.8±0.6	67.9±5.8	73.4±2.3

This variability makes it difficult to credibly express wipe test results in DPM, as needed for comparison with DPM-based contamination limits. Assuming a reasonably low "worst case" counting efficiency and adopting a simple, intuitive "100 CPM above background" limit for triggering cleanup of the sampled area saves considerable time and effort while, as indicated in Table 2, providing an action limit that is consistent with or more conservative than the Radiation Safety Manual DPM-based limits. Wipe samples containing gamma-emitting nuclides are generally counted in gamma counters, which typically have greater than 50% efficiency (e.g. approximately 80% for ^{125}I using 1.5 inch NaI gamma counter), so the CPM/DPM conversion is easier and tends to be dominated by the abundance of the particular nuclide's emissions. A "100 CPM above background" limit nonetheless generally satisfies the DPM-based limits for gamma emitters as well.

Table 2: Radiation Safety Manual DPM limits expressed as worst-case CPM values

Radioisotope Category	Action Level (DPM) for Area		Action Level CPM
	Restricted Area	Unrestricted Area	Unrestricted Area
Gamma	2,200	220	Approx. CPM x abundance
High-Energy Beta	2,200	220	Approx. 200
Low-Energy Beta	22,000	2,200	Approx. 100

Conclusion: A "100 CPM above background" decision limit reasonably satisfies the corresponding DPM limits without requiring the unnecessary extra effort and inherent variability of converting CPM results to DPM.

* Klein, RC, Linins, I, Gershey, EL. Detecting removable surface contamination. Health Physics 62(2):186-189; 1992.

Appendix D: VUMC Release of Individuals Administered Radioactive Materials

I. Purpose

This document establishes the activities of radioactive materials administered to patients or human research subjects (HRS) that is unlikely to cause a radiation dose to any member of the public exceeding the 5 mSv (0.5 rem) limit specified in TN Rule 0400-20-07-.35(1) and the corresponding NRC regulation 10cfr35.75(a), and that no record of release is required for each administration of radioactive material in patients or HRS.

This document also establishes the activities of radioactive materials administered to patient or HRS that requires VUMC to provide instructions, including written release instructions, to released patients or HRS specified in TN Rule 0400-20-07-.35(2) and the corresponding NRC regulation 10cfr35.75(b).

II. Background

TN Rule 0400-20-07-.35(1) indicates that patients or HRS administered radioactive material may not be released unless the licensee demonstrates that the resulting radiation dose to any member of the public will not exceed 0.5 rem. The acceptable methods for demonstrating compliance with this release criterion are provided in the NRC's Reg Guide 8.39, and include either keeping the administered activity below the amount specified in Table 1 Column 1 of that Guide, or documenting by calculation in a Release Criteria document that the public dose limit will not be exceeded.

TN Rule 0400-20-07-.35(2) indicates that released patients or HRS administered radioactive material must be provided instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent (TEDE) to any other individual is likely to exceed 0.1 rem. The acceptable method for determining the necessity for release instructions are provided in NRC's Reg Guide 8.39, and include providing release instructions for administered activities in excess of the amounts specified in Table 2 Column 1 of that guide, or determining by calculation that the TEDE to other individuals is likely to exceed 0.1 rem.

III. Releasing Patients or HRS Administered Radioactive Materials by Established NRC Activity Limits

Releasing patients or HRS from VUMC at or below administered activities listed in Table 1 will not require a record of release.

Table 1. Activities for Authorizing Patient or HRS Release[a]

RADIONUCLIDE	(mCi)	(GBq)	RADIONUCLIDE	(mCi)	(GBq)
Ag-111	520	19	Pd-103 implant	40	1.5
Au-198	93	3.5	Re-186	770	28
Cr-51	130	4.8	Re-188	790	29
Cu-64	230	8.4	Sc-47	11	310
Cu-67	390	14	Se-75	2	0.089
Ga-67	240	6.7	Sm-153	700	26
I-123	160	6.0	Sn-117m	29	1.1
I-125	7	0.25	Sr-89	(b)	(b)
I-125 implant	9	0.33	Tc-99m	760	28
I-131	33	1.2	Tl-201	430	16
In-111	64	2.4	Y-90	(b)	(b)
Ir-192 implant	2	0.074	Yb-169	10	0.37
P-32	(b)	(b)			

a. These values are taken from US NRC Reg Guide 8.39 Revision 1 Release of Patients Administered Radioactive Materials (2020)
b. Activity limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

IV. Releasing Patients or HRS Administered Radioactive Materials by Calculated Activity Limits

For radionuclides not listed NRC's Reg Guide 8.39 Table 1. The NRC's NUREG 1556 v.9 Appendix U provides guidance on how to address such cases:

> *If a radionuclide that is not listed in Table U.1 is administered, the licensee can demonstrate compliance with the regulation by maintaining, for NRC inspection, a calculation of the release activity that corresponds to the dose limit of 5 mSv (0.5 rem).*

Reg Guide 8.39 provides the following formulas for calculating the administered activities of radionuclides that would produce an estimated dose of 0.5 rem to a member of the public:

For radionuclides with physical half-life greater than 1-day:

$$Q_o = D(100\text{ cm})^2/[34.6\ \Gamma\ Tp\ (0.25)] \quad \text{[Equation 1]}$$

Q_o = activity, mCi

D = dose limit to a member of the public; 0.5 rem

34.6 = conversion factor of 24 hrs/day times total integration of decay (1.44)

Γ = specific gamma ray constant for a point source, R/mCi·hr at 1 cm; [rem and R are not exactly equivalent, but the NRC guidance uses rem and R interchangeably]

Tp = Physical half-life in days

0.25 = default occupancy factor assumed for radionuclides with half-lives exceeding one day

For radionuclides with physical half-life less than 1-day:

$$Q_o = D(100\text{ cm})^2/[34.6\ \Gamma\ Tp\ (1.0)] \quad \text{[Equation 2]}$$

D = dose limit to a member of the public; 0.5 rem

34.6 = conversion factor of 24 hrs/day times total integration of decay (1.44)

Γ = specific gamma ray constant for a point source, R/mCi·hr at 1 cm; [rem and R are not exactly equivalent, but the NRC guidance uses rem and R interchangeably]

Tp = Physical half-life in days

1.0 = default occupancy factor assumed for radionuclides with half-lives less than one day

The following nuclides are used at VUMC and are not listed in Reg Guide 8.39:

Table 2. List of Radionuclides Used at VUMC and Not Provided in Reg Guide 8.39

Radionuclide	*Tp* (days)	Γ (R/mCi·hr at 1 cm)[a]
C-11	0.014	5.86
N-13	0.007	5.86
F-18	0.076	5.68
Ga-68	0.047	5.43
Cs-131	9.7	0.679
Lu-177	6.7	0.181
Ra-223	11.4	1.74[b]
Ac-225	9.92	1.25[b]

a. Taken from Smith & Stabin 2012 Exposure Rate Constants and Lead Shielding Values for Over 1,100 Radionuclides
b. This value is progeny in secular equilibrium for Ra-223 & Ac-225.

Using Equations (1), (2) and the values from Table 2:

Table 3. Calculated Administered Activities for Authorizing Release of Patients or HRS	
Radionuclide	**Activity (mCi)**
C-11	1761
N-13	3522
F-18	334
Ga-68	566
Cs-131	87
Lu-177	476
Ra-223	29
Ac-225	46

Releasing patients or HRS from VUMC at or below calculated administered activities listed in Table 3 will not require a record of release.

V. Established NRC Activity Thresholds Requiring VUMC to Provide Instructions to Released Patients or HRS

Releasing patients or HRS from VUMC above administered activity thresholds listed in Table 4 will require instructions to be provided to released patients.

Table 4. Administered Activities Which Instructions Should be Given When Authorizing Patient or HRS Release[a]					
RADIONUCLIDE	**(mCi)**	**(GBq)**	**RADIONUCLIDE**	**(mCi)**	**(GBq)**
Ag-111	100	3.8	Pd-103 implant	8	0.3
Au-198	19	0.69	Re-186	150	5.7
Cr-51	26	0.96	Re-188	160	5.8
Cu-64	45	1.7	Sc-47	62	2.3
Cu-67	77	2.9	Se-75	0.5	0.018
Ga-67	47	1.7	Sm-153	140	5.2
I-123	33	1.2	Sn-117m	6	0.21
I-125	1	0.05	Sr-89	(b)	(b)
I-125 implant	2	0.074	Tc-99m	150	5.6
I-131	7	0.24	Tl-201	85	3.1
In-111	13	0.47	Y-90	(b)	(b)
Ir-192 implant	0.3	0.011	Yb-169	2	0.073
P-32	(b)	(b)			

a. These values are taken from US NRC Reg Guide 8.39 Revision 1 Release of Patients Administered Radioactive Materials (2020)
b. Activity limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

VI. Calculated Activity Thresholds Requiring VUMC to Provide Instructions to Released Patients or HRS

For radionuclides not listed NRC's Reg Guide 8.39 Table 2, the same methodology from section IV of this document can be applied to determine activity thresholds requiring instructions to be provided to release patients or HRS.

Using Equations (1) and (2) with dose limit to a member of the public equivalent to 0.1 rem instead of 0.5 rem (D = 0.1 rem) and the values of Table 2 of this document:

Table 5. Calculated Administered Activities Which Instructions Should be Given When Authorizing Patient or HRS Release	
Radionuclide	**Activity (mCi)**
C-11	352
N-13	704
F-18	66
Ga-68	113
Cs-131	17.5
Lu-177	95
Ra-223	5.8
Ac-225	9.32

Releasing patients or HRS from VUMC above administered activity thresholds listed in Table 5 will require instructions to be provided.

VII. References

U.S. NRC. Regulatory Guide 8.39 Revision 1 Release of patients administered radioactive materials (2020)

U.S. NRC. NUREG 1556 vol. 9: Program-specific guidance about medical use licenses

Smith DS & Stabin MG. Exposure rate constants and lead shielding values for over 1,100 radionuclides. Health Phys. 102(3):271-291; 2012.

Approved by:

6/27/2022

Aaron Jessop, M.D., M.B.A, Associate Professor, VUMC Nuclear Medicine Date

6/27/2022

Eric Shinohara, M.D., M.S.C.I, Associate Professor & Chair, VUMC Radiation Oncology Date

6/27/2022

Marni Gardner, D.Ph, Chair, VUMC Radiation Safety Committee Date

6/27/2022

Christopher Helstern, Ph.D., CHP, RSO, Office of Clinical & Research Safety Date

Appendix E: Technical Basis: LDE Correction for Diagnostic X-ray Users

[state approved 2/28/2013]

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VEHS
VANDERBILT

February 26, 2013

State of Tennessee Dept. Env. & Conservation, Division of Radiological Health
3rd Floor L&C Annex
401 Church Street
Nashville, TN 37243-1532

Attn: Charles Arnott, Health Physicist

Dear Mr. Arnott,

By this letter, Vanderbilt University Medical Center requests permission to apply, at the RSO's discretion, a correction factor of 0.5 to the lens dose equivalent (LDE) provided by our dosimetry service provider, to calculate a more accurate LDE of record for personnel:

- whose only source of occupational radiation exposure is diagnostic X-ray equipment;
- who always wear leaded (Pb) eyewear during these X-ray procedures; and
- whose LDE as indicated by dosimetry badge results exceeds 25% of the LDE occupational dose limit for the monitoring interval during which the correction factor is applied.

This correction factor is needed to more accurately estimate the lens dose of physicians whose LDE, based solely on the collar dosimeter result, may approach the occupational dose limit, but whose only exposure is from diagnostic X-ray equipment and who always wear Pb eyewear during their use of such equipment. In such cases, LDE results from a dosimetry badge significantly overestimate the actual lens dose. These inflated LDE values may require removing of a physician from the operating room for part of the year to avoid having a significantly overstated LDE value exceed the annual limit.

Actual lens dose is much less than the LDE value provided by a collar dosimetry badge, due to both geometry (i.e. the eyes are farther from the scattering center than the collar badge) and shielding by Pb eyewear. Several researchers[1] have reported reduction factors due solely to geometry of 0.38 to 0.52. Sturchio et al[2] recently showed that reduction offered by Pb eyewear varied depending on the eyewear style and the wearer's head position with respect to the scattering center, but indicated that an overall reduction of at least 50% could reasonably be expected.

In conclusion, a 0.5 correction factor overestimates the actual lens dose, but more accurately reflects the actual dose while accommodating the wide variation in geometry and shielding factors, making it very improbable that the resulting corrected LDE would ever understate the actual lens dose in even the worst case. If you have any questions or need further information, please contact me at (615) 343-8220.

Sincerely,

Ben Edwards

Ben Edwards, MS, CLSO, CHP, Radiation Safety Officer, Vanderbilt Environmental Health and Safety

CC: Robert Wheaton, MPH, CIH, Executive Director, Vanderbilt Environmental Health & Safety
Michael Stabin, Ph.D., Chair, Vanderbilt Radiation Safety Committee

[1] Faulkner & Marshall, Health Phys 64(5):502-8, 1993; Li et al, Health Phys 69(2):261-4, 1995; Harstall, Spine 30(16):1893-8, 2005; Efstathopoulos et al, Europace 8:443-8, 2006.
[2] Sturchio et al, Health Phys 104(supplement):S11-S16, 2013.

Appendix F: Radioactive Waste Procedures

PIs are responsible for ensuring their staff is familiar with the rules and procedures governing the disposal of radioactive waste. All waste disposals must be accounted for on the accountability record that accompanies each order.

Radioactive waste is collected at the point of generation by OCRS and transported to the Hazardous Waste Management Facility. To request a waste collection, fill out the online "Radioactive Waste Collection Form" which can be found at https://www.vumc.org/safety/rad/radioactive-waste-collection-procedures.

Work involving radioactive materials should be carefully planned to minimize the volume of waste generated. Care must be exercised to separate radioactive waste from non-radioactive waste as it is generated. Non-radioactive waste must not be placed in radioactive waste container, as disposal of radioactive waste is very expensive.

Radioactive wastes must be stored only in restricted areas where they can be secured against unauthorized removal. Radioactive waste containers may not be left unattended in a corridor.

All receptacles for radioactive waste must be clearly labeled with an appropriate radiation warning sign.

Radioactive waste should not be allowed to accumulate in the lab. When a waste container is nearing full, a waste collection request should be submitted to OCRS for quick removal. Collection requests should be submitted more frequently for gamma emitters or high-energy beta emitters. All packaged radioactive waste is limited to a maximum of 15 pounds per container.

If the radioactive waste contains gamma emitters or high-energy beta emitters, attention should be given to the location of the waste container in the laboratory to minimize radiation exposure of laboratory personnel. Additional shielding may be required.

Separate waste containers must be set up for short half-life and long half-life wastes. This will reduce waste disposal costs.

Normally, no charge is made to a PI for disposal of radioactive waste. All radioactive waste disposal charges will be billed back to the PI's school or major division (School of Medicine, VUH, Arts and Sciences, Engineering, etc.). However, if unusually large volumes or special procedures become necessary, the school might decide that the PI should bear the unusual charges.

Radioactive waste packaging procedures are complicated due to the license restrictions and cost structures of commercial radioactive waste disposal facilities. Specific waste packaging procedures are as follows:

1. OCRS inspects radioactive waste packaging at the time the waste is collected. If the waste is improperly packaged, then OCRS will not collect the waste. The PI is responsible for ensuring that the waste is properly packaged. If OCRS determines that there are violations of the waste packaging procedures, it is the laboratory's responsibility to repackage the waste.
2. Each waste container must have a completed waste disposal tag. Waste cannot be accepted by OCRS unless it has been properly identified and tagged. These tags are only available from OCRS and specific to the type of waste being generated (dry solid, liquid, biowaste, etc.). The tags can be requested on the Radioactive Waste Collection Form.
3. Solid and liquid radioactive wastes must be kept separate. The laboratory must have a waste container for dry solid waste and a container for liquid waste.
4. All dry radioactive waste must be packaged in a yellow, transparent bag with the radiation emblem on the outside. Waste contaminated with radionuclides with a half-life less than 90 days should be disposed in the large bags available from RPI. Incinerable waste contaminated with radionuclides with a half-life greater than 90 days should be placed into the small bags available only from OCRS (ask for them on your waste collection form). All non-incinerable waste bags must be securely sealed with strong tape and have a "Dry Solid" waste identification tag.
5. Radioactive syringe needles, broken glassware, and other sharps must be packaged in a sharps container, clearly marked for radioactive sharps only. Please tag radioactive sharps with the biohazard radioactive waste tag.
6. All glass should be packaged separately from other dry waste and put into a box with a completed dry solid radioactive waste tag.

7. Liquid waste containers must be in a non-degradable container and have positive fitting caps that must be kept closed. Containers of liquid waste must be tagged with both radioactive liquid and chemical waste tags (both are available from OCRS). Liquid waste must be separated into aqueous liquid waste and chemical liquid waste. Liquid waste other than scintillation vials cannot be accepted in small vials or syringes. It must be emptied into a bulk liquid container. All liquid waste containers must be placed in secondary containment (a tub or enclosure that will catch any leakage from the bottle).
8. Sewer disposal is not to be used as a primary means of disposal; it should be limited to rinse water or the disposal of large volumes of low specific activity liquid. Liquid radioactive waste being disposed via the sewer must be readily soluble in water or biologically dispersible. Sewer disposal is limited to 0.2 mCi (7.4 MBq) per day per PI. Sinks used for sewer disposal must be designated for this purpose by OCRS and labeled as a "Radioactive Hot Sink". Significant amounts (i.e. anything other than trace amounts incidental to washing glassware etc.) of radioactive material disposed to sewer must be recorded on the Radioactive Sink Disposal Log for that sink. If a lab worker is uncomfortable with the process of pouring low specific activity down the drain, OCRS will collect the radioactive liquid waste for disposal.
9. Biodegradable scintillation cocktail should be used whenever possible. If your experiment requires EPA-hazardous scintillation cocktail (solvent based), you will need to request an exemption from OCRS.

   Scintillation vial/fluids must be separated into the following four waste streams:

   - Biodegradable cocktail with short-lived radionuclides (<90 day half-life)
   - Biodegradable cocktail with long-lived radionuclides (>90 day half-life)
   - EPA-hazardous cocktail with short-lived radionuclides (<90 day half-life)
   - EPA-hazardous cocktail with long-lived radionuclides (>90 day half-life)

   Liquid scintillation vials do not have to be emptied into a bulk liquid container. Keep the vials in the original box and trays. If there are no trays, seal the vials in a radioactive waste bag and place it in a box.
10. Mixed waste is radioactive waste mixed with hazardous chemicals. These wastes are not accepted for disposal by most commercial disposal facilities; therefore, they are difficult and costly to dispose of. Non-hazardous chemicals should always substitute whenever possible. Plans for proper disposal of mixed waste should be made in the design stage of the experiment. This may require special approval by the Radiation Safety Committee. Mixed waste requires both a radioactive liquid waste tag and the pink hazardous waste tag.
11. Radioactive waste containing infectious agents shall not be released from the laboratory unless it has been suitably deactivated.
12. Animal and tissue waste must be tagged with the Biowaste tag. The maximum weight of an animal carcass is 27 kg. For animal carcasses containing ^{3}H or ^{14}C, the maximum activity is 0.00005 mCi/gram (1.85 kBq/gram) of tissue. Disposal costs may be charged to the PI if activity is over this limit.
13. Special work hoods and exhaust systems must be used in operations involving the production of significant amounts of airborne wastes. Approval of the Radiation Safety Committee is required for these operations. Where maximum permissible concentrations may be exceeded, the investigator will be required to trap, or otherwise limit, the amount of airborne radioactivity released.

Appendix G: Research Use of Non-Clinical Radiation-Producing Machines

I. Policy:

A. Each Principal Investigator (PI) possessing and operating ionizing radiation producing devices:

1. Makes the required notifications regarding that equipment;
2. Verifies all operators are properly trained, provided with required personal protective equipment, abide by the VUMC Radiation Safety Manual and regulatory requirements; and
3. Promptly correct deficiencies noted by Tennessee State-Registered X-ray inspectors.

B. Where applicable regulations specify additional requirements not covered in, or in conflict with this appendix, the regulations take precedence. PIs may implement laboratory-specific policies that are more restrictive than this appendix, but they may not exempt laboratories from the requirements of this appendix and the VUMC Radiation Safety Manual.

C. This policy does not apply to ionizing radiation-producing devices to be used in the healing arts (e.g., use of X-rays in medicine, dentistry, osteopathy, chiropractic, and podiatry).

II. Definitions:

A. *ALARA* (acronym for as low as reasonably achievable) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these standards as is practical and consistent with the purpose for which the activity is undertaken.

B. *Enclosed Beam X-ray Device* means an analytical X-ray producing device designed in such a way that the primary beam is completely enclosed by the tube housing-apparatus complex during normal operation.

C. *Fail-Safe Design* means in which all failures of indicator of safety components that can reasonably be anticipated cause the equipment to fail in a mode such that personnel are safe from exposure to radiation.

D. *OCRS* is an acronym for The Office of Clinical and Research Safety.

E. *Open Beam X-ray Device* means an analytical X-ray producing device designed in such a way that the primary beam is not completely enclosed by the tube housing-apparatus complex during normal operation.

F. *Primary Beam* refers to that part of the radiation that passes through a window, aperture, cone, or other collimating device.

G. *PPE* is an acronym for person protective equipment.

H. *Restricted Area* means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to radiation.

I. *Shutter* means an adjustable device, generally of lead, fixed to an X-ray tube housing to intercept or collimate the useful beam.

J. *Tube Housing-Apparatus Complex* means those parts of an analytical X-ray device in which X-rays are produced and utilized.

K. *Unrestricted Area* means an area, access to which is neither limited nor controlled by the licensee or registrant.

III. Specific Education:

A. Cabinet X-ray Radiography Device Operators

1. PIs provide a copy of the operating procedures to all operators;
2. PIs provide instructions in the operating procedures;
3. Operators demonstrate an understanding of the operating procedures; and
4. Operators demonstrate competence in the use of the unit.

B. Analytical X-ray Device Operators

1. Complete requirements specified in Section III.A; and
2. Complete OCRS online Analytical X-ray Safety training annually.

C. Accelerator Operators

1. Complete training requirements specified in the accelerator's certified registration; and
2. Complete OCRS Accelerator Safety training annually.

D. Personnel *routinely exposed* (as determined by the PI) to radiation from X-ray devices complete appropriate radiation safety awareness training, either through OCRS or the PI's Laboratory.

IV. Specific Information:

A. Any person or laboratory bringing X-ray equipment on site notifies OCRS prior to installation, and within 5 days from when the equipment either arrives on site, leaves the site, or is relocated on site. Any PI failing to provide this prior notification is responsible for any fees, penalties, and interest resulting from late registration of the device(s).

B. Each laboratory possessing X-ray equipment designates a responsible individual for each piece of X-ray equipment. If no individual has been designated, the PI is responsible.

C. As Low as Reasonably Achievable (ALARA):

1. Use of imaging X-ray equipment on humans for research purposes complies with this policy and is specifically approved by the Institutional Review Board (IRB).
2. No person uses X-ray equipment to intentionally expose any human except under an IRB protocol.
3. All use of X-ray equipment adheres to established radiation protection principles and achieve occupational doses and doses to the members of the public that are ALARA.

D. Dosimetry Monitoring:

1. Dosimetry badges are issued to, and worn by:
    a. Personnel likely to receive an occupational radiation exposure exceeding 10% of an occupational dose limit; or
    b. Declared pregnant workers likely to receive more than 100 mrem during the entire pregnancy; or
    c. Individuals entering a high (could result in > 100 mrem/h [1 mSv/h] at 30 cm from accessible surface of radiation source) or very high (could result in > 500 rad/h [5 Gy/h] at one meter from accessible surface of radiation source) radiation area; or
    d. Personnel who hold human research subjects or imaging devices during imaging X-ray exposures
2. Personnel requiring dosimetry monitoring:
    a. Coordinate with the appropriate badge representative to obtain appropriate dosimetry monitoring devices through OCRS (contact OCRS for assistance identifying a badge representative)
    b. Wear the assigned dosimeter(s) in the proper location whenever working around radiation sources; and
    c. Exchange the dosimetry badge(s) on time with the appropriate badge representative
3. OCRS reviews radiation dosimetry monitoring results and notifies personnel who exceed the applicable investigational limits specified in the Vanderbilt University & VUMC ALARA Policy. Personnel have the ability to view their personal dosimetry results at any time by following the directions on the OCRS website.

E. Posting, Labeling and Indicators:

1. The entrance to any room containing fixed operational X-ray equipment is clearly posted as:
    a. "Caution Radiation Area" if radiation levels > 5 mrem/h at 30 cm from accessible surface of radiation source; or
    b. "Caution, High Radiation Area" if radiation levels > 100 mrem/h at 30 cm from accessible surface of radiation source; or
    c. "Grave Danger, Very High Radiation Area" if radiation levels > 500 rad/h at 1 meter from accessible surface of radiation source.
2. Current copies of the State of TN X-ray device registration, TN "Notice to Employees" and "Notice to Pregnant Radiation Workers" are posted conspicuously in sufficient places to permit workers to see them en route to locations where the documents apply, and replaced if removed or altered.
3. X-ray equipment is clearly labeled near the control panel switch, and at any remote switch, that energizes the apparatus, with the words:
    a. "CAUTION – RADIATION – THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED", or
    b. "DANGER – RADIATION – THIS EQUIPEMENT PRODUCES RADIATION WHEN ENERGIZED."

F. Security:

1. X-ray equipment is secured when unattended.

G. Cabinet X-ray Radiography Device:

1. Operation not possible unless all openings are closed with interlocks activated.
2. The device is shielded such that every exterior location meets the conditions for an unrestricted area.
3. The device is constructed or arranged as to exclude the entrance of any body part on an individual during irradiation.

H. Analytical X-ray Device:

1. Tubehead leakage cannot exceed 2.5 mR/hr at 5 centimeters from the tube at any rating.
2. Radiation leakage from the high voltage power supply cannot exceed 0.5 mR/hr at 5 centimeters from the power supply at any tube rating.
3. The control panel and tube housing must have warning lights or indicators that illuminate only when the X-ray tube is activated.
4. The warning lights or indicators must be labeled with the notation "X-ray On" or equivalent.
5. The warning lights or indicators must be of fail-safe design.
6. The device must have a beam trap sufficient to limit the exposure rate from the primary beam to less than 0.25 mR/hr at 5 centimeters in the primary beam.
7. A sign or label must be placed on or adjacent to each X-ray tube housing bearing the words:

    "CAUTION – HIGH INTENSITY X-RAY BEAM".
8. Devices equipped with couplings between the X-ray tube and the collimator must prevent radiation from escaping.
9. Each port of the radiation source housing provided with a beam shutter interlocked with the X-ray accessory apparatus coupling or collimator must only open when the collimator or coupling is in place.
10. Operating and emergency procedures must be posted near each device.

11. Safety devices (e.g., interlocks, shutters, warning lights, etc.) must be tested quarterly.
12. Documentation of the safety device test must be maintained by the PI.
13. Breaking interlocks to terminate X-ray production can only be used in an emergency or testing and after breaking an interlock, production of X-rays can only be reactivated from the control panel.
14. Alteration to safety devices must:
    a. Be approved in advance by the Radiation Safety Officer;
    b. Specify the device status in writing and be posted near the X-ray tube housing; and
    c. Be terminated as soon as possible.
    d. Documentation must be maintained of the alteration and include:
        i. The date the alteration was made
        ii. The type of alteration
        iii. Length of time the device remained in altered condition
        iv. Signature of the person who performed the alteration
        v. Signature of the person who restored the device to its original condition
15. Open Beam Analytical X-ray Devices must:
    a. Have a device indicating when shutters are open; and
    b. The indicator must be of fail-safe design.
16. Enclosed Beam Analytical X-ray Devices must:
    a. Be constructed in a manner that no part of the body may enter the primary beam during normal operation;
    b. Have sample chambers interlocked with the tube high voltage supply or a shutter in the primary beam and interlocks/shutters must be of fail-safe design.

I. Accelerator:

1. Current copy of the TN Accelerator Certified Registration, Operating Procedures, and Emergency Procedures are posted near the control panel.
2. PIs ensure all conditions of the Certified Registration are met.
3. Accelerators can only be activated from the control panel.
4. All entrances to high radiation areas must have interlocks.
5. The interlock system and emergency cut-off system must be on separate electrical circuits and/or mechanical systems.
6. Interlocks:
    a. Breaking interlocks must terminate the beam and after breaking an interlock, production of radiation can only be reactivated from the control panel.
    b. Interlocks can only be used to shut off the accelerator in an emergency or during testing.
    c. Interlocks must be tested quarterly to ensure they are functioning properly, and documentation of these tests must be maintained.
    d. Interlocks can only be bypassed for testing or maintenance if:
        i. A sign is posted at the control panel when interlocks are bypassed;

ii. Individuals entering the area, which is controlled by interlocks, are utilizing personnel monitoring equipment which will give an audible indication when a dose rate of 15 millirems per hour is exceeded; and

iii. Activities in which bypassed interlocks are:

1. Authorized by the Radiation Safety Officer;
2. Only performed for a specified time;
3. Performed at lower power and current if possible; and
4. Recorded showing the date, length of time bypassed, reason for bypassing, and signed by the individual installing and removing the bypass.

7. Emergency Shut-off Switches:
   a. Emergency Shut-off Switches must be located at the control panel and within the accelerator room.
   b. Emergency Shut-off Switches must be posted with a conspicuous sign adjacent to each switch that includes the mode of operation (e.g., "PUSH").
   c. Emergency Shut-off Switches must terminate the beam when engaged.
   d. Emergency Shut-off Switches must have a manual reset at each switch and after manual reset of the emergency shut-off switch, radiation can only be produced at the control panel.
   e. Emergency Shut-off Switches must be tested quarterly to ensure they are functioning properly, and documentation of these tests must be maintained.
8. Radiation Detection Equipment required by the certified registration:
   a. Must be readily accessible;
   b. Must be tested daily for operation;
   c. Must be calibrated in accordance with the certified registration requirements; and
   d. Must have a current calibration note attached.
9. The control panel and all entrances to high radiation areas must have a device that provides a continuous indication of radiation present in target areas or areas.
10. All high radiation areas must be constructed so that individuals within the area may at all times be able to escape.
11. Electrical circuit diagrams of the accelerator and associated interlock system must be kept current and at the control panel.
12. Only individuals meeting the training requirements Section III.C may operate and unlock the accelerator.
13. After radiation production of an accelerator, personnel entering the accelerator room must use the radiation area monitor or portable survey meter.

J. New Construction or Renovation:

Structural Shielding:

1. Each X-ray installation has primary barriers and/or secondary barriers as needed to ensure compliance with applicable occupational and public dose limits.
2. The shielding plan review for any new or relocated fixed X-ray equipment installation is performed prior to installation as part of the associated construction project; a copy of the plan review is provided to OCRS.
3. Upon or before installation of fixed X-ray equipment the PI arranges for a shielding continuity survey of the room housing the equipment; a copy of the shielding continuity shielding report is provided to OCRS.