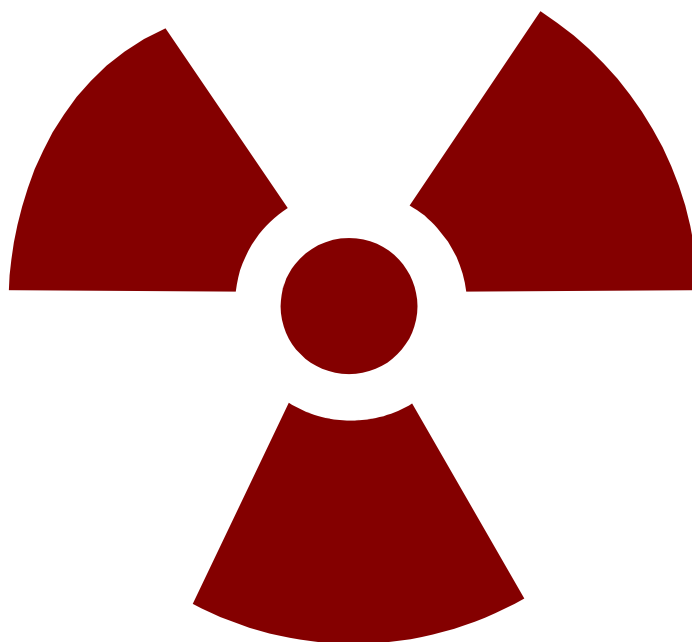


VANDERBILT UNIVERSITY

RADIATION SAFETY MANUAL



Office of Clinical and Research Safety

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Introduction

This manual contains the radiation safety policies established by the Vanderbilt University (VU) 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. The Office of Clinical and Research Safety (OCRS) administers the Vanderbilt radiation safety program. 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 web site). 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. Radiation Safety Committee (RSC)

The VU Radiation Safety Committee (RSC) oversees the Radiation Safety Program and is responsible for the safe use of ionizing radiation. Members of the RSC are selected to include faculty representatives from primary radiation use areas, individuals with technical expertise and individuals from management.

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 biannually 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 and the RSO to verify that 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 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, VU 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 biannually the RSO's summary report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive.
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., 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 entire 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. Office of Clinical and Research Safety (OCRS)

1. Order, receive and deliver radioactive materials.
2. Manage radioactive waste.
3. Perform laboratory audits and surveys.
4. Perform instrument calibration/performance checks.
5. Provide personnel monitoring/bioassay services.
6. Perform inventory/leak test/survey requirements for sealed sources.
7. Provide Radiation Safety Training.
8. Maintain emergency preparedness.

9. Maintain records.
10. Provide advice and consultation to faculty, on matters related to radiation safety.
11. Monitor radiation users for compliance with State and Federal regulations, license conditions, and policies of the Radiation Safety Committee.
12. Monitor radiation-emitting equipment requiring a certified registration for compliance with State regulations.
13. Provide administrative support for the RSC.
14. Provide initial review of proposals submitted to the RSC.
15. Prepare and ship all radioactive materials sent from Vanderbilt.

C. 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.

D. Principal Investigator (PI)

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
 - e. ensure employees have been instructed in radiation safety aspects of the specific operations in their laboratory or workplace, including on-the-job training.
5. 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 the University, 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 (e.g. 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.

E. 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 VU 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 VU 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: 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 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 VU, and cannot be a resident, or fellow, student, or visiting faculty; and
- d. be a full time VU 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 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 VU):
 - a. Basic Radiation Safety; all radioactive material users must satisfy one of the following:
 - i. attend the Initial Radiation Safety Course provided by OCRS;
 - ii. furnish evidence of previous attendance of a radiation safety course; or
 - iii. pass an exam administered by OCRS.

b. Vanderbilt Radiation Safety Orientation Training:

All personnel handling radioactive material, including the PI, are required to complete the provided training which covers Vanderbilt University 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.

| <u>Lab Hazard Rating</u> | <u>Approved No. of ALIs</u> |
|--------------------------|-----------------------------|
| 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.

| 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 Vanderbilt "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 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 D 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 facility.
- 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. PIs must place all radioactive material orders, including those for which there is no charge, through OCRS. 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 must be ordered online through the OCRS RAM Core in iLab.
 - d. 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.
 - e. 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.
 - f. 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.
 - g. 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 VU 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.
 - 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 VU lab, the same PI's Vanderbilt University Medical Center 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 VU, whether between VU sites or to non-VU sites, must be coordinated through OCRS.
7. Radioactive Waste Disposal

See Appendix D: 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/cm² 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 volatilized.
 - 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 of 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.

Section 3: 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.

| 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 exceed 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"]

1. 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.
2. 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.
3. The RSO will review occupational dosimetry records and investigate unusual results as indicated in the ALARA policy (see Appendix A).
 4. 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.
 5. Formerly badged radiation workers may obtain their previous occupational dose history from Vanderbilt by submitting a signed written request to OCRS Radiation Safety. Vanderbilt 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. 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 4: 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 3).

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 5: 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 6: Research Use of Radiation-Producing Machines

See Appendix E: Research Use of 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 monitoring¹; 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 guidance² requires personnel monitoring; also, NRC guidance³ 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 methods⁵ exist for correcting these measured DDE doses to more accurately reflect the worker's actual occupation dose, but the two recognized by the NRC² 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 such radiation workers who also wear leaded eye protection:

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

Radiation workers whose exposures meet this 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 See e.g. NRC 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

- 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.
- Actual measurable radioiodine intakes will continue to be rare.
- 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.
- 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.
- 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* = $0.3 \times$ 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 $1\mu\text{Ci}$ iodine content in the thyroid at time of measurement for any radioiodine. The PAL is based on ^{131}I 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 $0.1\mu\text{Ci}$ 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:

| 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 ¹²⁵I 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.

| 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: 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 repack 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 ^3H 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 E: Research Use of 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 VU 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 VU 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 direction 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 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.