

Vanderbilt Bedford Hospital Radiation Safety Manual

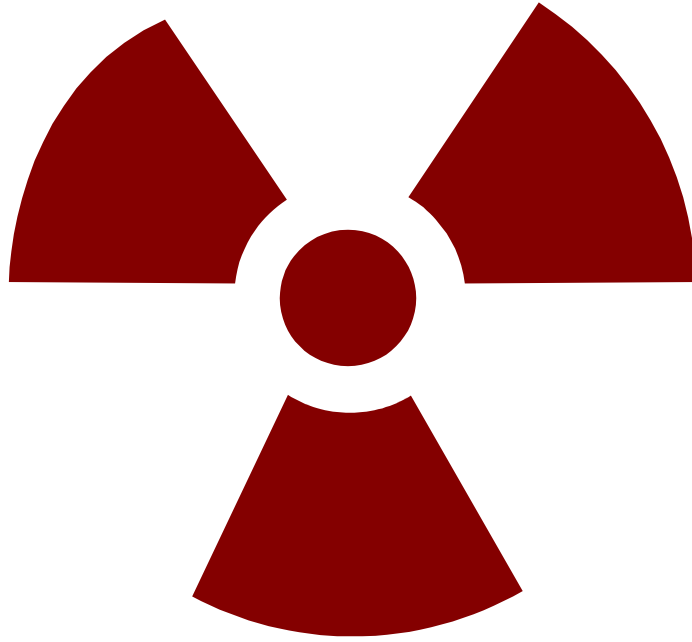


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Introduction

This manual contains the radiation safety policies established by the Vanderbilt Bedford Hospital (VBH) Radiation Safety Committee (RSC). Activities involving radiation sources are conducted under licenses and registrations for VBH issued by the Tennessee Department of Environment and Conservation, Division of Radiological Health. The Radiation Safety Officer (RSO) administers the VBH radiation safety program. Although the RSC approves Authorized User physicians.

All radiation users must know and comply with the applicable rules set forth in this manual and have access to the current version. No one may use, bring on site, or remove from VBH 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 the RSO.

Section 1: Roles and Responsibilities

A. VBH Radiation Safety Committee (RSC)

The VBH 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 from medical use areas, technical expertise and 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 semiannually 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 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, VBH 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 semiannually the RSO's summary report of the occupational radiation exposure records of all VBH 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 VBH 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.

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 VBH and the state Division of Radiological Health; maintain VBH's radioactive material license and certified registration.
10. Authorize all orders of radioactive materials.
11. Ensure radioactive waste is managed and disposed adequately.
12. Ensure instrument calibration/performance checks are performed.
13. Ensure required radiation surveys are being performed.
14. Provide personnel monitoring/bioassay services.
15. Ensure inventory/leak test/survey requirements for sealed sources are performed.
16. Provide Radiation Safety Training.
17. Maintain emergency preparedness.
18. Maintain records.
19. Provide advice and consultation to staff on matters related to radiation safety.
20. Monitor radiation users for compliance with State and Federal regulations, license conditions, and policies of the Radiation Safety Committee.
21. Monitor radiation-emitting equipment requiring a certified registration for compliance with State regulations.
22. Prepare and ship all radioactive materials sent from VBH, except for those items managed by the Nuclear Medicine.

D. Authorized User Physician

Authorized User Physician (AU) must meet the following criteria:

1. The AU must be a physician, dentist, or podiatrist licensed to practice medicine in the State of Tennessee.
2. 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.

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 VBH Radiation Safety Manual and any specific radiation safety procedures applicable to their work.
3. Complete all radiation safety training specified by the RSO.
4. Immediately report to the RSO incidents involving contamination of personnel, unconfined spills, theft or loss of radioactive material, suspected overexposures, or failure to comply with the VBH 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 the RSO at 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 the RSO 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: Clinical Radioactive Material Use

A. Radiation Safety Training Requirements

- a. All individuals handling radioactive materials or handling patients administered radioactive materials will be required to take initial and annual radiation safety training. This training will be presented in a manner that is appropriate for each individual's use of or exposure to radioactive materials.
- b. Perioperative staff working with radioactive material therapy patients must annually complete the 'Caring for Radiation Therapy Patients' refresher training.

B. Facilities and Equipment

1. Radioactive Material Storage and Use Areas

- a. Radioactive material may only be used or stored in areas listed approved by the RSC.
- b. Radioactive material use and storage should be confined to the minimum area necessary.
- c. Radioactive material presenting an external exposure hazard must be shielded to maintain radiation exposure to 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 1. 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 1: 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

C. Posting and Labeling Requirements

1. Areas authorized for radioactive materials use or storage are 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 Emergency Procedures in a conspicuous location.
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 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.
 - c. If any radioactive labeled equipment will no longer be used with radioactive material, or maintenance will be performed on the equipment, call the RSO 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

Sinks designated for sanitary sewer disposal must be posted with a "Radioactive Hot Sink" label. If any repairs are to be made to the posted sink, contact the RSO 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. If a radioactive waste container has been emptied by Environmental Services, contact the RSO immediately 615-875-3779.

D. 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 initial run from an individual 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.

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.
- 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 store food or beverages in a refrigerator designated as a radioactive materials storage facility.
- h. Use disposable absorbent pads or lipped trays to protect work surfaces and to confine spills.
- i. Hands should be checked often for contamination while working with radioactive material. If contamination is discovered, remove gloves and check hands.
- j. Limit as much as possible the amount of time spent handling radioactive material.
- k. Work with radioactive material must be confined to the work area.
- l. Radioactive materials should not be left in uncovered containers.
- m. All radioactive material containers should have the contents clearly labeled.
- n. Liquid radioactive material must be in a secondary container.
- o. Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10%.
- p. Use syringe shield for preparation of patient doses and administrations to patients, except in circumstances such as pediatric cases when their use would compromise the patient's well-being.
- q. Survey kit preparation and injections areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.
- r. Always transport radioactive material in shielded containers.
- s. Check patient's name and identification number, and the prescribed radionuclide, chemical form, and dosage before administering.

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.
- 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.).

E. Receipt, Transfer, and Disposal of Radioactive Material

1. Ordering Radioactive Material

- a. The RSO or designee must approve all radioactive material orders.
 - b. Radioactive materials may be ordered by radiation workers approved by the RSO.
2. License Exempt Purchases
 - a. Small "license exempt" (unregulated) quantities of radioactive material may be purchased by any radiation worker who has been authorized by the RSC to use those radionuclides as license exempt.
 - b. License-exempt purchases must be approved by the RSO.
 - 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 VBH staff.
 - e. Exempt quantities of radioactive material, including NORM, may not be transferred to any other individual or institution, nor disposed of, except as approved by the RSO.
 3. Receipt of Radioactive Material Packages
 - a. All radioactive material must be received by Nuclear Medicine or the RSO.
 - b. Nuclear Medicine or the RSO receives, surveys, inventories, and delivers radioactive material.
 - c. Radioactive material will only be released to trained radiation workers.
 4. Receipt and Disposal Records
 - a. The RSO maintains the total site inventory records for inspection by regulatory agencies.
 5. Transfer of Radioactive Material
 - a. All transfer of radioactive material must be approved by the RSO.
 6. Shipping Radioactive Material

All shipment or transfer of radioactive material from VBH, must be approved and coordinated through the RSO.
 7. Radioactive Waste Disposal
 - a. General Radioactive Waste Requirements
 - i. Separate long and short half-life materials.
 - ii. Label all waste with the radionuclide present and the maximum amount.
 - iii. Do not mix liquid waste with solid dry waste.
 - iv. If you have a hazardous chemical compound with a radioactive label, indicate the chemical, radionuclide and the amount of the radionuclide.
 - b. Decay-In-Storage
 - i. Radioactive waste (half-life < 120 days) may be placed in storage for decay and then final disposal to the sewage system, to normal trash, or shipped away for burial if:
 1. Radioactive waste is monitored in a low background area;
 2. Radiation surveys of radioactive waste at the surface the container is indistinguishable from background;
 3. The instrument used is set to the most sensitive scale with no interposed shielding and is capable of detection 0.01 mR/hr;
 4. All radiation labels are obliterated or removed except for those that that are with containers that will be treated as biomedical waste after release; and
 5. A record is maintained and includes:
 - a. The date of disposal;
 - b. The instrument used;

- c. The background radiation level;
 - d. The radiation level measured at the surface of each waste container; and
 - e. The name of the individual who performed the survey.
- c. Radioactive Waste Disposal to Sanitary Sewer
- i. Disposal to sanitary sewer is only used when instrumentation must be washed for reuse or when storage for decay is impractical.
 - ii. The material must be readily soluble or dispersible in water.
 - iii. A record must be maintained to include the disposed amount and radionuclide.
 - iv. Excreta from individuals under medical diagnosis or therapy with radioactive material shall be exempt from any limitations on dispersal by release into the sewage system.

F. Radiation and Radioactive Contamination Surveys

1. Surveys will be conducted in all areas where radioactive materials are stored, prepared, and/or administered.
2. Area surveys will be conducted daily with a GM survey instrument capable of detection 0.1 mR/hr.
3. Removable contamination surveys will be performed weekly.
4. A record will be maintained for three years for all survey results. The record must include:
 - a. The date of the survey;
 - b. The results of the survey;
 - c. The instrument used to make the survey;
 - d. The name of the individual who performed the survey; and
 - e. Any corrective action taken in the event of contamination or excessive exposure rate.
5. Unless otherwise authorized by the RSO, potentially contaminated items may not be removed from a radioactive material use or storage area, unless contamination levels do not exceed the levels in Table 2.

Table 2: 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

6. 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 2.
7. 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.

G. Use of Sealed Sources of Radioactive Material

1. Each sealed source must be:
 - 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 staff as needed for inspection, physical inventory, leak testing, etc.
2. Radiation workers must notify the RSO 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, RSO will ensure a physical inventory is conducted at intervals not to exceed six months, except for generally-licensed sources, which will undergo an annual physical inventory.
4. Leak Testing:
 - a. The RSO will ensure leak tests are conducted 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. any radionuclide other than tritium.
 - b. 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.

H. 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 VBH policies.

I. Diagnostic Use of Radioactive Materials

1. Diagnostic administration of radioactive material may only be performed by, or under the supervision of, an AU physician 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 the RSO. 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.

J. Therapeutic Use of Radioactive Materials – General Requirements

1. The administering AU physician's department must notify the RSO of all therapeutic radiopharmaceutical administrations requiring release documentation.
2. The administration of radioactive material in either unsealed form (radiopharmaceuticals) for therapeutic purposes may be performed only by, or under the supervision of, AU physicians approved by the RSC for that type of use.
3. For every therapeutic administration, an AU physician 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;

4. Individuals who have been administered therapeutic radioactive material must meet the applicable radiation release criteria, prior to discharge. Nuclear Medicine must document the basis for release, signed by an AU physician approved for that type of therapy, unless the type of therapy has been specifically exempted from this requirement (See Appendix C).
5. Nuclear Medicine 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 C).
6. Radiation monitoring badges will be issued to healthcare workers providing care to radioactive material therapy patients, unless the RSO determines dosimetry monitoring is not required.
7. Pregnant staff should not be responsible for the routine care of patients undergoing radioactive material therapy.

K. 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 the RSO.
 - a. The RSO 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, the RSO 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 Radiation Precautions remain in effect until discontinued by the RSO:
 - 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 Nuclear Medicine staff or the RSO 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 Nuclear Medicine or the RSO.
 - v. Bags of radioactive waste generated by radiotherapy patients will be collected and disposed by Nuclear Medicine or the RSO.
 - 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 the RSO 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. The RSO will post Radiation warning signs whenever the administered activity exceeds release criteria. These signs may only be removed by the RSO. If there are any special instructions for a particular patient, they will be noted on the therapy form provided by the RSO 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 the RSO 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 the RSO, Nuclear Medicine or the RSO will survey the room and decontaminate as needed to ensure that radiation and contamination levels meet requirements for unrestricted use. The RSO 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.

L. 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, the RSO must be notified immediately. **(615-875-3779)**

Section 3: Personnel Monitoring

A. Occupational Dose Limits

VBH 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 the Office of Clinical and Research Safety (OCRS) or Occupational Health Clinic (OHC). See Section 4 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 the RSO 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. The RSO 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 RSO, 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 the RSO 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 the RSO 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 the RSO upon request.
 - c. Badged radiation workers may also view their own dosimetry results online through the dosimetry vendor's website.
 6. Formerly badged radiation workers may obtain their previous occupational dose history from VBH by submitting a signed written request to the RSO. VBH 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 4, 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 4. The thyroid bioassay must be performed within the interval specified in Table 5.
 - 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 5. Repeat thyroid bioassays will be required for individuals with thyroid bioassay results indicating uptakes in excess of these action levels.

Table 4: 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 5: Bioassay Thyroid Action Levels*		
Nuclide	Thyroid Action Level (μCi)	Maximum Interval Between Handling Radioiodine and Conducting Bioassay (days)
¹²³ I	0.1	3
¹³¹ I	0.1	10

* See Appendix B for additional information.

2. 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.

3. Obtaining Bioassay Measurements

Contact the RSO for further information on how to obtain a bioassay.

4. Bioassay Records

Monitored radiation workers may receive their bioassay records from the RSO 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 the RSO

During normal business hours: 615-322-2057

After normal business hours: 615-875-3779

A. Minor Spills

1. **NOTIFY:** Notify persons in the area that a spill has occurred, also notify environmental services to obtain a spill kit.
2. **PREVENT THE SPREAD:** Cover the spill with absorbent paper.
3. **CLEAN UP:** Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Also, insert into the plastic bag all other contaminated materials, such as disposable gloves.
4. **SURVEY:** with a GM survey meter, check the area around the spill, hands, and clothing for contamination.
5. **REPORT:** Report the incident to the Radiation Safety Officer and your supervisor.

B. Major Spills of Radioactive Material

1. **CLEAR THE AREA:** Notify all personnel not involved in the spill to vacate the room.
2. **PREVENT THE SPREAD:** Cover the spill with absorbent pads, do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.
3. **SHIELD THE SOURCE:** If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.
4. **CLOSE THE ROOM:** Leave the room and lock the door(s) to prevent entry.
5. **CALL FOR HELP:** Notify the Radiation Safety Officer immediately.
6. **PERSONNEL DECONTAMINATION:** Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If contamination is present on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

Appendix A: VBH 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: The RSO 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 VBH RSC will review semiannually a summary of radiation dose records (ALARA report) as specified by the VBH 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 VBH 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 Limit⁴	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 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 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: VBH Thyroid Bioassay Program – Technical Basis Document

I. Radionuclides

The radioiodine isotopes used at VBH include: ^{123}I and ^{131}I

II. Assumptions

- a. Most radioiodine compounds used at VBH 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 measurable 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 VBH 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 VBH Radiation Safety Manual.
- 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* = $0.3 \times$ 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 VBH 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
^{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: VBH 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 VBH 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 VBH 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 Release of Patients Administered Radioactive Materials (1997)

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

Releasing patients or HRS from VBH above administered activity thresholds listed in Table 2 will require instructions to be provided to release patients.

Table 2. 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 Release of Patients Administered Radioactive Materials (1997)

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.

V. References

U.S. NRC. Regulatory Guide 8.39 Release of patients administered radioactive materials (1997)

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