5. RADIOACTIVE MATERIAL REQUESTED

5. Radioisotope	6. Form of Material	7. Maximum Activity	8. Authorized Use
Any radioactive material permitted by 25 TAC §289.256(ff)	Any radiopharmaceutical form, except gas	As needed	Any uptake, dilution and excretion study permitted by 25 TAC §289.256(ff).
Any radioactive material permitted by 25 TAC §289.256(hh)	Any radiopharmaceutical form, except gas	As needed	Any imaging and localization study permitted by 25 TAC §289.256(hh).
Any radioactive material permitted by 25 TAC §289.256(kk)	Any radiopharmaceutical form, except gas	5 curies	Any use of unsealed material that requires a written directive permitted by 25 TAC §289.256(kk).
Any radioactive material with atomic number 1 through 83 with a half-life less than 120 days, excluding alpha emitters, except otherwise specified	Any radiopharmaceutical form, except gas	600 millicuries	Research and education, including animal studies.
Any radioactive material with atomic numbers 1 through 83, except as listed below	Any, except sealed source	1 millicurie	Research and education.
Carbon-14	Any	No single source to exceed 1 millicurie Total 10 millicuries	Research and education, including animal studies.
Fluorine-18	Liquid	100 millicuries	Instrument calibration and reference.
Hydrogen-3	Any	No single source to exceed 1 millicurie Total 10 millicuries	Research and education, including animal studies.
Iodine-125	Any	No single source to exceed 1 millicurie Total 20 millicuries	Research and education, including animal studies.
Phosphorous-32	Any	No single source to exceed 1 millicurie Total 30 millicuries	Research and education, including animal studies.
Phosphorous-33	Any	No single source to exceed 1 millicurie Total 10 millicuries	Research and education, including animal studies.

Sulphur-35	Any	No single source to exceed 1 millicurie Total 10 millicuries	Research and education, including animal studies.

6. ADMINISTRATION OF THE RADIATION PROTECTION PROGRAM

6.1 RADIATION SAFETY COMMITTEE COMPOSITION

The Medical Use Radiation Safety Committee of The University of Texas at Austin Dell Medical School (DMS) shall be composed of a Chair and at least four additional members of which one shall serve as Vice-Chair. The Committee shall be appointed by the Dean and Vice President for Medical Affairs or the Dean's delegate. The Committee shall include, at a minimum, a representative from Executive Management with signature authority to commit University resources, at least one Authorized User representing each medical use category, a representative of the DMS nursing service, and such other members as deemed appropriate. The Radiation Safety Officer (RSO) shall be an ex-officio member of the Committee.

A. Quorum

A simple majority of members shall constitute a quorum, except a quorum may not be declared without the presence of the Chair or Vice-Chair, the representative from Executive Management or his/her delegate, and the RSO.

B. Meeting Frequency

The Committee shall meet at a minimum of three times per calendar year on a called basis. The Committee may meet at other times on request of the Chair, the representative from Executive Management, or the RSO. A meeting may be conducted in person or via teleconference.

6.2 COMMITTEE CHARTER

A. Charge

The Committee shall establish policies:

a) To ensure licensed radioactive materials are used safely. This includes the review of training programs, equipment, facilities, supplies, and procedures;

b) To ensure licensed radioactive materials are used in compliance with 25 TAC §289 and the License issued to The University of Texas at Austin Dell Medical School;

c) To ensure the use of licensed radioactive materials and exposure to radiation is consistent with the ALARA principle;

d) To establish a program to control individual occupational radiation exposures; and

e) To identify program deficiencies and ensure corrective actions are implemented.

B. Responsibilities

The Committee shall:

a) Retain expertise to be familiar with all pertinent regulations, the License, and amendments to the License;

b) Review the training and experience of proposed Authorized Users and the Radiation Safety Officer to determine qualifications in accordance with regulatory and License requirements;

c) Review and approve all requests for Authorization to Use radioactive materials under the DMS license to ensure the safe use of the materials;

d) Prescribe any special conditions for authorizing uses of radioactive materials;

e) Review the RSO's report on exposures of all personnel, and, when necessary, require modifications to the operations of the Radiation Protection Program to decrease the levels of exposure;

f) Review the RSO's annual summary report of the Radiation Protection Program.

g) Recommend and cause to be implemented remedial action to correct deficiencies identified in the Radiation Protection Program;

h) Review and approve minutes of all Committee meetings, including members present, members absent, agenda items, discussions, actions, recommendations, decisions, and results of all votes; and

6.3 COMMITTEE MEMBERS

Proposed members of the Radiation Safety Committee shall be submitted to the Texas Department of State Health Services per 25 TAC §289.252(h)(1)(c). A list of Committee members appears as Appendix I to this Manual.

6.4 RADIATION SAFETY OFFICER

The DMS Radiation Safety Officer is charged with implementing the DMS Radiation Safety Program. The RSO works within UT-Austin's department of Environmental Health & Safety (EHS). The RSO has authority, delegated by the Dean and Vice President for Medical Affairs to the Radiation Safety Committee, to take such actions as needed, including, but not limited to the cessation of the use of radioactive material, to safeguard the public welfare with regard to radiation and radioactive materials.

The RSO directs the Radiation Safety staff to effectively implement the requirements of the DMS Radioactive Materials License commitments.

APPENDIX I – Radiation Safety Committee Membership Roster

Chair

Mr. DeWayne Holcomb	Radiation Safety Officer, UT-Austin Environmental Health and Safety

Vice-Chair

Dr. Christopher Webb	Chief Research Officer Associate Dean for Research

Members

Dr. John Leahy	Medical Director of Imaging Assistant Professor Dell Medical School
Dr. Jeffrey J. Luci	Research Assistant Professor Department of Neuroscience
Dr. Donald Nolting	Facility Manager Biomedical Imaging Center
Mr. Paul Dubiel	Shared Services Manager, UT Health Austin Dell Medical School
Ms. Jennifer Harrison	Senior Director of Clinical Operations, UT Health Austin Dell Medical School
Dr. Stanislav Spiridonov	Assistant Professor, Dell Medical School

Ex-Officio Member

Kristi Powell	DMS Radiation Safety Officer Environmental Health and Safety

7. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

7.1 AUTHORIZED USERS FOR HUMAN USE

An Authorized User (AU) for human use is a physician licensed by the Texas Medical Board who meets the requirements of the specific subsection in 25 TAC §289.256 for which they are using radioactive materials, or who is identified as an Authorized User on any of the following:

(I) An agency, NRC, agreement state, or licensing state license that authorized the medical use of radioactive material;
(II) A permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material;
(III) A permit issued by a specific licensee with a broad scope authorization issued by the agency, the NRC, an agreement state, or licensing state authorizing the medical use of radioactive material; or
(IV) A permit issued by an NRC master material licensee with broad scope authorization that is authorized to permit the medical use of radioactive material.

In order to authorize the administration of radioactive materials in humans at DMS, an individual must be authorized to dispense and use drugs in the practice of medicine in the state of Texas. They must have basic clinical radionuclide training and experience commensurate with the intended use of the radioactive material.

7.2 TRAINING FOR UPTAKE, DILUTION AND EXCRETION STUDIES

The AU of a radiopharmaceutical for uptake, dilution and excretion studies shall be a physician who meets requirements of §289.256 (gg).

7.3 TRAINING FOR IMAGING AND LOCALIZATION STUDIES

The AU of a radiopharmaceutical for imaging and localization studies shall be a physician who meets requirements of §289.256 (jj).

7.4 TRAINING FOR USE OF UNSEALED MATERIAL THAT REQUIRES A WRITTEN DIRECTIVE PERMITTED BY 25 TAC §289.256 (kk)

The AU of unsealed material that requires a written directive shall be a physician who meets requirements of §289.256 (nn), (oo), (pp) or (qq) as applicable.

7.5 NUCLEAR MEDICINE TECHNOLOGISTS

Nuclear Medicine Technologists must be certified as a general certificate medical radiological technologist (MRT) under Texas Civil Statues, Article 4512M. In addition, each individual must:

(I) Be certified by the Nuclear Medicine Technologist Certification Board (CNMT); or
(II) Be certified in Nuclear Medicine by the American Registry of Radiologic Technologists (ARRT(N)); or
(III) Be board-eligible to take the CNMT or ARRT (N) examinations; or
(IV) Have graduated from an approved Joint Review Committee on Educational Program in Nuclear Medicine Technology (JRCNMT) program or be a student who is supervised and operating within such a program; or
(V) Have performed full-time nuclear medicine for a minimum of two years prior to January 1, 2007. This experience must be certified in writing by an authorized physician user.

7.6 AUTHORIZED USERS FOR NON-HUMAN USE

In order to become an Authorized User for non-human use of radioactive material, an applicant must (1) have a college degree at least at the bachelor's level and (2) be able to demonstrate prior training and experience through some combination of formal courses, on the job training, or isotope handling experience. The applicant may also demonstrate adequate prior training and experience by providing documentation of having been previously named on an NRC or Agreement State radioactive materials license.

7.7 RADIATION WORKERS

Any DMS employee or student who handles radioactive materials in any way (including direct handling, RAM receipt, or waste disposal) shall be classified as a Radiation Worker. Radiation Workers who do not have previous formal training in radiation safety must complete the DMS Radiation Worker Training course. The RSO may waive the course if the individual can provide documentation of previous equivalent training and/or experience.

Upon successful completion of the course, credit is posted to the individual's electronic training history in the campus-wide training database. If requested, the successful graduate is issued a certificate of completion.

Radiation safety courses are typically taught by staff of the Radiation Safety Office. If necessary or desired, outside training specialists may be utilized to present the courses. Subjects covered in the radiation worker training include, but are not limited to the following:

- Atomic Structure and Radioactivity
- Interactions of Radiation with Matter

- Quantities and Units of Radiation
- Basic Principles of Radiation Protection
- Safe Handling of Radioactive Materials and Sources
- Radiation Detection Instruments and Surveys
- Dosimetry
- Waste Disposal
- Purchasing and Receiving Radioactive Materials
- Applicable Sections of 25 TAC §289 and this license commitments document
- Emergency Procedures
- Record Keeping

The RSO may also require radiation workers to be trained in other areas, such as general hazard communication (Texas Hazard Communication Act) and laboratory safety.

The Radiation Safety Office shall maintain records of course attendance and course credit.

7.8 NON-RADIATION WORKERS

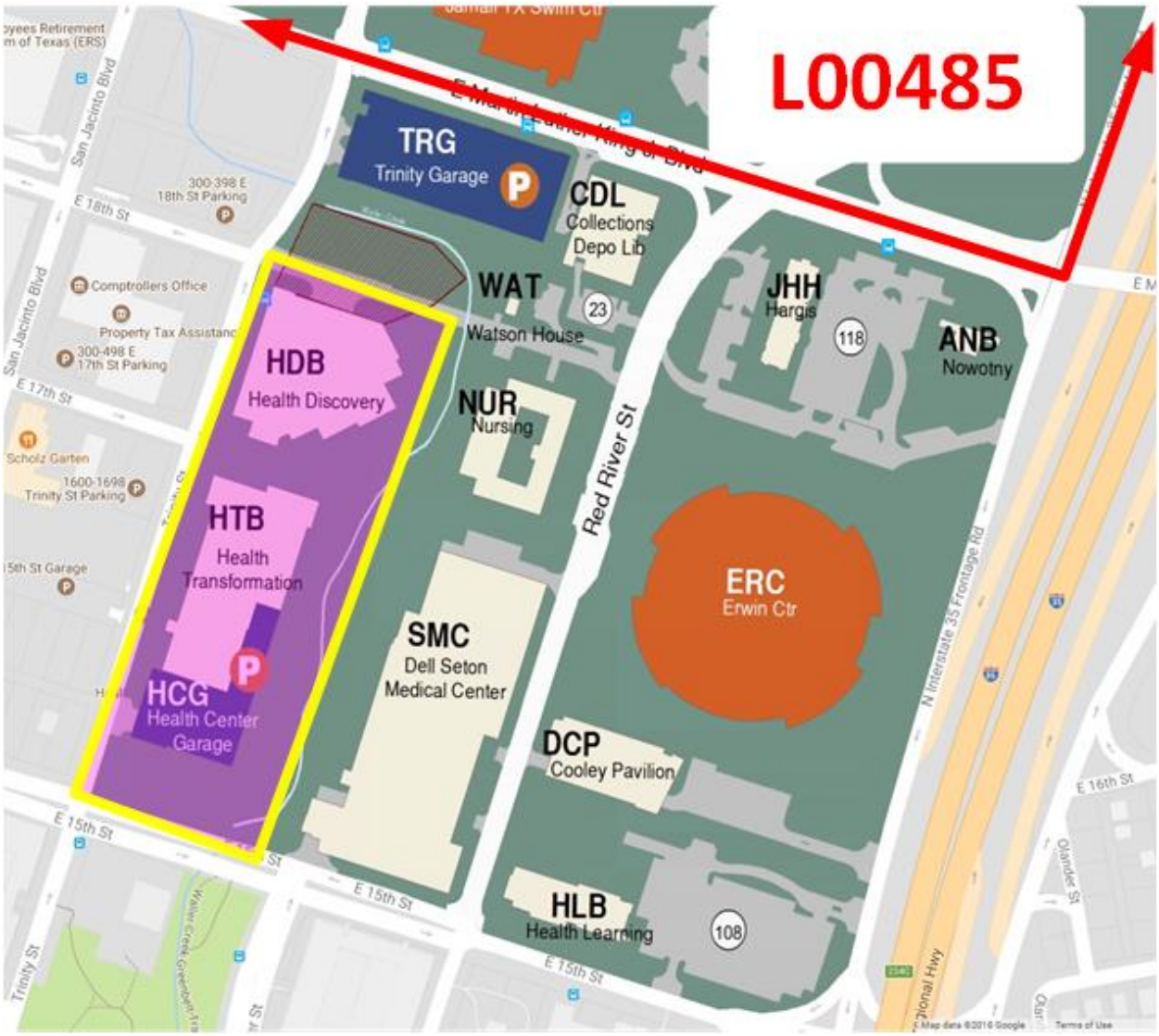
Any DMS employee, student, or contractor whose job duties do not include handling radioactive materials, but who may frequent areas where radioactive materials are stored, handled, or disposed will be given Radiation Awareness training. This training will be documented.

8. FACILITIES AND EQUIPMENT

8.1 THE UT DELL MEDICAL SCHOOL CAMPUS

The University of Texas at Austin Dell Medical School (DMS) campus is located adjacent to, and immediately south of the UT-Austin Main Campus. For the purposes of the requested broad scope RAM license, the DMS campus shall be bounded by the following streets, structures, and features:

- E 15th St to the south
- Trinity St to the west
- Waller Creek to the north and east



NOTE: This license does NOT include the possession and use of RAM at the Dell Seton Medical Center. Although the University of Texas owns the land on which the building sits, Seton maintains a separate license for RAM possession and use within the building.

The DMS campus is comprised of the following buildings in which RAM may be used and stored:

- The Health Transformation Building (HTB)
- The Health Discovery Building (HDB)

8.2 FACILITY REQUIREMENTS

All facilities at DMS where RAM use is authorized will be evaluated against a standard set of requirements. These requirements include, but are not limited to the following:

- All RAM work surfaces shall be non-porous and capable of being decontaminated.
- Any RAM stored in a laboratory or other work space must be capable of being secured against unauthorized removal.
- A sink and/or eyewash station must be readily available in the area.
- The use of certain isotopes and quantities of radioactive material may require additional shielding to maintain exposures to non-radiation workers to no greater than 100 mrem in a year and 2 mrem in an hour.

8.3 MEDICAL EQUIPMENT

DMS possesses one clinical PET/CT scanner (a GE Discovery MI), which will be housed on the first floor of the HDB located at 1601 Trinity St, Austin, TX 78712. The map included in Attachment A shows the location of the PET/CT scanner, along with the proposed work flow for clinical PET doses entering the building. The PET hot lab is located in HDB 1.524, also shown on the map. Alternate delivery routes may also be used as needed.

PET camera calibration shall be performed according to the manufacturer's recommendations.

8.4 DOSE CALIBRATORS

A dose calibrator will be maintained at all times for the measurement of radiopharmaceutical doses intended for human use. The following tests shall be performed on the dose calibrator at the frequency intervals indicated:

1. Constancy at least once each day prior to assay of patient doses
2. Linearity at installation, repair, and relocation, and at least quarterly thereafter.
3. Geometry dependence at installation.
4. Accuracy at installation and at least annually thereafter.

All calibration records shall include the date of calibration, the model and serial number of the dose calibrator and calibration source, and the individual who performed the calibration. Records of the calibration results shall be maintained and kept for review.

8.5 RADIATION SURVEY INSTRUMENTS

Each AU is required to purchase and use a survey instrument(s) specific for the laboratory's needs, and must use a detector appropriate for the type of radiation to be detected. Radiation Safety will assist AUs in identifying appropriate types of detection equipment and may recommend equipment manufacturers.

A. Instrument Type For Use

The instrument used to survey for radiation shall be the correct type to detect the radiation in question. For most purposes, a GM pancake detector is preferred. Phosphorous-32, Sulfur-35, and Carbon-14 may be detected with a pancake or a thin end-window probe. Carbon-14 emits a relatively weak beta; therefore, a survey should proceed carefully and slowly to allow detector response. Tritium must be detected using a liquid scintillation counter or special detector approved by Radiation Safety. Isotopes which emit gamma radiation or a combination of beta and gamma, such as Fluorine-18 and Cesium-137, may also be detected with a GM pancake probe. Any isotope or combination of isotopes which emits alpha radiation or neutron radiation must be detected with a detector approved by Radiation Safety. If any question arises regarding the type of detector to be used to perform a survey, contact Radiation Safety for advice and assistance.

Below is the current list of instruments (list will be kept current by RSO):

Type	# of Units
Ludlum 14C with 44-9 pancake probe	2
Liquid scintillation counter	1

B. Instrument Calibration Procedures

Radiation survey instruments at DMS shall be calibrated to read within ±20% of the actual

reading at least annually, and after each instrument repair. Calibrations shall be made by UT Austin EHS personnel designated by the RSO or RSC, or by individuals who are authorized by the Texas Department of State Health Services. Meter calibration may also be performed by a third party licensed to provide calibration services.

Calibration shall be made using an appropriate radiation source depending on the type of radiation the instrument is designed to detect. At least two radiation exposure values shall be checked for each meter scale on instruments used for measuring radiation fields. Instruments utilized for surface contamination measurements are typically calibrated with a pulser and checked with appropriate calibrated sources to determine efficiency. Both the pulser and calibration sources are traceable to the National Institute of Standards and Technology (NIST).

Records shall be established and maintained for each calibration at the main office of Radiation Safety for a minimum of three years. Each instrument shall be marked with a calibration sticker showing the date of calibration, the date the next calibration is due, and the name of the person performing the calibration. Further specific instructions for calibrating instruments are found in Appendix I of this document.

Appendix II

Procedures for Calibration of Radiation Survey Meters

1. The RSO will supervise the instrument calibration program. The RSO and Committee may delegate meter calibration activities to approved employees. Approved individuals will be trained on proper meter calibration procedures.

2. A list of instruments to be calibrated is maintained.

3. Calibration shall be performed with a radiation source and/or pulser traceable to the National Institute of Standards and Technology.

4. UT-Austin (L00485) possesses a Model 28-6A calibrator containing 496 mCi of Cs-137 (as of Feb 2018) that DMS will use to calibrate its instruments. The strength of the source shall be sufficient to calibrate instruments on all ranges, at least up to 1 R/hr on the higher ranges. Attenuators may be used to reduce the exposure rate to acceptable rates for calibration.

5. Each scale of the instrument will be calibrated at least at two points located approximately 20% and 80% of full scale. For logarithmic rate-changing instruments, a calibration will be made near the mid-range of each decade and two points will be calibrated on at least one of the decades.

6. The true exposure rate at any distance from the source shall be calculated based on known characteristics of the source and the inverse square law on the date of the calibration of the source.

7. The exposure rate (or count rate) measured by the instrument under calibration shall not differ from the true rate by more than 20% at any point of measurement.

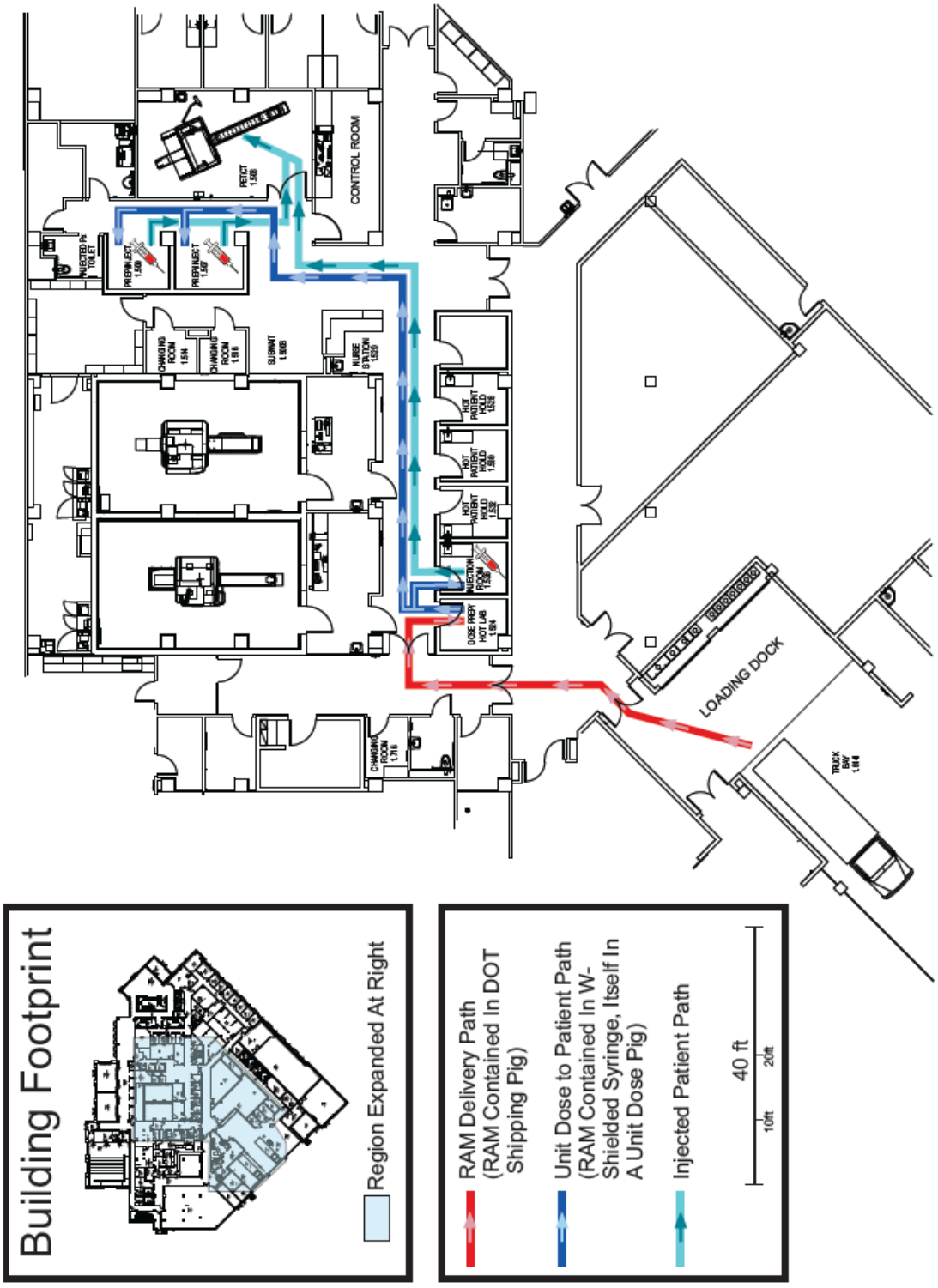
8. Instrument calibration records shall be maintained by the Radiation Safety Office for a minimum of three years. The records shall include at a minimum the make/model/serial number of the instrument, the detector type, the date of calibration, the individual performing the calibration, and measurements taken on each scale.

9. The date of calibration of the instrument, the initials or other designator of the calibrating individual, and the date the next calibration is due shall be affixed to the instrument on completion.

10. If repairs are made to an instrument, the instrument shall be recalibrated, records shall be generated, and the instrument may or may not be taken out of its regular calibration cycle. At no time shall the calibration of an instrument exceed annual interval.

Attachment A

RAM Flow Diagram in the Health Discovery Building (HDB)



9. RADIATION PROTECTION PROGRAM

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9. RADIATION PROTECTION PROGRAM

9.1 SCOPE OF OPERATION

The University of Texas at Austin Dell Medical School (DMS) intends to provide clinical diagnostic PET imaging for uptake/dilution/excretion studies, imaging/localization studies for both medical research and clinical diagnosis as well as radiopharmaceutical therapy for humans. In addition, DMS will facilitate basic laboratory research related to health and wellness.

The safe and compliant use of radioactive materials at DMS shall be overseen by the DMS Radiation Safety Committee, DMS Radiation Safety Officer, and the staff of the Radiation Safety Office (part of Environmental Health & Safety).

9.2 AUTHORIZATION TO USE RADIOACTIVE MATERIALS

Prior to any purchase or use of radioactive materials, a prospective user shall prepare and submit the Application to Use Radioactive Materials to the Radiation Safety Officer (RSO). A copy of the application form is shown in Appendix III and may be revised at the discretion of the RSO. The RSO shall review and make an evaluation of the prospective user's plans for radiation safety.

When the RSO completes the review, the application shall be submitted to the Radiation Safety Committee (the Committee) for review and approval. If any issue is raised by a Committee member, the issue shall be resolved prior to issuance of the Authorization.

New authorizations shall be approved by a majority of the Committee in attendance at a Committee meeting in which a quorum has been established. The Committee approval shall be maintained by the RSO and shall be noted in the minutes of Committee meetings.

If approval of an application cannot wait until a meeting of the Committee, the RSO may also request approval by a majority of the Committee members via email. Committee members shall then submit their written approvals to the RSO via email. Upon completion of the required radiation safety training by the applicant and the Committee's approval, the Authorization will be finalized and signed. A copy of the Authorization certificate with all signatures will be provided to the Authorized User.

NOTE: Visiting researchers may only use radioactive materials under the authorization and control of a currently approved Authorized User. No provision exists for granting a temporary authorization.

A. Amendments to Radioactive Materials Authorizations

An Authorized User may submit to the RSO a written request to amend his/her authorization. The RSO may review and approve certain requests (shown below) without Committee approval. The Committee shall be notified of all changes, and amended Authorizations shall be finalized and signed by the applicant and the RSO.

Requested Action	Approvals Required
• Add lab space in the same building or remove lab space • Permit lab close out • Remove radioisotopes from Authorization • Minor increase (<50%) or decrease in possession limit of already authorized isotopes	RSO only
• New radioisotopes • New experimental protocols • Major increase (>50%) in possession limit of already authorized isotope	RSO and Committee

9.3 ACCOUNTABILITY OF RADIOACTIVE MATERIALS

A. Purchasing Radioactive Materials

It is the responsibility of each DMS employee to comply with the following requirements regarding the purchase of radioactive materials at the University. In no event is any person authorized to purchase, receive, or transfer radioactive materials without approval of the RSO or his/her designee. No person shall circumvent the approval process described below.

After obtaining an Authorization to Use Radioactive Materials, the following procedures shall be observed in purchasing radioactive materials:

1. Nuclear medicine technologists may place orders through a licensed nuclear pharmacy. A contract shall be signed with the nuclear pharmacy and a purchase order shall be created. A copy of the pharmacy's RAM license will be kept on site.
2. A departmental requisition shall be prepared through the University's secure purchasing system and indicate the radioactive materials to be purchased, the activity of each radioactive material required, and the unique authorization number of the Authorized User purchasing the radioactive material. The purchasing system queries the radioactive material inventory tracking system for the Authorized User's authorized radioactive materials, activity limits, and current inventory. The system automatically limits the purchase of each radioactive material such that the summation of the proposed purchase and the current inventory does not exceed the authorization limit for the Authorized User.

3. The requisition is electronically forwarded to the Purchasing Office for processing and creation of a purchase order.

4. The Purchasing Office electronically forwards the purchase order to Radiation Safety for approval electronically.

With the exception of nuclear medicine technologists ordering doses from licensed nuclear pharmacies, repetitive or standing purchase orders with vendors to automatically replenish radioactive material inventories will not be authorized.

B. Receiving Radioactive Materials

Incoming shipments of radioactive material shall be delivered to the designated radioactive material receiving location on the DMS campus. Incoming doses for human use shall be delivered directly to the Hot Lab (HDB 1.524).

For non-human RAM, DMS personnel will retrieve each package and perform a survey as required by 25 TAC §289.202(ee), and then deliver the package to the Authorized User's laboratory. Packing materials will be surveyed for contamination prior to disposal in the general waste. All labels and markings shall be removed or defaced prior to disposal of the packaging in the trash.

A Radioactive Material Disposition Form or equivalent will be completed and delivered with the radioactive material to the User. Disposition of the radioactive materials received in the shipment shall be recorded on the form (or equivalent document) for each shipment.

1. Receipt and Inspection Procedure

When packages are received and readied for inspection, the person conducting the inspection shall wear appropriate protective equipment (such as gloves) and:

- Monitor the external surfaces of any package labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations Title 49 CFR §172.403 and 172.436-440, for radioactive contamination,
- Monitor the external surfaces of any package labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations 49 CFR §172.403 and 172.436-440, for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in §289.201(b) of this title and specified in §289.257(ff) of this title; and
- Survey all RAM packages for contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

Personnel shall perform the monitoring specified above as soon as practicable after receipt of the package, but not later than three hours after the package is received at the DMS facility if it is received during normal working hours. If a package is received after working hours, the package shall be surveyed no later than three hours from the beginning of the next working day. If there is evidence of degradation of package integrity, such as a package that is crushed, wet, or damaged, the package shall be surveyed immediately. Precautions shall be taken to prevent the spread of radioactive contamination.

Receiving personnel shall immediately notify the final delivery carrier when removable radioactive surface contamination or external radiation levels exceed the limits specified below. In addition, the RSO or his/her designee shall notify the Texas Department of State Health Services.

2. Limits for removable radioactive surface contamination

The level of removable radioactive contamination may be determined by wiping an area of 300 square centimeters (cm^2) of the surface concerned with an absorbent material, using moderate pressure, and measuring the activity on the wiping material. Sufficient measurements must be taken in the most appropriate locations to yield a representative assessment of the removable contamination levels. The amount of radioactivity measured on any single wiping material, when averaged over the surface wiped, must not exceed the limits given in Table 1 below.

Table 1: Radioactive Material Package Contamination Limits

Contaminant	Maximum permitted on swipe	
	$\mu Ci/cm^2$	dpm/cm^2
Beta-gamma emitting radionuclides, including positron emitters; all radionuclides with half-lives <10 days	10^{-4}	220
All other alpha emitters	10^{-5}	22

3. Limits for external radiation levels

External radiation levels around the package may not exceed 200 mrem/hr at any point on the external surface of the package. The transport index shall not exceed 10.

C. Shipping of Radioactive Materials

Shipments of radioactive materials from or by DMS personnel shall comply with the requirements of the appropriate regulatory agencies. A Radioactive Material Shipment Form or equivalent shall be completed for each shipment. All shipments shall be approved by Radiation Safety and/or other University personnel possessing the appropriate US Department of Transportation training.

9.4 RADIOPHARMACEUTICAL ADMINISTRATION

Clinical Diagnostic and Research Procedures for Humans

- Prior to the administration of any radiopharmaceutical to a patient, an Authorized Physician User shall authorize the procedure, dose or dose range, radionuclide, and route of administration.
- Doses will be received from a Nuclear Pharmacy as a pre-calibrated unit dose in an individual shielded syringe carrier. A dose calibrator will be available in the hot lab for confirming dose activities prior to administration.
- Each dose received shall indicate the date, the name of the Authorized Physician User, the radiopharmaceutical and activity, the dose volume, the time of calibration, date of administration, and route of administration. A record of each dose received, patient name, type of study, and procedure date shall be recorded by the technologist.
- Unless otherwise directed by the authorized user, do not use a dose that differs from the prescribed dose by 20% or more.
- Spent radiopharmaceutical syringes may either be stored for decay in a shielded syringe carrier, or returned to the nuclear pharmacy that sent them.
- Administration of radiopharmaceuticals for PET imaging exams shall be performed by a technologist.
- The technologist shall not administer radioactive material to a patient if there is any uncertainty regarding the identity of the patient or the procedure that was ordered.
- If there is any question regarding the appropriateness of the procedure, the clinical condition or pregnancy status of a patient, the type of dose ordered, or the need for modifications of standard protocol for a given patient, the DMS Imaging Medical Director shall be contacted immediately.

Clinical Therapeutic Procedures for Humans

- An Authorized User (AU) specially authorized by the RSC for uses under 25 §TAC 289.256 (nn), (oo), (pp), or (qq), as applicable to the procedure will be responsible for providing a signed and dated **Written Directive** to nuclear medicine personnel prior to ordering a therapeutic radiopharmaceutical dose. The Written Directive will

include the name, birth date, and other information specific to the patient. The written directive will also include the radiopharmaceutical, the dosage and the route of administration. Unless otherwise directed by the authorized user, do not use a dose that differs from the prescribed dose by 20% or more.

- If revisions to the written directive are needed there is a clearly labeled revisions section on the written directive where the AU will document the revisions.
- The Radiation Safety Office must be notified prior to ordering a therapeutic dose and advised when the dose will be administered to the patient.
- If the patient is a woman of child bearing age and has not had a tubal ligation or hysterectomy, a pregnancy test must be ordered. If the woman is pregnant, therapeutic administration cannot be performed.
- The AU must be physically present during the therapeutic administration. Prior to administration, at least two forms of patient identification must be verified. The AU will verify that the administration is in accordance with the treatment plan, and will check both manual and computer generator dose calculations, as applicable, per 25 §289.256 (t) (4). The AU will counsel the patient verbally and provide discharge instructions in written form to all patients receiving a therapeutic dose requiring a written directive. Administration cannot proceed if the patient is unable to abide by the discharge instructions.
- The Radiation Safety staff must assure that records of all therapeutic administrations are complete. Copies of the Written Directive, dosing information, and the completed and signed patient discharge instructions will be maintained in file for at least 3 years.
- The model procedure for release criteria in Appendix P of the agency's Application Guide 3.1 will be followed to determine patient release. If the patient cannot be released in accordance with 25 TAC §289.256 (cc), the patient will not be treated.
- Performance of a survey with a radiation detection instrument will be performed at the end of each day of use in all areas where RAM requiring a written directive was prepared for use and administered, per 25 TAC §289.256 (t)(4).

9.5 GENERAL HANDLING GUIDELINES FOR RADIOACTIVE MATERIAL

A. Authorized User Responsibilities

Each Authorized User (AU) is responsible for the safe use of his/her radioactive materials. The AU shall do all of the following:

1) Establish a local radiation safety program,

2) Carry out the required administrative and safety procedures,

3) Select those laboratory practices which are applicable to the work,

4) Ensure proper training of personnel,

5) Supervise all operations carried out under the Authorization,

6) Maintain a record which documents the receipt, use, transfer, storage, and disposal of radioactive materials, and the radiation surveys conducted as part of the local program,

7) Ensure the laboratory is properly posted as required by 25 TAC §289, and

8) Immediately notify the Radiation Safety Officer if any unexpected difficulties arise which might affect the safety of personnel, procedural violations, health hazards, or danger to the community.

A current copy of the DMS Radioactive Materials License shall be made available to the Authorized User upon request. All personnel shall be trained and acquainted with proper radiation safety practices and supervised to see that these practices are observed. Every effort is to be made to conduct experiments and operations in ways that will result in radiation exposures to workers and members of the public as low as reasonably achievable (**ALARA**).

B. Guidelines for Authorized Users

Radioactive materials may be present in two physical configurations: Open Form and Sealed Sources. Open Form radioactive materials may be in liquid or solid form. Radioactive gases may be used only with express consent of the DMS RSO or Radiation Safety Committee on a case-by-case basis. In order to maintain compliance with the 25 TAC §289, the DMS Radioactive Materials License, and to ensure protection for all personnel, the following procedures shall be incorporated into each local radiation safety program by the Authorized User:

1) Signs shall be posted where radioactive materials are present per 25 TAC §289.

2) Radioactive materials shall be secure at all times. Specifically, all radioactive materials shall be stored in a locked cabinet, refrigerator, freezer, or room. When not otherwise secured, it shall be accompanied by trained personnel at all times.

3) If required by the Authorization, dosimeters shall be worn by personnel pursuant to Section 9.7 of this document.

4) The RSO shall be notified before entering a high radiation area. Special procedures (such as wearing direct reading dosimeters) may be required at the discretion of the RSO.

5) Working areas shall be surveyed as necessary after the use of Open Form radioactive material to determine the presence of contamination.

6) Radiation survey instruments should be checked before use each day to ensure proper operating conditions.

7) Minor spills as defined in 9.10 shall be cleaned up immediately. If a major spill occurs, do not attempt decontamination. Isolate the area and notify the Radiation Safety Office immediately.

8) Protective clothing and hands shall be monitored upon completion of laboratory work involving the handling of unsealed radioactive materials.

9) Smoking, drinking, or eating shall not be allowed in any area where Open Form radioactive materials are used, or where the area is posted prohibiting such activity.

10) Employees shall wash their hands thoroughly before leaving an area where unsealed radioactive materials are being used.

11) Mouth pipetting of liquid radioactive materials is strictly forbidden.

12) Calibrated radiation detection instruments shall be used in all radioactive material use areas when applicable. The instrument shall be capable of detecting the type of radiation in question.

13) Gloves and lab coats should be worn by individuals when working with Open Form radioactive materials.

14) Open-form radioactive materials shall not be handled with bare hands, nor shall sealed sources be opened.

15) Control of access into restricted areas is the responsibility of the individual supervising the laboratory.

16) Radioactive materials producing a radiation dose rate in excess of 2 mrem/hr at a distance of 30 cm from the source shall be stored within shielding (typically Plexiglas for high energy beta emitters and lead for gamma emitters) sufficient to reduce the dose rate to less than 2 mrem/hr at a distance of 30 cm. Radiation dose rates shall not exist in an unrestricted area that could result in a personnel exposure which exceeds 100 mrem per year or 2 mrem in one hour. Routine use of shielding is not required for H-3, C-14, S-35, I-125, and other low energy emitters as determined by the RSO.

17) Open form radioactive materials should be stored in non-breakable, leak-proof containers.

18) Work involving liquids containing radioactive materials shall be performed on trays lined with absorbent paper or on surfaces protected with plastic-backed absorbent paper.

19) Any animals administered radioactive materials, or the products of such animals, shall not be used for human consumption.

20) Radioactive materials shall not be used in field applications where activity is released without prior approval of the Radiation Safety Committee.

21) Chemical hoods in which radioactive materials are used shall have a minimum air face velocity of 100 linear feet per minute.

22) Glassware and equipment used with radioactive material shall be properly labeled.

23) Trial runs should be made when practicable to determine proper procedures and to evaluate necessary radiation protection measures.

24) Only designated sinks shall be used for washing contaminated glassware or for disposing radioactive materials. Quantities of radioactive materials disposed in the

designated sinks to the sanitary sewer may not exceed the limits specified in 25 TAC §289.202(ggg), for the entire University.

25) Only designated storage boxes, freezers and refrigerators shall be used for the storage of radioactive materials. **DO NOT** put food in any freezer or refrigerator used for this purpose.

26) Radioactive material storage containers shall be labeled in accordance with the 25 TAC §289, with the following information:

a. Radioactive material
b. Activity and date
c. Authorized user
d. Caution-Radioactive Materials (with radiation symbol)

27) If a suspected or known overexposure occurs to any individual, the RSO must be notified immediately.

28) Proposed changes in the current authorization shall be submitted in writing to the Committee (via the RSO) for approval, and shall be submitted and approved prior to changing the authorized use of radioactive material.

29) Approval of the RSO shall be obtained prior to the transfer of any radioactive material to any other User, institution, or licensee.

30) Copies of the "*NOTICE TO EMPLOYEES AND STUDENTS*" signs shall be posted in a sufficient number of places in every establishment where personnel are engaged in activities using radioactive materials so that they can be seen by personnel entering the area. The information contained in the notice is equivalent to or exceeds that specified in the "*NOTICE TO EMPLOYEES*" of 25 TAC §289.203.

31) Each individual using radioactive materials shall be familiar with the appropriate regulations of this document and of 25 TAC §289. Copies of these regulations are available upon request from the Radiation Safety Officer and via the Internet at http://www.dshs.state.tx.us/radiation/rules.shtm.

32) Individuals involved in or near operations which utilize tritium in any chemical or physical form, other than metallic foil, shall adhere to the bioassay program specified in Section 9.8 of this document.

33) Additions and alterations to the License Commitments may be made by the Radiation Safety Committee when in the estimation of the Committee such additions and alterations are necessary for the protection of the University and its employees, students, and visitors. Approval of substantive changes to the License

Commitments shall be requested of the Texas Department of State Health Services Radiation Control.

34) For activities involving radioactive materials and animals, Authorized Users shall comply with the procedures titled "Procedures for Research Involving Animals" found in Appendix IV of this document.

35) Use of syringe shields for routine preparation of patient doses and administration to patients, except in circumstances when their use may compromise safe patient administration.

36) Determine and record the activity of each dose of unsealed radioactive material for medical use prior to administration.

37) Do not use any doses that are not within the prescribed dosage range or differ from the prescribed dose by more than 20% unless specifically approved, in writing, by an Authorized User.

9.6 LABORATORY SURVEYS AND INSPECTIONS

A. Surveys by Laboratory Personnel

Personnel in each radioactive materials laboratory shall perform regular surveys. These in-lab surveys are separate and distinct from the surveys and inspections performed by Radiation Safety.

Working areas shall be surveyed as necessary after the use of Open Form radioactive material to determine the presence of contamination. Contamination levels should be determined using an instrument capable of detecting the radiation in question. The counting efficiency of this instrument should be known in order to convert the counts per minute (cpm) to disintegrations per minute (dpm). Direct surveys and/or wipe testing will be performed as appropriate. If surveys indicate contamination levels of 1000 dpm beta/gamma or 100 dpm alpha activity per 100 cm^2 of surface area, the area shall be cleaned until the contamination is reduced significantly below these levels.

Frequency of the surveys shall be determined by level of isotope usage. If the laboratory receives a shipment of isotopes in open form, a survey shall be performed at a minimum:

A. On termination of activities the day radioactive materials are opened and used, or
B. As specified in the conditions of the Authorization (typically on a weekly basis).

Records of all surveys shall be recorded in a Laboratory Logbook or equivalent. The Logbook shall be available for review by Radiation Safety at any time. Information recorded as part of the Survey shall be at a minimum:

- The date of the survey.
- The person performing the survey.
- The make, model, and serial number of the survey instrument used.
- The latest calibration date of the survey instrument.
- The background reading in the laboratory
- The specific location(s) of the survey.
- The specific location of elevated instrument readings and wipe tests.
- Corrective action taken to remove radioactive contamination if found.

Action levels requiring corrective actions are:

Contamination Surveys	Restricted areas	= 1,000 dpm
	Unrestricted areas	= 500 dpm
Radiation Surveys	All areas	= 0.5 net mr/hr

B. Inspections and Surveys by Radiation Safety Staff

The RSO shall cause a risk-based laboratory inspection program to be performed by qualified personnel who report to the RSO. Surveys shall be sufficient to detect radiation fields or contamination to ensure that hazards do not exist to personnel apart from expected exposure to radiation workers. The frequency of the surveys shall be determined by the RSO based on the isotope and quantity in use, the history of the laboratory, and the general level of radiation hazard presented by the laboratory's working environment.

Radiation Safety staff shall periodically inspect isotope usage, storage and disposal records that are maintained in the user's laboratory to determine if the user is in compliance with DMS procedures and applicable regulations. Laboratories and facilities where radioactive materials are used or stored shall be surveyed periodically in order to detect any changes in radiation levels and to prevent the spread of radioactive contamination. If the inspections detect an unsafe condition, the RSO shall cause the unsafe condition to be corrected by cleanup, shielding, removal of personnel or equipment, or any other available means

Records of these inspections shall be maintained by Radiation Safety.

1. Frequency of Routine Inspections

Laboratory inspection intervals will be either quarterly or annually based on the inspection classification (high-frequency or low-frequency) determined by the criteria outlined below.

<u>Quantities of Radioactive Materials (Open Form) Used</u>
Laboratories that use more than a predetermined amount of any particular radioactive material in a certain time period (typically 10 mCi in a calendar quarter) will be classified as high-frequency. All other laboratories will be classified as low-frequency. Radioactive

materials use is determined by amount of radioactive material received and/or amount of radioactive waste generated in the specified time period.

Additional Factors

A laboratory classified as low-frequency based on the criteria above may be reclassified as high-frequency due to other factors such as failure to mitigate compliance issues identified during inspections, repeat offenses, etc. A laboratory classified as high-frequency based on the criteria above may be reclassified as low-frequency with a consistent history of good compliance with radioactive materials regulations.

Inspections shall be performed at a minimum according to the laboratory's frequency classification. The listing of laboratory frequency classifications shall be maintained by the Radiation Safety Office. High-frequency laboratories shall be inspected quarterly. Low-frequency laboratories shall be inspected annually.

2. Non-routine Inspections

A non-routine inspection may be performed after any of the following events occur:

- Cleanup of a spill.
- Laboratory decommissioning.
- On request.
- Detection of an unsafe condition.

C. Violations of Regulations

In the event of an alleged violation of the requirements set forth in this document, or those prescribed in the 25 TAC §289, the person noting the alleged violation shall immediately contact the RSO or a member of the Radiation Safety Committee. The Committee may request the Authorized User to meet and discuss the alleged violation with the Committee. Subsequent action taken by the Committee will depend on the seriousness of the violation and the Authorized User's past record. If the alleged violation is found to be minor, the RSO shall clarify the policies for using radioactive materials and shall explain the hazards associated with the violation. If the alleged violation is serious, or the alleged violator shows a flagrant disregard for proper operating procedures, the Committee may revoke the Authorized User's privilege of using radioactive materials.

9.7 DOSIMETRY

A centralized dosimetry service is available to authorized users of radioactive materials at DMS. The University maintains a service contract with a NVLAP-accredited dosimetry provider. Requests for additions and deletions of dosimeters shall be made through the Radiation Safety office. All reports on dosimetry provided by the service will be furnished to the Radiation Safety Office.

To initiate the dosimetry service, staff will complete and submit the Dosimetry Service Request form. Individuals issued dosimeters will be instructed to wear them when handling radioactive materials. Whole-body dosimeters will be worn at the chest or waist level as appropriate. If required by the AU's authorization, extremity monitors shall be required for personnel who handle unsealed radioactive materials. These monitors shall be worn on the dominant hand of the worker and the dosimeter turned "palm down". When not worn, dosimeters shall be stored in a low-background area. The control dosimeters will also be stored in a low-background area, and the proper controls must be returned with each set of dosimeters.

Dosimeters are to be worn by University personnel who may be working in areas where the following conditions exist:

- Any person likely to receive 10% of any annual regulatory limit.
- Any person working within a high radiation area.
- Other situations as determined by the RSO.

Dosimetry reports will be reviewed regularly by Radiation Safety staff, and the reports will be maintained by the Radiation Safety Office. Copies will be provided to Authorized Users. Dosimetry records shall be maintained for the life of the Radioactive Materials License.

Annual dosimetry reports (NRC Form 5 or equivalent) will be reviewed and furnished to any individual who exceeds 100 mrem total effective dose equivalent, or 100 mrem to any individual organ or tissue during the calendar year.

9.8 BIOASSAY PROGRAM FOR RADIOIODINE

Since iodinated solutions and compounds undergo decomposition which may result in the volatilization of radioiodine, individuals working with these materials have a potential for uptake of radioactive iodine. This bioassay program will enable the Radiation Safety staff to determine an individual's radioiodine thyroid burden, so that a thyroid organ dose can be determined for those who have had an uptake. In addition, the program will monitor the effectiveness of radioiodine handling procedures.

TABLE 2: ACTIVITY LEVELS ABOVE WHICH BIOASSAY FOR RADIOIODINE IS REQUIRED

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

PROGRAM REQUIREMENTS

1. PROGRAM PARTICIPATION

   a. Individuals who handle unsealed quantities of ^{125}I and ^{131}I in excess of the quantities listed in Table 2, and those individuals who work close enough to such handling that uptake is possible (within a few meters) should participate in this bioassay program. The quantities in Table 2 apply to that amount handled either in a single usage or the total amount handled over a period of three consecutive months.

   b. It shall be the responsibility of individual Authorized Users to notify the Radiation Safety Office of the names of those individuals working under his/her Authorization who require bioassay for radioiodine.

2. FREQUENCY OF BIOASSAY

   a. Prior to beginning work with ^{125}I or ^{131}I in quantities which require participation in the bioassay program, individuals shall be given a "baseline" or "preoperational" bioassay.

   b. A "routine" bioassay shall be performed within 72 hours (but not less than six hours) on individuals following commencement of work with quantities of radioiodine necessitating participation in this program. Bioassays shall continue on a biweekly schedule as long as conditions exist which necessitate an individual's participation in the program. When work with radioiodine is less frequent than every two weeks, a bioassay shall be performed within 10 days of the end of radioiodine operations. Individuals who work under

conditions which present a high potential for uptake may be required to submit to bioassay more frequently than biweekly.

c. After three months of routine biweekly bioassays the frequency of bioassay may be reduced to quarterly, at the discretion of the Radiation Safety Officer.

d. An "emergency" bioassay shall be performed on any individual as soon as possible following an incident in which that individual may have received an uptake in excess of 2.5 µCi of I-125 and 2.0 µCi of I-131.

e. Individuals who are required to participate in this program shall undergo a "postoperational" bioassay within two weeks (but not less than six hours) after discontinuing operations with radioiodine. This bioassay shall be performed prior to the end an individual's employment with DMS.

3. ACTION LEVELS AND CORRESPONDING ACTIONS:

a. When the thyroid burden at the time of measurement exceeds 0.75 µCi of I-125 and 0.63 µCi of I-131 or a corresponding appropriate amount of a mixture of these two isotopes, the following actions shall be taken:

(1) An investigation of isotope handling procedures shall be conducted. If this investigation indicates that a continuation of current operations would cause further uptake of radioiodine in excess of the above limits, operations using radioiodine in that lab shall be discontinued until corrective actions can be implemented that will lower the potential for uptake.

(2) Restrict the affected individual from further work with radioiodine until the thyroid burden is less than the above limits.

(3) Perform "diagnostic" bioassays on the affected individual at biweekly intervals until the thyroid burden is less that the above limits.

(4) Calculate the committed thyroid dose base on biological half-life determined from follow-up bioassays.

(5) Make exposure record entries and notify state or federal agencies as appropriate.

b. In addition to the actions in 3.a, when the thyroid burden exceeds 2.5 µCi of I-125 or 2.0 µCi of I-131 or a corresponding appropriate amount of a mixture of these two isotopes, the following actions shall be taken.

(1) Refer the case to appropriate medical consultation.

(2) Perform diagnostic bioassays at weekly intervals until the thyroid burden is less than the values stated in 3.a.

(3) If the affected individual and others working in the same area were on a quarterly bioassay schedule at the time the limits of 3.a were exceeded, reinstate biweekly bioassay schedule until it has been demonstrated that further exposures will not cause the limits of 3.a to be exceeded.

4. BIOASSAY PROCEDURES:

A. Prior to commencement of operations using quantities of ^{125}I or ^{131}I in excess of those listed in Table 2, Authorized Users shall notify the Radiation Safety Office of such and provide the names of those individuals who meet the criteria of 9.8.1 of this Section. Authorized Users shall not permit any individual who meets the criteria of 9.8.1 to work with or near radioiodines until they have undergone a baseline bioassay.

B. The Radiation Safety Office shall contact these individuals and schedule baseline bioassays at a time and place convenient to both parties.

C. Individuals participating in this program shall notify the Radiation Safety Office following their initial contact with radioiodine to schedule the first routine bioassay (to be performed within 6-72 hours). Upon completion of this first bioassay, a bioassay schedule shall be established for the individual in accordance with 9.8.2.b and 9.8.2.c of this Section.

D. Any individual involved in a radiological incident who may have exceeded the limits of 9.8.3.b of this Section shall notify the Radiation Safety Office immediately.

E. Any individual who is participating in this program shall notify the Radiation Safety Office prior to terminating employment with or otherwise leaving the University.

F. Bioassay shall be performed by individuals designated by the RSO and shall be conducted in accordance with the bioassay test instructions as modified to the specific test area.

G. A background shall be taken of the room environment; a reading shall be taken of the individual's thigh, and a reading of the individual's thyroid for each bioassay.

9.9 SEALED SOURCES

A. Inventory Verification

An inventory of sealed sources shall be conducted at least semiannually by the Authorized User or Radiation Safety Office. This inventory verification will include the radionuclide and activity in each sealed source, the location of the sealed source, the name of the individual conducting the inventory, and the date of the inventory. Records of the Sealed Source inventory shall be maintained for a minimum of five years.

B. Leak Tests

The RSO is responsible for the sealed radiation source leak testing program at DMS. Leak tests shall be made by UT Austin EHS personnel designated by the RSO or Committee, or by individuals who are authorized by the Texas Department of State Health Services, another Agreement State, or the U.S. Nuclear Regulatory Commission. Approved University personnel will be trained on proper leak test procedures. When leak tests are due, arrangements shall be made with the Authorized User for the test to be performed.

The following procedures shall be followed in leak testing sealed sources:

1) Wipe the surface of the source with an appropriate piece of paper or fabric. Wetting the paper or fabric may be considered as moisture allows contamination to stick better.

2) If the source is located inside an apparatus and cannot be removed from the unit, wipe around the irradiation port and source placement tube or other accessible part of the unit where contamination might collect.

3) Wear a dosimeter during leak testing operation if appropriate or required. Use long-handled tongs or suitable method to limit exposure to hands and body.

4) The wipe test shall be evaluated by counting in an appropriately calibrated laboratory instrument capable of detecting 0.005 μCi of removable activity. The results shall be recorded and maintained as appropriate.

5) If analysis reveals leakage greater than 0.005 μCi, take the source out of service. Notify the RSO or his/her designee immediately.

9.10 EMERGENCY PROCEDURES

A. General

In the event of an emergency involving radioactive materials, the following materials can be obtained by contacting the Radiation Safety Office: coveralls, disposable gloves and shoe covers, respirators, decontamination wash materials, high- and low-range survey instruments, radiation signs, tags, labels, aprons, handling tongs, plastic bags, high volume air samplers, filters, and vacuum cleaning equipment.

A radiation incident shall be defined as an accident or unusual occurrence that causes unplanned exposure to personnel, or results in a spill of material. In the event of a radiation incident, the procedures outlined in subsequent parts of this Section shall be followed immediately. A current list of Emergency Phone Numbers for Radiation Safety shall be available in each area where radioactive materials are used.

B. Spills of Radioactive Materials

1. Minor Spill (<100 µCi)

A minor spill is defined as a spill of less than 100 µCi. The laboratory shall initiate and complete cleanup operations, and document the spill and cleanup. The following procedures should be followed in the event of a minor spill. Personnel are expected to use sound judgment in initiating clean-up efforts.

- Notify persons in the area that a spill has occurred.
- Prevent the spread of contamination by covering the spill with absorbent paper.
- Clean up the spill, wearing disposable gloves and using absorbent paper.
- Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Put contaminated gloves and any other contaminated disposable material in the bag.
- Survey the area with an appropriate low-range radiation detector survey meter or other appropriate technique. Check the area around the spill for contamination. Also check hands, clothing, and shoes for contamination.
- Allow no one to return to work in the area until the incident is resolved.
- Report the incident to the RSO promptly if complications are encountered.
    - Cooperate as needed with the RSO and/or Radiation Safety staff (e.g., investigation of root cause, provision of requested bioassay samples).
    - Follow any instructions of the RSO and/or Radiation Safety staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

Reminders to RSO for Minor Spills

- Follow up on the decontamination activities and document the results.
- As appropriate, determine cause and corrective actions needed; consider bioassays, if there is a potential for internal contamination.
- If necessary, notify the TDSHS.

2. Major Spills (>100 µCi)

A major spill is defined as a spill of greater than 100 µCi. The laboratory shall notify the RSO and shall not initiate cleanup operations without authorization from the Radiation Safety Office. The following procedures should be followed in the event of a major spill. Personnel are expected to use sound judgment in initiating clean-up efforts.

- Clear the area. If appropriate, survey all persons not involved in the spill and vacate the room.
- Notify the RSO immediately.
- Prevent the spread of contamination by covering the spill with absorbent paper (paper should be dampened, if solids are spilled), but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.
- Shield the source only if it can be done without further contamination or significant increase in radiation exposure.
- Close the room and lock or otherwise secure the area to prevent entry. Post the room with a sign to warn anyone trying to enter that a spill of radioactive material has occurred.
- Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with a mild soap.
- Allow no one to return to work in the area unless approved by the RSO.
- Cooperate with the RSO and/or Radiation Safety staff (e.g., investigation of root cause, provision of requested bioassay samples).
- Follow the instructions of the RSO and/or Radiation Safety staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

Reminders to RSO

- Confirm decontamination of personnel. If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.
- Supervise decontamination activities and document the results. Documentation should include location of surveys and decontamination results.

- Determine cause and needed corrective actions; consider need for bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin.
- If necessary, notify the TDSHS.

3. Injuries Involving Radioactive Materials

If a person is both injured and contaminated, the following listed action will vary with different accident conditions. Contact Radiation Safety for assistance if needed.

1. For serious injuries, immediately call 911. Treatment of the serious injury should take precedence over almost all concern for contamination control and radiation exposure.

2. Notify Radiation Safety. (After normal working hours use emergency phone list).

3. No transport restrictions should be imposed that would seriously compromise the patient's medical care.

4. When transporting a contaminated patient to a hospital emergency room or the designated emergency receiving point, the following procedures should be followed:

    - Contaminated clothing should be removed if, possible.
    - If skin decontamination is necessary, wash the patient thoroughly with soap or detergent and water.
    - Wrap patient in a clean sheet or blanket.
    - A representative from Radiation Safety should accompany the patient, but do not delay transport if Radiation Safety personnel are not present.

5. External contamination is not immediately harmful to the patient unless the skin is badly punctured or wet.

6. Minor injuries can usually be treated at the scene and can usually wait until after an initial radiation survey has been completed.

7. Cuts which penetrate the skin offer a point of easy access to the body for radioactive materials. Radioactive materials should not be allowed to come in contact with a cut anywhere on the body. If a person is cut by a contaminated article, this should receive immediate treatment. It should first be cleansed very thoroughly. The wound should be checked for contamination if a high energy beta or gamma emitter is known to be involved. Soft beta and gamma cannot be easily detected in a cut, particularly in the presence of water. Cuts involving possible contamination should be reported to Radiation Safety so that necessary steps can be taken immediately to evaluate the contamination.

C. Lost or Stolen Sources of Radioactive Materials

A report shall be made to the Radiation Safety Office as soon as it becomes known that a source of radioactive material has been lost or stolen. The Radiation Safety Office will determine if notification to the TDSHS Radiation Control Program is required according to 25 TAC §289.202(ww). The event will be reported to the Radiation Safety Committee.

D. Notification of Overexposure to Personnel

The Radiation Safety Committee shall determine an ALARA limit that requires action by the RSO and the Radiation Safety Office. The employee will be notified if an exposure exceeds 50% of the ALARA limit. If the exposure exceeds the ALARA limit, the RSO will perform a thorough investigation to determine why the limit was exceeded, if notification to the TDSHS Radiation Control Program is required, and will document the results of the investigation and corrective actions taken. A report will be provided to the Radiation Safety Committee.

E. Emergency Notification of TDSHS

The Texas Department of State Health Services has established a 24-HOUR RADIOLOGICAL EMERGENCY ASSISTANCE telephone number:

(512) 458-7460

This number shall be used for emergency assistance reporting only. For routine business matters call (512) 834-6688. Additional assistance may be obtained if necessary by contacting Radiation Safety, University Police or **911**.

The Radiation Safety Officer shall notify the Radiation Safety Committee immediately of the occurrence of any radiation incident that may affect the health or well-being of any individual.

D. Emergency Phone Numbers

RADIATION SAFETY

Environmental Health & Safety 24-hour Immediate Response Phone: 512-658-2411

Radiation Safety Personnel

Name	**Position**	**Office**	**Alternate**
Kristi Powell	Radiation Safety Officer	512-495-5742	512-585-4646
DeWayne Holcomb	UT-Austin RSO EHS Associate Director	512-471-2038	512-777-8829
Ryan Green	Radiation Safety Specialist	512-471-2029	512-964-1812
Eira De Los Reyes	Radiation Safety Specialist	512-232-3364	956-545-3892

University Emergency Phone Number **911**

The Radiation Safety Officer may revise this page as needed.

APPENDIX III – Application to Use Radioactive Material

THE UNIVERSITY OF TEXAS AT AUSTIN DELL MEDICAL SCHOOL
ENVIRONMENTAL HEALTH AND SAFETY
RADIATION SAFETY OFFICE

This form shall be completed and returned to the Radiation Safety Officer (RSO). It is suggested that an electronic draft be submitted to the RSO for review and comment prior to obtaining the required signatures. Only upon notification of approval shall use of radioactive material be permitted. Please type or electronically submit this form. Hand-written forms will not be accepted.

1) Name, department, campus address, phone number, and email of person responsible for possession, use, and disposal of radioactive material:

2) Address of Laboratory or place of use and storage, if different from 1):

3) Name, UTEID and title of individual(s) who will use or supervise the use of radioactive material:

4) Applicant's previous permits, authorizations or equivalent obtained under a NRC or Agreement State license or registration:

5) Radioactive material for which authorization is desired. (Be specific. List each radioactive material with the maximum quantity and chemical/physical form of each to be used in each procedure and to be possessed at any one time):

6) Describe, in detail, proposed uses for radionuclide(s) identified in item 5) and period of time radioactive material use is requested (use additional sheets if necessary):

7) Describe procedures which will ensure radiation doses to faculty, staff and students are **As Low As Reasonably Achievable** (ALARA) :

8) Describe the types of radioactive waste to be generated and radioactive waste collection and handling procedures (e.g., chemical and physical form of the waste, radioactive materials in each waste stream, other hazardous or potentially infectious materials present, total activity or concentration of radioactive material, and type of liquid scintillation cocktail used, if applicable).

9) Describe personnel training and experience. If applicable, provide certifications and medical license. Include, at a minimum, individual(s) identified in item 3):

10) Type and number of radiation detection instruments available for surface contamination and area surveys:

11) Proposed personnel monitoring devices:

12) Clearly identify locations(s) of use and describe facilities to be used (include fume hoods, sinks, refrigerator/freezer, etc.). Include a detailed sketch of the location(s) with this application:

13) Describe radiation survey procedures, methods of locating and remediating radioactive contamination, and record keeping of survey results:

14) If animals are to be used, describe procedures (handling, disposal, etc.):

15) If human subjects, animals, biological materials (recombinant DNA, human or non-human primate tissue, blood or body fluids, Select Agents or Biotoxins, or infectious agents) are to be used with radioactive materials, summarize and attach approved protocols:

16) In the event of an accident, describe emergency procedures:

_____ _____

Applicant's Signature Date

_____ _____

Dean or Department Chairperson's Signature Date

_____ _____

Reviewed, Radiation Safety Officer's Signature Date

APPENDIX IV - Procedures for Research Involving Animals

This procedure provides additional information on the use of radioactive materials in animals used for research.

Training

All personnel that come in contact with animals that have uptakes of radioactive materials will have taken the Radiation Worker training specified in Section 7 of this document.

Contamination Control and Waste Handling

In order to minimize the spread of contamination, animals used in studies with licensed material should be housed in cages or stalls separate from other animals. The cages or stalls shall be secured to prevent unauthorized access to the animals. Individuals caring for these animals should reduce the chance of personal contamination by wearing gloves, lab coat, and eye protection, as appropriate.

Special care should be observed when cleaning the cage or stall. The cage or stall, the bedding, and waste from the animal may contain radioactive material. Any radioactive material should be properly disposed of as described in the section waste processing procedures for animal materials.

Disposal of research animals that contain radioactive material require special procedures. Animal carcasses that contain less than 0.05 μCi/gram) of carbon-14, hydrogen-3, or iodine-125 may be disposed of by the same method as non-radioactive animal carcasses. Animal carcasses that contain radioactive material with a half-life of less than or equal to 120 days may be allowed to decay-in-storage in a freezer dedicated for radioactive material. Animal carcasses must be held for a sufficiently long time so the radioactive material has significantly decayed based on the longest lived isotope present. After storage, the animal carcasses may be disposed as non-radioactive, if radiation surveys (performed in a low background area and without any interposed shielding) of the carcasses at the end of the holding period indicate that radiation levels are indistinguishable from background.

Animal Materials

I. No animal waste will be picked up for disposal prior to suitable deactivation of infectious agents. Four types of radioactive waste are generated from animal experiments; bedding, dry, blood/urine, and carcasses. Each type is to be segregated and prepared for disposal.

II. Bedding

1. This consists of bedding material only.
2. Separate the bedding material by the half-life of the isotope that was used on the animal.
3. Separate bedding containing less than 0.05 µCi/gram for H-3, C-14, and I-125 and double bag in plastic bags.
4. If the above does not apply, separate bedding into the three following groups based on half-life and double bag in plastic bags.
    i. Less than or equal to 120 days.
    ii. Greater than 120 days but less than 300 days.
    iii. Greater than or equal to 300 days.

III. Solid dry waste also follows the Waste Processing Procedures located in Section 10.

IV. Blood/Urine

1. Collect blood/urine separately in plastic container.
2. Follow the bulk liquid waste procedures located in Section VII.

V. Carcasses

1. Separate the carcasses by the half-life of the isotope used in the animal. These carcasses should be double-bagged in plastic bags with as much of the air removed as possible.
2. Separate carcasses containing less than 0.05 µCi/gram for H-3, C-14, and I-125.
3. If the above does not apply, separate carcasses into the three following groups based on half-life.
    i. Less than or equal to 120 days.
    ii. Greater than 120 days but less than 300 days.
    iii. Greater than or equal to 300 days.

APPENDIX V - Periodic Intervals

It is recognized that periodic inspection, calibration, testing, etc. is required to maintain a successful radiation safety program. The intervals as listed below are to provide operational flexibility and not to reduce frequency of the required task. The listed intervals were chosen to be consistent with those authorized in licenses issued to the University by TDSHS and USNRC. Established frequencies shall be maintained over the long term. Allowable intervals shall not exceed the following:

Annual	Not to exceed 15 months
Semiannual	Not to exceed 7.5 months
Quarterly	Not to exceed 4 months
Monthly	Not to exceed 6 weeks
Weekly	Not to exceed 10 days

10. DISPOSAL OF RADIOACTIVE WASTE

10.1 WASTE GENERATION

Each Authorized User (AU) who generates waste contaminated with radioactive materials or possesses excess materials which are candidates for disposal as radioactive waste shall determine the category of the waste and document the actions taken regarding proper disposal. The most common types of radioactive waste and excess materials are Liquids, Dry Solids, Sharps, Sealed Sources, and Animal Waste.

10.2 LIQUID WASTE

Liquid radioactive wastes generally fall into two categories: Aqueous and Non-Aqueous. The two types are handled in a different manner. Aqueous waste may either be disposed by the AU via the sanitary sewer or offered for pickup by Radiation Safety. Liquid radioactive waste to be picked up by Radiation Safety shall be placed in non-breakable containers. If a breakable inner container is used, the non-breakable outer container shall have a sufficient amount of absorbent to absorb all of the liquid in the event of an inner container failure.

Liquid radioactive wastes containing other hazardous materials, such as solvents used for scintillation counting (toluene, xylene, etc.) shall not be disposed via the sanitary sewer. These liquids must be collected by Radiation Safety for analysis and proper disposal.

A. Aqueous Liquids

Aqueous biodegradable solutions that contain radioactive materials may be disposed by laboratory personnel or Radiation Safety staff via the sanitary sewer system in accordance with §289.202(gg), if the radioactive material is readily soluble, or readily dispersible biological material, in water.

Radiation Safety shall be responsible for collecting sanitary sewer release data to determine compliance with the monthly concentration limits (§289.202(ggg)(2)(F), Table III) and the sum of fractions requirement specified in §289.202(gg)(1)(C). Per §289.202(gg)(1)(D), the total radioactivity released into the sanitary sewer under the DMS Radioactive Material License cannot exceed 5 curies per year of hydrogen-3, one curie per year of carbon-14, and one curie per year of all other radioactive materials combined. Radiation Safety shall generate and retain records to demonstrate compliance with these requirements.

B. Non-Aqueous Liquids

All non-aqueous liquids containing radioactive materials shall be collected in dedicated, marked containers for pickup by Radiation Safety. The contents of the containers shall be documented and reported to Radiation Safety prior to pickup. Radiation Safety shall dispose of

non-aqueous liquids as regulated or exempt waste. If disposed as exempt waste per 25 TAC §289.202(fff), all procedures per Section 10.2.2 of this document will be followed.

10.3 DRY SOLID WASTE

Dry solid radioactive waste generated in DMS activities, which includes liquids in absorbed, adsorbed, or sequestered form, may either be transferred to Radiation Safety for processing and disposal, or if appropriate, held by the AU for decay in storage. Each AU shall collect solid radioactive waste in a dedicated, marked container. The contents of the container shall be documented on the Radioactive Materials Pickup form or equivalent, and reported to Radiation Safety prior to pickup.

The following instructions shall be observed when packaging excess dry solid materials for pickup by Radiation Safety:

- Solids shall be placed in approved containers with clear plastic bag liners.
- No liquids or sharps capable of penetrating the plastic liners shall be in the dry solids.
- All containers shall be marked "Caution-Radioactive Materials", unless specifically exempted from such markings by regulation.

All solid wastes containing radioactive materials shall be segregated by waste type and isotope, and the appropriate disposal method chosen based on the criteria described below.
NOTE: The Radiation Safety Office must be contacted prior to the generation of mixed wastes containing both radioactive materials and other hazardous materials.

A. Decay-in-Storage (DIS)

Radioactive materials with half-lives $\leq$ 120 days may be held for decay in storage (DIS) in a secure area. If more than one isotope is included in the materials held for DIS, the materials shall either be segregated or the longest half-life isotope shall be used to compute the amount of time required before disposal may occur. After storing the waste for a minimum of ten half-lives, the waste shall be surveyed in a low background area with an appropriate survey instrument to ensure that readings are indistinguishable from background prior to disposal. Defacing or removing radiation labels is not required if the labels are otherwise obscured in containers which are not designed to be opened (e.g. sharps or medical waste containers). Records shall be maintained to document proper disposal of the material and shall include the following information:

- The date of disposal
- Manufacturer's name, model number, and serial number of the survey instrument used
- Background radiation level
- Radiation level measured at the surface of the waste container
- Name of the individual performing the survey

B. Specifically Exempt Materials

25 TAC §289.202(fff)(1) provides for the disposal of certain materials without regard to its radioactivity:

1) 0.05 microcuries or less of H-3, C-14, or I-125 per gram of medium used for liquid scintillation counting or in vitro clinical or laboratory testing;
2) 0.05 microcuries or less of H-3, C-14, or I-125 per gram of animal tissue, averaged over the weight of the entire animal.

All radioactive waste containing H-3, C-14, or I-125 shall be picked up by Radiation Safety, and a determination made by Radiation Safety personnel as to the qualification of the materials with regard to 25 TAC §289.202(fff)(1). Documentation shall be generated and maintained to verify qualification of this waste as exempt waste.

Specifically exempt waste will be separated from other radioactive waste by Radiation Safety at the waste preparation facility. All signs, labels, or other markings which would indicate that the materials were radioactive shall be permanently and completely defaced or removed. No package will be sent for disposal until it is ascertained that all conditions of 25 TAC §289 are satisfied. If the waste is a non-aqueous liquid as defined in Section 10.2.2, it will be transferred in containers with no radiation markings to the EHS Hazardous Materials Section for disposal.

C. Disposal via a Licensed Low-Level Radioactive Waste Facility

Any radioactive wastes which do not meet the criteria specified in 25 TAC §289.202(fff) or (gg) shall be disposed at a facility licensed to accept radioactive materials for disposal. The materials shall be packaged according to USDOT, waste processor, and disposal site requirements as applicable, and shall be identified by isotope, quantity, chemical form, and any other requirements which are levied for the proper manifesting, processing, and disposal of these items. Transportation shall be via a carrier licensed to accept and deliver radioactive materials. The University currently uses the services of a licensed waste broker for the off-site treatment and/or disposal of radioactive waste.

Radioactive waste and mixed wastes, defined as any waste containing radioactive materials plus another hazardous chemical, may be transferred to the main University broad scope License No. L00485, for the purpose of disposal by a licensed waste broker. Prior to any transfer of solid or liquid radioactive waste, the waste shall be characterized to determine for each radioactive material the activity, physical and chemical form, as well as volume and/or weight. The RSO shall review the characterization for adequacy and determine whether the radioactive material is within the material authorizations of License No. L00485. Upon approval from the RSO, the transfer may then occur. Immediately upon receipt, the radioactive material inventory records shall be updated. The waste shall be disposed in the same manner as described in the previous paragraph.

10.4 SHARPS

A “sharp” is generally defined as an item which will penetrate the plastic liners placed in a dry solid container with minimal effort. Examples of sharps are broken glass, needles, and pipette tips. Sharps must be packaged in specially designed puncture-resistant containers. Sharps that are contaminated with radioactive materials and do not qualify for decay in storage must be packaged for pickup by Radiation Safety, who will make determination of the classification of the sharps, and will dispose appropriately.

10.5 SEALED SOURCES

All sealed sources past their useful life or no longer needed by users shall be held separately from other radioactive wastes and submitted to Radiation Safety. A determination will be made by Radiation Safety as to the disposition of the source. Under no circumstances shall a sealed source be disposed with other radioactive waste by any AU.

10.6 ANIMAL TISSUE AND CARCASSES

All animal tissues, carcasses, excrement, and bedding which have been contaminated with radioactive materials must either be disposed through Radiation Safety or held by the AU for Decay in Storage. These items must be double bagged to prevent leaks and tears. If pickup is requested, Radiation Safety will determine the proper type of disposal based on the isotopes and concentration. Animal disposal will follow the procedures in Section 10.3 of this document.

10.7 PATIENT EXCRETA

All radioactive excreta from individuals undergoing procedures shall be exempt from reporting requirements and regulatory limits.

10.8 RELEASE INTO THE ATMOSPHERE

Release of radioactive materials into the atmosphere shall only be incidental to working with radioactive materials in solid or liquid form, unless specific permission is given to use radioactive gases by the RSC. Although limitations on the atmospheric effluent are given in 25 TAC §289.202, Radiation Safety shall be contacted prior to using any radioactive materials in a situation where release to the atmosphere may occur. Any actions which might result in release of radioactive materials into the atmosphere shall be conducted in an area with a forced ventilation system such as a fume hood or other area where characteristics of the airflow are known. All releases to the atmosphere shall comply with requirements of 25 TAC §289.202(o)(2)(B)(i).

10.9 RECORDS

All radioactive wastes shall be documented prior to pick-up by Radiation Safety on the Radioactive Materials Pickup form (or equivalent). Radiation Safety will document the isotope and quantity, chemical form, physical form, date received, Purchase Order number (if available), the type of disposition, date of disposal, and the concentration in µCi/gm if 25 TAC §289.202(fff)(1) is used for disposal, and will retain copies of these records. Information for the instrument used to survey the materials for separation and disposition will be recorded, including the name of the surveyor, the date of survey, the instrument type, model number, serial number, and the date of calibration.