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1.0 INTRODUCTION

1.1 Purpose  The objective of the University of Texas Health Science Center at San Antonio (UTHSCSA) Radiation Safety Program is to assist in all levels of management in fulfilling the UTHSCSA commitment to furnish a place of employment and learning that is as free as possible from recognized radiation hazards that are likely to cause harm to UTHSCSA personnel or our community. It is vital that faculty, staff, and students have enough information available to aid them in the safe conduct of their daily work activities relating to radiation.

To that end, the Texas Department of State Health Services has granted a license to the UTHSCSA authorizing the use of radioactive material. An essential component of that license is the Radiation Safety Handbook. A significant factor in being allowed the flexibility of a radioactive material license by the Texas Department of State Health Services is that UTHSCSA implicitly accepts the responsibility to regulate and control the use of radioactive material in the furtherance of our education, patient care, and research missions. This responsibility is not to be taken lightly.

The purpose of the UTHSCSA Radiation Safety Handbook is to assist in both personnel and management in complying with the objectives of the Texas Department of State Health Services, Bureau of Radiation Control regulations and the institutional health and safety policies. The Radiation Safety Division addresses many of the items in this Handbook in periodic Radiation Safety training sessions.

This Handbook is not intended to be an exhaustive or fully comprehensive reference, rather a guide for authorized users and other qualified individuals. Further advice concerning hazards associated with specific substances, devices, and the development of new or unfamiliar activities shall be obtained through consultation with the Radiation Safety Committee, the Radiation Safety Officer, or the Radiation Safety Division.

All users of radioactive material must be familiar with the requirements set forth in this Handbook and must conduct their operations in accordance with them.

Signature on File

Jennifer Cerecero, MS
Radiation Safety Officer
The University of Texas Health Science Center at San Antonio

Signature on File

William Moore, DDS, MS
Chair, Radiation Safety Committee
The University of Texas Health Science Center at San Antonio

Signature on File

James D. Kazen
Executive Vice President for Facilities Planning & Operations
The University of Texas Health Science Center at San Antonio

Signature on File

William Henrich, M.D.
President
The University of Texas Health Science Center at San Antonio
1.2 Emergency Telephone Numbers

<table>
<thead>
<tr>
<th>Contact</th>
<th>8am-5pm</th>
<th>After Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation Safety Office</td>
<td>(210)567-2955</td>
<td>(210)567-2800</td>
</tr>
<tr>
<td>Dental Building Room 1.343T</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiation Safety Officer (Jennifer Cerecero)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>University Police</td>
<td></td>
<td>(210)567-2800</td>
</tr>
</tbody>
</table>

In case of incidents involving unusual radiation exposure, patient safety or laboratory accidents involving radioactive materials, all personnel are required to notify the Radiation Safety Office immediately.

After 5:00 pm, University Police will assist in contacting Radiation Safety personnel.

1.3 Responsibilities

1.3.1 Radiation Safety Committee The Radiation Safety Committee will be appointed by the President of the University of Texas Health Science Center at San Antonio, with membership including faculty representatives from Basic Sciences, Dental School, Medical School, Nuclear Medicine, Radiation Oncology; a radiologist, a veterinarian; a person from the administration office of UTHSCSA and from Bexar County Hospital District, doing business as University Health System; and a nursing representative. This committee reports to the President of the University of Texas Health Science Center at San Antonio. Hereafter, in the Handbook, the Radiation Safety Committee will be referred to as the RSC. The RSC is responsible for:

1. Approving policies and practices regarding license, registration, and the use of radioactive materials and sources of ionizing and non-ionizing radiation at the Health Science Center and at the University Health System. The implementation of the approved policies is delegated to the Radiation Safety Officer.
2. Serving in an advisory and consultative capacity to the President and the Executive Vice President for Facilities Planning & Operations.
3. Reviewing all applications to use radioactive material, authorizing all Principal Investigators, and appending special conditions as needed.
4. Reviewing the human use applications, clinical and research, particularly scrutinizing the training and experience of the applying practitioner and the proposed radiation dose and/or exposure to the patient as outlined by the submitted protocol and application. The overall feasibility of the protocol will be determined by the Institutional Review Board.
5. Reviewing accidents, injuries, and illnesses involving radiation sources and approving corrective actions.
6. Reviewing periodic audits performed by the RSO.
7. Reviewing the annual Radiation Protection Program report.
8. Interacting with the Radioactive Drug Research Committee as needed.
9. Acting as an avenue of appeal in cases of disputes or exceptions.
10. Maintaining minutes of the meeting delineating the date, members present, members absent, review actions including committee response, appended conditions, recommended actions, Audits, RPP, ALARA reviews, and RSO reports.
1.3.2 Radiation Safety Officer (RSO)  The Radiation Safety Officer is responsible for:

1. Reviewing all proposals for use of radioactive sources and recommending action to the Radiation Safety Committee and the Radioactive Drug Research Committee.
2. Inspecting facilities and equipment through radiation safety evaluations and monitoring all facilities in which radioactive material is used, or radiation-producing equipment resides.
3. Prescribing special conditions and requirements as may be necessary for safe and proper use of all radiation sources in UTHSCSA/UHS research, education, and patient care.
4. Acting as consultant in the design of all new facilities using radioactive material for the purpose of providing protection against radiation exposure.
5. Preparing and disseminating information on radiation safety for faculty, staff, and students as necessary.
6. Authorizing, receiving, storing, and processing incoming radioactive material orders.
7. Supervising, packaging, monitoring and recording the disposal of radioactive waste.
8. Providing personnel monitoring services, including the reviewing and recording of commercially processed dosimeter reports.
9. Performing six (6) month leak testing on all non-exempt registered sealed-sources.
10. Completing or providing internal dose assessment in accordance with the conditions of the University's license or when ingestion of radioactive materials is suspected.
11. Executing environmental surveys as required.
12. Preparing license applications, amendment applications, and required reports as well as acting as the primary contact for correspondence with state radiation control authorities on a timely basis.
13. Investigating incidents involving radiation exposures including overexposures, incidents, theft, loss of sources, and accidents.
14. Notifying the Texas Department of State Health Services of all reportable incidents including overexposures, theft, loss of sources and submitting reports as required.
15. Reacting to any situation that is imminently dangerous to life and health and/or not in compliance with regulatory standards or University policy. Corrective actions shall include the authority to stop or shut down use of radiation sources until the situation is deemed safe by the Radiation Safety Officer.
17. Directing and supervising emergency response and decontamination efforts.
18. Ensuring that radiation doses are maintained as low as reasonably achievable (ALARA).
19. Maintaining records of the radiation protection program.

1.3.3 Principal Investigator  Principal investigators are responsible for obtaining the required radioactive material authorization and ensuring that individual responsibilities are properly carried out. Every principal investigator is responsible for:

1. Adequate planning. Before experiments are performed, the PI shall determine the types and amount of radiation or radioactive material to be used. This generally indicates the protection required. A written procedure involving the use of radioactive material shall be outlined. In any situation where there is an appreciable radiation hazard, the Radiation Safety Office shall be consulted before proceeding.
2. Instructing employees in the use of safe clinical and laboratory techniques.
3. Ensuring that all persons using radioactive material under their authorization are familiar with and comply with radiation safety policies outlined in this Handbook.
4. Furnishing the Radiation Safety Office with information concerning individuals and activities in their areas:
   a. Personnel changes
   b. Laboratory location changes
   c. Any major changes in operational procedures and new techniques
   d. Any alterations in the laboratory (e.g., the removal of radiochemical fume hood) that are anticipated.

5. Complying with the applicable regulations and policies governing the safe use of radioactive materials. These are:
   a. Maintaining proper procedures for the procurement of radioactive materials by purchase or transfer.
   b. Posting areas containing radiation sources with signage necessary to notify personnel of the hazard with appropriate signs where radioisotopes are kept or used, or where radiation fields may exist.
   c. Recording the receipt, use, transfer, and disposal of radioactive materials in their area. This includes sealed sources, such as ion sources in gas chromatographs, static eliminators, and liquid scintillation counters.
   d. Ensuring appropriate security of all radiation sources under their authority.
   e. Assuring that all radioactive waste materials are consigned to the EH&S Radiation Safety Office for disposal.
   f. Ensuring contamination surveys are performed at the necessary frequency and maintaining a written record of the survey results.
   g. Having all records available for inspection by the Radiation Safety Office or the Texas Department of State Health Services during normal working hours including the current copy of the Radiation Safety Handbook in each laboratory where radiation sources are being used or stored.
   h. Ensuring that radiation doses are maintained as low as reasonably achievable.
   i. Following emergency procedures outlined in Chapter 13.
   j. Ensuring that the appropriate personal protective equipment is worn by all laboratory personnel.
   k. Following the policy of no eating, drinking, smoking, or applying cosmetics in the laboratory.
   l. Labeling all radiation sources properly.

6. Requiring that all personnel attend mandatory radiation safety training.

7. Complying with proper procedure upon termination of association with UTHSCSA. Particular care shall be exercised to see that specialized equipment, such as personnel monitoring devices, (e.g. dosimeter badges), survey instruments, and shielding materials are returned to the Radiation Safety Office.

1.3.4 Individual Faculty, Staff and Students  All personnel at UTHSCSA and UHS are expected to follow these responsibilities:

1. Wearing personnel dosimeters when appropriate based on the radiation risk.
2. Utilizing all appropriate laboratory measures including:
   a. Wearing all appropriate personal protective equipment including gloves, eye protection, and laboratory coats.
   b. Not wearing shorts or open toed shoes within the laboratory.
   c. Using protective barriers and other shields when possible.
   d. Using mechanical devices whenever their aid will reduce exposure.
   e. Pipetting with mechanical devices only – never pipette radioactive solutions by mouth.
   f. Performing radioactive work within the confines of an approved hood, unless serious consideration has indicated the safety of working in the open. All
iodinations and handling of unbound radioiodine solutions are to be carried out in an approved chemical fume hood.
g. No smoking, drinking, eating or applying cosmetics permitted in radioisotope laboratories.
h. Maintaining personal safety by not working with radioactive materials if there is a break in the skin and washing hands upon completion of radioactive material use.
i. Checking the immediate radioactive material work areas, e.g., hoods, benches, etc., according to Chapter 8.3.2, for contamination. A record shall be maintained of these surveys, including results which are entirely negative. Any contamination observed shall be cleaned, resurveyed, and actions recorded.
j. Keeping the laboratory neat and clean. The work area shall be free from equipment and materials not required for the immediate procedure.
k. Keeping or transporting materials in such a manner as to prevent breakage or spillage (double container), and to ensure adequate shielding.
l. Keeping work surfaces covered with plastic backed absorbent material to limit and collect spillage in case of accident.
m. Labeling and isolating radioactive waste. See Chapter 12.
n. Labeling equipment, used for radioactive material, such as glassware and pipetters. Once used for radioactive substances, equipment should not be used for other work.
o. Contaminated equipment shall not be sent from the area to central cleaning facilities, repair shops, or to surplus, until demonstrated to be free of contamination.
p. Requesting Radiation Safety Office supervision of any emergency repair of contaminated equipment in the laboratory by shop personnel or by commercial service contractors. At no time shall servicing personnel be permitted to work on equipment in radiation areas without the presence of a member of the laboratory staff to provide specific information.
q. Immediately reporting accidental inhalation, ingestion, or injury involving radioactive material to his supervisor and the radiation safety office and carrying out their recommended corrective measures. The individual shall cooperate in any and all attempts to evaluate his exposure.
r. Carrying out decontamination procedures when necessary, and taking the appropriate steps to prevent the spread of contamination to other areas.
s. Complying with requests from the Radiation Safety Office for body burden measurements of the thyroid and the submission of urine samples for radioassay.

3. Ensuring that security procedures outlined in Chapter 7 are followed.
4. Complying with proper procedure when terminating employment or the use of radioactive materials or radiation.

1.3.5 Radioactive Drug Research Committee The Radioactive Drug Research Committee is appointed by the President of the University of Texas Health Science Center at San Antonio, with a minimum membership of five including but not limited to a physician specializing in Nuclear Medicine, a person qualified by training and experience to formulate radioactive drugs and a person with special competence in radiation safety and radiation dosimetry. The remainder of the committee should consist of individuals qualified in various disciplines pertinent to the field of nuclear medicine (e.g., radiology, internal medicine, clinical pathology, hematology, endocrinology, radiation therapy, radiation physics, radiation biophysics, health physics, and radio pharmacy). The Committee may request individuals with specialized expertise to serve as consultants for individual protocols. This Committee reports to the President of the University of Texas
Health Science Center at San Antonio. Hereafter, in this Handbook, the Radioactive Drug Research Committee will be referred to as the RDRC. This Committee is registered with the Food and Drug Administration and is identified as Committee Number 56. The RDRC is responsible for:

1. Reviewing all research involving the use of radioactive drugs and/or agents with human subjects conducted at or by employees of the University of Texas Health Science Center at San Antonio; the Audie L. Murphy Memorial Veterans’ Hospital; and the University Health System as required by 21 CFR, Part 361.1 regulations.
2. Serving in an advisory and consultative capacity to the President of the University of Texas Health Science Center at San Antonio and the Vice President for Research.
3. Serving in accordance with the Food and Drug Administration (21 CFR, Part 361.1) regulations.
4. Interacting with the Radiation Safety Committee as needed.
5. Reviewing a protocol involving a radiopharmaceutical not requiring approval by the RDRC upon request.

1.3.6 Radiation Safety Division  The Radiation Safety Division, under the direction of the Radiation Safety Officer is responsible for:

1. Conducting safety evaluations of facilities and equipment through performing radiation surveys and monitoring all facilities in which radioactive material is used, or radiation-producing equipment resides. Surveys include contamination and record checks.
2. Authorizing orders, receiving, storing, processing, and dispensing radioactive material, and maintaining records on all of the preceding transactions.
3. Supervising, packaging, monitoring and recording the disposal of radioactive waste.
4. Performing semi-annual leak testing on all non-exempt registered sealed-sources.
5. Performing or providing internal dose assessment in accordance with the conditions of the University's license or when ingestion of radioactive materials is suspected.
6. Performing environmental surveys as required.
7. Reacting to any situation that is imminently dangerous to life and health and/or not in compliance with regulatory standards or University policy. Corrective actions shall include the authority to stop or shut down use of radiation sources until the situation is deemed safe by the Radiation Safety Officer.
8. Performing emergency response and decontamination efforts.

1.4 Corrective Action  Items of non-compliance or deficiency noted during a laboratory evaluation, an inspection, or a walk through will generate corrective actions depending upon the severity of the deficiency noted. The following action will be taken:

1. **Serious deficiency:** Any uncorrected deficiency deemed to be serious in the opinion of the Safety Specialist will be evaluated by the RSO. The RSO will establish a corrective action plan, which may include an on-site re-evaluation within a specified time period or additional training.
   a. Failure by the PI or supervisor to correct a serious deficiency within the time frame specified will result in an Escalated Deficiency Notification follow-up as noted in item 3(a), this section.

2. **Other deficiencies:** Other deficiencies observed will be followed up by an e-mail (preferred) or written notification to the respective PI or Supervisor by the evaluating
Safety Specialist. The evaluating Safety Specialist will retain documentation of this notification in the appropriate investigator file.

a. **Repeat deficiencies:** Any deficiencies from a previous evaluation that are noted as a repeat violation during the evaluation process will be treated with greater severity, and will be noted on the Deficiency Notification letter. Any repeat deficiencies which are not addressed by the PI / supervisor with a plan for corrective action within the required time frame (normally 30 days) listed on the deficiency report will result in an *Escalated Deficiency Notification* follow-up as noted in item 3(a), this section.

3. **Disputed Deficiencies:** If a Principal Investigator disputes a noted deficiency, and the dispute cannot be resolved by discussion with the RSO, or Director of Environmental Health & Safety, then the dispute will be forwarded to the Chair of the Radiation Safety Committee for resolution as outlined in the UTHSCSA Handbook of Operating Procedures.

a. **Escalated Deficiency Notification:** Deficiencies posing an unusual hazard, or those of a serious nature that have not been resolved after a 60 day period, will use the following notification methods and time line.

   i. A letter from the Environmental Health & Safety Director to the PI / Supervisor - (30 days to respond)
   ii. A letter from the Radiation Safety Committee Chair to PI / Supervisor - (30 days to respond)
   iii. A letter from the Environmental Health & Safety Officer to Department Chair - (30 days to respond)
   iv. A letter from the Environmental Health & Safety Officer to Dean of supervising School - (30 days to respond)
   v. A letter from the Environmental Health & Safety Officer to the Executive Vice President for Facilities Planning and Operations – (30 days to respond)
   vi. Letter to the UTHSCSA President - (30 days to respond)

Extenuating or mitigating circumstances will be considered by the Radiation Safety Committee.

1.5 **Imminently Dangerous to Life & Health (IDLH)** If a Safety Specialist notes any condition where there is risk of imminent danger to life, health, or facilities, this condition will be brought to the immediate attention of the RSO or appropriate Safety Manager(s) and the Environmental Health & Safety Officer (Director of Environmental Health & Safety). Corrective action may include immediate shut down of all operations as outlined in the January 1, 1995 memorandum from the UTHSCSA President titled, *Responsibility and Authority of the Institutional Safety Officer.*
2.0 APPROVAL AND AUTHORIZATION

2.1 Procedure for Radioactive Material Authorization  The University of Texas Health Science Center at San Antonio has been issued a Broad Scope Radioactive Material license to possess radioactive material by the Texas Department of State Health Services. UTHSCSA, in turn, will issue authorization to faculty members on campus engaged in medical research, diagnosis, and/or therapy using radioactive material. Each applicant will submit the following required forms to the Radiation Safety Committee, RSC:

1. A completed Radioactive Material Authorization Application form to the RSC for evaluation and approval. The Application can be found in Appendix A. An electronic version of the form can be found at http://research.uthscsa.edu/safety under forms.
2. Training page for PI and all employees on application using the Radioactive Training and Experience form.
3. Diagram of laboratory

2.2 Procedure for Application Approval  The RSC will review the following:

1. The qualifications and training of the applicant with regard to the use of radioactive material. The RSC will require two years of experience working with radioactive material for a Principal Investigator. Additional training requirements are outlined in Chapter 5 of this Handbook.
2. Safety considerations of the requested radionuclides: maximum activity limits, physical form, and intended use as well as the laboratory space, shielding requirements, security, and any special considerations.
3. The training and experience of all individuals requested by the applicant. Additional individuals to the PI’s authorization may be added or removed and approved by the Radiation Safety Officer.
4. Radioactive waste management and disposal.
5. Appropriate radiation detection and measurement for the radionuclides requested.
6. Clinical Human Use application review will be performed as per section 16.
7. Research Human Use Protocol application review will be performed as per section 16.
8. The setup/diagram of a laboratory utilizing radioactive material.

2.3 Amendment of Authorization  The RSC must be notified of any changes occurring to the original application for radioactive materials usage as outlined below.

2.3.1 Inactive Status  Inactive status is obtained by notifying the Radiation Safety Officer in writing by the Principal Investigator that they wish to go inactive. By going inactive, the laboratory will be cleared by the Radiation Safety Office. Once inactive, the laboratory cannot possess any radioactive material until reactivation is requested. The benefit of inactive status is that no contamination surveys are required during this time and upon request to the RSO through a memo the radioactive material authorization can be easily reactivated without a formal request to the RSC.

2.3.2 Clearance of Laboratory  Clearance of a laboratory can occur due to moving, going inactive, or termination. The clearance process is performed by the Radiation Safety Office.

The following is the outlined process for clearance:
1. Must have disposed of all radioactive materials and radioactive waste prior to requesting the clearance.
2. Laboratory shall be completely empty when requesting the clearance.
3. The laboratory clearance can be requested by calling the EH&S office or by filling out a form for clearance on the EH&S website, research.uthscsa.edu/safety. Upon request, the Radiation Safety Office will perform a contamination survey of the complete laboratory and any equipment that might have been used in conjunction with radioisotopes.
4. When the contamination survey is below the required limits of 1000 dpm/100 cm$^2$, then the Radiation Safety Office will come back by and scrape all radioactive stickers.
5. Once cleared, a white sticker will be placed over the authorization sticker within the plexiglass placard outside the laboratory.

No further radioisotopes or equipment used in conjunction with radioisotopes shall be placed in the laboratory until laboratory authorization has been provided by the Radiation Safety Officer.

2.3.3 Reactivation of Material Usage  Reactivation of material usage can be implemented by providing written notification from the Principal Investigator to the Radiation Safety Officer along with a floor plan of the laboratory. Once reauthorized by the Radiation Safety Officer, the Radiation Safety Office will come by and re-setup the laboratory for usage.

2.3.4 Changes in Activities  Anytime a Principal Investigator wishes to change activity and radionuclides that they are licensed for, they shall submit a request to the RSO with the new requested activity limits.

2.3.5 Changes in Radionuclides  Anytime a Principal Investigator wishes to add a new radionuclide, they must submit a new application listing the radionuclide and activity desired.

2.3.6 Changes in lab personnel  The radiation safety office shall be notified of any changes in lab personnel. Training documentation shall be provided for any new personnel as appropriate.

2.3.7 Modifications of Research Protocols  Any time that a research protocol involving human use is modified in the use of radioactive material or radiation producing machines, the protocol must be re-approved by the RSC or RDRC as appropriate.

2.3.8 New or Modified Research Laboratories  Anytime a new lab is commissioned for use of radioactive material or a currently active lab is modified, a diagram of the lab noting area’s of radiation usage must be submitted to the Radiation Safety Office.

2.3.9 Misconduct  The Radiation Safety Committee reserves the right to terminate a radioactive material authorization due to misconduct, unsafe policies, or negligent use of radioactive material. Refer to section 1.4 for further discussion.

2.4 Absence of the Authorized User  In the event of a prolonged absence of a Principal Investigator one of the following steps shall be approved by the RSC:

1. Radioactive material work will be conducted under the supervision of another authorized PI.
2. Radioactive material usage will be transferred to another authorized PI.
3. The head of the lab may be approved as an interim PI for the duration of the absence.

2.5 Termination of Authorization of Radioactive Material Use  Employment termination includes separation from the University or the Principal Investigator terminates operations involving radioactive material. Upon termination the PI or the designated department personnel must complete the following steps:

1. Notify the Radiation Safety Office as soon as possible of the termination.
2. Account for all radioactive material in possession and arrange for the final disposition.
3. Arrange for pickup of all radioactive waste.
4. Request a clearance survey of the laboratory.
5. Return all personnel dosimeters.

Radioactive material may not be removed from the UTHSCSA campus without approval and shipping arrangements from the RSO.
3.0 PERSONNEL MONITORING AND DOSIMETRY

3.1 Exposure Limits of Personnel

The maximum permissible radiation dose limits are found in 25TAC §289.202(f) and may be summarized:

Table 3.1

<table>
<thead>
<tr>
<th>Regulatory Dose Limits</th>
<th>Maximum Annual Individual Dose (mrem/year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole body; head and trunk; active blood forming organs; or gonads</td>
<td>5,000</td>
</tr>
<tr>
<td>Hands and forearms; feet and ankles; skin of whole body</td>
<td>50,000</td>
</tr>
<tr>
<td>Lens of the eye</td>
<td>15,000</td>
</tr>
<tr>
<td>Minors</td>
<td>500</td>
</tr>
<tr>
<td>Declared Pregnant Worker</td>
<td>500 mrem / 9 months</td>
</tr>
<tr>
<td>General Public</td>
<td>100</td>
</tr>
</tbody>
</table>

3.2 Radiation Exposure Assessment & Dosimeter Application

Personnel are monitored with commercial dosimeters. Persons working in low exposure areas are furnished with bimonthly dosimeters. Monthly dosimeters are assigned to personnel working in higher exposure risk positions (i.e. X-ray technicians, Radiology residents, PET users).

Dosimeters will be issued to personnel who enter a high radiation area and who enter a restricted area (Restricted areas will only be authorized by joint approval of the Radiation Safety Committee and the Radiation Safety Officer.)

In accordance with 25TAC §289.202(f), dosimeters will be issued to any person likely to receive greater than 10% of the annual allowable limit

To assist in determining who initially is likely to receive more than 10%, dosimeters may be issued in the following manner.

1. Any person working with greater than 1 millicurie of a beta emitter with energies greater than 1 MeV.
2. Any person working with greater than 10 millicuries of a gamma emitter with energy less than 100 keV.
3. Any person working with greater than 1 millicurie of a gamma emitter with energies greater than 100 keV.
4. Ring badges will be issued to persons using greater than 1 millicurie of a beta emitting radionuclide with an endpoint energy > 1 MeV or gamma emitter.

An individual’s dosimeter history may be reviewed by the Radiation Safety Officer and if found to be less than 10% of the annual dose for an adult worker, consideration may be given to discontinue the dosimeter.
Please review carefully the Section 2 “Dosimetry Service Assessment & Exposure History Form” and mark yes or no to each of the questions. This section is a risk assessment relating to the radionuclide and quantity used/stored in the laboratory and/or the radiation producing device utilized.

A copy of the dosimeter application is attached in Appendix A. The application can be accessed through the EH&S website, research.uthscsa.edu/safety under Radiation Forms.

3.3 How to Wear a Whole Body Dosimeter

3.4 How to Wear an Extremity Monitor The extremity monitor, known as ring badge, must be worn with the label facing the radiation source and underneath of the glove.
3.5 How to Wear a Fetal Monitor  The fetal monitor shall be placed in the umbilical region of the female as seen below:

3.6 Protective Devices  Protective devices shall be worn when working with x-ray equipment including lead aprons and lead thyroid collars. All protective devices are annually inspected by the Radiation Safety Office. The dosimeter shall be worn outside of the lead apron near the collar area so that special calculations can be performed for actual dose to the personnel. Here is how to wear these devices:

3.7 Do's and Don'ts of Dosimetry

**Do's**
1. Do wear ring badge under gloves
2. Do store dosimeters in a safe area
3. Do wear the dosimeter issued only to you
4. Do wear dosimeter when working with radiation
5. Do wear the dosimeter where designated (example: whole body badge on chest area)
6. Do turn in dosimeter to supervisor at end of monitoring period
7. Do notify your supervisor immediately if the dosimeter is lost

**Don'ts**
1. Do not wear another person's dosimeter
2. Do not leave dosimeter in extreme temperatures
3. Do not ever expose deliberately
4. Do not willfully damage the dosimeter
3.8 Declared Pregnant Worker

3.8.1 Application A radiation worker who is pregnant may voluntarily declare her pregnancy, but is not required to do so. The declaration automatically reduces the regulatory occupational limit to 500 millirem for the entire nine months. An embryo/fetal dosimeter will be issued and is to be worn at the waist level. The form "Pregnancy Declaration" may be obtained from the Radiation Safety Office or on the EH&S website, research.uthscsa.edu/safety under Radiation Forms. The actual application is located in Appendix A of this Handbook. It must be completed and returned to Radiation Safety to initiate the necessary actions.

Should a radiation worker choose not to declare, the regulatory occupational limit for the embryo/fetus remains at the whole body limits shown in Table 3.1

3.8.2 Concerns The pregnant worker handout in Appendix A is provided to all personnel declaring themselves pregnant to the Radiation Safety Office. It answers some of the frequently asked questions and concerns that pertain to a pregnant radiation worker. Please review and any additional questions can be directed towards the Radiation Safety Officer.

3.9 Internal Dose Assessments The Radiation Safety Office will perform or provide for bioassays in accordance with the conditions of the University's license, or when ingestion/inhalation of radioactive materials is suspected. Any significant, positive results will initiate an investigation of the working conditions and the work habits of the individual. Follow-up bioassays will be performed as is deemed necessary.

Requirements for Bioassays:

1. Persons handling certain radioisotopes may be required to have routine bioassays performed. The reports of the bioassay become a part of the individual's exposure history and are kept on file in the Radiation Safety Office.
2. Table 3.2 describes the type of dose assessment/sample that is required for each type of material necessary for the Internal Dose Assessment Program.

Table 3.2

<table>
<thead>
<tr>
<th>Type of Material</th>
<th>Sample/Time Allocated</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 mCi of tritiated (H-3) material</td>
<td>Urine Sample within 24 hours</td>
</tr>
<tr>
<td>&gt; 1mCi activities of unbound radioactive iodine</td>
<td>Baseline Thyroid Bioassay and Quarterly</td>
</tr>
<tr>
<td></td>
<td>Follow-ups</td>
</tr>
</tbody>
</table>

3. An individual who suspects that an uptake of radioactive iodine has occurred is to notify the Radiation Safety Office immediately. Supersaturated potassium iodide may be obtained by prescription from Nuclear Medicine for immediate use. A thyroid bioassay will then be performed within the next 24 hours (next working day).

4. For a suspected uptake of tritium or any other radioisotope, contact the Radiation Safety Office immediately. A urine sample will be needed the next day.
5. To collect the sample, please contact the Radiation Safety Office to provide you with a specimen bottle for the 24 hour sample. The bottle will be marked with the maximum fill line and shall not be overfilled.

6. Once collected, the sample shall be returned to the Radiation Safety Office to be shipped out to an outside laboratory for evaluation.
4.0 RADIATION PROTECTION

4.1 Introduction  The Radiation Protection Procedures outlined in this Handbook are designed to protect three types of individuals:

1. Laboratory/Clinical Personnel: Workers in a radioisotope laboratory, or workers who may work with radioactive material or ionizing radiation in other parts of the University or in the University Health System.
2. General Public/Staff: Persons inside or outside of the University or the University Hospital, who might be exposed unknowingly, and without their permission.
3. Patients or Subjects: Patients must be protected against unnecessary exposure to radiation.

4.2 Basic Principles  It is the responsibility of any person involved in radiation procedures to maintain his or her own exposure below the regulatory limits. The philosophy "As Low As Reasonably Achievable" (ALARA) is to be used as guidance in reducing occupational exposures. The following principles, which apply whether the material is within a patient, within a storage container, or being used on the laboratory bench will help personnel reduce their exposure:

4.2.1 Time  Since accumulated dose is directly proportional to exposure time, the less time one spends around a radiation source, the less radiation exposure one receives.

4.2.2 Distance  The rate of radiation exposure is inversely proportional to the square of the distance from the source. Thus, maintaining more distance from a source of radiation offers increasingly helpful levels of radiation protection.

Employee exposure drops dramatically with increased distance
4.2.3 Shielding
Shielding is a form of protection that requires prior planning and anticipation of safety requirements. Protection from radiation exposure offered by shielding depends on the following:

1. Initial radiation dose rate without shield
2. Material used for shielding
   a) For gamma radiation the higher the atomic number of the material the better it is as a shield.
   b) For high energy beta radiation plexiglass is recommended.
3. Thickness of the shield
4. Type and energy of radiation

4.2.4 Contamination Control
Control of contamination is necessary in order to prevent internal uptake of radioactive material, to prevent the spread of radioactive material through the laboratory and to maintain the integrity of the experiments. Contamination control may be achieved through careful handling and the use of:

1. Personnel Protective Equipment- disposable gloves, laboratory coats, etc.,
2. Absorbent plastic-backed material covering radiation work areas,
3. Use of secondary containment,
4. Surveying of work area upon completion of handling material,
5. Surveying of self upon completion of handling material,
6. Proper disposal of waste material, and
7. Proper storage of radioactive material.

4.3 Radiation Exposure Sources

1. External Sources: These are sources, or radioactive materials, which are not in direct contact with the body, but which may expose an individual to radiation.
2. Internal Sources: These are sources which enter the body. Radioactive materials may enter the body by five routes, namely:
   a. Ingestion with food or drinks, or with other materials which come into contact with the mouth.
   b. Inhalation of radioactive gases and vapors.
   c. Absorption through the skin, or by means of a break in the skin.
   d. Accidental injection with a needle or micropipette.
   e. Cutting the skin with a contaminated sharp such as broken glass.
3. Protection from External Sources: This is established by the use of shields and containers made of lead, or other suitable materials; by use of distance as afforded
by instruments with long handles, remote handling devices, etc; and by reduction of
time spent in the vicinity of radioactive materials, through rapid and careful work.

4. **Protection Against Internal Sources**: This is achieved by preventing the entry of
radioactive materials into the body. Radioactive materials shall not be permitted to
contaminate the skin, nor enter into the body through a break in the skin through the
use of disposable gloves and a lab coat; radioactive gases shall not be released in
the laboratory when a proper use of a hood or traps are employed. No radioactive
materials shall be allowed to enter the mouth by such methods as chewing on a
pencil used to record data during an experiment.

4.4 **Biological Effects of Radiation** If an organism is given a significantly large dose of ionizing
radiation within a relatively short period of time, there will be definite effects due to the irradiation.
For example, a dose of several hundred rads delivered rapidly to the whole body of a mammal
produces the "acute radiation syndrome" with severe illness or possibly death. Exposures of less
than that required to produce the acute radiation syndrome may still produce genetic effects and will
affect growth and development, the incidence of neoplasm, and the life span.

These effects have been observed at doses greatly in excess of those presently recommended by
International, National, and State radiation protection agencies. At the present acceptable levels of
radiation exposure, no cellular changes in mammals can be detected. There is no lower level to the
amount of radiation that can produce gene mutations.

All these aspects of radiation damage were taken into consideration when the National Council on
Radiation Protection and Measurements (NCRP), the unofficial authority on radiation protection,
established recommended maximum permissible dose (MPD) values for different segments of the
population.

There are two objectives in the creation of maximum permissible dose values. The primary
objective in establishing MPD values for a person who works with radiation in his occupation is to
keep their exposure below a level at which adverse effects will occur during his lifetime. Another
objective is to minimize the incidence of non-stochastic effects for the employee. These dose limits
do not include any dose received by an individual as a patient or the dose from natural background
radiation.

It must be emphasized that the risk to individuals exposed to the dose limits for the population is
considered to be very small; however, risk increases with increasing dose. For this reason, it is
desirable to keep radiation exposure as low as achievable with due consideration to medical
objectives, feasibility, and efficiency of operation. For the same reason, small deviations in the
exposure of an individual above prescribed levels are unimportant except as an indication of
adequate protection practices. For more information the Nuclear Regulatory Commission
Regulatory Guide 8.29 "Instruction Concerning Risks from Occupational Radiation Exposure" can
be accessed online at research.uthscsa.edu/safety.

Nuclear Regulatory Commission Regulatory Guide 8.13 "Instruction Concerning Prenatal Radiation
Exposure" can be accessed online at research.uthscsa.edu/safety. Any woman that is of
childbearing age, particularly any woman that is planning a family or is pregnant, should read this.
The Radiation Safety Officer is always available to provide additional information and to assess
the personal work conditions of the declared pregnant worker. Contact the Radiation Safety Office if
you have any questions or to schedule an appointment (567-2955).

4.5 **As Low as Reasonably Achievable (ALARA)** The specific objectives of radiation protection can
be defined as the prevention of clinically significant radiation-induced deterministic effects and the
limitation of stochastic effects (cancer and genetic effects) to what has been deemed a reasonable
level. In this context, the ALARA philosophy can be defined as making every reasonable effort to maintain radiation doses to individuals and the general public below regulatory dose limits, while taking into account social, economical, practical and public policy considerations. The regulated dose limits for stochastic effects are not based on a threshold value, but instead on what constitutes an acceptable risk to individuals and the public. It is therefore reasonable to minimize the risk that can be presumed to exist even at levels below the regulatory dose limits.

The current system of radiological protection reflected in the National Council on Radiation Protection and Measurements (NCRP) Report No. 116, “Limitation of Exposure to Ionizing Radiation” is based on three general criteria:

1. **Justification** – the need to justify any activity which involves radiation exposure on the basis that the expected benefits to society exceed the overall societal cost.
2. **Optimization** - the need to ensure that the benefits of such justifiable activities or practices is maximized for the minimum associated societal detriment
3. **Limitation** – the need to employ individual dose limits to ensure that the procedures of justification and optimization do not result in individuals or groups of individuals exceeding levels of acceptable risk

Monitoring the radiation dose received by individuals through the use of personnel dosimeters allows radioactive material work techniques to be consistently monitored over a given work period. ALARA dose limits implemented for individual monitoring periods allow for the evaluation and potential modification of radiation use practices before a substantial accumulated dose can be received by the individual over a longer period of time. Individuals receiving radiation doses above the ALARA limits (as outlined in Table 4.1) for the monitoring period will be contacted by Radiation Safety and an evaluation of potential causes of the dose received will be performed.

<table>
<thead>
<tr>
<th>Monitor</th>
<th>Monthly Dose Limit</th>
<th>Bi-Monthly Dose Limit</th>
<th>Quarterly Dose Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Area Monitor</td>
<td>0.008 rem</td>
<td>0.016 rem</td>
<td>0.025 rem</td>
</tr>
<tr>
<td>Whole Body</td>
<td>0.4 rem</td>
<td>0.8 rem</td>
<td>1.25 rem</td>
</tr>
<tr>
<td>Extremity</td>
<td>4.0 rem</td>
<td>8.0 rem</td>
<td>12.5 rem</td>
</tr>
</tbody>
</table>

4.6 Airborne Releases of Radioactive Material Prior to using gaseous radionuclides, special approval must be obtained from the Radiation Safety Committee and the Environmental Health & Safety Office. This special approval is not necessary for releases occurring from volatilization, heating, spraying, etc. Prior to approval, the Authorized User must supply procedures to the Environmental Health & Safety office which identifies:

A. Measures to ensure compliance with 25 TAC 289.202 (ggg)(2).
B. A method for reporting all pertinent disposal information (example: radionuclide, activity concentration, chemical form, and date) to the Environmental Health & Safety Office.
C. Procedures for controlling doses resulting from airborne contamination including directional airflow, respiratory protection, and emergency response.
5.0 TRAINING REQUIREMENTS

5.1 Background
Personnel handling radioactive material under the principal investigator must satisfy one of the following three criteria. The principal investigator must take responsibility for ensuring their personnel meet training requirements and have on-the-job training.

Training Requirements: All personnel using radioactive material at UTHSCSA in research laboratories must meet the following training requirements:

1. Successfully complete the Fundamentals of Laboratory Radiation Safety, Section 5.3; or
2. Advanced Radiation Safety Course; or
3. Completion of a radiation safety course at another University with documented evidence. (The course content must be equivalent to that shown in section 5.3; or
4. Demonstrate proficiency in radiation protection principles by passing a written exam administered by the Radiation Safety Office which covers contents of the course; or
5. An equivalent combination of these options with approval of the Radiation Safety Officer.

5.2 Basic Radiation Safety Awareness Training

**Intended Audience:** Ancillary Personnel/Laboratory Workers  **Duration:** 1 hour
New personnel of the Health Science Center who will be using radioactive material or will be working in a laboratory using radioactive material, and have never worked with radioactive material will be required to attend a one hour (1 hr.) basic radiation safety awareness training. This course must be completed prior to handling radioactive material under the supervision of their principal investigator or in upon start of employment for ancillary personnel within a radioactive laboratory. The Basic Radiation Safety Awareness training will be offered as a web-based course. For specific details, contact the Radiation Safety Office.

5.3 Fundamentals of Laboratory Radiation Safety

**Intended Audience:** Laboratory Worker/P.I.  **Duration:** 9 hours
Laboratory workers using radioactive materials for non-human use are required to take a radiation safety training course covering the following concepts:

1. General information on radioactivity
2. Biological effects of radiation
3. Radiation units
4. Dose limits and proper use of personnel monitors
5. Declared pregnant workers
6. UTHSCSA policies
   a. Security
   b. Radioisotope package ordering and receipt
   c. Storage and use of radioisotopes
   d. Postings and signs
   e. Emergency response
7. Radioactive waste management
8. Laboratory safety rules and contamination surveys
9. Individual radioisotope characteristics and handling precautions.
10. Radiation detection and measurement
The Nine Hour Laboratory Worker Course will be comprised of a comprehensive bundle of web-based modules with an examination at the completion of the modules and a one hour hands-on course on radiation detection given by the Radiation Safety Office offered once a week.

5.4 Advanced Radiation Safety Training Course

**Intended Audience:** Human Use Principal Investigators  **Duration:** 15 hours

The advanced radiation safety course is designed primarily for the principal investigators. Investigators participating in human use protocols and graduate students. This course is offered as a semester long lunch seminar course given by the Director of Environmental Health & Safety through the Radiological Sciences program. It offers the students a wide spectrum of topics including those in the nine hour laboratory worker course plus additional topics related to human use of radioactive material. These topics include:

1. Internal dosimetry
2. Radiation detection and instrumentation
3. Regulatory components of a radiation safety program
4. In depth laboratory requirements
5. Hands-on clinical training experience

There are options to help comply with the course requirements:

1. Successfully complete the Fundamentals of Laboratory Radiation Safety and additional modules listed in Section 5.4; or
2. Successfully complete the lunch seminar offered by Radiological Sciences (currently RADI 5001); or
3. Completion of a radiation safety course at another institution with proper documentation; or
4. Demonstrate proficiency in human use radiation protection principles by passing a written exam administered by the Radiation Safety Office which covers the content of the course; or
5. An equivalent combination of these options with approval of the Radiation Safety Officer.

5.5 Refresher Radiation Safety Training

Periodic updates on radiation safety will be conveyed to authorized users deemed necessary by new regulations, incidents, or radiation protection program changes. The schedule or frequency for any refresher training will be based on the risk and approved by the Radiation Safety Committee.
6.0 RADIOISOTOPE PACKAGES

6.1 Process to Order Radioisotopes

How To Send Pending Hazardous Material Requisitions

1. Which Items Require Approval from EH&S Prior to Purchase?
   a. High Powered Lasers (Class 3b and 4)
   b. Select Biological Agents and Toxins
   c. Extremely Toxic Chemicals/ Military Agents
   d. X-ray Machines
   e. Radioactive Materials

2. When you Add A Requisition that is radioactive, make sure to:
   a. Check the box marked “Radioactive/Hazardous” on the Requisition Defaults page.
   b. Include Necessary Information: P.I. Name (Dr. John Doe), Isotope (P-32), Compound (ATP), Amount of Activity (.250 mCi), Vendor (Perkinelmer), Catalog Number (BLU-513H) Room Number (1.343T), Contact Person (Jane Doe) and Phone Number (7-5555).

3. EH&S Process of Approving Requisitions
   a. An email is sent to EH&S as notification that there is a pending requisition needing approval.
   b. Requisitions will be approved the day submitted if it is in by 3:30 p.m., and if all necessary information is provided. If information is incomplete, then you will receive a phone call from EH&S.
   c. After approving the requested hazardous materials, it is immediately sent to Purchasing for disposition.

If You Have Questions Please Contact EH&S: By Phone: 567-2955 or By Visiting: 1.343T DTL

Example of Radioactive Requisition in PeopleSoft

As a reminder, to obtain approval by Safety, the Principal Investigator requesting the Radioactive Material must be within the licensee set limits given by the Radiation Safety Committee.
Create Requisition

Specify and Modify requisition name, requester, and other information that applies to the entire requisition.

- Requester: SULLIVAN
- Requisition Name: Sample
- Origin: ONL
- Requisition Type: BASIC REQUISITION
- Priority: Medium
- Vendor ID: 003003600
- Project: 121593
- Ship To: MAIN
- Fiscal Year: 2011
- Due Date: 12/03/2010
- Radioactive Hazardous

Contact Information
- Contact Name:
- Contact Phone:
- Contact Email:
- Same As Contact
- Deliver To:
- Deliver Name:
- Deliver Phone:

Create Requisition

Add lines to the requisition, specifying the information necessary to procure each item or service.

Special Item
- Item Description: Alpha P-32 DCTP
- Price: $100
- Quantity: 1.0000
- Category: PRENC
- Unit of Measure: MCI
- Vendor ID: 000003600
- Vendor Item ID:
- Due Date: 12/03/2010

Additional Information

Add Item  Cancel
6.2 Receipt of Radioisotopes
   After accepting the package from Receiving, each package is processed by Radiation Safety. This is a seven step process:

   1. Meter survey of the package for contamination and exposure level.
   2. Wipe test survey of package for removable contamination.
   3. Check package for correct isotope, compound, and activity.
   4. Input of package into EH&S Onsite System.
   5. Delivery of package to Principal Investigator.
   6. Signature on receipt and receiving paperwork.
   7. General receiving paperwork returned.

Above is an example of how the package is surveyed by a meter and wipe tested for contamination.

If levels are above 22 dpm/cm², the package is reported to the Department of Transportation within three hours of receipt in order to meet regulatory requirements. Once wipe tested and checked with the appropriate meter, the package data is entered into our EH&S Onsite System. The package is then delivered to the authorized laboratory for that Principal Investigator. The following is a copy of the receipt form that must be signed by one of the laboratory personnel.
6.3 Inventory of Radioisotopes
Each laboratory must keep an accurate inventory of all radioactive material within the laboratory. The Radiation Safety Division maintains a separate inventory of radioactive material and will need the laboratory personnel/Principal Investigator to verify the inventory during the laboratory safety evaluation. Periodically, the Radiation Safety Office will send out an inventory for verification.

6.4 Transfer of Radioisotopes
Transfer forms may be obtained at the Radiation Safety Office. The Radiation Safety Office working in conjunction with Central Receiving will prepare shipments of radioactive material via commercial transportation.

1. On Campus Transfers: Radioactive material is not to be transferred from one investigator to another without the approval and authorization of the Radiation Safety Office, since approval for use of radioactive materials is given only for the original working area and the original investigator.

2. Off Campus Transfers: Radioactive material shall not be shipped or transferred to an outside facility from any UT Health Science Center facility without the approval of the Radiation Safety office.

3. Cyclotron Transfers: Radioactive material may be transferred from the cyclotrons located on License L05217 through the use of a specific transfer form approved by TDSHS. The radioactive material is transferred for research uses to the Broad Scope license.

6.5 Disposal of Radioisotopes
All radioisotopes must be disposed of properly according to the Waste Management Guidelines provided in Chapter 12 of this Handbook. All waste must be recorded on the disposal form given to
the Principal Investigator at the time of the receipt of the package. Here is an example of a completely filled out Radioactive Material Receipt and Disposal Form:

![Radioactive Material Receipt and Disposal Form](image)

This disposal form shall be returned to the Radiation Safety Office upon completion by the laboratory personnel with a signature.

### 6.6 Shipment of Radioactive Material

All shipments of radioactive materials must be approved by the Radiation Safety Division. Shipment of any radioactive materials to an outside institution requires verification that the other institution has a license to receive the materials. In addition, the shipper must be trained in accordance with the US Department of Transportation (DOT) regulations. The Radiation Safety Division will be the responsible shipper for the materials. All regulated radioactive materials and devices will be shipped from the Health Science Center in accordance with DOT regulations and Health Science Center policy:

- Licensed radioactive materials must not be removed from the Health Science Center without specific approval from the Radiation Safety Division.
- Each package must be transported or shipped from the Health Science Center will be inspected for safety and compliance with transport regulations by the Radiation Safety Division. Adverse or non-compliant shipping events must follow the appropriate regulatory reporting.
- All costs for inspection and transport or shipping will be assessed to the originating department.
- Failure to follow appropriate procedures will result in delay of delivery and possible additional costs.

Inspection and transport/shipping records will be maintained by the Radiation Safety Division at an interval dictated by the DOT and other pertinent regulations.
7.0 SECURITY OF RADIOACTIVE MATERIAL

7.1 Background All radioactive material at the University of Texas Health Science Center at San Antonio facilities must be used or stored in a manner which will provide adequate security and prevent unauthorized use or removal while promoting the beneficial utilization of these research tools. Radioactive material use in the laboratory may be kept secure by keeping the material under supervision, having the ability to lock the storage container such as a freezer or a plastic box within the laboratory, or by keeping the laboratory door locked when personnel are not present. Any radioactive material stored in a freezer or refrigerator in the hallway is to be kept locked at all times. The storage unit is to be opened only when placing items in the unit or when removing items from the unit. Do not allow any unknown individual to use, handle, take, or store radioactive material in your laboratory. Contact your supervisor if you do not know an individual; or, contact University Police and report the occurrence.

7.2 Laboratory
The laboratory shall be locked when no one is in the lab. If you leave the laboratory to go down the hallway, make sure you can challenge anyone who enters the laboratory. In other words, question why they need to be in your laboratory. This meets the security requirements for radioactive material usage within the laboratory.

7.3 Hallway Refrigerators/Freezers
All hallway refrigerators/freezers must follow these guidelines:

1. Needs to be approved by Physical Safety prior to placement in the hallway.
2. Needs to be marked with a no food and drink contains radioactive material label
3. Needs to have the name of the contact in charge and phone number in the event of an emergency or operation failure.
4. Needs to be locked at all times when marked with radioactive material label.
5. Radiation levels must be indistinguishable from background at the surface of the refrigerator/freezer.

7.4 Sealed Sources
The non-exempt sealed sources must be kept under lock and key. All of the radioisotope sealed sources shall be stored in a safe location such as a source locker. The irradiators and teletherapy units that contain sealed sources will be kept secure through the use of access control devices. These devices will only allow authorized individuals determined to be trustworthy and reliable to enter the area of the unit. The access control devices will monitor and log entrance into the room housing the irradiator.

If at any time you believe that there has been a breach of security in regards to radioisotopes or sealed sources, please contact the University Police at 567-2800 and the Radiation Safety Office immediately.

7.5 Radioactive Security Incident Procedures
The following procedures shall be followed in the event of any security incident:

1. Call Radiation Safety during normal working hours or UT Police after hours
2. Report the location
3. Report any injuries
4. Report any radioactive material involved
5. Give contact information
6. Report what was seen

The Radiation Safety Office and UT Police will follow up on any reported security incidents.
8.0 LABORATORY PROCEDURES

8.1 Posting Requirements
Laboratory areas shall have the following items visibly posted and available to all employees in the laboratory:

1. "Notice to Employees" form
2. Emergency telephone numbers for incidents involving radioactive materials.
3. The location of the license, regulations, inspection reports, etc. may be found.
4. A copy of the UTHSCSA Radiation Safety Handbook will be kept in the primary approved laboratory for each investigator and made available to all persons working in the laboratory.

8.2 Locations of Use of Radioactive Material
Radioactive materials are to be used only in those facilities approved by the Radiation Safety Committee. Investigators wishing to expand their areas approved for radioactive materials or investigators moving to new locations must follow the procedures for amending their authorization per Chapter 2.

8.3 Survey Methods

8.3.1 Radioactive Material Contamination Surveys
Radioactive Material contamination surveys must be performed prior to and after working with radioisotopes within the laboratory to ensure the absence of radioactive material contamination. A Geiger Muller (G-M) detector can be used for performing contamination surveys when working with most laboratory radioactive materials except $^3$H (which requires wipe tests). If possible, a thin-window NaI detector shall be used for detecting low-energy gamma radiation (i.e. $^{125}$I).

Post-work Contamination Surveys
When using a survey meter, it is important to perform a battery check and function check (using a check source, if possible) to verify the meter is working properly. Upon completion of work with the radioisotope, a contamination survey shall be performed on the work surface, personal protective equipment (i.e. lab coat), and surrounding areas and equipment. Hands and the bottom of shoes shall also be checked to ensure no contamination can be spread to surrounding areas. If the contamination survey indicates the presence of radiation contamination in an area, a wipe test shall be performed on the area and decontamination performed until the removable activity is less than 1000 dpm/100cm².

8.3.2 Wipe Tests

8.3.2.1 Active Use
Laboratory areas shall be periodically surveyed for removable contamination during the time period radioisotopes are in use. Table 8.1 shows the frequency that contamination surveys must be performed:

<table>
<thead>
<tr>
<th>Radioisotope Characteristics</th>
<th>Frequency of Survey</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tritium, low-energy beta emitters $&lt; 100$ mCi per protocol</td>
<td>Weekly</td>
</tr>
<tr>
<td>High-energy beta emitters (i.e. $^{32}$P, $^{86}$Rb) $&lt; 100$ mCi per protocol</td>
<td>Weekly</td>
</tr>
</tbody>
</table>
Contamination surveys will be performed using swipe or wipe tests and counted in the appropriate counter. Below is an example of a liquid scintillation counter used to analyze wipe test samples:

The liquid scintillation counter (LSC) shall have an efficiency performed on it annually for each isotope used in the department (see Chapter 11 for procedure to calculate LSC efficiencies). Radiation Safety is available to perform efficiency calculations for LSCs upon request. The efficiency calculated is then used to calculate the wipe test results using the following formula:

\[
\text{Removable Activity (DPM)} = \frac{(CPM - \text{Background Count Rate})}{\text{Efficiency}}
\]

The removable activity limit for any area is one thousand disintegrations per minute per one hundred square centimeters (\(< 1000 \text{ dpm/100 cm}^2\)). Any area with removable contamination higher than 1000 dpm/100cm\(^2\) is considered contaminated and must be decontaminated and rewiped. Subsequent wipe test results shall be recorded to document the decontamination survey. The results of all contamination survey wipe tests and follow-up surveys shall be kept for three years after the date of completion for inspection. These should be stored in the Radiation Handbook binder or in a binder directly next to the handbook.

8.3.2.2 Storage Only If radioisotopes have not been actively used during the frequency period given in Table 8.1 but have been stored a wipe test of the refrigerator/storage area must be performed.

8.3.2.3 No Radioactive Materials Used or Stored If no radioisotopes have been used or stored in the laboratory Weekly Wipe Test Action log found in Appendix A must be filled out. Please keep the Action log in the same binder as the Radiation Handbook or a binder directly next to the Handbook.

8.4 Laboratory Labeling Requirements
1. Work areas for radioactive materials shall be marked with the work area sticker.
2. Label refrigerators, freezers, and fume hoods where radioisotopes are stored.
3. All secondary containers for radioactive materials must be labeled.
4. Waste containers and areas must be labeled.
5. Equipment used in conjunction with radioisotopes shall be labeled.
6. See Chapter 12 for more information.

8.5 Work Area Requirements

1. Work areas for radioactive materials will be covered with absorbent, plastic-backed paper (diaper pads).

2. Shielding appropriate to the radioisotope shall be used when warranted by the hazard.

3. Radioisotopes are to be stored in a secure manner. Material stored in a refrigerator or freezer in a hallway must be equipped with a locking device and must be kept locked even during normal working hours.

4. Liquid containers particularly for waste will be kept in a secondary container such as a plastic tub. The secondary container shall be large enough to hold the amount of liquid in the waste container.
5. The liquid waste container shall remain capped when not in use. Please remove funnel and cap the container when not in use.

6. No consumption of food and beverage, smoking or applying cosmetics is allowed in a laboratory utilizing or storing radioactive material.

8.6 Permissible Radiation Levels in Laboratory Areas

Table 8.2

<table>
<thead>
<tr>
<th>Location</th>
<th>Permissible Radiation Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory Area</td>
<td>&lt; 2mR/hr</td>
</tr>
<tr>
<td>Laboratory Apparel i.e. clothes, apron, gloves, etc.</td>
<td>&lt; twice background</td>
</tr>
<tr>
<td>Glassware</td>
<td>&lt; twice background</td>
</tr>
<tr>
<td>Surfaces i.e. tabletops, walls, floors, sinks, drains, etc.</td>
<td>&lt; 1000 dpm/100cm²</td>
</tr>
<tr>
<td>Sealed Source Removable Contamination Leak Testing</td>
<td>≤ 0.005 µCi</td>
</tr>
</tbody>
</table>

8.7 Utilization of Animals

Inform the Radiation Safety Officer of the intended use of radioactive material in animals and apply for the necessary authorization. Ensure the use of a specific radioisotope may be disposed and not require long-term storage. Special precautions are to be followed, when laboratory animals are injected with or ingest radioactive materials

1. Animals are to be housed in such a manner as to contain any radioactive material that is voided. Bedding, urine, and feces are to be collected and checked for contamination.
2. Cages are to be labeled with a radioactive sticker and be identified with the radioisotope and activity.

The Principal Investigator is responsible for the following:

1. Amending Radioisotope Authorization to include each Institutional Animal Care and Use Committee (IACUC) Protocol involving the use of radioisotopes.
2. Conforming with all Laboratory Animal Resource and IACUC regulations regarding use and housing of animals.
3. Notifying Laboratory Animal Resources that animals containing radioisotopes will be housed in LAR facilities prior to placement of animals.
4. Notifying the Radiation Safety Office that animals containing radioisotopes will be maintained in LAR, and furnishing additional information as requested, i.e. animal usage form.
5. Ensure cages are decontaminated before they are turned over to LAR personnel for cleaning.
6. Dispose of the carcass and bedding in accordance with the radioactive waste program.

8.8 General Rules of Conduct

1. The use of a radiation detection device (survey meter) shall be available to the laboratory personnel. The survey meter is to be used to monitor the work area and an individual after using radioactive material before the individual leaves the area.
2. Absorbent paper shall cover workbenches, trays, and other work surfaces where radioactive materials are handled.
3. The laboratory shall be kept clean and orderly at all times.
4. Avoid carelessness in handling radioactive materials. Do not splash, splatter, or spill radioactive liquid.
5. Always handle volatile material or potentially airborne radioactive material in appropriate fume hood.
6. Notify the Radiation Safety Division (567-2955) immediately in the event of a spill or an accident.
7. Disposable gloves shall be worn while working with radioactive solutions, when hand contamination is deemed possible.
8. All laboratory personnel working with radioactive material must wear some type of outer-garment to prevent contamination of personal clothing. Change laboratory coat if the survey meter reading is twice background. Never wear a contaminated coat. Only wear the coat when detected levels are at background levels.
9. Pipetting by mouth is prohibited. Use mechanical pipetters.
10. Every bottle, flask, tube, etc., which contains radioactive material shall be identified by a proper radiation warning label.
11. When storing radioactive material, always cover or stopper the container.
12. Bottles, flasks, beakers, and other vessels which contain more than 100 microcuries of activity shall not be picked up by hand for more than a few seconds; for longer periods of time, tongs or forceps shall be used, whenever practical.
13. Glassware containing radioactive material is never to be turned in to a central washroom, unless it has been decontaminated first.
14. All radioactive waste and contaminated material must be placed in receptacles especially marked for radioactive material storage.
15. When a procedure is completed -- before leaving the lab, thoroughly wash hands and monitor for radioactive contamination.
16. Decontamination of the hands is not easy and may require repeated washings. Wash hands over the sink in full stream of water; use cool water, non-abrasive soap, and a soft surgical scrub-brush, taking care to not abrade the skin.
17. No food or beverage is to be stored in the same refrigerator or freezer as radioactive material.
18. No eating, drinking, smoking, or applying of cosmetics is allowed in a laboratory using or storing radioactive material.
19. The proper radiation caution signs are to be posted in the appropriate areas containing radioactive materials.
20. A “Notice to Employees” sign must be posted in a sufficient number of places so that employees may observe a copy on their way to and from their place of employment.
21. Radioactive materials, which emit penetrating radiation, and whose activity exceeds 500 microcuries, shall be kept behind lead shields or inside of lead-lined vessels. Plastic shielding will be used with high-energy beta emitters, i.e. $^{32}$P.
22. Protective eyewear is to be worn when working on the open bench top with more than 10 millicuries of a beta emitter. It is recommended that the eyewear be worn anytime > 1 millicurie of a beta emitter is to be used on the bench top.
23. Radioactive material is to be stored and kept in a secured manner. Security procedures are outlined in Chapter 7.
24. Do not block the path to an electrical panel in the laboratory with the radioactive material work area.
25. Turn off the vacuum flask in the radioactive material work area when not in use.

8.9 Availability of Personal Protective Equipment   A variety of personal protective equipment (PPE) is available which when correctly used helps protect laboratory workers from hazards in the work environment. PPE must be provided by the responsible supervisor/Principal Investigator. At a
minimum, all employees who work with radioactive materials in any laboratory at UTHSCSA are required to wear the following:

a) Closed toe shoes (no sandals)
b) Long pants or skirts below knee (no shorts)
c) Lab coat, apron or gown
d) Safety glasses
e) Gloves (latex, nitrile, vinyl, or other appropriate gloves)

Additional PPE may be necessary, depending on the procedures and exposure risks involved. It is the responsibility of each worker to wear the appropriate PPE when necessary and to talk with your supervisor if questions arise regarding additional PPE that may be needed. Environmental Health & Safety will perform exposure assessments as a means to determine additional PPE requirements.
9.0 POSTINGS AND LABELING

9.1 Background
All laboratories containing radioactive material or x-ray producing devices shall be labeled as such. Each piece of equipment in the laboratory shall be labeled with the appropriate hazard. **All clinical facilities utilizing radioactive materials or sources shall be labeled as such.** All postings shall be done by radiation safety personnel and if the appropriate stickers or postings are not found in the laboratory then Radiation Safety shall be contacted.

9.2 Radioactive Material Use

9.2.1 Laboratory Entry Posting: The outside of the laboratory shall be labeled with the posting shown below. This is to notify those entering the laboratory that radioactive material is present and to take the necessary protective actions. This posting will also contain emergency contact information for that lab in case there were ever an incident involving this lab, University Police and/or Environmental Health and Safety would know the appropriate person to contact.

![Laboratory Entry Posting](image)

9.2.2 Radioactive Material Work Area: All areas in the laboratory designated for radioactive use must be labeled as a "radioactive work area" with the sticker shown below. This sticker shall be placed over work benches where the experiments will occur.

![Radioactive Material Work Area](image)

9.2.3 Refrigerator Containing Radioactive Material: All refrigerators and freezers containing radioactive material must be labeled with a sticker indicating its contents. If the refrigerator is inside of a laboratory that is capable of being locked, then the following sticker must be applied to the door of that refrigerator:
If the laboratory is not capable of being locked or the refrigerator is in the hallway then
the refrigerator must remain locked and the following sticker must be placed on the door
of the refrigerator with current contact information:

9.2.4 Emergency Numbers: In case of a radioactive material spill or other emergency in the
laboratory the lab workers shall call Radiation Safety at (210) 567-2955 during normal
business hours and contact University Police during any other time. There shall be a
sticker near the phone in the laboratory stating this, an example sticker is shown below:
9.2.5 Notice to Employees: The Texas Department of State Health Services Notice to Employees must be posted in every laboratory containing radioactive materials.

9.2.6 Supplemental Information: Supplemental Information including regulations, licenses, and notices of violations are posted with the Texas Department of State Health Services Notice to Employees. An example is pictured below:

9.2.7 Radioactive Waste Areas: This is to notify lab personnel, Environmental Health and Safety and other Health Science Center employees of the location of the radioactive waste. Radioactive waste areas shall be labeled with the following sticker:
9.2.8 **Radioactive Waste Containers:** Radioactive waste containers shall be tagged with the information shown below issued by Radiation Safety. This tag shall include information about the contents of the waste container such as isotope and activity. An example waste tag includes:

![Radioactive Waste Tag](image)

9.2.9 **No Food or Drink:** Absolutely no food or drink shall be in a laboratory that uses radioactive materials. There shall be a sign in the laboratory stating this requirement. Two acceptable posting used by Radiation Safety are shown below:
9.2.10 Equipment Clearance Label  All equipment must be cleared and labeled for the following:

1. Equipment that will be going into surplus
2. Equipment that is being moved out of the lab
3. Any equipment that is in need of repair

An example of the equipment clearance label is shown below:

University of Texas Health Science Center at San Antonio

Equipment Clearance Notice

This unit has been cleared by Environmental Health & Safety for the following hazards:

☐ Chemical
☐ Biological
☐ Radiological

Clearance Valid Until ________ for:

Moving, Service/Repair
Surplus/Warehouse

Questions? Contact Environmental Health and Safety at 7-2955
9.2.11 **Caution Radiation Area** All facilities that could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates. Example: PET Scanning suites

![Caution Radiation Area Sign](image)

9.2.12 **Restricted Area** An area where access is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. These areas have specific license restrictions and personnel monitoring with limited access for necessary and approved personnel. Any facility that has specific license restrictions will be labeled with restricted area signs. Example: PET Facility Suites

![Restricted Area Sign](image)

9.3 **Radioactive Material Labeling** All containers holding licensed material in greater quantities than Table 9.1 shall be labeled appropriately using the caution radioactive material label and symbol.

**Table 9.1**

<table>
<thead>
<tr>
<th>Radionuclide</th>
<th>Quantity (µCi)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrogen-3</td>
<td>1000</td>
</tr>
<tr>
<td>Carbon-11</td>
<td>1000</td>
</tr>
<tr>
<td>Carbon-14</td>
<td>1000</td>
</tr>
<tr>
<td>Fluorine-18</td>
<td>1000</td>
</tr>
<tr>
<td>Sodium-22</td>
<td>10</td>
</tr>
<tr>
<td>Phosphorus-32</td>
<td>10</td>
</tr>
<tr>
<td>Phosphorus-33</td>
<td>100</td>
</tr>
<tr>
<td>Element</td>
<td>Concentration</td>
</tr>
<tr>
<td>------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Sulfur-35</td>
<td>100</td>
</tr>
<tr>
<td>Chlorine-36</td>
<td>10</td>
</tr>
<tr>
<td>Calcium-45</td>
<td>100</td>
</tr>
<tr>
<td>Iron-59</td>
<td>10</td>
</tr>
<tr>
<td>Cobalt-56</td>
<td>10</td>
</tr>
<tr>
<td>Cobalt-57</td>
<td>100</td>
</tr>
<tr>
<td>Cobalt-60</td>
<td>1</td>
</tr>
<tr>
<td>Nickel-63</td>
<td>100</td>
</tr>
<tr>
<td>Copper-64</td>
<td>1000</td>
</tr>
<tr>
<td>Zinc-72</td>
<td>100</td>
</tr>
<tr>
<td>Germanium-68</td>
<td>10</td>
</tr>
<tr>
<td>Strontium-90</td>
<td>0.1</td>
</tr>
<tr>
<td>Yttrium-90</td>
<td>10</td>
</tr>
<tr>
<td>Technitium-99m</td>
<td>1000</td>
</tr>
<tr>
<td>Indium-111</td>
<td>100</td>
</tr>
<tr>
<td>Iodine-131</td>
<td>1</td>
</tr>
<tr>
<td>Xenon-133</td>
<td>1000</td>
</tr>
<tr>
<td>Cesium-137</td>
<td>10</td>
</tr>
<tr>
<td>Iodine-124</td>
<td>10</td>
</tr>
<tr>
<td>Iodine-125</td>
<td>1</td>
</tr>
<tr>
<td>Rhenium-186</td>
<td>100</td>
</tr>
</tbody>
</table>

For any additional nuclides that become authorized as an amendment to our Radioactive Material License or not listed above, please refer to 25TAC §289.202(ggg)(3).
10.0 LABORATORY SAFETY EVALUATIONS

10.1 Background
Laboratory safety evaluations of all authorized laboratories are performed by the Radiation Safety Division on a semi-annual basis. These evaluations are intended to assist the laboratory personnel in maintaining radiation doses as low as reasonably achievable. The evaluations cover a wide spectrum of issues pertaining to safe work with radioactive materials.

10.2 Laboratory Evaluation Record Report
The laboratory evaluation record report is stored within the EH&S Onsite Database and a copy is maintained within the Radiation Safety Division records until the termination of the Principal Investigator. A letter is furnished to the Principal Investigator stating any deficiencies observed during the evaluation.

10.3 Requirements for Evaluations
The Radiation Safety Laboratory Evaluation report is completed by the Safety Specialists in the Radiation Safety Division. A copy of this evaluation profile can be found in Appendix A of this Handbook. The following are some of the radiation safety parameters observed during the laboratory safety evaluation.

1. Laboratory Contamination Surveys performed by laboratory
2. Evidence of RAM security
3. No food or drink
4. Proper postings
5. Ambient radiation level survey
6. Handbook and Notices posted
7. Prudent radioactive waste management
8. Shielding
9. Training Records
10. Proper PPE within the laboratory

10.4 Follow-Up Procedures
Refer to follow up procedures for items of non-compliance or deficiency noted during a laboratory evaluation, an inspection, or a walk through as outlined in Section 1.4.

10.5 Enhanced Frequency
Environmental Health & Safety may alter the frequency of laboratory safety evaluations stated in Section 10.1 if warranted by the number or severity of identified safety deficiencies.
11.0 INSTRUMENTS AND CALibrATIONS

11.1 Portable Radiation Detectors The use of radiation survey meters is an important component of ensuring contamination is not present on work surface and equipment in the laboratory. All radiation survey meters in an approved radioactive material laboratory must be in an operating condition with functioning batteries unless tagged inoperable. Three main types of radiation detectors from a variety of manufacturers are used in laboratories at the Health Science Center. Several examples of the survey meters and detector types are shown below:

Geiger-Muller (G-M) Detectors:
   a. Sensitive to low fluence fields of alpha, beta, and gamma radiation
   b. Examples of common GM detectors:

Thin Window Sodium Iodide (NaI) Detectors:
   - Higher detection efficiency of low-energy gamma radiation (i.e. $^{125}\text{I}$) than G-M detectors

Pressurized Ionization Chambers (PICs):
   - Measure exposure and exposure rate from high fluence x-ray and gamma radiation fields

11.1.1 Calibration of Radiation Survey Instruments Portable survey instruments must be calibrated annually by either the Radiation Safety Office or by an outside company.
Calibrations performed by the Radiation Safety Office use either a pulser or a source. Additional tests performed during the calibration process include a battery check, voltage check and response check. An estimate of the detection efficiency for common radioisotopes used in the laboratory is also calculated using check sources. Meters shall be delivered to the Radiation Safety Lab prior to the calibration due date. The following is an example of the calibration sticker placed on the survey meter once it has been calibrated by the Radiation Safety Division:

<table>
<thead>
<tr>
<th>SURVEY METER CALIBRATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Texas Health Science Center at San Antonio</td>
</tr>
<tr>
<td>Manuf/Model: _____________  Serial No: ______________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Scale</th>
<th>within +/- 10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>x0.1</td>
<td></td>
</tr>
<tr>
<td>x1</td>
<td></td>
</tr>
<tr>
<td>x10</td>
<td></td>
</tr>
<tr>
<td>x100</td>
<td></td>
</tr>
<tr>
<td>x1000</td>
<td></td>
</tr>
</tbody>
</table>

Calibrated by: __________________          Date: ___________
Cal. Due: ___________

11.1.2 Broken Survey Meters  If a survey meter is found in need of repair, Radiation Safety must be notified and the meter placed out of service. Do not use an inoperable survey meter to ascertain radiation levels. It is the responsibility of the laboratory to have the meter repaired before it is brought back into use. Once the meter has been repaired, Radiation Safety shall be notified and the meter shall be calibrated before being placed back into service.

11.2 Performing Liquid Scintillation Counter Efficiencies  A scintillation standard with a known activity of the radioisotope is required to perform an efficiency calculation. Below are examples of scintillation standards used in a Beckman LS6500 liquid scintillation counter:

To perform an LSC efficiency, perform a 10-minute count on the scintillation standard and background standard using the channel corresponding to the emission energy measured. The detection efficiency for the isotope can then be calculated using the following equation:

\[
\text{Isotope Efficiency} \%(\%) = \frac{(\text{CPM} - \text{Background Count Rate})}{\text{Current Activity of Standard} \cdot \text{(DPM)}} \cdot 100
\]
12.0 RADIOACTIVE WASTE MANAGEMENT

12.1 Background  The disposal of radioactive waste presents a very real management challenge to the University. The waste disposal program has been established to ensure the proper disposal of radioactive waste and also minimize its bulk. The program instructions will change from time to time in order to accommodate waste site regulations and new regulations from the Texas Commission on Environmental Quality and the Environmental Protection Agency. The waste program instructions are available at all times in the Radiation Safety Office (1.343T DTL) or in the Radiation Safety Laboratory (116C).

Waste will usually be picked up and containers exchanged every Wednesday from laboratories on main campus that have requested pickups prior to Tuesday at 5:00 P.M. To request a pickup, exchange, or delivery of additional containers, please go to the EH&S Website, http://research.uthscsa.edu/safety and click on the icon entitled Radioactive Waste Pickup to obtain the form. Off-campus sites shall request a waste exchange/pickup by using the same website form; however, this exchange/pickup will be accomplished on a different day of the week.

It is the responsibility of each Principal Investigator to ensure the preparation for disposal of all radioactive material under his authorization.

12.2 Liquid Scintillation Vial Waste

1. Liquid scintillation vials will be placed in the provided 10 gallon liquid scintillation white trash cans as shown below:

2. Radioisotopes must be separated by half-life and placed in separate containers. The container must be labeled with the radioisotope information at the start of waste collection.
3. The container must contain only scintillation vials and no solid waste or other liquid waste.
4. Close all vial lids tightly.
5. Complete the full label before pick up.
6. Glass and plastic scintillation vials can go into the same container.
7. All radiation symbols must be completely obliterated before the vials are placed in the container.
12.3 Solid Radioactive Waste

1. Special waste containers for dry waste are to be available in all laboratories. These containers are 10 gallon white trash cans as seen below:

2. No liquid scintillation vials or liquids of any kind can be put in the solid waste container.
3. No lead shall be discarded in these containers.
4. Radioisotopes must be separated by half-life and placed in separate containers. The container must be labeled with radioisotope information at the start of collection of waste.
5. Needles and syringes shall be placed in special sharps containers provided by the Environmental Protection Division.
6. Do not overfill the container. The liner bag shall be tied or taped closed and the container top securely attached.
7. No biohazard or red bags shall be placed in the designated dry waste containers.
8. Complete the full label for the container before pick up.
9. All radiation symbols must be completely obliterated before the waste is placed in the container.

12.4 Liquid Radioactive Waste

1. Special containers for liquid waste are available as needed in all laboratories. The containers provided are available in one gallon and five gallon sizes.
2. Organic solvents must be collected in separate containers from aqueous based liquids.
3. Radioisotopes must be separated by half-life and placed in separate containers. The container must be labeled with the radioisotope information at the start of collection of waste.
4. No solid waste or scintillation vials shall be inserted into the liquid waste containers.
5. Complete the radioactive waste tag and affix to container before pickup.
6. The liquid waste and primary container must be in a secondary container able to contain the amount of liquid in the container.
7. Do not overfill the container past the fill line.
8. The container must be tightly capped at all times when liquid waste is present.
9. Liquid waste containers cannot be stored under a sink in the laboratory.

12.5 Pathological Radioactive Waste

1. All pathological waste (e.g. carcasses) is to be placed in a freezer provided especially for the disposal of animal tissue and animal waste. Access to the freezer will be only through Radiation Safety.
2. Pathological waste must be double bagged in a heavy gauge plastic bag. Tags issued by Radiation Safety are to be completed and attached to the bags.

12.6 Radioactive Sharps Containers

1. Radioactive Sharps shall be placed in the provided container below:
2. Do not place radioactive sharps within the biohazard sharps container and do not place non-radioactive biohazard sharps in the radioactive sharps container.
3. The label must be filled out to indicate isotope and activity used in conjunction with the sharps.

12.7 Labeling Requirements  All waste containers shall be labeled at all times. This includes while still in the laboratory in the event of a spill. The labels are provided by the Environmental Protection Division with the containers. If the label is not completely filled out, the waste container will not be picked up during the regularly scheduled pickup. The following is an example of a properly filled out label.

12.8 Sealed Sources  Sealed sources must be disposed of through the Radiation Safety Division. Radiation Safety will either return them to the manufacturer or through the utilization of an authorized radioactive waste broker. All documentation for the disposal or return will be kept by Radiation Safety for the required documentation period.
13.0 RADIATION SPILLS AND EMERGENCY RESPONSE

13.1 Reporting a Radiation Spill  Please call 567-2955 and provide the following information to the best of your ability:

1. Location
2. Name
3. Phone Number
4. Area Secured
5. Any injuries
6. Isotope
7. Activity

13.2 Radiation Spill Response and Decontamination Procedures

1. Begin immediately. Confine the spill using paper towels or absorbent pads. Limit personnel in the area to those essential to the decontamination process. Call the Radiation Safety Office, 567-2955 or after hours call UT Police at 567-2800.
2. Determine the extent of radiation hazard. The degree of protection required is dependent upon the amount and nature of the activity involved. Protective clothing, including impermeable gloves, shall be worn for all decontamination work, and impermeable over-shoes shall be used if the material has been spilled on the floor. The contaminated area shall be monitored periodically during the cleaning process with a suitable survey instrument, in order to determine the degree of decontamination being achieved and the radiation hazard remaining.
3. Confine the radioactive solution to as small an area as possible.
4. Draw off or remove the radioactive solution. This may be accomplished with absorbent pads or with an adaptation of the transfer - pipette technique, and will substantially reduce the radiation and retard further contamination of the surface.
5. Keep contaminated area moist. If affected area is permitted to become dry, difficulty of removal of the decontamination becomes ten times greater; it also becomes a more intense source of radiation.
6. Do not use highly alkaline soaps or abrasive material.
7. Leach the contaminated area two or three times with a suitable decontamination agent. The Radiation Safety Office will provide a list of commercial preparations available for this purpose. Clean area from the outside of the spill inward and up. This will usually remove the majority of the contamination.
8. Accomplish remaining decontamination necessary with scrub brush and suitable reagent until monitoring shows that the area is safe or that the contaminated area cannot be cleaned and other protection measures must be initiated. Discard the scrub brush with other radioactive waste.
9. Re-wipe test the area to determine if contamination remains and record the final wipe test results. Area is to be less than 1000 dpm/100 cm².
<table>
<thead>
<tr>
<th>EMERGENCY TYPE</th>
<th>HAZARD</th>
<th>IMMEDIATE ACTIONS</th>
<th>FOLLOW-UP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor Spills (Typically microcurie Amounts)</td>
<td>Radiation: No immediate radiation hazard to personnel. Contamination: Low</td>
<td>1. Notify all persons in the room. 2. Confine spill immediately. 3. Notify Radiation Safety Office or Lab. Ext. 7-2955</td>
<td>Permit no one to work in area until approved by Radiation Safety Office.</td>
</tr>
<tr>
<td>Major Spills (Typically Millicurie Amounts)</td>
<td>Radiation: May be great hazard to personnel Contamination: Great hazard to personnel and equipment.</td>
<td>1. Notify all persons to vacate room or area. 2. Make NO attempt to clean up the spill. 3. Switch off all fans and vacate lab or area. 4. Provide temporary barricade and warning signs. 5. Notify Radiation Safety Office or Lab. Ext. 7-2955.</td>
<td>Decontamination of personnel and equipment, including spill, to be carried out by or under the supervision of the Radiation Safety Office.</td>
</tr>
<tr>
<td>Accidents Involving: • Mist • Fumes • Vapors • Gases</td>
<td>Radiation: Internal hazard from airborne activity. Contamination: Great hazard to personnel and equipment.</td>
<td>1. Notify all persons to vacate room. 2. Provide temporary barrier and warning signs. 3. Notify Radiation Safety Office or Lab. Ext. 7-2955.</td>
<td>Do not re-enter until approved by Radiation Safety Office. O-15 gas specifically requires at least 30 minutes prior to reentry of the room but requires the approval of the Radiation Safety Officer.</td>
</tr>
<tr>
<td>Injuries Involving: • Radiation Hazard • Contamination</td>
<td>Contamination: Wounds usually greatest hazard.</td>
<td>1. Wash wound immediately in running water. 1. Seek Medical Assistance if necessary for wound. 2. Notify Radiation Safety Office or Lab. Ext. 7-2955.</td>
<td>Permit no one involved in accident to return to work until approved by physician or Radiation Safety Office.</td>
</tr>
<tr>
<td>Fires Involving: • Radioactivity</td>
<td>Radiation: Internal hazard from airborne activity. Contamination: Great hazard to personnel and equipment.</td>
<td>1. Notify all persons in room and area at once. 2. Attempt to extinguish fire if radiation hazard is not immediately present. 3. Notify Radiation Safety Office or Lab. Ext. 7-2955.</td>
<td>Emergency activities will be governed by or in cooperation with the Radiation Safety Office.</td>
</tr>
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</table>
14.1 Applications

14.1.1 Radioactive Material License The Health Science Center holds a Broad Scope Medical Radioactive Material License from the Texas Department of State Health Services. The Radiation Safety Officer will submit all correspondence to the licensing agency with regard to the maintenance of and to securing amendments to the University License.

14.1.2 Laser Registrations The Health Science Center holds a laser registration from the Texas Department of State Health Services. The Radiation Safety Officer will submit all correspondence with regard to the maintenance of the laser registration and amending as necessary.

14.1.3 X-ray Registration The Health Science Center holds an x-ray registration from the Texas Department of State Health Services. The Radiation Safety Officer will submit all correspondence with regard to the maintenance of the x-ray registration and amending as necessary.

14.2 Reportable Events The following incidents must be reported to the Radiation Safety Division as soon as possible:

1) Personal Dosimetry greater than 5 Rem
2) Personal Dosimetry greater than 25 Rem
3) Doses in Excess of the Occupational Limit For the Embryo/fetus of a Declared Pregnant Women, for a Minor, for a member of the General Public
4) Loss of Control of a Source
5) Theft of a Source
6) Unplanned Contamination Event
7) Leaking Sealed Sources
8) Unplanned Medical Treatment
9) Medical Event
10) Fire Involving Radioactive Material

The Radiation Safety Division will investigate each incident and determine necessary corrective actions and regulatory reporting.

14.3 Responses

14.3.1 NOV’S Notices of Items of Non-Compliance from the Department of State Health Services generated from inspections conducted during site visits requires a response on the part of the University. The RSO will respond on behalf of the University outlining corrective action from necessary to prevent reoccurrences.

14.3.2 Complaints The University must respond if a complaint has been made to the DSHS regarding a situation involving radiation. The RSO will respond on behalf of the University.
14.3.3 FDA Reports

14.3.3.1 Annual Report The Radioactive Drug Research Committee submits an annual report to the Food and Drug Administration each year by January 31st of all human use research protocols involving a radiopharmaceutical drug.

14.3.3.2 Special Summary Report The Radioactive Drug Research Committee will submit a special summary report to the FDA for a human use research protocol involving a radiopharmaceutical drug that has requested permission to exceed more than 30 subjects.
15.0 RECORD KEEPING

15.1 Record Keeping Requirements for Laboratories All laboratories using radioactive materials are required to keep copies of records as follows:

15.1.1 Radiation Safety Handbook All labs shall have a current copy of the Radiation Safety Handbook accessible by all personnel.

15.1.2 Radiation Safety Contamination Surveys Records of surveys performed to detect the presence of radioactive material contamination must be kept for a minimum of 3 years.

15.2 Record Keeping Requirements for Radiation Safety Office

15.2.1 Radioactive Material Handling and Disposal Records Radioactive material records of reception, handling, shipment of or disposal of radioactive material or radioactive hazardous wastes to comply with state record keeping and reporting requirements as outlined in 25 TAC 289.202 shall be kept permanently.

15.2.2 Radiation Protection Program (RPP) Records The RPP records includes RSC minutes and supporting documentation as well as applications to the committee and correspondence between the committee and the authorized user. All documentation of licensing and registration of the the institution by the state to receive, use, store, dispose of, and ship radioactive materials and radiation producing machines. These records include State Applications and certificates required by the Texas Department of State Health Services and any correspondence and documentation of regulatory agency inspections. These shall be kept as permanent records.

15.2.3 Radioactive Drug Research Committee All minutes and annual reports shall be kept as permanent records.

15.2.4 Records of Terminated Principal Investigators Records of Terminated Principal Investigators (PI's) Includes correspondence related to safety issues, surveys performed in their laboratories, spills/injuries that may have occurred, and shall be kept for 10 years past termination date.

15.2.5 Radiation Monitoring and Exposure Records This series provides a record of radiation testing and monitoring of employees, embryo/fetus dose, visitors, individual members of public, facilities, and the surrounding environment and is used to comply with federal and state reporting and licensing requirements and insurance carrier reporting requirements. These records shall be kept as permanent records.

15.2.6 Radiation Safety Contamination Surveys Records of surveys performed to detect the presence of radioactive material contamination shall be kept for 3 years.

15.2.7 University Hospital (UH)/CTRC Patient Surveys/Release Includes brachytherapy patient monitoring records, records of radiation area surveys performed on patients treated with radioactive materials in order to document compliance with state and federal regulations. These records shall be maintained as permanent records.

15.2.8 Assessment of Internal Radiation Exposures/Bioassays Records of bioassay uptake measurements and associated calculations to determine presence of internal contamination of radioactive material shall be maintained as permanent records.
16.0 HUMAN USE OF RADIOACTIVE MATERIALS

16.1 Authorization  A practitioner applying for authorization for the Human Use of radioactive material must submit the Human Use Radioactive Material Authorization Application For Clinical Use or The Human Use Radioactive Material Authorization Application for Research Use to the Radiation Safety Committee. Each applicant or the co-investigator is to be a Texas licensed physician and is to have experience in the handling and administration of radioisotopes as required by the 25 Texas Administrative Code §289.256. The Committee will review extensively the following:

1. The qualifications and training of the applicant by reviewing documentation listing the practitioner as an Authorized User on an NRC or Agreement State license and/or board certifications, preceptor statements and course work. Board certifications considered as acceptable criteria for approval are American Board of Radiology with special competency in Nuclear Radiology or the American Board of Nuclear Medicine in Nuclear Medicine.
2. Individual radioisotope(s) and procedures being requested.
3. The submitted protocol with the research protocol to include the consent form.
4. The risk to the patient; using the recommended FDA dose limits for research patients as guidelines.
5. FDA requirements may include Radioactive Drug Research Committee review, or an IND from FDA covering the research, radiopharmaceutical quality, dose of the radiopharmaceutical.
6. The dose to the patient for a research procedure utilizing a radiation producing machine as part of the protocol, will include the exposure from the x-ray procedure in the total dose to the patient.
7. The Human Use Radioactive Material Application for Clinical Use or for Application for Research Use. The two application forms may be accessed through the EH&S website, research.uthscsa.edu/safety under Radiation Forms. These application forms may also be seen in Appendix A.

Please note that any human use research protocol involving the use of radioactive material requires Institutional Review Board review and approval in addition to the Radiation Safety Committee.

16.2 Clinical Facility Authorization  The Nuclear Radiology Clinical facilities at University Health System and the Radiation Oncology Clinical facilities at University Health System will be authorized under the Chief Director of the division or the department. The Texas licensed practitioner must meet the qualifications listed in 16.1 above and the requirements for the radioisotope(s) and the appropriate “Group” listed in 25 Texas Administrative Code §289.256. Individual practitioners working under the Director must also meet the training qualifications listed in 25 Texas Administrative Code §289.256 and be approved individually by the Radiation Safety Committee. Any additional credentialing required by the University Health System must also be met by each practitioner.

16.3 Individual Investigator Responsibility  The investigator/practitioner has primary responsibility for the use of the radioactive material, for the protection of the patient, and for the safe handling of any material removed for study.

When considering the utilization of radioactive material/radiopharmaceutical for human research and diagnosis, the investigator is urged to be aware of and carefully consider the following factors:
1. Type and energy of the radiation.
2. Physical half-life.
3. Biological half-life.
4. Effective half-life
5. Body retention of the radioactive materials.
7. Critical organ/tissues.
8. Total body effective dose equivalent of the protocol
9. Accumulation of effects of combined or sequentially administered radioactive materials.

The individual Investigator must ensure that the protocol is reviewed by all applicable Radiation Safety Committees as well as the Institutional Review Board. Also, any amendment to the IRB involving a change in the radiation utilized in the protocol requires an amendment submittal to the RSC and possibly the RDRC. Consent forms are also to be updated.

It is the responsibility of the individual investigator to inquire if a potential research subject has participated in other protocols during the year and received radiation exposure.

The Radiation Safety Division staff is responsible for the protection of the patient-care staff, for instructions needed to ensure radiation-safe conditions, and for the disposal of contaminated human-use materials, equipment and waste.

16.4 General Rules

16.4.1 Medical Use of Radioisotopes

1. It is the responsibility of any person involved in human use radiation to be aware of the basic methods of radiation protection: time, distance, shielding, and contamination control. (Refer to Chapter 4 of the Handbook.)
2. Personnel Dosimeters will be issued as deemed necessary by the Radiation Safety Officer in accordance with chapter 3 of the Handbook.
3. Radionuclide procedures will vary in the amount of associated hazard. For activity at low levels, such as diagnostic doses, the hazard will be very small. Diagnostic dose administrations will not require special precautions. PET diagnostic administrations will require some precautions, but limited. In some therapy procedures, the hazard may be considerable and will require special precautions to be issued.
4. Diagnostic amounts of radioactive material are regarded as minimal external hazards requiring no special precautions other than “universal precautions” and the application of normal radiation safety principles, except where instructions pertaining to the particular patient are issued by the responsible physician, the Radiation Oncology Department or Nuclear Radiology, and/or are included in the doctor's order sheet. The patient may be released from control of the Nuclear Medicine Clinic back into the general population.
5. PET diagnostic dose administrations will require separation from the general public upon the initial administration of the isotope before scanning. Once the patient has completed the scan procedure, the patient is treated as any other diagnostic patient.
6. A written directive will be signed and dated by the authorized user prior to any therapy administration of radioactive nuclide.
7. Prior to administration of any radiopharmaceutical to the patient, an authorized physician user shall authorize the procedure, dose or dose range, radionuclide, and route of administration.

8. Radioactive materials will be ordered by either an authorized technologist or physician.

9. For all therapy administrations of radioactive materials, an appropriate entry shall be made in the patient’s clinical record, along with the request and signed consent form. This entry shall include the date of administration, the activity, and the identity of the radionuclide. Special precautions will be issued to the nursing staff applicable to the individual therapy.

10. In-house radionuclide therapy patients will have a "Radioactivity Precautions" designation placed in the patient’s chart.

11. Radionuclide therapy treatment of in-house patients requires the notification of the Radiation Safety Division, 567-2955 prior to administration of the therapy.

12. Therapy patients that receive more than 100 millicuries of $^{131\text{I}}$ or 30 millicuries of $^{198\text{Au}}$ will remain in the hospital until such time they are below the specified limit.

13. Patients treated with temporary implanted sealed sources will also remain in the hospital except for eye plaque therapies. All in house therapy patients will be treated with special precautions, detailed in the section 16.5.2 of "Special Rules For Nurses". Eye plaque patients and permanently placed sealed source patients are handled separately. Refer to section for "Therapy Implants – Temporary and Permanent 

14. In house patients that receive less than 30 millicuries of $^{131\text{I}}$ will still be treated as therapy patients and the precautions to control contamination and exposure will be followed. The RSO may allow modifications to the precautions due to the level of the activity of the therapy.

15. An individual room or an isolated bed with a separate commode and separate shower is necessary in order to comply with the Texas State Regulations when large amounts of radioactive material are present in or on the patient. Contact Radiation Safety Division regarding the room requirements. The room is best located in the end of the hallway next to a stairwell.

16. Patients containing therapy amounts of radioactive material must be confined to their rooms, except for specified medical nursing purposes. They must not be allowed to sit in visitor lounges or walk the hallways.

17. Visitors must remain about six feet or more from the patient who contains radioactive material, except for a brief period to deliver mail, etc. If a time limit is necessary, it will be posted on the door. Pregnant women and children shall not, in general, be allowed to visit patients having an appreciable radioactive burden.

18. No patient will be permitted to leave the hospital with more than 100 millicuries of $^{131\text{I}}$ or 30 millicuries $^{198\text{Au}}$ unless approved by the Radiation Safety Officer.

19. When a patient leaves the hospital with more than the prescribed level of Table 4, column 2 of NCRP Report 37, he shall be given detailed instructions by the responsible physician so as to avoid exposure or contamination of other individuals. The physician may check this with the Radiation Safety Office. NCRP Report 37 is titled "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radioactive Material".

20. Radioactive Excreta: In general radioactive excreta from radiiodine cases will not be collected but allow the patient to utilize bathroom facilities. However if handling is required, personnel protective equipment is to be used. This includes double layer of disposable gloves, eye shields and disposable isolation gown are to be used to handle excreta or body fluids from the therapy patient.

21. If a patient dies before he is released by Radiation Safety, the head nurse will notify the attending physician. The head nurse or the attending physician will then notify
the physician in charge of treating the patient with radiation, the Radiation Safety Officer, and the pathologist. (RSO, 567-2955 or 567-2800)

22. The Radiation Safety Officer will survey the patient and complete the statement to the funeral director. The warning notice will be attached to the outside of the shroud covering the body.

23. If there is no autopsy, the attending physician shall obtain the signature of the Radiation Safety Officer on the statement to the funeral director, or mortician, regarding the radiation hazard presented by the body and the procedures necessary for safety. Call the Radiation Safety office.

24. If there is an autopsy and the patient was not released by Radiation Safety, special precautions must be taken by the pathologist performing the autopsy. The procedures to be followed will be outlined in the individual instructions to the pathologist. Note: Some of the bodies having no warning notice attached to the outside of the shroud may contain radioactive material below release limits and have been released from radiation precautions by Radiation Safety. If the pathologist has any doubt, he shall check the amount given the patient as recorded in the patient's chart and estimate and amount present, allowing for decay. If he is still in doubt, he shall check with the Radiation Safety Office (567-2955 or 567-2800).

16.4.2 In-Patient Requirements for Unsealed Radiation Therapy

1. The patient must be placed in a private room with an adjoining latrine restricted solely for the patient's use. The better placed room is at the end of a hallway next to a stairwell.

2. Appropriate radiation signs will be placed on the patient's door.

3. Radiation Safety staff will prepare the patient room appropriately for the therapy.

4. The patient will wear hospital pajamas and use disposable articles, (e.g., food trays, etc.). No items entering the patient's room may be removed from that room until monitored for the presence of radioactive contamination.

5. Consistent with adequate patient care, carry out only minimum nursing procedures close to the patient. If the patient's clinical status requires constant observation, rotate personnel required to perform adequate care in order to minimize exposure to personnel. Radiation Safety Officer shall be consulted if rotation is necessary.

6. Wear your personal dosimeter as assigned.
7. Personnel shall not remain in patient's room unless engaged in required activity. Persons who are pregnant will not attend or visit the patient during the course of therapy. Persons under the age of 18 will not normally visit the patient. Maintenance shall not enter the room unless they receive permission and instructions from the charge nurse.

8. Wear disposable gloves when changing bed linens, dressings, etc. Urine is radioactive. Spills, bed-wetting or any accident with urine is a radiation hazard. Cover with absorbent material. Notify the Radiation Safety Officer and Nuclear Medicine Division immediately.

9. Place waste, soiled linen, etc., in separate designated containers for monitoring and disposal by the Radiation Safety staff.

10. Personal items for patient care (thermometers, bedpans, etc.) will remain in the patient's room, until released by the Radiation Safety staff.

11. Ambulatory patients must remain in their rooms.

12. Diagnostic samples of blood, urine, saliva and feces are radioactive and shall only be obtained when authorized by the Chief of the Nuclear Medicine Department and the Radiation Safety Officer.

13. Precautions for visitors will be determined and posted by the Radiation Safety Officer or Radiation Safety staff depending on the isotope and activity administered.

14. Blocked drains and plumbing problems in the patient's lavatory may be a radiation hazard. Notify the Radiation Safety Office if problems arise. (567-2955 or after hours 567-2800 and request notification of Radiation Safety.)

15. If emergency surgery is required, notify the Chief of Nuclear Medicine and the Radiation Safety Officer immediately.

16. If the patient expires, the Chief of Nuclear Medicine and the Radiation Safety Officer must be notified prior to releasing the body to the morgue. (567-2955 or after hours 567-2800 and request notification of Radiation Safety.)

17. No patient who has received an unsealed radioactive therapy dose as a therapy dose may be discharged until the Radiation Safety Officer or Radiation Safety staff verifies that the residual activity is within permissible limits.

18. Postings placed on the door of the therapy room by Radiation Safety include a check list of specific instructions for any staff tending the patient and for visitor instructions. Emergency numbers and radiation caution signs are also posted. Refer to Appendix A for the forms.
19. Radiation Safety staff will at a minimum survey the patient at the time of dosing and prior to discharge.
20. Radiation Safety staff will decontaminate the patient room prior to releasing it back to the floor for general use.
21. The Radiation Safety Officer will provide guidance and instructions on a case by case basis if the need arises. Special instructions may be given and posted as needed.

16.5 Special Rules

16.5.1 Medical Staff Members

1. It is the responsibility of all physicians using radioactive materials in humans to be familiar with the general and specific principles of radiation protection in this Handbook. They shall be familiar with methods of minimizing radiation exposure, recommended maximum permissible radiation exposure levels, and the interpretation of these levels to nursing staff and other technical personnel. The attitude of the professional staff with regard to radiation protection is quickly copied by technical and nursing staff. Consequently, healthy respect for radiation protection problems on the part of the physician is of great importance. However, neglect of necessary patient care in the name of radiation precautions cannot be tolerated as long as personnel exposures remain within acceptable guidelines.

2. If a patient containing radioactive material dies, the responsibility of pronouncing the patient dead and writing the final progress note may fall on any member of the medical staff, depending on the circumstances. If there is no autopsy, it will be the responsibility of this staff member to obtain, at the time, a certificate from the Radiation Safety Officer specifying the amount of radioactive material in the body, in order that this certificate may be sent to the funeral director. If there is an autopsy, it will be the responsibility of the staff member to inform the pathologist of the radioactive material in the body. Obtain assistance from the Radiation Safety Officer in determining the amount of radioactive material remaining in the body. (Day number 567-2955, after hours, 567-2800, request Radiation Safety be notified.)

3. It is the responsibility of all physicians to observe the rules regarding the discharge of patients who have received therapeutic amounts of radioactive material from the hospital. (See paragraphs 15 and 16 in the previous subsection) The physician has the services of the Radiation Safety Officer or his staff available in estimating when this level will be reached.

4. It is also the responsibility of the attending physician to see that the rules regarding visitors are observed as well as any other rules pertaining to the conduct of the nursing and technical staff relative to radioactive patients. The checklist of rules is in Appendix A.

5. Visitors are to be restricted as indicated on the form on the door by the Radiation Safety staff.

6. Special medical procedures may be necessary with patients containing radioactive material. This may involve the removal of body fluids containing radioactive material, or some other procedures. It is the responsibility of the attending physician to receive authorization from the Chief of Nuclear Medicine Division and to see that radioactive fluids and specimens of this kind are properly handled.

7. Questions shall be directed to the Radiation Safety Office, the Nuclear Medicine of the Department of Radiology or Radiation Oncology

16.5.2 Nurses
1. Read thoroughly and observe all general rules.
2. Consistent with adequate care for the patients, carry out nursing procedures to minimize the time close to the patient (as specified in doctor's orders and on the notice posted by the bed.
3. Special Instructions for temporary implant sealed sources (\(^{137}\)Cs, \(^{192}\)Ir, \(^{125}\)I, \(^{201}\)Pd):
   a. Sealed sources may be placed temporarily within a patient. At the time of placement, the Radiation Safety staff will survey the patient and record the survey. When the temporary sealed source implant is removed from the patient, it must be stored in a lead-lined container provided for the purpose and this container must be returned to the special storage area provided. Personnel must avoid spending unnecessary time close to this storage area.
   b. Precisely follow any special instructions issued relative to the handling of implant sources by the physician in charge.
   c. Refer to the specific UHS Nursing Policy or Health Science Center Policy for Handling Radioactive Material for instructions
4. Special instructions for temporary implant sealed sources in the operating rooms (i.e., \(^{125}\)I seeds for eye implants), operating room personnel shall obey the standard radiation safety principals, time, distance and shielding. It shall be emphasized that only personnel actually required for the procedure shall be present. All other personnel shall leave the room if feasible, or stand at least five feet from the source of radiation. Radiation Safety staff will be in attendance in the OR when the implant is placed and the removed.

5. Special Instructions for permanent implant sealed sources (i.e., \(^{198}\)Au, \(^{125}\)I Seeds): The same instructions apply as for temporary implant sealed sources, except that, since the material is decaying, the patient may eventually present a radioactive level below the level requiring precautions.
Note: With all encapsulated sources, no special precautions need to be taken with regard to food, bedding, excreta, etc., except to be sure that no source is lost via these routes. If a source (Cesium needles or Iridium wire filament, Palladium or Iodine seeds) shall get loose while the patient is in an area, it shall be picked up immediately with forceps and placed in a container away from the other personnel in the patient’s room. Contact the Radiation Safety Officer immediately at 567-2955 or after hours at 567-2800. A patient is not radioactive after a radiation source is removed or after external beam therapy.

5. Special Instructions for Non-Sealed Radiation Sources:

Non-sealed radioactive sources may be in capsule/liquid form and are most commonly administered orally (i.e., radioiodine). The radioactive material will remain in the patient until it is excreted or undergoes decay. All body fluids are potentially radioactive. In the case of radioiodine therapy patients, the urine has a very high amount of radioactive material during the first 24 hours after administration.

The thyroid ablation patient may become nauseated requiring the receiving of prescribed medication right away.

The patient is to be furnished water or juices to keep them well hydrated.

Have the patient shower twice a day to assist in the lowering the contamination level in the room.

Notify Radiation Safety in the event of a spill or incident with the patient. Contain any liquid with absorbent pads.

Utilize patient shower if necessary to decontaminate self if you are contaminated by the patient. Have other staff contact Radiation Safety immediately for assistance.

Nursing staff providing care to ablation patients shall obtain specific training for the non-sealed radioactive source therapy patients.

16.5.3 Pathologist

1. The pathologist shall understand that since he is rarely exposed to radiation from radioactive materials, and then usually in small amounts, his hazard is a minor one. He can minimize even this exposure by observing the General Rules.

2. The body which will present a radiation hazard will have a tagged wristband. The pathologist can find out the extent of the radiation hazard by reference to the patient’s chart, which states the date of administration, the radionuclide, and the amount of activity.

3. An estimate may be made of the radioactive material still remaining in the body by monitoring with an appropriate radiation detector. Call the Radiation Safety Office (telephone 567-2955) or the Nuclear Medicine division for measurement of the radiation level.

4. If the dose is below the prescribed level, no special precautions need be taken other than the wearing of gloves. However, in the case of $^{131}$I, obtain the service of the Radiation Safety Officer. He/she will issue a certificate of his findings to the funeral director when necessary.
16.5.4 Nuclear Medicine Technologist

1. Wear whole body and ring badge at all time.
2. Protective clothing and disposable gloves are to be worn with gloves being changed after each patient injection.
3. Check the identity of the patient before administering prescribed dose.
4. Check the dose received from outside radiopharmacy in the dose calibrator and log in the results. Diagnostic doses must be reported if greater than 50% or if the wrong pharmaceutical. Therapeutic doses must be reported if greater than 10%.
5. Ensure all possible contaminated material is consigned to the proper waste following an injection, i.e. cotton ball, contaminated diaper pad, syringe.
6. Sharps containers are to be used for all needles. Store the sharp container behind shielding until it is decayed.
7. Notify the Radiation Safety Office in the event of a misadministration or a spill.
8. Notify the Nuclear Medicine physician of any adverse reactions by the patient.
9. Ensure the daily and weekly QC for the dose calibrator and the cameras are performed and recorded.
10. Report any electrical or mechanical problems to the Director of the X-ray department and the Chief of Nuclear Medicine.
11. Technologists are to meet credentialing requirements of the DSHS.
12. PET specific guidelines are outlined in 16.5.5.

16.5.5 PET Technologist  Must meet the same rules as 16.5.4 with some additional requirements:

1. PET Specific Training – 24 hours of supervised PET radiopharmaceuticals training in the handling of PET pharmaceuticals as well as 10 cases of clinical experience before being authorized to perform unsupervised diagnostic procedures involving PET. Documentation of this supervised training for each technologist will be kept in the Radiation Safety Office.
2. For a diagnostic PET exam requested by an outside physician, the request shall indicate the patient’s name, the exam ordered, and the reason for the exam. Final approval shall be made by an authorized physician user.
3. Administration of radiopharmaceuticals for diagnostic PET exams shall be performed by a technologist. Unless the technologist encounters problems during the exam, the exam shall be started and completed by the technologist.
4. The technologist shall not administer radioactive material to a patient if there is any question regarding the procedure ordered or the identity of the patient.
5. If there is any question regarding the appropriateness of a procedure, the clinical condition or pregnancy status of a patient, the type or dose of a radiopharmaceutical to be used, or the need for modifications of standard protocol for a given patient, the RII Director shall be contacted immediately.
6. Doses will be received from the Nuclear Pharmacy or Cyclotron Facility as a pre-calibrated unit dose in an individual shielded syringe carrier. A dose calibrator is available in the PET suite, if necessary. All doses are administered within the PET suites.
7. Each dose received shall indicate the date, the name of the authorized user physician, the name of the radioactive material administered, amount of radioactivity, volume, time of calibration, and route of administration. A record of each dose received, patient name, type of study, and date shall be recorded by the technologist in the PET log book.
8. Spent doses are either stored for decay to background in a shielded-syringe carrier, or returned to the Nuclear Pharmacy or the Cyclotron Facility.

9. Any female patient of childbearing age shall have a urine or serum pregnancy test performed (with negative result) prior to initiation of any PET procedure. This test should be within 24 hours prior to the initiation of the study.

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

16.6 Research Use for Human Subjects

a. Prior to the administration of any radiopharmaceutical to a subject, an authorized physician user shall authorize the procedure, dose or dose range, radionuclide and route of administration.

b. Administration of radiopharmaceuticals for research PET studies shall be performed by a technologist, and or Medical Doctor subject to the following requirements:
   i. The radiopharmaceuticals are administered under the authority of a physician approved by the authorized physician user and the RII Radiation Safety Committee.
   ii. The individual has been trained by the authorized physician user and/or a technologist and will perform all administrations under the direct supervision of the authorized physician.
   iii. The designated individual must observe the authorized physician user and/or a technologist for a minimum of ten (10) PET radiopharmaceutical administrations.
   iv. The designated individual must be supervised by the authorized physician user and/or a technologist for a minimum of ten (10) PET radiopharmaceutical administrations.

c. The radiopharmaceutical has been approved on a UTHSCSA Institutional Review Board approved protocol or annotated on the consult by the authorized physician user.

d. The technologist or designated individual shall not administer radioactive material to a subject if there is any question regarding the procedure ordered or the identity of the subject.

e. If there is any question regarding the appropriateness of a procedure, the physical condition or pregnancy status of a subject, the type or dose of a radiopharmaceutical to be used, or the need for modifications of standard protocol for a given subject, the authorized physician user or the principal investigator of the research protocol shall be contacted immediately.

f. Doses will be received from the Cyclotron Facility or Nuclear Pharmacy as a pre-calibrated unit dose in an individual shielded syringe carrier. A dose calibrator is available in the PET suite, if necessary.

g. Each dose received shall indicate the date, the name of the authorized user physician, the name of the radioactive material administered, amount of radioactivity, volume, time of calibration, and route of administration. A record of each dose received, patient name, type of study, and date shall be recorded by the technologist in the PET log book and maintained for the required documentation period.

h. Spent doses are either stored for decay to background in a shielded-syringe carrier, or returned to the Cyclotron Facility or Nuclear Pharmacy.

i. Any female subject of childbearing age shall have a urine or serum pregnancy test performed (with negative result) prior to initiation of any PET research procedure.
16.7 Disposing of Short-lived Radioactive Waste

A. $T_{1/2} \leq 1$ day
   Short-lived radioactive material will be stored in appropriate lead shielding or designated waste container shield until decay to background.

B. $T_{1/2} \geq 1$ day
   Sealed calibration pin sources for the PET scanners are either housed in retractable lead shielding inside the PET scanner or contained in locked lead shield containers. At the discretion of Radiation Safety personnel, used sealed calibration source material shall be transferred and stored for decay in a designated radioactive waste storage area.

16.8 Dose Calibrator/$^{15}$O Gas Delivery System

1. The following tests shall be performed on the dose calibrator at the frequency intervals indicated:
   a. Constancy at least once each day prior to assay of patient doses.
   b. Linearity at installation, repair, relocation, and at least quarterly.
   c. Geometry dependence at installation.
   d. Accuracy at installation and at least annually thereafter.

2. Calibration results shall include the following:
   a. Date of calibration
   b. Model and serial number of the dose calibrator and calibration source respectively.
   c. Individual who performed the calibration

Records of calibration results for the dose calibrator shall be maintained and kept for review for the documentation period required.
17.0 CANCER THERAPY & RESEARCH CENTER PROCEDURES

17.1 Authorization  A practitioner applying for authorization for the Human Use of radioactive material must submit the Human Use Radioactive Material Authorization Application For Clinical Use or The Human Use Radioactive Material Authorization Application for Research Use to the Radiation Safety Committee. Each applicant or the co-investigator is to be a Texas licensed physician and is to have experience in the handling and administration of radioisotopes as required by the 25 Texas Administrative Code §289.256. The Committee will review extensively the following:

1. The qualifications and training of the applicant by reviewing documentation listing the practitioner as an Authorized User on an NRC or Agreement State license and/or board certifications, preceptor statements and course work. Board certifications considered as acceptable criteria for approval are the American Board of Radiology with special competency in Radiation Oncology or Therapy Radiation (previously approved Board Certificate).
2. Individual radioisotope(s) and procedures being requested.
3. The submitted protocol with the research protocol to include the consent form.
4. The risk to the patient; using the recommended FDA dose limits for research patients as guidelines.
5. FDA requirements may include Radioactive Drug Research Committee review, or an IND from FDA covering the research, radiopharmaceutical quality, dose of the radiopharmaceutical.
6. The dose to the patient for a research procedure utilizing a radiation producing machine as part of the protocol, will include the exposure from the x-ray procedure in the total dose to the patient.

A licensed medical physicist must hold a license as a therapy licensed medical physicist and/or have the appropriate training and experience required per 25 TAC 289.256 or be listed on a medical radioactive material license from TDSHS, NRC, or another agreement state.

17.2 Individual Investigator Responsibility  The investigator/practitioner has primary responsibility for the use of the radioactive material, for the protection of the patient, and for the safe handling of any material removed for study.

When considering the utilization of radioactive material/radiopharmaceutical for human research and diagnosis, the investigator is urged to be aware of and carefully consider the following factors:

1. Type and energy of the radiation.
2. Physical half-life.
3. Biological half-life.
4. Effective half-life
5. Body retention of the radioactive materials.
7. Critical organ/tissues.
8. Total body effective dose equivalent of the protocol
9. Accumulation of effects of combined or sequentially administered radioactive materials.

The individual Investigator must ensure that the protocol is reviewed by all applicable Radiation Safety Committees as well as the Institutional Review Board. Also, any amendment to the IRB
involving a change in the radiation utilized in the protocol requires an amendment submittal to the RSC and possibly the RDRC. Consent forms are also to be updated.

It is the responsibility of the individual investigator to inquire if a potential research subject has participated in other protocols during the year and received radiation exposure.

17.3 General Procedures

17.3.1 Brachytherapy Use of Radioactive Material

17.3.1.1 High Dose Rate Remote Control Brachytherapy

1. The Ir-192 source will be changed out four times a year and the depleted radioactive source will be returned to the manufacturer. If the source is being used for longer than six months a leak test will be performed by the Radiation Safety Division.

2. After the Ir-192 source exchange, calibration will be repeated to determine the dose accuracy and output. The source strength is measured with a calibrated well chamber and the source strength is corrected daily. These calibrations will be performed under a licensed medical physicist.

3. Source exchange will be performed by a representative from the manufacturer trained and experienced in source exchange and maintenance of the HDR remote control brachytherapy unit.

4. After each exchange, a radiation survey will be taken of the source housing radiation levels, the areas adjacent to the treatment room, and the any other necessary surveys to verify that the radiation levels in restricted areas and unrestricted areas is not exceeded.

5. Prior to each treatment requiring CT scans, CT scans will be taken using dummy sources placed in the applicator and the locations of the dummy sources will be used to reconstruct the applicators in the treatment planning system. A treatment plan with calculated dwell times and source positions is obtained.

6. An authorized user must approve the treatment plan with an independent second check by a member of the licensed medical physics team to verify the dwell times, dwell positions, correct reconstruction of the applicators, and corrected output due to source decay.

7. Once the plan is verified, the patient is placed in the treatment room. All personnel will remain outside of the room during the treatment but the patient can be viewed via an audiovisual communication system. A video camera is available for observing the treatment continuously and audio communication is available all the time during treatment. If this contact fails, the treatment will be discontinued.

8. The individuals required to be present in the control room during HDR treatment include the Licensed Medical Physicist or temporary LMP working under the LMP, Radiation Therapist, and Nursing Staff when needed. The Authorized User will be within standard verbal distance from the control room.

9. The HDR unit is secured in a locked vault area during non-working hours and on days when the unit is not in use. During working hours, the vault area is under observation by Radiation Oncology personnel.

10. The HDR treatment room is interlocked such that if the door is opened during treatment, the source will retract immediately and treatment will be terminated. The treatment cannot begin again until the timer is reset.

11. Emergency procedures are posted above the treatment console and an emergency stop button is located on the console for use by the Radiation Therapist.
12. The safety device checks must be done on a daily basis when the HDR is to be operated and recorded by the Radiation Therapist.

17.3.1.2 Sealed Source Implants

Personnel shall obey the standard radiation safety principals, time, distance and shielding. It shall be emphasized that only personnel actually required for the procedure shall be present. All other personnel shall leave the room if feasible, or stand at least five feet from the source of radiation.

Note: With all encapsulated sources, no special precautions need to be taken with regard to food, bedding, excreta, etc., except to be sure that no source is lost via these routes. If a source (Cesium needles or Iridium wire filament, or Palladium/Iodine seeds) shall get loose while the patient is in an area, it shall be picked up immediately with forceps and placed in a container away from the other personnel in the patient's room. Contact the Radiation Safety Officer immediately at 567-2955 or after hours at 567-2800. A patient is not radioactive after a radiation source is removed or after external beam therapy.

17.3.2 Unsealed Use of Radioactive Material

1. The authorized user will complete an order/prescription form and forward that completed form to the Radiation Safety Division. See Appendix A for a copy of the form.
2. Patient verification and dose validation against the written prescription is required prior to administration.
3. Administration of the dose will comply with the manufacturers’ recommendations and the patient will be measured prior to release to ensure that the measured rate is less than the maximum limits allowed by NRC Guide 8.39.
4. The unit dose will be dispensed by the Nuclear Pharmacy and thereby a dose calibrator is not needed onsite. If the dose is not administered at the calibration time, the activity will have to be corrected by mathematical decay.
5. For Ra-223, a dose calibrator will be required to verify the dose prior to administration per the manufacturer’s instructions. Injections involving Ra-223 must follow the specific guidelines from Bayer as it involves an alpha and beta emitter.
6. The radiopharmaceutical doses will be delivered to receiving and sent over to Radiation Safety where contamination surveys will be performed of the package. Utilization logs will be kept of the surveys and receipt.
7. The syringe shall include a syringe shield of lead, lead glass, or tungsten to decrease the external exposure hazard.
8. A calibrated GM survey meter with pancake probe needs to be used to survey administration and preparation areas immediately after use.
9. After administration, the syringes will be returned to the licensed nuclear pharmacy and all other contamination items will be kept in storage to decay in place for ten half-lives. After ten half-lives, the items will be surveyed and if indistinguishable from background they will be disposed of as biohazard waste.
10. Upon patient release the patient will be notified to take the following precautions for twelve hours after administration to protect themselves:
   a. Use a toilet rather than a urinal and flush several times after each use
   b. Spilled urine shall be cleaned completely and hands washed thoroughly
   c. If blood or urine is on clothing, they shall be washed separately or stored for one week to allow for decay
d. Contact facility if other questions or problems present themselves
University of Texas Health Science Center  
Environmental Health & Safety Department  
Radiation Safety Division

**DOSIMETRY SERVICE ASSESSMENT AND EXPOSURE HISTORY FORM**

Section 1: Participant Data

As required in the *Texas Administrative Code*, Chapter 25, §289.202, the following information regarding your radiation exposure history this calendar year is necessary for assessment of dosimetry service. Please complete the following items, then sign and return this form to: *Radiation Safety Division, EH&S*

**Full Name:**

- **Last**
- **First**
- **Middle**

**Employee Identification Number:**

**Date of Birth:**

**Gender:** Female Male

**Over the age of 18:** Yes/No

**Office phone number:**

**Location:**

List any other name(s) under which you have been monitored: _________________________________________________________

Section 2: Circle the appropriate response:

(a) I will work with $^3$H, $^{14}$C, $^{35}$S, $^{33}$P, $^{125}$I only: Yes No

(b) I will work with $^{32}$P or $^{36}$Cl >1 mCi per protocol: Yes No

(c) I will work with $^{32}$P or $^{36}$Cl >10 mCi per protocol: Yes No

(d) I will work with $^{86}$Rb, $^{22}$Na, $^{51}$Cr, $^{131}$I >1 mCi per protocol: Yes No

(e) I will work with fluoroscopy/radiographic equipment: Yes No

(f) I will work with PET or nuclear medicine isotopes: Yes No

(g) I will work for Environmental Health & Safety: Yes No

(h) I am a voluntarily declared pregnant worker: Yes No

(i) I will work with Dental x-ray equipment: Yes No

(j) I will work with Brachytherapy or LINAC Procedures: Yes No

**Classification:** Faculty Laboratory Staff Student Resident Other-Specify ________________________

With which Authorized User, Principal Investigator, or Department will you be working? __________________________________

Section 3: Previous employment(s) involving radiation exposure this calendar year

Have you been occupationally exposed to radiation sources this calendar year at another institution? Yes No

Does any concurrent employment to UTHSCSA require exposure to radiation sources this calendar year? Yes No

**Facility Name:**

**Department:**

**Mailing Address:**

______________________________________________________________

______________________________________________________________

**Dates:** _______________ through _______________

**Facility Name:**

**Department:**

**Mailing Address:**

______________________________________________________________

______________________________________________________________

**Dates:** _______________ through _______________

Section 4: Signature

I authorize the release of my radiation exposure history to the University of Texas Health Science Center San Antonio and will notify Environmental Health & Safety in the event of changes to the above information.

**Applicant:** _________________________________________  **Date:** ___________________________

**Signature**

**Permanent Address:**   ________________________________

___________________________________  

_______________  

Return the completed form to: *Radiation Safety Division, Environmental Health & Safety, Room 1.343T Dental School; Fax: 210-567-2965*

For EHS Use Only:

**Account:** ______________  **Series:** _________  **Frequency:** ______  **Spare Issued:** Yes/No  **Spare#:** ________________________
PREGNANCY DECLARATION, INSTRUCTION & DOSIMETRY EVALUATION

Section 1 – Voluntary Pregnancy Statement

I, __________________________, voluntarily declare my pregnancy to the University of Texas Health Science Center at San Antonio Radiation Safety Division, as stated in 25 Texas Administrative Code (TAC) Section 289.202(c)(7) and Section 289.202(rr). The estimated date of conception for this pregnancy is __________________________. I understand the radiation dose to my embryo/fetus during my entire pregnancy will not be allowed to exceed 0.5 rem (5 millisievert) (unless that dose has already been exceeded between the time of conception and submitting this letter). I also understand that meeting the lower dose limit may require a change in job or job responsibilities during my pregnancy.

DOB: ______________________, *SSN __________________________

Signature: ____________________________ Date: ______________

* See Reverse for Details

Section 2 – Instruction to Employee

Oral and written information about prenatal occupational radiation exposure has been provided to the individual declaring pregnancy at this time. This information includes:

1. The risk associated with prenatal radiation exposure and methods available for minimizing risk.
2. A review of previous personnel monitoring results for the individual, if available.
3. The fetal dose limit of 0.5 rem during the gestation period for occupationally exposed declared pregnant workers.
5. An opportunity to ask questions and receive answers concerning the information provided.

[Fetal dose limits and time period information are taken from TAC §289.202(m)(1) – (4).]

Section 3 – Dosimetry Evaluation

Additional fetal dosimetry devices are available for those individuals likely to receive fetal doses in excess of 10% of the established fetal dose limit, as proscribed in the 25 TAC §289.202(q)(1)(A) and §289.202(m)(1) – (m)(4). The utilization and application of such devices has been discussed with the individual declaring pregnancy at this time.

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<thead>
<tr>
<th>Yes</th>
<th>No</th>
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<tr>
<td>2.</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
</tr>
</tbody>
</table>

1 Note: Fetal dosimetry service is issued for the duration of the declared pregnancy.

Section 4 – Acknowledgments

I acknowledge that the above information relating to occupational exposure to radiation has been discussed and an opportunity to ask questions was available.

Declarer: ____________________________ Date: ____________________________
Radiation Safety Representative: ____________________________ Date: ____________________________

Return the completed form to: Radiation Safety Division, Environmental Health & Safety, Room 1.343T
Fax: (210) 567-2965
*Disclosure of your Social Security Number ("SSN") is required of you in order for The University of Texas Health Science Center at San Antonio to enroll you into the Dosimetry Program and to complete the Radiation Occupational Exposure Dosimeter Application and History, as mandated by 25 Texas Administrative Code (TAC) Section 289.202(c)(3) and Section 289.202(rr). Further disclosure of your SSN is governed by the Public Information Act (Chapter 552 of the Texas Government Code) and other applicable law.

1. With few exceptions, you are entitled on your request to be informed about the information The University of Texas Health Science Center at San Antonio collects about you;
2. Under Sections 552.021 and 552.023 of the Texas Government Code, you are entitled to receive and review the information; and
3. Under Section 559.004 of the Texas Government Code, you are entitled to have The University of Texas Health Science Center at San Antonio correct information about you that is held by The University of Texas Health Science Center at San Antonio and that is incorrect, in accordance with the procedures set forth in The University of Texas System Business Procedures Memorandum 32, Texas Public Information Act.

The information that The University of Texas Health Science Center at San Antonio collects will be retained and maintained as required by Texas records retention laws (Section 441.180 et seq. of the Texas Government Code) and rules. Different types of information are kept for different periods of time.

<table>
<thead>
<tr>
<th>You may send any requests to Andrea Marks MBA, CPA</th>
</tr>
</thead>
<tbody>
<tr>
<td>By mail to: 7703 Floyd Curl Drive, San Antonio, TX 78229-3900</td>
</tr>
<tr>
<td>By e-mail to: <a href="mailto:marksa@uthscsa.edu">marksa@uthscsa.edu</a></td>
</tr>
<tr>
<td>By fax to: (210)567-7020</td>
</tr>
<tr>
<td>In person at: Academic Administrative Building, Room 4.448</td>
</tr>
</tbody>
</table>

Return the completed form to: Radiation Safety Division, Environmental Health & Safety, Room 1.343T
Fax: (210) 567-2965

Revised 01/09
Pregnant Employee's Guide to Radiation

This document attempts to explain the risks associated with radiation and pregnancy and compares these risks with other risks to the unborn child. This will assist the pregnant, occupationally exposed employee in assessing the potential risk to the unborn child during the course of employment. Also discussed are methods of minimizing the radiation dose and the risk to the unborn child and maintaining the radiation doses as low as reasonably achievable.

There are things in our surroundings and in our lifestyles that can affect an unborn child. It is especially important that individuals who work with sources of radiation understand the risks of radiation to the unborn child.

Everyone is exposed daily to various kinds of radiation: heat, light, ultraviolet, microwave, ionizing, and so on. All human activities involve exposure to radiation. People are exposed to different amounts of background ionizing radiation depending on where they live, what they eat and drink, and how they live. Background radiation comes from many sources: radon, soil, rocks, cosmic rays, water, air, consumer products, etc. The average person is exposed to approximately 360 mrem per year from these background sources of ionizing radiation.

Questions? Please call 567-2955 or come by the Environmental Health and Safety Office Radiation Safety Division, DTL 1.343T

References:
National Council on Radiation Protection and Measurements.
- National Council on Radiation Protection and Measurement.

Sources of Radiation Exposure

Effects on the Embryo/Fetus of Exposure to Radiation and Other Environmental Hazards

To understand the potential effects of different levels of radiation on an embryo/fetus, it is helpful to compare them to the naturally occurring effects and the environmentally produced risks such as smoking and drinking. This will allow someone to contrast these risks with those produced by exposure to ionizing radiation.

The natural risks for birth defects are as follows: 3-5% of all births have some type of abnormality detectable at birth and 3-5% of all births have some type of condition or disease that develops later in life (not detectable at birth). The risk of a known pregnancy ending in a miscarriage or stillbirth is 20-30%.

The following table compares the radiation risks (childhood cancer, abnormalities) and non-radiation risks (stillbirth or spontaneous abortion due to high-risk occupations such as the lead industry, fetal alcohol syndrome and prenatal death due to alcohol or smoking) with their natural occurrence as birth defects.
Natural Occurrence of Birth Defects v. Excess Defects Due to Types of Risk

<table>
<thead>
<tr>
<th>Effect Occurring From Natural Causes</th>
<th>Type of Risk</th>
<th>Excess Occurrence Due to Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NATURAL RISK Per 1000</strong></td>
<td><strong>RADIATION RISK Per 1000</strong></td>
<td></td>
</tr>
<tr>
<td>Childhood Cancer</td>
<td>Radiation dose of 1 rem received before birth</td>
<td>0.6</td>
</tr>
<tr>
<td>Cancer death</td>
<td>Radiation dose of 1 rem received during specific periods after conception</td>
<td></td>
</tr>
<tr>
<td>Abnormalities</td>
<td>4-7 weeks</td>
<td>6</td>
</tr>
<tr>
<td>Small head size</td>
<td>8-11 weeks</td>
<td>9</td>
</tr>
<tr>
<td>Mental retardation</td>
<td>8-15 weeks</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>NATURAL RISK Per 1000</strong></th>
<th><strong>NON RADIATION RISK Per 1000</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Occupation</td>
<td>Occupational Risk</td>
</tr>
<tr>
<td>Stillbirth or 200 spontaneous abortion</td>
<td>Work in high-risk occupations</td>
</tr>
<tr>
<td>Alcohol Consumption</td>
<td>Alcohol Risk</td>
</tr>
<tr>
<td>Fetal alcohol syndrome 1-2</td>
<td>2-4 drinks per day</td>
</tr>
<tr>
<td></td>
<td>&gt;4 drinks per day</td>
</tr>
<tr>
<td></td>
<td>Chronic alcoholic (&gt;10 drinks per day)</td>
</tr>
<tr>
<td>Prenatal infant death (around time of birth)</td>
<td>23 Chronic alcoholic (&gt;10 drinks per day)</td>
</tr>
<tr>
<td>Smoking</td>
<td>Smoking Risk</td>
</tr>
<tr>
<td>Prenatal infant death</td>
<td>&lt;1 pack per day</td>
</tr>
<tr>
<td></td>
<td>&gt;1 pack per day</td>
</tr>
</tbody>
</table>

**Nuclear Regulatory Commission and the Texas Bureau of Radiation Control Position**

Regulations and guidance are based on the conservative assumption that any amount of radiation, no matter how small, can have a harmful effect on an adult, child, or unborn child. Because it is known that the unborn child is more sensitive to radiation than adults, particularly during certain stages of development, a special dose limit for protection of the unborn child has been established. Such a limit could result in job discrimination for women of child-bearing age, and perhaps an invasion of privacy (if pregnancy tests were required).

Therefore, the regulatory agencies have taken the position that special protection of the unborn child should be voluntary and should be based on decisions made by workers and by employers who are well informed about the risks involved. It is important that the employee understand the risk to the unborn child from radiation received as a result of the occupational exposure of the mother.

**Radiation Dose Limits**

Because of the sensitivity of the unborn child, the Texas Administrative Code and the Code of Federal Regulations Part 20 has recommended that the dose equivalent to the unborn child from occupational exposure of the expectant mother be limited to 500 mrem for the entire pregnancy.

This radiation exposure limit can only be enforced if the pregnancy is declared by the mother. A declared pregnancy is one in which a woman voluntarily informs her employer, in writing, of her pregnancy and gives the estimated date of conception. An employee can declare her pregnancy by filling out a Pregnancy Declaration form available in the Radiation Safety Office.

**Advice for Employee and Employer**

Although the risks to the unborn child are small under normal working conditions, it is a regulatory requirement to limit the radiation dose from occupational exposure to not more than 500 mrem for the total pregnancy and to not more than 50 mrem in any month. Employee and employer should work together to decide the best method for accomplishing this goal. Some methods that might be used include: reducing the time spent in radiation areas, wearing some shielding over the abdominal area, and keeping an extra distance from radiation sources when possible. The Radiation Safety Officer will be able to estimate the probable dose to the unborn child during the normal nine-month pregnancy period based on the exposure history. If the predicted dose approaches the limit, the employee and employer should work out schedules or procedures to confine the dose to less than the 500 mrem required limit.

**Internal Hazards**

Workers should be aware that radiation exposure to the fetus could be from internal sources as well as from external sources. In workplaces such as nuclear medicine clinics and research laboratories where unsealed radioactive materials are routinely used, there is a greater risk of radioactive material entering the body. Pertinent standard radiation precautions include the following:

1. **Never smoke, eat, drink, or apply cosmetics where radioactive materials are used.**
2. **Never pipette by mouth.**
3. **Use disposable gloves while handling radioactive materials.**
4. **Wash hands and monitor for radioactive contamination frequently.**
5. **Wear lab coats or other protective clothing around loose radioactive material.**
6. **Use certified ventilation hoods when handling volatile or potentially volatile radionuclides.**
# UT HEALTH SCIENCE CENTER AT SAN ANTONIO LABORATORY CONTAMINATION SURVEY

## Environmental Health and Safety Department

### Radiation Safety Division

**PRINCIPAL INVESTIGATOR:** CERECERO, JENNIFER A  
**Laboratory:** ____________

**Department:** ENVIRONMENTAL HEALTH & SAFETY  
**Inspection Date:** ____________

**Person Present:** __________________________________________  
**Tele. No.:** ____________

**PURPOSE:** Contamination Wipe Tests, Meter Survey, and Observe General Laboratory Conditions.

### 1. POSTINGS:

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
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</table>

- a. Outside Placard
- b. Notice to Employees
- c. Emergency Numbers
- d. "Follow-Up" Card
- e. No Food/Drink Sign
- f. Waste Area Signs Posted
- g. Radiation Use Area Signs Posted
- h. Sink Posted
- i. Frig/Freezer Signs Posted

### 2. RECORDS:

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
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</table>

- a. Receipt Disposal Forms Verified
- b. Current Inventory Verified
- c. Inventory Listings Returned Promptly
- d. Personnel Training Verified
- e. Wipe Test Records Current
- f. Action Logs Current
- g. Waste Disposal Records Adequate
- h. Class 3b or 4 Laser Present (SN, Make, Model)

### 3. RADIATION SAFETY CONDITIONS:

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
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</table>

- a. Evident RAM Security
- b. Hallway Freezer Locked
- c. Work Area Covered
- d. Labware Properly Labeled
- e. Solid Waste Properly Segregated
- f. Solid Waste Properly Labeled
- g. Scintillation Vials Properly Segregated
- h. Scintillation Vials Properly Labeled
- i. Liquid Waste Properly Segregated
- j. Liquid Waste Properly Labeled
UT HEALTH SCIENCE CENTER AT SAN ANTONIO LABORATORY CONTAMINATION SURVEY  
Environmental Health and Safety Department  
Radiation Safety Division

4. LABORATORY SAFETY CONDITIONS:  YES  NO

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>a. No Evidence of Food/Drink</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Proper PPE worn</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Eyewash Station Works Properly</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. Safety Shower Certification Current</td>
<td></td>
<td></td>
</tr>
<tr>
<td>e. Fume Hood Certification Current</td>
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<td></td>
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<tr>
<td>f. Laboratory Airflow Verified</td>
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<td></td>
</tr>
<tr>
<td>g. No Mercury Thermometers Present</td>
<td></td>
<td></td>
</tr>
<tr>
<td>h. No Cloth Chairs in Lab Areas</td>
<td></td>
<td></td>
</tr>
<tr>
<td>i. No Outdated/Potentially Explosive Chemicals</td>
<td></td>
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<tr>
<td>j. 18” Clearance from Ceiling Maintained</td>
<td></td>
<td></td>
</tr>
<tr>
<td>k. Chemicals Properly Segregated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>l. Liquid Chemicals Stored Properly</td>
<td></td>
<td></td>
</tr>
<tr>
<td>m. No Excessive Chemicals in Fume Hood</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n. No Excessive Equipment in Fume Hood</td>
<td></td>
<td></td>
</tr>
<tr>
<td>k. Heat Sources separated from Combustibles</td>
<td></td>
<td></td>
</tr>
<tr>
<td>l. No Flammable chemicals in Fridge/Freezer</td>
<td></td>
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COMMENTS:  

__________________________________________________________________________  
__________________________________________________________________________  
__________________________________________________________________________  
__________________________________________________________________________  
__________________________________________________________________________
Radioactive materials were not actively used in Laboratory during this week.

<table>
<thead>
<tr>
<th>Week</th>
<th>Signature</th>
<th>Date Signed</th>
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For all weeks that radioactive materials were used, there is a corresponding wipe test.
THE UNIVERSITY OF TEXAS
HEALTH SCIENCE CENTER AT SAN ANTONIO
APPLICATION FOR USE OF RADIOACTIVE MATERIAL

INITIAL APPLICATION AMENDEMENT TO CURRENT AUTHORIZATION
APPLICATION MUST BE TYPED
1) Principal Investigator: __________________________ Office Telephone: ________________
   Department: __________________ Section: __________ Lab Telephone: ________________

2) Laboratory(s) at which radioactive material will be used and/or stored:

3) List name and Title of Personnel Handling Radioactive Material

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
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</table>

4) List Radioactive Material, Chemical and/or Physical Form and Max. Activity Limit:

<table>
<thead>
<tr>
<th>Nuclide</th>
<th>Chemical/Physical Form</th>
<th>Maximum Activity Limit</th>
</tr>
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<tbody>
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</table>

5) Describe purpose for each radioactive isotope that will be used

__________________________________________________________________________________
__________________________________________________________________________________
__________________________________________________________________________________
__________________________________________________________________________________
__________________________________________________________________________________
__________________________________________________________________________________

6) Waste Disposal: The Investigator Will Comply with the waste disposal requirements issued by the Radiation Safety Office. Indicate the type of waste expected.

Solid Waste:  GLASS _____ PLASTIC _____ NEEDLES _____

Liquid Waste: ORGANIC SOLVENTS _____ AQUEOUS LIQUIDS _____ CARCINOGENS _____

Other:  SCINTILLATION VIALS _____ ANIMAL TISSUE _____ BIOHAZARDOUS _____
7) Instrumentation: An investigator must have access to a liquid scintillation counter and/or gamma counter to perform wipe tests. He must also have access to a survey meter when using millicurie amounts of high energy beta emitters and gamma emitters. List equipment available

<table>
<thead>
<tr>
<th>TYPE OF INSTRUMENT (make and model)</th>
<th>RADIATION DETECTED (beta and/or gamma)</th>
<th>RANGE OF SURVEY METER (ie-1 to 250 mR/hr)</th>
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Survey meters shall be calibrated once a year by either the RSO or another qualified party. Please indicate the name of the company or person if "other" is indicated.
Radiation Safety Office ____________________________ Other ____________________________

8) Facilities and Equipment:
   a) **SUBMIT A DIAGRAM OF EACH LABORATORY** indicating radioactive work areas, sinks, refrigerators, freezers, fume hoods, desk areas, etc.

   b) Please check the items below which are applicable to your laboratory.

   Laboratory Requirements

   - Plastic-backed absorbent paper will cover each work area.
   - A fume hood will be utilized for radioisotope work.
   - A biohazard cabinet will be utilized for radioisotope work.
   - Iodinations will be performed. Laboratory Room # ____________
   - Lead shielding will be used for the radioisotope
   - Plexiglass/Plastic shielding will be used for the radioisotope.
   - Gloves and laboratory coats will be utilized as protective clothing.
   - Remove handling tools (forceps, tongs, etc.) and the lead shipping containers will be utilized when handling large quantities of high energy beta and gamma emitters.
   - Personnel dosimeters will be worn and returned as required by the Manual.
   - □ Thyroid checks will be obtained for personnel using unbound radiiodine.
   - □ Wipe tests will be performed and recorded WEEKLY.

Security: Specify the precautions and procedures which will be taken during your possession of the radioisotopes to secure and prevent any unauthorized access and removal of the material.
Contamination Control: Specify the precautions and procedures which will be taken to prevent excessive levels of radiation or contamination in the work or adjacent areas.

Posting Requirements: The documents listed below are to be posted or kept in EACH laboratory. Check items that are currently in each laboratory.

- Notice to Employees
- The Following Regulation and Documents May Be Examined…
- Emergency Telephone List
- Radiation Safety Handbook (September 2013 edition)
- Radiation Labels (door, refrigerator, work areas, fume hood, waste containers, etc.)

9) Animal Use: Complete the attached form “In Vivo Radioactive Material Containment” and submit with this application.

10) Training and Experience with Radiation: Complete the form “radioisotope training and experience: for EACH individual that is listed on items 1 and 3.

11) Human Use of Radioactive Material: The research or clinical application of Human use of Radioactive Material must be submitted in addition to this application.

12) CERTIFICATION: THE PRINCIPAL INVESTIGATOR CERTIFIES THAT HE/SHE WILL COMPLY WITH THE RADIATION SAFETY HANDBOOK, THE BROAD LICENSE REQUIREMENTS AND THE POLICIES ESTABLISHED BY THE RADIATION SAFETY SUBCOMMITTEE AND INSTRUCTIONS ISSUED BY RADIATION SAFETY OFFICE, THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED, IS TRUE AND CORRECT TO THE BEST OF HIS/HER KNOWLEDGE AND BELIEF.

Principal Investigator’s Signature    Date

Department Chairman’s Signature    Date
In Vivo Radioactive Material Containment

(If Yes complete items 1 - 6, sign and return) (If No sign and complete the bottom line of form)

PROTOCOL#: ____________________________ PROTOCOL TITLE: ____________________________

1. Will you utilize animals? ________________ Yes ________________ No

   List radioisotope being used

   Animal(s) being used

   Number of animal(s)

   ____________________________ ____________________________ ____________________________

2. Activity administered per animal ____________________ Average weight of animal ________________

3. Will the animals be terminated within 24 hrs? ________________ Yes ________________ No

   If not, estimate longevity following isotope administration.

   ____________________________

4. Where will the radioactivity be administered? Room No. ____________________________

5. Where will the animals be housed? ________________ LAR facilities ________________ Your laboratory

6. Routes and quantity of excretion of radioactive material.

<table>
<thead>
<tr>
<th>Routes</th>
<th>Percentage of Isotope Excreted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine</td>
<td>________________________________</td>
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<tr>
<td>Feces</td>
<td>________________________________</td>
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<tr>
<td>Aerosol</td>
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7. Who will be responsible for the disposal of the animals in accordance with the Radiation Safety Office regulations?

   ____________________________

8. Who will be responsible for decontaminating the animal cages, sipper tubes, etc., prior to LAR's normal cage sanitizing procedure?

   ____________________________

Principal investigators and laboratory supervisors working with radioactive materials are the ones primarily responsible for control of these materials. Before work commences in animals, instructions must be given to animal care and technical personnel concerning contamination, containment procedures and what to do in cases of personal injury or accidents. This can be arranged through the LAR office at least five (5) days prior to animal housing. The Radiation Safety Office will provide technical assistance to LAR on containment and handling procedures for radioactive animals house in LAR facilities.

   ____________________________

PI Signature  Date  Department
RADIOISOTOPE TRAINING AND EXPERIENCE

TRAINING FORM IS REQUIRED FOR EACH PERSON LISTED IN APPLICATION

Name ___________________________  Department/Division ___________________________

Principal Investigator ___________________________  Date ___________________________

FORMAL TRAINING:  Indicate if you have attended a radiation safety course.

☐  UTHSCSA Radiation Orientation (1 1/2 hr.)  Date: ___________________________

☐  UTHSCSA/STVHCS User’s Course (20hr.)  Date: ___________________________

Name or Type of Training course ___________________________  Duration (hrs.): ___________________________

Where: ___________________________  Date ___________________________

Name or Type of Training course ___________________________  Duration (hrs.): ___________________________

Where: ___________________________  Date ___________________________

ON-THE-JOB TRAINING:

<table>
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<tr>
<th>Where</th>
<th>Duration</th>
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EXPERIENCE WITH RADIATION (Actual Use of Radioisotopes or Equivalent Experience):

<table>
<thead>
<tr>
<th>Isotope</th>
<th>Maximum Amount Handled</th>
<th>Where Experience Was Gained</th>
<th>Duration</th>
<th>Type of Use</th>
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Individual’s Signature ___________________________  Date ___________________________  Department ___________________________
APPLICATION FOR CLINICAL USE OF RADIOACTIVE MATERIAL

AUTHORIZED USER

<table>
<thead>
<tr>
<th>Name</th>
<th>Department</th>
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<tbody>
<tr>
<td>Office Location</td>
<td>Office Telephone</td>
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<tr>
<td>E-Mail Address</td>
<td>Emergency Contact Telephone</td>
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AUTHORIZED USER QUALIFICATION

Texas Medical License Number

Board Certified: ☐ Yes (please attach) ☐ No (complete Supplement A & B, NRC Training & Experience and Preceptor Statement for each type of procedure)

Board Certification Date:

CLINICAL PROCEDURE (check all that apply)

§289.256 (ff) & (gg) – Diagnostic Nuclear Medicine, Nuclear Cardiology

☐ Uptake, Dilution and Excretion

☐ Imaging and Localization – bone scans, heart scans, liver scans, etc.

☐ Sentinel Node Injections – breast imaging

§289.256 (kk) - Unsealed Therapy, includes I-131, Sr-89/Sm-153/Y-90, Y-90 microspheres

☐ Unsealed Therapy, general

☐ I-131 < 33 mCi

☐ I-131 > 33 mCi

☐ Parenteral Unsealed Therapy (Sr-89, Sm-153, Y-90)

☐ Y-90 microsphere (attach manufacturer proctor training certificate)

§289.256 (rr) – Manual Brachytherapy

☐ Manual Brachytherapy, includes I-125 permanent & temporary implants, Au-198 prostate implants

☐ Sr-90 Ophthalmic

§289.256 (bbb) – Sealed Sources for Diagnosis

☐ Sealed Sources for Diagnosis

§289.256 (ddd) – High Dose Rate Brachytherapy

☐ Ir-192 High Dose Rate Brachytherapy
§289.256 – Emerging Technologies

☐ Intravascular Brachytherapy

☐ Other – Attach a complete description

§289.256 – Other Radioactive Materials

<table>
<thead>
<tr>
<th>Radioactive Material</th>
<th>Chemical/Physical Form</th>
<th>Maximum Activity</th>
<th>Type of Procedure</th>
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PERSONNEL

1. Have the supervised individuals involved been trained for this procedure? ☐ Yes ☐ No (If yes, please provide documented training for the radiation safety or for the use of the device)

2. List all personnel who will be involved in the preparation, handling, and administration of radioactive materials. Please include each individual’s training and credentials:

RADIATION SAFETY:

1. Will body fluids/excreta contain radioactive material? ☐ Yes ☐ No

2. Describe procedures for controlling the spread of radioactive contamination. Take into account the physical form (gas, liquid, solid) and list any specific requirements for controlling the contamination.

3. How will each patient be identified prior to administration or treatment?

4. How will the non-pregnant status of female subjects of childbearing potential be established and documented?

5. Will patients be inpatients or outpatients? ☐ Inpatients ☐ Outpatients

6. If inpatients, which nursing unit?

7. Attach copy of radiation safety instructions given to the nursing staff for therapy procedures.

8. Are there special radiation dose reductions required for personnel (ex: syringe shield)?

9. Dosimetry required for faculty/staff? ☐ Yes ☐ No

10. Is the facility adequate (lead shields in walls, etc)? ☐ Yes ☐ No

11. Describe any special precautions for handling radioactive waste.

12. Attach patient radiation exposure information (MIRD, ICRP, etc).

Revision 6/25/2010
I certify that the material requested will be used in accordance with the Radiation Safety Regulations at this institution, with all requirements of the law, and with Regulation of the Texas Department of State Health Services, Bureau of Radiation Control. I certify that all information contained herein, including any supplements attached, is true and correct to the best of my knowledge.

Authorized User Signature  

Date

Department Chair Signature  

Date

Revision 6/25/2010

A-16
APPLICATION FOR THE HUMAN USE OF RADIOACTIVE MATERIAL - RESEARCH

PROJECT TITLE

PURPOSE OF THE STUDY

AUTHORIZED USER (person authorized to administer radionuclides to humans)
Name
Mailing Address
Telephone No ( )
Email Address

Faculty Title
Fax No ( )

AUTHORIZED USER QUALIFICATION
Texas Medical License Number
Board Certified: □ Yes (please attach) □ No (complete Supplement A & B, NRC Training & Experience and Preceptor Statement)

PRINCIPAL INVESTIGATOR OF STUDY (if different from Authorized User)
Name
Mailing Address
Telephone No ( )
Email Address

Faculty Title
Fax No ( )

PART 1: RADIONUCLIDES AND INSTRUMENTATION
RADIONUCLIDES

<table>
<thead>
<tr>
<th>Radionuclide</th>
<th>Chemical Form</th>
<th>Volatile</th>
<th>Vendor</th>
<th>Possession Activity (mCi)</th>
<th>Purchase Activity (mCi)</th>
<th>Activity per Subject (mCi)</th>
<th>Room #</th>
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A-17
INSTRUMENTATION

**Dose Assay:** What instrument(s) will be used to assay the activity prior to administration?

| Type of instrument (dose calibrator): | Calibration Date |
| Make | Model | Serial No |

Planned time interval between assay and use

**Contamination Survey:** What instrument(s) will be used to monitor for potential radioactive contamination?

| Type of instrument (survey meter and probe type): | Calibration Date |
| Make | Model | Serial No |

| Type of instrument (liquid scintillation or well counter): | Calibration Date |
| Make | Model | Serial No |

PART 2: RADIOACTIVE DRUG RESEARCH COMMITTEE INFORMATION

Radioactive agents not approved under an IND may not be administered without RSC, RDRC, and IRB approval. Please submit a copy of the submission for the IRB to the RSC and RDRC for approval prior to the IRB.

SUBJECT INFORMATION

Total Number of Subjects _________ Age range of subjects will be from ___ to ___

Number of Adult Males: ____ Females: ____ Number of Minor (up to age 18) Males: ____ Females: ____

Will any subject be involved in any other studies using radioactive material in the same 12 month period? □ Yes □ No

How will the non-pregnant status of female subjects of childbearing potential be established and documented?

Provide justification for studying more than 30 subjects or minors:

RADIOACTIVE DRUG INFORMATION

1. Identity of Radioactive Drug

2. Route of Administration

3. Estimated Radiation Dose to Human Subjects
   a. Absorbed dose calculations:
b. Method of radioassay:

c. Assay instrumentation quality control:

4. Pharmacological Dosage of Active Ingredient

5. Quality of Radioactive Drug
   a. Method of preparation/dispensing:

   b. Minimum acceptance criteria/Routine Quality Control Procedures:

      Visual appearance:
      pH:
      Radiochemical purity:
      Chemical purity:
      Specific activity:
      Radionuclide purity or identification:
      Pyrogens or bacterial endotoxins (parental only):
      Sterility (parental only):

   c. Preclinical validation studies:

   d. Expiration dating:

6. Labeling of radioactive drug
RADIATION DOSIMETRY

1. Does the pharmacological drug dosage cause any clinically detectable effect in human beings? □ Yes □ No

2. Dose Calculation Reference:

3. Maximum Number of administrations per subject:

4. Organs Receiving the highest Effective Dose Equivalent:

PERSONNEL

1. Have the personnel involved been trained for this procedure? □ Yes □ No

2. List all personnel who will be involved in the preparation, handling, and administration of radioactive agent(s). Please include each individual's training and credentials:

RADIATION SAFETY:

1. Will body fluids/excreta contain radioactive material? □ Yes □ No

2. Describe procedures for controlling the spread of radioactive contamination.

SUBMISSION REQUIREMENTS:

□ Copy of IRB application (Form A, B, B-2, C, and D)
□ Radiation Worksheet (Form Q)
□ Pertinent References regarding dosimetry (if applicable)
□ FDA 2915 Special Summary Form (if over 30 subjects requested)

I certify that the material requested will be used in accordance with the Radiation Safety Regulations at this institution, with all requirements of the law, and with Regulation of the Texas Department of State Health Services, Bureau of Radiation Control. That all information contained herein, including any supplements attached, is true and correct.

__________________________________________  _______________________
Authorized User Signature                   Date

__________________________________________  _______________________
Principal Investigator Signature            Date
SPECIFIC INSTRUCTIONS FOR ANY STAFF TENDING THE PATIENT:
(Complete checked items.)

__X__ 1. Wear dosimeter provided.
__X__ 2. Wear disposable gloves.
__X__ 3. Cover any instrument with disposable glove OR leave it in the room.
__X__ 4. Place all laundry in the linen container in room.
__X__ 5. Place all disposable items, ie food trays, gloves, etc., in containers in the room.
__X__ 6. Patient may be given food 2 hours after dosing time. Patient should always be given a low iodine diet.
__X__ 7. Patient may be given water 1 hour after dosing time. Patient should be given plenty of water at their request.
__X__ 8. DO NOT REMOVE ANY ITEMS FROM THE ROOM.
__X__ 9. HOUSEKEEPING MAY NOT ENTER THE ROOM.
__X__ 10. A dismissal survey must be performed before patient is discharged.
__X__ 11. Radiation Safety will decontaminate room before Housekeeping cleans.
_____ 12. See Special Instructions.

VISITOR INSTRUCTIONS:
(Complete checked items.)

_____ 1. Patient may NOT have visitors.
__X__ 2. Patient may have visitors after 24 hours.
__X__ 3. Visitors MUST remain at a distance of 10 feet!
__X__ 4. No pregnant Visitors.
__X__ 5. No visitors under 18 years of age.

Radiation Safety Officer: Jennifer Cerecero Telephone # 567-2955 / UTPD 567-2800
Name on duty / off duty
Sm-153 Quadramet Order/Prescription Form

Patient Name: _____________________________________________________

Patient No.:_______________________  Sex:   Male   Female

Proposed Date of Treatment: _________________________________________

Patient Weight (Kg): ________________________ DOB: __________________

Treatment consent signed: ________________ Insurance signed:_________

WBC:_________________________ Platelets: __________________________

(Blood draw must be with two weeks of Injection Date)
(Platelet Count must be greater than or equal to 100,000)
(WBC must be greater or equal to 4,000)

Sm-153 Quadramet Prescription

_________________________ (1.0 mCi/Kg)

Radiation Oncologist Signature: ________________________ Date__________

Tony Eng, M.D.            William E. Jones, III, MD. (Trey)
Richard Crownover, M.D.   Chul Ha, M.D.

Insurance Verified: ________________________________________________

Radiation Safety Officer: __________________________________________

Ordered by: _______________________________ On: _________________

Pharmaceutical Representative Receiving Order: ______________________

Delivery Date: ____________________________________________________

Patient Survey:
Exposure at 1 meter: ______________________________
Instrument Used: ______________________________
Serial Number: ______________________________

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A-23
Ra-223 Xofigo Order/Prescription Form

Patient Name: _____________________________________________________

Patient No.: ____________________________ Sex: Male Female

Proposed Date of Treatment: _________________________________________

Patient Weight (Kg): ________________________ DOB: ________________

Treatment consent signed: ________________ Insurance signed:_________

WBC: ______________________ Platelets: ____________________________

First injection
(Platelet Count must be greater than or equal to ≥ 100 x 10⁹ /L)
(Hemoglobin ≥ 10g/dL)
Subsequent administrations.
(Platelet Count must be greater than or equal to ≥ 1 x 10⁹ /L)
(Platelet ≥ 50 x 10⁹/L)

Ra-223 Xofigo Prescription
_________________________ (1.35 uCi/Kg)

Radiation Oncologist Signature: ____________________________ Date__________
Tony Eng, M.D.  Chu1 Ha M.D.
Richard Crownover, M.D.

Insurance Verified: _____________________________________________

Radiation Safety Officer: _________________________________________

Ordered by: ____________________________ On: _________________

Pharmaceutical Representative Receiving Order: ______________________

Delivery Date: _________________________________________________

Patient Survey:
Exposure at 1 meter: ______________________
Instrument Used: _________________________
Serial Number: ___________________________

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