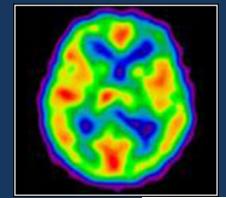


# Radiation Safety Manual for Medical Applications

The purpose of this manual is to provide authorized users, clinicians, medical physicists and technologists who administer radioactive material to patients with policy and procedure regarding the safe use and disposal of radioactive material as approved for human use by the West Virginia University Radiation Safety Committee under the West Virginia University Hospital's NRC Broad Scope License.

# 2023 Revision







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# **1. INTRODUCTION**

#### 1.1 RADIOACTIVITY AND RADIATION

All matter in our environment is made of atoms and most atoms we encounter on Earth are stable. Some atoms are unstable, giving off energy in the form of radiation in order to reach a stable state. This process is called radioactive decay or radioactivity, and atoms that go through this process are called radioisotopes. An example is the radioisotope, Carbon-14 (C-14, <sup>14</sup>C), produced in the atmosphere when cosmic rays interact with stable nitrogen atoms. When a Carbon-14 atom undergoes radioactive decay, it gives off radiation in the form of a beta particle and then becomes a stable nitrogen atom once again. The existence of Carbon-14 in all living things enables archaeologists to date ancient artifacts. This is but one example of how radioisotopes can be utilized. Radiation can be naturally emitted from radioisotopes through the decay process, or can be electrically generated by a radiation-producing device, such as in an x-ray tube or linear accelerator. Radiation can only be detected by specially designed instruments. Radiation may pass through an object, but it may be absorbed and cause changes at the site of absorption. At high enough levels, ionizing radiation is known to cause cancer and birth defects in animals and humans. The risk of radiation damage is related to the amount of radiation absorbed by an individual.

There are small amounts of naturally occurring radioactive substances in soil, rocks, plants, animals, and in our own bodies, all of which give off radiation. A well-known example of naturally occurring radiation is radon, which is a radioactive gas that comes from the ground. Large amounts of radiation are present in outer space and a small portion of this radiation penetrates the atmosphere. This low level of naturally occurring radiation is known as background radiation. Background radiation accounts for approximately half of the average person's annual radiation exposure.

Radiation is useful in medicine because of its ability to penetrate tissue, allowing imaging of internal structures. In addition, radiation's ability to damage biological tissue is useful in the treatment of certain types of diseases, such as cancer. However, those properties which make radiation useful in medicine, can also produce harmful biological effects. Observations of exposed human populations and animal experimentation indicate that exposure to low levels of radiation over a period of years may lead to an increased incidence of cancer. Exposures to high levels of radiation produce the same effects faster and may also cause hair loss, skin burns, radiation sickness or even death. Radiation may also increase the risk of genetic abnormalities.

#### **1.2** Commitment to safety

The Administration of West Virginia University Hospitals has a commitment to providing a safe environment for faculty, staff and patients during the medical use of radioactive material. It is the responsibility of all Deans, Department Chairs and clinicians to implement radiation safety policy and procedure as approved by the West Virginia University Radiation Safety Committee under the authority delegated by the Administration. Oversight of these policies and procedures is carried out by the Radiation Safety Department under the supervision of the Radiation Safety Officer (RSO).

# **1.3** REGULATION AND BROAD SCOPE LICENSE

The United States Nuclear Regulatory Commission (NRC) has issued a specific Broad Scope License to West Virginia University and West Virginia University Hospitals that permits the procurement, storage, and use of radioactive materials. These radioactive materials include byproduct materials (radioactive materials that were made in a reactor or particle accelerator) and naturally occurring radioactive materials. In addition, radiation producing devices are subject to the regulations of the West Virginia Department of Health and Human Resources' (WVDHHR) Radiological Health Program (WVRHP), see WVU Radiation Producing Device Policy Manual.

# 1.4 RADIATION PROTECTION – ALARA

To minimize the biological effects of radiation, special rules and regulations are set forth for individuals occupationally exposed to radiation. There is, in general, minimal external radiation hazard to personnel from procedures involving radiation. Adherence to guidelines contained in this manual will help employees and students keep their exposures as low as reasonably achievable (ALARA), and should reduce radiation exposures to levels allowable for individuals or in some cases, to levels indistinguishable from natural background.

The radiation protection program is guided by the concept of keeping radiation exposure ALARA. The ALARA concept assumes that any radiation dose, no matter how small, can have some adverse effect. Under the ALARA program, every reasonable means of lowering exposure is used.

Radiation exposure can be minimized by utilizing three basic principles:

- 1. Time: Minimizing the time spent in a radioactive field, reduces the radiation dose received.
- 2. Distance: Maximizing distance from a source of radiation reduces the radiation dose received.
- **3.** Shielding: The use of <u>appropriate</u> shielding greatly reduces the radiation dose received.

Remember that radiation cannot be seen or felt, but can be detected with radiation survey meters.

# 2. RADIATION SAFETY COMMITTEES AND USER RESPONSIBILITIES

#### 2.1 RADIATION SAFETY COMMITTEE (RSC)

The Radiation Safety Committee is composed of WVUH Executive Management or his/her representative, WVU Health Sciences Executive Management or his/her representative, the RSO, others who may be nominated by any of the above, a representative from each authorized area of use, faculty Authorized Users, and the chairperson of each of the Radiation Safety Sub-Committees reporting to the Radiation Safety Committee.

The committee meets at least quarterly to:

- A. Review and approve permitted program and procedural changes prior to implementation;
- B. Implementation of program and procedural changes;
- C. Take appropriate actions when non-compliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence;
- D. Adopt rules and policies on the use of ionizing radiation within the university and the hospital;
- E. Review plans for all new buildings and modifications of existing structures where ionizing radiation is to be used;
- F. Audit of licensed operations to determine compliance;
- G. Review reports by the RSO and the chairs of the Radiation Safety Sub-Committees;
- H. Approve or modify proposals for amendments to the various licenses or applications for new licenses;
- I. Perform an annual review of the content and implementation of the Radiation Safety Program including ALARA considerations. This includes a review of the operation of the Radiation Safety Department on, at least, an annual basis to ensure that all license obligations and regulations of the U.S. Nuclear Regulatory Commission and the West Virginia Department of Health are met and that sources of ionizing radiation are being used in a safe manner;
- J. Approve changes in the Radiation Safety Manual and recommend changes when these become necessary.
- K. Review and approve any changes to or the introduction of new training before implementation.

#### 2.2 HUMAN USE OF RADIATION AND RADIONUCLIDES COMMITTEE

The Committee is composed of the chair of the Radiology Department or his/her representative, the Director of Nursing Service or his/her representative, physicians who are experts in radiation therapy, nuclear medicine, internal medicine, hematology or cardiology, a person experienced in the assay of radionuclides, and the RSO, as well as such additional members as shall be nominated by the chair of the Radiation Safety Committee and the RSO in consultation with the Committee. This committee functions as the Radiation Safety Committee of the hospital so far as the diagnostic or therapeutic use of radiation on humans is concerned.

The committee meets at least quarterly to:

- A. Adopt rules and policies pertaining to the use of ionizing radiation in or on humans at WVU Medicine Ruby Memorial Hospital or the Robert C. Byrd Health Sciences Center.
- B. Review and either approve or return for amendment all proposals for the use of radiation or radionuclides in or on humans.
- C. Evaluate the qualifications of all persons proposing to use radiation or radionuclides in or on humans to ensure that they are adequate for the proposed use.
- D. Review plans for all new buildings and modifications of existing buildings where ionizing radiation is to be used in or on humans and to send its recommendations to the Radiation Safety Committee.
- E. Review proposed shielding and operations of all radiation producing machines and equipment used for the exposure of humans.
- F. Review all instances of alleged infractions of rules and unsafe practices in the human use of ionizing radiation, and take the steps necessary to ensure safe practice. This may entail recommendations to the Radiation Safety Committee or to appropriate supervisory personnel in the department in which an offense occurs.
- G. Review reports from the Radiation Safety Department on the use of ionizing radiation in or on humans, including any changes or impending changes in regulations.
- H. Ensure that all license obligations and federal and state regulations are met and that safe practice is maintained in the human use of ionizing radiation.

#### 2.3 NON-HUMAN USE OF RADIATION AND RADIONUCLIDES COMMITTEE

The Committee is composed of faculty members experienced in the laboratory use of radionuclides, the chairs of the Committee on the Use of Radiation and Radionuclides in Animals and the Radiation Research Committee or their representative, the RSO, and others who may be nominated by the chair of the Radiation Safety Committee and the RSO.

The committee meets at least quarterly to:

- A. Adopt rules and policies for use of radiation in vitro and in animals at West Virginia University Ruby Memorial Hospital and West Virginia University.
- B. Review and either approve or return for amendment all proposals for the use of ionizing radiation in vitro or in animals.
- C. Evaluate the qualifications of all persons proposing the use of radiation in vitro, or in animals, to ensure that they are adequate for the proposed use.
- D. Review plans for all new buildings and modifications of existing buildings where ionizing radiation is to be used in vitro or in animals and send its recommendations to the Radiation Safety Committee.
- E. Review all instances of alleged infractions of rules and unsafe practices in the use of ionizing radiation in vitro, or in animals, and take the steps necessary to ensure safe practice. This may entail recommendations to the Radiation Safety Committee or to appropriate supervisory personnel in the department in which an offense occurs.
- F. Review reports from the Radiation Safety Department on the use of ionizing radiation in vitro, and in animals including any changes or impending changes in regulations.
- G. Ensure that all license obligations and federal and state regulations are met and that safe practice is maintained in the use of ionizing radiation in vitro and in animals.
- H. Activate the subcommittees on Animal Use or Radiation Research necessary to review activities within their jurisdiction.

#### 2.4 COMMITTEE ON THE USE OF RADIATION AND RADIONUCLIDES IN ANIMALS

The Committee is composed of the director of the animal quarters, a person experienced in the assay of radionuclides, the RSO, and others who may be nominated by the chair of the Radiation Safety Committee and the RSO. The committee functions as a subcommittee of the Non-Human Use of Radiation and Radionuclides Committee.

The committee will meet when necessary to:

- A. Adopt rules and policies for the use of ionizing radiation in or on animals.
- B. Review and either approve or return for amendment all proposals for the use of ionizing radiation in or on animals.
- C. Evaluate the qualifications of all persons proposing to use radiation or radionuclides in or on animals to ensure that they are adequate for the proposed use.
- D. Review plans for all new buildings and modifications of existing buildings where ionizing radiation is to be used in or on animals and send its recommendations to the Radiation Safety Committee.
- E. Review all instances of alleged infractions of rules and unsafe practices in the use of ionizing radiation in or on animals and take the necessary steps to ensure safe practice.

This may entail recommendations to the Radiation Safety Committee or to appropriate supervisory personnel in the department in which an offense occurs.

- F. Review reports from the Radiation Safety Department on the use of ionizing radiation in or on animals including any changes or impending changes in regulations.
- G. Ensure that all license obligations and federal and state regulations are met and that safe practice is maintained in the use of ionizing radiation in or on animals.

#### 2.5 RADIATION RESEARCH COMMITTEE

The committee is composed of scientists and engineers of the Downtown and Evansdale campuses of WVU who have experience in the use of radionuclides in research protocols, the RSO, and others who may be nominated by the chairman of the Radiation Safety Committee and the RSO. The committee functions as a subcommittee of the Non-Human Use of Radiation and Radionuclides Committee.

The committee will meet when necessary to:

- A. Adopt rules and policies on the use of ionizing radiation on the Downtown and Evansdale campuses.
- B. Review and either approve or return for amendment all proposals for the use of radiation or radionuclides on the Downtown or Evansdale campus.
- C. Evaluate the qualifications of all persons proposing to use radionuclides on the Downtown or Evansdale campus to ensure that they are adequate for the proposed use.
- D. Review plans for all new buildings and modifications of existing buildings where ionizing radiation is to be used on the Downtown or Evansdale campus and send its recommendations to the Radiation Safety Committee.
- E. Review all instances of alleged infractions of rules and unsafe practices in using ionizing radiation on either the Downtown or Evansdale campus and take the necessary steps to ensure safe practice. This may entail recommendations to the Radiation Safety Committee or to supervisory personnel in the department in which an offense occurs.
- F. Review reports from the Radiation Safety Department on the use of ionizing radiation on either the Downtown or the Evansdale campus including any changes or impending changes in regulations that might affect these campuses.
- G. Ensure that all license obligations and federal and state regulations are met and that safe practice is maintained in the use of ionizing radiation on the Downtown and Evansdale campuses.

# 2.6 RADIOACTIVE DRUG RESEARCH COMMITTEE (RDRC)

The committee is composed of at least five members, three of which must be: (1) a physician recognized as a specialist in nuclear medicine, (2) a person qualified by training and experience to formulate radioactive drugs, and (3) a person with special competence in radiation safety and

radiation dosimetry. The remainder of the committee shall consist of individuals qualified in specialties related to nuclear medicine, and the RSO or his/her designee. The membership shall be diverse enough to permit expert review of the technical and scientific aspects of proposals to the committee.

The RDRC Program, administered by the FDA, permits basic research of radioactive drugs in humans without an investigational new drug application (IND). The committee must meet quarterly when research has been authorized and conducted and the committee must have a quorum of more than 50 percent to vote and hold a meeting. No member of the RDRC shall have a vote on a protocol in which he/she is an investigator. The RDRC shall furnish a report to the FDA annually, which includes the names and qualifications of members, consultants (if applicable), and a summary of each study performed in the calendar year.

Full details on the formation, procedures, and reporting requirements for the RDRC can be found in 21 CFR 361.1 – Radioactive drugs research uses. RDRC policies and procedures as well as applicable forms can be found at the Radiation Safety Department website at https://www.hsc.wvu.edu/rsafety/wvuh-rdrc-radioactive-drug-research-committee/

#### 2.7 RADIATION SAFETY OFFICER/ RADIATION SAFETY DEPARTMENT

The responsibilities of the RSO/Radiation Safety Department include the following:

- A. To furnish consulting services to any potential user of ionizing radiation and to advise the potential user on radiation safety procedures.
- B. To ensure that all license obligations and regulations of the federal and state government are met.
- C. To provide general surveillance of all health physics activities, including assisting all personnel in discharging their responsibilities.
- D. To supervise the procurement and receipt of all radioactive materials coming to the West Virginia University and the West Virginia University Ruby Memorial Hospital.
- E. To provide for individual and laboratory monitoring.
- F. To instruct university and hospital personnel in radiation safety.
- G. To administer a radioactive waste disposal program.
- H. To perform leak tests on sealed sources.
- I. To provide radiation surveys after installation of radiation producing machines.
- J. To supervise decontamination in case of accidents.
- K. To provide a continuous program of environmental radiation hazard evaluation and hazard elimination.
- L. To provide advice and assistance in the acquisition of dosimeters and monitoring equipment.
- M. To provide maintenance and calibration of survey instruments in the Radiation Safety Department.
- N. To maintain all centralized records pertinent to the radiation safety program.
- O. To develop and refine radiation detection, shielding and health protection techniques.

- P. To be responsible for the overall day-to-day administration of the radiation safety program.
- Q. To suspend any operation causing excessive radiation hazard as rapidly and safely as possible. (In carrying out this duty the RSO will report directly to WVUH Executive Management or WVU Health Sciences Executive Management.
- R. To present periodic reports to the various committees on matters related to their functions.
- S. To keep each department chair informed of all Authorized Users in the department who are conducting projects approved by a Radiation Safety Committee.
- T. To provide timely reports to the U.S. Nuclear Regulatory Commission and the West Virginia Department of Health as required by regulation.
- U. To maintain an inventory and accountability record of the radioactive material used at the university and the hospital to ensure compliance with license limits.

#### **2.8** DEPARTMENT CHAIRS

The Department Chairs' responsibilities include the following:

- A. To have plans for all new buildings and modifications of existing structures, where ionizing radiation is to be used, submitted through the Radiation Safety Department for approval by the appropriate Radiation Safety Committee prior to the construction or modification.
- B. To have any area where radionuclides were previously used surveyed by the Radiation Safety Department before any maintenance, architectural, or engineering work is conducted. Call the Radiation Safety Department (304-293-3413) to ensure that any needed decontamination or disposal is carried out properly.
- C. To have new staff members who desire to use ionizing radiation should secure and read a copy of this Radiation Safety Manual for Medical Applications from the Radiation Safety Department.
- D. To have Authorized Users who are leaving the University or changing laboratories inform the Radiation Safety Department. They should arrange, with guidance from the Radiation Safety Department, for the transfer of unused radionuclides to other Authorized Users and have any radioactive waste picked up by Radiation Safety. This will keep any potentially hazardous material from being unsupervised when a faculty member terminates.

Note: The RSO will keep each Department Chair informed of all Authorized Users in the department who are conducting projects approved by any of the radiation safety committees.

#### **2.9** AUTHORIZED USERS

The Authorized User shall be responsible for:

- A. Controlling employee and visitor exposures, keeping them ALARA and always below the dose limits in Section 6.2, "Requirement to Keep Doses ALARA."
- B. Requesting proper radiation monitoring devices for laboratory personnel.
- C. Providing suitable monitoring instruments, protective clothing, equipment (such as shielding, if required) and supplies for employees.
- D. Notifying the Radiation Safety Department of any change or proposed change in radionuclide use which might affect radiation protection procedures.
- E. Following correct procedures for procurement of radionuclides and radiation producing devices.
- F. Maintaining up-to-date marking and labeling of laboratories, radioactive materials and equipment.
- G. Properly disposing of radioactive wastes and producing accurate disposal records.
- H. Immediately reporting to the Radiation Safety Department any spills, suspected overexposures, theft or misuse of radioactive material, and other accidents or incidents involving radiation or radioactive materials.
- I. Safely operating any radiation producing device for which s/he is listed as the possessor.
- J. Testing and care of radiation sources made by university or hospital personnel.
- K. Properly administering and using sources of radiation in or on humans (if authorized for this type of use).
- L. Providing employees with copies of portions of the Radiation Safety Manual applicable to them, such as:
  - 1. General Procedures for Physicians (Section 8.1)
  - 2. General Procedures for Nurses (Section 8.2)
  - 3. Emergency Procedures and Decontamination Procedures (Sections 10 and 11)
- M. Attending periodic in-service training sessions presented by the Radiation Safety Department and requiring that students and employees attend the orientation and inservice training sessions appropriate for them.
- N. Properly using radiation sources in or on animals (if applicable).
- O. Properly using a sealed source irradiator facility (if applicable).
- P. Securely storing all radiation sources used under his or her direction.
- Q. Making sure that appropriate surveys and monitoring are performed, any needed corrective action is carried out and that necessary records are maintained.
- R. Properly transferring radioactive material while working at the university or hospital and prior to leaving (as applicable).
- S. Ensuring that radiation survey instruments are calibrated periodically for the type of radiation to be measured.

Note: The Authorized User is fully responsible for adherence to these requirements and the safe use of ionizing radiation by him/herself and those under his/her direction.

#### 2.10 INDIVIDUAL RADIATION WORKERS

An individual shall be responsible for:

- A. Controlling his/her radiation exposure, keeping it as low as is reasonably achievable and always below the dose limits in Section 6.
- B. Assisting the Authorized User in keeping the marking and labeling of laboratories, radioactive materials and equipment up-to-date.
- C. Maintaining good housekeeping, minimizing clutter, and reducing the chance of transfer of contamination.
- D. Carrying out monitoring of self, work area and lab, and producing required records of the monitoring performed.
- E. Using appropriate instruments, checking for proper operation before use and reporting any problems to the Authorized User in a timely manner.
- F. Storing and securing radioactive material properly.
- G. Wearing appropriate protective clothing such as a lab coat and gloves.
- H. Wearing and storing personal radiation monitors properly.
- I. Disposing of radioactive wastes appropriately and keeping accurate disposal records.
- J. Properly testing and caring for radiation sources made by university or hospital personnel.
- K. Promptly reporting spills, suspected overexposures, theft of material and other incidents to the Radiation Safety Department.
- L. Maintaining a working knowledge of emergency and decontamination procedures.
- M. Becoming familiar with his or her specific area of concern.

# 3. CRITERIA FOR EVALUATING USER QUALIFICATIONS FOR THE USE OF RADIOACTIVE MATERIALS

# **3.1** HUMAN USE OF RADIOPHARMACEUTICAL DRUG PRODUCTS APPROVED FOR ROUTINE DIAGNOSTIC AND THERAPEUTIC PROCEDURES

Individuals seeking authorization for human use of radioactive materials licensed by the U.S. NRC must first be approved by the WVU Radiation Safety Committee. A prospective Authorized User (AU) or Authorized Medical Physicist (AMP) must submit an application for the human use of radioactive materials to the Radiation Safety Department (see Contact Information). Once the application is approved by the RSD, it will be forwarded to the Radiation Safety Committee for final review and approval. Applications shall include documentation showing how the applicant meets the training and experience requirements outlined in the NRC regulations 10 CFR Part 35, or other available licensing guidance, applicable to their desired use and pathway for approval.

Applicants must also submit related recent continuing education and experience documentation if training and experience was completed more than 7 years before the date of the application, per 10 CFR 35.59.

All prospective AUs and AMPs applying for authorization following the training and experience pathway must provide a preceptor attestation statement as part of their documentation of training and experience.

#### 3.2 HUMAN USE OF RADIONUCLIDES IN NON-ROUTINE OR EXPERIMENTAL PROCEDURES

The use of all experimental techniques on humans involving radioactive material or otherwise is governed by the WVU Institutional Review Board (IRB). All experimental procedures involving radiation exposure must also be approved by the Human Use of Radiation and Radionuclides Committee and Radiation Safety Committee. Individuals seeking authorization for non-medical use must submit an application to the RSC for review and approval. The application shall include description of the type, quantity, and proposed non-medical uses requested and documentation of detailed radiation training and experience applicable to the use requested. Individuals authorized for non-medical use must have adequate training and experience with the types and quantities of licensed material they propose to use.

Protocols which involve procedures which are in clinical practice or have been approved by the Human Use Committee may be approved by the RSO. The RSO's technical review will include an assessment of the prospective AUs prior training and experience (on-the-job or formal coursework). The training should cover (a) principles and practices of radiation protection, (b) radioactivity measurements, standardization, and monitoring techniques and instruments, (c) mathematics and calculations basic to the use and measurement of radioactivity, and (d) biological effects of radiation. The description of the use of licensed materials should include the

specific isotopes handled, the maximum quantities of materials handled, where the experience was gained, the duration of experience, and the type of use.

The Human Use Committee has adopted the radiation exposure limits for all research subjects which are required for FDA studies per 21 CFR 361.1(b)(3)(i & ii). These limits are given in Table 1, Radiation Dose Limits for Research Subjects. Research protocols should be submitted to the RSO as early as possible to permit an adequate review and estimation of patient exposure.

		Whole Body (EDE <sup>a</sup> )	Organ Maximum
Adult	Per Study	3,000 mrem	5,000 mrem
	Annual	5,000 mrem	15,000 mrem
Under Age	Per Study	300 mrem	500 mrem
18	Annual	500 mrem	1,500 mrem

# TABLE 1: RADIATION DOSE LIMITS FOR RESEARCH SUBJECTS

a. EDE: Effective Dose Equivalent

In addition to IRB review and approval, the experimental technique must be reviewed and approved by the Radioactive Drug Research Committee, without needing an Investigational New Drug (IND) application.

Similarly, all research protocols which involve the use of radiation or radionuclides in animals must be approved by the Animal Care and Use Committee, a branch of the IRB. Contact the Institutional Review Board at (304) 293-7073 or P.O. Box 6845 for further information.

# 4. PROCUREMENT OF RADIOACTIVE MATERIALS

#### 4.1 ORDERING OF ROUTINELY USED MATERIAL

The immediate approval of a purchase order for radioactive material is delegated by the Nuclear Medicine Physician to the Nuclear Medicine Technologist. The Nuclear Medicine Physician must be authorized by the WVU Radiation Safety Committee to use radiopharmaceuticals for human use and such uses must be reviewed by the RSO. The Nuclear Medicine Technologist is responsible for the inventory of all radioactive material used routinely. Radioactive materials will be procured from NRC or State licensed suppliers.

#### 4.2 QUALITY MANAGEMENT

- A. A written directive will be obtained from the physician who will perform or oversee the procedure. The written directive will contain the isotope, total prescribed dose and signature and date of the authorized user.
- B. Persons ordering the material will reference the physician's written request when placing the order. The physician's request will indicate isotope, compound, activity level, patient's name, etc.
- C. The physician's written request will be referenced when receiving, opening, or storing the radioactive material.
- D. It is essential that written records be maintained for all ordering and receipt procedures.
- E. Appendix 1 will serve as a model for ordering and receiving radioactive material.

# 4.3 RECEIPTS, TRANSFERS, UNPACKING AND STORAGE

Radioactive materials are normally delivered to the Nuclear Medicine Hot Laboratory during working hours. During off duty hours, the packages are received as per Appendix 1.

All personnel involved with the receipt of radioactive material shipments must be instructed in the proper procedures and precautions. Appendix 1 is a model for written instructions for this purpose. A copy of these instructions is to be given to all involved individuals.

Unpacking of radioactive material receipts must be done in accordance with the established safety procedures described on Appendix 1.

#### 4.4 RECORDS

Each clinical area is responsible for maintaining the master record file or log of all radioactive material ordered, received, transferred, used and disposed. The Nuclear Medicine Technologist, Medical Physicist, or Dosimetrist will maintain these records under the supervision of the RSO. Records of radiation surveys, incident reports, personnel dosimetry results, leak tests, and survey instrument calibration shall also be maintained in each clinical area.

- A. The following records must be kept and are to be available for inspection at *any time* by the Radiation Safety Department and authorized regulatory agency representatives:
  - 1. Type and amount of radionuclides on hand.
  - 2. Results of radiation surveys.
  - 3. Sealed source leak tests and inventories, dose calibrator quality control testing, and survey meter calibrations control testing, and survey meter calibrations.
  - 4. Method and amount of disposal, including radiation survey results for material held for decay.
  - 5. Patient dose records, including patient's name dose prescribed, dose assayed, type of procedure, and date. Records will be retained for review by the licensing body for the periods specified below.
- B. The following records must be kept indefinitely:
  - 1. Personnel Monitoring and Bioassay Records
  - 2. Radiation Accident Investigation Results
  - 3. Radiation Safety Committee Minutes
- C. The following records must be kept for ten (10) years:
  - 1. Medical Event Reports
- D. The following records must be kept for five (5) years:
  - 1. Sealed Source Leak Test and Inventory Results
- E. The following records must be kept for three (3) years:
  - 1. Patient Dose Records
  - 2. Survey Results, Including Area Surveys and Hold for Decay Surveys
  - 3. Mo-99 Breakthrough Results
  - 4. Survey Meter Calibration and Dose Calibrator QC Test Results

# 5. STORAGE OF RADIONUCLIDES

#### 5.1 LIQUIDS AND SOLIDS

All sources of radiation shall be secured against unauthorized removal from the places of storage or use and shall be provided with reasonable protection against loss, leakage, or dispersion by the effects of fire or water. Radioactive material in a controlled or unrestricted area that is not in storage shall be controlled and given constant surveillance.

It is important that all stored radioactive samples be clearly labeled at all times. The label should show the radionuclides, their activity and date of activity, the chemical form, and the name of the responsible Authorized User plus any additional information that would help an individual to minimize his or her exposure.

Storage sites for large amounts of radioactive materials should be as remote from occupied areas as practicable. Materials must be stored so that the dose in any unrestricted area from external sources does not exceed 0.02 mSv (2 mrems) in any one hour. The total effective dose equivalent to individual members of the public shall not exceed 1 mSv (100 mrems) in a year.

Storage areas must be well-marked with appropriate signs. These should read "Caution-Radioactive Materials" or "Caution-Radiation Area." The name, address, and phone number of the responsible person and the RSO shall be posted in a conspicuous place near the area. See Appendix 2 for examples of approved signs and labels.

#### 5.2 GASES

The storage requirements listed above apply as well to radioactive gases. In addition, radioactive gas cylinders or ampoules and radioactive solutions that emit gases should be labeled and kept in approved hoods which are provided with appropriate filters. Only the amounts of material necessary for immediate use should be stored.

# 6. RADIATION PROTECTION MEASURES

#### 6.1 INTRODUCTION

There are two general ways in which the body may be irradiated:

- A. Radionuclides outside the body (external sources of gamma and/or high energy beta emitters)
- B. Radionuclides inside the body (internal exposures from any radionuclide)
  - 1. Breathing radioactive vapor
  - 2. Ingesting radioactive material food, water, or from contaminated hands
  - 3. Entering through a cut
  - 4. Absorption through the skin

Exposure limits have been set for the protection of both personnel and the general public. It must be emphasized that the following limits are maximum permissible limits. The WVU Radiation Safety Committee (RSC) has adopted the policy that all radiation exposures are kept as low as reasonably achievable (ALARA).

The radiation protection limits specified in this section are set so that an individual could be allowed to receive doses up to the limits each year for all of his/her working life. Most radiation protection guidelines assume that any dose of ionizing radiation, no matter how small, may produce some genetic or somatic damage, and thus it is considered wise to avoid all unnecessary exposure to radiation.

# 6.2 REQUIREMENT TO KEEP DOSES ALARA

All licensees and are required by the Nuclear Regulatory Commission (NRC) and to use, to the extent practicable, procedures and engineering controls that are based upon sound radiation protection principles so that occupational doses and doses to members of the public are ALARA.

This means that operations must be planned, monitored, and carried out so that any dose received is not only below the limits established in this manual, but also is as far below the limits as is reasonable to achieve. Adequate preparation must be made so that appropriate engineering provisions can be installed.

# 6.3 RADIATION PROTECTION LIMITS

West Virginia University and West Virginia University Hospitals are committed to compliance with the radiation protection limits specified by United States Nuclear Regulatory Commission (NRC) in 10 CFR 20. These dose limits apply to radiation exposures above those received from background radiation and medical exposure.

The regulations require that doses from external and internal sources must be monitored if an individual is likely to receive a dose in excess of 10% of the applicable dose limits. If both external and internal doses must be monitored, the dose resulting from each must be added together and the sum compared to the appropriate annual limit.

Limits are issued for occupationally exposed individuals: adults, minors, and an embryo/fetus. Dose limits for individual members of the public are also included.

# 6.3.1 NRC OCCUPATIONAL DOSE LIMITS

For adults, an annual limit shall not exceed:

- A. 5 rems (0.05 Sv) for the total effective dose equivalent (TEDE), which is the sum of the deep dose equivalent (DDE) from external exposure to the whole body and the committed effective dose equivalent (CEDE) from intakes of radioactive material.
- B. 50 rems (0.5 Sv) for the total organ dose equivalent (TODE), which is the sum of the DDE from external exposure to the whole body and the committed dose equivalent (CDE) from intakes of radioactive material to any individual organ or tissue, other than the lens of the eye.
- C. 15 rems (0.15 Sv) for the lens dose equivalent (LDE), which is the external dose to the lens of the eye.
- D. 50 rems (0.5 Sv) for the shallow dose equivalent (SDE), which is the external dose to the skin or to any extremity.

For minor workers, the annual occupational dose limits are ten percent (10%) of the dose limits for adult workers.

For protection of the embryo/fetus of a declared pregnant woman, the dose limit is 500 mrem (5 mSv) during the entire pregnancy. Efforts must be made to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the aforementioned limit. Thus, the monthly exposure during pregnancy should be less than 50 mrems (0.5 mSv).

For individual members of the public, the total effective dose equivalent to individual members of the public from licensed operations at the University or Hospital shall not exceed 100 mrems (1 mSv) in a year, exclusive of any dose contribution from the Authorized User's disposal of radioactive material into sanitary sewage, and the dose in any unrestricted area from external sources shall not exceed 2 mrems (0.02 mSv) in any one hour.

#### 6.4 INDIVIDUAL MONITORING

#### 6.4.1 CONDITIONS REQUIRING MONITORING

- A. Each Authorized User must monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this section. As a minimum each Authorized User must monitor occupational exposure to radiation and must supply/require the use of individual monitoring devices by:
  - A. Adults likely to receive a dose in excess of ten percent (10%) of the limits specified above in one (1) year from sources external to the body.
  - B. Minors and declared pregnant women likely to receive a dose in excess of ten percent (10%) of the applicable limits in one (1) year from sources external to the body, and
  - C. Individuals entering a high or very high radiation area.
- B. Each Authorized User must monitor the occupational intake of radioactive material by and have the committed effective dose equivalent calculated for:
  - 1. Adults likely to receive an intake in excess of ten percent (10%) of the applicable Annual Limit on Intake<sup>1</sup> (ALI) in one (1) year, and
  - 2. Minors and declared pregnant women likely to receive a committed effective dose equivalent in excess of 50 mrems (0.5 mSv) in one (1) year.

Contact the Radiation Safety Department for advice and help if you believe that monitoring will be required for internal exposures.

#### 6.4.2 Types and Use of Monitoring Devices

There are dosimeters available through RSD for external personal radiation monitoring.



#### Thermoluminescent Whole Body Dosimeter (whole body badge):

External exposure to radiation is monitored by wearing a dosimeter "badge". The Genesis Ultra TLD-BP<sup>TM</sup> radiation dosimeter is used for determining radiation exposure to the torso and head from external sources of gamma radiation, x-ray, or beta radiation with maximum energy greater than 0.25 MeV. The minimum reportable dose is 1 mrem. Thus, the dosimeter will not record the low energy beta

radiation of H-3, C-14 or S-35, because these betas are too weak to penetrate the paper wrapping on the film. However, these betas are too weak to penetrate the outer layer of skin. The dosimeters we currently use are customized to include the department, user name, wear date, account number, participant number, and serial number. The whole body dosimeter will be

<sup>&</sup>lt;sup>1</sup> A comprehensive review of such isotopes is available on the NRC web site. (http://www.nrc.gov/reading-rm/doc-collections/cfr/part020/appb/)

labeled with a WB and the collar dosimeter will be labeled with a CL, and a fetal dosimeter is a blue or white dosimeter and will be labeled with an FET or Fetus.



**TLD Ring Dosimeter**: This Ultra Ring<sup>TM</sup> is an extremity dosimeter (ring badge) and is worn on the finger and used to determine shallow-dose equivalent from external sources of gamma, x-ray, and beta radiation to the fingers and hands. The 0.25 MeV cutoff for radiation applies here also. The minimum reportable dose is 20 mrem. Identification is permanently engraved by laser and cannot peel, smear,

or wash off. The ring badge is safely encapsulated inside the tamper-resistant cover. Smooth edges allow rings to easily slide and fit inside surgical gloves. It has a strong hard plastic construction and is available in three sizes (S, M, L). The ring is customized to include wear date, account number, participant number, user name and serial number.

It is the responsibility of the Authorized User to request individual monitoring devices for him/herself and for personnel under his/her supervision. The Radiation Safety Department sends personal monitors to a designated representative in each work area for distribution every month or quarter, depending upon the department's exposure monitoring frequency. The representative should collect the old monitors and return them to the Radiation Safety Department promptly, but no later than the 15<sup>th</sup> day of the new exposure monitoring cycle. If monitoring devices are not received by that time they will be considered delinquent. Temporary TLD badges and TLD rings may be obtained from the Radiation Safety Department for new personnel or to replace a lost monitoring device.

In order for measured exposures to be truly representative of actual occupational exposures, several precautions should be followed. At the end of the work day, monitoring devices should be left at work in a place where it will not be exposed to radiation. Devices should not be deliberately exposed to radiation other than while being worn. Badges and rings should only be worn by the person to whom they are assigned.

Exposure results are sent to the Radiation Safety Department and are promptly reviewed by the Radiation Safety Officer. Monthly/Quarterly exposure results will be sent to each Department or area. These results should be posted for the information of those being monitored. Note that there may be a delay of a few months from the time a monitoring device is returned to the office before the report is available. An individual who has questions about his/her exposure should contact the Radiation Safety Department. The Radiation Safety Officer will contact anyone who receives an unexpectedly high exposure. The reason for the exposure will be determined and, if necessary, changes in procedures to prevent future exposures will be discussed or required.

Additional information regarding the radiation monitoring program can be found on the WVU Radiation Safety Department's Radiation Monitoring Policy Statement, Form 801, available on the WVU RSD website at <u>https://www.hsc.wvu.edu/rsafety/dosimetry/</u>.

#### 6.4.3 INVESTIGATIONAL LEVELS

The investigational level exposure notice is investigated by the RSO to determine the cause of the unusual exposure and may require additional action from the appropriate administrator. If an occupational worker's radiation dose reaches the levels in the table below, the worker is required to complete a questionnaire sent to them by RSD and return it to the RSO as part of the investigation. This process is intended to identify any deficiencies in the Radiation Protection Program to further the goal of ALARA.

	Investigational Level (mrem/calendar qtr)
Total Dose Equivalent	375
Sum of Deep-Dose Equivalent and Individual organ or tissue other than the lens of the eye	3750
Eye Dose	1125
Shallow Dose Equivalent to skin or any extremity	3750

#### 6.4.4 BIOASSAYS

Internal radiation exposure is rare, but it can occur if radioactive materials are inhaled, ingested, or absorbed. When this occurs, a bioassay may be necessary to measure the amount of radioactive materials in the body. A bioassay is an after-the-fact check as to whether or not a significant amount of radionuclide entered the body despite what were thought to have been safe procedures. Should such an amount be found, it would signal the need for additional monitoring and a change in procedures so that a work area's tasks can be carried out without undue risk.

The need for a bioassay will depend on the radionuclide used, circumstances under which it is used, the volatility of the substance, and amount of activity involved, in brief, the likelihood of

airborne contamination. Bioassays may involve collection of urine, blood, saliva, or nasal mucus. Thyroid bioassays are completed on individuals who have been exposed to volatile radioiodine using an external detector.

Those individuals utilizing radiation in a human-use clinical or research setting should reference bioassay requirements in this section. Those utilizing radiation in a non-human use research setting should reference bioassay requirements in chapter 10 of the WVU Radiation Manual for Research Applications.

The following table indicates the quantities of radioiodine and circumstances of use in which a thyroid bioassay must be performed:

Location of Use	Volatile or Dispersible	Bound to Nonvolatile Agent	
	Radioiodine Activity	Radioiodine Activity	
Open Room or Bench	1 mCi	10 mCi	
Fume Hood	10 mCi	100 mCi	
Closed Glove Box	100 mCi	1 Ci	

Table 2: Radioactivity levels in unsealed form above which bioassay for radioiodine is necessary

Note: Quantities should consider the amount used at one time or in one day and the cumulative amount of radioactivity in the process handled by a worker during a 3-month period.

In order to establish a baseline, a worker should have a routine bioassay, whether it be urinalysis or thyroid scan, before exposure to radionuclides but not over one month prior. Subsequent to exposure, a bioassay should be conducted between 24 and 72 hours after exposure to activity greater than or equal to those listed in Table 2. Should exposure to this activity be frequent, it is sufficient to repeat the test every two (2) weeks. Workers in areas having on hand or having used in a calendar quarter an activity greater than or equal to that listed in the "Closed Glove Box" entry for Table 2 should have a bioassay at least quarterly.

If a thyroid scan is the proposed method of bioassay, call Nuclear Medicine and arrange an appointment. If a scan will be needed over a weekend, call the Radiation Safety Department for assistance.

Should a thyroid bioassay show more than 1  $\mu$ Ci radioiodine, notify the Radiation Safety Department immediately so an investigation, corrective actions, and additional monitoring can be initiated. If the thyroid bioassay exceeds 5  $\mu$ Ci, notify the Radiation Safety Department immediately so that medical consultation and additional monitoring can be initiated as described in NRC Regulatory Guide 8.20, Revision 2. Medical personnel participating in administration of greater than 1 mCi of liquid radioiodine to patients are required to have a thyroid bioassay performed between 24 and 72 hours after administration. Capsules containing radioiodine may be considered to contain the iodine in sealed form, and bioassay would not be necessary unless a capsule were inadvertently opened (e.g., dropped or crushed).

Analysis of urine samples is the responsibility of the Authorized User. If assistance is needed, call the Radiation Safety Department.

Individuals involved in operations that utilize more than 100 mCi of H-3 (tritium) in a noncontained form (other than metallic foil), within a 30-day period, shall have bioassays performed within one week following a single operation and at weekly intervals for continuing operations.

Should a urine sample show more than 5  $\mu$ Ci/liter of H-3, the Radiation Safety Department should be notified. A second sample will normally be tested 24 hours later. If this sample still indicates high activity then additional monitoring and corrective action will be initiated per NRC Regulatory Guide 8.32.

Bioassays performed in conjunction with other radionuclides may be required by the Committee. The Radiation Safety Department shall maintain reports of bioassay results.

#### 6.5 USE OF CAUTION SIGNS AND LABELS

The following use of caution signs and labels is required by the NRC and the WVDOH. Although these signs and labels initially will be available from the Radiation Safety Department, Authorized Users should purchase their own if there is a continuing need. Assistance in marking and labeling may be requested by contacting the Radiation Safety Department. Examples of appropriate signs and labels can be found in Appendix 2.

Signs and labels must be current and updated as conditions change. More than one sign may be required. The signs and labels used must describe the actual condition(s) present as defined in the following sections.

# 6.5.1 RADIOACTIVE MATERIAL

The following shall be posted with a "Caution-Radioactive Material" sign or label:

A. Each location of the work area where radioactive materials are USED or STORED in an amount exceeding ten (10) times the quantity of radioactive material specified in 10 CFR 20, Appendix C. A table addressing the most common isotopes at this facility can be found in Appendix 3 of this manual.

B. Each container in which radioactive material is TRANSPORTED, USED or STORED in amounts greater than the quantity specified in Appendix 3.

Labels on containers must provide sufficient information to permit individuals in the vicinity of the containers to take precautions to avoid or minimize exposures. Such information includes the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, or kinds of materials.

Note: Equipment such as refrigerators or freezers that are used for storage should bear a **"Caution - Radioactive Material"** sign also.

#### 6.5.2 RADIATION AREA

The following area(s) shall be posted with the radiation symbol and a **"Caution - Radiation Area"** sign: any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05mSv (5 mrems) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

#### 6.5.3 HIGH RADIATION AREA

The following area(s) shall be posted with the radiation symbol and a "**Caution - High Radiation Area**" sign: any area, accessible to individuals, in which radiation levels could result in an excess of 1 mSv (100 mrems) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

#### 6.5.4 VERY HIGH RADIATION AREA

The following area(s) shall be posted with the radiation symbol and a sign bearing the words **"GRAVE DANGER, VERY HIGH RADIATION AREA"**: any area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of 5 Grays (500 rads) in 1 hour at 1 meter from a radiation source or from any surface that the radiation penetrates.

#### 6.5.5 AIRBORNE RADIOACTIVITY AREA

The following area(s) shall be posted with a **"Caution - Airborne Radioactivity Area"** sign: a room, enclosure or area in which airborne radioactive materials exist in concentrations -

- A. In excess of the derived air concentrations (DACs) specified in 10 CFR 20 Appendix B (http://www.nrc.gov/reading-rm/doc-collections/cfr/part020/appb/) or,
- B. To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

#### 6.6 CONTROL OF ACCESS TO HIGH RADIATION AREAS

The Authorized User must ensure that each entrance or access point to a high radiation area has one or more of the following features:

- A. A control device that, upon entry into the area, causes the level of radiation to be reduced below the level at which an individual might receive a deep-dose equivalent of 1 mSv (100 mrems) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates;
- B. A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or
- C. Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

In place of these, continuous electronic surveillance that is capable of preventing unauthorized entry may be substituted. The controls for controlling access must not prevent anyone from leaving the high radiation area.

Control of entrance or access to rooms or other areas in the hospital is not required solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who will take the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the limits and to operate within the ALARA provisions of the radiation safety program.

#### 6.7 CONTROL OF ACCESS TO VERY HIGH RADIATION AREAS

In addition to the requirements in the previous section, the Authorized User must institute additional measures to ensure that an individual is not able to gain access to areas in which radiation levels could be encountered at 5 Grays (500 rads) or more in 1 hour from a radiation source or any surface through which the radiation penetrates.

# 7. RADIATION SAFETY TRAINING

The goal of providing radiation safety training to the employees of West Virginia University Hospitals is to empower workers to take personal responsibility for minimizing their exposure to radiation. By providing each employee with knowledge of radiation and its biological effects and the regulations governing its use, the WVUH can help provide an environment that is safe for its patients, students, visitors and employees. The content of radiation safety training courses will be determined by the RSO and the appropriate Radiation Safety Committee based on applicable regulatory guidance, industry consensus standards, and the specific needs of the target audience. Authorized Users are responsible for ensuring that their staff members have received instruction regarding the safe use of radioactive material and radiation sources in their specific laboratory settings, both through on-the-job training and through formal training offered by the Radiation Safety Department. The Authorized User is responsible for maintaining documentation of the completion of required training and will be required to supply such documentation to the RSO or his/her designee as a condition for continued Authorization to use radioactive material or radiation sources.

#### 7.1 INDIVIDUALS OR GROUPS REQUIRING TRAINING

Individuals employed by WVUH fall into three general categories with respect to their exposure to radiation:

- A. <u>Radiation Workers</u>: those workers whose major responsibilities involve working with sources of ionizing radiation or radioactive material. This would include radiologists; radiographers; nuclear medicine physicians and technologists; radiopharmacy technologists; radiation therapy technologists; cardiology technologists working with fluoroscopy equipment; research scientists who are Authorized Users of radioactive material or radiation sources; faculty, technicians and graduate students in certain campus laboratories; nurses on hospital divisions regularly caring for radionuclide therapy patients.
- B. <u>Ancillary Workers</u>: All personnel who may come in contact with or enter an area that contains radioactive material or sources of ionizing radiation. This would include non-radiology physicians and residents, phlebotomists, Environmental Services workers, waste processors and animal caretakers.
- C. <u>Non-Radiation Workers</u>: personnel who would not normally be expected to encounter radioactive material or radiation sources in the course of their employment at WVUH. This would include administrators and administrative assistants, Nutrition Services employees, clerical staff, Materials Management and so forth.

These groups will require different levels and frequencies of training. Authorized Users are required to submit evidence of prior training during the application process for medical or research use of radioactive material and radiation sources. This prior education and training may be applied in lieu of certain initial and update training requirements.

#### 7.2 TRAINING FREQUENCY

Training occurs on an as-needed basis. However, the Radiation Safety Department subscribes to some basic guidelines for the frequency and intensity with which different groups receive their training. These include:

- A. All new employees of WVUH: safety orientation training, including basic information concerning the existence of sources of ionizing radiation and the Radiation Safety program.
- B. Radiation workers: initial training including instruction in the proper use and handling of radioactive material and other sources of ionizing radiation. The content of the initial training may be modified for the specific job responsibilities.
- C. Radiation workers and certain ancillary workers: annual refresher training.
- D. Re-training of workers whose job responsibilities change concerning their use of or exposure to ionizing radiation, or who request additional radiation safety training.
- E. Special training in connection with incidents involving a procedure of concern, spill, incident, misadministration, change in regulations, or a documented overexposure.

# 8. MEDICAL USE OF RADIATION AND RADIONUCLIDES

8.1 GENERAL PROCEDURES FOR PHYSICIANS

#### 8.1.1 SEALED SOURCE IMPLANTS

- A. It is the physician's responsibility to request a private room for all sealed source therapy patients (Cs-137, Ir-192, I-125).
- B. Procurement of all sources follows the procedure in Section 4. The radionuclide requisition must be filled out and signed by the Authorized User, then brought to the Radiation Safety office to obtain the purchase order number.
- C. All personnel participating in the procedure must be familiar with and comply with the Radiation Oncology quality Management Program. Copies of the program are available from the radiation oncology physicist or chief technologist.
- D. The Radiation Safety Department must be informed of all implants so that the necessary warning signs and labels can be posted and shields prepared. These will be removed by RSD personnel after the sources are removed, counted, and the patient surveyed.
- E. Each patient must be restricted to his or her room during the therapy treatment. An exception may be made for some patients treated with I-125 seeds.
- F. Each patient must remain hospitalized until the sources are removed, or in the case of permanent implants, the radiation level is low enough to be no hazard to those in the home.
- G. The Chief of Radiation Oncology has responsibility for insertion and removal of sources, and for ensuring that the sources are properly inventoried. The sources must be inventoried at the time of insertion or immediately afterward.
- H. A log book of issues and return must be maintained as a part of the inventory procedure. The inventory must be performed directly after removal of the sources. Therefore, sources will either be in the patient or in inventory, and not temporarily stored somewhere in between.
- I. The following information must be in the patient's chart:
  - 1. Radionuclide;
  - 2. Total activity in millicuries and number of sealed sources;
  - 3. Location in body;
  - 4. Date of insertion and anticipated date of removal.

#### **8.1.2** RADIONUCLIDE THERAPEUTIC ADMINISTRATION-PATIENTS REQUIRING HOSPITALIZATION

A. Patients receiving a therapeutic dose of a radionuclide that is greater than the limit in Column 1 of Table 3 and are expected to present an estimated dose to others of greater than 5 mSv (500 mrem) must be hospitalized in a private room with a private bath for radiation protection purposes.

- B. Contact the RSD before administration so that arrangements can be made to provide absorbent paper for the room or any other precautions which may be necessary. RSD personnel will provide the necessary warning signs and labels and survey the patient after administration.
- C. Administer the radiopharmaceutical in the patient's room taking precautions discussed in the "Diagnostic Dose" section below.
- D. All personnel participating in the procedure must be familiar with and comply with the appropriate Quality Management Program. Copies of the program are available from the chief technologist.
- E. The chief technologist is responsible for safe disposal of all radioactive solutions and contaminated equipment. Such solutions and equipment are not to be left on the nursing unit or disposal responsibility relegated to the nursing staff.
- F. The following information must be on the patient's chart:
  - 1. Radionuclide and number of millicuries
  - 2. Location in body
  - 3. Date administered
- G. Each patient must be restricted to his/her room during the therapy treatment.
- H. All wastes generated from the patient's room must be handled properly:
  - 1. Bodily waste (urine, feces, vomit) may be disposed of via the toilet.
  - 2. Other wastes such as contaminated syringes, etc. must be bagged and marked as described in Section 9, "Radioactive Waste Disposal."
  - 3. Contaminated return items:
    - i. Hold these for decay whenever possible
    - ii. Decontaminate items if necessary
- I. RSD will assist and monitor materials leaving the room. The use of disposable items is encouraged.
- J. Any tissue samples, blood, excreta, etc. that are contaminated must be marked with a "Caution Radioactive Material" sticker and any special handling instructions forwarded to the analyzing laboratory. Assistance in determining the above is available from the RSD.
- K. Each patient must remain hospitalized until the residual activity or the measured dose rate at 1 meter is less than the corresponding value in Table 3: Activities and Dose Rates for Authorizing Patient Release (table follows section). Consideration should be given to possible exposure of other family members at home, especially children and pregnant women.
- L. The radiation warning sign(s) on radioactive patient rooms will be removed by the RSD when:
  - The patient is discharged; or
  - The residual activity is below the value established by Table 3; or
  - The exposure rate is less than the value established by Table 3.
- M. When a patient containing residual activity leaves the hospital, the physician must give written instructions on how to minimize exposures to others if the dose to an individual exposed to the patient is likely to exceed 1 mSv (100 mrem). The RSD will assist in this.

Table 3: Activities and Dose Rates for Authorizing Patient Release <sup>a</sup> COLUMN 1					
	COLUMN 1 Activity at or Below Which		COLUMN 2 Dose Rate at 1 Meter, at or Below		
	•	Be Released	Which Patients May Be Released <sup>b</sup>		
Radionuclide	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)	
Ag-111	19	520	0.08	8	
Au-198	3.5	93	0.21	21	
Cr-51	4.8	130	0.02	2	
Cu-64	8.4	230	0.27	27	
Cu-67	14	390	0.22	22	
Ga-67	8.7	240	0.18	18	
I-123	6.0	160	0.26	26	
I-125	0.25	7	0.01	1	
I-125 implant	0.33	9	0.01	1	
I-131	1.2	33	0.07	7	
In-111	2.4	64	0.2	20	
Ir-192 implant	0.074	2	0.008	0.8	
P-32	с	с	с	с	
Pd-103 implant	1.5	40	0.03	3	
Re-186	28	770	0.15	15	
Re-188	29	790	0.20	20	
Sc-47	11	310	0.17	17	
Se-75	0.089	2	0.005	0.5	
Sm-153	26	700	0.3	30	
Sn-117m	1.1	29	0.04	4	
Sr-89	с	с	с	с	
Tc-99m	28	760	0.58	58	
T1-201	16	430	0.19	19	
Yb-169	0.37	10	0.02	2	

a The activity values were computed based on 5 millisieverts (0.5 rem) total effective dose equivalent.

b If the release is based on the dose rate at 1 meter in Column 2, the licensee must maintain a record as required by 10 CFR 35.75(c) and 35.2075(a)(4) because the measurement includes shielding by tissue. See Staff Regulatory Guidance 3.1, "Records of Release," for information on records.

c Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes. NOTES FOR TABLE 1:

The millicurie values were calculated using Equations 2 or 3 and the physical half-life. The gigabecquerel (GBq) values were calculated based on the millicurie (mCi) values and the conversion factor from millicuries to gigabecquerels. The dose rate values are calculated based on the millicurie values and the exposure rate constants. In general, the values are rounded to two significant figures. However, values less than 0.37 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492. Agreement State regulations may vary. Agreement State licensees should check with their State regulations prior to using these values.

# **8.1.3** *RADIONUCLIDE THERAPEUTIC ADMINISTRATION-PATIENTS* <u>NOT REQUIRING</u> *HOSPITALIZATION*

- A. Patients receiving a therapeutic dose of a radionuclide who are not required to be hospitalized, and are being sent home, must be given radiation safety instructions to be observed at home. The physician ordering the treatment is responsible for seeing that this instruction is given; specific instructions may be developed in consultation with Radiation Safety.
- B. Some patients who receive a therapeutic dose of a radionuclide may not require hospitalization because of the dose administered but may be required to stay in the hospital because of some other condition. In this case, the physician must also inform the Radiation Safety office so that Radiation Safety personnel can give instructions on radiation safety precautions that should be observed by those attending the patient.
- C. When the patient has a private room, radionuclides should be administered in the patient's room; otherwise, a treatment room is preferable.
- D. Follow the other precautions discussed in the "Diagnostic Dose" section below for administration of the radionuclide.
- 8.1.4 RADIONUCLIDE DIAGNOSTIC ADMINISTRATION
  - A. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
  - B. Wear disposable gloves at all times while handling radioactive materials.
  - C. The patient, if wearing street clothes, must be suitably protected from accidental contamination with a lab coat, sheet, etc.
  - D. If contamination of the floor or table top is likely, absorbent mats should be used to reduce decontamination work.
  - E. It is strongly recommended that disposable syringes and needles be used whenever possible. Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins, infants).
  - F. Each syringe or syringe shield must display the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's name.
  - G. Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area with a suitable instrument such as a crystal probe or camera.

#### **8.1.5** *Emergency Surgery*

The physician or resident must:

- A. Inform the surgeon of:
  - 1. The date of the radionuclide therapy,
  - 2. The amount and kind of radionuclide,
  - 3. The location of the radionuclide in the patient.

#### B. Inform the RSD before the surgery of:

- 1. The above information,
- 2. The time and place of surgery.
- C. The Radiation Safety Department will provide necessary monitoring and advice on exposure.

#### 8.1.6 CADAVERS

- A. If a patient who has received a therapeutic dose of any radionuclide dies in the hospital within a three week period after administration, the physician must:
  - 1. Notify the Radiation Safety Department, night or day. The RSO will give suitable instructions to the pathologist and funeral director.
  - 2. Notify the pathologist, if an autopsy is to be performed, that the cadaver contains radioactive material and that the Radiation Safety office will provide necessary monitoring during autopsy.

Refer to NCRP Report 155 for additional information concerning radioactive cadavers and/or the death of a radioactive patient.

#### **8.2** GENERAL PROCEDURES FOR NURSES

#### **8.2.1** *RADIOTHERAPY PATIENT*

A radiotherapy patient is defined as a patient who has been given radionuclides orally or intravenously or has received a sealed source implant. Specifically excluded are patients who have been irradiated only by x-ray or accelerator machines. These latter patients will not contain any residual radioactivity from the x-ray or accelerator treatments. Consequently, no special precautions are necessary as they do not present any radiation hazard. Patients who have received diagnostic doses of radiopharmaceuticals also do not require any special precautions. For caregiver guidelines regarding the most common procedures with potential for radiation exposure, see Appendix 4.

#### **8.2.2** Types of Hazards

Radiation hazards may arise by four means:

- A. External irradiation due to radionuclides or radiation sources in the patient.
- B. Contamination of the skin in the course of patient care (for radionuclides).
- C. Ingestion of radioactive material (probably from hands contaminated from radionuclides).
- D. Inhalation of volatile radioactive materials.

#### 8.2.3 RADIATION PROTECTION PROCEDURES

The following procedures are given in order to keep radiation exposure to nursing personnel as low as is reasonably achievable:

- A. Nurses who are pregnant must not be assigned to radiotherapy patients.
- B. It is the physician's responsibility to have all therapy patients housed in a private room if they have received sealed source implants or are hospitalized during treatment with an unsealed radionuclide. The most desirable room is the isolation room, followed by the end rooms with side walls on the outside of the building.
- C. A patient who has been administered radionuclides or sealed source implants can be identified by:
  - 1. A "Temporary Implant" or "Permanent Implant or Internal Dose" sticker on the front cover of the patient's chart and information in the chart.
  - 2. A "Caution Radiation Area" or "Caution Radioactive Materials" sign on the patient's door.
- D. The sticker and signs are placed there by a person from the Radiation Safety office. Neither may be removed except by a representative of the Radiation Safety office.
- E. A written training module or in person in-service will be provided to answer questions nursing personnel may have regarding care of radioactive patients. Nursing personnel should review these before administering care to these patients.
- F. Specific instructions for each patient will be posted on the door or in the patient's chart.
- G. Additional questions may be directed to the Radiation Safety representative assigned to the patient or to the RSD. A member of the Radiation Safety staff is always on call and is available at (304) 293-6430.
- H. Radiation dosimeters will be provided for personnel caring for the radiation therapy patient, if necessary; these must be worn during the entire shift. Each person must sign for his or her own radiation dosimeter and not wear anyone else's. These will be collected after the patient is discharged.
- I. The trash can in the radiotherapy patient's room is kept lined with a plastic bag. This will facilitate the radiation survey of the trash.
- J. Limit each visitor to the length of time indicated by the RSD for that procedure.
- K. For additional information, see the previous section "General Procedures for Physicians."

#### 8.2.4 PREVENTION OF UNNECESSARY EXTERNAL IRRADIATION

- A. Do not neglect the patient, but do not linger unnecessarily either.
- B. Keep as much distance as possible between the patient and yourself while working in the room; the further away the patient is, the less the exposure rate will be. If a bedside shield is provided, work behind it as much as possible.
- C. Unless specifically ordered by the doctor, the patient's bath should be postponed for the first 48 hours. Thereafter, baths may be given every second day for the first week. However, the patient may bathe himself or herself as often as desired unless restricted by the doctor.
- D. For patients with sealed source implants (Ir-192, Cs-137, etc.):
  - 1. Linen, trash, etc. should be left in the patient's room until surveyed by Radiation Safety office personnel.
  - 2. If a sealed source becomes displaced, contain the source in the lead container left in the room WITHOUT TOUCHING IT with your fingers. Use forceps or other handling devices to keep the source at least 6 - 12 inches from your hands and body. Notify the physician and the Radiation Safety office at once.
  - 3. The room is not to be cleaned by housekeeping or released for other patients until it has been surveyed by Radiation Safety office personnel and all warning signs have been removed. A sticker which says "OK Radiation Safety Department" is left on or adjacent to the door after the survey.
  - 4. Gynecological patients are restricted to bed during the therapy treatment. Patients receiving other types of radiotherapy should be either in bed or on the far side of the bed when staff or visitors are in the room.
  - 5. Exception: Patients who have been implanted with I-125 seeds in the prostate or brain represent minimal threat from external radiation. The radiation that gets through the body from the implanted seeds is so weak that the patient may be allowed to walk the corridor before being discharged. The seeds themselves may become dislodged, however, and should not be handled except as indicated above.
  - 6. Surgical dressings and bandages should be changed only as directed by the physician. This is one of the more likely places for dislodged sources to appear.
  - 7. Barring a rupture of one of the sealed sources, instruments and containers used to handle them do not become radioactive.
  - 8. Perineal care is not normally given during the treatment, but the perineal pad may be changed when necessary. If the pad is changed, be sure the radioactive sources are not disturbed. Should a bowel movement necessitate perineal care, it should be given with due consideration to distance, time and shielding.

#### 8.2.5 PREVENTION OF CONTAMINATION AND INGESTION

A. This is normally only a problem for patients administered volatile radionuclides like I-131 and is not a problem in sealed source therapy unless one of the sources has ruptured (rupture of a source would be extremely unusual).

- B. If there is leakage from an intracavity injection or spillage of radioactive vomitus or urine, put on surgical gloves and mask and try to contain the liquid without directly touching it. Use paper towels or other disposable absorbent materials if immediately available. Keep the gloves with other contaminated material for monitoring. Notify the responsible physician and the Radiation Safety office at once. In the meantime, keep those not involved away from the area so as to prevent spread of the contamination.
- C. Urine and feces may be disposed of in the toilet. If a bedpan is used, it must be handled by hospital personnel wearing gloves, gown and mask. The bedpan may be rinsed and the rinse water disposed of via the toilet. Keep the same bedpan for use until the treatment is completed; it will be checked for contamination at that time.
- D. Disposable dishes and utensils should be used for the patient's meals. No linen or trash should leave the room until it has been checked by Radiation Safety office personnel.
- E. Radioactive material should not be allowed to touch the skin. Wear disposable gloves whenever contact is possible.
- F. Practice good housekeeping when working with radiotherapy patients. Wash hands thoroughly before eating or engaging in any other hand-to-mouth activity following care of the patient.
- G. When a patient is first administered I-131, practically anything he or she touches will be contaminated by radioactive perspiration. Also, as much as 80% of the iodine may appear in the urine during the first 48 hours. Therefore, wear disposable gloves when changing the bed linen, touching the patient or other activities. Put a plastic or rubber cover on the pillow and materials during the first 48 hours (at least) to prevent contamination of these items.

## **8.2.6** SUMMARY

- A. Do not neglect patient care.
- B. Wear your radiation dosimeter.
- C. Keep as much distance as possible between you and the patient; perform the necessary duties in as little time as possible.
- D. Nothing should be removed from the patient's room unless it has been monitored by personnel from the Radiation Safety office.
- E. Use disposable gloves when handling any items that might be contaminated.
- F. Call the physician in charge and the Radiation Safety office if a spill occurs or a loose source is found.
- G. For additional information, refer to Appendix 1 " Guidelines for Nursing Personnel for Procedures of Concern" or contact the Radiation Safety office.

#### **8.3** Emergency Surgery

Patients who have received temporary sealed source implants must have them removed before having surgery. Once they have been removed, no radiation precautions will be required for the surgery itself unless somehow there has been a rupture of a source (which is extremely unlikely). If the patient does not contain more than 5 mCi of any radionuclide, surgery may be performed with no attention to the radioactivity. Larger quantities may be present in patients with radioactive colloid in a cavity or injected into tissues, with radioactive iodine for a thyroid condition, or with metallic radioactive implants. In these cases, certain precautions may be necessary.

- A. Radioactive Iodine It is highly unlikely that emergency surgery will be essential within 24 hours after the administration of a dose. After this period, if the surgeon can avoid actual manipulation of the thyroid gland or of regions containing active metastases, he or she will not receive an undue exposure during the period of any likely emergency operation.
- B. Radioactive Colloidal Chromic Phosphors in Pleural or Abdominal Cavity The radionuclide will be deposited more or less uniformly over all the serous surfaces, and when the body is unopened, the P-32 betas are largely absorbed by the superficial tissues of the body. Once the body is opened, the surgeon's hands and face (if the body is opened widely) may be exposed to relatively intense beta radiation\*.
- C. Colloidal or Metallic Radioactive Implants in Tissues. It is usually possible to avoid direct contact with the implanted region. There is little use in trying to block the radiation by shielding. For high energy gamma-emitting nuclides (such as Cs-137) lead aprons or sheets are of little value. It is more important for everyone on the surgical team to stand as far as practicable from the radioactive material.

\*Beta radiation may be attenuated by providing shielding between the source and the surgeon. The use of gloves can reduce the shallow-dose equivalent significantly as is shown in the following table.

Dose rate in mrems/h	our from 1 mCi of P-32	
No Gloves	Single Surgical Gloves	Double Autopsy Gloves
800	600	300

At these dose rates, the shallow-dose equivalent limit may be approached in some surgical procedures. The Radiation Safety Department must be consulted to advise on ways to limit doses during surgery.

Glasses or goggles should be worn by the surgeon and assistants to protect against a possible splash of radioactive material into the eyes, as well as from beta radiation.

## **8.4 DEATH**

The physician who pronounces the patient dead and sends the body to the morgue must make sure that a radioactivity label remains affixed to the history and accompanies the body if it contains more than 5 mCi of a radionuclide. He or she should also attach blank copies of a suitable radioactivity form to the death certificate, to the patient's chart, and to the autopsy permission slip if there is one.

The physician should notify the Radiation Safety Department so that Radiation Safety personnel can provide instructions for handling the body to those who come into contact with it.

To set down here details of procedure for autopsy or embalming would be simply to copy NCRP Report No. 155 Section 6. It is evident that if the radionuclide content is above 5 mCi the RSO will have to be involved in autopsy procedure, and if more than 30 mCi, must be present for either embalming or autopsy. Copies of NCRP Report No. 155 Section 6 are available from the Radiation Safety Department.

# 8.4.1 ACCIDENT OR INJURY DURING SURGERY OR AUTOPSY

In case of an injury occurring during surgery or autopsy whereby the gloves are cut or torn and radioactive material may have been introduced into the wound, the gloves should be removed and the wound washed with large quantities of running water, spreading the edges of the wound to facilitate flushing action. The Radiation Safety Department should be notified at once, and should check for residual contamination.

# 8.4.2 Contaminated Clothing or Instruments

Clothing or instruments that become contaminated during surgery or autopsy should be turned over to the Radiation Safety Department for decontamination or disposal. Contaminated disposable materials should be handled as described in the section titled: "Radioactive Waste Disposal". RSD personnel can assist with this as necessary.

Special care should be taken to prevent the floor of the operating room or the autopsy room from being contaminated. Such contamination is inevitably transferred to the shoes and thereby spread all over the institution. In addition, the floors of autopsy rooms are often of rough concrete or other material that is difficult to decontaminate, and flushing them or scrubbing them with water may only spread the contamination. Therefore, great care should be taken that all body fluids are properly discharged down the drain or given other disposal as recommended by the RSD.

In the case of accidental overflow, the fluid should immediately be taken up as completely as possible, with dry waste held in tongs or forceps, and put promptly into a suitable receptacle.

# 8.5 WRITTEN DIRECTIVES

- A. The administration of a therapeutic dose of radiation from unsealed or sealed sources of radioactive material may be performed only by, or under the supervision of, an Authorized User who has been approved by the WVU RSC for that type of use.
- B. A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 30  $\mu$ Ci, any therapeutic dosage of

unsealed byproduct material, or any therapeutic dose of radiation from byproduct material.

- C. The written directive must contain the patient or human research subject's name and the following information:
  - 1. For any administration of quantities greater than 30  $\mu$ Ci of sodium iodide I-131: the dosage;
  - 2. For an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;
  - 3. For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;
  - 4. For high dose-rate afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose;
  - 5. For permanent implant brachytherapy:
    - i. Before implantation: the treatment site, the radionuclide, and the total source strength; and
    - ii. After implantation but before the patient leaves the post-treatment recovery area: the treatment site, the number of sources implanted, the total source strength implanted, and the date; or
  - 6. For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:
    - i. Before implantation: the treatment site, radionuclide, and dose; and
    - ii. After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, total source strength and exposure time (or the total dose), and date.

# 8.6 MEDICAL EVENTS

- A. A medical event is defined as the administration of radioactive material which results in -
  - 1. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem effective dose equivalent, 50 rem to an organ or tissue, of 50 rem shallow dose equivalent to the skin; and
    - i. The total dose delivered differs from the prescribed dose by 20% or more;
    - ii. The dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range; or
    - iii. The fractionated dose delivered differs from the prescribed dose for a single fraction, by 50% or more.

- 2. A dose that exceeds 5 rem effective dose equivalent, 50 rem to an organ or tissue, or 50 rem shallow dose equivalent to the skin from any of the following:
  - i. An administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure;
  - ii. An administration of a radioactive drug containing byproduct material by the wrong route of administration;
  - iii. An administration of a dose or dosage to the wrong individual or human research subject;
  - iv. An administration of a dose or dosage delivered by the wrong mode of treatment; or
  - v. A leaking sealed source.
- 3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and 50% or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.
- B. Upon discovery of a medical event, the WVU Radiation Safety Department must be notified immediately.
- C. A notification by telephone to the NRC Operation Center must be made no later than the next calendar day after discovery of the medical event.
- D. A written report must be submitted to the NRC Regional Office within 15 days after discovery of the medical event.

# 9. RADIOACTIVE WASTE DISPOSAL

#### 9.1 GENERAL CONSIDERATIONS

Proper handling, labeling and packaging of radioactive waste is essential to minimize the chance for contamination, spills or other accidents in the work area or as the waste is handled further by Radiation Safety staff. Waste drums are being more closely inspected at disposal sites as rules become stricter and disposal sites may refuse to take waste from generators that do not comply with the rules.

Because of escalating disposal costs, it is also important that only radioactive waste be disposed of in the radioactive waste containers. Minimizing the volumes generated helps to keep costs down.

The Radiation Safety office may provide containers to use in the work area for radioactive waste disposal. Please call 304-293-3413 to obtain the types you need.

Radioactive waste is picked up from the work area by Radiation Safety personnel, repacked as necessary, and either held for decay or sent to commercial waste disposal centers. Departments utilizing certain short half-life isotopes may be permitted to dispose of radioactive waste via the decay-in-storage method, with prior approval from the Radiation Safety Department. See 9.3 Short Half-Life in this section for the decay-in-storage disposal procedure.

Call 304-293-3413 to schedule radioactive waste pick-ups. Please do not wait until the container is overflowing! If you know a big experiment will generate a lot of waste on a particular day, please notify Radiation Safety in advance so that your lab is assured of getting a pick-up on the desired day.

No radioactive waste disposal by burial is permitted on any of the hospital or university campuses, and incineration is performed by the Radiation Safety Department only under tightly controlled circumstances, as permitted by the U.S. Nuclear Regulatory Commission and the U.S. Environmental Protection Agency.

Always maintain accurate records of the waste disposed in each container.

Radioactive waste must not be disposed of in any manner other than as outlined below.

## 9.2 TYPES OF WASTE

For purposes of disposal, radioactive wastes will be divided into the following categories:

- A. Dry Solid Radioactive Waste
- B. Solid Biological Radioactive Waste
- C. Liquid Radioactive Waste
- D. Liquid Scintillation Vials
- E. Radioactive/Hazardous Mixed Waste

All categories of waste should be separated according to the half-life of the radionuclide involved.

#### 9.3 SHORT HALF-LIFE WASTE

Radionuclides with physical half-lives of 120 days or less are considered short half-life, and may be held for decay-in-storage. Decay-in-storage means that short half-life radionuclides may be stored and allowed to sufficiently decay after which it can be disposed of as ordinary waste when radiation surveys of the waste indicate that radiation levels are indistinguishable from background. If short half-life waste is mixed with long half-life waste the entire container must be treated as long half-life, and disposed of by a more expensive method.

If you hold waste for decay in your lab, storage area or freezer, call the Radiation Safety Department when you want to dispose of it (after 10 half-lives have passed). Radiation Safety personnel must perform the final monitoring and give approval before the waste may be disposed. Certain areas may be approved by RSD to decay-in-storage within their department.

Decay-in-storage disposal procedure:

- 1. Only short half-life waste may be disposed of by decay-in-storage, and must be segregated from long half-life waste.
- 2. Waste must be stored in suitable well-marked containers, and the containers should provide adequate shielding.
- 3. Liquid and solid waste will be stored separately.
- 4. When a container is full, it should be sealed. The container should be labeled with the date it was sealed and the longest half-life radionuclide in the container.
- 5. Move the container to the decay-in-storage area.
- 6. The contents of the container should be allowed to decay for a period of time after which it is expected that the radiation levels would not be distinguishable from background. As a guideline radioactive waste should be allowed to decay at least 10 half-lives.
- 7. Prior to disposal as ordinary waste, each container must be monitored with an appropriate radiation detection instrument, on the lowest setting, as follows:
  - a. Check the radiation survey meter for proper operation.
  - b. Survey the contents of each container in a low background area.
  - c. Remove any shielding from around the container.
  - d. Monitor all surfaces of the container.

- e. If the surveys of the contents indicate no residual activity (i.e., surface readings are indistinguishable from background), deface or remove all radiation labels from the container and discard as ordinary trash.
- f. If the surveys indicate residual activity, return the container to the decay-instorage area for further decay.
- g. If the surveys indicate no residual radioactivity, record the date when the container was sealed, the disposal date, type of waste, survey instrument used, and the name of the individual performing surveys and disposing of the waste.

# 9.4 DISPOSAL OF DRY SOLID RADIOACTIVE WASTE (NON-BIOLOGICAL)

The general procedure is as follows:

- A. When using 5-gallon cans for solid waste, use plastic bags to line cans. Fold top of bag down over side of can. When a can is not used, pack up waste in plastic bags.
- B. Place needles and other sharp objects in puncture proof containers or sharps boxes before being put in the plastic bag.
- C. Wrap broken glassware in paper towels to prevent the plastic bag (and someone's hand) from being punctured.
- D. Place only radioactive materials in radioactive designated containers. Other materials only increase volume and raise the cost of disposal.
- E. When a bag is full, close the bag and seal the top with tape. If a can reads greater than 2 mR/hr at one meter from the can, close the plastic bag and tape up the top whether the bag is full or not. Always tape according to Bag Sealing Instructions.
- F. Transfer the closed and marked plastic bags to the shipping barrel if one is provided to the department. Complete the pertinent entries on the waste disposal record attached to the outside of the barrel or 5 gallon can.

# 9.5 DISPOSAL OF SOLID BIOLOGICAL RADIOACTIVE WASTE

Radioactive biological wastes include radioactively-contaminated animal carcasses, feces, and bedding; tissue samples; and radioactive plants. It is very important that these wastes are properly bagged. No liquid must be able to leak out.

Waste material contained inside must be prepared so that it cannot pierce the bag. This may entail padding parts of the biological waste with gauze pads or other material to keep the plastic bags from being torn and punctured.

The NRC has issued an exemption for disposal of certain animal tissues. Those containing 50 nCi per gram or less (as averaged over the weight of the entire animal) of carbon-14 or tritium may be disposed of as if they were not radioactive. Please call the Radiation Safety Department

if you need assistance with this procedure. It is essential that proper records be kept of all disposals made in this manner.

# 9.6 MATERIALS

The Radiation Safety Department will provide each Authorized User or research group with Radionuclide Waste Identification Forms and yellow plastic bags for biological waste disposal. Call the Radiation Safety office when you start to run low on these items to obtain replacements.

# 9.7 **PROPER BAGGING**

Place radioactive biological material in YELLOW plastic bags. Make sure the material will not puncture or tear the bag. YELLOW bags are used only for radioactive material. Non-radioactive biological waste must not be placed in yellow plastic bags. Seal the bag as described in "Bag Sealing Instructions".

# 9.8 LIQUID WASTE BARRELS

Liquid waste intended for disposal into liquid waste barrels is to be separated into three categories by chemical composition of the liquid:

- A. Aqueous liquids with no organic solvents
- B. Liquid scintillation fluids
- C. Radioactive/hazardous mixed liquid waste

Heavy plastic one- or five-gallon containers are to be used for liquids if they are appropriate for the solvent being used.

# NOTE: IT IS EXTREMELY IMPORTANT TO USE VENTED CAPS OR LOOSE CAPS ON THE STORED WASTE. THERE HAVE BEEN EXPLOSIONS IN SEVERAL LABS BECAUSE OF PRESSURE BUILD UP.

All of the waste containers must be labeled "Caution, Radioactive Material" and stored in an appropriate secondary, larger container to protect against leakage.

The use of glass waste containers is not recommended. If it is necessary to store waste in a glass container, place it in a secondary break-resistant container in a location where it will not be dropped or knocked over.

For pickup of waste, call the Radiation Safety office at 304-293-3413. Pick up will be as needed.

Prior to pick up, fill out a radioactive materials tag (provided by the Radiation Safety Department) and attach it to the waste container. It is very important that all solvents and their percentage composition be listed on this tag.

### 9.9 DISPOSAL IN THE SANITARY SEWER SYSTEM

Disposal of radioactive waste into the sanitary sewer system is not permitted as the primary means of disposal. However, contaminated bodily waste (urine, feces, vomit) may be disposed of via the toilet.

You may use a sink for rinsing of glassware and disposal of wash water. Designate a sink in the laboratory as a "Radioactive Waste Sink" and have the Radiation Safety Department mark it as such. Do not use an unmarked sink for washing contaminated glassware and disposing of wash water.

Wash water generated from the first few washes of items contaminated with radioactive material shall be contained in liquid waste barrels. Rinse the items multiple times into the liquid radioactive waste barrels, and then wash in a radioactive material labeled sink a final time, using plenty of clean water. Rinse the sink with plenty of water after washing contaminated items in it. This will both reduce the contamination in the sink and further dilute the small amount of radionuclide released in the sanitary sewer.

## 9.10 DISPOSAL OF LIQUID SCINTILLATION VIALS

Liquid scintillation vials are glass or plastic vials having a capacity of 20 ml or less that are used in scintillation counting. Small amounts of tritium and carbon-14 (50 nanocuries/gram or less) are commonly employed. The NRC has issued an exemption that allows persons to dispose of vials containing these low amounts of tritium and carbon-14 as if they were not radioactive.

However, in most cases, a "cocktail" must be used to produce the scintillations that are counted. Some of these cocktails contain a solvent (such as xylene) that has to be treated as a hazardous waste when it is time for disposal. Waste disposal facilities for this type of waste are very few and disposal costs are high.

Therefore, these types of scintillation fluid are not permitted for use. The WVU RSD can recommend specific scintillation fluids, or your equipment manufacturer may have a suggested fluid.

There are alternative types of liquid scintillation cocktails that contain solvents that are not considered "hazardous" for purposes of disposal. Use these cocktails whenever possible! A list of

currently available cocktails is available from Radiation Safety.

Liquid scintillation vials must be packed separately from other items such as gloves, etc., but glass and plastic vials may be mixed. In addition separate vials by:

- A. Half-life (short half-life, i.e., 120 days or less vs. long half-life)
- B. Type of cocktail (hazardous vs. non-hazardous)
- C. Activity of H-3 and C-14 (50 nCi/g or less vs. greater than 50 nCi/g)

After use, store the vials in the five gallon open head pails with lever lock lids that are provided by Radiation Safety. These pails should be opened in a hood and, if feasible, stored in a hood when they contain hazardous scintillation fluids.

A record sheet is provided with each pail to record the date, radionuclides, total number of vials, total volume of fluid and total activity of the radionuclides in the pail. Call the Radiation Safety Department at 304-293-3413 for a pick up at your lab.

# 9.11 RADIOACTIVE/HAZARDOUS MIXED WASTE

There are no facilities that are authorized to take this type of waste at the present time. Therefore every effort should be made not to generate this type of waste.

If the radioactive material in the waste has a short enough half-life it can safely be held for decay. In that case, the waste will have to be disposed of as hazardous waste after the radioactivity decays away. It is essential to record the chemical composition of the waste on the label in order to be able to dispose of it properly. Extra costs involved in determining the chemical composition will be passed on to the authorized User.

## 9.12 **BAG SEALING DIRECTIONS**

- A. Twist the top of the bag tightly. Wrap tape tightly two or three times around the twisted section.
- B. Fold twisted section in half and wrap the tape two or three more turns.
- C. If a bag tears, then re-bag it before putting it in the waste container.
- D. Place extra bags around the original bag if necessary in order to ensure against leakage or puncture, and seal each additional bag according to the bag sealing instructions above.

#### 9.13 ADDITIONAL REQUIREMENTS FOR ALL RADIOACTIVE WASTE

Only radioactive materials with an atomic number between 1 and 83 can be placed in waste barrels. All other materials with a higher atomic number such as radium (atomic no. 88), uranium (atomic no. 92), plutonium (atomic no. 94) and other source material or special nuclear material must be brought to the Radiation Safety office for separate disposal. Example: smoke detectors containing americium-241 (atomic no. 95) must have special handling.

- A. The chemical form of all waste must be specified.
- B. All waste must contain less than 1% oil by volume.
- C. Ion exchange resins and filter media must be dewatered.
- D. There must not be any detectable free standing liquids in waste barrels.
- E. No radioactive waste may contain pyrophoric materials or materials that react violently with water.
- F. The radioactive hazard must be greater than the chemical hazard. We must have an analysis of the chemical, biological, and radioactive hazard.
- G. The physical form of all waste must be specified, e.g., compressed paper, glass, etc.
- H. Biological (excluding animal carcasses), pathogenic or infectious material or equipment (e.g., syringes, test tubes, capillary tubes) used to handle such material shall be treated so that the material, if not radioactive, could have been disposed of as infectious waste.

The radionuclide and activity must be specified in microcuries or millicuries. Radionuclides and activity must coincide exactly with the barrel sheet.

# **10. EMERGENCY PROCEDURES**

#### **10.1** INTRODUCTION

Emergencies resulting from accidents in areas working with radioactive materials can range from simple spills of small amounts of radioactive materials, where no serious contamination problem results, to major disasters occurring from explosions, fires or natural phenomena.

Correspondingly, the hazards resulting from such accidents will cover the range of situations from minor hazards to very serious situations involving extreme radiation hazards and bodily injury or both.

In view of the complicating factors that may arise during such emergencies, simple rules of procedure cannot be set down covering all situations of radiation danger. However, in any emergency the primary concern must always be the protection of personnel. Second should be the confinement of the contamination to the local area of the accident, if this is possible.

#### **10.2** Response of Laboratory Personnel

#### 10.2.1 MINOR SPILLS OF LIQUIDS AND SOLIDS INVOLVING NO AIRBORNE CONTAMINATION

- A. Notify persons in the area that a spill has occurred.
- B. Prevent the spread of contamination by covering the spill with absorbent paper. (Paper should be dampened if solids are spilled.)
- C. Clean up the spill, wearing disposable gloves and using absorbent paper.
- D. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Put contaminated gloves and any other contaminated disposable material in the bag.
- E. Survey the area with an appropriate low-range radiation survey meter or other appropriate technique. Check the area around the spill for contamination. Also check hands, clothing, and shoes for contamination.
- F. Promptly report the incident to the Radiation Safety Department

#### **10.2.2** Major Spills of Liquid and Solids Involving No Airborne Contamination

- A. Clear the area. If appropriate, survey all persons not invoved in the spill and vacate the room.
- B. Prevent the spread of contamination by covering the spill with absorbent paper (paper should be dampened if solids are spilled), but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.
- C. Shield the source only if it can be done without further contamination or significant increase in radiation exposure.

- D. Notify the Radiation Safety Department immediately.
- E. Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with a mild soap. Follow personnel decontamination procedures in Section 11 of this manual.
- F. Allow no one to return to work in the area unless approved by Radiation Safety.

# **10.2.3** Incidents with Airborne Contamination (Radioactive Dusts, Mists, Fumes, Vapors, Gases, Aerosols)

- A. Notify all personnel to vacate the room immediately.
- B. If time permits, hold your breath and shut off the source of contamination. (Example: If radioactive gas is leaking from a cylinder, close the cylinder valve if you can.)
- C. Shut down ventilation system, if possible, unless it is determined that the room ventilation system needs to be used to clear the air for access purposes.
- D. Vacate the room. Shut all doors to the laboratory. Seal the area, if possible.
- E. Notify Radiation Safety immediately.
- F. Ensure that all access doors to the area are closed and posted with appropriate warning signs, or post guards at all access doors to prevent accidental opening of the doors or entry to the area.
- G. Survey all persons who could possibly have been contaminated. Decontaminate as directed by Radiation Safety.
- H. Promptly report suspected inhalations and ingestions of licensed material to the Radiation Safety Department.
- I. Decontaminate the area only when advised and/or supervised by Radiation Safety.
- J. Allow no one to return to work in the area unless approved by Radiation Safety.

## **10.2.4** Injury to Personnel

- A. If contamination is found in open wounds, flush the wound immediately with running water while spreading the edges of the wound.
- B. In cases where radionuclides have accidentally been released into a finger or other extremity by a needle, induce the wound to bleed by "bleeding" it as a cleansing action in addition to the running water.
- C. If contamination is found in the eyes, flush the eyes with running water.
- D. Notify RSO immediately at 304-293-3413.
- E. Perform, or have performed, any bioassays required by the RSO.
  - a. If the injury is serious, the person should be taken directly to the Emergency Room.

#### **10.2.5** Ingestion of radioactive material

If radioactive material has been taken into the mouth, it should be assumed that some of the material has been ingested.

- A. Notify RSO immediately at 304-293-3413.
- B. If advised to do so by the RSD, induce vomiting.
- C. Take appropriate steps, as recommended by RSD, to prevent or mitigate uptake of radioactivity into tissues.
- D. Perform, or have performed, any bioassays required by the RSD.

#### 10.2.6 Fire

- A. Notify all persons in immediate area.
- B. Activate nearest fire alarm signal.
- C. Call 9-911, give location of fire or smoke and any other information requested.
- D. Attempt to put out small fires if radiation hazard is not serious.
- E. Notify the Radiation Safety office, 304-293-3413 when it is safe to do so.
- F. Follow instructions given in posted Fire Emergency Plan.

#### **10.3 Emergency Response/Security Personnel**

#### 10.3.1 EVALUATION OF RISK

The number of places where a high amount of radiation will be present is extremely limited. The large sources of radiation, whether in the university or the hospital, are generally sealed sources. These cannot explode and they would be involved in fire only if it started elsewhere. Many laboratories use radioactive materials but almost all use small amounts. Should there be an injured person or fire in a lab, attention should be given to these conditions first; the radioactivity will be of secondary concern.

Nuclear Medicine has large amounts of radioactive materials present in forms that can be spilled or volatilized, so caution is necessary in accidents there.

Radiation Therapy has sealed sources of radiation in relatively higher activities used for treatment of diseases. Caution may be necessary in that area.

Patients receiving treatments that involve actually giving them radioactive material (brachytherapy or radiopharmaceutical therapy), rather than external radiation (such as accelerator treatments) may be very radioactive.

Medical or Radiation Safety personnel should be able to assist in evaluating the risk in responding to emergencies in these areas.

# 10.3.2 Actions to be Taken in an Emergency

Care of the injured and response to fire should proceed without regard to radiation.

In case of grave danger or serious injury, even in instances of high radiation risk, a victim should be tended to without regard to radiation.

In any radiation emergency, make sure that the university or hospital operator has notified the Radiation Safety personnel on call.

In cases where airborne radioactive material may be present, such as in an explosion, the ventilation system may have to be shut down to prevent the spread of contamination. This may mean that self-contained breathing apparatus will need to be used by emergency response teams.

Laboratory personnel, if present, may be able to advise you if airborne material is likely to be present. If conditions permit, wait until a representative from the Radiation Safety office arrives before attempting to enter an area containing airborne radioactive material.

Secure the area. Security officers and other emergency workers should make sure that no one enters the radiation emergency area and that potentially contaminated individuals do not leave until they have been checked and cleared by Radiation Safety.

If there are seriously injured accident victims who may be contaminated by radioactive material, notify the hospital Emergency Department and have them institute their Radiation Mass Casualty Plan.

Decontamination of the injured and any emergency workers caring for them will then take place at the hospital.

Clean up and decontamination should take place under the supervision of Radiation Safety.

The Radiation Safety Department will advise concerning the need for individual monitoring devices and any follow-up actions (such as bioassays) that could be required for Emergency Response, Security, or other personnel.

# **11. DECONTAMINATION PROCEDURES**

#### 11.1 DECONTAMINATION OF PERSONNEL

The objective of personnel decontamination is to reduce radiation exposure promptly, minimize absorption of radionuclides though the skin, and keep localized contamination from spreading. A survey instrument is absolutely necessary.

If a person is found to have radioactive contamination on their clothing or body, the following steps should be taken:

#### 11.1.1 SKIN

- A. Remove any clothing found to be contaminated before determining levels of skin contamination. Generally, levels below 0.1 mrem/hr present a minimal hazard, but still should be removed if possible.
- B. Specific hot spots or areas of contamination on the skin should be located with a survey meter. (Note: Tritium cannot be detected with a survey meter. Use a wipe test to look for tritium contamination.) The hot spots should be cleaned up so as to prevent the spread of contamination to clean areas of the body.
- C. Ordinarily, soap and lukewarm water (or detergent) will remove most of the contamination.
  - 1. Wash for 1-2 minutes, rinse, and dry the areas. Pay particular attention to the hands and fingernails. Monitor with a survey meter (except for tritium). Repeat if contamination is still present.
  - 2. If contamination is still present, wash again using plenty of soap and a soft brush. Apply only light pressure to the brush. Rinse, dry and resurvey. Repeat if contamination is still present.
  - 3. Take care to keep radioactivity from being washed into any skin breaks. A sterile bandage will help.
  - 4. Even if contamination still persists, these efforts should be halted before the skin becomes reddened and irritated.
  - 5. ALWAYS contact the Radiation Safety office, 304-293-3413 for advice and final monitoring. Radiation Safety will also estimate the dose to areas where fixed contamination cannot be removed and will make appropriate notations on dose records.
- D. If contamination is widespread over the body, shower with soap and water, dry and repeat the survey. Radiation Safety will advise on how and where this should be done. If contamination is still widespread, shower with scrubbing, dry and resurvey. If contamination still exists, select the most highly contaminated areas and proceed as in C 1. and 2. above. Never let the skin become irritated.

- E. DO NOT use organic solvents. These may only increase the probability of radioactive material penetrating the skin.
- F. When decontamination is completed, apply lanolin or hand cream to prevent chapping.
- G. The Radiation Safety office should provide final monitoring and/or further requirements. The RSO will estimate the dose to any area where fixed contamination cannot be removed and make appropriate notations on dose records.

# 11.1.2 HAIR

- A. If the hair is contaminated, try up to three washings with shampoo or liquid soap and rinse with water. Use towels to keep water from running onto the face and shoulders.
- B. The Radiation Safety Department should provide final monitoring.

# 11.1.3 CLOTHES

- A. Contaminated clothes (or shoes) should be removed from the body to prevent further spread of the contamination. Place these items in plastic bags or containers.
- B. After necessary body decontamination has been accomplished, put on protective gloves and lab coat (or surgical gown) and rinse the clothing in a Radioactive Waste Sink (providing the sink is less contaminated than the clothing).
- C. Re-check the surface of the garments with a survey meter. (Tritium is not detectable with a survey meter.) Maximum permissible contamination is:
  - 1. 22 dpm/100 cm2 above background for radionuclides in Group 1 of Appendix 5;
  - 2. 220 dpm/100 cm2 above background for radionuclides in Groups 2, 3 and 4 of Appendix 5.
  - 3. If clothing reads less than these limits it may be released directly to the laundry.
- D. If several washing still are not able to lower the contamination then either hold it for decay if the half-life is short, or treat it as solid radioactive waste (see Section 9, "Radioactive Waste Disposal").
- E. The Radiation Safety office will provide final monitoring and advice.

**11.2** DECONTAMINATION OF LABORATORIES

Decontamination will be much easier if appropriate planning and precautions are made ahead of time.

- 1. The general procedure is to confine the radioactive material as much as possible and prevent spread to other areas.
- 2. Prepare yourself for this job by putting on protective gloves, lab coat or surgical gown, and shoe covers if the floor is contaminated.
- 3. A survey instrument is a must; otherwise you are only guessing where the contamination lies. (Use a wipe test for tritium.)
- 4. First remove the gross contamination caused by the spill; start at the edges of the contaminated area and work inward.
  - 1. If a large amount of gamma or high energy beta emitter has been spilled (example: a patient vomits shortly after receiving an oral therapy dose of I-131)

manipulate the cleaning rags or towels with long forceps or tongs; this will significantly reduce hand exposure.

- 2. Once a cleaning rag has become contaminated, it should be disposed of rather than reused.
- 5. After removing spilled liquids or other material, soap and water or commercially available decontamination solutions should be used to remove the remainder of the contamination.
- 6. All waste material should be placed in a plastic bag or other container to prevent recontaminating the area. The waste must eventually be sealed in plastic bags as described in Section 9, "Radioactive Waste Disposal".
- 7. The individual involved in the spill is responsible for the cleanup. DO NOT CALL THE JANITOR OR HOUSEKEEPING TO CLEAN UP RADIOACTIVE SPILLS.
- 8. The Radiation Safety office will advise in the cleanup procedures and will provide final monitoring. Call 304-293-3413.

# APPENDIX 1: ORDERING, RECEIVING, OPENING, AND SHIPPING PACKAGES CONTAINING RADIOACTIVE MATERIAL

#### A1.1 ORDERING

- A. Radioactive material will be ordered by an Authorized User or a qualified individual designated by the RSO.
- B. The RSO must approve or place all orders for radioactive material and ensure that the requested radioactive material(s), quantities, manufacturer and model are authorized by the license and that possession limits are not exceeded.
- C. A system for ordering and receiving radioactive material shall include the following information:
  - 1. Records that identify the Authorized User or department, radionuclide, physical and/or chemical form, activity, and supplier;
  - 2. Confirmation, through the above records, that material received was ordered through proper channels.
  - 3. For deliveries during normal working hours, inform carriers to deliver radioactive packages directly to a specified area.
  - 4. For deliveries during off-duty hours, inform security personnel or other designated persons if they should accept the delivery in accordance with Radiation Safety Precautions and provide designated persons with RSD contact information.

## A1.2 RECEIVING

Only Authorized Users or specifically identified designees are permitted to open shipping packages (shipping/transport containers) containing radioactive material. If an Authorized User, designee, or RSD representative is not available when the package is delivered, the package will be placed in a secure, pre-designated remote location of the facility awaiting such person(s). The package will not be opened. Packages containing radioactive material shall be inspected and surveyed as soon as practical after receipt of the package, but not later than three (3) hours after the package is received at the facility if it is **received during normal working hours**. Packages containing radioactive material that are **received after normal working hours** at the facility shall be inspected and surveyed not later than three (3) hours from the beginning of the next working day.

#### A1.3 OPENING

A. Put on gloves to prevent contamination. Always assume that the package and material inside are contaminated until proven otherwise.

- B. Visually inspect the package for evidence of potential contamination (crushed, wet, damaged). If damage is noted, stop the procedure and notify the RSD or other knowledgeable person.
- C. Measure the dose rate from the package at 1 meter and at the package surface. If it is higher than expected, stop and notify the RSD. The expected dose rate in mrem/hr at one meter should be close to the transportation index (T.I.) value as noted on the package [49 CFR 173.403]. The expected maximum dose rates at the surface of the package and Transportation Indices are listed below [49 CFR 172.403(c)]:

Label Type	Maximum Surface Reading	Transportation Index
	(mrem/hr)	(mrem/hr)
White I	0.5	0
Yellow II	0.5 - 50	$0 < T.I. \le 1.0$
Yellow III	50-200	1.0 < T.I.

\* The final delivery carrier and the NRC Operations Center (301-816-5100) or appropriate Agreement State Agency must be immediately notified by telephone [10 CFR 20.1906(d)] if external radiation levels exceed limits specified in 10 CFR 71.47.

- D. Wipe at least 300 cm<sup>2</sup> of the exterior of the package and analyze the wipe. The final delivery carrier and the NRC Operations Center (301-816-5100) or appropriate Agreement State Agency must be immediately notified by telephone [10 CFR 20.1906(d)] if removable surface contamination levels exceed the limits specified in 49 CFR 173.443.
- E. Record the results of the external radiation (if applicable) and removable contamination surveys (if applicable).
- F. Remove packing slip.
- G. Open the outer package following the supplier's instructions, if provided.
- H. Open the inner package and verify that the contents agree with the packing slip.
- I. Check the integrity of the final source container if not a gas or special form material. Look for broken seals or vials, loss of liquid, condensation, or discoloration of packing material. If anything unusual is found, stop and notify the RSD. Take appropriate precautions to prevent the spread of contamination. Notify the user of the material of any contamination found.
- J. Check the user request to ensure that the material received is the material that was ordered.
- K. Monitor the packing material and empty packages for contamination with a radiation detection survey instrument prior to discarding. If it is contaminated, treat it as radioactive waste.

#### A1.4 PREPARING PACKAGES FOR SHIPMENT

Packages of radioactive material offered to common carriers for shipment will be prepared in accordance with applicable U.S. Department of Transportation regulations. Proper packaging, markings and labels will be used, and proper shipping papers and emergency response information will be provided with each package. Transfer records will be maintained on file for inspection purposes. Packages of radioactive material will be prepared for shipment only by personnel that have completed training specified in the U.S. Department of Transportation, Subpart H, 49 CFR Part 172.

# **APPENDIX 2: RADIATION SIGNS AND SYMBOLS**



# APPENDIX 3: QUANTITIES OF LICENSED MATERIAL REQUIRING LABELING <sup>A, B</sup>

Radionuclide	Abbreviation	Quantity (µCi)
Hydrogen-3	H-3	1,000
Carbon-14	C-14	1,000
Fluorine-18	F-18	1,000
Sodium-22	Na-22	10
Sodium-24	Na-24	100
Phosphorus-32	P-32	10
Phosphorus-33	P-33	100
Sulfur-35	S-35	100
Calcium-45	Ca-45	100
Chromium-51	Cr-51	1,000
Cobalt-57	Co-57	100
Cobalt-60	Co-60	1
Nickel-63	Ni-63	100
Gallium-67	Ga-67	1,000
Gallium-68	Ga-68	1,000
Germanium-68	Ge-68	10
Strontium-89	Sr-89	10
Molybdenum-99	Mo-99	100
Technium-99m	Tc-99m	1,000
Indium-111	In-111	100
Iodine-123	I-123	100
Iodine-125	I-125	1
Iodine-129	I-129	1
Iodine-131	I-131	1
Xenon-133	Xe-133	1,000
Cesium-137	Cs-137	10
Barium-133	Ba-133	100
Gold-198	Au-198	100
Thallium-201	T1-201	1,000
Rubidium-86	Rb-86	100
Radon-222	Rn-222	1
Radium-226	Ra-226	0.1
Uranium-235	U-235	0.001
Uranium-238	U-238	100
Americium-241	Am-241	0.001

- a. Each <u>container</u> in which radioactive material is transported, used or stored in amounts greater than the quantity specified above require labeling.
- b. Each <u>area</u> of the laboratory in which radioactive materials are used or stored in an amount exceeding 10 times the quantity of radioactive material specified above require labeling.

For a complete listing of nuclides refer to 10 CFR 20 Appendix C

# APPENDIX 4: GUIDELINES FOR NURSING PERSONNEL FOR PROCEDURES OF CONCERN

#### A4.1 I-131 THERAPY PATIENTS

I-131 is used to treat patients with thyroid carcinoma or hyperthyroidism. I-131 is generally administered orally in a liquid, capsule, or caplet form. Major therapies are procedures involving 33 millicuries (mCi) or more. Any patient receiving major therapies may be admitted to the hospital as determined by patient-specific dose calculations. If calculations demonstrate the potential total effective dose equivalent to any individual would be greater than 500 millirem, the patient shall remain hospitalized until the activity is less than 33 mCi, the measured dose rate at one meter from the patient is less than 7 millirem per hour, or patient-specific calculation demonstrates that the potential total effective dose to any individual would not be greater than 500 millirem. Radiation **exposure and contamination** are both concerns when working with I-131 patients as the patient will be emitting radiation and bodily fluids, especially urine, will be contaminated with radioactive material. The following guidelines should be observed when working with I-131 patients:

- A. I-131 therapeutic, in-patient procedures may only be performed in single occupancy, corner room with only one wall adjacent to another patient room, with private restroom.
- B. Visitors are not permitted in the room during the patient's stay.
- C. Pregnant women are not permitted in the room.
- D. Persons under the age of 18 are not permitted in the room.
- E. Caregivers requiring access to the patient room will be provided radiation dosimeters (badges) to monitor radiation exposure from the patient. Always wear your badge when attending the patient. Wear the badge between your waist and collar and make sure that the badge worn is the one issued in your name for the current monitoring period. Do not share badges with other workers. When you are not working, store your badge in a controlled area away from all radiation sources.
- F. Provide all necessary care, however work quickly but effectively. Minimize your time in the room. Maintain the greatest distance possible from the patient consistent with effective care. Utilize the lead shielding provided to the maximum.
- G. Put on gloves, shoe covers, mask, and gown before entering patient's room. Upon leaving the room, remove gloves, shoe covers, mask, and gown and place them in the trash receptacles inside the room. After leaving room, wash hands.
- H. Carefully note instructions posted with the "Caution Radiation" sign and any radiation safety instructions written in the patient's chart.
- I. Environmental and Nutrition Services staff are NOT permitted in I-131 patient rooms. I-131 patients are to be provided with disposable food trays.

- J. Nothing may leave the room until surveyed by Radiation Safety Staff. This includes linens, food trays, food items, trash and medical monitoring equipment. Utilize disposable medical monitoring equipment if possible.
- K. The Radiation Safety Department will survey the patient daily and will notify personnel when activity contained in the patient is below release criteria.
- L. The room may not be released to Environmental Services after patient discharge until decontaminated and released by Radiation Safety Department. Radiation Safety will place a green "OK" sticker on the door and provide room release documentation to nursing staff indicating the room is released for public use.
- M. Notify Radiation Safety Department immediately if there is a spill of patient urine, or if the patient vomits within the first 24 hours of dose administration.
- N. Notify Radiation Safety Department immediately if there is a medical emergency or death of the patient.

# A4.2 LUTATHERA RADIONUCLIDE THERAPY

Lutathera is a radiopharmaceutical that uses Lutetium-177 (Lu-177) to treat gastroenteropancreatic neuroendocrine tumors. Lutathera is delivered via intravenous infusion over a period of approximately 30 minutes. The patient must remain at the Hospital for approximately 4 hours after the completion of Lutathera infusion to allow administration of additional medications. The patient will be emitting radiation and bodily fluids, especially urine, will be contaminated with the radioactive material. Therefore, nursing staff caring for the patient should observe the following guidelines:

- A. Pregnant women are not permitted in the room.
- B. Persons under the age of 18 are not permitted in the room.
- C. Visitors are not permitted in the room any time after infusion of the radionuclide.
- D. Provide all necessary care, however work quickly but effectively. Minimize your time in the room. Maintain the greatest distance possible from the patient consistent with effective care.
- E. The use of radiation dosimeters is not necessary while attending these patients. The radiation exposure is very low.
- F. Put on gloves and shoe covers before entering patient's room. Upon leaving the room, remove gloves and shoe covers and place them in the trash receptacles inside the room. After leaving room, wash hands.
- G. Environmental and Nutrition Services are not permitted in the room.
- H. The room may not be released to Environmental Services after patient discharge until decontaminated and released by Radiation Safety Department. Radiation Safety will place a green "OK" sticker on the door and provide room release documentation to nursing staff indicating the room is released for public use.

I. Notify Radiation Safety Department immediately in case of medical emergency or death of the patient.

# A4.3 EYE PLAQUE IMPLANT TEMPORARY BRACHYTHERAPY PATIENTS

Eye plaque implant brachytherapy is a procedure which involves a gold plaque loaded with several radioactive seeds which is surgically implanted onto the patient's eye to treat ocular disease. The seeds are about the size of a grain of rice and emit very low energy gamma radiation. Typically, 10-30 seeds containing radioactive I-125 are loaded into the gold plaque.

These patients usually emit radiation at a level that is below regulatory release limits, and under normal conditions, patients would be allowed to go home during treatment. However, for certain reasons these patients are hospitalized during their treatment. These patients must be assigned a private room with a private restroom. The patient's bodily fluids will not be contaminated with radioactive material. However, the patient will be emitting radiation. The following guidelines should be observed:

- A. Pregnant women are not permitted in the room.
- B. Persons under the age of 18 are not permitted in the room.
- C. The use of personnel radiation dosimeters is not necessary when attending these patients. Radiation exposure is very low.
- D. Provide all necessary care, but work quickly but effectively. Minimize your time in the room. Maintain the greatest distance possible from the patient consistent with effective care.
- E. Put on gloves before entering patient's room. Upon leaving, remove gloves and place them in trash receptacles inside the room. After leaving room, wash hands.
- F. Stay behind the red line on the floor when possible.
- G. Visitors are limited to 2 hours per day and should stay behind the red line on floor.
- H. No trash or linens may leave the room until surveyed by Radiation Safety staff.
- I. Contact Radiation Safety Department immediately in the event of medical emergency or death of the patient.

## A4.4 PROSTATE SEED IMPLANT BRACHYTHERAPY PATIENTS

Prostate brachytherapy is a minimally invasive procedure that implants small radioactive pellets (called seeds) that are about the size of a grain of rice into the prostate where they emit very low energy radiation, which is primarily absorbed in the treatment area immediately surrounding the seeds. Needles containing the seeds are inserted through the skin of the perineum. The radioactive material within the seeds gives off localized radiation for a number of months. Typically 50-100 seeds containing I-125 are permanently implanted.

These patients usually are administered an amount of radioactive material that is below regulatory release limits, and under normal conditions, patients can go home. For certain

reasons, these patients may be hospitalized during treatment. These patients must be assigned a private room with a private restroom. The following guidelines should be observed:

- A. The use of personnel radiation dosimeters is not necessary when attending these patients. Radiation exposure is very low.
- B. Provide all necessary care, but work quickly but effectively. Minimize your time in the room. Maintain the greatest distance possible from the patient consistent with effective care.
- C. Primary hazard: Some seeds may be lost through urination. If the patient does not have a urinary catheter in place, any seed(s) that are lost through urination can be flushed. If a patient does have a catheter and catheter bag in place, the bag should be visually inspected for seeds. If a seed is found do not attempt to remove the seed. Immediately notify the Radiation Safety Department for disposal.
- D. No room items are to be removed without clearance from Radiation Safety. It is especially important to hold the catheter and bag for survey.

Notify Radiation Safety (Office: 304-293-3413, On Call Specialist: 304-293-6430) if there is a medical emergency (including patient death).

If a source becomes dislodged from the patient:

Do NOT touch the source! If possible, use a broom or some long handling tool to move it to a room corner.

Remove all unnecessary personnel from source area and call Radiation Safety.

Do not leave source near patient or attempt to re-insert source in patient.

# **APPENDIX 5: CLASSIFICATION OF ISOTOPES ACCORDING TO RELATIVE RADIOTOXICITY PER UNIT ACTIVITY**

Radiotoxicity Group	Radioisotopes
Very High (group 1)	Pb-210, Po-210, Ra-223, Ra-226, Ra-228, Ac-227, Th-227, Th-228, Th-230, Pa-231, U-230, U-232, U-233, U-234, Np-237, Pu-238, Pu-239, Pu-240, Pu-241, Pu-242, Am-241, Am-243, Cm-242, Cm-243, Cm-244, Cm-245, Cm-246, Cf-249, Cf-250, Cf-252
High (group 2)	Na-22, Cl-36, Ca-45, Sc-46, Mn-54, Co-56, Co-60, Sr-89, Sr-90, Y-91, Zr-95, Ru-106, Ag-110m, Cd-115m, In-114m, Sb-124, Sb-125, Te-127m, Te-129m, I-124, I-125, I-126, I-131, Cs-134, Cs-137, Ba-140, Ce-144, Eu-152, Eu-154, Tb-160, Tm-170, Hf-181, Ta-182, Ir-192, Tl-204, Bi- 207, Bi-210, At-211, Pb-212, Ra-224, Ac-228, Pa-230, Th-234, U-236, Bk-249
Moderate (group 3)	Be-7, C-14, F-18, Na-24, C1-38, Si-31, P-32, P-33, S-35, Ar-41, K-42, K-43, Ca-47, Sc-47, Sc-48, V-48, Cr-51, Mn-52, Mn-56, Fe-52, Fe-55, Fe-59, Co-57, Co-58, Ni-63, Ni-65, Cu-64, Zn-65, Zn-69m, Ga-72, As-73, As-74, As-76, As-77, Se-75, Br-82, Kr-85m, Kr-87, Rb-86, Sr-85, Sr-91, Y-90, Y-92, Y-93, Zr-97, Nb-93m, Nb-95, Mo-99, Tc-96, Tc-97m, Tc-97, Tc-99, Ru-97, Ru-103, Ru-105, Rh-105, Pd-103, Pd-109, Ag-105, Ag-111, Cd-109, Cd-115, In-115m, Sn-113, Sn-125, Sb-122, Te-125m, Te-127, Te-129, Te-131m, Te-132, I-130, I-132, I-133, I-134, I-135, Xe-135, Cs-131, Cs-136, Ba-131, La-140, Ce-141, Ce-143, Pr-142, Pr-143, Nd-147, Nd-149, Pm-147, Pm-149, Sm-151, Sm-153, Eu-152, Eu-155, Gd-153, Gd-159, Dy-165, Dy-166, Ho-166, Er-169, Er-171 (9.2 hr), Tm-171, Yb-175, Lu-177, W-181, W-185, W-187, Re-183, Re-186, Re-188, Os-185, Os-191, Os-193, Ir-190, Ir-194, Pt-191, Pt-193, Pt-197, Au-196, Au-198, Au-199, Hg-197, Hg-197m, Hg-203, TI-200, TI-201, TI-202, Pb-203, Bi-206, Bi-212, Rn-220, Rn-222, Th-231, Pa-233, Np-239
Low (group 4)	H-3, O-15, Ar-37, Co-58m, Ni-59, Zn-69, Ge-71, Kr-85, Sr-85m, Rb-87, Y-9lm, Zr-93, Nb-97, Tc-96m Tc-99m, Rh-103m, In-113m, I-129, Xe-131m, Xe-133, Cs-134m, Cs-135, Sm-147, Re-187, Os-191m, Pt-193m, Pt-197m, Th-232, Th-Nat, U-235, U-238, U-Nat

## REFERENCES

- 1. Food and Drug Administration 21 CFR 361.1 (Table 1)
- 2. Applications of Bioassay for Radioiodine. U.S. Nuclear Regulatory Commission Regulatory Guide 8.20, Revision 2, September 2014. (Table 2)
- 3. Release of Patients Administered Radioactive Material. U.S. Nuclear Regulatory Commission Regulatory Guide 8.39, Revision 1, April 2020. (Table 3)
- 4. Criteria for Establishing a Tritium Bioassay Program. U.S. Nuclear Regulatory Commission Regulatory Guide 8.32, July 1988.
- 5. NCRP Report No. 155, "Management of Radionuclide Therapy Patients," December 2006.
- 6. U.S. Nuclear Regulatory Commission regulations 10 CFR 20
- 7. U.S. Nuclear Regulatory Commission regulations 10 CFR 35
- 8. U.S. Department of Transportation regulations 49 CFR 172 & 49 CFR Part 173 Subpart I

IN CASE OF A RADIATION EMERGENCY				
DURING NORMAL WORKING HOURS: (Monday through Friday 8:15 am – 4:45 pm)	Call the RSO at (304) 293-3413			
OUTSIDE NORMAL WORKING HOURS:	Phone the on call Radiation Safety Specialist at (304) 293-6430			
Radiation Safety Department				
Health Sciences Center – North, Room G-139				
P.O. Box 9006				
Morgantown, WV 26506-9006				
Office Phone: (304) 293-3413				
Fax: (304) 293-4529				
Email: radiationsafety@hsc.wvu.edu				
Website: http://www.hsc.wvu.edu/rsafety/				