

Radiation Protection Guide

For Medical Use of Radioactive Materials & Radiation Producing Machines

EHS Radiation Safety

122 Grand Ave. Ct.

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PREFACE

The University of Iowa is committed to providing its patients, visitors, students and employees with an environment where sources of radiation are used safely for the purposes of medicine, research and teaching. Attainment of this goal requires the cooperation and commitment of all persons involved.

The Environmental Health & Safety (formerly Health Protection Office) is responsible for implementing the University's radiation safety program as defined by its Radiation Safety Committees, broadscope license, and state and federal regulations. Department heads, faculty members, supervisors and individual users are directly responsible for maintaining an environment that promotes compliance with these policies, license conditions, and regulations.

The purpose of this guide is to provide the necessary operational and procedural information for the safe use of sources of ionizing radiation at The University of Iowa. This guide, along with the information available from the Environmental Health & Safety's radiation safety training sessions and educational materials should enable the radiation worker to understand and practice the safe use of ionizing radiation sources to ensure that any resultant exposure is "as low as reasonably achievable."

This guide was prepared by the Environmental Health & Safety and approved by The University of Iowa's Hospital Radiation Safety Review Group.

It supersedes previous University radiation protection guides.

RADIOACTIVE MATERIAL SPILL RESPONSE INFORMATION

In the event of a spill or accident involving radioactive materials,
contact Environmental Health & Safety at 335-8501.

If the phone call is placed outside of normal working hours,
you will be connected to UI Public Safety.

UIHC Routine Security – 356-2658

UIHC Emergencies – 195

- **Serious Accidents**
- **Fire (outside UIHC dial 911)**
- **Unmanageable Chemical Spill**
- **Disruptive, Hostile, Threatening Visitor, Family, or Staff**
- **Patient Safety/Security Threat**
- **Possession of Deadly Weapons by Patients, Visitors, or Staff**
- **Bomb Threat**

UI Public Safety – 335-5022

UI Emergencies - 911

- **Serious Accidents**
- **Fire (inside UIHC dial 195)**
- **Unmanageable Chemical Spill**
- **Ambulance**

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1.0 ADMINISTRATIVE ORGANIZATION

1.1 Radiation Safety Committees

The University of Iowa's radiation safety program operates under the management oversight of the Vice President for Research. Operation of the radiation safety program is delegated to the Radiation Safety Committee (RSC) and the Radiation Safety Officer (RSO). The RSC and the RSO have the authority to communicate with, enforce, and direct University personnel regarding radioactive material regulations, license conditions, and University radiation safety policies. The RSC is comprised of four interrelated committees that function to provide radiation protection program oversight, review, policy development, and radioactive materials use authorization under the management of the Vice President for Research.

Executive Committee

The Radiation Protection Executive Committee is responsible for providing oversight and review of the University's radiation protection program and establishing radiation safety use and enforcement policies. The Executive Committee is comprised of representatives of university administration, the Environmental Health & Safety (EHS), the chair and vice-chairpersons of the Basic Science Radiation Protection Committee, the Medical Radiation Protection Committee, and the Hospital Radiation Safety Review Group.

Basic Science Radiation Protection Committee

The Basic Science Radiation Protection Committee (BSRPC) is responsible for the review of applications for non-human use of radioactive materials to ensure that they conform to currently accepted radiation protection practices, regulations, and license conditions. The Committee also provides radiation protection policy recommendations to the Executive Committee. The membership of the BSRPC is comprised of authorized radioactive material users from within the University's Basic and Health Sciences and a representative from EHS. The chair and vice-chairpersons serve as representatives to the Executive Committee.

Medical Radiation Protection Committee

The Medical Radiation Protection Committee (MRPC) is responsible for ascertaining that all experimental or research uses of radiation in or on human beings conform to currently accepted radiation protection practices, regulations, and license conditions. The Committee also provides radiation protection policy recommendations to the Executive Committee.

Medical Radiation Protection Committee - Continued

The membership of the MRPC is comprised of licensed physicians, individuals with specialized training and knowledge as necessary, and a representative from EHS. The chair and vice-chairpersons serve as representatives to the Executive Committee.

The membership of the MRPC also serves as the Radioactive Drug Research Committee (RDRC). The RDRC is responsible for the review and approval of certain proposed uses of radioactive drugs for human research intended to obtain basic information regarding metabolism, dosimetry, human physiology, pathophysiology, or biochemistry, but not for diagnostic or therapeutic use or for clinical trials.

Hospital Radiation Safety Review Group

The Hospital Radiation Safety Review Group (HRSRG) is responsible for the review of the University Hospital's radiation protection program. This includes approving individuals to work in the healing arts as an authorized user, nuclear pharmacist, teletherapy physicist, or radiation safety officer; and proposed uses of radioactive material or radiation producing equipment for healing arts purposes. The Review Group also provides radiation protection policy recommendations to the Executive Committee. The membership of the HRSRG is comprised of representatives of the UIHC's administration, nursing service, licensed physicians, and other individuals with specialized training and knowledge as necessary, and a representative from EHS. The chair and vice-chairpersons serve as representatives to the Executive Committee.

1.2 Radiation Safety Officer (RSO)

The RSO is responsible for the day-to-day implementation of the University's radiation safety program as outlined by the Radiation Safety Committees, the University's radioactive materials license, and state and federal regulations. The RSO has authority to communicate with, enforce, and direct University personnel regarding radioactive material regulations, license conditions, and University radiation safety policies. The RSO also has the authority to terminate the use of any licensed radioactive material.

1.3 Radiation Safety Staff

EHS's Radiation Safety Staff is responsible for promoting radiation safety for the protection of employees, the general public, and UI property. The staff is responsible for conducting surveys, audits, and reviews to help ensure that all radioactive material and radiation producing equipment is used safely and in accordance with applicable policies and regulations. EHS maintains the University's radioactive materials license and all radiation-producing machine registrations.

2.0 REGULATORY and UNIVERSITY REQUIREMENTS

2.1 Agreement State Status

In 1986, the State of Iowa signed an agreement with the Nuclear Regulatory Commission (NRC) to regulate radioactive materials within its borders with the exception of federal institutions (e.g., the Veteran's Administration Medical Center) and nuclear power plants, which remain under NRC control. The NRC periodically reviews this "agreement" and the actions taken by the state under this agreement to ensure regulatory compliance.

2.2 Iowa Department of Public Health

The Iowa Department of Public Health (IDPH) regulates the use of sources of ionizing radiation and the registration of radiation-producing machines within the State of Iowa.

2.3 Radioactive Materials License

The use of radioactive materials at The University of Iowa is conducted under the authority of the University's "broadscope academic-medical license" issued by the IDPH. This type of license allows the University considerable flexibility in its use of radioactive materials in exchange for the establishment of a radiation safety program for managing their use.

The broadscope license covers all radioactive materials use for the entire university. Any individual or action that jeopardizes the license endangers the permission of all clinicians and researchers who utilize radioactive materials at The University of Iowa. Therefore, this license places significant responsibility on individuals who use radioactive materials to conform to safe work practices, and to conduct and complete all required compliance activities in the course of their use of radioactive materials.

Permission to use radioactive materials or radiation-producing machines at The University of Iowa does not constitute permission to use the same materials or machines at the Veteran's Administration Medical Center (VAMC). The VAMC is a federal agency regulated by the NRC. The VAMC has its own separate radioactive materials license and radiation safety policies. For information on obtaining use authorization at the VAMC, contact the VAMC radiation safety office at 158-5753 or 338-0581 extension 5753.

2.4 Notice to Workers and Reporting Violations

State regulations require the University to provide workers access to certain notices, instructions and reports, and the options available to individuals in conjunction with IDPH inspections, safety concerns, and suspected violations.

Inspecting Documents Concerning Licensed Activities

Staff and students of this facility may examine copies of the following documents located at EHS; 122 Grand Avenue Court, by contacting EHS at 335-8501.

- IDPH Regulations and Inspection Reports for Radiation Machines and Radioactive Materials
- The University's Broadscope License
- Your individual monthly dosimeter report

Reporting Concerns and Violations

If you believe that a violation of State regulations or this facility's radioactive materials license has occurred, you should report the violation to the authorized user supervising the work or area involved. If you believe that adequate corrective action has not been taken, you should notify the Radiation Safety Officer at 335-8501. You also have the right to contact the Bureau of Radiological Health, IDPH, at 515-281-3478.

Notice to Workers

State regulations require that the "Notice to Workers" posting is available to radiation workers. This posting is displayed in various locations throughout the University and can be accessed online at <https://research.uiowa.edu/ehs/>. It provides information regarding your rights and responsibilities as a radiation worker as well as your employer's responsibilities. Information contained in the Notice includes the location on campus where the regulations and regulatory correspondence can be reviewed, and the location and phone numbers of the IDPH.

2.5 Regulations

Regulations pertaining to the use of radioactive materials and radiation-producing machines are found in the Iowa Administrative Code (IAC) Section 641 Chapters 38-45. Copies of the regulations are available for review at the EHS or can be accessed online at <https://research.uiowa.edu/ehs/> via our government links to the Iowa Department of Public Health – Bureau of Radiological Health.

2.6 Non-Compliance Policy

EHS responds to non-compliance with regulations, University policy and the University's license as directed by any of The University of Iowa's Radiation Protection Safety Committees. Any violation of policy or regulations may result in the revocation of use privileges by the University's Radiation Safety Committees and/or the Radiation Safety Officer.

If the RSO at any time is not satisfied with the adequacy of safety practices employed by any user, cessation of use may be required until satisfactory procedures have been adopted.

3.0 DOSE LIMITS and ASSESSMENT

3.1 Maximum Permissible Dose Limits

3.1.1 Radiation Workers

Maximum permissible dose limits for adult radiation workers (listed below) apply to any combination of dose received from external or internal exposure. These limits do not apply to doses received from background radiation or from medical procedures. An adult radiation worker is defined as an individual 18 years of age or older. Iowa child labor laws prohibit individuals under the age of 18 from working with certain types of radioactive materials or in certain areas where occupational radiation exposure may occur. It is the policy of EHS that minors are not normally permitted to work with sources of ionizing radiation at The University of Iowa. For more information regarding this policy, contact the Radiation Safety Officer at 335-8501.

Annual Maximum Permissible Dose Limits		
mrem	rem	
5,000	5	Whole Body Deep Dose Equivalent <i>(Head, trunk, active blood-forming organs & reproductive organs)</i>
50,000	50	Whole Body Shallow Dose Equivalent <i>(Skin of the whole body)</i>
15,000	15	Lens of Eye Dose Equivalent
50,000	50	Extremities <i>(Hands, forearms, feet and ankles)</i>

3.1.2 Declared Pregnant Radiation Worker

Under state and federal law, the dose limit of a pregnant radiation worker remains at 5,000 mrem per year until she specifically declares her pregnancy in a written and signed statement directed to EHS. The declaration is voluntary. Following EHS's receipt of a signed Declaration of Pregnancy form, the dose limit to the worker's embryo/fetus is limited to 500 mrem for the duration of her pregnancy.

Upon the receipt of a signed Declaration of Pregnancy form, EHS will monitor potential internal and/or external exposure to the embryo/fetus as appropriate. A copy of EHS's pregnancy declaration form is available online at

<https://research.uiowa.edu/ehs/files/documents/radiation/pregform.doc>

EHS recommends that a pregnant radiation worker declare her pregnancy so that her occupational radiation exposure potential can be evaluated to ensure that the dose to the unborn child does not exceed 500 mrem over the duration of the pregnancy.

3.1.3 General Public

The limit to members of the general public (including employees not involved in working with sources of ionizing radiation) is 100 mrem per year resulting from licensed or registered activities at this institution.

3.2 ALARA Program

The maximum permissible occupational dose limits established by regulation are based on limiting individual radiation dose to what is considered to be an acceptable level of occupational risk. Although radiation doses below the regulatory limits are presumed to pose little health risk, it is assumed that any radiation exposure may carry some risk. Therefore, regulation requires that the University provide a program designed to reduce exposures to As Low As Reasonably Achievable (ALARA) to the extent practical, utilizing procedural and engineering controls.

The University's ALARA Program provides a process for the RSC and the RSO to review all occupational radiation exposure reports; and investigate any occurrences where occupational exposures exceed established program action levels. Additionally, EHS provides instruction on implementing ALARA practices to minimize radiation exposure.

Action Levels

The University has established investigational levels for occupational exposure to radiation (see next page).

ALARA Level I

EHS contacts individuals and their supervisor/department head if their cumulative quarterly exposure exceeds any of the action levels listed in the table found on the next page.

ALARA Level II

In addition to “Level I” notifications, EHS requires the completion of a questionnaire for “Action Level II” exposures and may include a meeting with the staff member and their supervisor to discuss the individual’s exposure and potential actions.

ALARA Level I	ALARA Level II	
200 mrem/month	400 Mrem/month	Whole Body Deep Dose Equivalent <i>(Head, trunk, active blood-forming organs & reproductive organs)</i>
2000 mrem/month	4000 mrem/month	Whole Body Shallow Dose Equivalent <i>(Skin of the whole body)</i>
600 mrem/month	1200 mrem/month	Lens of Eye Dose Equivalent
2000 mrem/month	4000 mrem/month	Extremities <i>(Hands, forearms, feet and ankles)</i>

3.3 Determination of Exposure

3.3.1 Dosimeters

Personal dosimeters used to record occupational radiation exposures are supplied and processed through a commercial dosimeter service. The administration and management of the personnel monitoring program is provided by EHS. Personal dosimeters are available upon request and are assigned to individuals based upon regulatory requirements and their potential for occupational exposure to penetrating radiation. Dosimeters are normally exchanged on a monthly basis. Copies of dosimetry reports are provided for each dosimeter account and are maintained on file at EHS. Temporary dosimeters are available for interim issue until a permanent dosimeter assignment is established, or in the case of a lost or damaged dosimeter. Contact 335-8501 if you have questions concerning dosimeters or dosimeter reporting.

Documented completion of EHS radiation safety training applicable to job function is required as a prerequisite to obtaining a personal dosimeter. A listing of EHS radiation safety training courses available online can be accessed from the EHS's web page at <https://research.uiowa.edu/ehs/training> or contact EHS at 335-8501 for more information regarding applicable training for your job function. Dosimeter service request forms are also available from our web site at <https://research.uiowa.edu/ehs/files/documents/radiation/daddform.doc>

Types of Dosimeters

Whole Body and Collar Dosimeters provide measurement of penetrating and non-penetrating radiation exposure. Penetrating radiation is designated on reports as "DDE" for deep dose equivalent and includes exposure to the whole body (head, trunk, active blood-forming organs, and reproductive organs). Non-penetrating radiation is designated as "SDE" for shallow dose equivalent, and includes exposure to the skin and extremities. Lens of the eye dose equivalent is designated as "LDE."

Whole body dosimeters are to be worn on the torso in the region likely to receive the highest radiation exposure. If a protective lead apron is worn, wear the whole body dosimeter underneath your lead apron. Collar dosimeters are to be worn at the collar and external to a thyroid shield or lead apron.

Ring dosimeters provide measurement of radiation exposure to the extremities (hands and forearms). The ring dosimeter is to be worn under your disposable glove and on the hand most likely to receive the highest radiation dose. The label side of the dosimeter should face the side of the highest potential exposure.

3.3.2 Specific-Use Dosimeter Requirements

Bone Densitometer Operators

Personnel operating newly purchased X-ray bone densitometers are required to wear whole body dosimeters for the first six months of the new unit's operation. Operators may discontinue dosimeter use after six months if minimal operator exposure has been demonstrated for the new densitometer.

Diagnostic Radiology and Fluoroscopy Personnel

Diagnostic Radiology personnel directly involved in radiographic procedures are recommended to wear a whole body dosimeter. Individuals operating fluoroscopic equipment are required by regulation to wear a whole body dosimeter under their lead apron. A collar

dosimeter worn outside the lead apron at collar level and ring dosimeters is also recommended.

3.3.2 Specific-Use Dosimeter Requirements - continued

Nuclear Medicine Personnel

Personnel directly involved in radiopharmaceutical dosage administration and/or radiochemistry procedures are required to wear both a whole body and ring dosimeter.

Nursing Services Personnel

Whole body dosimeters are required for Nursing Services personnel routinely involved in radiopharmaceutical and/or brachytherapy patient care. Nursing Services personnel utilizing lead aprons during fluoroscopy or other X-ray procedures should wear the whole body dosimeter under the lead apron at waist or chest level.

Positron Emission Tomography Personnel

Personnel directly involved in radiopharmaceutical dosage administration, radiochemistry procedures, and service or maintenance to the cyclotron are required to wear both a whole body and a ring dosimeter. A second ring dosimeter is recommended for individuals who routinely prepare and/or administer radiopharmaceuticals. The label side of the ring should face the palm side of the hand.

Radiation Oncology Personnel

Whole body dosimeters are required to be worn by radiation oncology therapists, dosimetrists, medical physicists and physicians. Additionally, ring dosimeters are required to be worn by individuals directly involved in brachytherapy source preparation and administration. The label side of the ring should face the palm side of the hand.

3.3.3 Bioassays

Thyroid and/or urine bioassays are performed for personnel for whom internal exposure to radioactive materials is considered most likely. Bioassays are normally performed for:

- Individuals who prepare and administer radiopharmaceutical dosages of I-131.
- Individuals performing iodination procedures with I-125 or I-131.
- Individuals using quantities of radioactive materials above the bioassay threshold level, as determined by EHS.
- Declared pregnant radiation workers working with unsealed radioactive material.
- Individuals with an accidental or suspected intake of radioactive material.

3.3.4 Accidental Exposure Assessment

Anyone suspecting that they have had an intake of radioactive material through any pathway (e.g., ingestion, inhalation, or skin absorption) should contact EHS immediately at 335-8501 so that an evaluation can be performed.

4.0 RADIATION SAFETY TRAINING REQUIREMENTS

4.1 Initial Radiation Safety Training

Initial EHS radiation safety training is required for health care workers likely to receive an occupational whole-body radiation dose in excess of 100 mrem per year and as a prerequisite to obtaining a personal dosimeter. A listing of EHS radiation safety training courses available online can be accessed from the EHS web page at <https://research.uiowa.edu/ehs/training> or contact EHS at 335-8501 for more information regarding applicable training for your job function.

4.2 Annual Radiation Safety Training

The following individuals are required to complete annual radiation safety training:

- Personnel providing direct care of radiopharmaceutical therapy and/or brachytherapy patients.
- Personnel who receive a whole body dose of more than 100 mrem in one year.

A listing of EHS radiation safety training courses available online can be accessed from the EHS's web page at <https://research.uiowa.edu/ehs/training> or contact EHS at 335-8501 for more information regarding applicable training for your job function.

4.3 Individuals Who Operate X-ray Systems

Departments are responsible for ensuring that individuals who operate X-ray systems are adequately instructed and competent in safe operating procedures and use of diagnostic X-ray equipment.

4.4 Requirements for Operators of Diagnostic X-Ray Equipment

Individuals who operate any diagnostic x-ray system must:

- Have obtained a permit to practice from Iowa Department of Public Health (see the Iowa Administrative Code (IAC), Section 641, Chapter 42 for requirements)
- Submit an annual renewal application with applicable fees
- Report continuing education as required
- Post the permit to practice in the immediate vicinity of the general work area and visible to the public
- Work under the supervision of a licensed practitioner

4.5 Requirements for Operators of Dual Imaging Devices

In addition to the requirements specified under 4.4, staff seeking to operate dual imaging systems such as SPECT/CT or PET/CT must meet the requirements specified in the Iowa Administrative Code (IAC), Section 641, Chapter 42, Paragraphs 42.2(7) and 42.2(9). For assistance contact the Radiation Safety Officer at 335-8501.

5.0 UNIVERSAL SAFETY GUIDELINES & REQUIREMENTS

5.1 Time

Radiation dose is directly proportional to the length of time an individual is exposed to a source of ionizing radiation. Therefore, the less time spent near a radiation source, the smaller the total dose received.

5.2 Distance – Radioactive Materials

Distance is one of the simplest and most effective means of reducing radiation exposure. Increasing the distance from the radiation source can significantly reduce radiation exposure. The use of tongs or other handling devices that increase distance from radioactive material during manipulation can significantly reduce extremity and body exposures.

5.3 Distance – X-rays

Two types of radiation are produced by X-ray equipment: direct (or useful) beam radiation used to image or treat the patient, and scattered radiation, which is a non-useful by-product of X-ray machine use. Always avoid contact with the direct X-ray beam and apply the principles of time, distance, and shielding to minimize exposure to scattered radiation.

Scattered radiation is greatest in the area directly adjacent to the X-ray tube and the X-ray table. The exposure rate due to scattered radiation decreases rapidly with distance. Personnel not directly involved in the X-ray procedure should stand at least 2 meters from the X-ray tube.

5.4 Shielding

Properly shielding sources of radiation and/or personnel working near a source of radiation can dramatically reduce radiation exposure. It is important to choose shielding appropriate for the type of radiation and usage involved. Shielding is available in a variety of forms for various use applications. Contact EHS at 335-8501 for guidance regarding shielding types, application, and suppliers.

5.5 Shielding Evaluation

The amount of shielding required for new or re-modeled radiation use areas must be evaluated and approved by EHS and submitted to the Iowa Department of Public Health. Please contact EHS at 335-8501 to have these evaluations completed.

5.6 Security Requirements

All radioactive material and radiation producing equipment must be secured from unauthorized use or removal.

5.7 Warning Signs and Labels



Magenta or black on a yellow background is the internationally recognized color scheme used to indicate the presence of ionizing radiation. The symbol is the trefoil. Radiation warning signs indicate the types of exposure levels that may be present in the posted area.

Caution – Radioactive Materials

This warning sign is used to indicate that radioactive materials may be used or stored in the area.

Caution – Radiation Area

This warning sign is used to indicate areas where radiation levels may exist that are in excess of 5 mrem per hour at a distance of 30 cm from the source of radiation, or from any surface that the radiation penetrates.

Caution – High Radiation Area

This warning sign is used to indicate areas where radiation levels may exist that are in excess of 100 mrem per hour at a distance of 30 cm from the source of radiation, or from any surface that the radiation penetrates.

Caution – Very High Radiation Area

This warning sign is used to indicate areas where radiation levels may exist that are in excess of 500 mrem per hour at a distance of 1 meter from the source of radiation, or from any surface that the radiation penetrates.

5.7 Warning Signs and Labels - continued

Radiation Warning Labels

Use radiation warning labels to mark containers and equipment used to manipulate or store radioactive materials, contaminated items, or other sources of ionizing radiation.

Remove or obliterate all radiation warning labels on items that no longer contain radioactive material, are no longer contaminated as determined by the appropriate survey, or can no longer produce ionizing radiation.

5.8 General Rules of Good Practice

All work with radioactive material should be conducted in a manner designed to keep radiation exposure “as low as reasonably achievable” (ALARA).

- Review protocols involving radioactive materials to determine which activities have the potential to produce contamination, volatile materials, and/or aerosols. Work efficiently to minimize radiation exposure.
- Know emergency information and have available in the posted area. Consider all hazards involved in the work, such as mechanical, electrical, chemical, biological, and fire, as well as radiological.
- Work over absorbent, plastic-backed bench paper or spill trays to prevent contamination of facilities.
- Keep radioactive waste containers covered/capped when not in use.
- After working with radioactive materials, personnel should wash their hands and check hands and shoes for contamination.
- Monitor work surfaces and equipment for contamination.

5.9 Prohibited Activities

- Eating, drinking, smoking, food storage or the application of cosmetics in any area posted for the use and/or storage of radioactive materials.
- The use of microwave ovens in posted areas to heat food or beverages for human consumption.
- Pipetting of radioactive solutions by mouth.
- Storage or use of radioactive materials in areas not approved by EHS (such as non-authorized laboratories, hallways, and stairwells).

5.10 Personal Protective Equipment (PPE)

Minimize skin exposure at all times. A lab coat and disposable gloves are recommended when handling or manipulating radioactive materials. Use other PPE as needed or required, including safety glasses, full-face shields, leaded-safety glasses, and/or lead aprons. Contact EHS at 335-8501 for more information regarding PPE appropriate for your work environment.

5.11 Biosafety Cabinets/Culture Hoods

The use of volatile radioactive material in biosafety cabinets that recirculate some fraction of air back into the room is not recommended. If you need to use radioactive materials in a biological safety cabinet or culture hood, contact EHS's Biological Safety Officer at 335-8501.

5.12 Fume Hoods

Radioactive material operations producing aerosols or volatile compounds should be performed in a fume hood that has a current EHS air flow performance sticker. Contact EHS at 335-8501 for additional information on specific use requirements, or to schedule an airflow performance check.

5.13 Facility Maintenance and Renovation

All facilities in which radioactive materials have been used or stored need to be surveyed prior to maintenance or renovation activities. Contact EHS at 335-8501 a minimum of 1 week prior to scheduled work so that required surveys can be performed.

5.14 Equipment Service and Surplus

Any equipment or items used to manipulate or store radioactive material must be free of radioactive contamination prior to servicing or disposal. Contact EHS at 335-8501 prior to scheduled work so that required surveys can be performed.

5.15 Calibration Requirements for Radiation Monitoring Instruments

Radiation monitoring instruments used for quantitative radiation measurements are required, by regulation, to be calibrated at intervals not to exceed 12 months. Survey instruments that have never been calibrated or are out-of-calibration cannot be used. Instruments found out-of-calibration by the EHS will be tagged as "out-of-service."

5.16 Calibration Services for Radiation Monitoring Instruments

Instrument calibrations must be performed by EHS or another appropriately licensed vendor. Further information can be accessed at <https://research.uiowa.edu/ehs/files/documents/radiation/instrumentcal.pdf>, or by calling 335-8501.

6.0 AUTHORIZATION TO USE RADIATION

Medical use of radiation is defined as the intentional internal or external administration of ionizing radiation, and/or radioactive material to human beings for diagnostic, therapeutic, and/or medical research purposes. All medical use of ionizing radiation at The University of Iowa Hospitals & Clinics (UIHC) must conform to current regulations, license conditions, and radiation protection policies.

Clinical staff requesting to practice nuclear medicine, radiation therapy or otherwise obtain authorization to use radioactive material for diagnosis and/or therapy for patient care or medical research must obtain approval as an authorized user from the Hospital Radiation Safety Review Group (HRSRG) of the University's Radiation Safety Committee prior to assuming clinical responsibility.

Permission to use radioactive materials or radiation producing machines at The University of Iowa does not constitute permission to use the same materials or machines at the Veteran's Administration Medical Center (VAMC). The VAMC is a federal agency regulated by the NRC. The VAMC has a separate radioactive materials license and radiation safety policies. For information on obtaining use authorization at the VAMC, contact the VAMC radiation safety office at 338-0581 extension 5753.

6.1 Obtaining Authorization

Authorized User

Licensed physicians requesting permission to use/prescribe radioactive materials and/or radiation therapy machines for medical use must submit evidence of qualifications of training and experience to the UIHC's Clinical Staff Office for verification and review and approval by the HRSRG, the Medical Credentials Panel, and the Hospital Advisory Committee prior to assuming clinical responsibility.

Requests for approval as an authorized user must be made in writing. The request shall include a description of the use(s) for which authorization is being requested and a recommendation from the head of the clinic service in which the approval is sought. The written request for authorization should be sent to the UIHC's Clinical Staff Office with the following information:

6.1 Obtaining Authorization - continued

1. Curriculum vitae, Iowa Medical Examiners physician credentials, and a copy of specialty board certification in nuclear medicine, diagnostic radiology, radiology, therapeutic radiology and/or radiation oncology; or
2. Curriculum vitae, Iowa Medical Examiners physician credentials and a preceptor statement identifying the individual as an authorized user on a current Agreement State or NRC license; or
3. Curriculum vitae, Iowa Medical Examiners physician credentials, a completed copy of the Iowa Department of Public Health's Medical Use Training and Experience & Preceptor Attestation. Copies of the IDPH's training and experience preceptor form are available from EHS or can be accessed online at <https://research.uiowa.edu/ehs/> via our government links.

Regulations specifying the training and experience standards for authorized users are found in the Iowa Administrative Code (IAC), Section 641, Chapter 41.2 and 41.3. Copies of the regulations are available for review at EHS or can be accessed online at <https://research.uiowa.edu/ehs/> via our government links.

Upon completion of the HRSRG review the action of the group (i.e., approval or disapproval of the individual as an authorized user) will be communicated to the Clinical Staff Office and the head of the clinic service to which the staff member has been appointed.

Licensed Practitioner

Individuals licensed or otherwise authorized by law to practice medicine, osteopathy, chiropractic, podiatry, dentistry, or certified as a physician assistant or advanced registered nurse practitioner requesting permission to use/prescribe diagnostic X-rays for medical use must meet the requirements specified by the UIHC By-Laws. Contact the UIHC's Clinical Staff Office for information.

Authorized Nuclear Pharmacist, Radiation Safety Officer, Radiation Therapy Physicist and/or Medical Physicist

Prospective individuals appointed to serve as an authorized nuclear pharmacist, radiation safety officer, radiation therapy physicist or medical physicist use must submit evidence of qualifications of training and experience to the UIHC's Clinical Staff Office for verification and review and approval by the HRSRG, the Medical Credentials Panel, and the Hospital Advisory Committee prior to assuming responsibility for any of these respective positions.

6.1 Obtaining Authorization - continued

Requests for approval as an authorized nuclear pharmacist, radiation safety officer, radiation therapy physicist and/or medical physicist must be made in writing. The request shall include the name of the position for which approval is requested and a recommendation from the head of the department or service in which the approval is sought. The written request for authorization should be sent to Clinical Staff Office along with the following information:

- 1) Curriculum vitae, Iowa Pharmacy Examiners pharmacist credentials if applicable, and applicable board certification; or
- 2) Curriculum vitae, Iowa Pharmacy Examiners pharmacist credentials if applicable, and a preceptor statement identifying the individual as an authorized nuclear pharmacist, radiation safety officer, medical physicist and/or radiation therapy physicist, respectively, on a current Agreement State or NRC license; or
- 3) Curriculum vitae, Iowa Pharmacy Examiners pharmacist credentials if applicable, and a completed copy of the IDPH's Medical Use Training and Experience & Preceptor Attestation. Copies of the training and experience preceptor form are available from EHS or can be accessed online at <https://research.uiowa.edu/ehs/> via our government links.

Regulations specifying the training and experience standards for an authorized nuclear pharmacist, radiation safety officer, radiation therapy physicist or teletherapy physicist, respectively, are found in the Iowa Administrative Code (IAC), Section 641, Chapter 41.2 and 41.3. Copies of the regulations are available for review at EHS or can be accessed online at <https://research.uiowa.edu/ehs/> via our government links.

Upon completion of the HRSRG review, the action of the group (i.e., approval or disapproval of the individual for the position) will be communicated to the Clinical Staff Office and the head of the department or service to which the staff member has been appointed.

6.2 Clinical Protocols for Use of Radioactive Materials

Prior to routine clinical usage, each proposed clinical use of radioactive material must be submitted to the HRSRG for review and approval using the applicable Application for Clinical Use Form. Application forms for the clinical use of FDA Approved Radiopharmaceuticals; Compounded Radiopharmaceuticals; Radioactive Material Devices are available from EHS or online at <https://research.uiowa.edu/ehs/> . The use of radioactive materials for clinical use is permitted only by or under the supervision of an authorized user approved by the HRSRG.

6.3 Clinical Use of Machine Produced Radiation

Diagnostic Use of X-Ray Machines

The medical use of X-ray machines is permitted only by or under the prescription of a licensed practitioner.

Fluoroscopy

The medical use of fluoroscopic equipment is permitted only by or under the direct supervision of a licensed practitioner.

Therapeutic Use of X-Ray Machines

The use of radiation therapy machines is permitted only by or under the supervision of an authorized user (radiation therapy machines) approved by the HRSRG.

6.4 Research Involving Human Subjects

Each proposed human subjects research protocol involving the research-related use of radioactive material and/or other sources of ionizing radiation (i.e., not clinically indicated procedures) requires the approval of the University's Investigational Review Board (IRB). Completion of the **Human Subjects Review Application** process allows the investigator to determine whether or not completion of the Medical Radiation Protection Committee Research Application Form and review by the Medical Radiation Protection Committee (MRPC) is also required. Human Subjects application forms are available from the Human Subjects Office (335-6564). MRPC application forms are available from EHS and online at <https://research.uiowa.edu/ehs/>.

The use of radioactive materials for research use is permitted only by or under the supervision of an authorized user approved by the HRSRG. For additional information regarding MRPC review policies and forms, contact the Radiation Safety Officer at 335-8501.

6.5 Responsibilities of the Authorized User

Authorized users are ultimately responsible for the safe use of radioactive materials or radiation-producing machines under their control. This includes responsibility for ensuring that:

- Personnel receive applicable radiation safety training as required and adhere to radiation safety policies and regulations.
- An auditable record of radioactive material in their possession is maintained from the time of acquisition through use, storage, and final disposition as radioactive waste or transfer to another approved individual. Inventory records are required to be maintained for three years and available for inspection.

6.5 Responsibilities of the Authorized User - Continued

- Radiation surveys of use and storage areas are performed and documented as required by regulation.
- EHS is notified of spills involving radioactive materials.
- EHS is notified immediately of missing sources of radioactive materials and incidents of personnel contamination.
- EHS is notified immediately in the event of a known or suspected problem with an administration of radioactive materials or radiation. Refer to Chapters 9 and 10 of this manual for definitions of these events.

7.0 ACQUISITION of RADIOACTIVE MATERIALS

7.1 General Requirements

Radioactive materials for medical use are normally dispensed only from the Division of Nuclear Medicine, the Positron Emission Tomography Imaging Center, and the Department of Radiation Oncology. Pending approval from the Radiation Safety Committee and the RSO, radioactive materials for medical use may be ordered as needed by these divisions or departments provided inventory records are maintained and current.

Radioactive materials ordered from licensed vendors or obtained through transfers from another licensed facility are required, by license condition, to be shipped to and received by EHS. Alternatively, license condition exceptions also permit radioactive material shipments ordered by Nuclear Medicine to be shipped directly to the Division of Nuclear Medicine, and Positron Emission Tomography (PET) radiopharmaceuticals to be shipped directly to the Positron Emission Tomography Imaging Center.

7.2 Procurement (except for Nuclear Medicine or PET radiopharmaceuticals)

Ordering

Obtain PO # from the Purchasing Department. Place the order with the licensed vendor, and instruct them to ship the material to:

The University of Iowa
Environmental Health & Safety
311 Grand Avenue
Iowa City, Iowa 52246-2503
Attention: Division/Dept. or Authorized User's Name

7.2 Procurement (except for Nuclear Medicine or PET radiopharmaceuticals) - *continued* ***Delivery***

Radioactive material shipments normally arrive at EHS by mid-morning during normal weather conditions. At the time of delivery, EHS inspects the shipment for damage, exposure rate and contamination. You can expect EHS to deliver your shipment by early to mid-afternoon unless prior arrangements are made for expedited delivery.

7.3 Package Receipt and Survey Requirements

Prior to delivery of the package, EHS verifies that the outer surface of the shipment is free of contamination. However, the user should assume that the internal surfaces of the package (packaging material and source vial) may be contaminated and handle accordingly until proven free of contamination by the user's own survey. The authorized user is ultimately responsible for the accountability of the radioactive material that they order.

User package surveys should include the following:

- Appropriate personal protective equipment (i.e. gloves, lab-coat) should be utilized when opening incoming radioactive materials shipments.
- Packages containing radioactive sodium iodide or other volatile radionuclide compounds should be opened in an operating fume hood.
- Open the outer package, remove the packing slip, and ensure that the material received is the material ordered.
- Check the integrity of the final source container.
- Perform a wipe test of the external surface of the final source container to verify it is free of contamination.
- Add the shipment to the authorized user's inventory record.
- Survey the packing material to ensure that it is free of contamination and obliterate all radiation warning labels before discarding as regular trash.

7.4 Nuclear Medicine Shipments

Radioactive materials shipments for the Nuclear Medicine Department are addressed to:

The University of Iowa Hospitals and Clinics
Nuclear Medicine Department (3835 JPP)
200 Hawkins Drive
Iowa City, Iowa 52252-1009

7.4 Nuclear Medicine Shipments - continued

Such shipments must be delivered by the carrier directly to 3835 JPP. If delivery is made during other than regular work hours, the carrier will contact UIHC Safety & Security. Safety & Security will:

- Log in the call requesting that the Nuclear Medicine Department be opened for delivery of package(s) containing radioactive material.
- Arrange to have a security officer proceed to the Nuclear Medicine Department and open the single entrance door.
- The security officer signs for the receipt of the package(s) assuring that the stated number of packages are in fact delivered and have no apparent damage. Observe the carrier as they deposit the package(s) in 3835 JPP.
- Lock 3835 JPP upon completion of the delivery.
- If any problem is encountered, EHS should be notified immediately.

Nuclear Medicine personnel receiving the package are required to follow the package opening procedures outlined in section 7.3.

7.5 Positron Emission Tomography Radiopharmaceutical Shipments

PET radiopharmaceutical unit dose shipments for the Positron Emission Tomography Imaging Center are addressed to:

The University of Iowa Hospitals and Clinics
Positron Emission Tomography Imaging Center (0911 Z JPP)
200 Hawkins Drive
Iowa City, Iowa 52252-1009

Such shipments must be delivered by the carrier directly to 0911 Z JPP. Positron Emission Tomography Imaging Center personnel receiving the package are required to follow the package opening procedures outlined in section 7.3.

8.0 TRANSFER of RADIOACTIVE MATERIALS

8.1 On-Campus Transfers

Radioactive materials transfers are only permitted between authorized users. Transfer recipients must be approved for the radionuclide, chemical form and quantity of radioactive material they wish to receive.

For each transfer, obtain a "Transfer of Radioactive Materials" form available online from EHS at <https://research.uiowa.edu/ehs/>. This form serves to document the exchange of inventory between the two applications. Forward a copy of the completed transfer form to EHS. The radioactive material must be transported on foot in an unbreakable, secondary container to ensure that it cannot be spilled if the container is dropped or bumped. For identification purposes, place a radioactive material warning label on the secondary container. Never leave the material you are transferring unattended. Radioactive material cannot be transferred in a motor vehicle or on public transportation unless specifically authorized by EHS to ensure that it meets all applicable Department of Transportation Regulations.

If radioactive material must be transferred other than by foot, contact EHS at 335-8501. Transport of radioactive material on public roads and highways must comply with Department of Transportation (DOT) regulations. EHS requests at least 24 hours notice prior to the date you need the material transported.

8.2 Off-Campus Shipping

EHS must prepare all off-campus shipments of radioactive material with exception of spent Tc-99m generators and vendor performed shipments (i.e., Ir-192 HDR source change outs). The shipment of radioactive material must comply with Department of Transportation (DOT) and IATA regulations. EHS requires at least 24-48 hours notice to prepare the shipment prior to the date you need the material sent from the University to its recipient.

9.0 NUCLEAR MEDICINE GUIDELINES and REQUIREMENTS

Medical administrations of radiopharmaceuticals must be performed under the prescription and supervision of an authorized user physician.

Radiopharmaceuticals are radioactive drugs, which, following administration, undergo distribution, metabolism, and/or excretion from the body.

Radiopharmaceuticals typically act as tracers of biological function and thereby selectively localize in specific organs and tissues.

Diagnostic Administrations

Diagnostic administrations typically involve the injection, ingestion, or inhalation of a relatively small dosage (typically <30 mCi) of a radiopharmaceutical for the purpose of imaging and/or measuring the function of a body organ. Diagnostic administrations of radioactive material can be performed on an outpatient basis. Care of hospitalized patients undergoing diagnostic administrations normally require no special radiation safety precautions beyond utilizing universal precautions when handling blood or other body fluids and excretions.

Therapeutic Administrations

Therapeutic administrations generally involve the injection or ingestion of a relatively large dosage (typically >30 mCi) of a radiopharmaceutical or the temporary or permanent implant of a sealed radioactive source for the purpose of treating a disease or condition. In general, most therapeutic administrations of radioactive materials require observance of specified radiation safety precautions.

9.1 General Guidelines and Requirements

- Keep inventory and radioactive waste records current.
- Maintain written quality control procedures and records for all equipment used to measure radioactivity and obtain images from radionuclide studies.
- Prior to the administration of radiopharmaceutical doses, verify that the patient's name, radionuclide, chemical form, activity, and administration site agree with the authorized user physician's written order.
- Prior to the administration of a radiopharmaceutical dose, verify the identity of the patient by more than one method.
- Use syringe shields and syringe labels as required by regulation and local policy.
- Use vial shields and vial labels as required by regulation and local policy.

9.1 General Guidelines and Requirements - Continued

- Wear appropriate protective apparel and use protective equipment and remote handling tools as necessary for the type and quantity of ionizing radiation present.
- Wear assigned personal dosimeters while working in areas where radioactive materials are used and stored.
- Do not eat, drink, apply cosmetics or store personal effects in areas where radioactive materials are used or stored.
- Use spill trays and absorbent bench paper to prevent/control contamination from radioactive materials.
- Perform and document radiation contamination and ambient surveys as required by regulation.
- Decontaminate items and equipment promptly. Remove or obliterate all radiation warning labels on items that are no longer contaminated or contain radioactive material as determined by the appropriate survey.
- Notify EHS of spills and incidents of personnel contamination.
- Notify EHS of any suspected error in a radiopharmaceutical administration.
- Pregnant staff should not assist with radiopharmaceutical therapies.

9.2 Additional Guidelines and Requirements for Positron Emission Tomography

- Perform and document ambient radiation surveys and wipe surveys for removable contamination prior to maintenance or repair of the cyclotron or associated equipment located in high radiation areas, i.e., cyclotron vault or hot cells.
- Never directly handle radioactive cyclotron targets or components, synthesis modules, or unshielded dose delivery syringes/vials. Use remote handling tools, appropriate shielding or allow the radioactivity to decay to safe levels.
- Report exhaust stack effluent releases that exceed established ALARA release levels to EHS, investigate the cause of the release, initiate appropriate corrective action, and document the event.

9.3 Radiation Surveys

Radiation surveys for contamination and ambient exposure rates are required by regulation at specified intervals in areas where radiopharmaceuticals are routinely used, stored, prepared or administered.

Survey methods must be capable of detecting the type(s) of radioactive material in use and in storage. It is prudent practice to perform surveys after each use or before leaving an area posted for radioactive materials work. Decontaminate items and equipment promptly. EHS audits survey records and the effectiveness of user contamination and exposure control on a periodic basis.

If necessary, contact EHS for assistance in decontamination of equipment or work areas.

Area Contamination Action Levels

Unrestricted Area

- Action Required: ≥ 200 dpm/100 cm² for radioiodine
- Action Required: $\geq 2,000$ dpm/100 cm² for all other radionuclides

Restricted Area

- Action Required: $\geq 2,000$ dpm/100 cm² for all radionuclides

9.4 Radiopharmaceutical Patient Release Criteria

Regulations permit the outpatient treatment or release from hospitalization of any individual who has been administered radiopharmaceuticals if the total effective dose equivalent (TEDE) to any other person coming into contact with the released individual is not likely to exceed 500 mrem. The regulations also require that written instructions are provided to the patient recommending actions to reduce doses to other individuals as low as reasonably achievable if the total effective dose equivalent to any other person coming into contact with the released individual is likely to exceed 100 mrem.

If the dose to a breast-feeding child of a mother treated with radioactive materials could exceed 100 mrem (assuming there is no interruption of breast-feeding), the written instructions shall also include guidance on the interruption or discontinuation of breast-feeding and information regarding the consequences of failure to follow the guidance.

The determination of the suitability for the outpatient treatment and release of patients receiving radiopharmaceutical administrations is the responsibility of the administering authorized user, requires that the patient can reasonably be expected to follow written instructions, and concurrence of EHS.

9.4 Radiopharmaceutical Patient Release Criteria – Continued

Records of the basis for authorizing patient release shall be maintained for a minimum of 3 years. Records that dose reduction and/or breast-feeding discontinuation instructions were provided where applicable shall also be maintained. The responsibility for communicating the radiation safety dose reduction instructions to the patient rests with the authorized user physician who administered the radioactive material.

9.5 Iodine Therapy Requirements and Precautions

The following steps are required for individuals involved with the preparation and/or administration of radioiodine therapy doses:

- Obtain a thyroid bioassay within one to four days following the administration. Contact EHS to schedule this bioassay.
- Therapy dose preparations involving aqueous solutions of sodium iodide are to be performed in an operating fume hood with a current EHS airflow performance sticker.
- Always wear disposable gloves and a lab coat when preparing or administering I-131.
- Monitor hands, feet and clothing for contamination after each procedure prior to leaving the area.
- Transport therapy doses in shielded containers. Following administration, treat the outer surface of the shielded dosage container as contaminated until proven otherwise by a radiation survey.

9.6 Radiopharmaceutical Patient Isolation Precautions

The following isolation precautions are required for patients receiving radiopharmaceuticals that do not meet the patient release criteria.

Radiopharmaceutical therapy patients who require hospitalization for other medical reasons are also normally isolated while hospitalized in order to control radiation exposure and radioactive contamination.

- Unless otherwise noted, hospitalized patients receiving radiopharmaceutical therapy require a private hospital room with a private bath.
- Iodine-131 therapy patients are normally required to be housed in a lead-lined room on 3 JPP.
- The patient's room door must be posted with a "Caution – Radioactive Materials/Radiation Area" warning sign.

9.6 Radiopharmaceutical Patient Isolation Precautions - Continued

- Complete Part A of EHS's "Radiation Protection Guidelines for Patients Treated with Radioactive Materials" form and attach it to the patient's chart.
- Contact EHS to arrange for patient monitoring immediately following the radiopharmaceutical administration. An EHS representative will perform the required patient dose rate measurements and complete Part B of the "Radiation Protection Guidelines for Patients Treated with Radioactive Materials" form and attach it to the patient's chart. The completed form provides patient specific information regarding radiation exposure levels, recommended attendant and visitor stay times, and other patient care guidance. This information is also posted on the door to the patient's room.
- When entering the patient's room following the administration of the radiopharmaceutical, use protective apparel and any other radiation safety instructions posted on the door to the patient's room and included on the "Radiation Protection Guidelines for Patients Treated with Radioactive Materials" form, attached to the patient's chart.
- Pregnant visitors or staff and individuals under the age of 18 are normally not permitted in a radiopharmaceutical therapy patient's room. No visitors are typically permitted in a radioiodine therapy patient's room.
- Patients treated with therapeutic quantities of radioactive materials are normally confined to their rooms except as necessary for medical or nursing procedures.
- When transporting patients who have received radiopharmaceutical therapy, the gurney or wheelchair used for transport should be surveyed to ensure that no radioactive contamination is present prior to returning it to service.
- Laboratory procedures should be performed as ordered. However, laboratory specimens should be labeled as "radioactive" and returned to Nuclear Medicine for disposal.
- Bodily fluids and excreta from radiopharmaceutical patients are potentially contaminated with radioactive material and should be handled accordingly. Notify EHS of any spills of bodily fluids or excreta from a radiopharmaceutical patient.
- All items in a radiopharmaceutical therapy patient's room, including the room itself and its fixtures, should be considered contaminated with radioactive material until surveyed and released by EHS.

9.7 Radiopharmaceutical Therapy Patient Medical Emergencies

Emergency medical care should not be delayed because of radiopharmaceutical therapy. Inform the medical staff performing the emergency procedure(s) of the patient's radiopharmaceutical therapy status and radiation exposure level. Contact the attending or on-call Nuclear Medicine physician immediately and notify EHS as soon as possible in the event of any of the following:

- A patient containing therapeutic quantities of a radiopharmaceutical has a medical emergency.
- A patient containing therapeutic quantities of a radiopharmaceutical requires emergency surgery or is moved to another room.

9.8 Radiopharmaceutical Therapy Patient Death

Contact the attending or on-call Nuclear Medicine physician immediately if a patient containing therapeutic quantities of a radiopharmaceutical expires. Notify EHS as soon as possible.

- Notify the hospital morgue prior to transferring a body containing therapeutic quantities of radioactive material.
- Prior to transfer to the hospital morgue, a record must be attached to the body indicating the radionuclide, date, quantity, and area of the radiopharmaceutical administration.

9.9 Requirements for Dose Calibrators

Each radiopharmaceutical dosage must be assayed, to quantify its activity, in a calibrated dose calibrator prior to medical administration as required by regulation.

Dose calibrators used to measure the amount of activity administered to patients must be checked for constancy, accuracy, linearity, and geometry dependence according to regulatory requirements. Additionally, these checks must be repeated following dose calibrator repair or adjustment prior to returning the unit to service. The use of a dose calibrator for patient dosage assay that has not been tested, or has failed testing as required, is a violation of regulations.

9.10 Written Directives

Patient-specific (or human subject-specific) written orders detailing the following information are required by regulation for:

- The administration of any quantity of sodium iodide I-131 greater than 30 microcuries. Each patient-specific written order must state the prescribed dosage.

9.10 Written Directives - Continued

- The therapeutic administration of a radiopharmaceutical other than sodium iodide I-131. Each patient-specific written order must state the prescribed radiopharmaceutical, dosage, and route of administration.

Each written directive required by regulation must be signed and dated by an authorized user prior to patient administration. Copies of written directives shall be maintained on file for inspection.

9.11 Radiopharmaceutical Administration Errors

Radiopharmaceutical administration errors involving a deviation in the administration of a radiopharmaceutical from that prescribed by the authorized user must be recorded and reported according to regulatory requirements. **Notify EHS immediately upon discovery of any of the following deviations from a prescribed radiopharmaceutical administration:**

- The administration of a radiopharmaceutical other than the one prescribed.
- The administration of a radiopharmaceutical to the wrong patient or research subject.
- The administration of a radiopharmaceutical by a route of administration other than prescribed.
- The administration of a radiopharmaceutical that was not prescribed by an authorized user.
- The administration of a dosage of a radiopharmaceutical differing from the prescribed dosage by more than 20 percent.

10.0 RADIATION ONCOLOGY GUIDELINES and REQUIREMENTS

Medical administrations of radiopharmaceuticals, sealed sources, and external beam radiation therapy must be performed under the prescription and supervision of an authorized user physician. Radiopharmaceuticals are radioactive drugs, which, following administration, undergo distribution, metabolism, and/or excretion from the body. Sealed radioactive sources consist of radioactive material permanently bonded or fixed in a capsule or matrix designed to prevent the release, dispersal, or metabolism of the radioactive material. Sealed sources are typically inserted into a body cavity or surgically implanted into body tissues. Sealed source implants can be either temporary or permanent. External beam radiation therapy consists of radiation delivered from radioactive material sources or radiation producing machines that are external to the body.

Diagnostic Administrations

Diagnostic administrations of radiopharmaceuticals for PET scans involve the injection of a relatively small dosage (typically <30 mCi) of a radiopharmaceutical for the purpose of imaging and/or measuring the function of a body organ. PET radiopharmaceutical administrations can be performed on an outpatient basis. Care of hospitalized patients undergoing PET radiopharmaceutical administrations normally require no special radiation safety precautions beyond utilizing universal precautions when handling blood or other body fluids and excretions.

Therapeutic Administrations

Therapeutic administrations for the purpose of treating a disease or condition include: the injection or ingestion of a relatively large dosage (typically >30 mCi) of a radiopharmaceutical; the temporary or permanent implant of a radioactive sealed source (brachytherapy, HDR); or the administration of external beam radiation. Therapeutic administrations of radioactive materials and radiation require observance of specified radiation safety precautions.

10.1 General Guidelines and Requirements

- Prior to any diagnostic or therapeutic administration verify the identity of the patient by more than one method.
- Prior to a brachytherapy administration verify that, the patient's name, radionuclide, activity, treatment site, and source removal time (if applicable) agree with the treatment plan and the written order of the authorized user physician.

10.1 General Guidelines and Requirements - Continued

- Prior to an HDR administration verify that, the patient's name, treatment site, and treatment plan agree with the written order of the authorized user physician.
- Prior to the administration of an external beam therapy dose verify that, the patient's name, treatment mode, dose fractionation, and site of treatment agree with the treatment plan and the written order of the authorized user physician.
- Prior to the administration of radiopharmaceuticals verify that, the patient's name, radionuclide, chemical form, activity, and administration site agree with the authorized user physician's written order.
- Maintain written quality control procedures and records for all equipment used to measure radioactivity and obtain images from radionuclide studies.
- Maintain written quality control procedures and records of HDR, external beam therapy machines, and treatment planning equipment as required by regulation.
- Maintain an accurate inventory record of radiopharmaceuticals, sealed sources and radioactive waste.
- Perform and document radiation contamination and ambient surveys of areas where PET radiopharmaceuticals are stored and administered as required by regulation.
- Pregnant staff should not assist with brachytherapy patient care or source manipulation.
- Wear appropriate protective apparel and use protective equipment and remote handling tools as necessary for the type and quantity of ionizing radiation present.
- Wear assigned personal dosimeters while working in areas where radioactive materials are used and stored.
- Do not eat, drink, apply cosmetics, or store personal effects in areas where radioactive materials are used or stored.
- Remove or obliterate all radiation warning labels on items that no longer contain radioactive material or produce ionizing radiation as determined by the appropriate survey.

10.1 General Guidelines and Requirements - Continued

- Notify EHS of any suspected diagnostic or therapeutic administration error.
- Notify EHS of any radioactive material spills, and/or incidents involving potential personnel contamination, or exposure.

10.2 Brachytherapy Patient Release Criteria

Regulations permit the outpatient treatment or release from hospitalization of any individual who has been administered permanent brachytherapy implants containing radioactive material, if the total effective dose equivalent (TEDE) to any other person coming into contact with the released individual is not likely to exceed 500 mrem. In addition, the regulations also require that written instructions recommending actions to maintain doses to other individuals as low as reasonably achievable be provided if the total effective dose equivalent to any other person coming into contact with the released individual is likely to exceed 100 mrem.

If the dose to a breast-feeding child of a mother treated with radioactive materials could exceed 100 mrem (assuming there is no interruption of breast-feeding), the written instructions shall also include guidance on the interruption or discontinuation of breast-feeding, and information regarding the consequences of failure to follow the guidance.

The determination of the suitability for outpatient treatment and release of patients receiving medical administrations of radioactive material is the responsibility of the administering authorized user, requires that the patient can reasonably be expected to follow written instructions, and concurrence of EHS. Records of the basis for authorizing patient release shall be maintained for a minimum of 3 years. Records that dose reduction and/or breast-feeding discontinuation instructions were provided where applicable shall also be maintained. The responsibility for communicating the radiation safety dose reduction instructions to the patient rests with the authorized user physician who administered the radioactive material.

10.3 Brachytherapy Inpatient Precautions

Patients receiving temporary brachytherapy implants and patients administered permanent brachytherapy implants that do not meet the patient release criteria (i.e., the maximum dose to any individual from exposure to the released individual is likely to exceed 500 mrem) require the following isolation precautions while they remain in the hospital. Patients administered permanent implants that meet release criteria, but require hospitalization for other medical reasons, are normally isolated while hospitalized in order to control radiation exposure. Bodily fluids and excreta from brachytherapy patients do not represent a radioactive contamination or exposure hazard.

- Unless otherwise noted, hospitalized patients containing brachytherapy implants require a private hospital room with a private bath.
- Cesium-137 and Iridium-192 implant patients are normally required to be admitted to a lead-lined room on 3 JPP.
- I-125 eye plaque and prostate patients (when applicable) are housed in a private room on 3 RCP.
- The door of a radioactive materials therapy patient's room is required to be posted with a "Caution – Radioactive Materials/Radiation Area" warning sign.
- Complete Part A of EHS's "Radiation Protection Guidelines for Patients Treated with Radioactive Materials" form and attach it to the patient's chart.
- Contact EHS to arrange for patient monitoring immediately following the brachytherapy administration. An EHS representative will perform the required patient dose rate measurements and complete Part B of the "Radiation Protection Guidelines for Patients Treated with Radioactive Materials" form and attach it to the patient's chart. The completed form provides patient specific information regarding radiation exposure levels, recommended attendant and visitor stay times, and other patient care guidance. This information is also posted on the door to the patient's room.
- Pregnant visitors or staff and individuals under the age of 18 are normally not permitted in a radioactive material therapy patient's room.
- Patients treated with therapeutic quantities of radioactive materials are normally confined to their rooms except as necessary for medical or nursing procedures. Brachytherapy patients should remain in bed unless otherwise medically ordered.

10.3 Brachytherapy Inpatient Precautions - Continued

- If a temporary implant source or applicator becomes dislodged, contact the attending or on-call Radiation Oncologist at once.
- Permanent implants used for treating prostate cancer can be passed in the patient's urine. It is therefore important to strain the urine for a prostate cancer patient.
- Never handle a brachytherapy source directly. If a dislodged source or applicator is discovered on or near the patient, use long forceps or other remote handling tools to move it to an unoccupied area of the room. Notify EHS immediately.
- Temporary brachytherapy implants must be removed from the patient at the prescribed time. Contact the attending or on-call Radiation Oncologist immediately if the sources are not removed as scheduled.
- All brachytherapy patient linens, surgical dressings, and trash should be saved in the patient's room until surveyed for radioactive material and released by EHS or Radiation Oncology.
- Patients receiving temporary brachytherapy implants can be released only after the attending Radiation Oncologist has removed all sealed radioactive sources from the patient and performed a radiation survey of the patient's body.
- Following brachytherapy patient release, the room and its contents cannot be released until Radiation Oncology or EHS completes a radiation survey.

10.4 Brachytherapy Patient Medical Emergencies

Emergency medical care should not be delayed because of radioactive source implants. Inform the medical staff performing the emergency procedure(s) of the patient's radioactive source implant status and radiation exposure level. Contact the attending or on-call Radiation Oncologist immediately and notify EHS as soon as possible in the event of any of the following:

- If a patient containing implanted radioactive sources has a medical emergency.
- If a patient containing implanted radioactive sources requires emergency surgery or is moved to another room.
- If an implanted radioactive source(s) or the applicator containing the source(s) becomes loose or separated from the patient.

10.5 Brachytherapy Patient Death

Contact the attending or on-call Radiation Oncologist immediately if a patient containing brachytherapy sources expires. Notify EHS as soon as possible.

- If the deceased contains a temporary implant, e.g., after-loaded sealed radioactive sources, the Radiation Oncologist should remove the radioactive sources and survey the body prior to transferring it to the hospital morgue.
- If the deceased contains permanently implanted sealed sources, a record indicating the implanted radionuclide, date and quantity of implant, and the area of implant must be attached to the body prior to transfer to the hospital morgue.
- Notify the hospital morgue prior to transferring a body containing radioactive sealed sources.

10.6 Radiopharmaceutical Therapy Guidelines and Requirements

Refer to Section 9 of this guide for release criteria, isolation precautions, handling and use requirements.

10.7 Requirements for Use of High Dose Rate (HDR) Brachytherapy Unit

- Maintain written records of QC testing, source changes and other system testing.
- Maintain written operation and emergency procedures at the operator station.
- Prior to each day of use, check the operation of the radiation monitor, video monitoring system and interlock functions.
- Prior to the administration of radiation, verify that the patient's name and treatment plan agree with the authorized user's written order.
- Prior to treatment, verify the identity of the patient by more than one method.
- Contact EHS prior to each source change.
- An ambient radiation level survey must be completed and documented after each source change prior to use for patient treatment. Contact EHS to arrange for the survey.

10.8 Requirements for the Use of the Linear Accelerators

- Maintain written quality control procedures and records of periodic and annual checks and calibrations as required by regulation.
- Maintain written safety procedures at the control console.
- Prior to each day of use, verify that the viewing system is operational. Notify a radiation therapy physicist of any malfunction.
- Notify a radiation therapy physicist if any of the daily QC tests fall out of the acceptable range.
- Prior to the administration of external beam therapy, verify that the patient's name and treatment plan agree with the authorized user physician's written order.
- Prior to the administration of radiation, verify the identity of the patient by more than one method.

10.9 Written Directives

Patient-specific (or human subject-specific) written orders stating the following information are required by regulation for:

- ***The administration of external beam therapy, (particle accelerator or X-ray).*** Each written order must indicate the total prescribed dose, the dose per fraction, the treatment site, and number of fractions.
- ***The administration of external beam, gamma stereotactic radiosurgery.*** Each written order must indicate the target coordinates, collimator size, plug pattern, and the total prescribed dose.
- ***The administration of high-dose-rate remote afterloading brachytherapy (HDR).*** Each written order must indicate the radionuclide, the treatment site, and the total prescribed dose.
- ***The administration of brachytherapy, excluding HDR.*** Each written order must indicate the radionuclide, and the number and activity of sources to be implanted. Following source implantation and prior to completion of the brachytherapy procedure, each written order must specify the radionuclide, the treatment site, and total prescribed dose (or, equivalently, the total source strength and exposure time).
- ***The therapeutic administration of a radiopharmaceutical other than sodium iodide I-131.*** Each patient-specific written order must state the prescribed radiopharmaceutical, dosage, and route of administration.

10.9 Written Directives - Continued

Each written directive required by regulation must be signed and dated by an authorized user prior to patient administration. Copies of written directives shall be maintained on file for inspection.

10.10 Medical Administration Errors

Medical administration errors involving a deviation in the administration of radioactive materials or radiation from that prescribed by the authorized user must be recorded and reported according to regulatory requirements.

Notify EHS immediately upon discovery of any of the following deviations from a prescribed administration:

Errors involving the administration of radioactive material or radiation from radioactive material

- The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range.
- The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.
- The administration of the wrong radioactive material.
- The administration of radioactive material by the wrong route of administration.
- The administration of a dose or dosage to the wrong patient or human research subject.
- The administration of a dose or dosage delivered by the wrong mode of treatment.
- The administration of a leaking sealed source.
- Patient or human research subject intervention which alters the prescribed dose or dosage delivered.

Errors involving the administration of radiation from linear accelerators therapy, deep X-Ray therapy, or superficial therapy

- The total dose delivered differs from the prescribed dose by 20 percent or more.
- The fractionated dose delivered differs from the prescribed dose for a single fraction by 50 percent or more.

10.10 Medical Administration Errors - Continued

Errors involving the administration of radiation from linear accelerators therapy, deep X-Ray therapy, or superficial therapy

- An administration of the wrong treatment modality.
- An administration to the wrong patient or human research subject.
- Administration of external beam radiation that results, or will result, in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

11.0 DIAGNOSTIC RADIOLOGY GUIDELINES and REQUIREMENTS

11.1 General Guidelines and Requirements

- All X-ray machines must be registered with EHS.
- EHS requires the submission of a room plan and equipment specifications for each new installation of a unit.
- The medical use of X-ray machines is permitted only by or under the prescription of a licensed practitioner or advanced registered nurse practitioner who meet the requirements specified by the UIHC By-Laws.
- The medical use of fluoroscopic equipment is permitted only by or under the direct supervision of a licensed practitioner who meets the requirements specified by the UIHC By-Laws.
- Only certified X-ray technologists who meet the regulatory requirements as a diagnostic radiographer as specified in the Iowa Administrative Code (IAC) 641- Chapter 42 may operate X-ray machines for medical use under the supervision of a licensed practitioner or advanced registered nurse practitioner. Certified X-ray technologists are required by regulation to post their State of Iowa permit to practice. No X-ray certification or permit to practice is required for operators of dual energy X-ray bone densitometers (DEXA). DEXA operators are required to complete bone densitometry training provided by the manufacturer or an equivalent.
- Operators of dual imaging systems such as SPECT/CT or PET/CT must meet the requirements specified in the Iowa Administrative Code (IAC) 641- Chapter 42, Paragraphs 42.2(7) and 42.2(9). For assistance contact the Radiation Safety Officer at 335-8501.
- Adjust diagnostic radiographic procedures and CT protocols to minimize radiation doses to pediatric patients.
- Lead aprons or whole body protective barriers are required by regulation to be used by all staff continuously present in the room during the use of an X-ray unit. The lead aprons or protective barriers must contain at least 0.25 mm lead-equivalency to protect against scattered radiation. Aprons with a lead-equivalency of 0.5 mm are required for individuals receiving direct beam exposure. DEXA units do not require the use of protective barriers or aprons. However, DEXA unit operators and ancillary personnel are required by regulation to remain at least 1 meter from the unit during operation.

11.1 General Guidelines and Requirements – Continued

- When using mobile or portable X-ray units notify the individuals present to clear the room prior to making an exposure. Patients who cannot be moved out of the area must be protected from scatter radiation by using lead aprons or by moving them to a distance of 2 meters from both the tube head and the nearest edge of the image receptor.
- When a patient or film requires auxiliary support during a radiographic procedure, mechanical holding devices should be used whenever possible.
- No individual shall be routinely employed to hold patients and film.
- Personnel or members of the patient's family that volunteer to hold patients must wear lead protective apparel of the required lead-equivalency to protect against scattered radiation or direct beam exposure as applicable.
- Wear assigned personal dosimeters while operating X-ray units or assisting in radiographic procedures.
- Use all protective devices supplied with the X-ray unit whenever possible.

11.2 Fluoroscopy Safety Information

- All personnel present during fluoroscopic procedures are required to wear lead aprons.
- Be aware of the location of the primary beam.
- Whenever possible, remain at least 2 meters from the point where the primary beam enters the patient.
- Radiation doses during image recording can be significantly higher than during normal fluoroscopy.
- Mobile C-arms have no built-in shielding to reduce radiation scatter. Scatter can be 100-200 mrad/hour next to the patient and 10-20 mrad/hour at the unit controls.
- Bi-plane units have the potential to produce scatter radiation as high as 200-300 mrad/hour at tableside and 30-50 mrad/hour at 1 meter. It is important to remember that as the orientation of the X-ray tube changes, so does the location and magnitude of the scattered radiation.

11.2 Fluoroscopy Safety Information - Continued

- Use mobile shields for persons seated near the procedure table during fluoroscopy procedures. Shields are recommended, for example, during angiography so that the physician has a barrier to step behind during rapid filming.

11.3 Fluoroscopy Patient Safety Information

During some fluoroscopically guided procedures, patient skin entrance exposure rates can be as high as 10-20 rad/min. Radiation-induced skin injuries can occur with absorbed skin doses of approximately 300 rads.

- For fluoroscopically guided procedures, the cumulative fluoroscopic exposure time and the number of spot films for each examination shall be recorded. The average technique factors should be recorded for each patient.
- Patients receiving a cumulative skin exposure in excess of 100 rad should have the exposure noted in their medical record and/or be made aware of the potential for skin injury.
- It is important to note that the skin injury may not appear until several weeks or months after the exposure.

Use the following techniques whenever possible to reduce radiation exposure to the patient and X-ray staff.

- Minimize fluoroscopic beam-on time. Utilize the image hold function when appropriate.
- Use normal image mode instead of the magnification mode.
- Collimate the beam to expose only the clinical area of interest.
- Position the image intensifier as close as possible to the patient.
- Do not alter or modify fluoroscopic equipment.

12.0 SPILL RESPONSE and EMERGENCY PROCEDURES

Each radioactive material user must be ready and equipped to handle a radiological spill or emergency. Information and knowledge concerning the type of radioactive materials being used, the availability of adequate spill response supplies, and knowing when and who to call for assistance are all critical elements needed to effectively respond to any type of radioactive material incident. It is the responsibility of the authorized user to ensure that personnel are trained and periodically practice spill or emergency response scenarios. EHS is available to provide guidance, training, and support regarding spill and emergency response strategies and management.

Emergency and spill response procedures are required to be developed and readily available to personnel as a condition of radioactive materials use authorization. The information should include recognition of spills and emergencies; how to handle the spill/emergency; first aid, and containment and clean up. Keep this information up-to-date.

12.1 Emergency Contact Phone Numbers

UIHC Safety & Security Dial 356-2658

UIHC Emergencies Dial 195

- Serious Accidents
- Fire
- Unmanageable Chemical Spill
- Disruptive, Hostile, Threatening Visitor, Family or Staff
- Patient Safety/Security Threat
- Possession of Deadly Weapons by Patients, Visitors, or Staff
- Bomb Threat

UIHC Emergency Treatment Center Dial 356-2233

UI Public Safety Dial 335-5022

UI Emergencies Dial 911

- Fire
- Serious Personal Injury
- Unmanageable Chemical Spill
- Ambulance

12.2 Spill Response Guidance

Collect Material Safety Data Sheets (MSDS) for all hazardous chemicals that may be used in conjunction with radioactive materials work. Maintain a call list (daytime and after-hours) of individuals who should be notified in the event of a spill. Maintain appropriate spill response supplies. These can be obtained from lab safety suppliers, and the University's General, Biochemistry and Chemistry Stores.

Some general guidelines include:

- **Report all spills and personnel contamination to EHS (335-8501) and your supervisor or the authorized user for your department.**
- Notify others in the area that a spill has occurred and restrict access to the area to avoid the spread of contamination.
- If the spill involves other hazards such as a serious personal injury or fire, call 195 within the UIHC or 911 outside the UIHC.
- In the event of personal injury, do not delay medical assistance because of the possibility of contamination.
- Monitor uninjured individuals for possible contamination prior to their leaving the area. Monitoring should include hands, feet and soles of shoes.
- In the event of a spill or emergency, do not risk contamination unless not doing so would cause a significant safety risk.
- If necessary, cover the spill with absorbent material to prevent the spread of contamination.
- Survey the area, as appropriate, to determine the extent of the contamination. Wear appropriate protective apparel such as shoe covers, disposable gloves, and a lab coat when cleaning up a radioactive materials spill.

12.3 Missing Radioactive Material

Immediately report all missing sources of radioactive material to EHS (335-8501). Unaccounted radioactive material can result in a serious safety concern and regulatory consequences.

12.4 Personal Contamination and Injury

Remove contaminated clothing and flood the exposed area with warm water and wash with a mild soap. Continue until contamination has been removed or upon the advice of EHS. Avoid the use of abrasive materials that could injure skin and increase absorption.

12.4 Personal Contamination and Injury - Continued

Do not use organic solvents because these compounds may increase the probability of the radioactive material penetrating the pores of the skin. In some instances, it may be possible to cover that contaminated area with plastic wrap to induce perspiration that can help remove contamination from the skin. **Notify EHS of all incidents involving personal contamination without delay.**

Do not delay medical attention because of radioactive contamination. Medical attention is available 24 hours a day at the UIHC's Emergency Treatment Center, or call 356-2233. Report all personal injuries as required to your supervisor and EHS.

Minor injuries

Wash with soap and water to remove contamination.

Major injuries

Call 195 within the UIHC or 911 outside the UIHC and provide medical treatment according to the nature of the injury.

Splash in Eyes

Immediately rinse eyes with water, continuing for 15 minutes. Obtain medical attention as needed.

13.0 RADIOACTIVE WASTE

13.1 General Guidelines

Radioactive waste must be properly prepared to ensure that all regulatory requirements are met. Waste not properly identified and prepared will not be picked up for disposal. Radioactive waste tags are supplied with the waste containers. Radioactive waste is considered licensed material and remains subject to the same regulatory requirements as the original radioactive material. Maintain secure storage of radioactive waste at all times. If possible, store waste in the area where it is generated.

Disposal of liquid radioactive waste via the sanitary sewer is prohibited (except for patient excreta) unless specifically authorized by EHS. Patient excreta containing radioactive material may be disposed of in the sanitary sewer as normal.

Some general guidelines for radioactive waste handling and disposal are outlined below.

- Keep volumes of liquid waste small.
- Store liquid waste containers in a secondary container capable of containing the entire volume should the primary one break.
- Avoid accumulating radioactive waste containers – arrange for timely radioactive waste pick-ups by EHS.
- Ensure that lids and caps of radioactive waste containers are securely in place at all times when the container is not in use.
- When necessary, shield radioactive waste stored in frequently occupied areas in accordance with the ALARA requirements. ALARA objectives should be 0.5 mR/hour for any lab areas where personnel are routinely present.
- Be aware that dangerous chemical reactions can occur between mixtures of liquid wastes. Personnel should not mix waste if they are unsure of the result – contact EHS at 335-8501 for information before proceeding.
- Keep a record of each radionuclide and its activity that is consigned to waste. Record keeping is a requirement of authorization and will facilitate the user's quick and accurate completion of the waste tag.
- Radioactive waste containing infectious material must be treated to render it non-infectious prior to pick-up by EHS.

13.1 General Guidelines - Continued

For specific information on properly packaging and preparing radioactive waste for collection, refer to EHS's "Waste Management Guidelines and Procedures" manual. Copies of the EHS's "Radioactive Waste Pickup Request and Shipping Paper" form is available from the EHS. Both the waste manual and pickup request form are available online from the EHS's web site at <https://research.uiowa.edu/ehs/>.

13.2 Decay-In-Storage

Departments possessing adequately shielded facilities may hold radioactive material with physical half-lives less than 90 days for decay-in-storage before disposal as ordinary trash, provided the following conditions are met:

- The radioactive material is held for decay a minimum of 10 half-lives;
- The radioactivity at the container surface cannot be distinguished from the background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;
- All radiation labels are removed or obliterated; and
- A record is maintained that includes the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the model and serial number of the survey instrument used, the background radiation exposure rate, the radiation exposure rate measured at the surface of each waste container, and the name of the individual who performed the disposal. Decay-in-storage records shall be retained for 3 years and available for inspection.