# RADIATION SAFETY MANUAL

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Introduction

The purpose of this program is to provide researchers who use radioactive material with policy/direction and procedure regarding the safe use and disposal of radioactive material as approved by the University Radiation Safety Committee under the University's Broad Medical License 202-029-22.

The Administration of the University of Louisville has a commitment to providing a safe environment for faculty, staff and the authorized user’s use of radioactive material. It is the responsibility of all authorized users and staff to implement radiation safety policy and procedure as approved by the University Radiation Safety Committee under the authority delegated by Administration. Oversight of this policy and procedure is carried out by the University Radiation Safety Officer under the supervision of the University Radiation Safety Officer.

A specialized part of the University's overall safety program is radiation safety. The elements of our Radiation Safety Program for research & medical use are contained in the following sections and exhibits. They have been carefully developed to help all involved individuals conduct their duties in an efficient and safe manner.

Radiation health and safety standards are among the best studied and most thoroughly applied in the safety field. While allowable human exposures are set well below the hazardous levels, this university also strongly supports the "As Low As Reasonably Achievable" (ALARA) radiation safety philosophy regarding radiation dose. It is essential that all staff members know their duties and responsibilities regarding radiation safety, and constantly practice good safety technique.

ALARA Program

The University license requires a Radiation Safety Committee be formed and monitor all aspects of radiation use within the facilities. See the Radiation Safety Committee Charter for the duties of the Committee.

As stated before, we support the ALARA philosophy. Part of this program requires the use of dividual radiation monitoring devices to ensure the exposure to personnel stay As Low As Reasonably Achievable. These records will be monitored at least each quarter by the Radiation Safety Officer; attention will be given to individuals or groups of workers whose occupational exposure appears excessive. These results will be reviewed at the Radiation Safety Committee meetings. Investigational levels will be set as listed below. Generally, any doses that are above normal exposures for personnel will be investigated.

<table>
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<tr>
<th>AREA OF EXPOSURE</th>
<th>LEVEL 1</th>
<th>LEVEL 2</th>
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<tr>
<td>WHOLE BODY DOSE</td>
<td>125 mRem</td>
<td>375 mRem</td>
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<tr>
<td>EYE DOSE</td>
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The levels listed above are based on the occupational dose limits as set forth in 902 KAR 100:019 section 3. If the occupational dose exceeds level 1 within a year, the dose is noted and if found to be normal, no action is required. If the occupational dose exceeds level 2, an investigation will be made and any recommendations will be given and recorded. If an exposure exceeds level 2 on a regular basis, such as Interventional Radiology or
Cath Lab use, separate limits may be set according to the Radiation Safety Committee ensuring that the overall annual exposure is not exceeded.

The following policies and procedures are utilized to keep radiation exposures ALARA:

- The Radiation Safety Committee will review quarterly and annually radiation worker doses, investigating ALARA notifications to determine whether exposures are being kept to a minimum.

- The Radiation Safety Officer will brief management once per year regarding occupational exposure levels.

- The Radiation Safety Committee will carefully review applications for radioactive material authorization, to ensure that the applicant is qualified and that the proposal incorporates the ALARA philosophy.

- Investigation levels for occupational radiation exposures will be adopted by the Radiation Safety Committee. When these levels are exceeded, the Radiation Safety Officer will notify the recipient and review work practices, etc., in order to attempt to lower the exposure if possible. See levels listed in the table above.

- The Radiation Safety Officer will provide training classes to radiation workers and ancillary personnel regarding the ALARA philosophy and methods to keep exposures ALARA.
## CHAPTER 2

THE UNIVERSITY OF LOUISVILLE RADIATION SAFETY COMMITTEE CHARTER

### Convening Authority and Composition

The President of the University of Louisville, upon recommendation of the Dean of the Medical School, Vice President for Research, Vice President for Administration and the University Provost, shall appoint a University Radiation Safety committee. The committee membership shall, at the minimum, include representatives from University Administration, and nursing service, the University Radiation Safety Officer and University faculty members that will represent each type of authorized use on the license. The membership requires expertise in the following areas:

1. **Research (Non-human) Use Sub-committee**
   - Concerned with protection and safety aspects of radioactive materials use in the research environment; including contamination control, ventilation, proper waste disposal safety aspects and training of lab personnel as well as approval of research protocols involving in-vitro radioactive materials use and in-vivo use of radionuclides in animals.

2. **Human Use Sub-committee**
   - Concerned with protection and safety aspects of radionuclide use in the clinical setting, including all areas of radiation safety for patients, occupationally exposed personnel and approval of authorization applications in human use protocols.

3. **Ionizing and non-ionizing radiation machines**
   - Concerned with protection and safety aspects of machines and instruments that produce ionizing and non-ionizing radiation, including proper shielding of operators and training.

4. **U of L Hospital administration nursing**
   - Concerned with radiation safety issues of patient services care as well as nursing service.

5. **University Administration**
   - Concerned with radiation safety issues regarding University faculty/staff and students as well as research grant activity.

6. **University Radiation Safety Officer**
   - Ex-officio member providing radiation safety expertise to all committee members.

7. **Other ex-officio members as deemed**
   - Members from other University necessary by the areas where radioactive material is used or stored, who can provide assistance to the committee as requested.

The membership of the committee, both voting and ex-officio shall be selected to provide expertise in each of the areas of clinical and research uses of radiation outlined above. Collectively, the members of this committee must have the capability of assessing the safety of research projects, human use involving radionuclides and the use of both ionizing and non-ionizing radiation producing machines. Appointments to the committee are for a minimum of three (3) years.
General Purpose

The Radiation Safety Committee has two main charges:

1. Ensuring that all individuals who work with or in the vicinity of radioactive materials or radiation have sufficient training and experience to enable them to perform their duties safely and in accordance with Kentucky Cabinet for Human Resources regulations 902 KAR:100, conditions of the radioactive material licenses, tenants of the Radiation Safety Manual and good radiation safety practice.

2. Ensuring that all use of radioactive material and radiation is conducted in accordance with Kentucky 902KAR:100 regulations, license conditions, and radiation safety manual policy and procedure.

Specific Duties

The University Radiation Safety Committee shall:

1. Be familiar with all pertinent regulations, the terms of the license, the Radiation Safety Manual, and information submitted in support of the request for amendments to authorizations for the use of radionuclides and radioactive material licenses. Be familiar with all pertinent regulations of the Kentucky’s Cabinet for Health and Family Services, Radiation Control Branch.

2. Review the training and experience of all individuals who use radioactive material (including clinicians, researchers, and pharmacists) and proposed new authorized users and determine that their qualifications are sufficient to enable them to perform their duties safely and in accordance with Kentucky 902 KAR:100 regulations, license conditions and Radiation Safety Manual policy and procedures.

3. Review programs to ensure that all individuals whose duties may require them to work in the vicinity of radioactive materials (e.g. lab technicians, nursing personnel, physical plant, custodial and security personnel) are properly instructed as required by 902 KAR 100:165, section 2. Review all requests for use of radioactive materials within the University. Approvals of research grant proposals that involve the use of radiation in animals. Prescribe special conditions that will be required during a proposed use of radioactive materials such a bioassay, physical examinations of users and special monitoring procedures. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive materials (e.g. lab technicians, nursing personnel, physical plant, custodial and security personnel) are properly instructed as required by 902KAR 100:165, Section 2.

4. Review the entire Radiation Safety program annually to meet ALARA requirements and determine that all activities are being conducted safely and in accordance with Kentucky 902 KAR:100 regulations, license conditions, and radiation safety manual policy and procedures.

5. Recommend remedial action to correct any deficiencies identified in the radiation safety program.

6. Maintain written records of all committee meetings, actions, recommendations, and decisions. Meeting minutes will reflect the following: members in attendance and members absent, discussions, actions, recommendations, decisions and numerical results of all votes taken.

7. Ensure that the radioactive material license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures and personnel as deemed necessary.

8. Reviewing and approving or disapproving an individual who is to be listed as the Radiation Safety Officer. Establish a table of occupation dose levels that, if exceeded, shall initiate investigations and considerations of action by the Radiation Safety Officer.
Administrative Procedure

The new policies and procedures recommended by the committee shall be carried out and monitored by the University Radiation Safety Office and any other individuals or offices designated by Vice President of University. The Committee Chairman and University Radiation Safety Officer will sign off on proposals needing institutional review for radiation safety concerns.
All members of the University Radiation Safety Committee meet as often as necessary to carry out its duties, but at least each calendar quarter.
To establish a quorum, 50 percent of the committee's membership, including the University Radiation Safety Officer and the member from University administration must be present. Approval of motions shall require a majority of those present.

Administrations Obligation to the Radiation Safety Officer
A “letter of understanding” will be obtained when an agreement has been made between administration and the prospective Radiation Safety Officer (RSO). The “Letter of Understanding” is to be prepared to comply with Title 10 Code of Federal Regulations (CFR) Part 35.24(b) & 902 KAR 100:72 section 10 & 902 KAR 100:019. Administration shall grant the RSO the authority required to perform the duties and responsibilities. They will make sure he/she will have the necessary time, authority, organizational freedom, resources and management prerogative to:
1. Identify radiation safety problems
2. Initiate, recommend, or provide corrective actions;
3. Stop unsafe operations, and
4. Verify implementation of corrective actions.
A written agreement will be made between administration and the RSO and a copy sent to the State as verification of the agreement and acceptance from both parties.

Radiation Safety Officer (RSO)
The RSO is responsible for the administration of the radiation safety program and is delegated the necessary authority to carry out his/her responsibilities by the Radiation Safety Committee. Arrangements may be made as needed for radiation safety consultants to supplement the RSO in conducting surveys, waste management and general radiation safety matters. The authority and responsibility of the RSO shall include, but is not limited to, the following:
1. General supervision of procurement, receipt, storage and record keeping of radioactive material and sources.
2. Instruction of personnel in radiation safety.
3. Conducting investigations of incidents and reporting to the Radiation Safety Committee.
4. Authority to terminate immediately a project or activity which is a threat to health or property.
5. He/she will provide general surveillance over all radiation source activities, and consultative radiation safety services.
6. He/she will perform quarterly review of all personnel monitoring records for regulatory compliance and ALARA commitments.
7. Periodic review of radiation safety documentation (i.e. sealed source leak tests and inventories and surveys).

Department Chair Responsibilities:
Department chairs have the responsibility to ensure that individual researchers in their departments are following radiation safety policy and procedure as approved by the University Radiation Safety Committee. They must sign off on all applications to use radioactive material in their departments. Occasionally the Radiation Safety Officer or the Radiation Safety Committee may call upon a chair to assist in rectifying unsafe conditions that may exist in his/her department.
CHAPTER 3
PERSONNEL EXPOSURE MONITORING PROGRAM

Any personnel who might be likely to require individual monitoring of external and internal occupational dose as listed in 902 KAR 100:019 section 13 will be monitored for exposure. This institution will follow the program:

1. The RSO will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low.

2. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a dosimetry whole body monitor that will be processed by a contract service on a regular basis.

3. All individuals who, on a regular basis, handle radioactive material that emits ionizing photons will be issued a dosimetry finger monitor that will be processed by a contract service on a regular basis.

4. Any individuals who are exposed to radiation on an occasional basis such as security personnel who deliver packages, secretarial personnel who work in the research area but do not work with directly with radioactive material will not normally be issued exposure monitors.

5. All individuals who are less than 18 years of age and are likely to receive a radiation dose in any calendar quarter in excess of 10 percent of the dose limits listed below will be issued a dosimetry badge.

6. All individuals who are radiation workers and have declared a pregnancy or planned pregnancy may be issued a dosimetry badge based on review by the Radiation Safety Officer.

7. All individuals who meet special criteria as assessed by the Radiation Safety Officer or his/her delegated representative may be issued a dosimetry badge.

**Occupational exposures will not exceed the annual limits as listed below:**

- Whole Body, Total effective dose equivalent: 5000 mRem
- Eye dose equivalent: 15000 mRem
- Shallow-dose equivalent to skin and extremities: 50000 mRem
- Fetal Dose: (limit for the gestational period) 500 mRem

**Overexposure**

(902 KAR 100:019 sections 39 & 40) a written report in 30 days of occurrence shall be submitted to the state. If an exposure exceeds the maximum allowable dose, the employee and supervisor will be notified and the required reports will be filed with the State of Ky. Radiation Control Branch.
PROCEDURES FOR RECEIVING DOSIMETRY BADGES

Personnel will be assessed as to whether a dosimetry badge is required. Further evaluations, and re-evaluations, will be made through radiation employees’ registration updates, application reviews, personnel monitoring reports, ALARA investigations, surveys, and individual interviews by responsible Radiation Safety staff members. To receive a radiation badge, the following procedures must be followed:

1. The radiation worker must complete a dosimetry badge application. For each individual who may work with radiation sources. During Radiation Safety Training Orientation, personnel will be assessed as to whether a dosimetry badge is required.
2. The application is to be completed and turned into the Radiation Safety Office.
3. Upon receiving the application, the Radiation Safety Office will order the badge.
4. When the badge is received, a list of instructions and the badge will be sent to the badge coordinator of the department.
5. Badges are exchanged on a monthly or quarterly basis. Badges must be returned to the Radiation Safety Office by the 10th of the month (or start of the new quarter) so that they may be properly processed.

PERSONNEL MONITORING PROTOCOL

- The Radiation Safety office will request prior dose histories from all past employers.
- The Radiation Safety Office will maintain all personnel occupational dose records.
- It will be the responsibility of each individual badge recipient to wear and use the badge(s) properly.
- Authorized users are responsible for assuring their radiation workers are wearing badges appropriately and that badges are returned on time for processing.
- Authorized Users/Radiation workers may be penalized for late or lost badges.
- The Radiation Safety Office will monitor proper use of the badges during their periodic inspections.
- The Radiation Safety Office will contact personnel when they receive an exposure reading on their badge that warrants an investigation.
- The Radiation Safety Office has records of all personnel past dosimetry.
- Each department receives a report of the readings of the badges after they are received.

USE OF PERSONNEL MONITORING DEVICES

- The whole body badge (or other device) is to be worn on the body where it will most likely approximate the radiation exposure to the head and torso of the wearer.
- A badge assigned for whole body monitoring is not to be used to monitor the extremities (hands, forearms, feet, ankles). Separate badges must be assigned for extremity monitoring.
- Badges shall be worn only by the person they are assigned to and only at the facility they work in.
- Whole body badges are to be worn between the waist and neck.
- When a lead apron is worn the badge will be worn outside the apron at the collar level.
- The Radiation Safety Officer should be consulted for guidance in these circumstances.
- Ring badges are to be worn whenever working with applicable sources. They come in large or small sizes, and should be worn with the monitoring element (label area) turned toward the palm. Gloves should be worn over the ring badge when contamination is possible.

*KAR 100:105, 2(g) prohibits exposure to a monitoring device deceptively to indicate a dose delivered to an individual that is not true.*
Bioassay Program  (902 KAR 100:019 section 6)

Bioassay is the determination of the kind, quantity or concentration, and location of radioactive material in the human body by direct (in-vivo) measurement or by analysis (in-vitro) of materials excreted from the body. Commonly employed bioassay techniques include urinalysis and thyroid monitoring. U of L bioassay program provides the necessary personnel monitoring to measure operation or accidental uptake by radiation workers.

Radioactive material usage is approved only when the associated safety program, equipment, facilities and staff experience assures that safe use will be routinely maintained,. The potential for radiation exposure due to inadvertent failure of procedures and equipment may increase, however, when certain combinations of radionuclides, chemicals or physical forms and activities are involved.

Current health physics practices and safety survey result provide evidence that few, if any, radioactive material procedures currently in use allow routes for personnel uptakes. Some procedures do incorporate radionuclide form and activity combinations which warrant bioassay monitoring to assure that designated precautions remain effective.

The Radiation Safety Officer, during the review of applications of personnel monitoring needs and frequency, will make a determination of bioassay needs. The status of usage programs is periodically reviewed through radiation worker registrations, surveys, inventory records, and verification of radiation staff and radionuclide use limits.
DATE: _______________________

FULL NAME: ________________________________
      (LAST)      (FIRST)   (MI)
SOCIAL SECURITY #: __________________________ D.O.B. __________________________ SEX ____________

TYPE OF BADGE: CHEST: (G1)__________________ COLLAR (G13) ___________ (Lead Apron Wearers ONLY)
RING: (CIRCLE ONE)  Right Finger (U3)  Left Finger (U4)   Small ____ Medium ____  Large____
DEPARTMENT: ______________________________ PHONE NUMBER: ______________________

CAMPUS MAILING ADDRESS: ______________________________ POSITION: ______________________

PRINCIPAL INVESTIGATOR PRINTED NAME: ______________________________

U OF L SPEEDTYPE TO BE CHARGED: ______________________ (Not Applicable for U of L Hospital)

SIGNATURE OF INDIVIDUAL APPROVING EXPENDITURE: ______________________________

FOR URSO USE ONLY:
TEMPORARY BADGE ISSUED: yes__ no___ TEMPORARY BADGE NUMBER: __________________
DATE TRANSMITTED TO VENDOR: ___________________________ GROUP #: ____________________
VENDOR REPRESENTATIVE NAME: ___________________________ BADGE #: __________________

HAVE YOU EVER WORN A BADGE BEFORE: YES ____  NO _____

IF YES, GIVE THE COMPLETE NAME AND ADDRESS OF THAT EMPLOYER AND THE TIME EMPLOYED THERE.

FACILITY NAME: __________________________________________

ADDRESS: ________________________________________________

CITY: __________________________ STATE/COUNTRY: ____________ ZIP: ______________________

DATES EMPLOYED: FROM ___________ TO ________________

      (M/Y)                           (M/Y)

I HEREBY AUTHORIZE MY PREVIOUS EMPLOYER TO RELEASE MY PAST RADIATION EXPOSURE HISTORY.

SIGNATURE OF INDIVIDUAL BEING BADGED: ______________________________

DATE: ______________________________
PERSONNEL RADIATION MONITORING BADGE PROGRAM

FULL NAME (print): ____________________________________________________________________________

(Last)                                                   (First)                                                   (MI)

GROUP #____________ BADGE #__________________ DATE ISSUED_________________________________

I understand that in conjunction with my application for and issuance of a “Personnel Radiation Monitoring Badge,” I will comply with the following instructions:

• Pick up my badge for each new cycle from my designated “Badge Coordinator”.

• Wear my badge whenever I am working in the vicinity of radiation or radioactive material.

• Return my old badge at the end of the wear cycle (last date on badge) to my designated “Badge Coordinator”.

• Wear my badge according to the appropriate type:


     The chest badge measures the deep dose equivalent or “whole body” radiation dose. If worn with a lead apron, wear this badge on the outside of the lead apron.

  2. Collar Badge – wear on collar of lab coat or scrubs.

     The collar badge measures the radiation dose to the lens of the eye.

     If you are assigned a chest and a collar badge, the chest badge must be worn underneath the lead apron. A special calculation is done with this two badge method that ensures proper recording of radiation dose.

  3. Fetal Badge – worn low in center of abdomen.

     The fetal badge measures the radiation dose to the unborn child. The fetal badge will be exchanged monthly, even if your chest badge is exchanged quarterly.

  4. Ring Badge – wear on hand.

     The ring badge measures radiation dose to the most exposed extremity, typically the dominant hand. Wear the ring on the hand closest to the source of radiation.

• If this is a Fetal Badge I have been counseled by the Radiation Safety Office about “Declaration of Pregnancy”.

• I understand returning my badge for reading is important and the best way to document my radiation dose.

• **I UNDERSTAND THAT FAILURE TO RETURN MY BADGE WHEN DUE WILL RESULT IN A $20.00 LATE FEE.**

I have read the above information and will comply with the best of my ability.

SIGNATURE: ____________________________________________________________________________

DATE: ________________________________
CHAPTER 4

FETAL DOSE POLICY FOR PREGNANT EMPLOYEES

The U of L fetal dose policy incorporates safety information and radiation dose guidelines for ensuring safe radiation limits for the embryo/fetus of occupationally exposed employees.

Radiation workers are strongly advised to notify the Radiation Safety Office as soon as possible after pregnancy is confirmed. The declaration of pregnancy is voluntary, but it must be made known in writing.

If an employee decides to declare her pregnancy in writing, the University will then take steps to ensure that the occupational radiation dose received by the embryo/fetus does not exceed the limit specified by the State and Federal regulations of 500 millirem for the remainder of the gestation period. In addition the National Council on Radiation Protection Measurements (NCRP) recommends that the dose for any one month during pregnancy not exceed 50 millirems.

It is the responsibility of the employee and her supervisor to observe the principles of radiation safety and use standard precautionary procedures in the performance of her duties to keep her radiation dose to as low as reasonably achievable (ALARA) at all times and especially during the gestation period. The Radiation Safety Office will provide training and assistance in maintaining doses ALARA.
DECLARATION OF PREGNANCY

Name:_________________________________________________________

Social Security#:_________________________________________________

Department: ___________________________________________________

Work Phone #:__________________________________________________

TYPE OF POTENTIAL RADIATION EXPOSURE

Please check which applies to your job duties:

Ionizing radiation producing machines:

Radiographic: □  Fluoroscopic: □  Special Procedures and Cardiac Cath: □
Therapeutic: □  Dental: □  Other (Specify) ____________________

Radioactive Material:

Research □  Diagnostic □  Radiopharmaceutical Therapy □  Teletherapy □
Brachytherapy/HDR □  Other (Specify) ____________________

DOSIMETRY INFORMATION

Do you wear a film badge?       Yes □    No □

MONTH OF PREGNANCY

Current month of pregnancy (circle)  1  2  3  4  5  6  7  8  9

“I hereby authorize and consent to disclosure of my declared pregnancy to the Authorized User or other personnel who need to be aware of the radiation exposure restrictions for me including those who must cooperate with such restrictions.”

I ____________________________ have chosen to declare my pregnancy to the Radiation Safety Office of the University of Louisville.

Signature _________________________________ Date _________________
CHAPTER 5
CRITERIA FOR EVALUATING USERS QUALIFICATIONS FOR THE USE OF RADIOACTIVE MATERIALS

Authorized Users

An authorized user is an individual who by virtue of position, training and experience is designated by the RSC as a user of radioactive material under the University of Louisville broad radioactive material license. This authorization permits the procurement and use of radioactive material within a defined protocol or work activity under the supervision of the authorized user provided that the materials are used within the guidelines of safe practice, and within the rules, regulations and recommendations of the RSC and U of L policy.

HOW TO BECOME AN AUTHORIZED USER

Anyone who would like to become an authorized user must complete the “Application for Authorization to Use Radioactive Material”, and sign the “Radiation Protection Guidelines”. The completed forms, and approved certification or documentation of training or another radioactive material license listing the proposed user as an authorized user must be sent to the Radiation Safety Office for review. The RSO, the Radiation Safety Committee Chair and at least half of the Committee must sign and approve the Authorized use of radioactive material.

AMENDMENT TO AN AUTHORIZATION

An Authorized User must submit an amendment request if other radionuclides are to be used or if procedures change that will significantly alter radiological hazards. A memo to the Radiation Safety Officer must be submitted for an increase in possession limits, changes in use and storage areas and other minor changes.

GUIDELINES FOR THE HUMAN USE OF RADIONUCLIDES IN NON-ROUTINE OR INVESTIGATIONAL PROCEDURES:

An applicant must already be authorized for Human use. In addition, review and approval guidelines of applications for experimental and non-routine medical uses of radioactive material have been adopted by the Committee. It should be emphasized that approval of the University Human Studies Committee is also mandatory prior to performing these procedures. When non-routine or investigational medical use proposals fall under the authority of U.S. Food and Drug Administration (FDA) regulations, the investigator shall satisfy all FDA requirements, including the filing of an Investigative New Drug (IND) application or become approved as an investigator under a sponsor's IND. The Committee will accept as adequate evidence for approval of the study, copies of the forms material, protocols and reports required to satisfy FDA requirements.

AUTHORIZED MEDICAL PHYSICISTS

Anyone who would like to be considered and Authorized Medical Physicist shall submit their proper certification and/or required training. Approval of the use of manual brachytherapy devices shall include the documentation of training or experience with the devices. The required documentation shall be submitted to the Radiation Safety Office and the Radiation Safety Committee will evaluate the criteria and make an evaluation to approve the authorization. Authorization shall be based on the training and experience as listed in 902 KAR 100:072 section 65.
ACCEPTABLE TRAINING AND EXPERIENCE FOR
MEDICAL USES OF RADIOACTIVE MATERIAL
(902 KAR 100:072, Sections 63 – 78)

General Criteria

Any human use of radioactive material (i.e., the internal or external administration of radioactive material, or the radiation there from, to human beings) must be carried out by or under the supervision of a physician.

902 KAR 100:072 allows the Radiation Safety Officer and Radiation Safety Committee, or the facility administration if a Committee is not required, to approve any new authorized users and authorized medical physicists who meet the requirements for training as listed in the chapter regulations. The Radiation Safety Office will keep files on all authorized users and authorized medical physicists for review during inspections by the state Radiation Control Branch.

A copy of certification or training will be kept on file at the facility location.

Criteria for Approval

A. Training for Routine Diagnostic Procedures (902 KAR 100:072, Sections 69 and 70)

To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Sections 30 and 31 in 902 KAR 100:072, a physician must have the following number of hours (hours are in terms of class, laboratory, or clinical experience rather than semester hours) in the topics listed.

1. Imaging and Localization Studies (minimum 700 hours of training and experience)

   (a) Training in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. This training must include laboratory and classroom training in the following areas:

   (1) Radiation physics and instrumentation
   (2) Radiation protection
   (3) Mathematics pertaining to the use and measurement of radioactivity
   (4) Chemistry of radioactive material for medical use
   (5) Radiation biology

   (b) Work experience under the supervision of an authorized user with the types and quantities of radioactive material for which the application is being made, or equivalent involving:

   (1) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys
   (2) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters
   (3) Calculating, measuring and safely preparing patient dosages
   (4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material
   (5) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures
   (6) Administering dosages of radioactive drugs to patients or human research subjects
   (7) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the elute for radionuclidic purity, and processing the elute with reagent kits to prepare labeled radioactive drugs.
3. **Uptake, Dilution and Excretion Studies (minimum 60 hours of training and experience)**

(a) Training in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution and excretion studies. This training should consist of laboratory and classroom instruction in the same topics described in Section A.1.(a) of this procedure.

(b) Work experience under the supervision of an authorized user with the types and quantities of radioactive material for which the application is being made, or equivalent.

   1. Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys
   2. Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters
   3. Calculating, measuring and safely preparing patient dosages
   4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material
   5. Using procedures to safely contain spilled radioactive material and using proper decontamination procedures
   6. Administering dosages of radioactive drugs to patients or human research subjects

**Alternatives**

In lieu of submitting the above, a physician may be named on a license by submitting one of the following:

1. Verification of certification by an appropriate recognized medical specialty board, or

2. A copy of an Agreement State or NRC license on which the individual has been named as approved user of the isotopes to be used by the institution.

**B. Training for Therapy Procedures Involving Radiopharmaceuticals (902 KAR 100:072 Section 71, 72 and 73)**

1. **The use of unsealed radioactive material for which a written directive is required (minimum of 700 hours of training and experience)**

   (a) Training in basic radioisotope handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. This training must include classroom and laboratory training in the following areas:
   
   1. Radiation physics and instrumentation
   2. Radiation protection
   3. Mathematics pertaining to the use and measurement of radioactivity
   4. Chemistry of radioactive material for medical use
   5. Radiation biology

   (These requirements are in lieu of, not in addition to, those Section A.1.(a) above.)

   (b) Work experience under the supervision of an authorized user with experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status. The work experience must involve:

   1. Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys
   2. Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters
   3. Calculating, measuring and safely preparing patient dosages
   4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material
(5) Using procedures to safely contain spilled radioactive material and using proper
decontamination procedures

(6) Eluting generator systems, measuring and testing the elute for radionuclidic purity, and
processing the elute with reagent kits to prepare labeled radioactive drugs

(7) Administering dosages of radioactive drugs to patients or human research subjects
involving a minimum of three cases in each of the following categories for which
the individual is requesting authorized user status:

(i) Oral administration of less than or equal to 33 mCi of I-131
(ii) Oral administration of greater than 33 mCi of I-131
(iii) Parenteral administration of any beta emitter or a photon-emitting radionuclide
     with a photon energy less than 150 keV
(iv) Parenteral administration of any other radionuclide

2. Oral administration of I-131 requiring a written directive in quantities less than or equal to 33 mCi
(minimum of 80 hours of classroom and laboratory training):
   (a) Training applicable to the medical use of I-131 for procedures requiring a written directive:
       (1) Radiation physics and instrumentation
       (2) Radiation protection
       (3) Mathematics pertaining to the use and measurement of radioactivity
       (4) Chemistry of radioactive material for medical use
       (5) Radiation biology
       (These requirements are in lieu of, not in addition to, those Section A.1.(a) above.)
   (b) Work experience under the supervision of an authorized user with experience in administering
dosages in the same dosage category as the individual requesting authorized user status.
The work experience must involve:
       (1) Ordering, receiving and unpacking radioactive materials safely and performing the
           related radiation surveys
       (2) Calibrating instruments used to determine the activity of dosages and performing
           checks for proper operation of survey meters
       (3) Calculating, measuring and safely preparing patient dosages
       (4) Using administrative controls to prevent a medical event involving the use of unsealed
           radioactive material
       (5) Using procedures to safely contain spilled radioactive material and using proper
           decontamination procedures
       (6) Administering dosages of radioactive drugs to patients or human research subjects that
           includes at least three cases involving the oral administration of less than or equal
to 33 mCi of I-131

3. Oral administration of I-131 requiring a written directive in quantities greater than 33 mCi (minimum
of 80 hours of classroom and laboratory training):
   (a) Training applicable to the medical use of I-131 for procedures requiring a written directive:
       (1) Radiation physics and instrumentation
       (2) Radiation protection
       (3) Mathematics pertaining to the use and measurement of radioactivity
       (4) Chemistry of radioactive material for medical use
       (5) Radiation biology
       (These requirements are in lieu of, not in addition to, those Section A.1.(a) above.)
   (b) Work experience under the supervision of an authorized user with experience in administering
dosages in the same dosage category as the individual requesting authorized user status.
The work experience must involve:
(1) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys
(2) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters
(3) Calculating, measuring and safely preparing patient dosages
(4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material
(5) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures
(6) Administering dosages of radioactive drugs to patients or human research subjects that includes at least three cases involving the oral administration of greater than 33 mCi of I-131

Alternatives

In lieu of submitting the above, a physician may be named on a license by submitting one of the following:
1. Verification of certification by an appropriate recognized medical specialty board, or
2. A copy of an Agreement State or NRC license on which the individual has been named as an approved user of the isotopes to be used by the institution.

C. Training for use of manual brachytherapy sources (902 KAR 100:072, Section 74)

1. To qualify as adequately trained to use or directly supervise the use of manual brachytherapy sources, a physician must have:
   (a) Training in basic radioisotope handling techniques applicable to the use of manual brachytherapy sources. This training must include a minimum of 200 hours of classroom and laboratory training in the following areas:
       (1) Radiation physics and instrumentation
       (2) Radiation protection
       (3) Mathematics pertaining to the use and measurement of radioactivity
       (4) Radiation biology
   (b) 500 hours of work experience under the supervision of an authorized user with the types and quantities of radioactive material for which the application is made, or equivalent involving:
       (1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys
       (2) Checking survey meters for proper operation
       (3) Preparing, implating, and removing brachytherapy sources
       (4) Maintaining running inventories of material on hand
       (5) Using administrative controls to prevent a medical event involving the use of radioactive material
       (6) Using emergency procedures to control radioactive material.
   (c) 3 years of supervised clinical experience under the supervision of an authorized user as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. Clinical experience may be obtained concurrently with the supervised work experience.
**Alternatives**

In lieu of submitting the above, a physician may be named on a license by submitting one of the following:

1. Verification of certification by an appropriate recognized medical specialty board, or
2. A copy of an Agreement State or NRC license on which the individual has been named as an approved user of the isotopes to be used by the institution.

A. Training for ophthalmic use of Sr-90 (902 KAR 100:072, Section 75)

1. To qualify as adequately trained to use or supervise the use of Sr-90 for ophthalmic radiotherapy, a physician must have:
   (a) 24 hours of classroom and laboratory training applicable to the ophthalmic use of Sr-90. This training must include:
   (1) Radiation physics and instrumentation
   (2) Radiation protection
   (3) Mathematics pertaining to the use and measurement of radioactivity
   (4) Radiation biology
   (b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of Sr-90 for the ophthalmic treatment of 5 individuals. This supervised clinical training must involve:
   (1) Examination of each individual to be treated
   (2) Calculation of the dose to be administered
   (3) Administration of the dose
   (4) Follow up and review of each individual’s case history

**Alternative**

In lieu of submitting the above, a physician may be named on a license by submitting a copy of an Agreement State or NRC license on which the individual has been named as an approved user of the isotopes to be used by the institution.
CHAPTER 6
EMERGENCY PROCEDURES

MINOR SPILLS:

1. Notify persons in the area that a spill has occurred.

2. Prevent the spread of contamination by covering the spill with absorbent paper.

3. Clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.

4. Survey the area with a low-range radiation detector survey meter. Check the area around the spill. Also check your hands, clothing and shoes for contamination.

5. The Radioactive Material Spill Report should be documented of the spill and cleanup


MAJOR SPILLS:

1. Clear the area. Notify persons not involved in the spill to vacate the room.

2. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.

3. Shield the source if possible. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.

4. Close the room and lock or otherwise secure the area to prevent entry.

5. Notify the RSO or alternate immediately.

   RADIATION SAFETY OFFICER:  __________Sarah Hughes___________

   PHONE:  Office: 852-5231        Cell phone:  502- 552-5454___________

6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and washing with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.
DETERMINATION OF MAJOR AND MINOR SPILLS:

Spills above the amounts listed below are considered major. Spills below the listed amounts are considered minor.

<table>
<thead>
<tr>
<th>Nuclide</th>
<th>Millicurie amount</th>
</tr>
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<tbody>
<tr>
<td>P-32</td>
<td>10</td>
</tr>
<tr>
<td>Co-57</td>
<td>100</td>
</tr>
<tr>
<td>Tc-99m</td>
<td>100</td>
</tr>
<tr>
<td>In-111</td>
<td>10</td>
</tr>
<tr>
<td>I-123</td>
<td>10</td>
</tr>
<tr>
<td>I-131</td>
<td>1</td>
</tr>
<tr>
<td>Tl-201</td>
<td>100</td>
</tr>
</tbody>
</table>

LABORATORY FIRES:

In the event of a laboratory fire, the following procedure is recommended:

A. Report the fire by calling DPS at 852-6111 or 911. The following information should be given:
   1. Identify yourself and phone number;
   2. Exact location of fire (building, laboratory number of the specific area);
   3. Extent of personnel injuries;
   4. Type of fire (electrical, flammable liquid, trash, etc.); and
   5. Extent of fire (severity of fire and smoke).
B. Close laboratory doors to contain the fire as you leave the laboratory area.
C. Activate the fire alarm system as you exit to the stairwell. Fire alarm pull stations are generally located near stairwells.
D. Evacuate to safe area after exiting through the stairwell.
E. Contact the Radiation Safety Office Immediately.

INCIDENTS INVOLVING AIRBORNE RADIOACTIVE MATERIAL:

A. Notify all personnel to vacate the room immediately.
B. Shut down ventilation system, if possible, unless it is determined that the room ventilation system needs to be used to clear the air for access purposes.
C. Vacate the room. Seal the area, if possible.
D. Notify the RSO immediately.
E. Ensure that all access doors to the area are closed and posted with radiation warning signs, or post guards (trained) at all access doors to prevent accidental opening of the doors or entry to the area.
F. Survey all persons who could have possibly been contaminated. Decontaminate as directed by the RSO.
G. Promptly report suspected inhalations and ingestions of licensed material to the RSO.
H. Decontaminate the area only when advised and/or supervised by the RSO.
I. Allow no one to return to work in the area unless approved by the RSO.
J. Cooperate with the RSO and/or the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
K. Follow the instructions of the RSO and/or the RSO's staff (e.g., decontamination techniques, surveys, provision and collection of bioassay samples, requested documentation).

DEFINING INCIDENTS OR EMERGENCIES:

The following may constitute an incident or emergency:

A. Loss or theft of any radioactive material or radiation producing device.
B. High or potentially high radiation exposure to an employee or member of the general public. For example:
   1. Greater than 1000 mrem whole-body in one month to an occupationally exposed individual;
   2. Greater than 10000 mrem in one month to the extremities of an occupationally exposed individual; or
   3. Greater than 100 mrem to any member of the general public.
C. Intake of radioactive material by inhalation, ingestion, skin absorption, or injection through the skin or wound.
D. Deceptive or potentially deceptive exposure of a dosimeter.
E. Personnel contamination which cannot be removed after two washes with soap and water.
F. Spills involving significant activities of $^{125}$I or $^{131}$I with the potential for inhalation.
G. Removable contamination in unrestricted areas (e.g. hallways, offices, vehicles, etc.) which exceed 200 dpm/100 cm$^2$.
H. Radiation fields in unrestricted areas which exceed the limits specified for members of the general public of 2 mR/hr.
I. Accidental or unmeasured releases of radioactive material to the environment.
J. Fire or floods which threaten to release radioactive material to the environment or which threaten to expose emergency response personnel.
RADIOACTIVE SPILL REPORT

The spill occurred at ___:___ pm on ___/___/____ in room ___________.

Instrument used to check for contamination:

G.M. Meter model: __________________________ Serial #: __________________________

Wipe test counter used: __________________________ Serial #: __________________________

Survey of the area of the spill:

<table>
<thead>
<tr>
<th>AREA OR PERSON SURVEYED:</th>
<th>GM METER SURVEY: mR/hr</th>
<th>WIPE TEST READING: DPM</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
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Report results of survey after cleaning; make sure to survey all material used in the cleanup including any personnel. Area is not considered clean until G.M. meter readings are below 0.2 mR/hr and wipe tests are below 200 dpm/100 cm².

* On the back of the sheet, indicate any personnel decontamination, additional monitoring, or care instituted.

* Survey the spill area to identify hot spots, then begin decontamination. When finished, conduct a post cleaning contamination wipe-test.

* Radioisotopes present or suspected in the spill:

____ mCi of _____ as ______________________________________________________

____ mCi of _____ as ______________________________________________________

____ mCi of _____ as ______________________________________________________

Give a brief description of the accident:

________________________________________________________________________

________________________________________________________________________

Give a brief description of follow up actions taken to prevent recurrence:

________________________________________________________________________

________________________________________________________________________

Name: _______________________________ Date: _____________________________
CHAPTER 7
PERSONNEL TRAINING PROGRAM

All personnel like to receive in 1 year during the course of employment, an occupational dose in excess of 100 millirems shall receive proper instruction, appropriate to their activities. Other personnel will be trained as deemed appropriate by the Radiation Safety Officer. Personnel include radiation workers, clerical, nursing, housekeeping, security and others. Records with the date, names of persons who attended training, and what was included in the training will be kept for review:

Personnel will be properly instructed:

a. Before assuming duties with, or in the vicinity of radioactive materials.

b. During annual refresher training.

c. Whenever there is a significant change in duties, regulations, or the terms of the license.

Instruction to personnel will include the following subjects:

a. All terms of the license pertinent to their duties.

b. Areas where radioactive material is used or stored.

c. Potential hazards associated with radioactive material in each area where the employees work.

d. Radiological safety procedures appropriate to their respective duties.

e. Pertinent Kentucky Administrative Regulations, 902 KAR 100.

f. Licensee’s in-house work rules.

g. Obligation to report unsafe conditions to the radiation safety officer.

h. Appropriate response to emergencies or unsafe conditions.

i. Right to be informed of their radiation exposure and bioassay results.

j. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 902 KAR 100:065.
CHAPTER 8
SEALED SOURCES

A list of all sealed sources are kept in the EH & S Assist program on the computers in Radiation Safety Office. Sealed sources above the exempt quantities listed in 902 KAR 100:080 will be inventoried periodically and records showing quantities and kinds of radioactive material, location of sources, date of inventory and survey of storage location shall be maintained for review.

LEAK TESTING

Sealed, foil or plated sources of gamma and beta emitting radioactive materials that require leak testing will be leak tested by the Radiation Safety Officer personnel not to exceed every 6 months and be counted in a suitable counter using the following procedure:

1. The closest accessible surface of the source, or source housing, will be wiped with an appropriate “swipe” (usually a cotton swab or filter paper).
2. The test samples will be immediately monitored with a suitably sensitive survey instrument in a low background area (0.05 mR/hr). If no significant radiation levels (twice background) are detected, the samples will be placed in a plastic envelope and returned to the laboratory for counting.
3. Counting will be done in an appropriate laboratory counting system.
4. The efficiency of the counting system will be determined to show that it will read below 0.005 uCi.
5. The results of the leak test will be reported in “DPM” and include:
   a. Model and serial number of the source if one is assigned.
   b. Identity of each source radionuclide and its activity
   c. Measured activity of each test sample
   d. Date of the test
   e. Name of the person who performed the test.

SEALED SOURCE INVENTORY

A physical inventory of all sealed sources that are required will be performed at least semiannually. Records will be kept and with appropriate information including:
   a. model and serial number of source if one is assigned
   b. identity of each source radionuclide and it estimated activity
   c. location of each source
   d. date of inventory
   e. name of the person who performed the inventory

IRRADIATOR

If you need access to any irradiator, or would like to purchase an irradiator, please contact the Radiation Safety Office. The quantity of radioactive material in an irradiator requires increased security controls of unauthorized removal or access of the material. The security controls procedures used by the University are confidential. Contact the Radiation Safety Office for questions.
SEALED SOURCES FOR IMPLANT THERAPY

1. The long-lived implant sources will be kept in a shielded and locked storage cabinet. For the short-lived sources that are sent back to the manufacturer, they will be kept in the container they were transported in and stored in a secured area.

2. A list of names of those individuals allowed to handle implant sources will be kept for review.

3. For the long-lived sources, a map of the storage drawers indicating the activity of the source at each storage point will be made. This map and the inventory will be kept in the room where the sources are stored.

4. Each time a source is removed, record of the number and activity of sources removed, the room number of use or patient’s name, and the time and date they were removed from storage; initial the record.

5. Each time the sources are returned to storage, immediately count them to ensure that every source removed has been returned. A record will be kept with the number and activity of sources returned, the room number of use or patient’s name, and the time and date they were returned to storage; initial the record.

6. If there is a discrepancy between the record and the number of sources in use and in storage, notify the RSO immediately.
CHAPTER 9

GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

1. Wear laboratory coats or other protective clothing at all time in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials.

3. Monitor hands and clothing for contamination after each procedure or before leaving the area.

4. Always use syringe shields for routine preparation of patient doses and administration to patients, except in circumstances such as pediatric cases when their use would compromise the patient's well-being. In these exceptional cases, use other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve.)

5. a. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

   b. Do not store food, drink, or personal effects with radioactive material.

6. Perform dose determination prior to administration.

7. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level. Personnel monitoring devices when not being worn to monitor occupational exposures should be stored in low background area.

8. Wear TLD finger badges when handling millicurie quantities of radioactive material. Ring badges should be worn toward the palm side of the hand for measuring hand exposure.

9. Dispose of radioactive waste only in specially designated and properly shielded receptacles.

10. Never pipette by mouth.

11. Perform surveys as required. Decontaminate as needed.

12. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity and radiation level, if applicable.

13. Always transport and store radioactive material in shielded containers.

14. If appropriate, use remote handling devices (tongs) when working with radioactive material.
CHAPTER 10

PROCEDURE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

An approved Nuclear Medicine Technologist, authorized user, authorized Medical Physicist, or the Radiation Safety Office will place all orders for radioactive material and ensure that the requested material and quantities are authorized by the license and possession limits are not exceeded.

A system for ordering and receiving routinely used radioactive material will be established and maintained. The system will include:

1. Using records to identify the radioactive material required for patient dosing.
2. Monitoring the correct doses are received and given to the correct patients.

A system for ordering and receiving specially used material (therapy doses):

1. A request will be obtained from an authorized user.
2. Person ordering the material will reference the written request.
3. The written request will be referenced when receiving and opening the material.

The carrier of the material will be informed of where the package shall be delivered to ensure security of the package at all times. If material will be going to one of the hot lab rooms in HCOC, the nuclear medicine or PET department, the pharmacy will be given the code or key to the room. The packages will stay in the secured area until trained personnel are able to open packages as stated in the procedure for Safely Opening Packages Containing Radioactive Material. All necessary individuals involved in receiving material will be instructed as necessary. Any package not being delivered by the nuclear pharmacy will be requested to only deliver the material during normal business hours.
Generators will not be used at this facility. Only unit doses or doses for multi-vial usage will be used. All doses will be either measured in a dose calibrator or measurement will be calculated by decay and volume. Doses given to human patients will be within a given dose range or with +/- 20% of the prescribed dose.

**Records of Unit Dosage:**

For each unit dosage received from a supplier, a record will be made that includes:

1. Radiopharmaceutical
2. Date of receipt.
3. Supplier.
4. Lot number if one is assigned.
5. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and it associated time.
6. Date of administration or disposal.
7. If administered:
   a. Prescribed dose
   b. Measured activity in millicuries or microcuries and date and time of measurement if using a dose calibrator.
   c. Patient name and identification number if one has been assigned.
8. If discarded, the date
9. Initials of the individual who made the record.

**Records of multi-doses:**

Radiopharmaceuticals are received in multi-dose shipments in addition to the unit dose shipments mentioned above. For these materials, the hospital records the following:

1. Radiopharmaceutical
2. Date of receipt of preparation
3. Date and time of initial assay and activity
4. Supplier or kit manufacturer
5. If administered: the prescribed dosage, date and time dose was drawn, the calculated volume needed for the dose prescribed, the measured activity and the patient’s name.
6. If discarded, the date discarded.
7. The initials of the individual making the record.
CHAPTER 12

PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

Monitoring of packages as required by 902 KAR 100:019 section 28 will be performed as soon as practicable after receipt, but not later than 3 hours after being received during normal working hours, and if received during off-duty hours, not later than 3 hours from the beginning of the next working shift.

The facility shall immediately notify the delivery carrier and the Manager of the Radiation Control Branch if the external radiation levels exceed the 2200 dpm/100 cm², or 200 mR/hr at the surface, or 10 mR/hr at 1 meter.

The external surfaces of a package shall be monitored for:

- Radioactive contamination (by wipe testing) unless the package contains only radioactive material in the form of a gas or in special form
- Radiation levels (by survey meter) unless the package contains quantities of radioactive material that are less than or equal to Type A quantity defined in 902 KAR 100:010.
- Any package received that is known to contain radioactive material and has evidence of potential contamination such as being crushed, wet, or damaged will be monitored by wipe test and survey meter.

Receiving packages:

1. Put on gloves to prevent hand contamination
2. Visually inspect that package for any sign of damage. If damage is noted, stop, notify the RSO, and monitor the packages as listed above.
3. If no damage is suspected, monitor the package as listed above.
4. Remove the packing slip.
5. Open the outer package, following any instructions that may be provided by the supplier.
6. Open the inner package and verify that the contents agree with the packing slip.
7. Check the integrity of the final source container. Notify the RSO of any broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
8. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. An appropriate instrument with sufficient sensitivity will be sued to assay the sample. Take precautions against the potential spread of contamination.
9. Check the user request to ensure that the material received is the material that was ordered.
10. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding. If contaminated, treat this material as radioactive waste; otherwise remove or obliterate the radiation label before discarding in regular trash.
11. Make a record of the receipt.
CHAPTER 13
AREA SURVEY PROCEDURES

The facility shall conduct the following surveys as applicable with instruments and equipment that are properly calibrated for the radiation to be measured:

- At the end of each day of use in area where unsealed radioactive material requiring a written directive was prepared for use or administered.
- A survey will be conducted, reasonable under the circumstances, to evaluate the extent of radiation levels, concentrations or quantities of radioactive material, and potential radiological hazards that may be present as listed in 902 KAR 100:019.

Each survey record will include, but is not limited to:

- Date of the survey
- Results of the survey
- Instrument used to conduct the survey
- Initials of the individual who performed the survey

Any radioactive sources used for therapy will be surveyed as required by the regulations listed in 902 KAR 100:072.
CHAPTER 14
STORAGE AND DISPOSAL OF RADIOACTIVE MATERIAL

All radioactive material either not being used or that is considered waste will be stored in an appropriately shielded and secured area that has been approved. All contaminated waste will be stored in containers to ensure radiation levels do not exceed regulatory limits. All waste with a physical half-life of less than 120 days will be decayed in storage as stated in 902 KAR 100:072.

1. All waste will be held for storage in a proper container lined with appropriate shielding.

2. Waste will be held for at least 10 half-lives.

3. At the end of 10 half-lives, the waste will be surveyed with an appropriate survey meter to determine that its radioactivity cannot be distinguished from the background radiation level. If background levels are found, waste will be disposed in the normal trash. If waste still reads > background, it will be kept longer and surveyed periodically until radiation levels show no reading above background.

4. All radiation labels will be obliterated or removed before disposing.

5. Records of the disposal will be kept for 3 years and include:
   - Date of disposal
   - Date when material was placed in storage
   - Radionuclide being held
   - Model and serial number of survey instrument used
   - Background radiation dose
   - Radiation dose measured at the surface of the waste container
   - Name of individual who performed the disposal

6. No radioactive material will be disposed of per sewer disposal.
A written directive must be dated and signed by an authorized user before the administration of I-131 greater than 30 microcuries, any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record.

A written directive must be prepared within forty-eight (48) hours of the oral directive.

A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material or brachytherapy dose.

If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record.

A revised written directive must be signed by the authorized user within forty-eight (48) hours of the oral revision.

The licensee shall retain a copy of the written directive for three (3) years.

For any administration requiring a written directive, the licensee shall develop, implement and maintain written procedures to provide high confidence that:

- The patient’s or human research subject’s identity is verified before each administration, and
- Each administration is in accordance with the written directive

A licensee shall retain a copy of the written procedures for the duration of the license.

An annual review of each type of therapy requiring a written directive will be performed.
PROCEDURES FOR THERAPIES REQUIRING A WRITTEN DIRECTIVE FOR RADIOPHARMACEUTICAL THERAPY

Oral and written instructions will be given to each patient as required in 902 KAR 100:072 section 27 prior to treatment on actions recommended to maintain doses to other individuals as low as reasonably achievable. A record will be maintained on the basis for authorizing release of an individual given a therapeutic dosage of radioactive material.

Prior to administration, a written directive issued by an authorized user will be prepared. A written directive is defined as an order, in writing, for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical. The written directive should contain the following information:

- Patient’s name
- Patient identification number, if available
- Radioactive drug
- Sign and dated by authorized user

AND

For administration of I-131 greater than 30 microcuries:

- The dosage

For administration of therapeutic dosage of unsealed radioactive material other than I-131:

- The dosage
- Route of administration

Each administration will be in accordance with the written directive. The physician or nuclear medicine technologist shall read the written directive before preparing or administering the radiopharmaceutical. If any portion of the written directive is unclear, the specific authorized user must be contacted to provide clarification. The radiopharmaceutical shall not be administered until the intent of the written directive is thoroughly understood by the person administering the dose. If the person preparing the dose is different from the one administering the dose, both shall read and understand the written directive. The persons who prepare and administer the dose shall verify that the specific details of the administration (radiopharmaceutical, dosage, and route of administration, etc.) are in accordance with the written directive.

Prior to administration, the patient’s identity is verified as the patient named in the written directive. The person responsible for the administration will complete the verification. Verification of identity must include at least one of the following methods:

- The patient shall be asked to state and spell their name.
- The patient shall be asked to state their birth date.
- The patient shall be asked to state their social security number.
- The patient shall be asked to state their address.
- The patient shall be asked for identification, i.e. driver’s license.
- The patient’s wrist identification band shall be checked for name and patient number.
- For patients unable to respond, an accompanying relative or friend may attest to the patient’s identity.
  Record name and relationship of same.
If the information obtained from any the methods listed above does not correspond to the information on the written directive, the radiopharmaceutical shall not be administered until conclusive verification is obtained.

Oral directives are permissible only when a patient’s medical condition is such that their health would be jeopardized by the delay needed for originating or revising a written directive. When oral directives are employed, the information contained in the oral directive is documented in writing as soon as possible in the patient’s record. A written directive must be prepared within 48 hours of the oral directive.

If any unintended deviation from the written directive is identified, it is evaluated and appropriate action taken. (See 902 KAR 100:072, Sections 15 &16)
If an individual receiving radiopharmaceutical therapy cannot be released under 902 KAR 100:072 section 27 certain safety precautions need to be followed as listed below:

1. The patient’s room will be a private room.
2. The patient’s door will be visibly posted with a “Radioactive Materials” sign.
3. It must be noted either on the door or in the patient’s chart where and how long visitors may stay in the patient’s room.
4. Monitoring of the material and items removed from the patient’s room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding must be done, or all items may be handled as radioactive waste.
5. The personnel handling the patient shall notify the radiation safety officer, or his/her designee, and the authorized user as soon as possible if the patient has a medical emergency or dies.

**Prepare the room for the procedure as follows:**

a. Use leak-proof absorbent paper to cover large surfaces (the bed, chairs, and the floor around the toilet) that are likely to be contaminated. Small items (telephone, doorknobs, bed remote control, television control, and nurse call cord) may be covered with absorbent paper or plastic bags if it is felt to be needed.

b. Several plastic bags may be used for garbage, linens, etc.

c. The patient may use the sanitary sewer system, but it is suggested they be informed to flush a few times after using the facility.

d. Showers are not suggested as it is very difficult to decontaminate.

d. Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use as necessary by nursing, nuclear medicine, and radiation safety personnel.

6. Order disposable table service for the duration of the patient’s stay. Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.

7. Supply the nurses with film badges or TLDs.

8. Brief the nurses on radiation safety precautions. Instruction must include but is not limited to:
   - Patient control (patient must stay in the room and may not wander out)
   - Visitor control (this may differ for each patient)
   - Contamination control
   - Waste control
   - Notification of the RSO and the authorized user if the patient has a medical emergency or dies.
   *Record of this instruction must be maintained and kept for 3 years. Records must include the topics covered, individuals present, instructor, and the date of the instruction.

9. Brief the patient on radiation safety procedures for the dosage administration, visitor control, urine collection, radioactive waste, and other items as applicable.

10. Only those persons needed for medical, safety, or training purposes should be present during the administration.

11. As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area.
12. Do not release any patient until either the exposure rate from the patient is less than 7 millirem per hour at 1 meter or the retained radioactivity is less than 33 millicuries. If you use the exposure rate standard as the release criterion, measure it with a radiation measurement survey meter at a distance of 1 meter from the umbilicus while the patient is standing or, if the patient is not ambulatory, 1 meter from the bedside with the patient supine.

13. Before using the room for general occupancy, it must be decontaminated and released to the Admitting Office. Any items contaminated must be held for decay prior to waste disposal or another use. Record of the holding must be recorded as listed in the “STORAGE AND DISPOSAL OF RADIOACTIVE MATERIAL”

Clean contaminated areas until removable contamination is less than 200 dpm/100 cm. 

CHAPTER 18

PROCEDURES FOR THERAPIES REQUIRING A WRITTEN DIRECTIVE FROM SEALED SOURCE RADIOACTIVE MATERIAL

Only therapies will be administered that can be performed on an outpatient basis. No therapies with sealed sources will be performed when it is required that the patient become an inpatient due to the radiation dosage received for treatment that required a written directive. Oral and written instructions will be given to each patient with permanent implants as required in 902 KAR 100:072 section 27 prior to treatment on actions recommended to maintain doses to other individuals as low as reasonably achievable.

Prior to administration, a written directive issued by an authorized user will be prepared. A written directive is defined as an order, in writing, for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical. The written directive should contain the following information:

BEFORE IMPLANTATION:
- Patient’s name
- Patient identification number, if available
- Authorized user and date AND

FOR ALL OTHER BRACHYTHERAPY (I-125 SEEDS, SR-90, P-32):
- Treatment site
- Radionuclide
- Dose

AFTER IMPLANTATION BUT BEFORE COMPLETION OF PROCEDURE:
- Radionuclide
- Treatment site
- Number of sources
- Total source strength
- Exposure time or total dose

Each administration will be in accordance with the written directive. The physician or authorized medical physicist shall read the written directive before preparing or administering the brachytherapy dose. If any portion of the written directive is unclear, the specific authorized user must be contacted to provide clarification. The radiopharmaceutical shall not be administered until the intent of the written directive is thoroughly understood by the person administering the dose. If the person preparing the dose is different from the one administering the dose, both shall read and understand the written directive. The persons who prepare and administer the dose shall verify that the specific details of the administration (radiopharmaceutical, dosage, and route of administration, etc.) are in accordance with the written directive.

Prior to administration, the patient’s identity is verified as the patient named in the written directive. The person responsible for the administration will complete the verification. Verification of identity must include at least one of the following methods:

- The patient shall be asked to state and spell their name.
- The patient shall be asked to state their birth date.
- The patient shall be asked to state their social security number.
- The patient shall be asked to state their address.
- The patient shall be asked for identification, i.e. driver’s license.
- The patient’s wrist identification band shall be checked for name and patient number.
• For patients unable to respond, an accompanying relative or friend may attest to the patient’s identity. Record name and relationship of same.

If the information obtained from any the methods listed above does not correspond to the information on the written directive, the brachytherapy dose shall not be administered until conclusive verification is obtained.

Prior to administration, verification will be made that the administration is in accordance with the treatment plan, if applicable, the written directive. When applicable, both manual and computer-generated dose calculations will be verified along with verification of any computer-generated dose calculations transferred into the consoles of therapeutic medical units.

Oral directives are permissible only when a patient’s medical condition is such that their health would be jeopardized by the delay needed for originating or revising a written directive. When oral directives are employed, the information contained in the oral directive is documented in writing as soon as possible in the patient’s record. A written directive must be prepared within 48 hours of the oral directive.

If any unintended deviation from the written directive is identified, it is evaluated and appropriate action taken. (See 902 KAR 100:072, Sections 15 &16)

SURVEYS AFTER SOURCE IMPLANT AND REMOVAL

 Immediately after implanting sources in a patient, a survey will be performed to locate and account for all sources that have not been implanted when applicable.
 Immediately after removing the last temporary implant source from the patient, a survey shall be performed of the patient with a radiation detection survey instrument to confirm that all sources have been removed.

A record of the surveys that are required as listed above will be retained for 3 years and include the date, results of the survey, survey instrument used and the name of the individual who performed the survey.

BRACHYTHERAPY SOURCE ACCOUNTABILITY

The facility shall maintain accountability at all times for all brachytherapy sources in storage or use.

For the permanent implants, a record of accountability shall include:
• The number and activity of sources removed from storage
• Date removed from storage
• Name of the individual who removed them from storage AND
• Number and activity of sources permanently implanted

Immediately after implanting sources in the patient, a survey will be performed to locate and account for all sources that have not been implanted. A record of the survey will be retained for 3 years. Each record shall include:
• Date
• Results of survey
• Survey instrument used
• Name of the individual who made the survey

For the temporary implants, after removal from the patient, the sources will be returned to the secured storage area as soon as possible. A record of accountability shall include:
• Number and activity of sources removed from storage
• Time and date they were removed from storage
• Name of individual who removed them
- Location of use
- Number and activity of sources returned to storage
- Time and date they were returned to storage
- Name of individual who returned them

Calibration measurements of brachytherapy sources and use of therapy-related computer systems will be performed as stated in 902 KAR 100:072 section 42 and 43.
The Radiation Safety Office and research labs employ equipment to monitor contamination and external radiation levels. The most commonly used equipment is the GM meter. This requires annual calibration; the procedures is listed below. Any other equipment used will be maintained per manufacturer’s recommendations; pulsar calibration is used a most equipment; procedures are listed below.

**Survey Meter Calibration Procedure**

1. **PURPOSE:** To establish the procedures used for calibration and maintenance of radiation detection equipment at Uof L Radiation Safety Office (RSO).

2. **SCOPE:** This SOP is applicable to the RSO, Health Science Center, Uof L Hospital, and other parties requesting calibration or maintenance service of radiation detection equipment.

3. **REFERENCES:**
   A. 902 KAR 100:073
   B. NCRP Report 112.
   F. Instrument manufacturer’s individual equipment manuals.

4. **RESPONSIBILITIES:**
   a. The Assistant Radiation Safety Officer will:
      1) supervise the daily operation of the calibration and maintenance program.
      2) train RSO personnel in performance of this procedure.
   b. RSO personnel will:
      1) perform calibrations and recordkeeping IAW this procedure.
      2) insure uncalibrated and non-servicable instruments are removed from use; calibrated or repaired; and returned to service promptly.
   c. Instrument Owners will:
      1) become familiar with requirements of this procedure.
      2) provide timely access to survey equipment needing calibration or repair.

5. **PROCEDURE:**
   A. Pulser Calibration Procedure
   B. Cs-137 Range Calibration Procedure
   C. Utilization of Health Physics Assistant Database
PULSER CALIBRATION OF COUNT RATE INSTRUMENTS

1. All information will be recorded on the following form, “Instrument Calibration Record– Count Rate”.

2. Record the instrument type, serial#, probe type, calibration date, and the person calibrating.

3. Check the instrument high voltage and battery. Replace battery if necessary. Verify ‘high voltage’ is appropriate for the detector. Record the battery status and the high voltage.

4. If the instrument will be calibrated with the detector connected (it is preferable that the instrument be calibrated with the detector disconnected), record the instrument reading on its lowest normally used scale. This will be the background which will be subtracted from each reading.

5. If the detector will be calibrated with the detector disconnected verify that the instrument reads zero with no pulses applied. If the meter does not read zero adjust the meter face and record the initial and final readings.

6. Determine the input sensitivity using the following method:
   a) Select the most sensitive amplitude range on the pulser
   b) Set the pulse frequency to the midpoint of one of the counting ranges.
   c) Observe the meter on the survey instrument.
   d) Set the pulse amplitude to zero
   e) Increase pulse amplitude, switching to next higher range if necessary, until the rate meter indicates a stable reading (i.e., further increases of pulse amplitude do not cause an increase in the meter reading). Now decrease the pulse height until the meter reading drops. Record this pulse height as the input sensitivity.

7. For calibration purposes set the pulse height to twice the input sensitivity of the detector. Record the pulse height, pulse polarity, pulser model#, and the pulser serial #.

8. All instruments will be calibrated at two points on each scale. The points shall be in the lower and upper third of the normally used span. If a range is not calibrated, note this on the instrument and on the instrument record. The instrument may then be used only on the calibrated ranges. (This is aimed at probes whose useful range is smaller than the range the instrument is capable of measuring).

9. If the detector does not automatically perform a dead time correction proceed to step 10. If the instrument performs a correction for detector dead time this will need to be compensated for at high count rates, otherwise a perfectly good instrument will appear to be over responding. The dead time correction becomes significant (>2%) at a count rate that depends on the dead time setting.

<table>
<thead>
<tr>
<th>Dead time (usec)</th>
<th>Significant Count rate (cpm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1,175,000</td>
</tr>
<tr>
<td>5</td>
<td>235,000</td>
</tr>
<tr>
<td>10</td>
<td>117,000</td>
</tr>
<tr>
<td>20</td>
<td>59,000</td>
</tr>
<tr>
<td>30</td>
<td>39,000</td>
</tr>
<tr>
<td>50</td>
<td>23,500</td>
</tr>
<tr>
<td>80</td>
<td>14,700</td>
</tr>
<tr>
<td>100</td>
<td>11,700</td>
</tr>
<tr>
<td>110</td>
<td>10,700</td>
</tr>
<tr>
<td>120</td>
<td>9,800</td>
</tr>
<tr>
<td>130</td>
<td>9,000</td>
</tr>
</tbody>
</table>

To compensate for dead time consult the appropriate instrument manual.
10. Apply a pulse rate appropriate for the calibration point. If the meter reading fluctuates, the meter reading will be defined as the center point of the needle movement, or in the case of digital meters, as the average of several meter readings. Record the meter range, the pulser reading (and if applicable, the desired reading) and the net meter reading (meter reading less background).

11. Repeat step 10 for each calibration point.

12. An instrument will be considered passing if it agrees to within +/- 10% of the pulser reading. If an instrument fails at any calibration point it will be removed from service until repaired or adjusted.

1. For GM probes, expose the detector to a radiation source. Verify the detector responds to the radiation. Indicate yes or no on “probe check” space on record sheet. If probe fails, meter will be removed from service until probe is repaired or replaced.

2. For NaI probes, expose the detector to a low energy gamma check source. Verify the detector responds to the radiation. Indicate yes or no on “probe check” space on record sheet. If probe fails, meter will be removed from service until probe is repaired or replaced.

3. Expose the probe to the instrument’s dedicated check source (if available). Record the indicated value onto the calibration record. This will be used to verify daily operation by the user. If, during daily check, the reading varies by more than +/- 20% of the indicated value, the instrument will be removed from service until repaired or adjusted.

4. Factory calibrations will be evaluated on a case by case basis. If the calibration is judged to have been performed acceptably it will be accepted by Uof L RSO.

5. Probe efficiency will not be calculated until RSO acquires NIST traceable calibration source for mid range beta.

13. Enclosure 1 follows on next page.
Instrument Calibration Record – Count Rate

Owner _____________________________  Calibration Date __________________

Meter Make_______________   Model _________________   S/N _______________

Probe Type ______________   Battery Check __________   Audio Check __________

High Voltage Setting ______________

**Pulser: Ludlum Model 500, S/N 189504**

Input Sensitivity _______ Input Signal _______   Scale Range _______ - _______

Scale Lower end Expected _______   Upper end Expected _______

X 0.1 __________________________
X 1.0 __________________________
X 10 __________________________
X 100 __________________________
X 1000 __________________________

Probe Check _______   Probe Efficiency _______ % for __________

Check Source Reading _________ cpm

Notes:_______________________________________________________________
____________________________________________________________________
____________________________________________________________________

Calibrated by: _________________________________________________________

University of Louisville
Radiation Safety Office, DEHS
HSC, Commons Bldg., Room 102
319 Abraham Flexner Way
Louisville, KY  40202
CALIBRATION OF DOSE RATE INSTRUMENTS

1. All information will be recorded on the following form, “Instrument Calibration Record Dose Rate”.

2. Record the instrument type, serial#, probe type, calibration date, and the person calibrating.

3. Check the instrument high voltage and battery. Replace battery if necessary. Verify high voltage is appropriate for the detector. Record the battery status and the high voltage.

4. Print a decay/output table for the Amersham Model 77302 calibration source, serial number S-706 [Cs137: 142.7 mCi, reference date 01-29-1990], for the week of calibration. The source certificate is kept on file at RSO.

5. Meters that have linear read dials two points on each scale on the meter to be calibrated are chosen for calibration checks. These points are generally approximately 1/3 from lower side of scale and 1/3 from upper side of scale. These points are found on the decay/output table, or as close as possible, and recorded on the calibration log sheet, as well as how far from the calibration source they occur in centimeters.

6. Meters with logarithmic readout several points on the scale are chosen. These points should cover the entire range of the meter from the lower decade to the upper decade. These points are found on the decay/output table, or as close as possible, and recorded on the calibration log sheet, as well as how far from the calibration source they occur in centimeters.

7. The meter and/or probe, as needed, is placed the correct distance from the calibration source, the sensor is placed so as to make the correct distance 1 centimeter inside of the detector. The detector is then raised to the correct height, center point of detector in line with center point of source output, using a lab ring stand and equipment clamp. Note distance from source is marked on calibration table in centimeters and height is verified using ruler kept with the calibration source.

8. Once the meter is at the predetermined distance from the calibration source, the source is unlocked and opened. The correct combination of attenuators is place in front of the output point to provide the desired reading for the calibration source for the scale being read; generally the lower point is read first followed by the upper point. The reading on the meter is checked to verify that it falls within ± 10% of desired. If the reading is outside of the ±10% range the other point on the scale is checked and appropriate adjustments are made using the calibration controls for that scale. As adjustments are made the scale is checked at both the upper and lower point to gain the best result for both points. If it is not possible to bring the scale to within the 10% range but within ±20% a correction factor maybe calculated and applied. This information is then recorded on the calibration log sheet. Once a scale has been satisfactorily calibrated the next scale is checked and adjusted as needed. Calibration is generally conducted from the farthest point from the calibration source and moved in as needed. If it is not possible to bring any give scale to within the ±20% range that scale is listed as out of service and the meter it taken out of service pending repair and recalibration.

9. Once a meter has been successfully calibrated a calibration certificate is prepared for the meter with name of the user, the calibration date, date of next calibration, calibration source output @ 1 meter, the check source value and the name and title of the person performing the calibration. A small copy of this is attached to the meter and a full size copy is provided to the user for their records. Once this is done the meter is either returned to the lab or the lab is contacted to pick up their meter.
INSTRUMENT CONSTANCY CHECK

A battery check and an instrument constancy check must be conducted each time your survey instrument is to be used.

CALIBRATION:

 Calibration will be performed at two points in each scale used for radiation protection purposes. The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument for each point checked. Readings within plus or minus twenty percent are considered acceptable if a calibration chart, graph, or response factor is prepared, and attached to the instrument, and used to interpret readings to within plus or minus ten percent.

BATTERY CHECK:

 Turn the instrument scale to battery check, or push battery check button. The instrument needle should deflect to the area on the scale that says battery o.k. If the needle does not go to this area, replace the batteries.

INSTRUMENT CONSTANCY CHECK:

 Turn the instrument scale switch to the appropriate scale.
 Expose the sensitive area of the detector against the affixed or attached check source and observe the deflection of the meter. (The instrument needle should deflect upward and read approximately the same as the check source reading at time of calibration recorded on the calibration label.)

If the instrument does not conform to the battery and check source criteria, contact the Radiation Safety Office as the instrument may be in need of repair.

These operational checks are used to make certain your instrument is operating properly prior to and during the survey.

EXAMPLE:

SURVEY METER CALIBRATION

<table>
<thead>
<tr>
<th>For</th>
<th>URSO A-Bldg Room 106</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meter</td>
<td>Inovision</td>
</tr>
<tr>
<td>Calibration Source</td>
<td>Cs-137</td>
</tr>
<tr>
<td>Radiation Output</td>
<td>27.95 mR/hr@1 meter</td>
</tr>
<tr>
<td>Batteries</td>
<td>O.K.</td>
</tr>
<tr>
<td>Batteries O.K.</td>
<td>10%</td>
</tr>
<tr>
<td>Calibration Date</td>
<td>August 3, 2010</td>
</tr>
<tr>
<td>Re-Calib. Due Before</td>
<td>August 3, 2011</td>
</tr>
<tr>
<td>Patrick C Glisson RRPT</td>
<td>Health Physicist Technologist</td>
</tr>
<tr>
<td>Radiation Safety DEHS</td>
<td>HSC</td>
</tr>
<tr>
<td>Rm 102, Commons Bldg, HSC</td>
<td>Louisville, KY 40202</td>
</tr>
<tr>
<td>(502) 852-5231</td>
<td></td>
</tr>
</tbody>
</table>

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Dose Calibrator QC Procedure

If a dose calibrator is used as a means by which the determination of activity for each patient dose is used, it shall be checked for accurate operation by either using the manufacturer’s instructions, or the nationally recognized standards as listed below. Records of calibration will be kept for at least 3 years.

1. Constancy will be done each day prior to use radioactive material usage with an appropriate sealed source and record will include:
   - Model and serial number of dose calibrator
   - Identity and activity of radionuclide contained in the check source
   - Date of the check
   - Activity measured
   - Instrument settings
   - Initials of individual performing test

2. Accuracy will be tested at installation and every 12 months thereafter. The record will include:
   - Model and serial number of dose calibrator
   - Model and serial number and activity of sources used
   - Date of test
   - Results of test
   - Instrument settings
   - Signature of individual performing test

3. Linearity will be tested at installation and at least every 3 months. The record will include:
   - Model and serial number of dose calibrator
   - Calculated activities
   - Measured activities
   - Date of test
   - Signature of individual performing test

4. Geometry dependence will be tested upon installation. The record will include:
   - Model and serial number of dose calibrator
   - Configuration and calibrated activity of source measured
   - Activity of source
   - Activity measured and instrument setting for each volume measured
   - Date of test
   - Signature of the individual who performed the test
Appendix A

Iridium 192 (Ir-192) Sealed Source Brachytherapy

The personnel involved in Ir-192 Brachytherapy and their responsibilities are listed in the table below:

<table>
<thead>
<tr>
<th>Personnel and Responsibilities</th>
<th>Personnel</th>
<th>Credentials</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>The personnel involved in Ir-192 Brachytherapy and their responsibilities are listed in the table below:</td>
<td>Radiation Oncologist</td>
<td>A staff physician with American Board of Radiology (or equivalent) Certification in Therapeutic Radiology or Radiation Oncology.</td>
<td>The Radiation Oncologist must be approved by the Radiation Safety Committee as an Authorized User for Ir-192 procedures.</td>
</tr>
<tr>
<td></td>
<td>Resident Physician</td>
<td>A house staff physician enrolled in a training program in Radiation Oncology at the University of Louisville.</td>
<td>While working under the supervision of the Radiation Oncologist, may perform any of their assigned duties.</td>
</tr>
<tr>
<td></td>
<td>Medical Dosimetrist</td>
<td>A staff medical dosimetrist with Certification in Medical Dosimetry by the Medical Dosimetrist Certification Board.</td>
<td>Responsible for generation of brachytherapy isodose curve information used in treatment planning.</td>
</tr>
<tr>
<td></td>
<td>Radiation Safety Officer/Radiation Safety Office Representative</td>
<td>Health Physicists or Health Physics Technicians who support the University’s Radiation Safety Officer.</td>
<td>Responsible for the conformance to the State of Kentucky issued radioactive materials license as well as applicable State and Federal Regulations governing human exposure to radiation.</td>
</tr>
</tbody>
</table>

Continued on next page
<table>
<thead>
<tr>
<th>Personnel</th>
<th>Credentials</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse</td>
<td>A staff nurse trained in caring for patients that are undergoing procedures involving radioactive materials.</td>
<td>Responsible for normal patient care duties, but with the added responsibility to monitor radiation safety compliance on the ward.</td>
</tr>
<tr>
<td>Authorized Radiation Physicist</td>
<td>A staff physicist with American Board of Radiology (or equivalent) Certification or Board eligibility in Therapeutic Radiological Physics, Radiation Oncology Physics or Radiological Physics.</td>
<td>The Authorized Radiation Physicist collaborates with the Radiation Oncologist and the Medical Dosimetrist to assure proper quality, quantity and placement of radiation doses, and to assure radiation safety for all patients, personnel and members of the general public.</td>
</tr>
</tbody>
</table>

The radionuclide Ir-192 has an extensive gamma-ray spectrum with an average energy of 0.38 MeV. Its half-life is 73.8 days. Ir-192 (alloy of 30% Ir and 70% Pt) sources are fabricated in the form of nylon ribbons containing Iridium seeds 3 mm long and 0.5 mm diameter, spaced with their centers 1 cm apart or thin flexible wires which can be cut to desired lengths. Both the seed ribbons and the wires are quite suitable for the afterloading technique.
The steps used in planning for an Ir-192 administration are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The Radiation Oncologist will determine the time and the desired radiation dosage to be delivered.</td>
</tr>
<tr>
<td>2</td>
<td>The Authorized Radiation Physicist or Medical Dosimetrist will complete computer dose calculations for the desired dose. A computer dosimetry printout shall be provided for each application.</td>
</tr>
<tr>
<td>3</td>
<td>Using the dosimetry printout, the Radiation Oncologist will indicate the desired radiation dosage to be delivered on the Radioactive Materials Order Form and will sign and date the form.</td>
</tr>
<tr>
<td>4</td>
<td>The Radiation Oncologist should inform the Authorized Radiation Physicist at least one week before planned routine treatment. The Authorized Radiation Physicist should be informed at least two weeks before any special application such as the use of multiple isotopes, devices or source types in a single patient procedure.</td>
</tr>
</tbody>
</table>
The steps used in preparing for an Ir-192 administration are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Before the treatment time, the Authorized Radiation Physicist will order and prepare the Iridium sources in conformance to the Treatment Plan specifics listed on the Radioactive Materials Order Form. After the surgical procedure and when the patient is returned to the hospital room, the iridium sources will be afterloaded into the implant.</td>
</tr>
<tr>
<td>2</td>
<td>Following the implantation, the length of Iridium ribbons will be determined. When the length is measured using dummy ribbons, it should be recorded and then the dummies left in place. The Authorized Radiation Physicist will complete the Source Implant Guide section of the Written Directive, which is mandatory for all Iridium Seed implants. The Radioactive Materials Order Form should be filled out along with the diagram, location, position, and number of seeds or active length used for each specific tube.</td>
</tr>
<tr>
<td>3</td>
<td>The Authorized Radiation Physicist will cut the source ribbons into the appropriate length and place the treatment Iridium sources into the transportable-shielded container.</td>
</tr>
<tr>
<td>4</td>
<td>The Radiation Oncology staff will reserve the patient room (usually one of four shielded rooms on the 6th floor).</td>
</tr>
<tr>
<td>5</td>
<td>Before the use of the patient room, the room shall be fully posted to state radiation safety requirements by Authorized Radiation Physicist.</td>
</tr>
</tbody>
</table>

Continued on next page
The steps used in the administration of Ir-192 to the patient are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The Authorized Radiation Physicist will log out the Iridium sources in the Log Out / Log In book maintained in the Hot Lab. The Iridium Sources will be logged in / logged out and will be dated and signed for in the Log Book.</td>
</tr>
<tr>
<td>2</td>
<td>The Authorized Radiation Physicist will transport the Iridium Sources to the patient room.</td>
</tr>
<tr>
<td>3</td>
<td>Before treatment, the Radiation Oncologist will complete the order portion of the Written Directive Form and the Authorized Radiation Physicist will complete this form through the “Pre-Verification” Section. (WD-764-003, Appendix D).</td>
</tr>
<tr>
<td>4</td>
<td>The Radiation Oncologist or Resident Physician will administer the Iridium Sources to the patient. The “Time In” will be recorded on the Written Directive Form (WD-764-003, Appendix D). During this procedure, a member of the Physics staff will record each individual ribbon being loaded.</td>
</tr>
<tr>
<td>5</td>
<td>Following the Iridium loading, the Authorized Radiation Physicist will inspect the implant to ensure all ribbons are securely in position. Forceps, cutter and pig are left in the patient’s room for possible emergency removal.</td>
</tr>
</tbody>
</table>
Step | Action
---|---
6 | Authorized Radiation Physicist will conduct a radiation survey of the patient and the surrounding area.
7 | Nursing care will be conducted per Nursing Procedures for Patients Containing Radioactive Iridium – 192

The steps used in the removal of Ir-192 sources from the patient are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The Iridium sources will be removed by the Radiation Oncologist or Resident Physician and placed in the transportable shield. The Radiation Oncologist or Resident Physician and Authorized Radiation Physicist will count the sources out and compare to the number of sources in. The remainder of the required treatment data (unload, unload time, etc.) will be recorded on the Written Directive Form, signed and dated.</td>
</tr>
<tr>
<td>2</td>
<td>Once the Iridium is removed, the Authorized Radiation Physicist will survey the patient and the patient’s room for any radioactivity.</td>
</tr>
<tr>
<td>3</td>
<td>The Authorized Radiation Physicist will complete “Post Verification, Radiation survey” portion of the Written Directive Form, sign and date the form.</td>
</tr>
</tbody>
</table>

Continued on next page
The steps used to return Ir-192 seeds to storage are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The Authorized Radiation Physicist will take the Iridium sources back to the Hot Lab in the Shielded Transportation container. This will occur immediately after the removal of the sources.</td>
</tr>
<tr>
<td>2</td>
<td>The Authorized Radiation Physicist will “Log in” the Iridium sources as they are returned to their storage location in the Iridium Safe within the Hot Lab. The logbook will be signed and dated. The Authorized Radiation Physicist will check the returned Iridium for proper number of ribbons and proper number of seeds per ribbon. After this is performed, the patient may be discharged.</td>
</tr>
</tbody>
</table>

The steps used for emergency procedures are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Should an Iridium source ribbon ever come out of a patient, the Radiation Oncologist is to be contacted immediately regarding the situation. He/she will decide and give further instructions as to the handling of the situation. Afterward, the Resident Physician, the Radiation Safety Officer and the Authorized Radiation Physicist are to be contacted. In case a radioactive Iridium source is misplaced or lost, the responsible Radiation Oncologist, Authorized Radiation Physicist, Radiation Safety Officer and Resident Physician on call should be notified immediately.</td>
</tr>
</tbody>
</table>
In the case of patient emergency, the Radiation Oncologist, the Resident Physician, and the Authorized Radiation Physicist are to be contacted immediately regarding the situation. Telephone numbers are posted on the patient’s door and in the nursing instructions on the patient’s chart. In the event these individuals are not immediately available, the remainder of the clinical staff will need to become involved. In most cases, the removal of the Iridium implants is indicated, particularly if the patient needs to be removed from their isolation room or if much personal attendance is required.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>In the case of patient emergency, The Radiation Oncologist, the Resident Physician, and the Authorized Radiation Physicist are to be contacted immediately regarding the situation. Telephone numbers are posted on the patient’s door and in the nursing instructions on the patient’s chart. In the event these individuals are not immediately available, the remainder of the clinical staff will need to become involved. In most cases, the removal of the Iridium implants is indicated, particularly if the patient needs to be removed from their isolation room or if much personal attendance is required.</td>
</tr>
</tbody>
</table>
The personnel involved in I-131 Therapy and their responsibilities are listed in the table below.

<table>
<thead>
<tr>
<th>Personnel</th>
<th>Credentials</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation Oncologist</td>
<td>A staff physician with American Board of Radiology (or equivalent) Certification in Therapeutic Radiology or Radiation Oncology.</td>
<td>The Radiation Oncologist must be approved by the Radiation Safety Committee as an Authorized User for I-131 procedures.</td>
</tr>
<tr>
<td>Resident Physician</td>
<td>A house staff physician enrolled in a training program in Radiation Oncology at the University of Louisville.</td>
<td>While working under the supervision of the Radiation Oncologist may perform any of their assigned duties.</td>
</tr>
</tbody>
</table>

*Continued on next page*
<table>
<thead>
<tr>
<th>Personnel</th>
<th>Credentials</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physics Assistant</td>
<td>A staff physics assistant or junior physicist trained to log and handle I-131 unsealed sources for patient procedures.</td>
<td>While working under the direct supervision of the Authorized Radiation Physicist, may perform any of their assigned duties.</td>
</tr>
<tr>
<td>Nurse</td>
<td>A staff nurse trained in caring for patients that are undergoing procedures involving radioactive materials.</td>
<td>Responsible for normal patient care duties, but with the added responsibility to monitor radiation safety compliance on the ward.</td>
</tr>
<tr>
<td>Authorized Radiation Physicist</td>
<td>A staff physicist with American Board of Radiology (or equivalent) Certification or Board eligibility in Therapeutic Radiological Physics, Radiation Oncology Physics or Radiological Physics.</td>
<td>The Authorized Radiation Physicist collaborates with the Radiation Oncologist and the Medical Dosimetrist to assure proper quality, quantity and placement of radiation doses, and to assure radiation safety for all patients, personnel and members of the general public.</td>
</tr>
</tbody>
</table>

Continued on next page
Personnel | Credentials | Responsibility
--- | --- | ---
Medical Dosimetrist | A staff medical dosimetrist with Certification in Medical Dosimetry by the Medical Dosimetrist Certification Board. | Responsible for generation of source calculation and other information used in treatment planning.
Radiation Safety Officer/Radiation Safety Office Representative | Health Physicists or Health Physics Technicians who support the University’s Radiation Safety Officer. | Responsible for the conformance to the State of Kentucky issued radioactive materials license as well as applicable State and Federal Regulations governing human exposure to radiation.

I-131 decays to Xe-131 with a half-life of 8.08 days. Principal emissions are 191.6 keV (beta) and 364.5 keV (gamma). In the hyperthyroid patient, a percent of the administered dose equal to the fractional radioiodide uptake (usually between 35 and 90%) of the administered sodium iodide I-131 is concentrated in the thyroid gland and has an effective half-life of approximately 4 to 6 days. The non-thyroid sodium iodide I-131 is distributed within the extra cellular fluid and has an effective half-life of approximately 0.34 days.
The steps used in planning for an I-131 administration are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The Radiation Oncologist will determine the time and the desired radiation dosage to be delivered.</td>
</tr>
<tr>
<td>2</td>
<td>The Radiation Oncologist will indicate the desired radiation dosage to be delivered on the I-131 Order Form and the I-131 Written Directive, and will sign and date the forms. For easy reference, this and all subsequent steps are listed on the Authorized Radiation Physicist Job Aid for I-131 Therapy.</td>
</tr>
<tr>
<td>3</td>
<td>The Radiation Oncologist should inform the Authorized Radiation Physicist at least 5 days before planned routine treatment. The Authorized Radiation Physicist should be informed at least two weeks before any special application such as the use of multiple isotopes, devices or source types in a single patient procedure.</td>
</tr>
<tr>
<td>4</td>
<td>The Authorized Radiation Physicist or Physics Assistant under the supervision of the Authorized Radiation Physicist will perform an outpatient release calculation to determine if the patient can be treated as an outpatient. The Authorized Radiation Physicist will sign the calculation. The criteria for this calculation include the living arrangements, the presence of children, and whether the patient is breast-feeding. An example of this calculation is given in I-131 Outpatient Release Calculation.</td>
</tr>
</tbody>
</table>
Preparing for an I-131 Administration

The steps used in preparing for an I-131 administration are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Before the treatment time, the Authorized Radiation Physicist or Physics Assistant will receive, count, calibrate and prepare the I-131 source for patient administration.</td>
</tr>
<tr>
<td>2</td>
<td>The Authorized Radiation Physicist or Physics Assistant will prepare the examination room by covering the floor and the countertop with chucks. A radioactive hazard disposal bag is available for gloves, chucks and other items that are contaminated.</td>
</tr>
<tr>
<td>3</td>
<td>The Authorized Radiation Physicist or Physics Assistant will place the I-131 into the transportable-shielded container and transport the sources to the examination room.</td>
</tr>
</tbody>
</table>

Administration of I-131 to the Patient

The steps used in the administration of I-131 to the patient are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Before administration, the Radiation Oncologist or Resident Physician will complete the “Pre Verification” portion of the Written Directive form.</td>
</tr>
<tr>
<td>2</td>
<td>The Authorized Radiation Physicist or Physics Assistant will provide the Patient Instruction Form to the patient. Have the patient sign a copy for our records, and give the patient another copy.</td>
</tr>
<tr>
<td>3</td>
<td>The Radiation Oncologist or Resident Physician under the direct supervision of the Radiation Oncologist will administer the I-131 sources to the patient. The time of administration will be recorded on the Written Directive Form.</td>
</tr>
<tr>
<td>4</td>
<td>The Authorized Radiation Physicist or Physics Assistant under the supervision of the Authorized Radiation Physicist will conduct a radiation survey of the patient in the examination room.</td>
</tr>
</tbody>
</table>

Continued on next page
Discharge of Patient

The steps used in the discharge of a patient given an I-131 administration are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The radiation survey will note the radiation readings at 1 meter and at the surface (stomach) of the patient. Patients may be discharged according to USNRC Regulatory Guide 8.39 “Release of Patients Administered Radioactive Material”. The Release Calculation will document the patient was released according to the specifics conditions contained in this regulation.</td>
</tr>
<tr>
<td>2</td>
<td>Before discharge of the implant patient, the Radiation Oncologist, Authorized Radiation Physicist or Physics Assistant will instruct the patient regarding recommended time of contact with family member, etc. The post-verification section of the Written Directive Form is completed and signed by either the Radiation Oncologist or the Resident Physician.</td>
</tr>
<tr>
<td>3</td>
<td>The Authorized Radiation Physicist or Physics Assistant surveys the examination room for contamination. Any contaminated areas must be cleaned and resurveyed for contamination.</td>
</tr>
<tr>
<td>4</td>
<td>If the patient requires hospitalization, the nursing instructions are posted on the patient’s door and in the patient’s chart.</td>
</tr>
</tbody>
</table>

Bioassay

If abnormal circumstances occur, a bioassay may be requested. The steps to perform a bioassay for personnel involved in an I-131 administered are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1-3 days after administration, measure the thyroid burden of all personnel that were in the room at the time of the administration if it is found to be necessary.</td>
</tr>
<tr>
<td>2</td>
<td>An iodine measurement above the action level will require further evaluation and possible treatment.</td>
</tr>
</tbody>
</table>

Continued on next page
The steps used for emergency procedures are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Should the patient become ill and expel fluids or material containing I-131, the Radiation Oncologist, the Authorized Radiation Physicist and the Radiation Safety Officer is to be contacted immediately regarding the situation. The Radiation Safety Officer will supervise the cleanup of the radioactive spill.</td>
</tr>
<tr>
<td>2</td>
<td>In the case of patient emergency, The Radiation Oncologist or the Resident Physician is to be contacted immediately regarding the situation.</td>
</tr>
</tbody>
</table>
The personnel involved in Sm-153 Therapy and their responsibilities are listed in the table below.

<table>
<thead>
<tr>
<th>Personnel</th>
<th>Credentials</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation Oncologist</td>
<td>A staff physician with American Board of Radiology (or equivalent) Certification in Therapeutic Radiology or Radiation Oncology.</td>
<td>The Radiation Oncologist must be approved by the Radiation Safety Committee as an Authorized User for Sm-153 procedures.</td>
</tr>
<tr>
<td>Resident Physician</td>
<td>A house staff physician enrolled in a training program in Radiation Oncology at the University of Louisville.</td>
<td>While working under the supervision of the Radiation Oncologist, may perform any of their assigned duties.</td>
</tr>
</tbody>
</table>

Continued on next page
<table>
<thead>
<tr>
<th>Personnel</th>
<th>Credentials</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physics Assistant</td>
<td>A staff physics assistant trained to log and handle Sm-153 unsealed sources for patient procedures.</td>
<td>While working under the supervision of the Authorized Radiation Physicist, may perform any of their assigned duties.</td>
</tr>
<tr>
<td>Nurse</td>
<td>A staff nurse trained in caring for patients that are undergoing procedures involving radioactive materials.</td>
<td>Responsible for normal patient care duties, but with the added responsibility to monitor radiation safety compliance on the ward.</td>
</tr>
<tr>
<td>Authorized Radiation</td>
<td>A staff physicist with American Board of Radiology (or equivalent) Certification or Board eligibility in Therapeutic Radiological Physics, Radiation Oncology Physics or Radiological Physics.</td>
<td>The Authorized Radiation Physicist collaborates with the Radiation Oncologist and the Medical Dosimetrist to assure proper quality, quantity and placement of radiation doses, and to assure radiation safety for all patients, personnel and members of the general public.</td>
</tr>
<tr>
<td>Physicist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Personnel</td>
<td>Credentials</td>
<td>Responsibility</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Medical Dosimetrist</td>
<td>A staff medical dosimetrist with Certification in Medical Dosimetry by the Medical Dosimetrist Certification Board.</td>
<td>Responsible for generation of source calculation and other information used in treatment planning.</td>
</tr>
<tr>
<td>Radiation Safety Officer/Radiation Safety Office Representative</td>
<td>Health Physicists or Health Physics Technicians who support the University’s Radiation Safety Officer.</td>
<td>Responsible for the conformance to the State of Kentucky issued radioactive materials license as well as applicable State and Federal Regulations governing human exposure to radiation.</td>
</tr>
</tbody>
</table>
The steps used in planning for a Sm-153 administration are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The Radiation Oncologist will determine the time and the desired radiation dosage to be delivered.</td>
</tr>
<tr>
<td>2</td>
<td>The Radiation Oncologist will indicate the desired radiation dosage to be delivered on the Sm-153 Order Form and the Sm-153 Written Directive, and will sign and date the forms. For easy reference, this and all subsequent steps are listed on the Authorized Radiation Physicist Job Aid for Sm-153 Therapy.</td>
</tr>
<tr>
<td>3</td>
<td>The Radiation Oncologist should inform the Authorized Radiation Physicist at least 5 days before planned routine treatment. The Authorized Radiation Physicist should be informed at least two weeks before any special application such as the use of multiple isotopes, devices or source types in a single patient procedure.</td>
</tr>
</tbody>
</table>

The steps used in preparing for a Sm-153 administration are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Before the treatment time, the Authorized Radiation Physicist or Physics Assistant will receive and prepare the Sm-153 source for patient administration.</td>
</tr>
<tr>
<td>2</td>
<td>The Authorized Radiation Physicist or Physics Assistant will place the Sm-153 into the transportable-shielded container.</td>
</tr>
</tbody>
</table>
The steps used in the administration of Sm-153 to the patient are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The Authorized Radiation Physicist or Physics Assistant will check the calibration of the Sm-153.</td>
</tr>
<tr>
<td>2</td>
<td>The Authorized Radiation Physicist or Physics Assistant will transport the Sm-153 Sources to the examination room.</td>
</tr>
<tr>
<td>3</td>
<td>At the examination room, before administration, the Radiation Oncologist will complete the “Pre Verification” portion of the Written Directive form.</td>
</tr>
<tr>
<td>4</td>
<td>The Radiation Oncologist will administer the Sm-153 source to the patient. The time of administration will be recorded on the Written Directive Form.</td>
</tr>
<tr>
<td>5</td>
<td>The Authorized Radiation Physicist, Physics Assistant, or Radiation Safety Staff will conduct a radiation survey of the patient and the surrounding areas in the examination room.</td>
</tr>
</tbody>
</table>

The steps used in the discharge of a patient given a Sm-153 administration are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Patients should be held for five minutes after administration to see that they are stable. Patients may be discharged according to USNRC Regulatory Guide 8.39 “Release of Patients Administered Radioactive Material.” If the patient measures an exposure rate greater than 30 mrem/hr at 1 meter, a release calculation will be performed by the Authorized Radiation Physicist and placed in the patient’s chart.</td>
</tr>
<tr>
<td>2</td>
<td>Before discharge of the implant patient, the Radiation Oncologist, Authorized Radiation Physicist or Physics Assistant will instruct the patient regarding recommended time of contact with family member, etc.</td>
</tr>
</tbody>
</table>

Continued on next page
Emergency Procedures

The steps used for emergency procedures are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Should the patient become ill and expel fluids or material containing Sm-153, the Radiation Oncologist, the Authorized Radiation Physicist, and the Radiation Safety Officer are to be contacted immediately regarding the situation. The Radiation Safety Officer will supervise the cleanup of the radioactive spill.</td>
</tr>
<tr>
<td>2</td>
<td>In the case of patient emergency, The Radiation Oncologist or the Resident Physician is to be contacted immediately regarding the situation.</td>
</tr>
</tbody>
</table>
Sealed Source Seed Implant - Radiation Oncology

The personnel involved in the Brachytherapy procedure and their responsibilities are listed in the table below.

<table>
<thead>
<tr>
<th>Personnel</th>
<th>Credentials</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation Oncologist</td>
<td>A staff physician with American Board of Radiology (or equivalent) Certification in Therapeutic Radiology or Radiation Oncology.</td>
<td>The Radiation Oncologist must be approved by the Radiation Safety Committee as an Authorized User for the procedures.</td>
</tr>
<tr>
<td>Resident Physician</td>
<td>A house staff physician enrolled in a training program in Radiation Oncology at the University of Louisville.</td>
<td>While working under the supervision of the Radiation Oncologist, may perform any of their assigned duties.</td>
</tr>
<tr>
<td>Personnel</td>
<td>Credentials</td>
<td>Responsibility</td>
</tr>
<tr>
<td>------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Nurse</td>
<td>A staff nurse trained in caring for patients that are undergoing procedures involving radioactive materials.</td>
<td>Responsible for normal patient care duties, but with the added responsibility to monitor radiation safety compliance on the ward.</td>
</tr>
<tr>
<td>Authorized Radiation Physicist</td>
<td>A staff physicist with American Board of Radiology (or equivalent) Certification or Board eligibility in Therapeutic Radiological Physics, Radiation Oncology Physics or Radiological Physics.</td>
<td>The Authorized Radiation Physicist collaborates with the Radiation Oncologist and the Medical Dosimetrist to assure proper quality, quantity and placement of radiation doses, and to assure radiation safety for all patients, personnel and members of the general public.</td>
</tr>
<tr>
<td>Personnel</td>
<td>Credentials</td>
<td>Responsibility</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Medical Dosimetrist</td>
<td>A staff medical dosimetrist with Certification in Medical Dosimetry by the Medical Dosimetrist Certification Board.</td>
<td>Responsible for generation of brachytherapy isodose curve information used in treatment planning.</td>
</tr>
<tr>
<td>Radiation Safety Officer/Radiation Safety Office Representative</td>
<td>Health Physicists or Health Physics Technicians who support the University’s Radiation Safety Officer.</td>
<td>Responsible for the conformance to the State of Kentucky issued radioactive materials license as well as applicable State and Federal Regulations governing human exposure to radiation.</td>
</tr>
</tbody>
</table>

Continued on next page
The steps used in planning for a sealed source seed administration are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The Radiation Oncologist will determine the time and the desired radiation dosage to be delivered.</td>
</tr>
<tr>
<td>2</td>
<td>The Medical Dosimetrist or Authorized Radiation Physicist will complete computer dose calculations for the desired dose. A computer dosimetry printout shall be provided for each application.</td>
</tr>
<tr>
<td>3</td>
<td>Using the dosimetry printout, the Radiation Oncologist will indicate the desired radiation dosage to be delivered on the Radioactive Materials Order Form and the Written Directive, and will sign and date the forms. For easy reference, this and all subsequent steps are listed on the Radiation Oncologist, Resident Physician, and Authorized Radiation Physicist Job Aid for Sealed Source Pd-103 Application to the Patient.</td>
</tr>
<tr>
<td>4</td>
<td>The Radiation Oncologist should inform the Authorized Radiation Physicist at least 10 days before planned routine treatment. The Authorized Radiation Physicist should be informed at least two weeks before any special application such as the use of multiple isotopes, devices or source types in a single patient procedure.</td>
</tr>
</tbody>
</table>

*Continued on next page*
The steps used in preparing for an administration are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Before the treatment time, the Authorized Radiation Physicist or will prepare the seed sources in conformance to the Treatment Plan specifics listed on the computer dosimetry printout and the Written Directive.</td>
</tr>
<tr>
<td>2</td>
<td>The Authorized Radiation Physicist will place the treatment Pd-103 sources into the transportable-shielded container.</td>
</tr>
<tr>
<td>3</td>
<td>The Radiation Oncology staff will reserve the patient room (usually one of four shielded rooms on the 6th floor), if the implant involves a patient admission.</td>
</tr>
<tr>
<td>4</td>
<td>Before the use of the patient room, the room shall be fully posted to radiation safety requirements by Radiation Safety Staff.</td>
</tr>
</tbody>
</table>

The steps used in the administration of seeds to the patient are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The Authorized Radiation Physicist will perform a source count and check the calibration certificate of the seeds. Afterward, Physics staff will log out, date and sign the sources in the Log Out / Log In book maintained in the Hot Lab. Physics staff will sterilize seeds as needed and load seeds into the applicator, if necessary.</td>
</tr>
<tr>
<td>2</td>
<td>The Authorized Radiation Physicist will transport the Sources to the operating room in a shielded container that reduces exposure to levels than 0.15 mR/hr at a distance of 1 meter from the source.</td>
</tr>
</tbody>
</table>

Continued on next page
Continued

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>At the operating room, before treatment, the Radiation Oncologist will complete the “Pre Verification” portion of the Written Directive form.</td>
</tr>
<tr>
<td>4</td>
<td>The Radiation Oncologist will administer the sources to the patient. The time of implant will be recorded on the Written Directive Form. During surgical implant, the Physics staff will maintain a running count of seeds inserted with the assistance of the Radiation Oncologist.</td>
</tr>
<tr>
<td>5</td>
<td>Radiation Safety Staff will conduct a radiation survey of the patient and the surrounding areas in the operating room.</td>
</tr>
<tr>
<td>6</td>
<td>Nursing care will be conducted per Summary of nursing care instructions for patients receiving radioactive implant therapy.</td>
</tr>
</tbody>
</table>

The steps used in the discharge of a patient implanted with the sources are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Patients may be discharged according to USNRC Regulatory Guide 8.39 “Release of Patients Administered Radioactive Material”. If the patient measures an exposure rate greater than 1 mR/hr at 1 meter from the geometric center of the sources, a release calculation will be performed by the Authorized Radiation Physicist and placed in the patient’s chart.</td>
</tr>
</tbody>
</table>
Prior to discharge of the implant patient, the Radiation Oncologist will instruct the patient regarding recommended time of contact with family member, handling of expelled seeds, etc... If the administration site is a neck or a superficial implant, use of the lead shield is required if the exposure rate is greater than 1 mR/hr. If this protective shield is worn to cover the implant area, the radiation level near the patient is minimal and no special distance or time precautions need be observed.

The steps used to return unused seeds to storage are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The Authorized Radiation Physicist will return any unused sources to the Hot Lab in the shielded transportation container. This will occur immediately after the implant is complete and the survey is performed.</td>
</tr>
<tr>
<td>2</td>
<td>The Authorized Radiation Physicist will “Log in” the sources when they are returned to their storage location within the Hot Lab. The logbook will be signed and dated by the Authorized Radiation Physicist.</td>
</tr>
</tbody>
</table>
The steps used for emergency procedures are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Should a source ever come out of a patient, the Radiation Oncologist, the Resident Physician, the Authorized Radiation Physicist and the Radiation Safety Officer is to be contacted immediately regarding the situation. One of these individuals will assume responsibility for returning the source to a shielded container and transporting it back to the Hot Lab.</td>
</tr>
<tr>
<td>2</td>
<td>In the case of patient emergency, The Radiation Oncologist, or the Resident Physician, is to be contacted immediately regarding the situation.</td>
</tr>
<tr>
<td>3</td>
<td>Should a source come out of a patient after the patient is discharged, the patient should be instructed to recover the source into a jar without touching it, and bring it back to the Radiation Oncologist. However, if the source is discharged during urination, the source should be flushed into the sewage system.</td>
</tr>
</tbody>
</table>

Follow up procedures to ensure dose received to the prostate will be performed and follow the American Brachytherapy Society guidelines.
The personnel involved in I-125 Brachytherapy and their responsibilities are listed in the table below.

<table>
<thead>
<tr>
<th>Personnel</th>
<th>Credentials</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation Oncologist</td>
<td>A staff physician with American Board of Radiology (or equivalent) Certification in Therapeutic Radiology or Radiation Oncology.</td>
<td>The Radiation Oncologist must be approved by the Radiation Safety Committee as an Authorized user for Iodine-125 procedures.</td>
</tr>
<tr>
<td>Resident Physician</td>
<td>A house staff physician enrolled in a training program in Radiation Oncology at the University of Louisville.</td>
<td>While working under the supervision of the Radiation Oncologist may perform any of their assigned duties.</td>
</tr>
<tr>
<td>Personnel</td>
<td>Credentials</td>
<td>Responsibility</td>
</tr>
<tr>
<td>----------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Nurse</td>
<td>A staff nurse trained in caring for patients that are undergoing procedures involving radioactive materials.</td>
<td>Responsible for normal patient care duties, but with the added responsibility to monitor radiation safety compliance on the ward.</td>
</tr>
<tr>
<td>Authorized Radiation Physicist</td>
<td>A staff physicist with American Board of Radiology (or equivalent) Certification or Board eligibility in Therapeutic Radiological Physics, Radiation Oncology Physics or Radiological Physics.</td>
<td>The Authorized Radiation Physicist collaborates with the Radiation Oncologist and the Medical Dosimetrist to assure proper quality, quantity and placement of radiation doses, and to assure radiation safety for all patients, personnel and members of the general public.</td>
</tr>
</tbody>
</table>
Personnel | Credentials | Responsibility
--- | --- | ---
Medical Dosimetrist | A staff medical dosimetrist with Certification in Medical Dosimetry by the Medical Dosimetrist Certification Board. | Responsible for generation of brachytherapy isodose curve information used in treatment planning.
Radiation Safety Officer/Radiation Safety Office Representative | Health Physicists or Health Physics Technicians who support the University’s Radiation Safety Officer. | Responsible for the conformance to the State of Kentucky issued radioactive materials license as well as applicable State and Federal Regulations governing human exposure to radiation.

I-125 seeds (4.5 mm long by 0.8 mm in diameter) emit low energy photons in the range of 27-35.5 keV. I-125 has a half-life of 60.2 days. It is encapsulated in titanium, which absorbs the electrons from the I-125 nuclide. The half-value layer (HVL) for I-125 is 0.025 mm of lead and 2 cm in tissue. A 0.25 mm lead sheet will provide > 99% reduction in exposure.

Continued on next page
The steps used in planning for an I-125 administration are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The Radiation Oncologist will determine the time and the desired radiation dosage to be delivered.</td>
</tr>
<tr>
<td>2</td>
<td>The Medical Dosimetrist or Authorized Radiation Physicist will complete computer dose calculations for the desired dose. A computer dosimetry printout shall be provided for each application.</td>
</tr>
<tr>
<td>3</td>
<td>Using the dosimetry printout, the Radiation Oncologist will indicate the desired radiation dosage to be delivered on the Radioactive Materials Order Form and the I-125 Written Directive, and will sign and date the forms. For easy reference, this and all subsequent steps are listed on the Radiation Oncologist, Resident Physician, and Authorized Radiation Physicist Job Aid for Sealed Source I-125 Application to the Patient.</td>
</tr>
<tr>
<td>4</td>
<td>The Radiation Oncologist should inform the Authorized Radiation Physicist at least 10 days before planned routine treatment. The Authorized Radiation Physicist should be informed at least two weeks before any special application such as the use of multiple isotopes, devices or source types in a single patient procedure.</td>
</tr>
</tbody>
</table>

Continued on next page
Preparing for an I-125 Administration

The steps used in preparing for an I-125 administration are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Before the treatment time, the Authorized Radiation Physicist will prepare the I-125 Sources in conformance to the Treatment Plan specifics listed on the computer dosimetry printout and the Written Directive.</td>
</tr>
<tr>
<td>2</td>
<td>The Authorized Radiation Physicist will place the treatment I-125 sources into the transportable-shielded container.</td>
</tr>
<tr>
<td>3</td>
<td>The Radiation Oncology staff will reserve the patient room (usually one of four shielded rooms on the 6th floor), if the implant involves a patient admission.</td>
</tr>
<tr>
<td>4</td>
<td>Before the use of the patient room, the room shall be fully posted to radiation safety requirements by the Authorized Radiation Physicist.</td>
</tr>
</tbody>
</table>

Administration of I-125 to the patient

The steps used in the administration of I-125 to the patient are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The Authorized Radiation Physicist will perform a source count and check the calibration certificate of the I-125 seeds. Afterward, Physics staff will log out, date and sign the I-125 sources in the Log Out / Log In book maintained in the Hot Lab. Physics staff will sterilize seeds as needed and load seeds into the applicator, if necessary.</td>
</tr>
<tr>
<td>2</td>
<td>The Authorized Radiation Physicist will transport the sources to surgery in a shielded container that reduces exposure to levels than 0.15 mR/hr at a distance of 1 meter from the source.</td>
</tr>
</tbody>
</table>
3. At the operating room, before treatment, the Radiation Oncologist will complete the “Pre Verification” portion of the Written Directive form.

4. The Radiation Oncologist will administer the I-125 sources to the patient. The time of implant will be recorded on the Written Directive Form. During surgical implant, the Physics staff will maintain a running count of seeds inserted with the assistance of the Radiation Oncologist.

5. Authorized Radiation Physicist will conduct a radiation survey of the patient and the surrounding areas in the operating room.

6. Nursing care will be conducted per Summary of nursing care instructions for patients receiving radioactive I-125 implant therapy.

---

Discharge of the Patient

The steps used in the discharge of a patient implanted with I-125 sources are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Patients may be discharged according to USNRC Regulatory Guide 8.39 “Release of Patients Administered Radioactive Material.” If the patient measures an exposure rate greater than 1 mR/hr at 1 meter from the geometric center of the sources, a release calculation will be performed by the Authorized Radiation Physicist and placed in the patient’s chart.</td>
</tr>
</tbody>
</table>
Prior to discharge of the implant patient, the Radiation Oncologist will instruct the patient regarding recommended time of contact with family member, handling of expelled seeds, etc. If the administration site is a neck or a superficial implant, use of the lead shield is required if the exposure rate is greater than 1 mR/hr. If this protective shield is worn to cover the implant area, the radiation level near the patient is minimal and no special distance or time precautions need be observed.

The steps used to return unused I-125 seeds to storage are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The Authorized Radiation Physicist will return any unused I-125 sources to the Hot Lab in the shielded transportation container. This will occur immediately after the implant is complete and the survey is performed.</td>
</tr>
<tr>
<td>2</td>
<td>The Authorized Radiation Physicist will “Log in” the I-125 sources when they are returned to their storage location within the Hot Lab. The logbook will be signed and dated by the Authorized Radiation Physicist.</td>
</tr>
</tbody>
</table>
Emergency Procedures

The steps used for emergency procedures are listed in the table below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Should an I-125 source every come out of a patient, the Resident Physician, the Radiation Oncologist, the Authorized Radiation Physicist and the Radiation Safety Officer are to be contacted immediately regarding the situation. One of these individuals will assume responsibility for returning the source to a shielded container and transporting it back to the Hot Lab.</td>
</tr>
<tr>
<td>2</td>
<td>In the case of patient emergency, The Resident Physician, the Radiation Oncologist and the Authorized Radiation Physicist are to be contacted immediately regarding the situation.</td>
</tr>
<tr>
<td>3</td>
<td>Should an I-125 source come out of a patient after the patient is discharged, the patient should be instructed to recover the source into a jar without touching it, and bring it back to the Radiation Oncologist. However, if the source is discharged during urination, the source should be flushed into the sewage system.</td>
</tr>
</tbody>
</table>

Follow up Procedures

Any follow up procedures will be performed based on the American Brachtherapy Society.
Guidelines for SIR-Spheres

A. Dose Receipt
   • The dose will be accepted and signed for in Nuclear Medicine and the receipt filed.
   • Package will be received as per the package receipt instructions listed in the Radiation Safety Manual.

B. Dose Preparation (step by step)
   • The written directive will be obtained from the authorized user and taken to the hot lab to use for the dose preparation.
   • Unpack SIR-Spheres microspheres, leaving shipping vial in lead pot.
   • Place on the bench top in a lead or acrylic shielded box if available.
   • Remove the center of aluminum seal from sterile v-vial with forceps, and clean the septum with an alcohol swab.
   • Place the v-vial in an empty lead pot (10 cm X 6 cm) for stability and shielding.
   • Insert a short 25 gauge needle through the septum of the vial until it just pierces the septum to create a vent.
   • Remove the SIR-Spheres microspheres shipping vial from the lead pot and shake vigorously to disperse the SIR-Spheres microspheres.
   • Using a dose calibrator, determine the activity in the shipping vial and return it to the lead pot.
     o The Sirsphere Draw Calculation sheet will be completed as the vial and the patient doses are drawn out of the vial.
   • Partially remove the aluminum seal of the SIR-Spheres microspheres shipping vial, then clean with an alcohol swab.
   • Insert a short 25 gauge needle through the septum of the shipping vial to create a vent, ensuring the needle is well clear of the contents in the shipping vial.
   • Use a shielded 5ml syringe with a 21 gauge hypodermic needle at least 50mm long to puncture the septum of the SIR-Spheres microspheres shipping vial and quickly draw back and forth several times in order to mix the SIR-Spheres microspheres thoroughly.
   • Quickly withdraw the pre-calculated patient radiation dose and transfer into the vented v-vial in the other lead pot. Then withdraw the required amount quickly before the contents of the shipping vial starts to settle.
   • Verify the patient dose in the v-vial by re-measuring the activity in the shipping vial with a dose calibrator and correct if necessary.
     o Document all readings on the Patient Calculation Sheet.
     o Draw out other doses as needed per the written directive.
   • Put the v-vial, containing the confirmed patient dose into the dedicated acrylic shield.
   • The v-vial shield will have the patient identification sticker attached.
• The patient doses will be marked as I, II or III as necessary.
• Surveys of each patient dose will be taken with the ion chamber with the dose in the acrylic
  shield. The dose will be placed on the template with the ion chamber in place; 4 readings of the
dose will be taken and averaged with the background subtracted.
• The patient dose(s) is now ready for transport to the SIR-Spheres microspheres implantation
  room. The dose will be transported in shielded containers.
• The Nuclear Medicine technologist or trained personnel from the Radiation Safety Office will
  accompany the dose to the Interventional Radiology suite to ensure security and accountability.
The trained personnel will stay during the procedure for surveying of personnel, materials, and
  room, then take used materials back to the Nuclear Medicine Department.
• There will be a “time out” to insure that the correct patient is receiving the correct dosage by
  identifying the patient with two forms of identification.
• During the injection of the material, if there should require a revision to the dose as prescribed
  on the written directive, the physician will make an oral directive and complete the documents
  as required for oral revisions.

C. IR Suite Preparation
• Tape carpet in place on the floor where the injection will be given.
• Tape sticky pads at each entrance into the room.
• All personnel in the room during the injection will be gloved and wear booties.
• Required inventory for IR Suite
  o Survey meters and shielding containers
  o Tweezers
  o Sir-spheres dose(s) in shielding with written directive
  o Sir-spheres delivery set.
  o Water for injection, contrast, syringes as needed
  o Other material as needed: alcohol pads, gauze pads, stopcock

D. Post dose delivery
• At anytime after the injection of the Sir-spheres, if any personnel need to vacate the room, a
  GM survey of their hands, feet, and other areas as needed will be performed to ensure no
  contamination is present. All personnel in the room during the injection will be surveyed prior
  to leaving the room.
  o If contamination is found, the person will take off the contaminated item. It will be
    taken to Radiation Safety Office to be held for decay. The person will be surveyed and
    cleaned until no contamination is found.
• Prior to leaving the IR suite, the patient will be surveyed at 1 meter and the reading will be
  recorded.
• After the implantation and all personnel in the room during injection are surveyed, the room
  will be surveyed for contamination. All items on the patient bed and around the patient bed
  will be surveyed. Any items found to be contaminated will be held for decay. All waste
  material will be secured by Radiation Safety Office personnel and taken to the storage facility to
  be held for decay.
• Any items found to be contaminated will be cleaned until background levels are reached. All
  items used for cleaning will be taken to the waste storage facility to be held for decay.
• The patient will be taken to the Nuclear Medicine area to have a SPECT scan.
DOSE: 

ASSAY OF VIAL:

<table>
<thead>
<tr>
<th>Activity (mCi)</th>
<th>Date</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Measured activity of full vial:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B. Specific activity: (activity/5 ml)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C. Prescribed patient dose: (mCi)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

VOLUME TO BE DRAWN INTO SYRINGE:

<table>
<thead>
<tr>
<th>ml</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>D. Patient Dose/ specific activity: (C/B)</td>
<td></td>
</tr>
</tbody>
</table>

DOSE TO BE LEFT IN VIAL AFTER DRAW:

<table>
<thead>
<tr>
<th>mCi</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>E. (Activity of vial) – (prescribed dose): (A-C)</td>
<td></td>
</tr>
<tr>
<td>1.1* activity to be left in vial:</td>
<td></td>
</tr>
<tr>
<td>0.9* activity to be left in vial:</td>
<td></td>
</tr>
</tbody>
</table>

MEASURED ACTIVITY IN VIAL AFTER DRAW: (may require multiple attempts – record all attempts below)

| mCi | mCi | mCi | mCi |

ACTIVITY IN SYRINGE PRIOR TO TREATMENT:

<table>
<thead>
<tr>
<th>mCi</th>
<th>Prescribed dose / activity in syringe: (must be +/- 10%)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial activity – residual activity:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Persons performing calculations and draw: ____________________________
**SIRSPHERES SURVEY RECORD**  

**DOSE:**

Date of surveys: __________________________

**PRE-TREATMENT SURVEY:**

- Place dose V-vial into center of Lucite Shield
- Take 4 ion chamber readings @ 30 cm distance from center of container in 4 cardinal directions (use template):
  
  Ion Chamber model and serial number used for all surveys: __________________________

<table>
<thead>
<tr>
<th>$90^\circ$ mR/hr</th>
<th>$180^\circ$ mR/hr</th>
<th>$270^\circ$ mR/hr</th>
<th>$360^\circ$ mR/hr</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Background reading: (mR/hr)  
Average of the 4 readings: (mR/hr)  
Average – Background: mR/hr  
Time of surveys: 

**POST-TREATMENT SURVEY:**

NOTE: Use the same CONTAINER, same 30 cm DISTANCE and the same ION CHAMBER for pre and post surveys.

- Place all IMPLANT related Y-90 contaminated syringe, tubing, pads, in jar and into the Lucite shield
- Take 4 ion chamber readings @ 30 cm distance from center of container in 4 cardinal directions (use template):

<table>
<thead>
<tr>
<th>$90^\circ$ mR/hr</th>
<th>$180^\circ$ mR/hr</th>
<th>$270^\circ$ mR/hr</th>
<th>$360^\circ$ mR/hr</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Background reading: (mR/hr)  
Average of the 4 readings: (mR/hr)  
Average – Background: mR/hr  
Time of surveys: 

Percent dose delivered: $1 - \left(\frac{\text{avg. post reading}}{\text{avg. pre reading}}\right) \times 100$:

\[
\%\]

Dose Delivered: (drawn dose x % dose delivered):

\[
mCi\]

Dose the dose administered differ from the prescribed dose by more than 20%:  
☐ Yes*  ☐ No

*If yes, explanation shall be written on the written directive
Date:_______________________

Survey meter used:_____________________________

Background: ___________________________ mR/hr

Person performing surveys:___________________________

Final Patient Survey @ 1 meter:__________________mR/hr

☐ Survey of individuals are at background levels.

☐ Survey of IR suite are at background. Areas include but are not limited to:
  • Patient bed
  • Floor
  • Counter top
  • Trash cans
  • Sticky pads

*If individuals or room survey are above background levels, items shall be cleaned and resurveyed. The room will not be available for use until areas are at background levels. Any items used for cleaning and items that cannot be cleaned shall be taken to the Radiation Safety Office storage area to be held for decay.
APPENDIX A-6
I-131 Radioiodine Therapy Guide line for Thyroid Treatment (Out-patient) – University of Louisville Hospital

I. Indication

Patients are treated with I-131 only after referral by their physician or consulting endocrinologist. The proposed treatment and its possible late effects are discussed with the patient and all questions are answered by the Nuclear Medicine Physician.

I-131 therapy detects and treats any areas of residual thyroid tissue or tumor.

II. Radiopharmaceutical

1. I-131 Sodium Iodine: Caps or Oral Solution
2. Range: 200 uCi-200 mCi (Out-patient treatment)

III. Patient Preparation

1. For at least 1 month prior to I-131 therapy you must not have had iodine containing preparations (certain vitamin tablets, cough mixtures and kelp tablets) or iodinated contrast agents used for X ray angiograms and CT scans.

2. Thyroid hormone medication will also need to be stopped for approximately 6 weeks before therapy. This will be arranged by your own doctor.

3. In addition, you require certain blood tests on the morning before I-131 administration (to check whether any residual thyroid tissue is adequately stimulated, and a pregnancy test if you are a woman of childbearing age). These tests will be organized by our own doctors.

IV. Pre-Administration

1. Only one technologist needs to perform the whole procedure from start to finish.
2. Technologist needs to have the patients order from referring Physician.
3. On female patient of childbearing age and have not had any surgery, they will need to have a pregnancy test done before the therapy dose is ordered.
4. The directive needs to be printed from E-forms and all other therapy documentation paperwork.
5. The directive needs to be signed by the Nuclear Physician.
6. The explanation sheet needs to be signed by the Patient.
7. The Doses ordering form that is sent to the pharmacy needs to be signed by the Nuclear Medicine Physician.
8. The patient’s informed consent needs to be signed by the Nuclear Medicine Physician, the Technologist, and the Patient before any therapy is given.
9. The technologist documents as much history from the patient onto the Nuclear Medicine history form.
10. The Nuclear Medicine Physician speaks with the patient and then OK’s the dose to be ordered.
IV. Radiopharmaceutical Check-In

1. The prescribed dose from the Nuclear Medicine Physician is ordered, once the physician gives the OK.
2. The technologist sends the signed pharmacy order form to the pharmacy and lets the patient know how long it will be before the dose arrives.
3. The technologist will call the RSO’s (Radiation Safety Office) to inform them the time that the therapy dose was ordered and to what time it is to be expected.
4. Once the dose arrives, A wipe and survey test will be performed and documented into the Syntrac Unit Dose Manager.

V. Dose Administration

1. The technologist will verify and print out any pregnancy results before proceeding to the next steps.
2. The technologist will prep the room for the patient by placing an absorbent chuck onto the table and getting the patient a cup of water to drink, along with the water the technologist will provide a set of gloves and gown for the patient to wear as needed.
3. The Technologist will check labels and assay dose in the dose calibrator and record value in the UDM and print out a patient safety card for the patient.
4. The technologist will make sure that a representative from the RSO’s (Radiation Safety Office) is present along with the Nuclear Medicine Physician before any dose is given to the patient. (In the event that a representative from the RSO’s (Radiation Safety Office) can’t be there it will be documented on the history sheet)
5. The technologist will verify patient information and complete the written directive as listed in the Radiation Safety Manual for Therapies Requiring a Written Directive, and the technologist will also verify that all the appropriate paperwork is completed including the patient consent form before the patient is dosed.
6. The technologist will bring the dose to the patient in the lead pig and set it down on the absorbent check on the table. Then the technologist will use the appropriate tongs to remove the dose from the lead container and open the vial for the patient to take the pill or pills.
7. After the patient is dosed the technologist will have the patient stand and a survey will be taken with the GM meter and the value recorded onto the directive form in mR/hr.
8. The technologist will complete the directive sheet to calculate the release rate before the patient is released from the department. The range is below 500 mrem.
9. The technologist will complete all the paperwork associated with the therapy and a copy will be given to the patient along with the patient safety card.
10. Once the patient has all the paperwork and they are below all the required ranges the patient may be released from the Nuclear Medicine department.
11. The technologist scans and completes all the necessary paperwork and turns the folder into the Nuclear Medicine physician to be read.
12. The technologist needs to schedule the follow up scan 3-5 days post treatment in the scheduling program.
DESCRIPTION

Zevalin (ibritumomab tiuxetan) is the immunoconjugate resulting from a stable thiourea covalent bond between the monoclonal antibody ibritumomab and the linker-chelator tiuxetan. This linker-chelator provides a high affinity, conformationally restricted chelation site for Indium-111 or Yttrium-90. The approximate molecular weight of ibritumomab tiuxetan is 148 kD. The antibody moiety of Zevalin is ibritumomab, a murine IgG1 kappa monoclonal antibody directed against the CD20 antigen. The CD20 antigen is expressed on pre-B and mature B lymphocytes and on > 90% of B-cell non-Hodgkin's lymphomas (NHL).

Ibritumomab tiuxetan is a clear, colorless, sterile, pyrogen-free, preservative-free solution that may contain translucent particles. Each single-use vial includes 3.2 mg of ibritumomab tiuxetan in 2 mL of 0.9% Sodium Chloride.

Indium-111 decays by electron capture, with a physical half-life of 67.3 hours (2.81 days). The exposure rate constant for 1 mCi (37 MBq) of In-111 is 8.3 x 10^-4 C/kg/hr (3.2 R/hr) at 1 cm. Yttrium-90 decays by emission of beta particles, with a physical half-life of 64.1 hours (2.67 days). The exposure rate for 1 mCi (37 MBq) of Y-90 is 8.3 x 10^-3 C/kg/hr (32 R/hr) at the mouth of an open Y-90 vial.

INDICATIONS AND USAGE

Zevalin is a CD20-directed radiotherapeutic antibody administered as part of the Zevalin therapeutic regimen indicated for the treatment of patients with:

- relapsed or refractory, low-grade or follicular B-cell non-Hodgkin's lymphoma (NHL)
- previously untreated follicular NHL who achieve a partial or complete response to first-line chemotherapy.

WARNING: SERIOUS INFUSION REACTIONS, PROLONGED AND SEVERE CYTOPENIAS, and SEVERE CUTANEOUS AND MUCOCUTANEOUS REACTIONS

See full prescribing information for complete boxed warning.

- Serious Infusion Reactions, some fatal, may occur within 24 hours of rituximab infusion.
- Prolonged and Severe Cytopenias occur in most patients.
- Severe Cutaneous and Mucocutaneous Reactions, some fatal, reported with Zevalin therapeutic regimen.
- Do not administer Y-90 Zevalin to patients with altered biodistribution.
- Do not exceed 32 mCi (1184 MBq) of Y-90 Zevalin.

Please see accompanying full prescribing information, including Boxed WARNINGS, for ZEVALIN. Because the ZEVALIN therapeutic regimen includes the use of rituximab, please consult prescribing information for rituximab.

CONTRAINDICATIONS

None.
EQUIPMENT AND SUPPLIES NEEDED FOR ADMINISTRATION

Required Equipment:
- Syringe Shield (lead for Indium-111, acrylic/plastic for Y-90)
- 0.22 micron low protein binding filter (supplies by nuclear pharmacy or by institution)
- Absorbent paper
- 10 ml syringes
- IV tubing with injection port
- 0.9% normal saline
- Butterfly needle or angiocath
- Waterproof gloves
- Alcohol prep pads
- 2 x 2 gauze pads
- 3 way stopcock
- Infusion pump (optional)

Indium-111 Zevalin Biodistribution Scans:
- Radiotracer: 5 mCi Indium-111 Zevalin
- Camera: Dual head LFOV gamma camera
- Collimator: Medium Energy
- Photo-Peak: 172 and 247 keV with a 15-20% window
- Matrix: 256 x 1024 or camera equivalent
- Scan Speed: 10 cm per minute at 48-72 hours
  - 7-10 cm/min for subsequent scans

DOSAGE AND ADMINISTRATION

Administer the Zevalin therapeutic regimen as outlined below.

Initiate the Zevalin therapeutic regimen following recovery of platelet counts to ≥150,000/mm³ at least 6 weeks, but no more than 12 weeks, following the last dose of first-line chemotherapy.

For patients with relapsed or refractory, Low-grade of Follicular NHL, Zevalin may be used
- Platelet count ≥ 100,000/mm³ (see section on platelet counts below to appropriately adjust dose).

All patients treated with Zevalin must have < 25% lymphoma marrow involvement and appropriate bone marrow reserves.

Zevalin Therapeutic Regimen Dosage and Administration

Day 1:
- Premedicate with acetaminophen 650 mg orally and diphenhydramine 50 mg orally prior to rituximab infusion.

- Administer rituximab 250 mg/m² intravenously at an initial rate of 50 mg/hr. In the absence of infusion reactions, escalate the infusion rate in 50 mg/hr increments every 30 minutes to a maximum of 400 mg/hr. Do not mix or dilute rituximab with other drugs.
• Immediately stop the rituximab infusion for serious infusion reactions and discontinue the Zevalin therapeutic regimen.

• Temporarily slow or interrupt the rituximab infusion for less severe infusion reactions. If symptoms improve, continue the infusion at one-half the previous rate.

• Administer 5 mCi In-111 Zevalin over 10 minutes as an intravenous injection within 4 hours following completion of the rituximab infusion. Use a 0.22 micron low-protein-binding in-line filter between the syringe and the infusion port. After injection, flush the line with at least 10 mL of normal saline.

Day 3 or 4:

Whole-body gamma camera images are required 48 to 72 hours following injection of In-111 ZEVALIN to assess biodistribution. Additional optional scans may be necessary to resolve ambiguities. The expected biodistribution of In-111 ZEVALIN must be present before proceeding with the ZEVALIN therapeutic regimen. Please see full Prescribing Information for ZEVALIN for further details on the expected biodistribution of In-111 ZEVALIN.

Do not administer Y-90 ZEVALIN to patients with altered biodistribution.
Re-assess biodistribution after correction of underlying factors.

Day 7, 8 or 9:

Verify that expected biodistribution is present (Please refer to the section ‘Image Acquisition and Interpretation of Biodistribution’ on Page 4)

• Premedicate with acetaminophen 650 mg orally and diphenhydramine 50 mg orally prior to rituximab infusion.

• Administer rituximab 250 mg/m² intravenously at an initial rate of 100 mg/hr. Increase rate by 100 mg/hr increments at 30 minute intervals, to a maximum of 400 mg/hr, as tolerated. If infusion reactions occurred during rituximab infusion on Day 1 of treatment, administer rituximab at an initial rate of 50 mg/hr and escalate the infusion rate in 50 mg/hr increments every 30 minutes to a maximum of 400 mg/hr.

• Administer Y-90 Zevalin injection through a free flowing intravenous line within 4 hours following completion of rituximab infusion. Use a 0.22 micron low-protein-binding in-line filter between the syringe and the infusion port. After injection, flush the line with at least 10 mL of normal saline.

  o If platelet count \(\geq 150,000/\text{mm}^3\), administer Y-90 Zevalin over 10 minutes as an intravenous injection at a dose of Y-90 0.4 mCi per kg (14.8 MBq per kg) actual body weight.

  o If platelet count \(100,000-149,000/\text{mm}^3\), in relapsed or refractory patients, administer Y-90 Zevalin over 10 minutes as an intravenous injection at a dose of Y-90 0.3 mCi per kg (11.1 MBq per kg) actual body weight.

  o Do not administer more than 32 mCi (1184 MBq) Y-90 Zevalin dose regardless of the patient’s body weight.

• Monitor patients closely for evidence of extravasation during the injection of Y-90 Zevalin. Immediately stop infusion and restart in another limb if any signs or symptoms of extravasation occur.
Y-90 Zevalin Administration:

Syringe shields and other materials used in the preparation and administration of the Y-90 Zevalin should be made of materials with low atomic numbers such as Lucite, plastic or acrylic. Lead or leaded glass should not be utilized in order to minimize the higher energy bremsstrahlung thicker shielding requirements with lead.

Prior to administration and post administration, the written directive will be completed as the procedure in the Radiation Safety Manual for Therapies Requiring a Written Directive.

Image Acquisition and Interpretation of Biodistribution

Assess the biodistribution of In-111 Zevalin by a visual evaluation of whole body planar view anterior and posterior gamma images obtained at 48 – 72 hours after injection. Images at additional time points may be necessary to resolve ambiguities. Acquire whole body anterior/posterior planar images using a large field-of-view gamma camera and medium energy collimators. Suggested gamma camera settings: 256 x 1024 matrix; dual energy photopeaks set at 172 and 247 keV; 15% symmetric window; scan speed of 10 cm/min for the 48-72 hour scan, and 7-10 cm/min for subsequent scans.

Expected Biodistribution

- Activity in the blood pool areas (heart, abdomen, neck, and extremities) may be faintly visible.
- Moderately high to high uptake in normal liver and spleen.
- Moderately low or very low uptake in normal kidneys, urinary bladder, and normal (uninvolved) bowel.
- Non-fixed areas within the bowel lumen that change position with time; delayed imaging as described above may be necessary to confirm gastrointestinal clearance.
- Focal fixed areas of uptake in the bowel wall (localization to lymphoid aggregates in bowel wall).

Tumor uptake may be visualized however tumor visualization on the In-111 Zevalin scan is not required for Y-90 Zevalin therapy.

Altered Biodistribution

The criteria for altered biodistribution are met if any of the following is detected on visual inspection of the required gamma images:
• Intense localization of radiotracer in the liver and spleen and bone marrow indicative of reticuloendothelial system uptake.

• Increased uptake in normal organs (not involved by tumor) such as:
  o Diffuse uptake in normal lung more intense than the liver.
  o Kidneys have greater intensity than the liver on the posterior view.
  o Fixed areas (unchanged with time) of uptake in the normal bowel greater than uptake in the liver.
  o In less than 0.5% of patients receiving In-111 Zevalin, prominent bone marrow uptake was observed, characterized by clear visualization of the long bones and ribs.

Consider bone marrow involvement by lymphoma, increased marrow activity due to recent hematopoietic growth factor administration, and increased reticuloendothelial uptake in patients with HAMA and HACA, as possible causes of prominent bone marrow uptake. Re-assess biodistribution after correction of underlying factors.

Altered Biodistribution

Do not administer Y-90 Zevalin to patients with altered biodistribution of In-111 Zevalin. In a post-marketing registry designed to collect biodistribution images and other information in reported cases of altered biodistribution, there were 12 (1.3%) patients reported to have altered biodistribution among 953 patients registered.

HAMA/HACA

Incidence of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparisons of the incidence of HAMA/HACA to the Zevalin therapeutic regimen with the incidence of antibodies to other products may be misleading.

HAMA and HACA response data on 446 patients from 8 clinical studies conducted over a 10-year time period are available. Overall, 11/446 (2.5%) had evidence of either HAMA formation (N=8) or HACA formation (N=4). Six of these patients developed HAMA/HACA after treatment with Zevalin and 5 were HAMA/HACA positive at baseline. Of the 6 who were HAMA/HACA positive, only one was positive for both. Furthermore, in 6 of the 11 patients, the HAMA/HACA reverted to negative within 2 weeks to 3 months. No patients had increasing levels of HAMA/HACA at the end of the studies.

WARNINGS AND PRECAUTIONS

Serious Infusion Reactions
See also prescribing information for rituximab.

Rituximab, alone or as a component of the Zevalin therapeutic regimen, can cause severe, including fatal, infusion reactions. These reactions typically occur during the first rituximab infusion with time to onset of 30 to 120 minutes. Signs and symptoms of severe infusion reactions may include urticaria, hypotension, angioedema, hypoxia, bronchospasm, pulmonary infiltrates, acute respiratory distress syndrome, myocardial infarction, ventricular fibrillation,
and cardiogenic shock. Temporarily slow or interrupt the rituximab infusion for less severe infusion reactions. Immediately stop rituximab, In-111 Zevalin, or Y-90 Zevalin administration for severe infusion reactions.

**Prolonged and Severe Cytopenias**
Cytopenias with delayed onset and prolonged duration, some complicated by hemorrhage and severe infection, are the most common severe adverse reactions of the Zevalin therapeutic regimen. When used according to recommended doses, the incidences of severe thrombocytopenia and neutropenia are greater in patients with mild baseline thrombocytopenia (100,000 to 149,000 /mm$^3$) compared to those with normal retreatment platelet counts. Severe cytopenias persisting more than 12 weeks following administration can occur [see Boxed Warning and Adverse Reactions (6.1)].

**Embryo-Fetal Toxicity**
Based on its radioactivity, Y-90 Zevalin may cause fetal harm when administered to a pregnant woman. If the Zevalin therapeutic regimen is administered during pregnancy, the patient should be apprised of the potential hazard to a fetus [see Use in Specific Populations (8.1)].

**Extravasation**
Monitor patients closely for evidence of extravasation during Zevalin infusion. Immediately terminate the infusion if signs or symptoms of extravasation occur and restart in another limb.

**Immunization**
The safety of immunization with live viral vaccines following the Zevalin therapeutic regimen has not been studied. Do not administer live viral vaccines to patients who have recently received Zevalin. The ability to generate an immune response to any vaccine following the Zevalin therapeutic regimen has not been studied.

**Laboratory Monitoring**
Monitor complete blood counts (CBC) and platelet counts following the Zevalin therapeutic regimen weekly until levels recover or as clinically indicated.

**Radionuclide Precautions**
During and after radiolabeling Zevalin with In-111 or Y-90, minimize radiation exposure to patients and to medical personnel, consistent with institutional good radiation safety practices and patient management procedures.

**POST-TREATMENT PRECAUTIONS**
Advis patients:
- To contact a healthcare professional for severe signs and symptoms of infusion reactions.
- To take premedications as prescribed [see Dosage and Administration (2.2) and Warnings and Precautions (5.1)].
- To report any signs or symptoms of cytopenias (bleeding, easy bruising, petechiae or purpura, pallor, weakness or fatigue).
- To avoid medications that interfere with platelet function, except as directed by a healthcare professional [see Warnings and Precautions (5.2)].
- To seek prompt medical evaluation for diffuse rash, bullae, or desquamation of the skin or oral mucosa.
- To immediately report symptoms of infection (e.g. pyrexia) [see Adverse Reactions (6.3)].
- That immunization with live viral vaccines is not recommended for 12 months following the Zevalin therapeutic regimen [see Warnings and Precautions (5.8)].
- To use effective contraceptive methods during treatment and for a minimum of 12 months following Zevalin therapy.
- To discontinue nursing during and after Zevalin treatment [see Use In Special Populations (8.3)].
PATIENT FOLLOW-UP

The patient will be followed by Medical Oncology. In general, complete CBC and platelet count are obtained weekly until levels recover or as clinically indicated.

REFERENCES


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1. The decision regarding the treatment with intraperitoneal P-32 is made at the time of surgery. If the treatment is thought to be appropriate, 1 or 2 small polyethylene catheters are left intraperitoneally through separate stab wounds. Very fine catheters can be removed without significant abdominal leakage. If larger catheters are used, a purse-string suture is usually inserted at the time of the abdominal surgery. The Radiation Physicist should complete and the Authorized User Radiation Oncologist should sign the Radioactive Materials Order form and the Written Directive Form
   a. Record Patient Name
   b. Record Date of Completion of Written Directive
   c. Record Date of Administration
   d. Record Time of Administration
   e. Note Treatment Site (e.g. Bone)
   f. Note Diagnosis and Procedure (e.g. ovarian carcinoma, etc.)
   g. Indicate if this is a female patient of childbearing age
   h. If the response to g) is yes, indicate the method to determine the patient is not pregnant
   i. Indicate the Radioisotope requested (e.g. P-32, etc.)
   j. Indicate the route of administration (e.g. intraperitoneal, etc.)
   k. Indicate activity in mCi
   l. Indicate the Company that supplies the radiopharmaceutical (e.g. Cardinal Health)
   m. Indicate the attending physician (not the resident) requesting the radiopharmaceutical procedure
   n. Have the attending physician (not the resident) sign the written directive

2. Documentation of Distribution: Before administering the P-32, adequate distribution throughout the abdominal cavity (intraperitoneally) must be documented. Documentation is possible through two basic techniques:
   a. Administration of Radio-opaque Dye. The procedure is usually done in the Diagnostic Radiology Department. 60 cc of gastrografin is mixed with 300 cc of saline.
      i. A flatplate of the abdomen is taken
      ii. Approximately 200 cc of the gastrografin saline mixture is infused intraperitoneally. This may be monitored fluoroscopically.
      iii. The patient is then “rocked” on the diagnostic table to distribute the dye.
      iv. The second flatplate of the abdomen is taken to visualize the distribution of contrast and to ascertain adequate distribution.
   b. Use of Radioactive Tracer Isotopes
      i. Adequate distribution can be documented with the use of Tc-99m. The procedure is done in the Nuclear Medicine Department.
      ii. The following items must accompany the patient, 2 bags of 500 cc V.S., I.V. tubing, 4 x 4 dressings, sterile gloves, and tape.
      iii. One millicurie of Tc-Sulfur Colloid is mixed with 500 cc of saline. Note: It is important to order the Tc-99m in a 10 cc volume solution. The majority of the radioactive material can be easily mixed with the 500 cc of saline.
      iv. Approximately 200 cc of the mixture is infused and then a scan is performed to check the adequacy of the distribution.
3. Complete Package Receipt section of Survey Record Form
   a. Order source
   b. Indicate the Well Counter, model, serial number. Indicate the Survey Meter, model, serial number
   c. Indicate the Patient Name and Date of the survey
   d. Indicate the Survey Meter Reading at the surface in mR/hr
   e. Indicate the Survey Meter Reading at 1 meter in mR/hr
   f. Open the package and look for signs of discoloration, leakage or dampness.
   g. Indicate the results of a surface wipe performed on innermost package in dpm/100 cm² (use tongs, do not wipe with hands)
   h. Indicate the results of a background count and calculate disintegrations per minute (dpm) above background
   i. Action level readings: > 200 mR/hr at the surface, > 10 mR/hr at 1 meter, > 200 dpm/100 cm²
   j. If action levels are exceeded, do not use package. Place in a plastic bag and notify Radiation Safety – 852-5231

4. Complete Pre-Verification Section of Written Directive Form
   a. Record Patient Name
   b. Record Date of Completion of Pre-Verification section of Written Directive Form
   c. Record Date of Administration
   d. Record Time of Administration
   e. Record Treatment Site (e.g. Peritoneum)
   f. Record Radioisotope to be administered (e.g. P-32)
   g. Indicate the route of administration (e.g. intraperitoneal, etc.)
   h. Indicate what two methods are used to identify the patient
   i. Assure that the patient has signed the consent form for P-32 administration
   j. Place P-32 Technical Information Sheet in the patient’s chart and give the patient a copy of the Patient Information Sheet

5. Administer radionuclide (P-32) to Patient and Complete Survey Section of Written Directive Form
   a. Have the patient lie on chucks; spread chucks on the floor and around the patient.
   b. Have the physician administer the injection of P-32
   c. Indicate survey meter manufacturer, model number, serial number, and calibration due date (on meter)
   d. Survey patient at 1 meter and record results on the Initial Reading line of Radiation Survey section
   e. Survey hands, feet and clothing of physician and physicist after handling radioactive or P-32
   f. Radiation Physicist will collect waste from the administration of the radionuclide into a plastic bag, seal it, date it, indicate the nuclide, and when the material may be disposed (15 half lives or 7 months). The bag will be stored in the Isotope Room (Hot Lab) in Radiation Oncology, then transferred to Radiation Safety for decay.
   g. Place a yellow radioactive sticker on the patient’s door. Place Nursing Instructions on the patient’s door and in the patient’s chart.
   h. Instruct the nurses to move the position of the bed 30 degrees above and below horizontal every ½ hour for 4 hours, every hour for the next 8 hours and 2 hours for the next 12 hours. The patient is normally discharged 24 hours after the procedure.
   i. When the patient is released (usually after 24 hours in the hospital), indicate Patient Release (check box) survey the room, and indicate readings at the bed, and linens (chucks)
   j. Store linens for 15 half lives (7 months) by transferring them to Radiation Safety for decay.

6. Complete Post Verification section of Written Directive Form
   a. Indicate this was the correct patient
b. Indicate correct radioisotope was administered
c. Indicate correct route of administration
d. Indicate correct administered activity
e. Have physician (resident physician is OK here) sign and date Post Verification Section

7. Complete Room Survey and Outgoing Package Survey section of Survey Record Form (Action levels in 3 i) above).
   a. Record Room Survey results of radiation survey in 4 g) on the Survey Record Form as well as the Written Directive Form
   b. Perform Room Survey wipes for patient bed, floor, counter and tray (if used). Record on Survey Record Form
   c. The floor nurse verifies the room is cleared by Radiation Safety for occupancy by another patient.
   d. Perform Outgoing Package Survey at surface, record reading on Survey Record Form
   e. Wipe package, subtract background and record readings on Survey Record Form for return of empty package
   f. Place Cardinal Health order form on Patient Release Calculation, place prescription administration form on Survey Record Form
   g. Radiation Safety stores any radioactive material (bed linens, etc.) for decay of at least 15 half-lives (7 months)
   h. If there is a source spill or other emergency, notify in order: Resident Physician, Radiation Oncologist, Radiation Physicist, and the RSO.
   i. Bill patient according to Physics Billing Sheet and prepare Special Medical Physics Consultation Report (77370)