

RADIATION SAFETY MANUAL FOR DUKE UNIVERSITY AND DUKE UNIVERSITY MEDICAL CENTER

**RADIATION SAFETY DIVISION
OCCUPATIONAL AND ENVIRONMENTAL SAFETY OFFICE
DUKE UNIVERSITY
DURHAM, NORTH CAROLINA**

**Revision Date: June 2016
Last Review Date: June 2016**

Contents

I. INTRODUCTION.....	3
II. FUNCTIONS AND RESPONSIBILITIES.....	7
III. ESCALATED ENFORCEMENT POLICY	13
IV. AUTHORIZATION TO USE RADIOACTIVE MATERIAL AND RADIATION SOURCES.....	15
V. PERSONNEL MONITORING.....	24
VI. REPRODUCTIVE HEALTH POLICY	30
VII. RADIATION SAFETY POLICIES FOR RESEARCH LABORATORIES	31
VIII. CAMPUS AND MEDICAL CENTER ACCELERATOR FACILITIES	40
X. RADIATION SAFETY TRAINING.....	43
XI. CLINICAL RADIATION SAFETY PROCEDURES	46
XII. EMERGENCY PROCEDURES FOR RADIOACTIVE MATERIAL	53
XIII. POLICY REGARDING ACCESS TO RADIOACTIVE MATERIAL PRESENT IN QUANTITIES OF CONCERN.....	53

I. INTRODUCTION

The policies outlined in the Duke University Radiation Safety Manual are intended to ensure that the use of radioactive material, ionizing radiation sources and radiation producing machines is in accordance with applicable State and Federal regulations and accepted standards for the protection of health and the minimization of hazard to life or property.

The statutory basis of the Duke University Radiation Safety Program includes, but is not limited to the following: 10A NCAC 15 (North Carolina Regulations for Protection Against Radiation, re-codified from 15A NCAC 11 effective 2/1/2015), 10 CFR 20 (Title 10 Code of Federal Regulations, Part 20), 10 CFR 35, 21 CFR 361, 10 CFR 37 and the radioactive material and accelerator licenses Duke holds with the State of North Carolina, as amended. Due to frequent changes in the regulatory climate and the needs of the users of radioactive material at Duke University, all policies and procedures outlined in this Manual shall be considered to be subject to change. The Duke University Radiation Safety Officer will transmit new policy information to the Authorized Users of radioactive material and radiation sources via the Occupational and Environmental Safety Office Web site, electronic mail or campus mail following approval by the Radiation Safety Committees. This manual is an overview of general radiation safety policies for the Duke University main campus and the Medical Center. Policies and standard operating procedures for specific programs are available on-line or at the Radiation Safety Division's office.

Although the safe use of lasers and other forms of non-ionizing radiation is an area of oversight by the Committees, complete coverage is provided in separate documents. Specific information on the organization, policies, procedures and training programs of the Laser Safety Program may be obtained by contacting the Radiation Safety Division.

A. ORGANIZATION OF RADIATION SAFETY PROGRAMS AT DUKE UNIVERSITY

The organization of the Radiation Safety Program at Duke University reflects the intent of North Carolina State and Federal laws regarding the administration of radiation protection programs.

The Administration of Duke University appoints two Radiation Safety Committees, one to provide radiation protection oversight to the Medical Center, the Medical School and selected Duke University Health System entities, and another for the University accelerator facilities and laboratories. The Duke Radiation Safety Officer reports to both Committees. The policies of the Committees are executed by the Radiation Safety Officer through the Radiation Safety Division of the Duke Occupational and Environmental Safety Office (OESO), hereinafter referred to as the "Radiation Safety Division". The Radiation Safety Division, in turn, provides guidance and oversight to Authorized Users of

radiation producing devices and radioactive material. In addition, the Radiation Safety Division provides support to the Radioactive Material Waste Program of OESO's Environmental Programs Division and provides oversight for the Laser Safety Program. To such an extent as required by inter-institutional agreements or North Carolina Regulations for Protection against Radiation, the Radiation Safety Committees and the Radiation Safety Division will provide guidance to the Radiation Safety programs of those components of the Duke University Health System which employ radiation-producing machines and/or utilize radioactive material.

1. *Administration* -- The Duke University/Medical Center administration works through the Committees and the Radiation Safety Officer to provide institutional oversight of radiation safety programs.
2. *Committees* -- The Duke University Committee on Radiological Safety ("University Committee"), the Duke University Medical Center Radiation Control and Radioactive Drug Research Committee ("Medical Center Committee"), and the Accelerator Radiation Safety Committees are responsible for establishing and enforcing policies and procedures for the procurement, use and disposal of radioactive material, devices emitting non-ionizing and ionizing radiation, and lasers.
3. *Radiation Safety Officer* -- The Radiation Safety Officer is the on-the-job representative of the University and Medical Center Committees for providing information and assistance on radiation safety matters and to assure adherence to regulations issued by the Committees and State or Federal agencies.
4. *Accelerator Director* -- provides administrative support to a specific campus accelerator facility.
5. *Radiation Safety Manager* -- provides local radiation safety support to a specific campus accelerator facility.
6. *Authorized User* -- Any person authorized by the University or Medical Center Committee to use or supervise the use of radioactive material and/or devices producing ionizing or non-ionizing radiation.
7. *Radiation Worker* -- A person utilizing ionizing radiation under the supervision of an Authorized User.

B. THE PRINCIPLE OF "ALARA"

Every employee of Duke University and its affiliated institutions is protected from unnecessary exposure to ionizing radiation by Federal and State law. Accordingly, every Duke employee is empowered to minimize his/her radiation exposure by being (a) advised of their recorded radiation exposure in relation to regulatory limits, and (b) informed about protective practices that can reduce exposure through education and training.

The United States Nuclear Regulatory Commission (US NRC regulations and the North Carolina Administrative code proscribe "maximum permissible dose limits" for individuals who are exposed to radioactive material or radiation sources during the course of their employment. These limits, which have been recommended to the Nuclear Regulatory Commission by various government and private advisory organizations, are believed to represent exposure levels that should not result in harm to the worker or his or her offspring during their lifetime.

In view of the uncertainty of the effects of low level radiation exposure, it appears prudent to keep all radiation exposures and releases of radioactive material to the environment to the lowest possible levels. This is the philosophy underlying the concept of "As Low As Reasonably Achievable", or ALARA. This principle is incorporated in North Carolina regulations by requiring that licensees implement policies and procedures so that environmental releases and personnel doses are in accordance with ALARA, and not simply meeting published regulatory limits. A program fully complying with ALARA will be within or below 10% of such limits.

"Occupational dose" refers to the radiation dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or licensed radioactive material. Occupational dose does not include the dose received from background radiation, as a patient from medical procedures, from voluntary participation in medical research programs, or as a member of the general public.

Table 1 lists the maximum permissible doses to personnel from ionizing radiation, as set forth in 10A NCAC 15. A column identifying current Duke University ALARA action levels has also been included for reference purposes.

Table 1. Annual Occupational Dose Limits and ALARA Goals

Body Part Exposed	Annual Occupational Limit	Duke ALARA goal (rem/calendar quarter)
Whole body (head, trunk, gonads, arms above elbows, legs above knees)	5.0 rem (50 mSv)	0.125 rem (1.25 mSv)
Lens of the eye	15 rem (150 mSv)	0.375 rem (3.75 mSv)
Single organ	50 rem (500 mSv)	1.25 rem (12.5 mSv)
Hands and forearms, ankles and feet	50 rem (500 mSv)	1.25 rem (12.5 mSv) [3.0 rem for PET]
Skin of whole body	50 rem (500 mSv)	1.25 rem (12.5 mSv)
Embryo/Fetus (see Note below)	0.5 rem (5 mSv) during gestational period	0.5 rem (5 mSv) during gestational period

Note on Fetal Radiation Dose: Fetal radiation dose is determined by appropriate monitoring of the declared pregnant woman. It is recommended that all women who work with radioactive material, who participate in the care of patients who are being treated with radionuclides, or who work in proximity to radiation-producing devices, declare their pregnancy (see Chapter VI, *Reproductive Health Policy*) in order to obtain appropriate monitoring and counseling.

II. FUNCTIONS AND RESPONSIBILITIES

Each component of the Duke University Radiation Safety chain of organization has specific responsibilities concerning the safe use of radioactive material and radiation sources. The functions, responsibilities, and enforcement duties of the major components are as follows:

A. ADMINISTRATION

The Duke University/Medical Center Administration is responsible for:

1. Establishment of a formal radiation safety structure that includes Radiation Safety Committees for Duke University and Duke University Medical Center and appointment of a Radiation Safety Officer.
2. Institutional oversight for specific accelerator licenses at Duke University/Medical Center through the Committees and the Radiation Safety Officer.
3. Commitment to the ALARA program.

B. COMMITTEES

The Medical Center and University Committees and each Local Accelerator Radiation Safety Committee, in collaboration with the Radiation Safety Officer and the Radiation Safety Division, shall:

1. Determine the adequacy of the training and experience of Authorized Users to possess and use radioactive material and radiation sources under the University and Medical Center's licenses.
2. Review applications for the use of radiation to determine the adequacy of associated equipment, facilities and safety procedures.
3. Establish maximum permissible occupational radiation levels for keeping individual and collective doses as low as reasonably achievable (ALARA).
4. Require any Authorized User of radioactive material, radiation-producing devices and/or lasers to allow inspections to assure safe operation.
5. Provide oversight for the specific accelerator licenses.
6. Require cessation of any operation involving radiation upon a determination of inadequate safety procedures.
7. Meet at least four times a year, or at a frequency determined by the Radiation Safety Officer, to review radiation safety issues and receive a status report on such issues from the Radiation Safety Officer. The Chairs of the Committees have the authority to make temporary policy decisions

when a formal Committee meeting cannot be scheduled in a timely fashion. Such temporary policy decisions are subject to a full review by the Committee at its next meeting.

8. Meet at the call of the Chairman to resolve matters of an emergency nature relating to health and safety arising from the use of radiation.
9. Participate in an annual review of the Radiation Safety Program, in collaboration with the Radiation Safety Officer.
10. Advise the Duke Administration regarding matters of radiation protection.
11. Provide oversight of the safe operation of lasers through formation of Laser Safety Committees. Policies and procedures of the Laser Safety Committees shall be implemented through the Laser Safety Manager.

In addition, each Local Accelerator Radiation Safety Committee shall:

1. Review and approve all proposed changes to the facility, procedures and technical specifications.
2. Assist in design of new accelerator configurations.
3. Review the operation and operational records of the facility.
4. Review unusual or abnormal occurrences or performance of equipment which are reportable under State of North Carolina Regulations.
5. Review and approve Authorized Accelerator Operators.

C. RADIATION SAFETY OFFICER AND DIVISION

1. The Radiation Safety Officer shall:
 - a. Determine compliance with policies issued by the Committees and by Federal, State and Local agencies.
 - b. Supervise radiation control activities.
 - c. Review all proposals for the use of radionuclides and radiation-producing devices and conditions of their use and transmit such proposals to the Committees with recommendations for approval or disapproval. This includes proposals for the investigational use of radioactive drugs in humans, as a member of the Radioactive Drug Research Committee.
 - d. Have the authority to halt operations involving radioactive material or radiation machines if unsafe or unacceptable conditions exist.
 - e. Control acquisition and transfers of radionuclides to individuals on and off campus and ensure that individual and institutional possession limits are not exceeded.
 - f. Implement institutional accelerator safety policies and regulations, as determined by the Committees.

- g. Through the Laser Safety Manager, implement the policies and procedures of the Laser Safety Committees.
 - h. Prepare an annual report for each radiation safety program.
 - i. Prepare license amendments and maintain timely renewals of licenses.
2. The Radiation Safety Division, under the supervision of the Radiation Safety Officer, shall:
- a. Maintain radiation dosimetry records of all persons issued personnel monitors and maintain records of bioassay results.
 - b. Maintain a registry of all campus facilities subject to the radiation safety program.
 - c. Maintain records of radioisotope procurement and disposal in a form suitable for timely retrieval and reporting to regulatory agencies.
 - d. Assist users in the storage, use and disposal of radioactive material at the laboratory level.
 - e. Audit clinical and research laboratories, and accelerator facilities, through meetings with Authorized Users and their designees and periodic inspection of operations, reporting any issues of non-compliance to the Radiation Safety Officer.
 - f. Monitor the Authorized Users' procurement, transportation, storage, use and disposal of radioactive materials to ensure compliance with the State of North Carolina licenses, the institutional ALARA program and applicable USDOT and EPA regulations.
 - g. Coordinate a radioactive waste management program for waste to be disposed of outside the laboratory setting in conjunction with the Environmental Programs Division of OESO. This includes receipt of waste, decay-in-storage, burial, incineration and disposal through commercial vendors.
 - h. Provide operational support to the Laser Safety Manager.
 - i. Calibrate radiation survey instruments for Authorized Users when required.
 - j. Perform leak tests on sealed sources as required by State regulations.
 - k. Receive, inspect and distribute incoming shipments of radioisotopes as required by North Carolina State and USDOT regulations.
 - l. Conduct educational programs in the safe use of radionuclides and radiation-producing machines through formal courses and electronic media.
 - m. Conduct an environmental monitoring program to ensure regulatory compliance.
 - n. Investigate incidents involving radioactive material or violations of regulations.

- o. Respond to emergencies and supervise decontamination operations by the Authorized Users.
- p. Monitor inpatient therapies utilizing unencapsulated or encapsulated radioactive material as required, and assist in determining when appropriate discharge criteria have been met.

D. ACCELERATOR FACILITIES

1. Each Accelerator Director shall:
 - a. Establish a local Accelerator Radiation Safety Committee structure that includes appointing local Committee members and a local Radiation Safety Manager.
 - b. Provide an operational budget and necessary personnel support for the management of the accelerator radiation safety program.
 - c. Function as a representative of the Duke Administration in the local Accelerator Radiation Safety Committee meetings.
 - d. Commit to the ALARA program.
2. Each local accelerator Radiation Safety Manager shall:
 - a. Be authorized to terminate immediately any project or operation that is found to be a threat to the health of employees and/or members of the public, or to the property or environment of the University and local community. Such operational decisions are subject to full review by the institutional Committees and the institutional Radiation Safety Officer.
 - b. Execute established radiation safety policies and ensure compliance with State of North Carolina license conditions.
 - c. Supervise radiation control activities.
 - d. Halt accelerator operations if unsafe or unacceptable conditions exist.

E. MARINE LAB AUTHORIZED USERS

The Duke University Marine Laboratory (DUML) does not have a full-time Radiation Safety specialist on site. Therefore each DUML Authorized User shall, in consultation with the Duke Radiation Safety Officer of his/her designee, be responsible for the following:

1. Approval of all DUML radioisotope purchase orders.

2. Ensuring that received radioactive packages are inspected at the time of receipt in accordance with the applicable regulations.
3. Ensuring that the use of radioactive material by Duke University Authorized Users aboard research vessels is in compliance with the applicable regulations in all jurisdictions, in conjunction with the Duke Radiation Safety Officer or his/her designee.

F. AUTHORIZED USER

Each Authorized User shall:

1. Develop written procedures for the use of radiation sources or radioactive material as appropriate for the intensity and scope of the activities covered in the Authorized User's laboratory and commensurate with good radiation protection practices.
2. Furnish all information requested by the Committee or Radiation Safety Officer concerning his/her qualifications, facilities, equipment and safety procedures.
3. Maintain records as required by this Manual.
4. Designate an alternate Authorized User to provide oversight of his/her laboratory operations during absences exceeding thirty days, and to transmit this information to the Radiation Safety Officer.
5. Comply with the applicable portions of this Manual.
6. Ensure that each individual using radioisotopes under his/her supervision has received radiation safety training appropriate to such use and to include special instructions for pregnant women or women of child-bearing potential.
7. Notify the Radiation Safety Officer of any changes in authorization status.
8. Notify the Radiation Safety Officer of intention to terminate the Authorization, no later than thirty days prior to the proposed termination.
9. Ensure that (a) survey meters in his/her lab are not used unless calibrated or operationally checked (as appropriate) by the Radiation Safety Division within the past 12 months, and (b) contact Radiation Safety when obtaining new survey meters, or if a meter requiring calibration or an operational check is discovered in the lab.

G. RADIATION WORKER

Each individual working with unsealed radioactive material, sealed sources or radiation-producing machines shall:

1. Understand and implement the appropriate radiation safety precautions for the specific radioactive nuclide(s) being used.
2. Conduct operations so as to minimize exposure (internal and external) to all personnel in the laboratory.
3. Wear a personnel monitor and/or ensure performance of bioassay procedures, as directed in Chapter V (*Personnel Monitoring*) and make the monitor available for scheduled exchanges.
4. Periodically survey his/her hands, feet and clothing, and the work area for contamination.
5. Periodically survey around storage and waste areas.

III. ESCALATED ENFORCEMENT POLICY

A. PURPOSE

This section specifies the actions of the Radiation Safety Officer (RSO) and the appropriate Radiation Safety Committee to correct specific items of non-compliance, ensuring that radiation users work with the Radiation Safety Officer and the Committee to maintain safety and compliance.

B. ENFORCEMENT PROCESS

1. The Radiation Safety Division auditor will provide the Authorized User (AU) with written notification of any items of non-compliance discovered in that Authorized User's area of responsibility. If appropriate, the Radiation Safety Division auditor may request a written response from the Authorized User regarding corrective measures for any items of non-compliance discovered during routine laboratory audits. Any such written response shall be provided by the Authorized User to the auditor on or before the date specified in the written notification.
2. Documented compliance issues should be resolved between the Authorized User and the RSO or his/her designee.
3. If routine Radiation Safety Division surveys show a repeat violation (i.e. same item cited on last inspection) or other pattern of multiple violations, the Authorized User must, within one week (or five business days) of notification, e-mail the laboratory auditor with a copy to the RSO, a brief written explanation of:
 - a. what caused the item(s) of non-compliance,
 - b. actions taken to date by the Authorized User to correct the item(s), and
 - c. corrective actions the Authorized User took or will take to prevent recurrence.
4. If the Authorized User has *not* achieved compliance to the satisfaction of the Radiation Safety auditor within a specified period of notification, an Operational Manager and the Authorized User will discuss the matter.
5. If satisfactory resolution still cannot be obtained at the Operational Manager level, the matter will be escalated to the RSO. The RSO may consult, with his/her own discretion, *key administration leadership*, including the appropriate chair of the Radiation Safety Committee, OESO director, the Departmental Chair, Dean, Vice Provost, and the Duke Compliance Officer.

C. ENFORCEMENT OPTIONS

1. Radiation Safety Intervention:

The Radiation Safety Officer is authorized to immediately order the termination or limitation of any procedure or other laboratory activity that in his/her professional opinion constitutes an immediate danger to life, health, property, or the environment. The RSO is also authorized to order the termination or limitation of any procedure or laboratory activity of an Authorized User who willfully violates the policies outlined in this Manual. Such intervention may include, but is not necessarily limited to, the suspension of radioactive materials orders, the withholding of pending deliveries of radioactive material and the confiscation of existing stocks of radioactive materials. The RSO will notify the Authorized User, the chair of the appropriate Radiation Safety Committee and appropriate senior management.
2. Withholding Material:
 - a. With the exception of the clinical use areas (Radiology, Radiation Oncology and Radiopharmacy), the RSO or his/her designee may withhold delivery of radioactive material from any Authorized User failing to meet their Radiation Safety Manual responsibilities. The RSO will immediately notify the Authorized User, the Authorized User's Departmental Chair or Faculty Dean, and the appropriate Institutional Administrators of any material being held and of the reason the material is being held.
 - b. The withheld material will be delivered immediately upon fulfillment of the outstanding obligations by the Authorized User.
3. Restriction and Revocation
 - a. The Chairman of the appropriate Radiation Safety Committee may, upon the RSO's recommendation, restrict the authority of an Authorized User as a result of repeated or serious violations of Duke University/Medical Center policy. The RSO or his/her designee shall immediately notify the Authorized User, the Authorized User's Departmental Chair or Faculty Dean, and the appropriate Institutional Administrators of any restriction and of the reason for that restriction.
 - b. Such restriction remains in effect until the appropriate Radiation Safety Committee either reinstates, modifies, or revokes the restricted privileges by a majority vote.

IV. AUTHORIZATION TO USE RADIOACTIVE MATERIAL AND RADIATION SOURCES

A. TYPES OF AUTHORIZATIONS

The two types of Authorizations to use radioactive material and radiation sources at Duke University and the Medical Center are:

1. Authorization for use in scientific research or other applications that do not involve human subjects; and
2. Authorization for clinical or research use in humans.

In addition, shipboard use associated with the Duke University Marine Laboratory must be covered under either the Duke University license or a license issued by the United States Nuclear Regulatory Commission, an Agreement State, or other recognized licensing agency.

B. STATUS OF AUTHORIZATIONS

The "status" of each Authorization (and Authorized User) falls into one of following three categories:

1. **Active:** The user is authorized by the Committees to use, purchase and possess radioactive material including equipment containing sealed sources, irradiators, or radiation producing machines. A person must remain classified as "active" if they possess any amount of usable unencapsulated radioactive material or if they are using equipment containing sealed sources, irradiators, or radiation producing machines.
2. **Inactive:** The user is authorized to use, purchase and possess radioactive material including equipment containing sealed sources, irradiators, or radiation producing machines. However, an inactive user has chosen not to perform experiments utilizing unencapsulated radioisotope or use radiation equipment for an extended period of time. An inactive user shall have no usable unencapsulated radioactive material (including radioactive waste) in their possession. A user who wishes to change to inactive status must notify the Radiation Safety Officer in writing of this decision. Inactive users who have equipment containing sealed sources, irradiators, or radiation producing machines must transfer them to an active Authorized User or dispose of them prior to requesting "inactive" status. "Inactive" status is confirmed only upon a close-out audit of the Authorization conducted by the Radiation Safety Division. If an inactive user desires to reinstate their "active" status, they must notify the Radiation Safety Officer in writing and fulfill "Active" status training requirements.

3. Terminated: The Authorized User is no longer employed by Duke University; is deceased; or has terminated, by their own choice or by the direction of the Committees, their Authorization to use, order or possess radioactive material including equipment containing sealed sources, irradiators, or radiation producing machines. This person has no radioactive material, equipment containing radioactive material, or radiation producing equipment. A "terminated status" Authorized User shall have a completed (either prior to termination or in absentia) a "close-out" procedure, in which the inventory of radioactive material under the Authorization has been disposed or transferred, radioactive waste has been removed, and rooms and facilities have been surveyed and determined to be free of radioactive contamination. Documentation of the "close-out" will be maintained by the Radiation Safety Division.

C. NON-HUMAN RESEARCH USE OF RADIOACTIVE MATERIAL

1. QUALIFICATIONS

a. Full-time Duke Faculty

An applicant for non-human radioisotope use shall be a full-time member of the faculty and have both training and experience commensurate with the types and quantities of radioactive material for which application is being made. "Full time member of the faculty" generally means a person holding a faculty rank that carries voting privileges on the Duke University Academic Council and permits a position on Departmental review panels for appointment, re-appointment and promotion of faculty. Such positions include, but are not necessarily limited to, the following: Professor, Associate Professor, and Assistant Professor; Research Professor, Associate Research Professor, and Assistant Research Professor; Associate and Assistant Professors Tracks IV/V; Professor "of the Practice of", Associate Professor "of the Practice of" and Assistant Professor "of the Practice of". Individuals holding full-time positions such as "Research Scientist" or the equivalent may also be eligible for Authorized User Status, depending upon their qualifications. Faculty ranks not eligible for Authorized User Status include Lecturer, Instructor, Associate, Research Associate, and all ranks qualified by terms such as "Consulting", "Visiting", or "Emeritus."

b. Adjunct Duke Faculty with Primary Academic Appointments at Other Institutions:

An applicant with an “Adjunct” faculty appointment at Duke who has a primary appointment at another institution may qualify for non-clinical Authorized User status provided the following conditions are met:

- The applicant has both training and experience commensurate with the types and quantities of radioactive material for which application is being made;
- He/she holds a full-time primary academic appointment at the other institution which carries a faculty rank of Assistant Professor or higher, as defined in (a) above; and
- His/her salary is supported in part by Duke University.

2. DEVELOPMENT OF WRITTEN STANDARD OPERATING PROCEDURES

Recognizing that the types of clinical and laboratory operations encompassed by the programs at Duke vary greatly, the Committees require that each Authorized User develop a set of written procedures that are specific to his/her laboratory. Laboratory-specific Standard Operating Procedures give the individual Authorized Users autonomy in determining the day-to-day conduct of radiation protection procedures in their laboratories, based on the nature of their use of radioactive material and/or radiation-producing devices.

Each Authorized User's written procedures should contain the following information, based upon the general requirements of the Duke Radiation Safety Program:

- a. The types of radioactive material and/or radiation-producing devices present in the laboratory.
- b. General safety issues that address the proper handling of radioactive material, use of fume hoods, wearing of personal protective equipment, etc.
- c. Laboratory-specific procedures for ordering, receiving, storing and disposing of radioactive material.
- d. Laboratory-specific procedures for conducting surveys for detection of contamination (wipe test locations, frequencies, etc.).
- e. Description of laboratory-specific record-keeping procedures. As an aid to formulating these laboratory-specific written procedures, the Radiation Safety Division will supply any current or prospective Authorized User with a template electronic document that is based on the radionuclides included in the User's authorization. The User may modify this template as required.

3. AMENDING THE AUTHORIZATION

If the Authorized User wishes to alter the conditions of the authorization (such as by adding or deleting permitted radionuclides or devices, changing locations of use or changing possession limits), he/she shall contact the Radiation Safety Officer directly to obtain approval to amend the authorization. The addition of new radionuclides or significant increases in possession limits shall be subject to special review by the Radiation Safety Officer and Operational Manager. "Special review" ensures that all appropriate protective measures, including shielding, survey instrumentation and facilities to handle volatile materials are in place prior to approval. All amendments to Authorizations are subject to review and approval by the appropriate Committee.

4. PRECEPTORS

The following requirements shall apply to an individual acting as a preceptor for the radioisotope program when the applicant does not meet the requirements stipulated above:

- a. The preceptor shall be an active-status Authorized User.
- b. The preceptor shall have such professional relationships with the applicant as would permit real knowledge of the day-to-day course of the use of radioisotopes. The preceptor shall have a relationship with the applicant which would give him/her veto power over the applicant's use of radioisotopes. Having this power, the preceptor must be willing to accept accountability for proper radioactive material usage.

D. AUTHORIZATION FOR MEDICAL USE OF RADIOACTIVE MATERIAL IN HUMANS: PHYSICIANS, MEDICAL PHYSICISTS AND NUCLEAR PHARMACISTS

The administration of radioactive material or therapeutic radiation to patients or research subjects at Duke University Medical Center is regulated by the US NRC, the US Food and Drug Administration (FDA), the State of North Carolina and the Medical Center Committee. In order to participate in the human use of radioactive material or accelerators, the applicant must provide evidence of training and experience that reflect those set forth in 10 CFR 35 and equivalent North Carolina regulations. These requirements generally involve (1) training in basic radioisotope handling techniques, (2) supervised clinical training in an institutional radiology, nuclear medicine or radiation oncology program, and (3) relevant experience.

The physician applicant for clinical use of radioactive material or accelerators must fulfill all of the following conditions:

1. Hold an active license to practice medicine in the State of North Carolina, as issued by the North Carolina Medical Board.
2. Have training and experience commensurate with the types and amounts of radioactive material applied for, as set forth in 10A NCAC 15.0318(c). Applicants may demonstrate fulfillment of the requirements either by (a) a combination of specialty board certification, documentation of alternative training and experience and by preceptor attestation; or (b) by having previously been

named as an Authorized User on an NRC or Agreement State license for the clinical use of radioactive material.

3. Have contacted the Secretary of the Radiation Safety Committees or the Radiation Safety Officer, through his/her Departmental Chair or other individual designated by the Department. The applicant should submit a copy of the licensee's registration certificate issued by the North Carolina Medical Board documenting current active licensure, a curriculum vitae, a copy of the applicant's specialty board certificate, or letter of intent to certify from the specialty board and a letter of attestation (if applicable). If Authorization is sought through preceptor attestation in lieu of board certification, a preceptor attestation form as provided by the North Carolina Radiation Protection Section, or equivalent Agreement State or USNRC form (e.g. Form 313a), is required.

The medical physicist applicant must fulfill all of the following conditions:

1. Have training and experience commensurate with the clinical activities applied for, as set forth in 10A NCAC 15.0318(a). Applicants may demonstrate fulfillment of the requirements either by specialty board certification, or by preceptor attestation.

2. Apply to the Secretary of the Radiation Safety Committees or the Radiation Safety Officer through his/her Departmental Chair or other individual designated by the Department. The application must be accompanied by a curriculum vitae and a copy of the applicant's specialty board certificate, or letter of intent to certify from the specialty board. If Authorization is sought through preceptor attestation, a complete, signed preceptor attestation form is required.

The nuclear pharmacist applicant for clinical use of radioactive material must fulfill all of the following conditions:

1. Hold an active license to practice pharmacy in the State of North Carolina, as issued by the North Carolina Board of Pharmacy.

2. Have training and experience commensurate with the types and amounts of radioactive material applied for, as set forth in 10A NCAC 15.0318(b). Applicants may demonstrate fulfillment of the requirements either by specialty board certification, or by preceptor attestation.

3. Make application to the Secretary of the Radiation Safety Committees or the Radiation Safety Officer. The application must be accompanied by a copy of the licensee's registration certificate issued by the North Carolina Board of Pharmacy as documentation of current active licensure, a curriculum vitae and a copy of the applicant's specialty board

certificate, or letter of intent to certify from the specialty board. If Authorization is sought through preceptor attestation, a complete, signed preceptor attestation form is required.

Once all the application materials are received by the Secretary, the applicant may be granted provisional approval as an Authorized User by the Human Use Subcommittee. Formal approval will be granted by vote of the full Medical Center Committee at its next scheduled meeting. Authorized User status terminates if either (a) the Authorized User leaves Duke University Medical Center, (b) the applicant does not maintain active licensure with the applicable North Carolina licensing board or (c) the Authorized User's clinical privileges at Duke University Medical center are suspended or terminated.

1. BASIC HUMAN RESEARCH AND THE RADIOACTIVE DRUG RESEARCH COMMITTEE

“Basic human research” means research intended to obtain basic information regarding the metabolism (including kinetics, distribution and localization) of a radioactively labeled drug or regarding human physiology, pathophysiology or biochemistry; but not intended for immediate therapeutic, diagnostic or similar benefit. For such studies, application must be made to the Duke University Medical Center Radioactive Drug Research Committee (RDRC). The RDRC reports to the US Food and Drug Administration (FDA). Investigators who wish to conduct basic human research on radioactive drugs shall make an application to the RDRC, consistent with the requirements of 21 CFR 361. Requirements include, but are not limited to, the following:

- a. the amount of active pharmaceutical ingredient or combination of pharmaceutical ingredients to be administered shall be known not to cause any clinically detectable pharmacological effect in human beings, and
- b. the radiation dose shall be the smallest practical to perform the study. Under no circumstances shall the whole body effective dose equivalent exceed a yearly cumulative value of 5 rem (50 mSv), or a single-exposure value of 3 rem (30 mSv). The total critical organ dose shall not exceed 15 rem (150 mSv) annually. For research subjects who have not reached 18 years of age, the maximum permissible whole body and critical organ exposure limits are 10 percent of the foregoing. A female research subject of childbearing potential shall state in writing that she is not pregnant, or shall be given a pregnancy test before participating in any study.
- c. Approval of a protocol by the RDRC does not relieve the applicant of obtaining the approval of other entities, including the Duke

Institutional Review Board, prior to conducting research in humans.

2. INFORMED CONSENT FOR PROCEDURES INVOLVING IONIZING RADIATION IN CLINICAL INVESTIGATIONS

Investigators supervising clinical trials that are subject to oversight by the Duke Institutional Review Board (IRB) must inform research subjects of any exposure to ionizing radiation consequential to participation in a clinical study (a) where the exposure exceeds the standard of care for the condition that is the subject of the study, or (b) as a normal volunteer. The IRB requires that such protocols undergo “Specialty Committee” review and approval. The Medical Center Committee acts as the Specialty Committee for protocols involving ionizing radiation. The Committee has adopted the following requirements relative to expressing radiation dosage to patients or research subjects who are participating in clinical or basic human research.

- a. The investigator or his/her designee shall determine the types and numbers of radiological or nuclear medicine examinations that are required for participation in the clinical trial, which are beyond the “standard of care”.
- b. The investigator or his/her designee may use the Duke Radiation Safety Committee’s web site (<http://vms-oeseapps.duhs.duke.edu/radsafety/consents/default.asp>) to compute the total effective radiation dose consequential to all procedures, and to use the resulting expression of risk in the “Risks and Discomforts” section of the informed consent document for the protocol. Benchmarks and wording formats suggested by the Web site include comparison to events encountered in daily living, such as airplane travel, and the annual natural background. The expression of risk is not restricted to the preceding formats. However, any expression of radiation dose must assist the subject in making an informed value judgment as to the magnitude of the risk attributable to ionizing radiation.

E. AUTHORIZATION FOR THE USE OF LASERS

The Principal Laser User (PLU) is directly responsible for the safe use of lasers under his/her control. New non-medical PLUs must meet with the Radiation Safety Officer to review the essential elements of the Duke Laser Safety program. Minimum Requirements for Class 3b or 4 lasers include, but are not limited to, the following:

1. Laser Registration: All Class 3b or 4 lasers must be registered with the Laser Safety Manager.

2. Training: All users, and non-using staff who will be present during open beam laser operation, must complete the appropriate laser safety training course. These courses are available in classroom format upon request, or in a Web-based format on the OESO On-line Training Page.

3. Pre-Operational Checklist: Prior to non-medical operation of Class 3b or 4 lasers, the responsible PLU must complete a Pre-Operational Checklist.

4. Standard Operating Procedure (SOP): Users of Class 3b and Class 4 lasers must have a written SOP available on-site.

5. Entryway Controls: The PLU must make adequate provisions to ensure that anyone who enters the laser lab inadvertently is protected against accidental exposure to the laser beam.

All policies addressing the use of Lasers at Duke University and Medical Center are contained in the Laser Policy Manual, available at http://vmw-oesoapp.duhs.duke.edu/RadSafety/laser_policy.pdf .

V. PERSONNEL MONITORING

The documentation of the radiation dose received by persons working with radioactive material and radiation-producing equipment is critical to minimizing such exposures, and ensuring compliance with state and federal regulations. The accepted approach to monitoring occupational radiation exposures to individuals is through the use of the *personal dosimeter*. Duke University actively encourages the appropriate use of dosimeters in a fashion that is minimally intrusive to the worker, yet effective in documentation of compliance with the ALARA principle of minimizing radiation exposure. Routine dosimeters are obtained through the Radiation Safety Division. The guidelines for personnel monitoring adopted by Duke University are summarized in the following sections.

A. DOSIMETERS AND ISSUANCE CRITERIA

Personnel dosimeters measure integrated external radiation dose received over extended time periods. The policies for obtaining a new dosimeter, exchanging badges, and obtaining an exposure history are outlined below..

1. All persons exposed to certain licensed or registered radiation sources on a routine basis shall wear an appropriate dosimeter if so directed by the Radiation Safety Officer or his/her designee. Unless otherwise directed by the Radiation Safety Officer:
 - a. Laboratories and departments using radiographic, fluoroscopic or therapeutic x-ray machines, analytical X-ray machines, chromium-51, radioiodine or other gamma emitters are issued whole body dosimeters.
 - b. Personnel working at the Free Electron Laser Laboratory (FELL) or at the Triangle University Nuclear Laboratory (TUNL) are issued whole body dosimeters that also monitor neutron exposure in addition to x-ray and gamma radiation.
 - c. Laboratories in the Medical Center or University that use phosphorus-32 or other energetic (>250 keV) beta emitters are issued finger rings. If there is a reason that a finger ring cannot be used, wrist badges can be issued.
 - d. Users of low-energy (<250 keV) beta emitters (e.g. hydrogen-3 [tritium], carbon-14, phosphorus-33, sulfur-35 and calcium-45) do not require external personnel monitoring and dosimeters will not be issued to employees whose radiation exposure is limited to the use of such radionuclides.
 - e. Individuals who may be expected to incur a cumulative annual radiation dose less than (a) 1 millisievert (100 millirem), or (b) the annual dose to the general public as determined by applicable

statute, whichever is lower, will not be issued a routine dosimeter, except as directed by the Radiation Safety Officer.

2. Dosimeters shall be processed on a periodic basis, the frequency to be determined by the Radiation Safety Division. The exchange cycle is either monthly or quarterly based on the types of radioactive material or radiation sources used, and average doses incurred during previous monitoring periods.. A contact person in each laboratory or department is responsible for management of dosimeter exchange at the determined frequency.
3. Records of personnel exposures shall be maintained by the Radiation Safety Division. Copies of the periodic occupational dose reports shall be made available to wearers through the departmental contacts. Wearers are responsible for reading their reports and directing inquiries to the Radiation Safety Division staff. Wearers will be notified of doses that exceed the applicable ALARA levels (see Section I.B, Table 1) during a given monitoring period. Reporting of individual annual doses that exceed 100 millirem (1 mSv) is accomplished through inspection of the "Year to Date" entry of the dose report that is issued for each fourth calendar quarter.
4. For dosimeters that are lost, damaged, inadvertently subjected to significant non-occupational exposure or otherwise considered to be incapable of providing a true indication of occupational dose during a monitoring period, the missing reported dose may be reconstructed as directed by the Radiation Safety Officer.
5. Each individual to whom a badge is issued has the responsibility to ensure its proper wear and use.
6. Small, portable ionization chambers or direct reading, digital, electronic dosimeters (so-called "pocket" dosimeters) may be used to monitor the absorbed dose received over brief intervals of time. These instruments give an immediate read-out of the absorbed dose to the individual. They may be worn at the discretion of the individual user. All visitors to FELL and TUNL should be given a pocket dosimeter prior to their entrance into the laboratory area. Records of the doses to visitors are kept in each lab. Under certain circumstances, the use of both a routine monitoring dosimeter and pocket dosimeter may be required. If pocket dosimeters are utilized, they must be calibrated annually by the Radiation Safety Division.
7. Other dosimetry monitoring may be provided as deemed appropriate by the Radiation Safety Officer.

B. MEDICAL X-RAY DOSIMETRY

1. Personnel operating portable x-ray machines and fluoroscopic units shall wear whole-body dosimeters at the collar level, as directed by the Radiation Safety Officer. Dosimeters shall be worn outside any shielding aprons or other shielding personal protective equipment, unless specified otherwise. In these cases, assigned personnel dose will be equal to the values of deep dose equivalent and shallow dose equivalent calculated by the dosimetry vendor, or as directed by the Radiation Safety Officer.
2. Two additional methods are available for determining personnel dose in instances where there is significant exposure to high x-ray fluoroscopic workloads and where personnel can demonstrate the routine use of shielding aprons as personal protective equipment. In the first method (designated as EDE-2), the radiation dose from a single external monitor is used to compute effective dose equivalent (EDE). In the second method (designated as EDE-1), two external monitors are used to compute EDE.
 - a. For personnel monitored using the EDE-2 calculation, the single dosimeter shall be worn outside the shielding apron at collar level.
 - b. For personnel monitored using the EDE-1 calculation, one dosimeter shall be worn outside the shielding apron at collar level. A second dosimeter shall be worn underneath the shielding apron at waist level. Wearing the two dosimeters consistently in the proper locations is important. The proper placement of each dosimeter in the EDE-1 system is depicted on the face of each badge.
3. Special Dose Calculations: The choice of method used to compute EDE for personnel who work with high-dose fluoroscopy (EDE-1 or EDE-2) will be determined by the Radiation Safety Officer on a case-by-case basis, and for individuals exceeding 25% of the annual whole-body dose limits.
 - a. Algorithms for the EDE-1 and EDE-2 computations will be employed as directed by the appropriate regulatory and advisory agencies (US NRC, Regulatory Issue Summary 2002-06, "Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-rays).
 - b. Effective dose to the lens of the eye or other organ dose weighting factors for external exposure will be evaluated and assigned to individuals by the Radiation Safety Officer on a case-by-case basis when reliable, accurate and predictable estimates of effective dose equivalent are possible, given the conditions of exposure, and are based upon methods that are acceptable to the Radiation Protection Section of the North Carolina Department of Health and Human Services.

C. REVIEW AND MAINTENANCE OF EXPOSURE RECORDS

The Radiation Safety Division reviews occupational dose reports upon receipt and maintains occupational radiation exposure records. Investigations of exposures exceeding ALARA levels are conducted in accordance with the Duke University and Duke University Medical Center ALARA Program Policy. The Radiation Safety Division receives and sends requests for individuals' occupational exposure records. Exposure records are confidential and a Release Form (available from the Radiation Safety Division) must be obtained from the requester and must be included in outgoing requests to other institutions.

D. THYROID BIOASSAYS

1. APPLICABILITY

- a. Individuals directly involved* in clinical radioiodine therapy using unencapsulated material shall obtain a thyroid burden measurement not to exceed seven (7) days following administration of the therapy dose. The Director of Nuclear Medicine, in consultation with the RSO, determines the assay time window.

*Definition of individuals who are "directly involved" with radioiodine therapy:

- i. For unsealed solutions of iodine-131 (I-131) sodium iodide for oral administration: The patient self-administers the material. Other individuals "directly involved" include the person who removes the lid from the vial, the person who holds the vial and straw while the patient ingests the solution, the person who rinses the vial to permit full ingestion and the person who handles the radioactive waste.
- ii. For closed-system intravenous or intrathecal administrations of bound forms of I-131: Individuals "directly involved" include the person who connects the I-131 syringe to the closed injection system, the person dispensing the radiopharmaceutical into the closed system, the person who manipulates any three-way stopcocks or other manual valves (or the connections to the intravenous or intrathecal lines during the administration), the person(s) who dismantles the closed system and the person who handles the radioactive waste.

- iii. Individuals excluded from the "directly involved" requirements are observers who are not physically contacting the patient, the administration paraphernalia or the radioactive waste.
- b. Individuals directly involved in the handling of stock vials and radioiodination procedures in the Radiopharmacy shall obtain a thyroid burden measurement not to exceed than seven (7) days following the procedure. Required bioassay time windows may vary depending on the nature of the procedure and the amount of radioiodine employed. The Director of Radiopharmacy, in consultation with the Radiation Safety Officer, determines the time window for each procedure involving radioiodine.
- c. Individuals directly involved in radioiodinations performed in authorized research laboratories shall obtain a thyroid burden measurement not to exceed than seven (7) days following the procedure. The amount of radioactivity and the conditions under which the procedure is performed are subject to the limits and conditions set forth in Section 3 below.

2. SPECIFIC RECOMMENDATIONS

Based on the biokinetics of radioiodine, it is generally recommended that thyroid monitoring be performed between 24 and 72 hours following a therapeutic administration or other procedure whenever practical. Individuals who are unable to comply with the requirements outlined in "Applicability" above should defer participation in procedures to others.

3. IODINATIONS PERFORMED IN AUTHORIZED RESEARCH LABORATORIES

Each individual handling radioiodine under any of the operations described below shall have thyroid monitoring if the quantities used exceed the quantities for the conditions specified in Table 2. Note that the quantities shown apply to both the quantity used at one time or integrated as the total amount of activity used over a 3 month period. Scheduling of the monitoring may be done through the Radiation Safety Division in cases where the research laboratory does not have equipment suitable for performing the required measurements. "Volatile" means that radioiodine may be given off as a gaseous or dispersible form, as opposed to bound to a non-dispersible substrate. Laboratory use in an open room or bench top is discouraged.

Table 2. Quantities Requiring Thyroid Monitoring (millicuries)

Radionuclide(s)	Volatile?	Open Room or Bench Top	Fume Hood*	Glove Box*
I-124, I-125 I-131	Yes	1	10	100
	No	10	100	1,000
I-123	Yes	100	1,000	1,000
	No	1,000	1,000	1,000
I-125 as RIA Kits	Not Required	---	---	---

*Fume hoods must have adequate design, face velocity/flow and performance reliability. Glove boxes must be closed, with recognition that escape and contamination may occur.

E. URINE BIOASSAYS

Individuals involved in operations that utilize more than 100 millicuries of hydrogen- 3 (tritium) in a non-contained form (other than metallic foil), within a 30 day period, shall have bioassays performed within one week following a single operation and at weekly intervals for continuing operations. Bioassays performed in conjunction with other radionuclides may be required by the Committee. The Radiation Safety Division shall maintain reports of bioassay results.

VI. REPRODUCTIVE HEALTH POLICY

Recognizing the need for the safety and well-being of the fetus during pregnancy, Federal and North Carolina State regulations and the Duke ALARA policy proscribes that the total dose equivalent to the embryo or fetus of a declared pregnant woman shall not exceed 5 mSv (500 millirem) during the period of gestation. Employees who become pregnant and must work with radioactive material or radiation sources during their pregnancy should contact Duke Employee Occupational Health and Wellness and complete a confidential Declaration of Pregnancy form. After declaring her pregnancy, the employee will then receive:

1. an evaluation of the radiation hazard from external and internal sources;
2. counseling from personnel of the Radiation Safety Division regarding modifications of technique that will help minimize exposure to the fetus;
3. a fetal dosimeter, if appropriate.

Employees who are not declared pregnant workers will not be issued a fetal dosimeter.

An employee who has declared her pregnancy shall inform the Employee Occupational Health and Wellness and the Radiation Safety Division if her pregnancy has ended for any reason.

VII. RADIATION SAFETY POLICIES FOR RESEARCH LABORATORIES

The Committees of Duke University and Duke University Medical Center have adopted a number of policies and procedures to ensure the proper procurement, distribution, use and disposal of radioactive material and radiation-producing equipment. This chapter outlines important general radiation safety practices and procedures that must be implemented by all Authorized Users.

A. BASIC LABORATORY RADIATION SAFETY POLICIES

All Authorized Users are responsible for strict adherence to standard radiation safety practices and procedures in their individual laboratories and clinical areas. The Radiation Safety Division will assist Authorized Users in developing satisfactory written procedures pertinent to their specific requirements. In general, the following guidelines regarding the safe storage, control, and use of radioactive material will apply.

1. RADIOACTIVE MATERIAL USE AND STORAGE AREAS

Each Authorized User shall:

- a. Take the necessary precautions to prevent the spread and ingestion of radioactive material that has been removed from stock and used in experiments. This is accomplished by means of training personnel in the proper handling of radioactive material, the use of hoods when working with materials that may become airborne, the proper performance of radiation surveys, and the application of proper techniques for decontamination of laboratory areas should contamination occur.
- b. Instruct all individuals working in or frequenting any portion of an area where radioactive material is used or stored or radiation-producing devices are employed regarding the health concerns associated with exposure to radiation. Female workers shall be given specific instructions about prenatal exposure risks to the developing embryo and fetus as required by the Duke University Reproductive Health Policy.
- c. Ensure that stock solutions of radioactive material and sealed sources containing radioactive material are stored in a locked room, locked cabinet, locked freezer/refrigerator or a commercially available lock-box when not in use. If locking the individual storage unit is not feasible, then the laboratory room containing the

storage area must be locked whenever the area is not under supervision or direct surveillance. Material in use need not be locked up provided it is kept under surveillance at all times. Users shall not permit unattended radioactive material on desks, tables or laboratory benches. Unauthorized personnel shall not be permitted in laboratories. The Authorized User shall enlist the aid of the Duke University Police to enforce the exclusion of unauthorized personnel, if necessary.

- d. Ensure that any entryway providing access from public areas into areas where radioactive material is used or stored or where radiation-emitting devices are used are posted with the appropriate official "Caution" signs. Assistance in obtaining official signs and their posting may be obtained from the Radiation Safety Division.
- e. Ensure radioactive material use areas, equipment, fixtures (e.g. sinks and hoods), etc. are clearly indicated as potentially contaminated (e.g. with "Caution - Radioactive Material" labels).
- f. Prohibit eating, drinking, smoking, and/or application of cosmetics within that area of the laboratory where radioisotopes are stored or used. Prohibit food storage in refrigerators where radioactive material is stored. Ensure that each person handling unencapsulated radioisotopes washes their hands thoroughly before eating, smoking, or leaving the work area.
- g. Enforce wearing appropriate personal protective equipment, including disposable protective gloves, laboratory coats, eye protection and so forth when handling unencapsulated radioactive material. Disposable gloves worn in radioactive use areas shall not be worn into areas not designated for radioactive material use, and shall be disposed of as radioactive waste before leaving the radioactive material area. Laboratory coats should be left in the laboratory rooms and not worn home.
- h. Prohibit operation of pipettes or siphons by mouth suction.
- i. Maintain exposure of personnel and release of radioactive material to levels as low as reasonably achievable (ALARA).
- j. Inform the Radiation Safety Officer whenever the location of radioactive material use (building and/or rooms) is changed from that identified on the initial application.
- k. Perform thyroid bioassays for each individual handling radioiodine , in quantities and in operations described in Chapter V. Intake of radioiodine shall be computed using the appropriate on-line application on the Radiation Safety web site and compared to applicable action levels. If the Authorized User is not equipped to perform the measurements, he/she must schedule bioassay measurements through the Radiation Safety Division.
- l. Instruct all individuals in the proper use and maintenance of proper detection instrumentation in the lab to ensure lack of contamination in the lab and on personnel.

- m. Ensure that appropriate measures, such as filters and traps, are placed between apparatus containing radioactive material and the house vacuum system, in order to prevent the entry of radioactive material into the vacuum system.

2. TERMINATION OF LABORATORY OPERATIONS (CLOSE-OUT)

When an Authorized User ends his/her affiliation with Duke University or desires to terminate his/her radiation license, any laboratory space controlled by that user must be decommissioned (cleaned out by the Authorized User and closed out by the Radiation Safety Division) before the area can be returned to non-radiation use or occupied by another Authorized User. Any Authorized User who anticipates terminating his/her Authorization shall notify the Radiation Safety Officer of the termination in writing or via electronic mail no less than thirty (30) days prior to the anticipated date of termination.

3. REMOVABLE CONTAMINATION SURVEYS

The specific contamination survey requirements for each laboratory are outlined in the authorization documentation of the responsible AU. Laboratories using low-energy beta (^3H [tritium], ^{14}C , ^{35}S) emitting nuclides and other nuclides as specified by the Radiation Safety Officer must perform periodic removable contamination (wipe) surveys. Records of these surveys shall be available for review by Radiation Safety Division personnel. The frequency of the wipe surveys will depend upon the materials being used in the individual laboratories, as specified in the written procedures for each laboratory and approved by the Radiation Safety Division.

The responsible AU must ensure that areas producing wipe test results in excess of the action limits specified in Table 3 are decontaminated. Documenting wipe test results in net counts per minute (CPM) and decontaminating areas producing greater than 100 net CPM per wipe will ensure compliance with the Table 3 limits. Alternatively wipe test results may be documented in disintegrations per minutes (DPM) using an appropriate conversion factor and compared directly to the Table 3 limits.

Table 3. Action Levels for Laboratory Contamination

Net DPM on wipe*		Action to be taken by laboratory personnel
Gamma and high energy (>250 keV) beta emitting radionuclides	Low energy (<250 keV) beta emitting radionuclides	
less than 220	less than 2,200	No action required
220-11,000	2,200-11,000	Clean area (see "Decontamination" below); repeat wipe(s)
11,000-110,000		Clean area; repeat wipe(s), notify RSD** to verify clean-up
>110,000		Cease radioactive material use. Notify RSD. Commence immediate cleanup under RSD supervision.

* Wipe area 100 cm² minimum.

** Radiation Safety Division designated personnel

4. DECONTAMINATION

Preparations for decontamination shall begin promptly. The user will determine the extent and hazard of contamination prior to commencing clean up. The individual responsible for the contamination is expected to perform the necessary clean up. The AU shall inform the Radiation Safety Division of all contamination incidents exceeding the notification level specified in Table 2 above. The Radiation Safety Division will oversee the associated decontamination process.

B. AIRBORNE RADIOACTIVE MATERIAL

Procedures that might produce airborne radioactivity shall be conducted in a hood, glove box, or other suitable closed system. Such airborne radioactivity hoods must undergo an annual certification of airflow.

The air concentrations of radioactive material due to potential discharges from fume hoods or the accelerator facilities will be evaluated by the Radiation Safety Division. Where indicated, appropriate control methods such as activated charcoal filters will be employed to ensure regulatory compliance.

C. RESEARCH ANIMALS

1. APPROVAL

The administration of radioactive material to research animals and the irradiation of research animals must be approved by the Institutional Animal Care and Use Committee and the Radiation Safety Division.

2. GENERAL POLICIES

- a. Injection of radioactive material into animals, where appropriate, shall be performed in trays lined with absorbent material.
- b. Cages must be labeled as to radionuclide, quantity of radionuclide administered per animal, date of administration, and authorized user.
- c. Special procedures shall be developed relative to the collection and disposition of the animal's excreta and carcass.
- d. Any live animal containing radioactive material being returned to the Vivarium shall have prior approval of the Division of Laboratory Animal Resources and the Radiation Safety Division.

D. ORDERING, RECEIPT, INVENTORY, TRANSPORT, AND DISPOSAL

1. ORDERING RADIOACTIVE MATERIAL

Radioactive material orders originating from research laboratories shall be approved by the Radiation Safety Division and may be submitted using an appropriate web-based ordering facility. Fax and email orders are also acceptable. Clinical areas (Radiation Oncology, Nuclear Medicine, etc.) may order directly from the supplier.

2. RECEIPT OF RADIOACTIVE MATERIAL

Clinical areas (Radiation Oncology, Nuclear Medicine, etc.) may receive radioactive material directly from the supplier. All other shipments of radioactive material, except as specifically exempted by the Radiation Safety Officer or his/her designee, shall be addressed to and received at the centralized location specified in the applicable Licenses of Broad Scope. The Radiation Safety Division shall be contacted if anyone other

than Radiation Safety Division personnel delivers radioactive packages to the laboratory (except for the exceptions noted above). The Radiation Safety Division will accept in-coming radioisotope shipments only during normal business hours,, excluding weekends and holidays. An Authorized User requiring radioactive material delivery outside of regular hours must contact the Radiation Safety Division in advance to make special arrangements.

Radiation Safety Division personnel will deliver radioactive material only to the requesting Authorized User or designee, and only if that designee is trained to accept radioactive material shipments. Upon receipt, the Authorized user is responsible for ensuring completion of the following tasks:

- a. Inspect the inner contents of the package and report discrepancies to the Radiation Safety Division.
- b. Store the material in a secure location.

3. INVENTORY OF RADIOACTIVE MATERIAL

Authorized Users shall complete their Radioisotope Inventory Reports within the intervals specified by the Radiation Safety Officer. The Inventory Reports must also include estimates of the amount(s) of radioactive material discharged into the sanitary sewer, if any.

Radioisotope Inventory Reports shall be submitted to the Radiation Safety Division using an on-line (Web-based) Radioactive Materials Inventory Reporting System that is maintained by the Radiation Safety Division for that purpose. Radioactive materials shipments will be entered into the Inventory Reporting System by the Radiation Safety Division upon delivery. Authorized Users will be responsible for using the system to periodically update their holdings. Failure to update holdings within the maximum time intervals specified by the Radiation Safety Officer may result in suspension of ordering privileges or withholding of material. Acceptable time intervals for submission of inventory updates for unencapsulated and encapsulated radioactive materials will be stated on the Web site.

4. TRANSFER OF RADIOACTIVE MATERIAL

- a. Transfer of radioactive material between Authorized Users, or between a User and an outside facility, are permitted as long as such transfers are in compliance with Duke University's license conditions and any other applicable regulatory requirements. Transfer of radioactive material to another institution requires an

NRC or Agreement State license to possess that material by the receiving institution, and oversight by the Radiation Safety Officer of the receiving institution. The Radiation Safety Division must be notified before any transfers take place, either between Duke Authorized Users or with outside facilities. Due to the short half-life of some accelerator-produced radionuclides, routine transfers of radioactive material from Duke accelerator facilities to on-campus research laboratories do not require prior approval by the Radiation Safety Officer. However, transfer, receipt and disposal of such material must be documented by the transferring facility and the recipient.

5. RELOCATION, TRANSPORTATION OR SHIPMENT OF RADIOACTIVE MATERIAL OR RADIATION SOURCES

The transportation or shipment of radioactive material or radiation-producing equipment on campus and to other institutions, including the Duke University Marine Laboratory, Duke laboratories in the Research Triangle Park and the Durham Veterans Affairs Medical Center, must comply with both State of North Carolina and United States Department of Transportation (USDOT) regulations. Unless specifically exempted by the Radiation Safety Officer, all such shipments and transport within or from Duke University shall be subject to prior approval from Radiation Safety. In addition:

- a. Transport of radioactive material off-campus by Duke employees as checked baggage on public conveyances is prohibited.
- b. Radiation sources (such as x-ray machines, x-ray diffraction systems, analytical units, accelerators, etc.) or equipment containing sealed sources of radioactive material (such as liquid scintillation/gamma counters, gas chromatograph electron capture detectors, moisture content gauges, etc.) shall not be relocated, transferred, donated, sold, discarded or otherwise disposed without notification of and approval by the Radiation Safety Officer.

6. DISPOSAL OF RADIOACTIVE WASTE

The Environmental Programs Division of OESO is responsible for radioactive waste management at Duke University and Medical Center. Authorized Users are responsible for ensuring that all their personnel working with isotopes understand the waste segregation and packaging

procedures set forth by the Environmental Programs Division. Specific requirements for the disposal and collection of radioactive waste are available on the Environmental Programs Division Web site (<http://www.safety.duke.edu/environmental-programs/>). Radioactive material, in any amount, must be disposed of as radioactive waste and not placed in the normal solid waste stream. Small amounts of residual radioactivity may be discharged into the sanitary sewer (i.e. sink drain) in the course of cleaning glassware and laboratory apparatus. However, discharge to the sewer shall not be used as a primary means of radioactive waste disposal, except as directed by the Radiation Safety Officer. Instead, liquid waste should be handled as specified by the Environmental Programs Division. Authorized Users shall record, via their monthly inventory report, their discharge of radioactive material into the wastewater stream. Any such discharges to the sanitary sewer must be in accordance with the Laboratory-specific Standard Operating Procedure.

While radioactive waste is in the lab, all waste containers must be clearly labeled with the radionuclide(s) contained within and a "Radioactive Material" label. In addition, each non-empty waste barrel provided by Environmental Programs must have a waste disposal sheet on or near the waste barrel, and the sheet must list the nuclide(s) and activity in the waste barrel. Finally, like all radioactive material, radioactive waste should be secured against unauthorized access.

VIII. CAMPUS AND MEDICAL CENTER ACCELERATOR FACILITIES

The particle accelerator facilities on campus, which include the Triangle Universities Nuclear Laboratory (TUNL), the Free Electron Laser Laboratory (FELL), the Medical Center Positron Emission Tomography (PET) Cyclotron Facility and the clinical Radiation Oncology linear accelerators, present special issues in regard to radiation safety. The potential for high external radiation fields and the large amounts of radioactive byproducts during operation of these machines require a high level of awareness of the potential hazards.

This section provides information on general radiation safety considerations associated with the accelerator facilities. Detailed information on the specific radiation safety-related policies for each facility is provided in the Radiation Safety Manual or clinical Quality Management Program for the facility.

The principal radiation hazards in all accelerator facilities are related to personnel exposure to the direct beam or secondary radiation. Exposure to tritium contamination in the beam lines and exposure to radioactivity induced in accelerator components by the primary beam or neutron activation constitute additional hazards.

A. DIRECT BEAM AND SECONDARY RADIATION

Other than for patients being irradiated for therapeutic purposes, personnel exposure to the direct particle beam or secondary radiation emitted from bombarded targets is prohibited. The Authorized User and/or Radiation Safety Manager shall provide instruction to all employees regarding:

1. Proper alert procedures prior to accelerator startup;
2. Audible and visible alarms indicating that the potential for beam activation is present;
3. Exit routes from the accelerator vault and research areas;
4. Methods to disable activation of the particle beam from within the accelerator vault research areas in the event the beam is introduced into the area.

B. ACCELERATOR COMPONENTS

Components of the accelerator can become radioactive during the course of operation due to neutron activation or interaction with the direct particle beam. The radioactive species produced in this manner depend upon the particle being accelerated, the energy of the particles and the materials present in the

components, including impurities. Components that may become activated include the beam line (including rubber O-ring seals), parts of the target assembly other than the target itself, the accelerator vacuum tank interior, bending and steering magnets, electrostatic deflectors, and the ion source.

Users should take the following general precautions when approaching components of the accelerator:

1. Items must be surveyed prior to handling. Radioactive components should then be handled according to each accelerators internal policies and internal Standard Operating Procedures.
2. When handling components that have come in contact with beam, proper personal protective equipment (PPE) shall be worn and properly disposed.

C. MACHINING OF RADIOACTIVE COMPONENTS

Each facility shall refer to their policies and procedures for the approved method for machining activated and/or contaminated components.

IX. SEALED SOURCES

- A. The Radiation Safety Officer shall ensure that leak tests and physical inventories are performed on those sealed sources specified and at the intervals specified in the applicable radioactive material license condition or applicable regulations.
- B. The responsible Authorized User shall ensure that:
 - 1. the Radiation Safety Officer is notified prior to the acquisition, transfer, relocation, destruction or disposal of any sealed source;
 - 2. the Radiation Safety Officer shall be notified immediately upon the loss or suspected theft of any sealed source;
 - 3. all sealed sources under the Authorized User's control are secured against unauthorized access or removal;
 - 4. a complete inventory of all sealed sources under the Authorized User's control is maintained and kept available for inspection by Radiation Safety.

X. RADIATION SAFETY TRAINING

The goal of providing radiation safety training to the employees of Duke University and Duke University Medical Center is to empower workers to take personal responsibility for minimizing their exposure to radiation. By providing each employee with knowledge of radiation and its biological effects and the regulations governing its use, the University and Medical Center can help provide an environment that is safe for its patients, students, visitors and workers. The content of radiation safety training courses will be determined by the Radiation Safety Officer and the appropriate Radiation Safety Committee based on applicable regulatory guidance, industry consensus standards, and the specific needs of the target audience.

Authorized Users are responsible for ensuring that their staff members have received instruction regarding the safe use of radioactive material and radiation sources in their specific laboratory settings, both through on-the-job training and through didactic training offered by the Radiation Safety Division. The Authorized User is responsible for maintaining documentation of the completion of required training and will be required to supply such documentation to the Radiation Safety Officer or his/her designee as a condition for continued Authorization to use radioactive material or radiation sources.

A. INDIVIDUALS OR GROUPS REQUIRING TRAINING

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

1. Radiation Workers¹: those workers whose major responsibilities involve working with sources of ionizing radiation or radioactive material.
2. Ancillary Workers²: All personnel who may come in contact with or enter an area that contains radioactive material or sources of ionizing radiation.
3. Non-Radiation Workers³: personnel who would not normally be expected to encounter radioactive material or radiation sources in the course of their employment at Duke.

¹"Radiation Workers" would include radiologists; radiographers; nuclear medicine physicians and technologists; radiopharmacy technologists; radiation therapy technologists; cardiology technologists working with fluoroscopy equipment; research scientists who are Authorized Users of radioactive material or radiation sources; faculty, technicians and graduate students in certain campus laboratories; nurses on hospital divisions regularly caring for radionuclide therapy patients.

²"Ancillary Workers" include non-radiology physicians, phlebotomists, Environmental Services workers, waste processors and animal caretakers.

³"Non-Radiation Workers" would include administrators and administrative assistants, Food Service employees, clerical staff, Materials Management and so forth.

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

B. SPECIFIC TRAINING REQUIREMENTS

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

1. All new employees of the Medical Center: job-specific, Web-based safety orientation training, including basic information concerning the existence of sources of ionizing radiation and the Radiation Safety program.
2. Radiation workers: initial training including instruction in the proper use and handling of radioactive material and other sources of ionizing radiation. The content of the initial training may be modified for the specific job responsibilities.
3. Radiation workers and certain ancillary workers: periodic refresher training.
4. Re-training of workers whose job responsibilities change concerning their use of or exposure to ionizing radiation, or who request additional radiation safety training.
5. Special training in connection with incidents involving a spill, accident, misadministration, change in regulations, or a documented overexposure.
6. Radiologists, radiographers, nuclear medicine technologists, radiation oncology technologists and radiation dosimetrists, by virtue of their professional education, certification, and continuing education requirements will be trained on an "as needed" basis. Training venues will include Grand Rounds, seminars and special in-service sessions.

C. SPECIFIC UPDATE TRAINING REQUIREMENTS FOR RESEARCH LABORATORIES

Periodic retraining of all staff in the biomedical research laboratories and in those University research laboratories which routinely employ unsealed radioactive material in research will be required at intervals determined by the Radiation Safety Committees. Currently, update training is required annually. The following guidelines will apply:

1. "Active" status Authorized Users (see Section IV.B) will periodically complete an update training module that emphasizes radiation laboratory management and policy issues.
2. Radiation workers, students and other users of unsealed radioactive material will periodically complete a module that emphasizes safe laboratory practices, including measures to minimize external exposure and to avoid ingestion of unsealed radioactive material. Participation in this module by Authorized Users is optional.
3. Both modules may be offered as lecture-style presentations and on-line self-study presentations. Verification of participation will be by certificates or an electronic record. Participants will be responsible for maintaining verification of their training and providing copies of verification of training to their Authorized Users if required.
4. Proper maintenance of training records in each laboratory is subject to periodic audit by the Radiation Safety Division.
5. Laboratories employing only radiation-producing machines or sealed sources will undergo re-training on an "as-needed" basis, at frequencies to be determined by the Radiation Safety Committees in conjunction with the Radiation Safety Officer.
6. Individuals working in accelerator facilities will undergo re-training on an "as-needed" basis, at frequencies to be determined by the Accelerator Radiation Safety Committees in conjunction with the Radiation Safety Officer.

XI. CLINICAL RADIATION SAFETY PROCEDURES

The purpose of this Chapter is to provide radiation protection information to nursing staff and other hospital personnel who may come in contact with patients who have received diagnostic or therapeutic amounts of radioisotopes or with radiation-producing devices such as portable x-ray machines.

Specific information on radiological protection for employees of the Radiology, Nuclear Medicine and Radiation Oncology Departments may be found in the Radiation Safety Procedures documents located in those departments.

A. NURSING CARE OF PATIENTS TREATED WITH RADIOPHARMACEUTICALS

Radiation hazards to nursing staff, ancillary personnel and visitors are due to (a) irradiation by emissions from radioactive isotopes in the patient, (b) accidental contamination of the skin by radioactive material, and (c) accidental ingestion of radioactive material. The following policies are intended to minimize the hazard associated with the therapeutic use of radiopharmaceuticals.

1. Patients requiring hospitalization for treatment with radiopharmaceuticals who cannot be released under the conditions of 10 CFR 35.75 or the applicable North Carolina regulations shall be provided with a private room with private bathroom facilities.
2. Before the patient is admitted to the room, the floors, and sink may be covered with a suitable removable protective material, if indicated by circumstances and consistent with patient safety. The Radiation Safety Division is responsible for the preparation of rooms used to house inpatients being treated with radiopharmaceuticals. Appropriate radioactive trash disposal containers will be placed in the room by Radiation Safety Division personnel.
3. Once the radioactive material has been administered to the patient, the patient will be considered to be restricted under "Radiation Precautions". The rooms occupied by these patients shall be posted with a sign bearing the standard radiation symbol (a black or magenta tri-blade on a yellow background) and the words "Caution: radioactive material". Ancillary personnel should not enter these rooms without consulting medical, nursing or the Radiation Safety Division.
4. "Radiation Precautions" shall be ordered by the Radiation Safety Officer or his/her designee for radiation therapy patients who fulfill the regulatory criteria for radiation isolation. Radiation precautions include, but are not limited to, restricting the patient to his/her private room and bath facilities, restricting public access to doorways and corridors adjacent to the room if

dose rates exceed applicable regulatory limits, limiting visitors, removal of bodily fluids and trash by Radiation Safety Division personnel, and exclusion of pregnant women or nursing mothers from the room.

Radiation precautions shall be discontinued only by order of the Radiation Safety Officer or his/her designee, and only when the patient has fulfilled the regulatory criteria for the discontinuation of radiation isolation.

5. Patients not being treated with radionuclides shall not occupy a room previously used for radionuclide treatment until that room has been cleaned and surveyed for residual contamination. Protective coverings and waste disposal containers located in patient rooms shall not be removed unless so directed by personnel of the Radiation Safety Division. These materials will generally be removed when radiation precautions have been discontinued and the patient has been discharged from the room. However, in the event that it is necessary for the patient to remain hospitalized after radiation precautions have been discontinued, any protective covering materials may be left in place at the discretion of the Radiation Safety Division.
6. Clinical specimens of urine or blood required for patient care should be obtained at the minimum frequency consistent with appropriate patient care. Hospital phlebotomists or clinical laboratory staff who obtain, transport and process clinical material shall do so while following the applicable policies and procedures of the Clinical Laboratory Service.
7. The body of a patient who dies while undergoing systemic radionuclide therapy should not be removed from the room until such transport has been approved by staff of the Radiation Safety Division.
8. Personnel shall not eat, drink or smoke in areas where unencapsulated radioactive material is used in patient treatment or if the possibility of contamination of the hands exists. Skin contamination, ingestion or inhalation of radioactive material can be avoided by wearing appropriate personal protective equipment (PPE) and frequent hand washing. In general, the protective principles based on the Standard Precautions for Blood and Body Fluids shall be followed.
9. Time spent close to patients should be limited to the minimum amount of time required to perform duties consistent with effective patient care. The Radiation Safety Division may issue special instructions, depending upon the nature of the treatment and any specific hazards associated with it.
10. For high-dose radioiodine treatments, protective gloves and shoe covers shall be worn upon entering a patient's room. Hands shall be washed with soap and water after leaving a patient's room. Contaminated materials, including urinals, bedpans, basins paper handkerchiefs, gauze sponges, shoe covers and gloves, shall be discarded into the non-porous garbage bags provided in the room and transported by the Radiation Safety Division for storage and decay. Sharps shall be disposed in the appropriate sharps disposal containers. Articles or utensils suspected of being contaminated, including the patient's personal effects, shall be monitored by the Radiation Safety Division prior to final disposition.

11. Linen which may be contaminated by vomiting, incontinence, or profuse perspiration shall be disposed in the box with the trash.
12. Protective gloves shall be worn while cleaning possibly contaminated equipment. In the case of radioiodine-131 therapy, patient urine will be collected in containers placed within special shields provided by the Nuclear Medicine Division, unless such collection would lead to unsafe conditions for personnel. These containers will be removed by Radiation Safety Division personnel. The patient is to be encouraged to take responsibility for his/her own urine collection, if possible. Stool may be disposed of via the sanitary sewer unless collection is specifically requested.
13. If there has been a spill of urine or other contaminated material, the Radiation Safety Division or Nuclear Medicine personnel shall be notified immediately.

B. VISITING POLICY FOR FAMILIES OF PATIENTS UNDERGOING SYSTEMIC RADIONUCLIDE THERAPY

The purpose of this policy is to enable patients being treated with systemic radionuclides such as radioiodine-131 to spend brief periods of time with family members during protracted hospitalization. Visit duration and frequency are intended to ensure that dose rates to the hospital staff and visitors are maintained below the applicable statutory limits on exposure to the general public.

1. No provision contained in this policy shall be construed to override a physician's written order that prohibits visitors, or hospital policies intended for infection control.
2. Children under age 18 or visitors who are pregnant shall not visit.
3. Visits shall not exceed 30 minutes.
4. Two visits per day per visitor are permitted, separated by one hour or more.
5. No more than two people may visit at a time.
6. The patient and the visitors should be positioned in the room so that the maximum practical distance is maintained between the patient and the visitors.
7. Visitors are to remain in the area of the room closest to the door. The door must remain closed during the visit.
8. Visitors must wear shoe covers and gloves while in the room, and should dispose of them in the box provided within the room. Visitors must not use the patient's bathroom or eat from the patient's food tray.
9. For patients housed in the shielded rooms on DHN Division 9300, visitors will not be permitted during the first 24 hours following administration of

radioiodine-131, except under circumstances as approved by the Radiation Safety Division.

C. RELEASE OF PATIENTS TREATED WITH RADIONUCLIDES FROM RADIATION PRECAUTIONS

Federal and North Carolina State regulations and the Duke University Medical Broad Scope Medical License conditions permit Duke University Medical Center to release patients from radiation precautions when certain conditions are met. The patient may be released from radiation precautions when:

1. The patient is continent of urine and is capable of an appropriate degree of self-care; and:
2. The exposure rate at one meter from the patient does not exceed seven (7) milliroentgens per hour; or
3. The iodine-131 radioactivity retained in the patient does not exceed 33 millicuries; or
4. Computations performed in accordance with Nuclear Regulatory Commission NUREG 1556, Volume 9, Revision 2, Appendix U determine that the estimated dose to a member of the general public consequential to release of the patient will not exceed 500 millirem (5 mSv) in one calendar year. If the calculation of estimated dose to the general public is based in part on tissue shielding, biological elimination and / or an occupancy factor less than 0.25 at one meter, then the release shall be documented and the record retained for three years. Instructions to patients regarding measures to ensure that dose to the public is ALARA, and instructions to women breast-feeding infants and children, shall be issued to patients in accordance with NUREG 1556.

Duke Radiation Safety personnel may release patients from Radiation Precautions whenever the applicable criteria are met. This "release from radiation precautions" shall not be construed as an order to discharge the patient from the hospital. At their discretion, Radiation Safety personnel may continue to require that patient waste be confined to the patient's room until it is removed by Radiation Safety.

D. PATIENTS TREATED WITH SEALED SOURCES (BRACHYTHERAPY IMPLANTS)

The following practices are intended to minimize the hazards associated with sealed brachytherapy sources.

1. Should an implant become dislodged during treatment, *it must never be touched with the bare hand*. Long tongs, forceps or other devices should be used to return it to an appropriate shielded container. Appropriate on-call medical staff, including the Radiation Oncology resident on call shall be notified immediately in the event an implant becomes dislodged. The Radiation Safety Division should also be contacted as soon as possible. Loss of a brachytherapy source shall be reported immediately to the Radiation Safety Officer of his/her designee.
2. Intact sealed sources do not usually present a contamination hazard. However, personnel must always be alert to the possibility that the integrity of any sealed source may be compromised in the event that it is damaged or mishandled. If this is suspected, notify personnel from the Radiation Safety Division immediately.
3. For temporary (removable) implants, patients shall be confined to their rooms until the implant is removed, unless otherwise authorized by the Radiation Safety Division. After the implant is removed, the patient poses no radiation hazard. While the implant is in place, the room will be posted with a "Caution: Radioactive Material" or "Caution: Radiation Area" sign until precautions are removed. Personnel or visitors should not enter these rooms without consulting medical or nursing staff, or the Radiation Safety Division.
4. Radiation exposure to personnel may be minimized by (a) working within the room as quickly as feasible, consistent with effective care, and by (b) spending as much time as possible behind any movable lead shields that may be placed around the bedside.

The body of a patient who dies while undergoing implant therapy should be removed from the room until such transport has been approved by the staff of the Radiation Safety Division.

E. MEDICAL CENTER AND CAMPUS X-RAY MACHINES

The State of North Carolina requires that all users of x-ray producing equipment register their x-ray machines with the North Carolina Division of Radiation Protection within thirty days of first use (North Carolina Administrative Code, Title 10A, Chapter 15, Section .0200).

1. ACQUISITION AND INSTALLATION OF X-RAY EQUIPMENT

The following policies pertain to the acquisition and installation of x-ray equipment facilities at the Duke University Medical Center or participating entities within the Duke University Health System.

- a. The Department or clinical entity responsible for the x-ray equipment shall notify the Duke Radiation Safety Officer prior to the new construction or the renovation of existing facilities that house x-ray producing equipment. To ensure that shielding calculations and other recommendations are compliant with radiation dose limits to the public, a review of the proposed floor plans and shielding will be completed and submitted to the North Carolina Radiation Protection Section for approval. Installation or relocation of x-ray equipment shall not take place until an acknowledgement letter from the North Carolina Radiation Protection Section is received.
- b. The Radiation Safety Division shall be notified immediately following purchase, acquisition or installation of any x-ray producing equipment.
- c. Upon completion of construction and/or renovations, a shielding continuity survey should be performed for the area covered in the shielding calculation report.
- d. Upon completion of the x-ray equipment installation, an environmental radiation protection survey of those unrestricted areas included in the shielding report shall be performed within thirty days of first use.
- e. All x-ray equipment, stationary and mobile, shall be added to the applicable registration with the State of North Carolina. All documentation will be kept on file at the offices of the Radiation Safety Division and a copy sent to the appropriate department manager.
- f. X-ray shielding aprons and other articles of x-ray shielding personal protective equipment shall be periodically inspected for integrity by each department. Results shall be submitted to the Radiation Safety Division via the Shielding PPE Registry Website: <http://vmw-oesoapps.duhs.duke.edu/radsafety/aprons/> .

2. GUIDELINES FOR THE SAFE USE OF X-RAY EQUIPMENT

The following policies pertain to the safe use of x-ray producing equipment. Such equipment includes, but is not limited to, digital and fixed plain-film radiographic equipment, bone densitometers, mobile (portable) units, CT scanners and fluoroscopy units. Other provisions set forth in pertinent subsections of the North Carolina Administrative Code, Title 10A, Chapter 15, Section .0600 shall also apply.

- a. Individuals who will be operating the x-ray equipment shall be instructed in the safe operating procedures and use of the equipment, and demonstrate an understanding of such procedures.
- b. Written safety procedures and rules shall be established and made available to each individual who operates x-ray equipment. All operators shall be familiar with these rules.
- c. Only the professional staff and ancillary personnel required for the medical procedure or for training shall be in the room during the radiographic exposure. "Ancillary personnel" may include parents of pediatric patients assisting with x-ray procedures for the purpose of avoiding sedation.
- d. All individuals shall be positioned so that any part of the body (including the extremities) which may be exposed to the primary (useful) beam is protected by 0.5 mm lead equivalent.
- e. Personnel not protected by shielding aprons shall avoid exposure to the primary beam, and should remain at least six feet away from the x-ray tube in order to minimize exposure to scattered radiation.
- f. Professional staff and ancillary personnel shall be protected from direct scatter radiation by protective aprons or whole body protective barriers of at least 0.25 mm lead equivalent.
- g. Mechanical holding devices shall be used whenever medical circumstances permit. If a human holder is required, the hand or other parts of the body that might be exposed to the primary beam shall be protected by 0.5 mm lead equivalent. No individual shall be used routinely to hold patients or film. Pregnant women and minors shall not hold patients or film during exposures.
- h. Gonad shielding of at least 0.5 mm lead equivalent shall be used for potentially procreative patients during radiographic procedures in which the gonads are within the primary beam, except when doing so would interfere with the diagnostic procedures.
- i. No individual shall be exposed to x-rays for purposes of education, demonstration, training, research or any other purpose not related to the healing arts, unless the individual is participating in clinical research approved by the Duke Institutional Review Board.

XII. EMERGENCY PROCEDURES FOR RADIOACTIVE MATERIAL

In the event that Radiation Safety Division personnel are needed to respond to an incident, contact may be established by calling the Duke Police Department (911 if the incident occurs on the main Duke University campus, or (919)684-2444 if off-campus).

A. Accidents or Injuries Involving Radioisotopes

1. For serious injuries - call the emergency number to arrange transport to the Emergency Department. Notify the Radiation Safety Division.
2. For minor injuries, wash the wound thoroughly under tepid water to flush out radioactive material. If an instrument contaminated with human blood or body fluids caused the wound, immediately call Duke's "Blood and Body Fluids Exposure Hotline" to report the exposure. Seek appropriate medical care from Employee Occupational Health & Wellness or the Emergency Department.
3. If anyone accidentally ingests, inhales, or otherwise absorbs any quantity of radioactive material, notify the Radiation Safety Division immediately.

B. Major Spills of Radioactive Material

1. Notify other persons in the area of the spill.
2. Evacuate area if spill is of a volatile material.
3. Immediately remove contaminated shoes or clothing.
4. Mark the spill area and limit access to avoid the inadvertent spread of contamination.
5. Flush contaminated skin thoroughly with tepid water.
6. Notify the Radiation Safety Division.

C. Fires Involving Radioisotopes

Follow the OESO Fire Safety site-specific fire plan for your area (<http://www.safety.duke.edu/fire-life-safety/site-specific-fire-plans>). If you discover a fire, follow the RACE procedures: Remove all persons in immediate danger to safety, activate manual pull station and call 911, close doors and fire shutters, and extinguish the fire if you are able to do so safely.

XIII. POLICY REGARDING ACCESS TO RADIOACTIVE MATERIAL PRESENT IN QUANTITIES OF CONCERN

The purpose of this policy is to ensure compliance with United States Nuclear Regulatory Commission Orders EA 05-090 and EA 07-305 and 10 CFR Part 37. This policy applies to entities at Duke University and the Duke University Health System that

possess and use such quantities of radioactive material which have the potential to result in significant adverse health impacts and could reasonably constitute a threat to the public health and safety through loss of control of the material, whether it be inadvertent or through a deliberate act (“Quantities of Concern”). Specifically, this policy addresses (a) access to irradiators containing encapsulated radioactive material that are used to irradiate blood products, small animals, cell cultures or other biological samples for clinical or research purposes and (b) access to certain high-dose-rate brachytherapy sources.

A. Unescorted access to irradiators or other quantities of concern will be granted only to personnel whose job duties require unescorted access, and for whom the RSO has approved an Application for Unescorted Access. Criteria for granting of unescorted access shall include, but not be limited to, obtaining the applicant’s fingerprints for submission to the Federal Bureau of Investigation, and completion of the required irradiator safety training. All other personnel may access quantities of concern only when escorted by, and under the direct constant supervision of, personnel who have been granted unescorted access. Personnel with escorted access must first complete the applicable safety training course.

B. Details of the policies and procedures required to obtain access to applicable Duke facilities may be found at the following web site: http://vmw-oesoapps.duhs.duke.edu/radsafety/irradiators/ic_policy.pdf . All questions regarding the policy, or the application, vetting and training process, shall be addressed to a Radiation Safety Division Operational Manager, or the Radiation Safety Officer.