

**RADIATION SAFETY
MANUAL FOR DUKE
UNIVERSITY AND
DUKE UNIVERSITY
MEDICAL CENTER**

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

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I. INTRODUCTION

The purpose of this manual is to describe the policies and procedures of the Radiation Protection Program for Duke University and the Duke University Medical Center. Specific conditions of the North Carolina Radioactive Material Licenses issued to Duke University and Duke University Medical Center require the establishment of peer committees to evaluate proposals for the use of radionuclides, the appointment of a radiation safety officer, and the implementation of a radiation safety program. In addition, the University and Medical Center administrations have determined that the use of radiation producing machines and non-ionizing radiation sources shall be included in the radiation safety program. These Radiation Safety policies are intended to ensure that such use is in accordance with applicable State and Federal regulations and accepted standards as directed towards the protection of health and the minimization of hazard to life or property.

The statutory basis of the Radiation Safety guidelines of the Duke University Radiation Safety Program includes 15A NCAC 11 (North Carolina Regulations for Protection Against Radiation), 10 CFR 20 (Title 10 Code of Federal Regulations, Part 20) and 10 CFR 35. In addition, stipulations of the Food and Drug Administration, the United States Department of Transportation, the Occupational Safety and Health Administration, the North Carolina Department of Environment and Natural Resources, and the Joint Commission contribute to the regulatory environment.

Due to frequent changes in the regulatory climate, and changes in 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 by posting material to the OESO Web site, via electronic mail or via campus mail as soon as it is approved by the Committees.

Although the safe use of lasers and other forms of non-ionizing radiation is an area of oversight by the Committees, complete coverage of these areas will be 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

and Medical School, and another to the University. 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, which, along with Biological Safety, Occupational Safety and Hygiene, Environmental Programs, Ergonomics, and Fire Safety, is a component of the Duke University Occupational and Environmental Safety Office (OESO). The Radiation Safety Division, in turn, provides guidance and oversight to all Authorized Users of radiation producing devices and radioactive material on campus, in the Medical Center, in the Medical School, and at specific accelerator facilities. In addition, the Radiation Safety Division provides support to the Radioactive Material Waste Program 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, the Duke University Medical Center Radiation Control and Radioactive Drug Research 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) and the Radiation Protection Act of the State of North Carolina define "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 / 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 phrase "As Low As Reasonably Achievable", or ALARA. This concept is incorporated in the regulations by requiring that all environmental releases and personnel doses be 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 a restricted area or in the course of employment in which the individual's assigned duties involve exposure to radiation or licensed radioactive material, whether in the possession of the licensee or registrant or other person. 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 described in 15A NCAC 11. A column identifying current Duke University ALARA action levels has also been included for reference purposes.

Table 1. Permissible Occupational and ALARA Doses

Body Part Exposed	Permissible Dose (Rem/Year)	Duke ALARA goal (Rem/Calendar Quarter)
Whole body (head, trunk, gonads, arms above elbows, legs above knees)	5.0	0.125
Lens of the eye	15.0	0.375
Single Organ	50.0	1.25
Hands and forearms, ankles and feet	50.0	1.25
Skin of whole body	50.0	1.25
Embryo/Fetus (see Note below)	0.5 rem during gestational period	0.5 rem during gestational period

Note on Fetal Radiation Dose: Fetal radiation dose is determined by appropriate monitoring of the pregnant woman. It is recommended that all women who work with radioactive material 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. Many of these are stipulations of North Carolina radiation protection regulations. 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 Duke University Committee on Radiological Safety (hereafter referred to as the "University Committee"), the Duke University Medical Center Radiation Control and Radioactive Drug Research Committee (hereafter referred to as the "Medical Center Committee"), and each Local Accelerator Radiation Safety Committee 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 to review matters pertaining to radiation safety, and receive a status report on such matters 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 conjunction 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. Investigate 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, in conjunction with 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 rapid 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.
 - 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. DUMML RADIATION SAFETY MANAGER

The Duke University Marine Laboratory (DUMML) does not have a full-time Radiation Safety Officer on site. Therefore the Marine Laboratory Director shall appoint a Radiation Safety Manager who will act as a representative of the Radiation Safety Officer. The DUMML Radiation Safety Manager is responsible for:

1. Approval of all DUMML radioisotope purchase orders.

2. Ensuring that received radioactive packages are checked in compliance with the applicable regulations.

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 to the best of his/her ability.
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 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 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. This enforcement policy does not apply to patient care areas (Radiology, Nuclear Medicine, Radiation Oncology, or Radiopharmacy). Instead, for these areas, the Division Director or Departmental Chair will receive copies of the audit results.

B. ENFORCEMENT PROCESS

1. The Radiation Safety Division will provide the Authorized User with written notification of any items of non-compliance discovered in that Authorized User's area of responsibility. If appropriate, the Radiation Safety Division 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 Radiation Safety Officer 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 of notification, send the Radiation Safety Officer a brief written explanation of:
 - a. what caused the item(s) of non-compliance,
 - b. steps taken to date by the Authorized User to correct the item(s),
 - c. further steps to be taken by the Authorized User, and
 - d. measures the Authorized User took or will take to prevent recurrence.
4. If the Authorized User has not achieved compliance to the satisfaction of the applicable Radiation Safety Division personnel within one week of notification, an Operational Manager and the Authorized User will discuss the matter.
5. If satisfactory resolution still cannot be obtained, the matter will be escalated to the Radiation Safety Officer, the appropriate Radiation Safety Committee and, if necessary, the Departmental Chair or Dean and senior Institutional Administration.

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 Radiation Safety Officer 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 Radiation Safety Officer will notify the Authorized User, the chair of the appropriate Radiation Safety Committee and appropriate senior management.
2. Withholding Material:
 - a. The Radiation Safety Officer or his/her designee may withhold delivery of radioactive material from any Authorized User failing to meet their Radiation Safety Manual responsibilities. The Radiation Safety Officer 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 Radiation Safety Officer's recommendation, restrict the authority of an Authorized User as a result of repeated or serious violations of Duke University/Medical Center policy. Radiation Safety Officer 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 review by 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

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, either tenure track or non-tenure track 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 "Senior Scientist" and "Research Senior Scientist" 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 "Adjunct", "Consulting" or "Visiting".

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 may contact the Radiation Safety Officer directly to obtain approval to amend the authorization. All such amendments 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 Radiation Control and Radioactive Drug Research 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 Title 10, Part 35 of the Code of Federal Regulations (10 CFR 35). These requirements generally involve (1) training in basic radioisotope handling techniques, (2) supervised clinical training in an institutional 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 15A NCAC 11.0318(c). Applicants may demonstrate fulfillment of the requirements either by specialty board certification, or by preceptor attestation.

3. Apply to the Secretary of the Radiation Safety Committees through his/her Departmental Chair or other individual designated by the Department. The application must be accompanied by a copy of the licensee's registration certificate issued by the North Carolina Medical Board documenting 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.

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 15A NCAC 11.0318(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 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 15A NCAC 11.0318(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. 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 Radiation Safety 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 includes projects 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, or a single-exposure value of 3 rem. The total critical organ dose shall not exceed 15 rem annually. For research subjects who have not reached 18 years of age, the maximum permissible whole body and critical organ exposure limitations 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.

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 a trial that is beyond the standard of care. The IRB requires that such protocols undergo “Specialty Committee” review and approval. The Medical Center Radiation Control and Radioactive Drug Research 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 shall use the Duke Radiation Safety Committee’s web site (<http://www.safety.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. Investigators may contact the Radiation Safety Division for assistance in using the Web site to create their study-specific radiation risk statements.

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://www.safety.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 best available 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 "As Low as Reasonably Achievable" (ALARA) approach to minimizing radiation exposure. Badges are obtained through the Radiation Safety Division of the Occupational and Environmental Safety Office (OESO). The guidelines for personnel monitoring adopted by Duke University are summarized in the following sections.

A. MONITORING BADGES AND ISSUANCE CRITERIA

Monitoring badges measure integrated external radiation dose received over extended time periods. The policies for obtaining a new monitoring badge, exchanging badges, and obtaining an exposure history are outlined below. Specific details may be obtained by consulting the current Personnel Dosimetry Procedure, which is available from the Radiation Safety Division.

1. All persons exposed to certain licensed or registered radiation sources on a routine basis shall wear an appropriate monitoring badge 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.
2. Badges 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 over a period of time. A contact person in each laboratory or department is responsible for badge exchange at the determined frequency.

3. Records of personnel exposures shall be maintained by the Radiation Safety Division.
4. Each individual to whom a badge is issued has the responsibility to ensure its proper wear and use.
5. Pocket dosimeters are an alternate form of obtaining a person's radiation exposure. These small, portable ionization chambers or direct reading, digital, electronic dosimeters enable the user to monitor the estimated absorbed dose received over brief intervals of time. They 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 must be given a pocket dosimeter prior to their entrance into the laboratory area. Records of the doses to visitors are kept in each lab. Pocket dosimeters shall not be utilized in lieu of a monitoring badge, if the person has been issued a badge. Under certain circumstances, the use of both a badge and pocket dosimeter may be required. If pocket dosimeters are utilized, they must be calibrated annually by the Radiation Safety Division.
6. 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, outside any shielding aprons or other shielding personal protective equipment. 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.
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 Environment and Natural Resources.

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 no more than 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 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 administrations of bound forms of I-131 such as I-131 MIBG, anti-B1, 81C6, etc: 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 standing across the room, and 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 iodination procedures in the Radiopharmacy shall obtain a thyroid burden measurement no more 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 iodinations performed in authorized research laboratories shall obtain a thyroid burden measurement no more than seven (7) days following the iodination procedure. The amount of radioactivity and the conditions of

iodination which trigger this requirement 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. 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 shall be done by the Radiation Safety Division.

Types of Operations Involving I-125 or I-131

- a. Processes in open room or bench; with possible escape of iodine (a situation strongly discouraged):
Quantities requiring thyroid monitoring:
Volatile or dispersible:.....1 mCi
Bound to non-volatile agent:.....10 mCi
- b. Processes with possible escape of iodine carried out within a fume hood of adequate design, face velocity, and performance reliability:
Quantities requiring thyroid monitoring:
Volatile or dispersible:.....10 mCi
Bound to non-volatile agent:.....100 mCi
- c. Processes carried out within glove boxes, ordinarily closed, but with possible release of iodine from process and occasional exposure to contaminated box and box leakage:
Quantities requiring thyroid monitoring:
Volatile or dispersible:.....100 mCi
Bound to non-volatile agent:.....1000 mCi
- d. In those laboratories working only with I-125 radioimmunoassay (RIA) kits, the quantities of I-125 are very small and contained in a non-volatile form. Thyroid monitoring is not required.

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 fetus shall not exceed 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 monitoring badge, if appropriate.

An employee who has declared her pregnancy shall inform the Employee Occupational Health and Wellness if her pregnancy is terminated 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. Schedule, via the Radiation Safety Division, thyroid bioassays for each individual handling radioiodine, e.g. I-125 or I-131, in quantities and in operations described in Chapter V.
- 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 checked 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 2 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 2 limits. Alternatively wipe test results may be documented in disintegrations per minutes (DPM) using an appropriate conversion factor and compared directly to the Table 2 limits.

Table 2. 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 must 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 Officer.

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

1. ORDERING RADIOACTIVE MATERIAL

Research laboratories must submit all radioactive material orders to the Radiation Safety Division using the web-based ordering facility specified by the Radiation Safety Officer (see the Radiation Safety Web Site for details). 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. Contact the Radiation Safety Division 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 Monday through Friday, excluding 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 their designee. 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 Radiation Safety 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. TRANSPORTATION OR SHIPMENT OF RADIOACTIVE MATERIAL

The transportation or shipment of radioactive material 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 radioactive shipments and transport within or from Duke University must receive 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 transferred, donated, sold or discarded without notification of and approval by the Radiation Safety Officer.

6. DISPOSAL OF RADIOACTIVE WASTE

The Environmental Programs Division of the Occupational and Environmental Safety Office handles radioactive waste management for 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. Direct questions to the Environmental Programs Division at (919)684-2794 or env.progs@mc.duke.edu.

Specific requirements for the disposal and collection of radioactive waste are available on the Environmental Programs Division Web site. Radioactive material, in any amount, must always be disposed of as radioactive waste and never 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 sewer should not be used as a primary means of radioactive waste disposal. Instead, liquid waste should be handled as specified by the OESO 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" 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 some 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 for that facility.

The principal radiation hazards in 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.

A. DIRECT BEAM AND SECONDARY RADIATION

Personnel exposure to the direct particle beam or secondary radiation emitted from bombarded targets shall not be permitted. 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. Short- or long-lived radioisotopes may be

present. For example, impurities in aluminum components may be activated to Co-56 by a proton beam or to At-211 (an alpha emitter) by a He-4 beam. Stainless steel screws or other parts not in the direct beam may be neutron-activated to Co-57. 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 of.

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

^{*}"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.

^{**}"Ancillary Workers" include non-radiology physicians and residents, phlebotomists, Environmental Services workers, waste processors and animal caretakers.

***"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 representatives of 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 shall be provided with a private room with private bathroom facilities.
2. Before the patient is admitted to the room, the floors, and sink should 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 personnel of the Radiation Safety Division.
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 will be posted with a sign bearing the standard radiation symbol (a black or magenta tri-blade on a white or yellow background) and the words "Caution: radioactive material". 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. These 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, limitation of 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 except 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. The body of a patient who dies while undergoing systemic radionuclide therapy is not to be removed from the room until such transport has been approved by staff of the Radiation Safety Division. Contact the Radiation Safety Division for instructions (Beeper ID 970-9703, or the Duke Police at 911 from campus, or (919)684-2444 from off-campus).
7. 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), practicing good housekeeping, clean work habits, and frequent hand washing. In general, the protective principles based on the Universal Precautions for Blood and Body Fluids shall be followed.
8. Time spent close to patients should be limited to the minimum amount of time required to perform duties consistent with effective patient care. If the hazard is high, the Radiation Safety Division or physician in charge will issue special instructions.
9. Protective gloves and shoe covers shall be worn upon entering a patient's room. Hands shall be washed after leaving a patient's room. Contaminated materials which can be incinerated, such as paper handkerchiefs, gauze sponges, shoe covers and gloves, shall be discarded into the non-porous garbage bags provided in the room and transported to the Radiation Safety Division for disposal. 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.
10. A laundry bag shall be used to collect linen where there is the possibility of contamination by vomiting, incontinence, or profuse perspiration.
11. Items such as bedpans, urinals, and basins, if disposable, may be disposed of as radioactive waste. If these items are not disposable, they shall be thoroughly washed with soap and running water. The same items should be used for the individual patient until his/her treatment is terminated and

must be monitored before being returned to general stock. Protective gloves shall be worn while cleaning possibly contaminated equipment. These gloves shall be washed with soap and running water while on the hands, and dried before removal.

12. In the case of radioiodine-131 therapy, all patient urine will be collected in bottles with special shields which will be provided by the Nuclear Medicine Laboratory. These 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. Any vomitus, gastric contents collected during the first 24 hours by nasogastric aspiration, or excessive sputum should be collected in a waterproof container and held for disposal by Radiation Safety Division personnel. If there has been a spill of urine, the Radiation Safety Division or Nuclear Medicine Laboratory 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.
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 (per existing hospital visiting policy).
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 exposure rate at one meter from the patient does not exceed seven (7) milliroentgens per hour; or
2. The iodine-131 radioactivity retained in the patient does not exceed 33 millicuries; or
3. 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 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 one or more of these 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)

These patients are treated with sealed sources of radioactive material that are configured for placement directly into tumors or into body cavities. Such sources, sometimes referred to as "implants", may be configured as needles, wires,

"seeds", ribbons or other geometric forms. The primary radiation hazard from patients treated with implants is external gamma irradiation. The following policies are intended to minimize this hazard.

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 (Beeper ID 970-9703, or the Duke Police at 911 from campus, or (919)684-2444 from off-campus).
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. 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 permitted 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, nursing 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.
5. The body of a patient who dies while undergoing implant therapy is not to be removed from the room until such transport has been approved by the staff of the Radiation Safety Division. Notify the Radiation Oncologist on call and contact the Radiation Safety Division for instructions (Beeper ID 970-9703, or the Duke Police at 911 from campus, or (919)684-2444 from off-campus).

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 15A, Chapter 11, 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 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. To ensure that shielding calculations and other recommendations are adequate to ensure that radiation dose to the public is below regulatory limits, a review of the proposed floor plans and shielding will be completed and submitted to the North Carolina Division of Radiation Protection for approval. Installation or relocation of x-ray equipment shall not take place until an acknowledgement letter from the North Carolina Division of Radiation Protection is received.
- b. Upon completion of construction and/or renovations, a shielding continuity survey should be performed for the area covered in the shielding calculation report.
- c. Upon completion of the x-ray equipment installation, an environmental radiation protection survey shall be performed within thirty days of first use.
- d. All x-ray equipment, stationary and mobile, will be added to the institutional registration with the State of North Carolina. All reports will be kept on file at the office of Radiation Safety and a copy to be sent to the appropriate department manager.
- e. X-ray shielding aprons and other articles of x-ray shielding personal protective equipment are periodically inspected for integrity by each department. Results are submitted to the Radiation Safety Division via the Shielding PPE Registry Website: <http://www.safety.duke.edu/radsafety/aprons/default.asp>

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 15A, Chapter 11, 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 operating 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.
- 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 from these units, and shall remain at least six feet away from the x-ray tube in order to avoid 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.
- 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.

F. PROCEDURE FOR HOSPITAL PHLEBOTOMISTS AND OTHER INDIVIDUALS OBTAINING CLINICAL SPECIMENS FROM RADIOISOTOPE THERAPY PATIENTS

1. APPLICABLE PERSONNEL

The following procedures for obtaining, transporting or analyzing clinical specimens from patients who are undergoing systemic therapy with radioactive material are intended for (but not limited to) hospital

phlebotomists, clinical laboratory workers, research technicians, transporters, nurses and physicians.

Special Note On Specimens From Patients Undergoing Diagnostic Radionuclide Tests

There are no special radiation precautions necessary for samples from patients undergoing diagnostic Nuclear Medicine procedures such as bone scans, PET scans, cardiac stress tests, etc. Diagnostic procedures typically use very small amounts of short-lived radionuclides, and specimens from these patients are not of a public health or regulatory concern. Specimens shall be obtained observing "Universal Precautions", and disposal may be made via the appropriate "Biohazard" waste stream.

2. GENERAL PROCEDURES FOR OBTAINING SPECIMENS FROM SYSTEMIC RADIONUCLIDE THERAPY PATIENTS

- a. *Read any instructions posted at the door.*
- b. *Specimen containers must be labeled with "Radioactive Material" labels or tape to identify them as radioactive. If these labels are not available in the chart box, in the patient's room or at the nursing station, call Radiation Safety at (919)684-2194 for supplies. Place all necessary labels on the specimen containers before entering the room, to minimize time spent in the room and handling samples. Do not bring open containers of food or beverage into the room.*
- c. *Put on a face-mask if the patient has a tracheostomy or has symptoms of a respiratory infection (sneezing, coughing). Respiratory secretions have been found to be a significant source of room contamination.*
- d. *Wear shoe covers while in the room. They should be removed upon leaving the room.*
- e. *Do not use the sink for hand-washing or use the patient's telephone while in the room.*
- f. *Put on protective gloves before entering the room. Obtain the specimen while abiding by "Universal Precautions".*
- g. *Spend the minimum amount of time in the room necessary to obtain the specimen consistent with courtesy and good technique.*
- h. *Remove any personal protective equipment and discard in the containers labeled for radioactive waste which will be located inside the room. After leaving the room, proceed to a "clean" sink and wash hands thoroughly with soap and water.*

3. GENERAL PROCEDURES FOR TRANSPORTING SPECIMENS TO THE LABORATORY

Transport the tubes to the appropriate Clinical Laboratory. Wear protective gloves when handling the specimen. No special radioactivity-related precautions are necessary during transport.

4. GENERAL PROCEDURES FOR PROCESSING SPECIMENS AND DISPOSAL

When handling and processing specimens, observe the procedures for 'Standard Blood and Body Fluid Precautions'. Once analyzed, the specimen containers should be segregated from the regular biological waste. *Do not discard in the regular trash or in the normal "biohazardous materials" waste stream.* Hold in a separate container, such as an appropriately labeled zip-lock storage bag, for specimen pick-up. If the material is to be refrigerated during storage, the refrigerator must not contain food, beverages or other items for human consumption. To arrange to have the specimens removed for final disposition, call Radiation Safety at (919)684-2194. If you wish to contact Radiation Safety regarding specimen disposal after normal business hours, you can send the request via facsimile to (919)668-2783.

5. REPRODUCTIVE HEALTH CONSIDERATIONS

Pregnancy: The small amounts of radioactive material encountered in clinical specimens do not present a significant external radiation hazard, so there is no significant risk to a pregnant employee being in close proximity to the specimens. However, due to the avidity of radioiodine-131 and radioastatine-211 for the fetal thyroid gland after the 12th week of gestation, it is recommended that pregnant employees not process clinical specimens from radionuclide therapy patients. Since it may not be possible to determine the exact radionuclide present in the sample, this recommendation is extended to specimens from any radionuclide therapy patient.

Due to the high external radiation levels encountered in the bodies of radionuclide therapy patients, and due to the possibility of contamination within the rooms, it is recommended that pregnant employees not obtain clinical samples from these patients.

Breastfeeding: Radioiodine-131 and other radionuclides can be secreted in breast milk and passed along to the nursing infant. Breastfeeding employees may safely process and transport clinical specimens from radionuclide therapy patients, as long as strict adherence to "Universal Precautions" is maintained. However, it is recommended that employees who are breastfeeding not obtain clinical specimens from radionuclide therapy patients.

XII. EMERGENCY PROCEDURES FOR RADIOISOTOPES

In Case of Emergency, Always Call for Help: Duke Police, 911 or (919)684-2444.

A. Accidents or Injuries Involving Radioisotopes

1. For serious injuries - call the emergency number (911) to arrange transport to the Emergency Department.
2. Notify the Radiation Safety Division.
3. Wash minor wounds thoroughly under tepid water to flush out radioactive material. If an instrument contaminated with human blood or body fluids caused the wound, immediately call the "Blood and Body Fluids Exposure Hotline", (919)684-8115, to report the exposure.
4. For minor injuries, seek appropriate medical care from Employee Occupational Health & Wellness or the Emergency Department.
5. If anyone accidentally ingests, inhales, or 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 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/FireSafety/SSFP/default.htm>) If you discover a fire, follow the RACE procedures: Remove all persons in immediate danger to safety, activate manual pull station and notify 911, close doors and fire shutters and extinguish the fire, if you are able to do so safely.