REGULATIONS REGARDING THE SAFE USE OF SOURCES OF IONIZING RADIATION

UNIVERSITY OF PITTSBURGH
RADIATION SAFETY COMMITTEE

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Revised - 2/03

Summary of 2/03 revisions to “Regulations Regarding the Safe Use of Sources of Ionizing Radiation” manual.

Chapter 2	Committees - editorial changes
Chapter 3	Changes in regard to transfer of Office responsibilities to the RCCO
Chapter 5	Radiation Producing Machines - moved to Chapter 4 and revised in its entirety.
Chapter 4	Radioisotopes - moved to Chapter 5
	Section 5.4 - on reporting pregnancies revised
Chapter 6	Section 6.3 - revised
Chapter 7	Revised in its entirety
Chapter 9	Waste Disposal - procedural material removed - with pointers to its new location
Chapter 10	Removed
Chapter 11	Training -editorial changes
Appendices	Remove

10CFR refers to Title 10 of the Code of Federal Regulations.

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Chapter 1

INTRODUCTION

Safety of personnel must be a major consideration when using radioisotopes, particle accelerators, x-ray producing machinery, and other sources of ionizing radiations. Federal regulations, under which the University possesses NRC licenses permitting the use of radioactive materials, require the existence of a radiation safety committee to coordinate such use, and supervise the institution's radiation safety program. The Commonwealth of Pennsylvania also has certain pertinent radiological health regulations requiring licensure and the maintenance of a radiation safety program. Accordingly, a committee, known as the Radiation Safety Committee has been authorized by the Chancellor of the University to review and make recommendations on proposals to utilize sources of ionizing radiations, and ensure the safety of such operations when they are established.

Nuclear Regulatory Commission (NRC) Regulations (Title 10 Code of Federal Regulations, CFR), Commonwealth of Pennsylvania Regulations (Title 25, Article V Radiological Health) and all license conditions and amendments regarding the safe uses of ionizing radiation sources, will be followed. In addition, the recommendations of the National Council on Radiation Protection and Measurements will be adopted as appropriate.

Copies of the above-named documents and all current licenses, license correspondence, and registrations relating to radiological safety are available through the Radiation Safety Office. Copies of current regulations may also be found on the respective agencies Web sites.

Chapter 2

THE RADIATION SAFETY COMMITTEE

2.1 PURPOSE

The Committee is advisory to the Chancellor, and under his direction, it acts as a regulatory body whose objective is to insure health standards to prevent over-exposure of personnel through appropriate supervision of the uses of all sources of ionizing radiations which come within its jurisdiction. These sources include all radioisotopes acquired under the University licenses and all other sources, including radiation producing machines and radium owned by and operated within the University. The Radiation Safety Officer and staff are authorized and directed to visit and oversee all installations owned by and operated within the University where sources of radiation are employed, whether or not they are operated under license or contract, so as to report apparent risks to the responsible persons. The Committee is concerned with the qualifications of users and with the uses, insofar as radiological safety is concerned on a University-wide basis. These regulations also apply to UPMC facilities which utilize the services of the University of Pittsburgh Radiation Safety Program. A list of these facilities may be found on the Radiation Safety Office Web site.

2.2 MEMBERSHIP AND TERMS OF REFERENCE

As in other major advisory committees within the University, appointment to the Radiation Safety Committee is made by the Chancellor or his designee. The Committee is composed of the Chairperson, the Vice-Chairperson, the University Radiation Safety Officer, the Committee Physician, general members (representative of each type of use of radioactive material or ionizing radiation generating source), a representative of the UPMC Nursing Service, and management representatives from the appropriate offices for academic and business affairs.

One half of the members of the Radiation Safety Committee including the Radiation Safety Officer and a management representative, must be present to constitute a quorum at the Committee's quarterly meetings.

The Radiation Safety Officer must be technically qualified to advise and assist on radiological safety problems of all types which might occur within the responsibilities of the University. This appointment must be acceptable to the reviewing regulatory agencies, to the administrative officers who are concerned, as well as to a majority of the Radiation Safety Committee and with final approval by the Chancellor.

The Committee Physician must be a physician technically qualified in the diagnosis and management of radiation over-exposure. The appointment is to be approved by a majority of the Radiation Safety Committee, as well as majority of the administrative officers who are concerned, with final approval by the Chancellor.

General members must be, in the Committee's view, technically qualified to use radiation sources in their respective fields of study.

The management representatives for academic and business affairs are designated by University administration.

A current list of the committee membership may be found on the Radiation Safety Office's web site.

2.3 STANDING COMMITTEES

2.3.1 Executive Committee:

This Committee is composed of the Chairperson and Vice-Chairperson of the Radiation Safety Committee, the Committee Physician, the Radiation Safety Officer, a management representative and a health physicist. The Executive Committee has the special function of acting on behalf of the

Radiation Safety Committee in emergency meetings. This Committee reviews and may give interim approval to applicants for Authorized User status. It also reviews and approves all uses of radioactive materials and radiation producing equipment, subject to final Committee approval.

2.3.2 Radioactive Drug Research Committee (RDRC)/Human Use Subcommittee (HUSC)

This combined committee's special function is to review and approve all uses of radioisotopes in humans for diagnostic, therapeutic and research purposes. The RDRC is established under the authority of the FDA in 21 CFR 361.1 and has responsibility for the review and approval of research studies involving radioactive drugs that are not currently the subject of an approved IND or NDA. The HUSC is responsible to assure that all clinical and research uses of radioisotopes are in compliance with the Nuclear Regulatory Commission or Commonwealth of Pennsylvania radioactive materials licenses and regulations. To facilitate the review and approval of the different categories of human use, the members of the RDRC also serve in the capacity of the HUSC. The committee consists of 5-8 individuals with required representation by a physician boarded in nuclear medicine, a radiopharmacist, and a person with special competence in radiation safety and radiation dosimetry. The remainder of the committee will include individuals with special competence in radiation therapy, radiology, internal medicine, endocrinology, cardiology, neurology, psychiatry, or other pertinent disciplines. The names and qualifications of the members of this committee shall be submitted to the FDA. A chairperson of the committee is designated by the chairperson of the Radiation Safety Committee to oversee the conduct of committee meetings and sign all applications, minutes and reports. The committee meets once each month with a quorum of more than 50 percent of the members required to be present. Members of the committee also review research protocols involving diagnostic X-ray procedures which are not part of a patient's routine clinical care. Review comments and recommendations on these protocols are submitted to the Biomedical Institutional Review Board, to be incorporated into their review and approval process.

Chapter 3

RADIATION SAFETY OFFICE

3.1 PURPOSE

In order to implement the rules and recommendations of the Radiation Safety Committee, the University has established the Radiation Safety Office, which administratively reports to the Vice Chancellor for Research Conduct and Compliance. The Radiation Safety Office is headed by the Radiation Safety Officer.

3.2 FUNCTIONS

1. Implement the recommendations of the Radiation Safety Committee.

2. Perform routine surveys as the University Radiation Safety Committee deems necessary, and as existing regulatory requirements mandate.

3. Evaluate qualifications of prospective Authorized Users of radioisotopes and provide all necessary information to the Executive Committee for approval as appropriate.

4. Approve purchases of radiation sources authorized by the Executive Committee.

5. Maintain records of occupational radiation exposures as measured by personnel monitoring dosimeters and bioassay determinations, records of radiation surveys, and records of the disposition of all radioisotopes and radiation producing machines in the University. This may include records maintained by users showing safe use of radiation sources, including records of users' surveys, and source disposition.

6. Perform evaluations and non-routine monitoring of operations in which there is reasonable possibility of hazard.

7. Perform surveys on incoming radioisotope package receipts in accordance with requirements of Title 10CFR20 or other applicable regulations.

8. Maintain current inventory of radionuclides.

9. Coordinate and maintain records of radioactive waste collection, processing, and disposal in accordance with all pertinent regulations.

10. Provide, or arrange for, radiation safety training of workers involved in the use of radioisotopes and/or radiation producing machines.

11. Provide advice and recommendations regarding safe and proper use of radioisotopes, radiation producing machines, decontamination, waste disposal, survey instrument purchases, etc.

12. Calibrate health physics radiation measuring and monitoring instruments used for personnel exposure determinations and contamination control.

13. Maintain all State and Federal licensing and registration documentation.

14. Assure compliance with all applicable regulatory, license and Radiation Safety Committee requirements.

15. Review (and approve) plans for construction or renovation of facilities utilizing radiation sources.

Violations of good laboratory practice leading to unnecessary exposure or violations of applicable safety regulations as found by the Health Physics staff will be brought to the attention of the responsible user. If the violations are not corrected, they will be reported to the Executive Committee which, after review of the facts, will recommend appropriate action that may include a formal report to the department chairman or revocation of approval to order and use radioisotopes or radiation producing equipment.

In emergency situations the Radiation Safety Officer is authorized to require immediate cessation of the use of radiation sources and implement any other actions necessary to ensure safe operating conditions. Such emergency action will be reviewed at a specially convened meeting of the Radiation Safety Committee or Executive Committee, with a recommendation for subsequent action being made to the University administration.

Chapter 4

PROCUREMENT AND USE OF RADIATION PRODUCING MACHINES AND EQUIPMENT

4.1 SCOPE OF AUTHORITY FOR MACHINE REGULATION

All machines which generate ionizing radiation are subject to regulation by the Radiation Safety Committee. This includes all clinical or research x-ray machines (radiographic, fluoroscopic, bone densitometers, etc.), analytical x-ray machines, electron microscopes and particle accelerators. Note: Any high voltage vacuum device may be capable of producing x-rays. If there are any questions regarding the capability of a device to produce ionizing radiation, contact the Radiation Safety Office.

4.2 REGISTRATION AND LICENSING OF RADIATION PRODUCING MACHINES

All machines producing ionizing radiation (radiographic, fluoroscopic, cabinet x-ray machines, particle accelerators, electron microscopes, analytical x ray units, etc.) must be registered with the Commonwealth of Pennsylvania. The Radiation Safety Office has the responsibility to maintain and modify these registrations. There are fees associated with these registrations.

For particle accelerators, the Radiation Safety Office must notify the Commonwealth within 30 days after the initial order is placed and a license must be obtained prior to the first use.

Effective February 1, 2003, all medical accelerators must be licensed by the Commonwealth of Pennsylvania, Department of Environmental Protection. The Radiation Safety Office has the responsibility to maintain and submit these licenses to the Commonwealth. Licensing fees will be managed by the Radiation Safety Office.

4.3 FACILITY DESIGN AND PREPARATION

Devices which produce significant external radiation fields may require that specialized shielding be installed. All shielding designs must be approved by the Radiation Safety Office prior to the start of construction.

4.4 PROCUREMENT AND INSTALLATION OF RADIATION PRODUCING MACHINES

Whenever radiation producing machines are purchased, transferred, or disposed-of, the Radiation Safety Office shall be notified in writing by the responsible individual prior to installation or disposal of the equipment.

Each newly purchased machine and the facility in which it is installed shall be surveyed by the Radiation Safety Office for compliance with applicable Commonwealth and Federal regulations.

4.5 AUTHORIZATION TO USE RADIATION PRODUCING MACHINES

4.5.1 UNIVERSITY

The faculty member who is responsible for the overall supervision of the operation of any radiation producing machine must submit an application for such use. The application “Application to Possess and Use Radiation Generating Devices” (Form RSO XR314) should be completed with sufficient detail for the Radiation Safety Committee to determine that the applicant’s radiation protection program, equipment and facilities are adequate to minimize radiation exposures to workers and the environs.

The application should be completed and sent to: Radiation Safety Office, G-7 Parran Hall, GSPH. Upon approval, a copy of the original application with all attachments will be returned to the applicant. Approval requires, as a condition, that the user follow all statements and representations set forth in the application and any supplements to it.

4.5.1.1 PERIOD OF AUTHORIZATION

Applications must be reviewed and updated on a periodic basis. Authorization will be granted for intervals not to exceed 4 years. At the time of expiration a renewal will be required. The Radiation Safety Office will initiate the renewal process.

4.5.1.2 MODIFICATIONS TO FACILITIES, EQUIPMENT OR PROGRAM

Modifications to facilities, equipment or the safety program requires prior approval of the Radiation Safety Officer and may require amendment to the Authorization and prior approval by the Radiation Safety Committee.

4.5.1.3 EXEMPTIONS

Electron Microscopes and Cabinet X-Ray machines are exempted from the application process; however they must still be registered with the Radiation Safety Office, they are subject to annual audits and operators must receive training. The Radiation Safety Office must be notified if repairs or modifications are made which might result in increased radiation exposures in the machine environment.

4.5.2 AUTHORIZATIONS WITHIN CLINICAL FACILITIES

Authorization (privileges) to use x-ray machines for clinical purposes is the responsibility of the facility's respective Medical Staff Credentialing Program.

4.6 USER RESPONSIBILITY

The individual responsible for the overall supervision of operation of any machine, designated as the User will be responsible for its safe operation and use. In addition to the stipulations indicated on the User's authorization, compliance with the applicable parts of Commonwealth of Pennsylvania's Title 25, Chapters 215 (General Provisions), 216 (Registration), 219 (Protection), 221 (Healing Arts), 223 (Veterinary), 225 (Industrial), 227 (Analytical and Electron Microscopes), and 228 (Accelerators) are mandatory. These regulations are available from the Radiation Safety Office or on-line at the Commonwealth's WEB site (http://www.pacode.com/secure/data/025/articleIDV_toc.html).

Assembly, modifications or repairs of equipment must be performed in accordance with Title 21 Code of Federal Regulations Parts 1000 and 1020 or other regulations as applicable, and are the responsibility of the User, or if appropriate, the manufacturer, service technician, etc.

It is the User's responsibility to keep the Radiation Safety Office apprised of any modifications to the machine, changes of personnel or any changes in the machine or facility which may impact safe use. The latter must be approved by the Radiation Safety Officer before the changes can be implemented.

The User shall assure that all items of noncompliance noted as a result of audits performed by Radiation Safety Office staff will be corrected within a reasonable period of time following notification.

In emergencies, or in situations of continued operation of radiation producing machines which fail to meet applicable regulations regarding their safe use, the Radiation Safety Officer is authorized to require immediate cessation of use of the machine and to take any other actions necessary to ensure safe conditions.

4.7 HUMAN USE FOR RESEARCH PURPOSES

Research conducted within the jurisdiction of the University or associated UPMC facilities must be adequately justified through written petition to the Human Use Subcommittee. This requirement does not exempt the petitioner from any requirements for applicable approvals by other committees constituted to review research with human subjects. Amendment of the application is necessary if conditions of the use change.

4.8 OTHER X RAY MACHINE USES

Although the prime responsibility of the Radiation Safety Committee lies in the areas of facility design, machine safety, and exposure limitation, the need for x-ray machines in University locations outside of a recognized clinical area will be reviewed; e.g., at athletic facilities. If the Committee determines that there exists insufficient justification for use or placement in a peripheral location, the matter will be presented to the appropriate responsible authorities for resolution.

Chapter 5

AUTHORIZED USER OF RADIOISOTOPES

5.1 DEFINITIONS

Authorized User: Any person approved by the Executive Committee of the Radiation Safety Committee to order, purchase, possess, and use radioisotopes in accordance with these regulations, shall be known as an Authorized User.

Human Use: The internal or external administration of radioactive material or the radiation there from to human beings

5.2 QUALIFICATIONS

University faculty and staff members who are engaged as a principal investigator and/or have significant responsibility for administrative, medical, academic, or experimental functions involving radioisotopes, and can demonstrate an acceptable level of competence in the safe handling of radioisotopes may apply to be Authorized Users.

5.3 BASIS FOR APPROVAL TO USE RADIOISOTOPES

Approval to use radioisotopes will be based upon the hazards involved with the type and activity of radioisotope requested, the training and experience of the applicant, and with the user's acknowledgment of his/her responsibility for: insuring the safety of employees and the public; minimizing exposures to employees, students, and the general public, both inside and outside the controlled area; and avoiding significant releases of radioactive material to the environment. The applicant must insure that the application correctly and adequately describes the procedures and safety precautions to be followed. These procedures should be evaluated in light of the following philosophy:

1. No practice shall be adopted unless its introduction produces a positive net benefit (justification).

2. All exposures shall be kept as low as reasonably achievable, economic, technological and social factors being taken into account (optimization).

3. The dose equivalent to individuals shall not exceed the limits recommended for appropriate circumstances (compliance with regulatory dose limits and ALARA).

Failure to do so may result in delay of application approval or rejection of the application.

5.4 RESPONSIBILITIES OF THE AUTHORIZED USER

The Authorized User has direct responsibility for all aspects of radiation safety associated with his/her possession and use of radioisotopes. Specifically, this responsibility includes but is not limited to the following:

1. Instruction in radiation safety practices for all personnel working with or around radioisotopes under the Authorized User's supervision or direction, including the proper response to emergencies[1].

[1] Specific information on emergency procedures can be found in the Radiation Training Manual or on the University of Pittsburgh EH&S Emergency Procedure card which should be posted in the laboratory.

2. Provision and maintenance of equipment necessary for the safe handling of radioisotopes and instruction on its proper use.

3. Establishment and maintenance of procedures for safely opening and handling packages in which radioactive material is received.

4. Notification to the Radiation Safety Office of any accident or abnormal occurrence involving, or suspected of involving, radioisotopes or radiation producing machines. Notification is required in all cases of personnel contamination or suspected ingestion.

5. Assurance of sufficient methods and materials for contamination control within each laboratory to prevent the spread of such contamination to other areas.

6. Proper labeling of sources, storage areas, waste containers, contaminated items and areas of use.

7. Provision of sufficient security measures against the misuse or theft of radiation sources under the Authorized User's possession.

8. Provision of sufficient shielding for stored materials to prevent unnecessary exposure.

9. Proper disposal of radioactive waste.

10. Provision of contamination surveys and maintenance of records of such surveys in laboratories as required by the Radiation Safety Program.

11. Maintenance of accurate inventory records of radioisotopes in use or storage.

12. Notification and arrangement with the Radiation Safety Office for transferring Authorized User responsibilities during extended leaves of absence such as sabbaticals.

13. Notification to the Radiation Safety Office when intending to transfer radioisotopes or radiation sources from the stated areas of use to another Authorized User. Such transfers must have prior approval to ensure that the uses and locations are properly identified and controlled.

14. Limit ordering to only radioisotopes and activity amounts for which the User has been pre-approved by the Radiation Safety Committee. Submit each purchase order or requisition to the Radiation Safety Office for approval.

15. Advise female radiation workers to review the Committee policy on pregnant radiation workers.

16. Notification of significant changes in approved user application information, such as new personnel, use in new locations, changes in research or clinical protocol involving new or increased activity amounts of radionuclides, changes from in-vitro to in-vivo testing with radioactive materials, etc.

17. Timely response to special requests for non-routine sampling, measurements, or tests for radioactivity.

18. A total commitment for maintaining all exposures to radiation sources "as low as reasonably achievable" (ALARA).

19. Notification to the Radiation Safety Office when permanently leaving the University in order to arrange for an orderly lab and radioactive material closeout.

20. Obtain approval from the Radioactive Drug Research Committee/Human Use Subcommittee when using radiation sources for research, diagnostic, or therapeutic purposes involving exposure to humans.

5.5 APPLICATION FOR LABORATORY USE OF RADIOACTIVE MATERIALS

Each prospective Authorized User shall submit an "Application for Authorization to Use Radionuclides" (Form RSO 313) to the Radiation Safety Office. All items on the application form should be completed in sufficient detail for the Radiation Safety Executive Committee to determine that the applicant's radiation protection program, equipment, and facilities are adequate to minimize health risks, adverse effects on other research, and property loss. The applicant is urged to be realistic with regard to the categories and quantities of radionuclides for which authorization is requested.

The application should be completed and sent to: Radiation Safety Office, G-7 Parran Hall, GSPH. Upon approval, a copy of the original application with all attachments will be returned to the applicant. Approval requires, as a condition, that the user follow all statements and representations set forth in the application and any supplements to it.

5.6 APPLICATION FOR THE USE OF RADIOACTIVE MATERIALS IN HUMANS

All human use of radioactive material must be carried out by or under the supervision of a licensed physician who has been approved for such use by the Subcommittee on Human Use of Radioisotopes. This requirement applies to both routine diagnostic and therapeutic uses, and to human use research. (See Section 6.4 for additional information.)

To obtain authorization for the “human use” of radioactive materials, the applicant shall file RSO Form 313HU with the Radiation Safety Office. Any physician requesting authorization for “human use”, at a minimum, must meet the training and experience requirements specified in NRC regulations (10CFR35.900 to 35.981). Details may be found in NRC publication NUREG 1556 Vol. 9. Additional forms, such as preceptor forms NRC 313A and 313B, are available from the Radiation Safety Office. Reapplication or the submission of an amendment is necessary when a nuclide, radiopharmaceutical or compound not previously applied for is desired, or if conditions of use change.

Approval to administer radioactive material to humans does not constitute implicit or explicit authorization to use the same or other radioactive material for other purposes, such as non-human, research, or animal use.

If the use is experimental, approval of the IRB is required prior to initiation of the use of the material. Following evaluation by the Subcommittee, the applicant will be notified as to the approval or disapproval of the request.

Use of experimental radiopharmaceuticals in humans may require animal studies to establish toxicity, biological half-life, distribution and efficacy prior to authorization. Also conformance with applicable FDA(NDA/IND) requirements must be assured.

By-product materials not approved under the IND/NDA process shall not be used in humans until their pharmaceutical quality and assay have been established. A Drug Master File (DMF) must be submitted to and be approved by the RDRC prior to the use of such materials in humans. The DMF must address issues related to assay, labeling, identity, quality, purity, sterility, non-pyrogenicity, etc.

5.7 PERIOD OF AUTHORIZATION

Much information supplied in the initial application changes over time; therefore, applications must be reviewed and updated periodically to insure that the information on file is current. Authorization to use radionuclides will be granted for intervals not to exceed two years. At the time of expiration a renewal of authorization will be required. A reminder for such purpose will be initiated by the Radiation Safety Office. The Authorized User,

however, may submit an amendment application at any time prior to the expiration of his/her authorization if the type of radionuclide, activity limits, or experimental protocol changes significantly. For timely processing, amendment requests should be submitted several weeks before the changes are to be implemented. The Radiation Safety Office is available to assist in the preparation of the application.

Chapter 6

PROCUREMENT AND USE OF RADIOISOTOPES

6.1 RADIOISOTOPE PROCUREMENT PROCEDURES

The Radiation Safety Office maintains a database of Authorized Users of radioisotopes. This list includes the radioisotopes and maximum amounts that each User is authorized to possess and the maximum amount of activity that may be purchased on a single order. Only Authorized Users may order or possess radioisotopes.

The procedures for acquisition of radioactive material under University licenses are as follows:

1. Each Authorized User ordering radioisotopes under the University licenses must fill out a purchase requisition form, and then forward this form to the Radiation Safety Office. Upon approval by the Radiation Safety Office, the requisition will be forwarded to the appropriate purchasing department. The purchasing department will not honor any requisition for radioactive material without the approval of the Radiation Safety Office. All package receipts of radioactive material must be routed through and received by the Radiation Safety Office. This includes shipments destined to outlying locations such as the Hillman Cancer Center, W.P.I.C., Children's Hospital, Magee Women's Hospital, etc. Any exception to this rule must be approved by the Radiation Safety Office.

2. An Authorized User who wishes to order, possess, and handle radioisotopes in excess the limits of his authorization must submit a written amendment to the Radiation Safety Office prior to placing the order.

3. Blanket orders for radioisotopes will be approved under the same procedures as outlined in Paragraph 1. All radioisotopes ordered under a blanket order must be shipped directly to the Radiation Safety Office. Free samples, unusual order circumstances, or new compounds offered gratis containing radioactive material accepted by researchers must also enter the University through this office for inventory update and radiological control surveys, as necessary. Exceptions to this rule must be approved by the Radiation Safety Officer.

4. The Authorized User's name must appear on purchase requisitions to assure proper inventory control and delivery.

Receipts containing quantities of radioactive material in excess of limits specified in 10CFR20 must be surveyed by the Radiation Safety Office. All packages are subject to safe opening procedures. All radioactive materials receipts are entered into the Radiation Safety data bases and all Authorized Users are required to submit updated inventories to the Radiation Safety Office on a quarterly basis.

6.2 TRANSFER OF ISOTOPES AND RADIATION SAFETY RESPONSIBILITY

No radioactive material or responsibility thereto can be transferred to another person who is not an Authorized User of radioisotopes. An Authorized User should not transfer radioactive material to another Authorized User without the knowledge and approval of the Radiation Safety Office. This includes any sale or transfer from the Medical Center to a University researcher or clinician. Once approval is obtained, the transfer is to be documented using an "Internal Radioisotope Transfer Form" available from the Radiation Safety Office or in the forms section of the Office web site..

When radioisotopes are to be transferred to another facility or person not regulated by the University of Pittsburgh's licenses, proof of possession of a valid NRC or State nuclear materials license must be obtained prior to the transfer. All such transfers must be made by the Radiation Safety Office.

6.3 EXTENDED LEAVES AND TERMINATIONS

Persons taking extended leaves, such as sabbatical leave or for illness, who intend to have research or studies using radioactive material continue during their absence, must designate a qualified co-worker or preferably another Authorized User to assume radiation safety responsibility during their absence. The Radiation Safety Office must be informed of and approve this delegation of responsibility.

Persons terminating their use of radioactive materials must notify the Radiation Safety Office in writing at least one month prior to the termination. All radioactive materials must be turned over to the Radiation Safety Office and the laboratories must be surveyed and down-posted prior to returning them to general use. If the Authorized User intends to transfer radioactive materials to another institution, the Radiation Safety Office has the responsibility to package and transfer the radionuclides. If laboratory equipment used in conjunction with radioactive materials is to be transferred to another institution, then the Radiation Safety Office must certify the equipment as free of radioactive materials prior to packing and shipping.

The Radiation Safety Office of the receiving institution must be notified in advance and approve of the shipment.

6.4 HUMAN USE

6.4.1 General

All uses of ionizing radiation are regulated under Federal (10CFR35) or Commonwealth (x ray uses and nuclear materials) regulations. These uses include uptake, dilution and excretion studies; imaging and localization studies, unsealed source radionuclide therapy, brachytherapy and both x ray and radionuclide teletherapy.

Only those radiopharmaceuticals which have either IND or NDA approval from the FDA may be routinely used. All other radiopharmaceuticals must have RDRC approval.

6.4.2 Diagnostic and Therapeutic Uses

Policies and procedures related to the administration of radiopharmaceuticals must be approved by the Radiation Safety Officer.

Written directives (an Authorized User's written order for the administration of ionizing radiation to a specific patient or human research subject, as specified in 10CFR35.40) are required for all therapeutic uses of ionizing radiation and for the administration of ^{131}I in quantities exceeding 30 microcuries. Specific procedures must be followed for administrations requiring a written directive, 10CFR35.41.

Patients treated with therapeutic quantities of nuclear materials shall be treated either as in-patients or out-patients in accordance with 10CFR35 requirements and their medical needs. Only sealed sources as approved in the Sealed Source and Device Registry or in accordance with an IDE application accepted by the FDA may be used for therapeutic purposes.

6.4.3 Medical Events

All "medical events", as defined in 10CFR35, Subpart M or in Title 25, Environmental Protection must be reported to the Radiation Safety Office immediately upon identification. Any notifications necessary to either the NRC or Commonwealth will be made by the Radiation Safety Office.

Chapter 7

PERSONNEL MONITORING

In general, all occupationally exposed personnel whose radiation exposure may exceed 10 percent of the annual allowable dose shall participate in a monitoring program. External exposure is monitored with the use of dosimeters which can be worn on the torso or the extremities. Exposure from internally deposited radioactive materials is monitored by either *in vivo* or *in vitro* procedures.

7.1 EXPOSURE INVESTIGATIONS

An investigation will be made of all annual exposures exceeding 10% of the allowable dose and the investigative results will be documented and presented for review at the next quarterly meeting of the Radiation Safety Committee. The purpose of such investigation is to maintain compliance with the ALARA concept. The investigation will be initiated by the Radiation Safety Officer and will either involve a requested response to a written questionnaire or require discussion with the individual involved and the appropriate supervisor. In the case of well defined jobs that involve significant exposures to ionizing radiation; e.g., fluoroscopic use in a cardiac catheterization facility, investigations may not be made until 30% of the annual limit is reached.

If the total dose exceeds 80% of the annual limit, the issue will be reviewed immediately by the Executive Committee. This committee may recommend to the appropriate administrative officer that the person receiving this level of dose be suspended from all further work with radioactive sources or radiation producing machines. It may also recommend more stringent actions depending on the magnitude of the exposure. The Committee shall also ensure that proper notification is made to the individuals and to the regulatory agencies.

7.2 DOSIMETERS

For external radiation fields, exposure determinations are made by the use of personnel monitoring devices worn for varying monitoring periods up to but no longer than a calendar quarter. These may be whole body or ring dosimeters (OSL, TLD, film, track etch, or self-reading), in any varying combinations. Application for personnel monitoring dosimeters are made in writing on the approved form. Criteria for the type of dosimeter assignment and wear period are determined by the Radiation Safety Office. If dosimeters are assigned to an individual then he/she is required to wear the devices. The Radiation Safety Office will distribute and receive dosimeters, keep records of exposures, and forward the exposure data to persons or regulatory agencies upon request and as required.

In cases involving non-homogeneous radiation fields, multiple body dosimeters or multiple ring dosimeters may be required. An additional dosimeter may be issued in the case of an individual who declares a pregnancy, to better estimate fetal dose.

7.3 MEDICAL EXAMINATIONS

7.3.1 Routine

No mandated medical examinations are required prior to or while working with ionizing radiation sources

7.3.2 Other

If dosimeter readings indicate or if a radiation worker thinks that a significant radiation exposure has occurred the Radiation Safety will investigate and the Committee Physician will be consulted. If a medical examination is warranted the individuals involved will be provided with the results of their examination.

7.4 BIOASSAYS

7.4.1 IN-VITRO MEASUREMENTS

Urine and/or fecal analyses shall be performed on persons engaged in procedures involving quantities of radioactive material that may pose a significant risk. The radionuclides and activities for which this requirement is made will be specified by the Radiation Safety Officer. All required bioassays will be performed within time limits specified by Radiation Safety Office policy. The need for bioassays may be based upon the quantity of radioactive material used on single occasion or be based on cumulative use.

7.4.2 IN-VIVO MEASUREMENTS

Persons engaged in frequent use of non-sealed gamma-emitting isotopes may be required to undergo whole body or specific organ in-vivo measurements at intervals specified by the Radiation Safety Officer.

Persons using or handling radioiodine in quantities exceeding those in Table I, of NRC Regulatory Guide 8.20 are required to have a thyroid uptake determination. Thyroid uptake measurements may also be required when lower radioiodine activities are used or processed, depending on the form or compound, degree of airborne radioactivity control, frequency of use, nature of the research or clinical use, and other such variables. Current applicable regulatory guides are used for evaluating specific situations.

In case of suspected internal contamination, the Radiation Safety Officer may require the performance of emergency whole body counting.

7.4.3 RESULTS OF BIOASSAYS

The results of bioassay measurements will be kept in the dosimetry files in the Radiation Safety Office and upon request will be provided to the individual on whom the measurements are performed.

7.5 PREGNANT EMPLOYEE OCCUPATIONAL EXPOSURE LIMITATIONS

Refer to the “Pregnant Radiation Worker Policy” in the Radiation Safety Training Manual.

7.6 DOSIMETRY AT NON-UNIVERSITY SITES

Personnel should wear their University assigned personnel monitoring devices for any University related work exposure potential, even if it exists at locations other than the University proper. All non-University related exposures received by University employed radiation workers must be reported to the Radiation Safety Office at least quarterly when a non-University assigned dosimeter is worn. Should a situation exist wherein radiation exposure from work is not University related and a personnel monitoring dosimeter is not assigned, the Radiation Safety Office should be notified so that arrangements can be made to assess the exposure.

Chapter 8

SURVEYS

8.1 LABORATORIES UTILIZING RADIOACTIVE MATERIAL

Periodic surveys will be conducted by the Radiation Safety Office in all areas where unsealed sources of ionizing radiations are used, stored, discarded, or otherwise manipulated. Since contamination may be inadvertently spread into areas not normally considered to contain sources of radiation, the Radiation Safety Office staff shall have access to any and all areas for survey purposes.

Documentation of survey results will be maintained in the Radiation Safety Office. Notification of excessive contamination or other program violations, and recommendations for corrective actions will be sent to the authorized user of the radiation source or area. The Chairperson of the Radiation Safety Committee shall be kept apprised of all situations involving significantly contaminated areas or labs.

In addition to the routine surveys, a Health Physicist shall be present during the performance of unusual and potentially hazardous operations involving large quantities of radioisotopes.

All Authorized Users are required to perform or have performed routine radiation surveys at a frequency established by the Radiation Safety Officer. All such surveys shall be documented and signed by the individual conducting the survey. Survey records are subject to inspection and review by Radiation Office Staff and regulatory personnel.

8.2 FACILITIES UTILIZING RADIATION PRODUCING MACHINES

Periodic surveys will be conducted by the Radiation Safety Office in and around all areas where radiation producing machines or equipment are used. Since radiation produced by such machines may scatter into areas other than the immediate location of the equipment, Radiation Safety Office staff shall have access to any and all areas for purposes of surveying. Survey criteria are based on compliance with applicable Commonwealth of Pennsylvania regulations. Written reports of the results of the survey will be maintained at the Radiation Safety Office. As needed, recommendations for corrective action will be sent to the responsible user and/or the departmental administrator of the radiation producing machine.

The Chairperson of the Radiation Safety Committee and the Committee at the quarterly meetings shall be kept apprised of all situations involving areas of excessive radiation exposure and other hazardous conditions.

Chapter 9

WASTE DISPOSAL

9.1 GENERAL INFORMATION

Radioactive waste shall be handled in accordance with 10CFR20, 10CFR35, the University's Federal and State licenses and programmatic requirements. Policies and procedures may be found in the training manual and on the Radiation Safety Office web site. Locations and access times for radioactive materials waste disposal sites may be obtained by contacting the Radiation Safety Office. Should any questions arise as to specific disposal procedures, the Radiation Safety Office should be consulted.

Chapter 10

SAFETY EDUCATION

10.1 SAFETY EDUCATION

All personnel, who are working with sources of ionizing radiation, shall be instructed on the basic principles of radiation protection and the potential risks of ionizing radiation. Radiation Safety Office personnel will provide this generalized instruction as required under 10CFR19.12. Authorized Users shall provide specialized training for the particular type of work being performed, in order for the work to be carried out in a safe manner.

Authorized Users must provide time off the job and encourage their personnel to attend these radiation worker training sessions.

Ancillary personnel in areas authorized for radiation source use shall be informed about the sources being used and any safety precautions to be taken. The information provided should be commensurate with their level of involvement in the work area. They should be encouraged to attend a training session and/or review material on the Radiation Safety Office WEB site.

Specialized training sessions may be required by the Radiation Safety Officer for workers in areas in which there are recognized lapses in safety.

The Radiation Safety Office staff is available to provide training on all aspects of radiation safety.