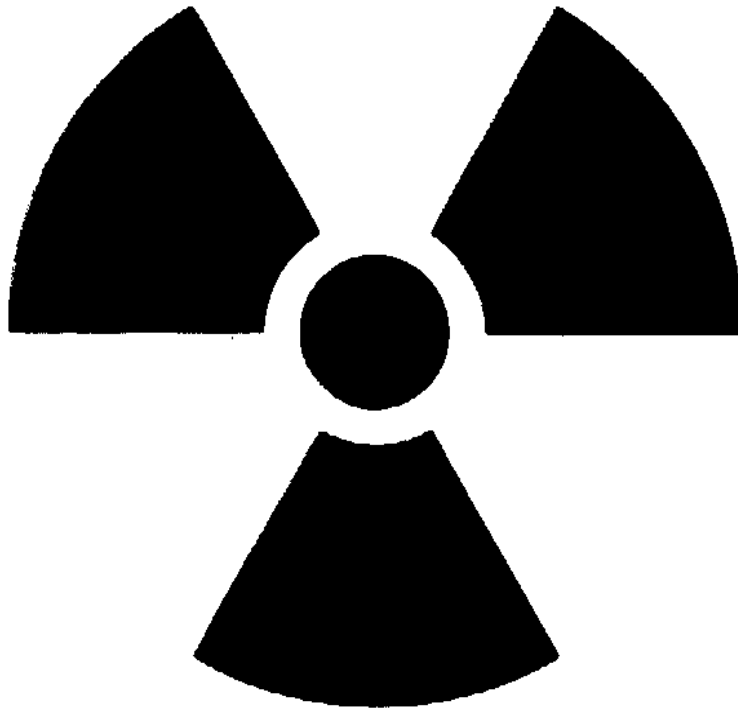


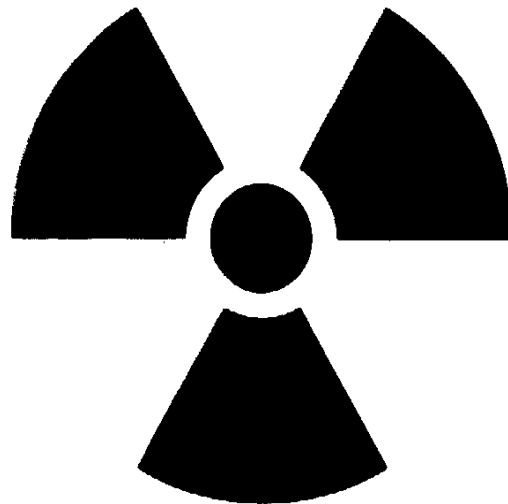
RADIATION CONTROL GUIDE



UNIVERSITY OF FLORIDA

Business Affairs
Radiation Control Committee

RADIATION CONTROL GUIDE



UNIVERSITY OF FLORIDA

Radiation Control Committee

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FORWARD

By authority delegated from the University President, the Vice President for Business Affairs is responsible for the safety of all University facilities. Under this authority, policies are developed to provide a safe teaching, research, service, housing and recreational environment.

The Environmental Health and Safety Division was established in 1974 and given the responsibility for the management of all safety practices and the effective administration of the program.

The mission of the Environmental Health and Safety (EH&S) Division is to minimize injury to faculty, staff, students and visitors and to minimize damage to University property. Inherent in this mission is the charge to provide a safe and healthy environment in which the University's activities can be pursued.

All applicable federal and state safety laws, rules and regulations are adopted by the University. In order to carry out its duties and responsibilities, the Environmental Health and Safety Division will reference standards or codes related to safety which have been adopted and promulgated by nationally recognized standards-setting organizations. The interpretation of safety codes and standards is the responsibility of the Environmental Health and Safety Division.

Environmental Health and Safety is divided into six functional Departments. Facility and Fire Safety includes the Pest Control and Fire Equipment Service Units. Radiation Control and Radiological Services (Radiation Safety) is responsible for University-wide radiation protection. Occupational and Research Safety is responsible for monitoring all biological and chemical research activities, clinic safety, accident prevention programs and also oversees safety issues at IFAS off-campus stations. Diving Science and Safety supports scientific diving for the University of Florida. Hazardous Materials Management coordinates the disposal of radioactive and chemical waste. Industrial Hygiene is responsible for asbestos, indoor air quality and other industrial hygiene programs.

In order to assure an effective Environmental Health and Safety Program for the University of Florida, it is imperative that all individuals associated with the University comply fully with the policies and procedures set forth in this Guide.

RADIATION SAFETY DEPARTMENT
EMERGENCY CALL LIST

(CALL IN ORDER UNTIL ONE PERSON IS NOTIFIED)

DAYS (8:00 AM - 5:00 PM)	PHONE	WORK CELL
Susan Stanford Radiation Safety Officer	(352) 294-1020	(352) 260-3133
Sofia Ioannidou Assistant Radiation Safety Officer	(352) 273-5765	(352) 226-9511
Les Hines Health Physicist II	(352) 273-5776	(352) 246-0019

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Susan Stanford Radiation Safety Officer	(865) 742-7336
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TABLE OF CONTENTS

CHAPTER I - RADIATION PROTECTION PROGRAM	1
I. INTRODUCTION	1
II. PROGRAM STRUCTURE	1
A. Responsibilities of Radiation Control Committee (RCC)	2
B. Responsibilities of Radiation Safety Officer (RSO)	4
C. Responsibilities of Principal Investigator (PI)	6
III. ALARA POLICY	7
A. Training	7
B. Occupational Dose Limits	7
1. Occupational Dose Limits for Adults	7
2. Occupational Dose Limits to Minors	9
3. Dose to an Embryo or Fetus for Women Who Have Declared Pregnancy	9
4. Planned Special Exposures	13
C. Maximum Permissible Exposures to Concentrations of Radioactive Material in Restricted Areas	13
D. Reporting Overexposures	13
IV. RADIATION SAFETY CRITERIA - VIOLATION ENFORCEMENT POLICY	14
A. Introduction	14
B. Enforcement Follow-up Procedures	14
1. Initial Follow-Up	14
2. Department Head Notification	14
3. Radiation Control Committee	15
C. Types of Violations	15
D. Deficiencies/Discrepancies	16
V. RADIATION SAFETY OFFICE NOTIFICATIONS	16
A. Notification of Radiation Safety Office	16
B. Emergency Notification Contacts	17
CHAPTER II - RADIOACTIVE MATERIALS	18
I. AUTHORIZATION TO USE RADIOACTIVE MATERIAL	18
A. Initial Approval	18
B. Renewal of Authorization to use Radioactive Material	19
C. Amendment to Proposals	19
D. Transfer of Responsibilities	19
E. Procurement and Receipt of Radioactive Materials	19
1. Approval	20
2. Purchase Order Numbers	20
3. Receipt of Radioactive Material Shipments	20
F. Facilities	21
G. Status of the Labs	21
1. Active	21
2. Inactive	21
3. Terminated	22
II. TRAINING IN THE USE OF RADIOACTIVE MATERIAL	22
A. Responsibility	22
B. Training and Experience Requirements for Use of Unsealed Sources of Radioactive Material	22
C. Training and Experience Requirements for Use of Sealed Sources of Radioactive Material	23
D. Formal or Informal Coursework	23

III. PERSONNEL MONITORING PROGRAM	24
A. Personnel Monitoring Requirements	24
1. Whole Body Luxel/TLD Badges	24
2. Extremity Badges or Rings:	25
3. Pocket Dosimeters	25
B. Exposure Reports	26
IV. BIOASSAY PROGRAM	26
A. Biological Samples	26
B. Partial body counting	26
C. Participation	26
D. Exposure Reports	27
E. Summation of External and Internal Exposures	27
V. SECURITY OF RADIOACTIVE MATERIAL	27
A. Monitoring	27
B. Limited Access	27
VI. CAUTION SIGNS, NOTICES, AND POSTERS	27
VII. RADIATION DETECTION INSTRUMENTATION AND SAFETY EQUIPMENT	28
A. Appropriate instrumentation	28
B. Radiation Detection Instruments (Survey Meters)	28
C. Contaminated Survey Meter	28
D. Inoperable Survey Meter	28
VIII. LABORATORY SURVEYING AND MONITORING	28
A. Surveys	29
1. Fixed contamination survey	29
2. Removable contamination survey (swipes/wipes)	29
3. Ambient radiation survey	29
B. Action/Trigger Levels	30
C. Record Keeping	30
IX. EMERGENCY PROCEDURES	30
A. Minor Spills (Less than 100 microcuries of activity and/or 5 mR/hr @ 1 foot)	30
B. Major Spills (More than 100 microcuries of activity or 5 mR/hr at 1 foot or personal contamination)	31
X. RADIOACTIVE MATERIAL INVENTORY	32
XI. TRANSFER OF RADIOACTIVE MATERIAL	32
A. On-Campus Transfers	32
B. Off-Campus Transfers	32
C. Disposal of Equipment Containing Radioactive Material	33
XII. RADIOACTIVE WASTE DISPOSAL	33
A. Procedures	33
B. Waste Reduction Methods	33
C. Radioactive Waste Guidelines/Instructions	34
XIII. SEALED SOURCE LEAK TEST	34
XIV. SPECIAL PROCEDURES FOR ANIMAL USE IN RESEARCH	35
A. Animal Cage	35
B. Radiation Protection Guidelines for Caregivers	35
CHAPTER III - RADIATION PRODUCING DEVICES	37
I. AUTHORIZATION TO USE RADIATION PRODUCING DEVICES	37

A.	Initial Approval _____	37
B.	Transfer of Responsibilities _____	38
C.	Registration of Radiation Producing Devices _____	38
D.	Facilities _____	39
II.	TRAINING IN THE USE OF RADIATION PRODUCING DEVICES _____	39
A.	Responsibility _____	39
B.	Training and Experience Requirements _____	40
C.	Formal or Informal Coursework _____	40
III.	PERSONNEL MONITORING PROGRAM _____	41
A.	Personnel Monitoring Requirements _____	41
B.	Exposure Reports _____	42
IV.	ANNUAL RADIATION SAFETY INSPECTION _____	42
V.	RADIATION PRODUCING DEVICE INVENTORY _____	43
VI.	TRANSFER OF RADIATION PRODUCING DEVICES _____	43
A.	On-Campus Transfers _____	43
B.	Off-Campus Transfers _____	43
C.	Disposal of Radiation Producing Device _____	43
VII.	TYPES OF RADIATION PRODUCING DEVICES (Non-Clinical Use) _____	43
A.	Electron Microscopes _____	43
B.	Cabinet X-ray Systems _____	44
C.	X-Ray Diffraction/Fluorescence Units _____	44
	CHAPTER IV - CLINICAL USE - HUMAN USE _____	46
I.	INTRODUCTION _____	46
II.	HUMAN USE OF RADIOISOTOPES AND RADIATION COMMITTEE _____	46
A.	Membership _____	46
B.	Committee Responsibilities _____	46
III.	ALARA POLICY _____	47
IV.	AUTHORIZED USER _____	49
A.	Training Requirements _____	49
B.	Becoming an Authorized User _____	50
V.	USE OF RADIOACTIVITY AND RADIATION FOR CLINICAL APPLICATIONS _____	50
VI.	SPECIAL OCCASIONS _____	52
A.	Fetal Radiation Exposure from Medical Procedures _____	52
B.	Death of a Patient Containing Radioactive Material _____	53
C.	Autopsy of a Body Containing Therapeutic Radiopharmaceuticals _____	53
D.	Surgery or biopsy in Patients Containing Radioactive Material _____	54
VII.	RADIATION SAFETY STANDARDS _____	54
	APPENDICES _____	56
	APPENDIX A _____	56
	APPENDIX B _____	67
	APPENDIX C _____	74
	APPENDIX D _____	78
	APPENDIX E _____	80
	APPENDIX F _____	83
	APPENDIX G _____	88
	APPENDIX H _____	92

CHAPTER I - RADIATION PROTECTION PROGRAM

I. INTRODUCTION

In view of increased utilization of ionizing and nonionizing radiation at the University of Florida, a university-wide Radiation Protection Program was established in September 1960. The primary responsibilities of the Radiation Protection Program are to assure radiological safety of all University personnel and the public, to guarantee that ionizing and nonionizing radiation sources are procured and used in accordance with Federal and State regulations, and to assure that radiation exposures are as low as reasonably achievable (ALARA).

This Guide sets forth policies, regulations, and procedures approved by the University's Radiation Control Committee and supersedes all other Guides and memoranda relating to radiation control/safety issued prior to this Guide. The regulations and procedures outlined in this Guide are intended to protect all individuals with a minimum of interference in their activities and are consistent with regulations of the U.S. Nuclear Regulatory Commission (NRC) and the Florida Department of Health (FLDOH). These policies and procedures apply to all facilities (on campus and off-site locations) utilizing radioactive materials or radiation producing devices under the administration of the University of Florida (UF). Several areas and uses, such as the training reactor, human use, nuclear gauge, and irradiators, require more specific regulations. Business Affairs Memorandum No. 22 of May 24, 1974, structures a Radiation Control and Radiological Services (Radiation Safety) Department, headed by the Radiation Safety Officer, under the Division of Environmental Health and Safety (EH&S).

II. PROGRAM STRUCTURE

The Radiation Protection Program at UF is responsible to ensure the safe use of ionizing radiation (receipt, handling, use, storage and disposal of radioactive material), and it is designed to protect personnel, the general public and the environment from unnecessary radiation exposure. The mission of the Radiation Protection Program is to employ optimization. Therefore, the facilities, equipment, and procedures are designed such as to maximize the benefits while minimizing the exposure.

The Radiation Protection Program is operated by the Radiation Control and Radiological Services Office (Radiation Safety Office), under the EH&S Division.

This Guide represents the Radiation Protection Program for all locations on each of the four radioactive material licenses held with the FLDOH and registrations including on and off Campus locations, UF Health/Shands hospital and clinic locations, and various Institute of Food and Agricultural Sciences facilities around the state. All Principal Investigators and approved radioactive material users are required to comply with all of its provisions.

Responsibilities

Ultimate responsibility for the implementation of the Radiation Protection Program lies with the President of the University. The following specific responsibilities of the Radiation Control Committee, the Radiation Safety Officer, and the Principal Investigator were set forth in a memorandum from the Office of the President on September 23, 1960 and have been revised as the Radiation Protection Program has evolved.

A. Responsibilities of Radiation Control Committee (RCC)

Federal and State regulations require the University of Florida to obtain a specific license for the receipt, use, and transfer of radioactive material, and to establish a Radiation Control Committee. Membership of the Radiation Control Committee shall include Principal Investigators for multiple types of uses permitted by the license, the Radiation Safety Officer, and a member of the University's Administration. Minutes of the proceedings shall be recorded and include the meeting date and time, members present and absent, summary of discussions and recommendations, results of votes, program changes and a record of the ALARA review undertaken. The responsibilities of the RCC include but are not limited to:

1. Review and grant permission for, or disapprove, the use of radioactive material or radiation producing devices within the institution from the standpoint of radiation safety.

2. Prescribe special conditions and requirements which may be necessary to ensure radiation safety (e.g., physical examinations, additional training, designation of limited areas or locations of use, disposal methods, etc.).
3. Prepare and disseminate information on radiological safety (including University, State and Federal regulations governing ionizing radiation), for use and guidance of students and staff.
4. Pass judgment on the adequacy of safety measures for safeguarding University research workers. Committee approval of health and safety measures must be obtained before initial use of radioactive materials or other sources of ionizing radiation is undertaken or before substantially different uses from those originally approved by the Committee are undertaken.
5. Keep records of the actions taken in approving the use of radioactive materials and other sources of ionizing radiation and other transactions, communications, and reports involved in the work of the Committee.
6. Delegate to the Radiation Safety Officer the authority to act for the Committee between meetings. His or her actions will be reported to the Committee for review at appropriate intervals.
7. Review plans for all new buildings and modifications of existing structures where radioactive material or radiation producing devices are to be used.
8. Recommend and implement procedures for radioactive waste disposal.
9. Periodically review actions of the Reactor Safety Review Subcommittee.
10. Review at least annually from a radiation safety standpoint, the activities of the Committee on Human Use of Radioisotopes and Radiation.
11. Review all ongoing projects at timely intervals.

12. Provide advice to research groups, departments, and investigators.
13. Additional responsibilities for the Radiation Control Committee are specified in 64E-5.606, Florida Administrative Code (F.A.C.).
14. Review at least annually the Laser Safety Program to determine that all activities are being conducted in accordance with regulatory requirements.

B. Responsibilities of Radiation Safety Officer (RSO)

The RSO supervises the Radiation Safety Office and reports to the Associate Director of Research Services, EH&S Division. The responsibilities of the RSO include but are not limited to:

1. Administer the overall day-to-day programs of the University's Radiation Safety Office and assure that all radiation exposures and practices follow the University's ALARA philosophy.
2. Approve all University procedures which might conceivably involve radiation exposure and all changes in such procedures. By agreement, the University maintains exclusive control over, and responsibility for, the use of radioactive materials and radiation producing devices at all UF Health/Shands facilities. Approval by the RSO of the policies and procedures at these facilities, from the radiation safety standpoint, is performed at the respective department level.
3. Act in a supervisory capacity in all aspects of radiation measurement and protection activities, such as personnel monitoring, maintenance of exposure records, survey methods, waste disposal and radiation safety practices.
4. Consult with potential radioactive material users and advise on radiation safety practices.

5. Suspend any operation causing excessive radiation hazards as rapidly and safely as possible. In carrying out this duty the RSO will report directly to the Associate Director of Research Services and Director of EH&S, and inform the RCC Chair.
6. Maintain a list of employees who work with radioactive materials and radiation producing devices.
7. Prescribe routine radiation surveying and personnel monitoring.
8. Establish standardized procedures for: 1) procurement of radioactive material; 2) receiving and opening packages of radioactive material; 3) storing radioactive material; 4) maintaining inventory records of radioactive material; 5) safe use of radioactive materials; 6) emergency actions if control of radioactive material is lost; 7) performance of periodic radiation surveys; 8) performance checks of survey instruments and other safety equipment; 9) disposal of radioactive materials; 10) training personnel who work in or frequent areas where radioactive material is used or stored; and 11) maintenance of all required records and reports.
9. Serve as ex-officio member of all radiation control/safety committees constituted at the departmental, college, experiment station, clinic or university levels.
10. Identify program weaknesses and develop appropriate corrective actions.
11. Investigating overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, and other deviations from approved radiation safety practice and implementing corrective actions as necessary.
12. Notify regulatory bodies, when necessary.
13. Additional duties and responsibilities for the RSO are specified in 64E-5.605, F.A.C., and 64E-5.1305, F.A.C.

C. Responsibilities of Principal Investigator (PI)

The PI also shares the responsibility for the safe use of radioactive materials and radiation producing devices, specifically:

1. Administer and enforce safety rules and regulations as stated in the Radiation Control Guide which are necessary to the Radiation Protection Program in all areas within the scope of their authority.
2. Inform all employees of potential health hazards and the necessary safeguards which are established to guard against them.
3. Ensure that all employees working with, or in the vicinity of, radioactive materials or radiation producing devices are properly trained and monitored.
4. Ensure that dosimetry is appropriately used and that dosimeters are returned on time.
5. Inform the Radiation Safety Office of all changes in personnel working with radioactive materials or radiation producing devices and changes in facilities or use/storage locations. Maintain inventory records.
6. Maintain control over radioactive material and maintain adequate inventory and utilization records. Perform weekly contamination surveys when radionuclides are in use.
7. Ensure that all radioactive waste is received by EH&S Hazardous Material Management for ultimate disposal.
8. Ensure safe and secure storage of all radioactive material.
9. Ensure survey meters are operable and calibrated.

10. Understand and follow the ALARA principles and the need to maintain exposures ALARA.
11. Minimize and properly package radioactive waste.
12. Notify the Radiation Safety Office immediately in the event of any radiological emergency.
13. Comply with the University's policies governing the use of radioactive materials and radiation-producing devices.

The RSO and/or Radiation Control Committee may disapprove or terminate any project involving serious or continued violation of the standards set forth in this Radiation Control Guide.

III. ALARA POLICY

A primary goal of the Radiation Protection Program is to reduce radiation doses wherever and whenever reasonably achievable, thereby reducing the health risk that is assumed to be proportional to the radiation dose. The As Low As Reasonably Achievable Policy adopted by the University describes the commitment to keep radiation doses ALARA, the actions to be taken and radiation dose guidelines. The ALARA Policy for the UF Health/Shands Health Care Facilities is available from the Radiation Safety Office. The main elements of the ALARA policy include:

A. Training

Appropriate training, which includes Radiation Safety/Protection Principles, the ALARA philosophy and the University's policies and procedures, is required for all individuals that use radioactive material and/or might be exposed to radiation. Principal Investigators are responsible to ensure that their staff complies with the training requirements.

B. Occupational Dose Limits

1. Occupational Dose Limits for Adults

Occupational dose limits for adults are specified by Federal regulations as set forth in the Code of Federal Regulations, Title 10, Part 20, "Standards for Protection Against

Ionizing Radiation," and by the Florida Department of Health, "Control of Radiation Hazard Regulations," 64E-5.304 F.A.C..

Since any radiation exposure is undesirable; following the ALARA commitment, it is important that all exposures be kept as low as reasonably achievable. The permissible ALARA radiation dose levels used at the University of Florida are more conservative than the State or Federal Regulations and are listed below.

Investigation Levels for Radiation Exposure (per calendar quarter)				
	Level I	Level II	Level III	Regulatory Limit (per year)
Deep Dose Equivalent (whole body- deep dose equivalent-DDE)*	125 mrem (1.25 mSv)	375 mrem (3.75 mSv)	1250 mrem (12.5 mSv)	5000 mrem (50 mSv)
Sum of the deep-dose equivalent and the committed dose equivalent to any organ or tissue other than the lens of the eye	1250 mrem (12.5 mSv)	3750 mrem (37.5 mSv)	12500 mrem (125 mSv)	50000 mrem (500 mSv)
Lens of the eye (eye dose equivalent-LDE)	375 mrem (3.75 mSv)	1125 mrem (11.25 mSv)	3750 mrem (37.5 mSv)	15000 mrem (150 mSv)
Skin (shallow dose equivalent or to any extremity-SDE)	1250 mrem (12.5 mSv)	3750 mrem (37.5 mSv)	12500 mrem (125 mSv)	50000 mrem (500 mSv)

- **DDE (Deep Dose Equivalent):** Dose equivalent from external whole body exposure at a tissue depth of 1.00 cm; it applies to the whole body.
- **LDE (Lens Dose Equivalent):** Dose equivalent from external exposure at a tissue depth of 0.30 cm; it applies to the lens of the eye.
- **SDE (Shallow Dose Equivalent):** Dose equivalent from external exposure at a tissue depth of 0.007 cm averaged over one (1) square cm; it applies to skin and extremities.

* **TEDE (Total Effective Dose Equivalent):** The sum of the effective dose equivalent (external exposures) and the committed effective dose equivalent (internal exposures). In most cases here at the University of Florida, TEDE equals DDE, as there are very few bioassays performed based on limited isotope use having the potential for internal contamination.

For doses, less than Level I (Notification Level), no action is required unless it is deemed appropriate by the RSO. For doses equal to or greater than Level I but less than Level II

(Investigational Level), the RSO shall review the doses and report the results at the first meeting of the Radiation Control Committee following the quarter that the doses occurred. The individual shall be notified in writing, but no further action is required unless it is deemed appropriate by the Radiation Control Committee. If the individual's dose is equal to or greater than Level II, the RSO must investigate as soon as possible the causes and take action, if warranted. A report of this investigation, the actions taken and the individual's dose record shall be reported to the Department's administrator, Department Chair, and the Radiation Control Committee. Notification to the individual shall be also sent. For DDE doses equal to or greater than Level III but lower than the regulatory limit, the RSO shall send a stop work order and conduct an immediate investigation to determine the cause of the exposure readings and take appropriate corrective actions. The RSO must immediately investigate the cause of any cumulative exposure that exceeds the annual regulatory limit, and take corrective actions to prevent any further exposures. In addition, a written report must be submitted to the State within 30 days. Such reports will be prepared by the RSO using information provided by the PI and/or users.

Specific approval to operate under the more liberal State or Federal regulations must be obtained for any such occasion from the Radiation Control Committee and/or Human Use of Radioisotopes and Radiation Committee by submitting a written proposal through the RSO.

2. Occupational Dose Limits to Minors

Occupational exposure to any individual who is under the age of 18 is permitted only if their exposure is limited to ten (10) percent or less of the limits specified above for adult workers. For this reason, it is recommended that minors not be employed as full-time occupationally exposed workers.

3. Dose to an Embryo or Fetus for Women Who Have Declared Pregnancy

The dose to an embryo or fetus during the entire pregnancy from occupational exposure of a declared pregnant woman shall not exceed 500 mrem (5 mSv). It is recommended that not more than 50 mrem (0.5 mSv) be received by the embryo or fetus in any one month. Radiation Safety Office personnel shall review the declared pregnant worker's radiation exposure history and require the adjustment of working conditions as necessary to avoid a monthly exposure higher than the recommended 50 mrem (0.5 mSv). Each individual that

has declared pregnancy shall wear a radiation monitor at waist level at all times at work. This monitor shall be used to estimate the fetal deep-dose equivalent. If protective equipment is worn, the waist dosimeter must be worn under the protective clothing; an additional dosimeter must be worn outside the clothing to estimate the dose to the worker. ALARA review of the declared pregnant worker's personal radiation dosimetry report shall be performed monthly to avoid a monthly exposure over 50 mrem (0.5 mSv). The declared pregnant worker shall be notified in writing if the monthly dose to her waist dosimeter exceeds the 50 mrem (0.5 mSv) and an investigation shall be performed.

Approved users at the University of Florida should be aware of the fact that the NRC and the FLDOH require instruction of occupational workers in the hazards associated with radioactive material and radiation, and in the precautions and safety measures to be followed to minimize radiation exposure. These basic requirements are contained in 10 CFR 19.12, and 64E-5.902 F.A.C., respectively.

The NRC and FLDOH have advised their licensees that such instruction must include special instructions to females of childbearing potential, regarding the risks to the unborn fetus associated with prenatal radiation exposure. In addition to the instruction requirement, the NRC and FLDOH require that special efforts be made to limit any exposure to the developing fetus.

The NRC has issued a regulatory guide to assist licensees in achieving compliance with this requirement. The regulatory guide requires that:

- a) Women in jobs involving radiation exposure must be explicitly advised of the risk associated with prenatal exposure.

- b) Particular efforts must be made to keep the radiation exposure of the embryo or fetus to the very lowest practical level during the entire gestation period in accordance with the National Council on Radiation Protection (NCRP), a recommendation adopted by the NRC and FLDOH.

- c) Female employees must be advised that the NRC and FLDOH have regulations to ensure that the dose to an embryo or fetus during the entire pregnancy from occupational exposure of a declared pregnant woman does not exceed 500 mrem (5 mSv).

The requirements of 10 CFR 19, 64E-5 F.A.C. and the Regulatory Guide have been reviewed by the Radiation Control Committee and the following policies have been established:

- a) An employee information packet (Appendix A) has been prepared by the Radiation Safety Office and is available for distribution via the PI, to all women who work with radioactive material and/or radiation producing devices or who have access to such areas.
- b) Each woman receiving the information packet should be given the opportunity to ask questions regarding the regulations.
- c) An attempt to selectively apply this requirement to certain women would necessitate soliciting personal information regarding fertility, intentions with respect to pregnancy, etc. Such questions are and would most certainly be so regarded as an invasion of privacy. Consequently, at the University of Florida, the information about risks of prenatal radiation exposure will be made available to all female employees and students through their PI.
- d) As an approved user and supervisor, the PI is responsible to ascertain that all female occupational workers are apprised of the risks of prenatal radiation exposure. He or she must also take steps to minimize exposure to female employees who are or who may be pregnant; make the information packet available to all women who work with radioactive material and/or radiation producing devices or who have access to such areas under his or her supervision, and provide all current and new female employees with an opportunity to ask questions concerning the regulations,

the information packet and the levels of radiation exposure likely to be received as a result of current or future job assignments she has made or may wish to make.

While the information packet may appear to be directed only to "employees," it must be noted that female undergraduate and graduate students, as well as faculty members and research assistants, must receive these instructions. It should be understood that this instruction packet is intended to apply equally to all occupational workers including users of x-ray diffraction units and x-ray machines, as well as radionuclide users.

In order to assist you, the following steps have been taken:

- a) Arrangements have been made with the appropriate University offices in order to ensure that applicants are advised that the positions in which they are interested involve work with radioactive materials and/or radiation producing devices or access to such areas prior to the supervisory interview. Thus, it is important that you inform appropriate offices on all future personnel requisitions initiated to fill positions for occupational workers and for others whose duties require frequent access to such areas. Correspondence for new staff and the requisitions for employees filed with the Division of Human Resources, Student Employment Office, or the Dean of the Graduate School, should contain an explicit and clear comment, i.e., "This position requires work with radioactive materials and/or radiation producing devices or access to such areas." In order to ensure that prospective occupational workers are fully informed prior to acceptance of your position, the employee or the student orientation obviously must include a discussion of the possible fetal radiation exposure risk involved and the duties, activities and job assignments you have or will establish for the position.

As an approved user and supervisor, the PI bears the ultimate responsibility to make certain that all female occupational workers have received the information packet and that they have acknowledged receipt thereof.

- b) The Radiation Safety Office is prepared to assist you in explaining this requirement to small groups (up to 10 persons), as arranged by the department and with the participation of the approved users.

The operation of this program requires the careful and timely review of radiation exposure reports and appropriate action taken. If the radiation exposure reports are sent to a designated departmental contact rather than the approved user, as is sometimes done as a convenience to the department, the PI must take steps to ensure that the contact keeps him or her informed of the exposure to their personnel. It will also require that the Radiation Safety Office be kept informed of the names of those persons who are using radioactive materials or radiation producing devices under the PI's supervision.

4. Planned Special Exposures

The Radiation Safety Officer shall evaluate planned special exposures on a case-by-case basis in compliance with regulatory requirements and University policies.

C. Maximum Permissible Exposures to Concentrations of Radioactive Material in Restricted Areas

No PI or approved user shall possess or use radioactive materials in such a manner as to result in an individual being present in an area where airborne radioactivity is present. In the event airborne radioactivity is suspected, the Radiation Safety Office should be contacted immediately.

D. Reporting Overexposures

In the event an exposure occurs which is suspected to exceed the University's permissible exposure limits (Page 8), the RSO is to be notified immediately.

The PI who is responsible for the area in which a radiation exposure equals or exceeds the University's permissible exposure shall provide the Radiation Safety Office with written details of the exposure and describe procedures which will be followed to prevent recurrence of such an exposure.

IV. RADIATION SAFETY CRITERIA - VIOLATION ENFORCEMENT POLICY

A. Introduction

The Radiation Control Committee recognizes the good working relationships between the RSO and PI and that continued noncompliance with established safety rules is a rare occurrence. The Committee recognizes the possibility of a problem and has established a three-stage follow-up enforcement program. The policy outlined below retains the initial follow-up authority with the RSO but establishes a more formalized procedure with deadlines. If the initial efforts of the RSO are unsuccessful, the Radiation Control Committee will involve itself and take steps as appropriate to obtain compliance.

B. Enforcement Follow-up Procedures

1. Initial Follow-Up

Following the identification of a deficiency in radiation safety criteria, the RSO or his or her designee will notify the PI in writing. A suggestion of how compliance with University requirements can be achieved will be included and the PI will be asked to notify the Radiation Safety Office within ten (10) days of the status of his or her efforts to make the correction. To facilitate compliance on the part of the PI, a standard Action Taken Form (ATF) will be utilized on which the violation will be identified with space to identify the correction carried out.

If the violation is of a major nature, the laboratory will be scheduled for a follow-up inspection.

2. Department Head Notification

If the RSO or his or her designee is not able to achieve compliance through the initial efforts outlined above, the status of the situation will be brought to the attention of the PI's department chair. The department chair will be asked to assist the RSO or his or her designee in making the corrections. If for any reason this second stage does not achieve compliance, the Radiation Control Committee will intercede.

3. Radiation Control Committee

If direct action of the RSO and the requested assistance of the department chair has not achieved correction of a safety violation, the RCC will take direct action. The Committee will review the situation to determine the seriousness of the identified violation and the action of the investigator. The PI will be requested to meet directly with the Committee to outline why he or she has not complied. The Committee will take whatever action is appropriate to achieve compliance. The action may vary from situation to situation but could be full support of the RSO's action to remove the PI's approval to work with radioactive material.

Three ATF's received by a PI within a twelve (12) month period is considered to be continued noncompliance and results in direct intervention by the Chair of the RCC.

The RSO may suspend or terminate any permit to use radioactive material when the actions of the personnel in the laboratory present an unacceptable risk or jeopardize the University's license.

C. Types of Violations

Audit findings that consist of violations and require immediate actions:

1. Eating, drinking or food storage in radiation areas.
2. Use of radioactive material or radiation producing devices in an unposted and unapproved area.
3. Loss of radioactive materials.
4. Unauthorized receipt, transfer, or shipping of radioactive material.
5. Use of radioactive material or radiation produced device by an unauthorized person or individual with inappropriate training.
6. Unlabeled contaminated equipment.
7. Failure to wear radiation dosimeters or wearing a dosimeter assigned to a different individual.
8. Failure to wear personal protective equipment.
9. Radioactive waste in normal trash containers.
10. Disposal of liquid radioactive waste in the sink.

11. Work in non-operational fume hoods.
12. Pipetting by mouth.
13. Failure to perform and document weekly contamination surveys, during the weeks that radioactive material is used.
14. Contamination of 5,000 dpm per 100 cm² or more in an area where radioactive material is used.

D. Deficiencies/Discrepancies

Audit findings that if no action is taken will be considered violations:

1. Evidence of drinking or eating in radiation areas.
2. Radiation dosimeters worn improperly.
3. Radiation dosimeters stored inappropriately when not in use.
4. Radiation dosimeters not returned in a timely manner.
5. Dosimetry reports not available.
6. Inoperable survey meter.
7. Incorrect documentation in the inventory.
8. Improperly labeled waste containers.
9. Improper waste segregation.
10. Waste containers overfilled or not capped when not in use.
11. Failure to remove radiation signs from empty containers.
12. Failure to report a radiological incident (e.g., spill, loss of radioactive material, skin contamination, etc.)
13. Failure to take immediate appropriate actions in case of a radiological incident or emergency.
14. Improper use of fume hood.
15. Contamination of 100 dpm / 100 cm² in any are that radioactive material.

V. RADIATION SAFETY OFFICE NOTIFICATIONS

A. Notification of Radiation Safety Office

The Radiation Safety Office must be notified in case of:

1. Radioactive contamination outside an authorized area.
2. Misuse of radioactive material.
3. Known or suspected personnel contamination with radioactive material.
4. Accidental exposure to personnel.
5. Known or suspected loss of radioactive material.
6. Contaminated or damaged radioactive material packages.

B. Emergency Notification Contacts

In case of emergency involving radioactive material contact the Radiation Safety Office immediately.

Mon-Fri (8am-5pm): 392-7359 or 392-1589

After hours: utilize the Emergency Call List (Page iii)

CHAPTER II - RADIOACTIVE MATERIALS

I. AUTHORIZATION TO USE RADIOACTIVE MATERIAL

A. *Initial Approval*

Any University faculty or staff member needing to utilize radioactive material in research studies must obtain approval and written authorization of the Radiation Control Committee before any radioactive material can be acquired. The authorization that a researcher can obtain depends on the nature of intended research. Specifically, i) non-human use, ii) animal use, iii) off-campus use, and iv) human use.

Approval is obtained by submitting a proposal to the Committee through the Radiation Safety Office describing such items as (a) the facility where the radioactive materials will be used (use and storage), (b) the radionuclide(s) which will be used, and (c) the procedures which will be followed in using radioactive materials (protective equipment and plan for disposal of radioactive waste). This proposal should point out radiation safety precautions which will be taken to prevent the spread of radioactivity to the environment and to protect University personnel. The aim of this approval process is to ensure that the individuals have the appropriate training and working conditions to safely perform the intended activities.

NOTE: See Appendix B for content and suggested format for proposals.

No request for approval to use radioactive material will be denied by the Radiation Control Committee before the investigator is given an opportunity to discuss his or her application with the Committee.

The following forms must be completed and submitted with the proposal:

1. "Statement of Training and Experience" (RC-1 Form), found in Appendix B, for each investigator, staff member and student who will be using radioactive material under the proposal.
2. "Proposal Summary Sheet," found in Appendix B.

Prior to Committee approval and usage of radioactive material, facilities will be inspected by Radiation Safety personnel. The Radiation Safety Office will also screen submitted RC-1 Forms. If it is determined an individual needs additional training or insufficient information is submitted, a Documentation of Training Form, found in Appendix B, will be sent. This form offers three options of training for consideration by the Radiation Safety Office.

NOTE: Investigators wanting to conduct studies involving human subjects (human use) must submit proposals to the Human Use of Radioisotopes and Radiation Committee. A set of forms, separate from those used for the Radiation Control Committee proposals, must be used and can be obtained by contacting the Radiation Safety Office at 392-7359 or through the University of Florida Institutional Review Board web site, www.irb.ufl.edu.

B. Renewal of Authorization to use Radioactive Material

Renewal of proposals is required on a two-year basis. A renewal form, found in Appendix B, will be sent from the Radiation Safety Office at least 15 days prior to the expiration of current approval.

C. Amendment to Proposals

If radioactive materials other than those which were included in the initial proposal and approval are requested, an amendment to the proposal must be submitted to the Radiation Safety Office describing the additional radioactive material, how, why and where it will be used. A Proposal Summary Form, found in Appendix B, must also be submitted.

D. Transfer of Responsibilities

Prior to extended leaves of absence and sabbaticals, the Principal Investigator (PI) must obtain Radiation Safety Office approval for transfer of responsibility for the day to day supervision of work involving radioactive material. The individual assuming the responsibility must be approved for the use of the same types of radioactive material.

E. Procurement and Receipt of Radioactive Materials

Principal Investigators may obtain radioactive materials after their proposal has been approved by the Committee. To comply with inventory and control requirements of the

Nuclear Regulatory Commission (NRC) and Florida Department of Health (FLDOH), the Radiation Safety Office shall approve all radioactive material requisitions and purchase orders prior to placement of orders.

1. Approval

The Purchasing Division will withhold issuing purchase orders for radioactive materials unless the Requisition or Purchase Order has been assigned an "RC Number" indicating approval by the Radiation Safety Office. The original Requisition to Purchase or Purchase Order must be submitted to Radiation Safety. Upon approval, each radioactive material order will be assigned an RC number, and the original requisition or purchase order will then be returned to Purchasing for further processing. The vendor must be provided with the following: 1) name of the approved PI for radioactive material. (The name of a laboratory director or laboratory technician will not be acceptable and is guaranteed to delay, if not prevent, the package from being delivered.) 2) The building and room where the radioactive material is authorized to be used. (Do not indicate to the vendor that the package will be delivered to that building and room since the only approved delivery location is 1929 Stadium Road, Room 212 Nuclear Sciences Building.) For telephone orders (on previously approved blanket accounts), the vendor must still be provided with the above information.

2. Purchase Order Numbers

It is the responsibility of the PI to notify the Radiation Safety Office when a purchase order number is issued for radioactive material orders. Since purchase order numbers are used in identifying incoming shipments, it is important that the Radiation Safety Office be informed as soon as possible.

3. Receipt of Radioactive Material Shipments

The Radiation Safety Office is required to inspect all incoming packages containing radioactive material. After this inspection, the package will be delivered to the ordering laboratory, the person accepting the package in the laboratory is required to sign for the package (printed names are preferred).

Off-Campus radioactive material shipment receipt is reported on the Radioactive Material Package Receipt Form, found in Appendix C. Appendix D contains a detailed procedure for opening packages containing radioactive material. The Radiation Safety Officer shall be notified immediately if damage of the package is observed or if there is evidence of leakage.

F. Facilities

Radioactive materials are not to be used in any University facility without approval of the Radiation Control Committee and/or the Radiation Safety Officer from the standpoint of radiation safety. Plans for all new buildings and modifications of existing structures, where radioactive materials are to be used, must be approved by the Radiation Safety Office prior to the construction or modification of the structure.

Prior to termination of activities involving radionuclides, the Radiation Safety Office must be notified in order to assure that facilities are free from contamination and that transfer of material is in accordance with regulations.

G. Status of the Labs

The laboratories may have one of the three (3) following statuses depending on the use of radioactive material.

1. Active

The laboratory uses radioactive material and/or has stocks or waste. Swipe tests should be performed within seven (7) days of use. If radioactive material is in storage only, then swipe tests should be done every month.

2. Inactive

The laboratory does not plan to use radioactive materials for six (6) months or more. The PI can initiate reactivation of their permit by submitting a request to the Radiation Safety Office. Radiation safety training for all personnel involved must be up-to-date prior to reactivation.

3. Terminated

Principal Investigators that plan to terminate an authorization, shall notify the Radiation Safety Office. It must be ensured that all radioactive material has been disposed or transferred appropriately. The PI is responsible for discontinuing personnel monitoring (radiation badges). Radiation Safety personnel will perform a close out survey of all authorized areas to ensure there is no contamination. Radiation Safety will remove all radiation postings.

II. TRAINING IN THE USE OF RADIOACTIVE MATERIAL

The Radiation Safety Officer and Radiation Control Committee are required to assure that all individuals approved to use radioactive material are competent to do so. The following standards are established in this regard.

A. Responsibility

The PI is the individual primarily responsible for planning, initiating and ultimately interpreting the results of the particular research or project employing radioactive material. In addition, there may be experienced assistants or trainees associated with the work. These individuals might be faculty, staff, students or approved visitors to the University.

B. Training and Experience Requirements for Use of Unsealed Sources of Radioactive Material

The PI must possess formal course or preceptor (on the job) training in all categories (A through F) called for in the Statement of Training and Experience. If the above requirement is not met, a faculty associate already approved as a PI for the radionuclide(s) to be used who does have this training and experience and will take responsibility for the radiation safety aspects of planning and execution of the experiment, must be added to the professional team undertaking the work. The level and extent of training and/or experience must be commensurate with the amount and type of radioactive material to be employed, the extent of hazard involved and sophistication of the techniques being employed. No individual may work independently with radioactive material unless he or she has been approved by the Radiation Control Committee in regard to training and experience. Trainees (whether students or otherwise) may handle radioactive material only under the

direct supervision of an approved authorized user. Experienced, approved users may undertake to train previously inexperienced individuals in the use of radioactive material using the traditional, well accepted Preceptor Method ("on the job training"). However, the individual in question must possess appropriate general technical experience and education to undertake the work, and his or her credentials must be registered with the Radiation Safety Officer.

Furthermore, the nature of the initial experimental work undertaken must be appropriate for the training of the inexperienced individual. Since preceptor training alone has limitations, formal or informal coursework may be required in some cases (Section D below).

C. Training and Experience Requirements for Use of Sealed Sources of Radioactive Material

The PI in charge of any facility utilizing sealed sources of radioactive material must be qualified in all aspects as listed on the Statement of Training and Experience form. Generally, other individuals can be designated experienced workers for use of the device in question provided they are trained in the normal use of the device, potential hazards, safety precautions and emergency procedures. In recent years, it has become common to include a moderate amount of radioactive material in certain devices designed for general laboratory or even consumer use, such as gas chromatography electron capture detectors. To use such a device, the PI is not necessarily required to meet all training requirements for general use of radioactive material, but, must be able to demonstrate competence in regard to the use of the device, potential hazards, safety precautions and emergency procedures.

D. Formal or Informal Coursework

Individuals applying to use radioactive material may be required by the Radiation Control Committee to successfully pursue a formal course, short course or other organized training sessions, in the following circumstances:

1. When the PI has neither formal nor preceptor training in handling radioactive material and no appropriate Co-Principal Investigator can be located.

2. When the duration of the work, level of radiation involved, or degree of sophistication of the work suggest that preceptor training alone may be inadequate. In general, the PI should require inexperienced associates to obtain some formal training if the duration of the work will exceed three (3) months; if the amount of radioactive material in use at one time exceeds 1 mCi (depending on the hazards of the radionuclides in question); if several different radionuclides are to be employed; or, if the procedures used will obviously be hazardous or difficult (i.e., vacuum line manipulation of high-level samples or multiple-step organic synthesis of high-level samples).
3. Where the initial level of training and experience of the trainee is inadequate to begin the preceptor training.

III. PERSONNEL MONITORING PROGRAM

The PI is responsible for assuring that personnel monitoring is provided in all radiation facilities for which he or she is responsible.

A. Personnel Monitoring Requirements

Personnel monitoring devices must be worn by personnel as specified below:

1. Whole Body Luxel/TLD Badges
 - a) Using or assisting in the use of unsealed sources of a beta emitter where the maximum beta energy is 300 keV or higher.
 - b) Using or assisting in the use of unsealed sources of a gamma emitter where the gamma-ray energy is 50 keV or higher.
 - c) Working with neutron sources. Special neutron badges may be required in addition to other badges.

d) Specified by the Radiation Safety Officer and/or the Radiation Control Committee.

2. Extremity Badges or Rings:

a) An individual is using or assisting in the use of sealed or unsealed sources of radioactive materials of 1 mCi (37 MBq) or more of beta-emitting radionuclides with the ability to emit a beta energy of 1 MeV or more.

b) An individual receives a dose of 40 mrem (0.4 mSv) or more on a whole body Luxel//TLD badge for two (2) consecutive months while working with unsealed sources.

c) Specified by the Radiation Safety Officer and/or the Radiation Control Committee.

All monitoring devices shall be obtained from the Radiation Safety Office, see Appendix C for Personnel Monitoring Device Application form. Each Luxel/TLD badge shall be assigned to and worn by only one individual. Luxel/TLD badges may be exchanged monthly or quarterly depending upon monitoring device wear location and expected radiation exposure. Delivery, exchange, and pickup of badges shall be the responsibility of the Radiation Safety Office; however, these functions are performed in cooperation with Badge Coordinators in some work areas. In the event that a badge is damaged, lost, or accidentally exposed, it is the responsibility of the Principal Investigator to notify the Radiation Safety Office immediately for badge replacement or processing. Permanent records of badge readings are maintained by the Radiation Safety Office. A copy of the monthly or quarterly readings is mailed to the Badge Coordinator in each work area. It is the responsibility of each PI to ensure that his/her staff are provided with appropriate radiation badges, and these are worn properly and returned promptly.

3. Pocket Dosimeters

Pocket dosimeters may be required to be worn in addition to the Luxel/TLD badge if other types of monitors are inadequate in the judgment of the Radiation Safety Officer

or Radiation Control Committee. This shall apply where the investigator is working in a high radiation area or in some instances, working with high-level radioactive materials or other ionizing radiation. When these devices are used, the PI is responsible for maintaining daily pocket dosimeter records.

B. Exposure Reports

The Radiation Safety Office will provide annual radiation exposure reports to those individuals who have been assigned a Luxel/TLD badge or another monitoring device. Termination radiation exposure reports will also be provided to those badged individuals who terminate employment requiring personnel dosimetry. Forwarding addresses must be available to facilitate this mailing.

IV. BIOASSAY PROGRAM

A. Biological Samples

Biological samples may be taken from all personnel working with heavy elements, millicurie quantities of tritium or other radionuclides, at intervals specified by the Radiation Safety Officer. Biological samples will be taken from all personnel who have ingested or who are suspected to have ingested, radioactive material and on other occasions deemed necessary. Requirements of the bioassay program for tritium are found in Appendix E, Application of Bioassay for Tritium.

B. Partial body counting

Thyroid monitoring of individuals working with radioiodine is required as specified in Appendix F, Application of Bioassay for I-125 and I-131.

C. Participation

All PIs working with tritium and radioiodine will have their shipments/receipts of radioactive material evaluated each month. If the amount of activity received does not meet the participation criteria this fact will be noted on the monthly inventories.

Analysis for other radionuclides can be performed upon request.

D. Exposure Reports

The Radiation Safety Office shall include bioassay results in the annual radiation exposure reports or upon request.

E. Summation of External and Internal Exposures

The Radiation Safety Officer will ensure compliance with ALARA and regulatory limits by summing the external and internal exposures of the individuals that wear personal radiation dosimeters and participate in the bioassay program.

V. SECURITY OF RADIOACTIVE MATERIAL

In order to maintain safety and security associated with the use of radioactive material, the PI or other individuals responsible for the use of radioactive material will maintain these materials in a locked enclosure (e.g., cabinet, refrigerator, etc.) or otherwise secure the facility from unauthorized access or removal.

A. Monitoring

Monitoring of access is necessary by using appropriate equipment and procedures to prevent the entrance of unauthorized individuals. If attempts of unauthorized access are detected, these incidents shall be reported along with the corrective actions taken to prevent the recurrence.

B. Limited Access

Only reliable and trustworthy individuals may have access to radioactive materials in quantities of concern. Authorized access may be granted to employees that meet certain criteria of employment history, education, references and being in the organization for more than six (6) months. Approval of authorized access shall be documented in writing, and a current list of authorized individuals shall be maintained at all times.

VI. CAUTION SIGNS, NOTICES, AND POSTERS

Each PI is responsible for posting of proper warning signs in all areas in which radioactive materials are used. Appropriate warning signs are available from the Radiation Safety Office.

The following signs must be posted in each laboratory authorized for radionuclide use or storage:

Emergency Notification

Emergency Procedures

Notice to Employees

Safety Rules for Radioisotope Laboratory

VII. RADIATION DETECTION INSTRUMENTATION AND SAFETY EQUIPMENT

A. Appropriate instrumentation

The PI is responsible for assuring that suitable radiation detection instruments and other necessary safety equipment are available in all radiation facilities for which he or she is responsible and that the equipment is in good working order.

B. Radiation Detection Instruments (Survey Meters)

Calibrated survey meters which are appropriate for the type and energy of ionizing radiation being used must be available. Survey meters must be calibrated every nine (9) months for non-human use and every six (6) months for human use. Contact the Radiation Safety Office for instrument calibration and minor repair services.

C. Contaminated Survey Meter

If a survey meter becomes contaminated and decontamination cannot be done, contact the Radiation Safety Office to obtain a loaner meter.

D. Inoperable Survey Meter

If a survey meter is inoperable but appears functional (no breaks), perform a battery check. If the batteries are dead, the user can replace the batteries and the meter does not need calibration. If the meter is still inoperable, contact the Radiation Safety Office for a loaner meter and to check the broken meter.

VIII. LABORATORY SURVEYING AND MONITORING

Each PI is responsible for routine (weekly) area surveying and monitoring of radiation facilities to assure the absence of contamination. Surveys after each use are recommended. Monthly surveys

are required when radioactive materials (or radioactive waste) are in storage. Permanent records shall be maintained by the PI, for at least three (3) years, for review by the Radiation Safety Office and FLDOH inspectors. The Radiation Safety Office may provide Radiation/Contamination Survey Forms for recording survey results upon request. Quarterly and unannounced surveys and monitoring of radiation facilities will be made by representatives of the Radiation Safety Office. Upon request, the Radiation Safety Officer or his or her representative will survey and monitor a laboratory, experimental setup, and/or waste storage facilities.

A. *Surveys*

1. Fixed contamination survey

For medium to high-energy beta emitters (e.g., P-32, Sr-90, etc.) a survey with Geiger-Mueller (GM) survey meter is appropriate. If contamination is detected the area should be decontaminated or the item must be appropriately disposed.

NOTE: GM detectors are not appropriate for H-3, C-14 or S-35 because of low detection efficiency.

2. Removable contamination survey (swipes/wipes)

All areas should be surveyed for removable contamination by taking swipes on sample locations. It is recommended that the swipes for H-3 be counted in a liquid scintillation counter (LSC). For other low energy beta emitters such as C-14 and S-35, a LSC must be used for proper documentation. The results shall be recorded in dpm taking into account the efficiency of the counter.

3. Ambient radiation survey

If gamma-emitting isotopes are used, a survey for ambient radiation levels must be performed. A survey meter (ion chamber) with sensitivity of 0.1 mR/h shall be used. Readings shall be recorded in mR/h or mrem/h.

NOTE: GM detectors can be used for these surveys only if they are calibrated for mR/h.

B. Action/Trigger Levels

Occasionally, a small amount of contamination is expected, but the extent of such contamination shall be kept ALARA. Action shall be taken following the finding of removable contamination above 100 dpm or GM counts above background levels.

Ambient radiation levels above 1 mR/h shall be addressed by adding appropriate shielding. Areas with radiation levels above 5 mR/h at 30 cm (1 foot) from the sealed source, must be posted with a “CAUTION- RADIATION AREA” sign.

C. Record Keeping

All records shall be kept for a minimum of three (3) years and be available during the quarterly Radiation Safety inspections.

IX. EMERGENCY PROCEDURES

A. Minor Spills (Less than 100 microcuries of activity and/or 5 mR/hr @ 1 foot)

1. NOTIFY - Notify persons in the area that a radioactive spill has occurred.
2. PREVENT THE SPREAD - Cover the spill with absorbent paper.
3. CALL FOR HELP - Report the incident to the Radiation Safety Office (392-7359 or 392-1589). If possible, have someone not involved in the spill make the report. In the event the Radiation Safety Office cannot be reached, utilize Emergency Call List (Page iii).
4. CLEAN UP - Use disposable gloves (and remote handling tongs for high energy beta's and gammas). Do not spread contamination – use absorbent paper and carefully wipe spill from outside to inside (low-level contamination towards the center of high contamination). Insert cleanup items into a plastic bag and dispose of all waste in a radioactive waste container. Include all contaminated materials such as disposable gloves.
5. SURVEY - If using an isotope other than a low energy beta emitter, use a survey meter and check the area around the spill, your hands, shoes, and clothes for contamination. A swipe survey shall be performed to demonstrate that decontamination results are below the University of Florida limit of 100 dpm/100

cm². If there is still contamination in the area, mark it with a marker or tape (CAUTION-RADIOACTIVE MATERIAL).

B. Major Spills (More than 100 microcuries of activity or 5 mR/hr at 1 foot or personal contamination)

1. CLEAR THE AREA - Notify all persons not involved in the spill to vacate the room. These people shall remain near the room to be checked for contamination.
2. PREVENT THE SPREAD - Cover the spill with absorbent material, but do not attempt to clean it up. Confine the movement of all potentially contaminated personnel to prevent the spread.
3. CALL FOR HELP - Notify the Radiation Safety Office (392-7359 or 392-1589) immediately. If possible, have someone not involved in the spill make the notification. In the event the Radiation Safety Office cannot be reached, utilize Emergency Call List. (Page iii).
4. SHIELD THE SOURCE - If possible shield the spill, but only if it can be done without further contamination or without significantly increasing your radiation exposure.
5. CLOSE THE ROOM - Leave the room and lock the door(s) to prevent entry. Post a sign "Contamination DO NOT enter until cleared by Radiation Safety."
6. PERSONNEL DECONTAMINATION - Contaminated clothing shall be removed and stored for further evaluation by the Radiation Safety Office. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water. Proceed to decontaminate and survey under the direction of Radiation Safety personnel.
7. FACILITY DECONTAMINATION – Upon direction of the Radiation Safety Office, proceed to clean up spill and survey. Shoe covers and double gloves shall be used to prevent personal contamination. Both body and extremity badges may be required.

NOTE: Decontamination shall be the responsibility of the experimenter and/or his supervisor and shall be carried out under the direction of the Radiation Safety Officer or persons designated by the RSO, and with the cognizance of other

University officials who may be responsible for the facility or laboratory. A final survey to document that the area has been successfully decontaminated is required.

X. RADIOACTIVE MATERIAL INVENTORY

Each PI is responsible for providing quarterly radioactive material inventory reports to the Radiation Safety Office. A permanent record of inventories shall be maintained by the PI for review by Radiation Safety personnel and FLDOH inspectors. Inventory record forms are available from Radiation Safety. Appendix G contains detailed instructions for completing the Quarterly Radioactive Material Inventory form. Maintenance of the Utilization Form, also described in Appendix G, will facilitate this process.

XI. TRANSFER OF RADIOACTIVE MATERIAL

A PI may neither transfer nor loan materials to an unauthorized person under any circumstances. All transfers of radioactive materials shall be carried out by properly trained and authorized personnel with the knowledge and approval of the Radiation Safety Officer. State, Federal DOT and international (IATA) regulations must be followed as applicable for appropriate packaging, labeling, and shipping of the radioactive material.

A. On-Campus Transfers

Since approval for the procurement and use of radioactive material was initially given for the original working area and proposed research under the supervision of the approved PI, radioactive material shall not be transferred from one area to another or to other individuals without the approval of the Radiation Safety Office.

After approval on the proper transfer form, transfers must be recorded on both the transferring and receiving laboratory's radionuclide utilization forms.

B. Off-Campus Transfers

Radioactive material shall not be shipped or transferred to, or from any University facility, or outside organization without prior approval of the Radiation Safety Office. The Radiation Safety Office must act as the shipper of radioactive materials.

C. Disposal of Equipment Containing Radioactive Material

Prior to the disposal of obsolete or irreparable equipment (e.g., radioactive material refrigerators, liquid scintillation counters, gas chromatographs, etc.), the Radiation Safety Office must be notified in order to remove warning labels and sources, amend inventory lists, and to verify the absence of contamination, where applicable.

XII. RADIOACTIVE WASTE DISPOSAL

A. Procedures

Radiation Control Technique #2, Instructions for Preparation of Radioactive Waste for Disposal, contains radioactive waste disposal procedures which are applicable to the majority of waste generated in laboratories and is available from the Radiation Safety Office or the Hazardous Materials Management Office. The Hazardous Materials Management Office (392-8400) should be contacted for disposal information for unusual types of waste. In addition to the radioactive material warning label, waste must be identified as to other hazards present such as poisons, carcinogens, organics or corrosives. Red or biohazard bagged waste will not be picked up. If you have active biohazardous waste and are unsure of an inactivation procedure, contact the Biological Safety Officer (392-1591).

B. Waste Reduction Methods

1. Minimize waste by preventing unnecessary contamination.
2. Clean and reuse lab equipment when possible. RECYCLE.
3. Only dispose of materials that are actually contaminated. Packing materials and boxes which have not been in contact with radioactive material shall be disposed of in regular trash after radioactive warning labels have been removed or obliterated. If a spill occurs on mat paper, only the contaminated paper should be placed in radioactive waste. Remaining paper may be placed in regular trash. SEPARATE RADIOACTIVE WASTE FROM NON-RADIOACTIVE WASTE.
4. Review your procedures and determine what processes contaminate clean material and formulate measures to minimize the amount of contamination, e.g.,

unnecessary transfer between pieces of glassware. PREPLANNING IS STRONGLY ENCOURAGED.

5. Your commitment is essential to achieve volume reduction and to assure ongoing employee training that reduces contamination.

C. Radioactive Waste Guidelines/Instructions

Radioactive waste shall be segregated by PI, isotope, and type of waste.

1. Principal Investigator

Radioisotope usage is tracked by the PI.

2. Radioisotope

- i. Short-lived radioisotopes (Half-life <90 days) must be separated from each other whenever possible and segregated from long-lived isotopes.
- ii. Long-lived radioisotopes (H-13, C-14) may be consolidated in the same container, provided they are the same type of waste and under the same PI.

All radioactive materials labels on empty shipping containers must be removed or defaced prior to disposing of the container in regular trash.

3. Type of Waste

Each type of radioactive waste should be separated. The most common waste categories include biological, solid waste, liquid waste, and liquid scintillation vials. For specific instructions refer to Radiation Control Technique #2, Instructions for Preparation of Radioactive Waste for Disposal.

XIII. SEALED SOURCE LEAK TEST

A sealed source is radioactive material that is fixed in a capsule or matrix designed to prevent release of the radioactive material under conditions of normal use and handling. All beta, gamma, and neutron sealed sources greater than 100 microcuries shall be leak tested at intervals not to exceed six (6) months, and all sealed alpha sources greater than 10 microcuries shall be leak tested at intervals not to exceed three (3) months, or any time there is a reason to suspect that the source had been damaged or might be leaking. Leak tests shall be performed according to written

procedures (Radiation Control Technique #5, Instructions for Leak Testing Sealed Sources). Removable contamination of 185 Bq (0.005 μ Ci) or more is considered evidence that a sealed source is leaking. If the source is determined to be leaking it will be removed by Radiation Safety personnel and stored in a secured location.

XIV. SPECIAL PROCEDURES FOR ANIMAL USE IN RESEARCH

Approval to use radioisotopes in animals requires written authorization from both the Institutional Animal Care and Use Committee (IACUC) and the Radiation Control Committee. The applicant shall prove that he or she has appropriate facilities to use and care for the animals.

General instructions include:

A. Animal Cage

Animals containing radioactive material shall not be caged and/or kept in a laboratory except with the consent of IACUC and the Radiation Safety Officer or designee. Special cage areas and a procedure room are available in the Animal Control areas. Procedures for radioactive material use in these areas will be posted at each location.

1. Use of animals in research shall conform to guidelines, policies, and requirements of the IACUC.
2. Animals administered radioactive materials, and their products, shall not be used for human consumption.

B. Radiation Protection Guidelines for Caregivers

1. Animals that have been externally irradiated (x-rays or gamma rays) do not present a radiation hazard.
2. Cages shall be posted with a Caution Radioactive Material sign. Information on the outside of the cage shall include the date of administration, the isotope, and the quantity administered.
3. Radiation surveys shall be made around the cages to determine levels of external radiation. A contamination survey shall be made of all cage facilities following use.

4. Absorbing material in a tray shall be provided within each cage for urine and fecal radioactive material excretion. The absorbent material shall be changed periodically and disposed of as radioactive waste.
5. Laboratory coats, appropriate eye protection, and disposable gloves must be worn during cage cleaning and when handling the animals.
6. Animal carcasses containing radioisotopes shall be properly disposed of. Radioactive animal carcasses and associated waste shall be placed in clear, double plastic bags. The bag shall be labeled with the type and number of animals and what radioisotope(s) they contained and the activity of each radioisotope. The animals will require temporary storage in a laboratory freezer or refrigerator to prevent biodegradation until picked up.

CHAPTER III - RADIATION PRODUCING DEVICES

I. AUTHORIZATION TO USE RADIATION PRODUCING DEVICES

All devices and apparatus capable of producing ionizing and non-ionizing radiation in potentially hazardous quantities must be approved by the Radiation Safety Office. The following types of devices and apparatus are among those requiring approval:

- x-ray machines (medical, dental, veterinary, irradiators, other)
- x-ray diffraction units
- electron microscopes
- particle accelerators
- static eliminators functioning by emitting ionizing radiation
- beta ray gauges and gas chromatographs with ECD
- devices using sealed gamma radiation sources (e.g., teletherapy units, irradiators, moisture density gauges, etc.)
- lasers and equipment incorporating a laser (Laser Safety Manual)

Contact the Radiation Safety Office to determine if a device is exempt from these requirements.

A. Initial Approval

Any University faculty or staff member wishing to utilize a radiation producing device in research studies must obtain approval of the Radiation Safety Office. Approval is obtained by submitting a request to the Radiation Safety Office describing such items as (a) the facility where the radiation producing device will be used, (b) the type of device which will be used, and (c) the procedures which will be followed in using the device. This request should point out radiation safety precautions which will be taken to protect University personnel.

No request for approval to use a radiation producing device will be denied by the Radiation Safety Office before the investigator is given an opportunity to discuss his or her application.

Investigators wanting to conduct studies involving human subjects must submit proposals to the Human Use of Radioisotopes and Radiation Committee. A set of forms, separate from those used for the Radiation Control Committee proposals, must be used and can be obtained through the Institutional Review Board's web page, www.irb.ufl.edu.

A Statement of Training and Experience for x-ray users (Appendix H) must be completed and submitted prior to use of x-ray producing devices.

Prior to usage of the device, facilities will be inspected by Radiation Safety personnel and registered with the State of Florida. The Radiation Safety Office will also screen submitted Statement of Training forms. If it is determined an individual needs additional training or insufficient information is submitted, a Documentation of Training Form, Appendix H, as appropriate, will be sent. This form offers three options of training for consideration by the RSO.

B. Transfer of Responsibilities

Prior to extended leaves of absence and sabbaticals, the Principal Investigator must notify Radiation Safety Office regarding transfer of responsibility for the day to day supervision of work involving the radiation producing device.

C. Registration of Radiation Producing Devices

To comply with inventory and control requirements of the NRC and FLDOH, the Radiation Safety Office shall approve all device requisitions and purchase orders prior to placement of orders. These devices include x-ray diffraction units, research irradiators, radiographic units, gas chromatographs (EC detector), electron microscopes, and lasers. For additional purchasing information, call the Radiation Safety Office at 392-7359.

1. Approval

Purchasing Division will withhold issuing purchase orders for a radiation producing device unless the Requisition or Purchase Order has been approved by the Radiation Safety Office. The original Requisition to Purchase or Purchase Order must be submitted to Radiation Safety. Upon approval, the original requisition or purchase order will then be returned to Purchasing for further processing.

2. Receipt of Device

The Radiation Safety Office may be required to perform acceptance testing of the device to ensure proper operation and safety. Off-Campus device procurement and receipt should be coordinated with the Radiation Safety Office.

D. Facilities

Radiation producing devices are not to be used in any University facility without approval of the Radiation Control Committee and/or the Radiation Safety Officer from the standpoint of radiation safety. Plans for all new buildings and modifications of existing structures, where devices are to be used, must be approved by the Radiation Safety Office prior to the construction or modification of the structure.

Upon termination of activities involving the device, the Radiation Safety Office must be notified in order to assure that transfer of the device is in accordance with regulations.

II. TRAINING IN THE USE OF RADIATION PRODUCING DEVICES

The Radiation Safety Officer is required to assure that all individuals approved to use radiation producing devices are competent to do so. Personnel shall receive training specific to the equipment to be used. The training should include but not limited to: background information for operation, normal use and emergency procedures, use of safety devices (interlocks), appropriate use of protective equipment, and radiation dosimeters and quality control. The following standards are established in this regard.

A. Responsibility

The Principal Investigator is the individual primarily responsible for planning, initiating and ultimately interpreting the results of the particular research or project employing the radiation producing device. In addition, there may be experienced assistants or trainees associated with the work. Any of these individuals might be faculty, staff, students or approved visitors to the University.

B. Training and Experience Requirements

The PI must possess formal course or preceptor (on the job) training in all categories called for in the Statement of Training and Experience form. If the above requirement is not met, a faculty associate already approved for the device to be used who has this training and experience, and who will take responsibility for the radiation safety aspects of planning and execution of the experiment must be added to the professional team undertaking the work. The level and extent of training and/or experience must be commensurate with the type of device to be employed, extent of hazard involved and sophistication of the techniques being employed. No individual may work independently with the device unless he or she has been approved by the Radiation Safety Office in regard to training and experience. Trainees (whether students or otherwise) may utilize the device only under the direct supervision of an approved experienced worker. Experienced, approved workers may undertake to train previously inexperienced individuals in the use of the device using the traditional, well-accepted Preceptor Method ("on the job training"). However, the individual in question must possess appropriate general technical experience and education to undertake the work, and their credentials must be registered with the Radiation Safety Officer.

Furthermore, the nature of the initial experimental work undertaken must be appropriate for the training of the inexperienced individual. Since preceptor training alone has limitations, formal or informal coursework may be required in some cases (Section C below).

C. Formal or Informal Coursework

Individuals applying to use a radiation producing device may be required by the Radiation Safety Office to successfully pursue a formal course, short course or other organized training session, in the following circumstances:

1. When the PI has neither formal nor preceptor training in utilizing the device, and no appropriate Co-PI can be located.

2. When the duration or degree of sophistication of the work suggest that preceptor training alone may be inadequate. In general, the PI should require inexperienced associates to obtain some formal training if the duration of the work will exceed three (3) months or if the procedures used will be hazardous or difficult.
3. Where the initial level of training and experience of the trainee is inadequate to begin the preceptor training.

III. PERSONNEL MONITORING PROGRAM

The PI is responsible for assuring that personnel monitoring is provided in all radiation facilities for which he or she is responsible.

A. Personnel Monitoring Requirements

Personnel monitoring devices must be worn by personnel as specified below:

1. Whole Body Luxel/TLD Badges
 - a. Working with any ionizing radiation producing device.
 - b. Specified by the Radiation Safety Officer.

When a lead apron or thyroid shield is worn, the whole-body monitoring device shall be worn at the collar outside the apron or shield.

2. Extremity Badges or Rings

Extremity Badges or rings are available upon request. All monitoring devices shall be obtained from the Radiation Safety Office. See Appendix C for "Personnel Monitoring Device Application." Each Luxel/TLD badge shall be assigned to and worn by only one individual. Luxel/TLD's may be exchanged monthly or quarterly depending upon monitoring device wear location and expected radiation exposure. Delivery, exchange and pickup of badges shall be the responsibility of the Radiation Safety Office; however, these functions are performed in cooperation with Badge Coordinators in some work areas. In the event that a badge is damaged, lost, or accidentally exposed, it is the responsibility of the PI to notify the Radiation Safety Office immediately for

badge replacement or processing. Permanent records of badge readings are maintained by the Radiation Safety Office. A copy of the monthly and/or quarterly readings is sent to the Badge Coordinator in each work area.

3. Pocket Dosimeters

Pocket dosimeters may be required to be worn in addition to the Luxel/TLD badge if other types of monitors are inadequate in the judgment of the Radiation Safety Officer or the Radiation Control Committee. This shall apply where the investigator is working in a high radiation area. When these devices are used, the PI is responsible for maintaining daily pocket dosimeter records. Copies of these records shall be submitted quarterly to the Radiation Safety Office.

B. Exposure Reports

The Radiation Safety Office will provide annual radiation exposure reports to those individuals who have been assigned a Luxel/TLD badge or other monitoring device. Termination radiation exposure reports will be provided to those badged individuals who terminate employment requiring personnel dosimetry. Forwarding addresses must be available to facilitate this mailing.

IV. ANNUAL RADIATION SAFETY INSPECTION

The Radiation Safety Office will perform an annual radiation safety inspection of ionizing radiation producing devices, where appropriate. A series of standardized tests will be conducted to evaluate the operating condition of the x-ray generator and components in order to verify proper operation of the unit and its compliance with regulations.

In addition, safety devices (e.g., warning lights, interlocks, shielding, etc.) shall be checked and maintained in a good working order. No replacement of such devices shall be done without the permission of the Radiation Safety Office. If a safety device is not operable, the x-ray machine **shall not** be operated until the device is properly repaired.

V. RADIATION PRODUCING DEVICE INVENTORY

The Radiation Safety Office will perform an annual physical inventory of all radiation producing devices to confirm registration with FLDOH. Each PI is responsible for notifying the Radiation Safety Office if there is any change which would render the registration inaccurate. Such information includes change of use location, sale, transfer or disposal of any radiation machine or major component thereof.

VI. TRANSFER OF RADIATION PRODUCING DEVICES

A. On-Campus Transfers

Since approval for the procurement and use of a radiation producing device was initially given for the original working area and proposed research under the supervision of the approved PI devices shall not be transferred from one area to another or to another individual without approval of the Radiation Safety Office.

B. Off-Campus Transfers

Radiation producing devices shall not be shipped or transferred to, or from any University facility, or outside organization without prior approval of the Radiation Safety Office.

C. Disposal of Radiation Producing Device

Prior to the disposal of obsolete or irreparable equipment, the Radiation Safety Office must be notified in order to amend inventory lists.

VII. TYPES OF RADIATION PRODUCING DEVICES (Non-Clinical Use)

A. Electron Microscopes

The following are general procedures for the safe use of electron microscopes:

1. Electron microscopes must be secured against unauthorized use. This can be accomplished through key control of the unit or the room.
2. Do not modify the built-in shielding and viewing ports. If modifications must be made, contact Radiation Safety to have a survey done of the unit prior to and after modifications.

3. Changes in the location or disposition of electron microscopes must have the approval of EH&S.
4. Notify Radiation Safety prior to the acquisition, disposal, or transfer of any electron microscope.

B. Cabinet X-ray Systems

The following are general procedures for the safe use of cabinet x-ray systems:

1. Only authorized individuals may operate Cabinet x-ray equipment.
2. DO NOT override the safety interlock.
3. DO NOT use the safety interlock to turn the machine off; use the main switch.
4. Make sure the machine is OFF before changing samples. Always check the current and voltage meters and/or use a survey meter to detect x-rays.
5. Do not modify the built-in shielding. If modifications must be made, contact Radiation Safety to request a unit and operation safety survey.
6. Cabinet x-ray systems must be secured against unauthorized use.
7. Changes in the location or disposition of x-ray units must have the approval of the Radiation Safety Office. Notify Radiation Safety prior to the acquisition, disposal, or transfer of any x-ray producing device.

C. X-Ray Diffraction/Fluorescence Units

X-ray diffraction units can be very hazardous because of extremely high primary beam exposure rates (several 100,000 R/minute) at the x-ray tube ports. Serious damage can result to an individual's eyes and skin, even if exposed to this intense radiation level for a

very short period of time. Extreme caution must be exercised in the use of x-ray diffraction equipment. The following are general requirements for the safe use of x-ray diffraction units:

1. Only authorized individuals may operate x-ray diffraction/fluorescence equipment.
2. Always confirm that the high voltage is OFF or that the shutter is CLOSED before changing samples. When using systems with shutters, a survey meter is required to confirm that the shutter is closed before changing samples.
3. DO NOT use the safety interlock to discontinue x-ray production; use the main switch.
4. Operations involving removal of covers, shielding materials, tube housings, or modifications to shutters, collimators, or beam stops must be performed by qualified personnel only.
5. Ring dosimetry is required for personnel performing beam alignment.
6. Check radiation leakage with a survey meter after each beam re-alignment.
7. Diffraction/fluorescence units must be secured against unauthorized use.
8. Changes in the location or disposition of diffraction/fluorescence units must have the approval of Radiation Safety. Notify Radiation Safety prior to the acquisition, disposal, or transfer of any diffraction/fluorescence x-ray equipment.

CHAPTER IV - CLINICAL USE - HUMAN USE

I. INTRODUCTION

Adherence to the principles of good clinical practices, including adequate protection for participants is universally recognized as a critical requirement to the conduct of research involving human use and clinical applications.

II. HUMAN USE OF RADIOISOTOPES AND RADIATION COMMITTEE

The Human Use of Radioisotopes and Radiation Committee (HURRC) was established in order to ensure that human use of radioisotopes, ionizing, and nonionizing radiation is in accordance with standard radiation safety practice, sound medical practice, and Federal and State regulations.

The HURRC meets on a quarterly basis and at least half of the committee members must be present including the Radiation Safety Officer, the Chair and a representative of UF Health Administration. Minutes of the meeting include the date and time, members present and absent, discussions, recommendations and the ALARA report.

A. Membership

The HURRC shall consist of at least four representatives from the Medical Staff, the Radiation Safety Officers from the University of Florida and the Veterans Administration Medical Center, and a representative from the UF Radiation Control Committee. Representatives from Nursing, Pharmacy, Safety, and Hospital Administration may also be appointed to the committee.

B. Committee Responsibilities

The HURRC shall comply with the requirements specified in 64E-5.606, F.A.C. Specific responsibilities shall be to:

1. Review and grant permission for human uses of radioisotopes and ionizing radiation.

2. Evaluate the training and experience of each physician who proposes to use radioactive materials or ionizing radiation in research, diagnosis or therapy in humans.
3. Approve the training of a physician, dentist or podiatrist to receive, possess, or use radioactive material under the supervision of an authorized user.
4. After completion of training, provide documentation to a physician, dentist or podiatrist that he/she has received the training and experience required by 64E-5 F.A.C.
5. Evaluate the overall radiation safety program, the Radiation Safety Officer performance, and the radiation control staff performance annually and report the results to senior management as part of the Committee's Annual Report.
6. Review the training programs, equipment, facilities, supplies, procedures and reports to ensure the safe use of radioactive material (i.e., the quarterly ALARA report).
7. Maintain records of the actions taken in approving or disapproving the human use of radioisotopes and ionizing radiation, and other transactions, communications, and reports involved in the work of the committee.
8. Prepare and disseminate information on radiation safety for the use and guidance of researchers, technologists, nurses, physicians, and dentists.
9. Prescribe special conditions and requirements that may be necessary (such as additional training, physical examinations, designation of limited areas or locations of use, disposal methods, etc.) to assure radiation safety.
10. Review all incidents/ medical events with respect to cause and the corrective actions taken quarterly.
11. Review and make recommendations for the Quality Management Program.

III. ALARA POLICY

The University and UF Health/Shands are each committed to keeping radiation exposures (individual and collective) As Low As Reasonably Achievable (ALARA). They have established

an administrative organization for radiation safety to develop the necessary policies, procedures and instructions to further each institution's express commitment.

The University and UF Health/Shands have established ALARA Levels for occupational radiation exposure which, when exceeded, will initiate review or investigation by the RCC, HURRC, and/or the RSO. The Investigation Levels that are adopted are listed in the table below. These levels apply to the exposure of individual workers.

A. ALARA Levels I and II

For personnel radiation exposure from radiation machines or radioisotope use:

- i. Monthly exposure of individuals to less than Notification Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases.

- ii. Personnel exposures equal to or greater than Notification Level I, but less than Investigational Level II.

The RSO will investigate the exposure of each individual whose monthly exposures equal or exceed Notification Level I.

- iii. Personnel exposures equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation and actions taken, if any, will be presented to the HURRC.

ALARA Levels for Radiation Exposure				
		Level I (per month)	Level II (per quarter)	Regulatory Limit (per year)
Research Laboratories, Nursing Staff, all others	DDE	40 mrem (0.4 mSv)	375 mrem (3.75 mSv)	5000 mrem (50 mSv)
	LDE	125 mrem (1.25 mSv)	1125 mrem (11.25 mSv)	15000 mrem (150 mSv)
	SDE	400 mrem (4.0 mSv)	3750 mrem (37.5 mSv)	50000 mrem (500 mSv)
Radiology and Cardiology (see NOTE below)	DDE	170 mrem (1.7 mSv)	N/A	
	LDE	1000 mrem (10 mSv)	N/A	
	SDE	3300 mrem	N/A	

		(33 mSv)		
Radiology, Cardiology, Nuclear Medicine, Nursing Staff	DDE	300 mrem (3.0 mSv)	N/A	
	LDE	1000 mrem (10 mSv)	N/A	
	SDE	3300 mrem (33 mSv)	N/A	

- **DDE (Deep Dose Equivalent):** Dose equivalent from external whole body exposure at a tissue depth of 1.00 cm; it applies to the whole body.
- **LDE (Lens Dose Equivalent):** Dose equivalent from external exposure at a tissue depth of 0.30 cm; it applies to the lens of the eye.
- **SDE (Shallow Dose Equivalent):** Dose equivalent from external exposure at a tissue depth of 0.007 cm averaged over one (1) square cm; it applies to skin and extremities.

NOTE: Only those physicians performing fluoroscopic procedures in cardiology and interventional radiology and for whom weighting factors are used.

IV. AUTHORIZED USER

Any University faculty or staff member needing to utilize radioactive material for human use must meet federal and state regulations to become an authorized user and be approved by the HURRC. The applicants shall send all of their credentials to the Radiation Safety Officer for review, and transmittal to the HURRC for approval. By definition, an authorized user for clinical use/human use of radioactive material or radiation emitted from radioactive material must have the adequate training, experience, and qualifications and be approved by the HURRC.

A. Training Requirements

- A physician, dentist, or podiatrist who meets the requirements in Rule 64E-5.658 and subsection 64E-5.649(1), 64E-5.652(1), 64E-5.654(1) or 64E-5.655(1), 64E-5.660(1), 64E-5.661(1), 64E-5.662(1), F.A.C.

OR

- An individual identified for medical use of radioactive materials on:

- a. An NRC or agreement state license that authorizes the medical use of radioactive material;
- b. A permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material;
- c. A permit issued by an NRC or agreement state specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or
- d. A permit issued by an NRC master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

B. Becoming an Authorized User

Any physician wishing to become an Authorized User should forward their credentials to the Radiation Safety Officer for review and transmittal to the HURRC for approval. At a minimum, the following information is required:

- a. Current State of Florida medical license;
- b. If board certified, provide a copy of board certification;
- c. Preceptor/attestation forms indicating training; and
- d. If certification is greater than seven (7) years then documentation of training to maintain certification for the time period.

NOTE: An individual that only operates a radiation-producing device (other than an electronic brachytherapy unit) is not required to obtain a permit as an Authorized User, although the Radiation Safety Office must be made aware of acquisition and use of such equipment to ensure proper registration and tracking.

V. USE OF RADIOACTIVITY AND RADIATION FOR CLINICAL APPLICATIONS

Radioactive materials intended for human diagnosis or therapy may be ordered, as necessary, provided the type, form, and quantity conforms to the provisions of the University of Florida Broad Scope License. Some radiopharmaceuticals are received by the Radiation Safety Officer. Nuclear Medicine Hot Labs are also approved to receive radiopharmaceuticals. Nuclear Medicine labs are

responsible for maintaining appropriate records of receipt surveys, inventory, use, and disposal. The Radiation Safety Office will audit these records to ensure that these requirements are met.

New radionuclides or novel uses of a currently authorized radionuclide may require amendment of the Broad Scope license.

A. Safety in Using Sealed Sources

Sealed sources can be sources for therapeutic purposes or check/calibration sources for quality control. Individuals that handle sealed sources shall wear finger radiation dosimeters. All sealed sources shall be secured and protected from unauthorized use or theft.

B. Safety in Radiation-Producing Devices

Radiation-producing devices are devices that can produce ionizing radiation for diagnostic or therapeutic purposes, such as CT scanners, mammography, orthovoltage and linear accelerators. Radiation safety guidelines include:

1. All users shall be appropriately trained to use such equipment.
2. Appropriate PPE (i.e., lead aprons, glasses, etc.,) shall be used as needed.
3. Fixed or portable barriers (shields) shall be utilized as needed.
4. Personnel shall employ ALARA principles (time, distance, shielding).

C. Quality Assurance Program

Departments that use radiopharmaceuticals or radiation producing devices for therapeutic or diagnostic purposes must adopt written policies and procedures to comply with federal and state regulations. These policies and procedures can be found in every department separately and must be updated periodically. The aim of these procedures is to ensure ALARA is maintained for personnel and patient doses through appropriate quality assurance protocols. The quality management program includes equipment inspections to ensure good quality of images and acceptable dose output, appropriate radiopharmaceutical administration and good practice in handling radiation producing devices and radiopharmaceuticals. For this purpose, periodic compliance audits (e.g., weekly, monthly, quarterly, or annually) are conducted by the Radiation Safety Office.

D. Radioactive Waste Disposal Shipments

Most of the radiopharmaceuticals used in clinical practice (therapeutic or diagnostic) are short-lived (physical half-life <90 days), and therefore can be stored for decay. The containers shall be appropriately labeled with the radioactive sign, the date of storage, the isotope and the Authorized User. The waste bags and containers shall be stored for ten (10) physical half-lives and then surveyed with an appropriate meter. The waste can be disposed of if there is no detectable radioactivity (above background) when the meter is used on the lowest scale. Records shall be maintained and must be available for monthly audits by the Radiation Safety Office.

Some sealed sources used for the quality control program (i.e., equipment inspections) are shipped back to the manufacturer using DOT and IATA guidelines.

VI. SPECIAL OCCASIONS

A. Fetal Radiation Exposure from Medical Procedures

The responsibility of calculating the fetal dose from an unintended exposure (unknown pregnancy) or due to medically justified diagnostic or therapeutic procedures during pregnancy lies with the UF Health Diagnostic Medical Physics Group.

The Radiation Safety Office must be immediately notified if:

1. Dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the Authorized User.
2. Dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that meets one of the following:
 - a. Greater than 50 mSv (5 rem) total effective dose equivalent
 - b. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

B. Death of a Patient Containing Radioactive Material

For diagnostic procedures, no special precautions are required other than those for handling patients with radioactivity from diagnostic nuclear medicine studies. Gloves, lab coats, and gowns must be used. For therapeutic administrations, special procedures are required.

Therapeutic Radiopharmaceuticals:

1. Immediately notify the Radiation Safety Office.
2. A report stating the treatment, isotope, date and time of administration, the administered activity or implants should accompany the body.
3. An autopsy shall be performed only after consultation and permission by the Radiation Safety Officer and under the supervision of the Radiation Safety Office.

C. Autopsy of a Body Containing Therapeutic Radiopharmaceuticals

An autopsy will be performed only after consultation and permission by the Radiation Safety Officer and under the supervision of the Radiation Safety Office.

1. Personnel should wear protective clothing (i.e., gowns, gloves, etc.) and eye protection.
2. If a cut or tear in the glove occurs monitor and decontaminate the wound under the instructions of the Radiation Safety personnel.
3. Dissection and tissue removal must be done from a low dose rate location.
4. First, remove organs with high activity. Shield and appropriately dispose of those tissues.
5. For radiopharmaceuticals that are known to concentrate in particular body fluids, appropriate drainage of those tissues may be necessary.
6. Implants (sealed sources) do not release any radioactivity in the body fluids. If removal of the particular organ is necessary, this should be handled briefly and by using tongs.
7. No pregnant personnel shall work with those bodies.

D. Surgery or biopsy in Patients Containing Radioactive Material

In some cases, patients that have administered radiopharmaceuticals require surgery or biopsies. For diagnostic radiopharmaceuticals, there is no need for particular precautions.

In the case of therapeutic radiopharmaceuticals special actions are required:

1. Notify the Radiation Safety Office.
2. A report stating the treatment, isotope, date and time of administration, and the administered activity or implants should accompany the patient.
3. Eye protection must be worn to protect from potential splashing of radioactive material.
4. If a cut or tear in the glove occurs monitor and decontaminate the wound under the instructions of Radiation Safety personnel.
5. In some cases it might be necessary for body fluids to be collected; consult with the Radiation Safety Office.
6. Radiation Safety Office personnel will provide personnel with guidelines to maintain the doses ALARA.
7. In the case of implants, all sources must be removed by the Authorized User, before surgery. If this is not possible, the Radiation Safety Officer must be notified.
8. The radiation dose to OR and Pathology personnel from sentinel nodes containing radioactive material, during removal is minimal and no radiation protection precautions are required.
9. If the tissue contains radioactive sources (seeds) then Pathology personnel shall remove these seeds under the supervision of Radiation Safety personnel. All such seeds are collected by the Radiation Safety Office.

VII. RADIATION SAFETY STANDARDS

The policies and procedures set forth in this Guide are based on the following regulations and standards:

1. Title 10 Code of Federal Regulations, Part 19: Notices, Instructions, and Reports to Workers.

2. Title 10 Code of Federal Regulations, Part 20: Standards for Protection Against Radiation.
3. U.S. Nuclear Regulatory Commission, NUREG 1556, Consolidated Guidance About Materials Licenses.
4. Florida Administrative Code 64-E Part III. Standards for Protection.
5. Florida Administrative Code 64-E Part VI. Use of Radionuclides in the Healing Arts.
6. Florida Administrative Code 64-E Part XIII. Radiation Safety Requirements for Possession and Use of Sealed or Unsealed Sources of Radioactive Materials.
7. Florida Administrative Code 64-E Part IX. Notices, Instructions, and Reports to Workers; Inspections.
8. Florida Administrative Code 64-E Part VII. Radiation Safety Requirements for Analytical X-ray Equipment.

APPENDICES

APPENDIX A

INSTRUCTION CONCERNING PRENATAL RADIATION EXPOSURE

A. INTRODUCTION

Section 64E-5.902 F.A.C., requires that all individuals whose work may involve exposure to radiation be instructed in the health protection problems associated with exposure to radioactive material or radiation, in precautions or procedures to minimize exposure and in the regulations that they are expected to observe. This appendix describes the instructions that should be provided concerning biological risks to the embryo/fetus exposed to radiation, a dose limit for the embryo/fetus, and suggestions for reducing radiation exposure.

B. DISCUSSION

Cells that are dividing very rapidly and are undifferentiated in their structure and function are generally more sensitive to radiation. In the embryo stage, cells meet both these criteria and thus would be expected to be highly sensitive to radiation. Furthermore, there is direct evidence that the embryo/fetus is generally radiosensitive and especially sensitive to certain radiation effects during certain periods after conception, particularly during the first 2 to 3 months after conception when a woman may not be aware that she is pregnant.

It is important to note that the mother assumes all risk until she specifically declares her pregnancy, in a written and signed statement, to her Principal Investigator and copies the statement to the Radiation Safety Officer. Upon receipt of the statement by the Radiation Safety Office, the University and Principal Investigator are responsible for assuring that the female worker's exposure will not result in 500 millirem to the fetus. After a female occupational worker voluntarily notifies her Principal Investigator and the Radiation Safety Officer in writing that she is pregnant and the estimated date of conception, for the purposes of fetal/embryo dose protection, she is considered a declared pregnant worker. Section 64E-5.311 F.A.C., places different radiation dose limits on declared pregnant workers than on adult workers. Specifically, for a declared pregnant worker who chooses to continue

working as an occupational worker, the dose limit for the embryo/fetus from conception to birth (entire gestation period) is 500 mrem. Further, efforts should be made to avoid exceeding 50 mrem per month to the pregnant worker. It is the responsibility of the pregnant worker to decide when or whether to formally declare her condition. If a woman chooses not to declare her pregnancy, she will continue to be governed by guidelines for adult occupational exposure.

Because of the sensitivity of the unborn fetus, the National Council on Radiation Protection and Measurements (NCRP) has recommended that substantial variations in the rate of exposure be avoided to the unborn fetus from occupational exposure of the expectant mother and that special precautions be taken to limit the exposure of pregnant or potentially pregnant women. If the dose to the fetus is determined to have already exceeded 500 mrem when a worker notifies her Principal Investigator and the Radiation Safety Officer of her pregnancy, the worker shall not be assigned to tasks where additional occupational radiation exposure is likely during the remainder of the gestation period.

C. REGULATORY POSITION

Instructions on radiation risks should be provided to workers, including supervisors, in accordance with 64E-5.902 F.A.C. before they are allowed to work with radioactive materials and/or radiation producing devices or access to such areas. In providing instructions on radiation risks, employers should include specific instructions about the risks of radiation exposure to the embryo/fetus. The instructions should be presented both orally and in printed form, and the instructions should include, as a minimum, the information provided in the Attachment to this Appendix. Individuals should be given the opportunity to ask questions and in turn should be questioned to determine whether they understand these instructions.

ATTACHMENT 1

PREGNANT WORKER'S GUIDE

POSSIBLE HEALTH RISKS TO THE FETUS OF WOMEN WHO ARE EXPOSED TO RADIATION DURING PREGNANCY

During pregnancy, you should be aware of things in your surroundings or in your style of life that could affect your unborn fetus. For those of you who work with radioactive materials and/or radiation producing devices or who have access to such areas, it is desirable that you understand the biological risks of radiation to your unborn fetus.

Everyone is exposed daily to various kinds of radiation: heat, light, ultraviolet, microwave, ionizing, and so on. For the purposes of this guide, only ionizing radiation (such as x-rays, gamma rays, neutrons, and other high-speed atomic particles) is considered. Actually, all human activities involve exposure to radiation. People are exposed to different amounts of natural "background" ionizing radiation depending on where they live. Radon gas in homes is a problem of growing concern. Background radiation comes from the four following sources:

	<u>Average Annual Dose</u>
Terrestrial: radiation from soil and rocks	21 millirem (0.21 mSv)
Cosmic: radiation from outer space	33 millirem (0.33 mSv)
Radioactivity normally found within the human body	28 millirem (0.28 mSv)
Radon	228 millirem (2.28 mSv)
	310 millirem (3.10 mSv) ¹
 Dosage range (geographic and other factors)	 75 to 5,000 millirem (0.75 mSv to 50.00 mSv)

¹ Radiation dose in this document is described in three different units. The rad is a measure of the amount of energy absorbed in a certain amount of material (100 ergs per gram). Equal amounts of energy absorbed from different types of radiation may lead to different biological effects. The rem is a unit that reflects the different biological effects done to the body by different types of radiation. The millirad and millirem refer to 1/1000 of a rad and rem, respectively. The Sievert (Sv) is the System Internationale unit that equivalent to 100 rem; the millisievert (mSv) refers to 1/1000 of a Sievert.

The first two of these sources expose the body from the outside, and the last two expose it from the inside. The average person is thus exposed to a total dose of about 310 millirem (3.1 mSv) per year from natural background radiation.

In addition to exposure from normal background radiation, radiation exposure can result from man-made materials and devices. Some consumer products such as smoke detectors, static eliminators and building materials contain radioactive material.

In summary, the average person is exposed to radiation daily, receiving a radiation dose of approximately 620 mrem/year (6.2 mSv/year). A dose of about 310 millirem/year (3.1mSv/year) is from natural background radiation, while medical radiation exposure and consumer products contribute the rest (Refs 4, 19, 20).

NUCLEAR REGULATORY COMMISSION POSITION

NRC and the State of Florida regulations and guidance are based on the conservative assumption that any amount of radiation, no matter how small, can have a harmful effect on an adult, child, or unborn fetus. This assumption is said to be conservative because there are no data showing ill effects from small doses; the National Academy of Sciences has expressed "uncertainty as to whether a dose of, say, 1 rad would have any effect at all." As it is known that the unborn fetus is more sensitive to radiation than adults, particularly during certain stages of development, the NRC and State of Florida have established a special dose limit for protection of the unborn fetus. However, such a limit could result in job discrimination for women of child-bearing potential. The NRC has taken the position that special protection of the unborn fetus should be voluntary and should be based on decisions made by workers and employers who are well informed about the risks involved.

For the NRC position to be effective, it is important that both the employee and the employer understand the risk to the unborn fetus from radiation received as a result of the occupational exposure of the mother. This document tries to explain the risk as clearly as possible and to compare it with other risks to the unborn fetus during pregnancy. It is

hoped this will help pregnant employees balance the risk to the unborn fetus against the benefits of employment to decide if the risk is worth taking. This document also discusses methods of keeping the dose, and therefore the risk, to the unborn fetus As Low As Reasonably Achievable (ALARA).

RADIATION EXPOSURE LIMITS

Rapidly dividing, undifferentiated cells are more sensitive to radiation. The embryo/fetus² is composed of cells that meet these criteria and are more sensitive to radiation. In addition, scientific studies have shown that the embryo/fetus is more sensitive to radiation than the adult (particularly during the first 2-3 months after conception when a woman may not be aware that she is pregnant). Because of the sensitivity of the unborn fetus, the exposure to the unborn fetus of a "declared pregnant worker" shall be limited to 500 millirem (5 mSv) for the entire pregnancy (Refs 20, 25, 26); the guidance also recommends that substantial variations in the rate of exposure be avoided and efforts should be made to avoid exceeding 50 mrem per month to the pregnant worker.

ADVICE FOR EMPLOYEE

Although the risks to the unborn fetus are small under normal working conditions, it is still advisable to limit the radiation dose from occupational exposure to be ALARA, not to exceed 500 millirem (5 mSv) for the total pregnancy. The employee, Principle Investigator

² In conformity with 10CFR20 and 64E-5, the term "embryo/fetus" is used throughout this document to represent all stages of pregnancy. The definitions are taken from Stedman's Medical dictionary, 21st edition, The Williams and Wilkins Company, Baltimore, MD 1966 and read as follows:

Embryo: An organism in the early stages of development; in man, from conception until approximately the end of the second month. Developmental stages from this time are commonly designated as fetal.

Fetus: The unborn young of a viviparous animal after it has taken form in the uterus; in man, the product of conception from the end of the eighth week to the moment of birth.

Undifferentiated Cells: Those cells in early development which have not progressed to a mature and specialized state, such as muscle or nerve cells.

and Radiation Safety Office should work together to decide the best method for minimizing exposure and accomplishing this goal. Some methods include reducing the time spent in radiation areas, wearing shielding over the abdominal area, and maximizing the distance from radiation sources. The medical/health physicist will be able to estimate the probable dose to the unborn fetus during the normal nine month pregnancy period and to inform the employee of the amount. If the predicted dose exceeds 50 millirem (0.5 mSv) per month, work schedules or procedures shall be modified to limit the dose to the 500 millirem recommended limit. It is important that the employee inform her Principal Investigator and the Radiation Safety Officer of her condition as soon as she realizes she is pregnant, so that the exposure to the unborn fetus can be minimized.

INTERNAL HAZARDS

This guidance has been directed primarily toward a discussion of radiation doses received from external sources. Workers must also be aware of the risk of radioactive material entering the body in working places where unsealed radioactive material is used. Nuclear medicine clinics, research laboratories, and certain manufacturers use radioactive material in bulk form, often as a liquid or a gas. General precautions³ include the following:

1. Do not smoke, eat, drink or apply cosmetics around radioactive material.
2. Do not pipette solutions by mouth.
3. Use disposable gloves while handling radioactive material.
4. Wash hands after working around radioactive material.
5. Wear lab coats or other protective clothing whenever there is a possibility of spills.

³ Specific precautions are made on a case-by-case basis for specific radionuclide of interest.

Remember that the Principal Investigator is required to have demonstrated that he/she will have safe procedures and practices before the Radiation Safety Office will authorize their approval to use radioactive material under one of the University's radioactive material licenses. Workers are urged to follow established procedures and consult the Radiation Safety Office or medical/health physicist whenever problems or questions arise.

RADIONUCLIDE CHARACTERISTICS

Biological data has been collected for a set of radionuclides which are expected to be of greatest significance for prenatal exposure in the work environment. These materials are: tritium, as gas and water; tritium and carbon in three typical organic forms--glucose, amino acid, and thymidine; and iodine.

TRITIUM

Trace amounts of inorganic tritium in gaseous form or when incorporated into water are readily absorbed from the lung or gastrointestinal (GI) tract. In air most tritium will form water, as will some small amount of that which is absorbed, so that little tritium actually enters the body as a gas. Physiologic studies demonstrate that water crosses the placenta in both directions. The percentage water content of the embryo and fetal tissues generally is measurable greater than that of the corresponding tissues in adults, so that their relative tritium concentrations may be slightly greater. For practical purposes, it may be assumed that the concentration of tritium in the conceptus is the same as that of the pregnant woman, and that it would be readily excreted in parallel with its loss from her body.

Tritium in the form of tritiated water is assumed to be uniformly distributed throughout the maternal and embryo/fetal soft tissues. It is assumed that tritiated water has a biological half-life of 10 days (Ref. 23).

ORGANICALLY BOUND TRITIUM AND CARBON

1. Glucose

Glucose is actively transported from maternal to fetal blood across the placental layers and uterine blood. Fetal brain, liver, kidney and skeletal muscle are the major organs that utilize glucose, and the overall glucose utilization rate is higher in the fetus than in the pregnant female.

Glycolysis of tritium-labeled glucose produces tritiated water, which then can exchange and distribute throughout the intracellular and extracellular water pools in both maternal and fetal compartments. A limited fraction of the tritiated water may subsequently become incorporated into lipid via lipogenesis, but this is sufficiently small that it can be ignored for dosimetry purposes. Catabolism of ^{14}C -labeled glucose results in $^{14}\text{CO}_2$ production in the fetus, but this does not accumulate in the fetus, rather it is randomly excreted to the mother via the placenta, and then exhaled. There are essentially no available concentration data for ^3H -glucose or ^{14}C -glucose applicable to radiation dosimetry (Ref. 23).

2. Amino Acids

In general, the concentrations of free amino acids in fetal tissues are similar to those in maternal tissues. Significant amounts of labeled amino acids are incorporated in protein during organogenesis or the growth phases of gestation. Concentration concurrently would be reduced through dilution by further incorporation of amino acids during progressive growth, so that consistently major deviations from maternal concentration would not be expected (Ref. 23).

3. Thymidine

Biological behavior of radiolabeled thymidine under conditions of accidental or environmental exposure is not clear. There does not appear to be any major differences between the metabolic behavior of ^3H - or ^{14}C -labeled thymidine and both precursors are incorporated into the DNA of proliferating cells. Only a

fraction (10%) of that which enters the adult is incorporated; most of the remainder is catabolized rapidly and excreted. There is long-term retention of incorporated thymidine; it remains in the DNA until the cell divides, where it is partitioned between the daughter cells, and some may be re-utilized when the cell dies. The processes by which thymidine crosses the placenta have not been established (Ref. 23).

IODINE

The fetal thyroid begins to concentrate iodine at about 90 days of age and continues to accumulate iodine throughout gestation. Inorganic iodine in the blood readily crosses the placenta and is accessible to the embryo or fetus. Depending on which iodine radionuclides are involved, their decay schemes and half-lives, and whether exposure is chronic or acute, the thyroid concentration in the last months of pregnancy has been estimated to be as much as three to nine-fold greater in the human fetus than in the adult.

The thyroid begins to secrete iodine shortly after it starts to concentrate iodine, and this secretion continues throughout gestation resulting in an organic iodine concentration of about 75% that in maternal blood. The concentrations of individual species of organic iodine (in particular triiodothyronine (T_3) and thyroxine (T_4) in fetal and maternal blood are not well correlated, which suggests that there is little, if any, placental transfer of organic iodine. Concentrations of T_3 and T_4 change abruptly at birth, and within about a week, reach values comparable to adults (Ref. 23, 24).

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APPENDIX B

Suggested Format for New Proposals to Use Radioactive Material to Radiation Control Committee.

In order to achieve uniformity and to cover the pertinent items required by the Radiation Control Committee, the following outline should be followed as closely as possible to save time in getting your proposal approved by the Radiation Control Committee:

Date: _____

TO: Radiation Control Committee

Attention: Susan E. Stanford

Radiation Safety Officer

Box 118340

FROM: Principal Investigator, (Signature required)

Department

Name of other users (i.e., technicians, students)

SUBJECT: Proposal to Use _____

Items that should be covered:

1. Brief description of the project.
2. Amount and chemical/physical form of radioactive material to be used.
3. Proposed use locations.
4. Proposed dates that this project will be carried out.
5. Protective clothing to be worn.
6. Whether or not work will be done in a hood.
7. Precautions to be taken to: (1) prevent the spread of contamination from unsealed sources, and (2) prevent external radiation exposure from penetrating radiation (x and gamma rays) by using proper shielding devices.
8. Radiation detection equipment that will be used for laboratory and personnel monitoring and frequency of use.
9. Disposal of radioactive waste.

Attach to proposal:

1. Statement of Training forms (RC-1) shall be attached for all individuals involved in the study.
2. Proposal Summary Sheet.

UNIVERSITY OF FLORIDA STATEMENT OF TRAINING AND EXPERIENCE

(To be completed by ALL personnel who will be working with radioactive material at the University of Florida)

NAME: _____ DEPARTMENT: _____ PHONE: _____

CLASSIFICATION (*Faculty, Technician, Student, etc.*): _____

RADIOACTIVE MATERIAL TO BE USED: _____ PRINCIPAL INVESTIGATOR: _____

RADIATION SAFETY TRAINING

<i>SUBJECT</i>	<i>WHERE TRAINED</i>	<i>DATES AND DURATION OF TRAINING</i>	<i>PRECEPTOR/ ON THE JOB (Circle Answer)</i>	<i>FORMAL COURSE (Circle Answer)</i>
A. <i>Principles and practices of radiation protection</i>			Yes No	Yes No
B. <i>Radioactivity Measurement, standardization, monitoring techniques, and instruments</i>			Yes No	Yes No
C. <i>Mathematics and calculations basic to use and measurement of radioactivity</i>			Yes No	Yes No
D. <i>Biological effects of radiation exposure</i>			Yes No	Yes No
E. <i>Transportation of radioactive material</i>			Yes No	Yes No
F. <i>Operating and Emergency procedures</i>			Yes No	Yes No

RADIOACTIVE MATERIAL HANDLING EXPERIENCE

<i>RADIONUCLIDE USED</i>	<i>MAXIMUM AMOUNT</i>	<i>WHERE EXPERIENCE WAS GAINED</i>	<i>DATES AND DURATION OF EXPERIENCE</i>	<i>TYPE OF USE</i>

Have radiation exposure records been maintained for you at another institution? Yes No
I have read and will abide by the University regulations as set forth in the RADIATION CONTROL GUIDE.

SIGNATURE: _____ DATE: _____

*If additional space is needed, use the back of this sheet. Keep a copy and return original to:
RADIATION SAFETY DEPARTMENT - 212 Nuclear Sciences Center - Box 118340*

SUMMARY SHEET
PROPOSAL TO USE RADIOACTIVE MATERIAL

1. Title of Proposal: _____

2. Radioactive material users:

<u>Name</u>	<u>Position</u>	<u>UF Approved User</u>	<u>Relation to Project</u>
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

3. Proposed Project Starting Date: _____

4. Radionuclides to be used:

<u>Radio- nuclide</u>	<u>Form</u>	<u>Half- life</u>	<u>Principal Radiation</u>	<u>Activity Inventory Amount</u>	<u>Activity Used Per Experiment</u>	<u>Activity Total Project</u>
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____

5. Where are radioactive materials to be used (include building and room)? _____

6. What physical facilities are available (i.e., fume hood)? _____

7. How will lab surveys be done? How often? What equipment? _____

8. Describe any problems associated with final disposal of radioactivity: _____

DOCUMENTATION OF TRAINING FORM:

NAME _____ DEPARTMENT _____ EXT. _____

CLASSIFICATION (*Faculty, Technician, Student, etc.*) _____

RADIOACTIVE MATERIAL TO BE USED: _____ PRINCIPAL INVESTIGATOR _____

Check appropriate response:_____ **Option 1: Radiation Safety Training Provided by Principal Investigator.**

<i>TYPE OF TRAINING</i>	<i>WHERE TRAINED</i>	<i>DATES AND DURATION OF TRAINING</i>	<i>TRAINING PROVIDER</i>
A. <i>Principles and practices of radiation protection</i>			
B. <i>Radioactivity Measurement, standardization, monitoring techniques, and instruments</i>			
C. <i>Mathematics and calculations basic to use and measurement of radioactivity</i>			
D. <i>Biological effects of radiation exposure</i>			
E. <i>Transportation of radioactive material</i>			
F. <i>Operating and Emergency procedures</i>			

_____ **Option 2: On-line Radiation Safety Training provided by EH&S.**

I have enrolled the above individual in the on-line Radiation Safety Short Course.

_____ **Option 3: Radiation Safety Training provided by credit course.**

I will assure that the above individual will enroll in and attend the following credit course:

PI Signature_____
Date

Return original to the:

*RADIATION SAFETY DEPARTMENT - 212 Nuclear Sciences Center
Box 118340*

Renewal of Radioactive Material Use Authorization

Proposal
Title:

Description of
Project:

Participants in Project:

Name	Position	Radioactive Material User	
		Yes	No

Radionuclides to be Used:

Radionuclides	Chemical Form(s)	Inventory Amount (mCi)	Activity per Experiment	Activity per Year (mCi)

Locations (buildings/rooms) where radioactive materials are used and stored:

Physical facilities and equipment	Yes	No	Location
fume hood			
ultra centrifuge			
centrifuge			
cold room			
other			

	Yes	No	Location	Make	Model
liquid scintillation counter (LSC)					
LSC with external standard					
gamma counter					
laser system					
GC with ECD					
portable radiation meter					
x-ray equipment					

other					
-------	--	--	--	--	--

Describe any anticipated problems associated with radioactive waste disposal:

Will you be generating radioactive mixed waste?

(Signature) First name Last name, Title _____ Date _____

APPENDIX C

Radiation Badge Application

Radioactive Material Package Receipt Form (Off-Campus Locations)

PERSONNEL MONITORING DEVICE APPLICATION

University of Florida
 Division of Environmental Health & Safety
 Department of Radiation Control & Radiological Services (Radiation Safety)
 P.O. Box 118340, 212 Nuclear Sciences Center, Gainesville, FL 32611
 Telephone: (352) 392-7359; Fax: (352) 846-0489

THIS REQUEST IS TO: Reactivate an old badge whole body, collar
 Apply for a new badge whole body, waist
 whole body, fetal*
 extremity, rt hand
 extremity, lt hand
 extremity, rt wrist
 extremity, lt wrist

*A request for a fetal monitor must be accompanied by a copy of the letter to the employee's supervisor declaring pregnancy and approximate date of conception.

PRINT NAME: _____ (LAST, FIRST, MIDDLE INITIAL)

UFID: _____ - _____

DATE OF BIRTH: __/ __/ __
 mo day yr

SEX: MALE FEMALE (circle one)

PRINCIPAL INVESTIGATOR/SUPERVISOR: _____

BADGE COORDINATOR: _____

DEPARTMENT: _____

FACILITY: _____ BLDG: _____ ROOM: _____

MAILING ADDRESS: _____ PHONE NUMBER: (____) ____ - ____

DO YOU WORK WITH: radiation producing device (x-ray machine, accelerator, irradiator)
 radioactive material; list radionuclide(s) _____

If you directly work with radioactive material or radiation producing devices, a completed *Statement of Training and Experience* form must be attached for approval.

If you do not work with radioactive material or a radiation producing device, list the reason for this badge request:

(Based on this reason, the badge may/may not be issued at the discretion of the Radiation Safety Officer.)

OFFICE USE ONLY	
RSO Approval	_____
Landauer #	_____
Binary #	_____
Part. ID#	_____
Series Code	_____

COMPLETE OTHER SIDE OF FORM OCCUPATIONAL RADIATION EXPOSURE HISTORY IDENTIFICATION

Have you **EVER** received a personnel monitoring device or participated in a bioassay program somewhere other than UF/Shands HealthCare System and Clinics:
(circle one)

YES NO

IF YES, COMPLETE THE FOLLOWING:

OCCUPATIONAL EXPOSURE--PREVIOUS HISTORY			
Previous employment involving occupational exposure--list name and address of employer	Date of Employment (From--To)	Period of Exposure (From--To)	Estimated Radiation Exposure (mrem)

Certification: I certify that the exposure history information listed above is correct and complete to the best of my knowledge. I authorize the release of my radiation exposure records to the University of Florida.

Employee's Signature

Name (Print)

UFID

Date

RADIOACTIVE MATERIAL PACKAGE RECEIPT FORM

RECEIVING DATA

Principal Investigator		Dept.	
Facility	Building	Lab Room	
Radionuclide	Activity (mCi)		
Date Received ____/____/____	Received By		
RC Number	PO Number		
Supplier			

RADIATION SURVEY DATA

Surface of Container	mR/hr
Packing Material	mR/hr

CONTAMINATION SURVEY

Surface of Container	dpm/100 sqcm
----------------------	--------------

RADIATION SAFETY OFFICE

Review Date ____/____/____	Approval
-------------------------------	----------

Complete form upon package receipt and return or FAX to:

University of Florida
 Radiation Control and Radiological Services
 PO Box 118340
 212 Nuclear Sciences Center
 Gainesville FL 32611

FAX: 352-846-0489

APPENDIX D

PROCEDURE FOR OPENING PACKAGES CONTAINING RADIONUCLIDES

Laboratory personnel should open and inspect packages immediately upon receipt. Claims for damaged or incorrect material must be submitted as soon as possible to the vendor. Return of radioactive material to the vendor must be coordinated with the Radiation Safety Office.

Procedure:

1. Place package in an approved hood if available. Always open package on absorbent paper. Wear gloves.
2. Open package and verify that contents agree in name and quantity with packing slip and with what was ordered.
3. If the package contains a gamma emitting radionuclide or more than 500 μCi of P-32, place the contents behind suitable shielding.
4. Check for breakage of seals or containers, loss of liquid or change in color of absorbing material.
5. The inner packaging which includes the liner, shield, and absorbent materials may be contaminated; they are to be discarded in the radioactive waste container unless shown to be uncontaminated by suitable monitoring techniques. **NOTE:** Any material placed in regular trash must be checked to be free of contamination and must have all radioactive labels removed or defaced.
6. Record radionuclides, quantity and date of receipt on the Radionuclide Utilization Form.
7. Follow any special handling or opening procedures that are supplied by the vendor when opening the vial.

8. Use extreme caution when opening the inner vial containing the radioactive material. Monitor yourself and work area after completion of procedure.
9. Store radioactive material in a secure location.
10. Report any problems to the Radiation Safety Officer.

NOTE: These procedures are general guidelines for opening packages containing millicurie quantities of radioactive material. The precautions which must be taken will depend on the quantities involved. Consult with Radiation Safety before opening any non-routine package or if you have any questions.

APPENDIX E**APPLICATION OF BIOASSAY FOR TRITIUM****A. CONDITIONS UNDER WHICH BIOASSAY IS NECESSARY**

1. Routine bioassay is necessary when quantities of tritium processed by an individual at any one time or the total amount processed per month exceed those for the forms of tritium shown in Table 1.

Table 1.**ACTIVITY LEVELS ABOVE WHICH TRITIUM BIOASSAY IS REQUIRED**

Types of Operation	HTO and Other Tritiated Compounds (Including Nucleotide Precursors)
Processes in open room or bench with possible escape of tritium from process vessels	25 mCi (925 MBq)
Processes with possible escape of tritium carried out within a fume hood of adequate design, face velocity and performance reliability	25 mCi (925 MBq)
Processes carried out with gloveboxes that are ordinarily closed but with possible release of tritium from process vessels and occasional exposure to contaminated box and box leakage	250 mCi (9250 MBq)

2. Bioassay is not required, when process quantities handled by an individual are less than those in Table 1.

B. PARTICIPATION

All individuals involved in the processing of tritium under conditions specified in Section 1 or in the immediate area of the process should participate in the bioassay program.

C. TYPES OF BIOASSAY THAT SHOULD BE PERFORMED

1. Baseline (pre-employment or pre-operational)

A baseline bioassay should be conducted no more than one month prior to the individual beginning work with tritium in amounts that would require participation in the bioassay program.

2. Routine Urinalysis

Regular bioassays should be conducted to monitor routine operations at frequencies specified in Section D.

3. Emergency

If the initial sample or other data indicates a possible exposure high enough to warrant immediate medical attention, a complete and immediate follow-up should be conducted as described in Section E.1.b.

4. Post-Operational and Termination of Usage

A bioassay should be performed within one month after the last possible exposure to tritium such as when operations are being discontinued, or when the individual is terminating activities with potential exposure.

5. Diagnostic

Follow-up bioassay should be performed as soon as possible but within one week of any sample exceeding levels given as action points in Section E, in order to confirm the initial results and in the case of a single intake, to allow an estimate of the effective half-life of the tritium in the body.

D. FREQUENCY OF SAMPLING

Initial Routine

A bioassay sample of at least 50 ml of urine should be taken within 72 hours following entry of an individual into an area where operations require bioassay according to Section A and then every month or more frequently thereafter, as long as the individual is working with tritium. When work with tritium is on an infrequent basis (less frequently than every month), bioassay should be performed within 10 days of the end of the work period during which tritium was handled.

E. ACTION POINTS AND CORRESPONDING ACTIONS

1. Monthly and Other Sampling

a. If urinary excretion rates exceed 5 $\mu\text{Ci/L}$ (0.18 MBq/L), but are less than 50 $\mu\text{Ci/L}$ (1.8 MBq/L), the following course of action should be taken:

- (1) A survey of the operations involved, including air and surface contamination monitoring, should be carried out to determine the causes of the exposure and evaluate the potential for further exposures or for the possible involvement of other individuals.

- (2) Any reasonable corrective actions that the survey indicates may lower the potential for further exposures should be implemented.
 - (3) A repeat urine sample should be taken within one week of the previous sample and should be evaluated within one week of collection. Internal dose commitments should be estimated using at least these two urine sample evaluations and other survey data, including the probable times of the intake of tritium.
 - (4) Any evidence indicating that further work in the area might result in an individual receiving a dose commitment in excess of the limits established in 64E-5.304 F.A.C., should serve as cause to remove the individual from work in this operation until the sources of exposure are discovered and corrected.
 - (5) Reports or notification must be provided as required by 64E-5.344 F.A.C. and 64E-5.345 F.A.C. or as required by conditions of the license.
- b. If urinary excretion rates exceed 50 $\mu\text{Ci/L}$ (1.8 MBq/L), the following course of action should be taken:
- (1) Carry out all steps in item a of Section E.1.
 - (2) If the projected dose commitment exceeds levels for whole body as provided in 64E-5.304 F.A.C., provide appropriate notification to FLDOH.
 - (3) Refer the case to appropriate medical/health physics consultation for recommendations regarding immediate therapeutic procedures that may be carried out to accelerate removal of tritium from the body and reduce the dose to as low as is reasonably achievable.
 - (4) Carry out repeated sampling (24 hour urine collections) at approximately one week intervals at least until samples show an excretion rate less than 5 $\mu\text{Ci/L}$ (0.18 MBq/L). If there is a possibility of long term organic compartments of tritium that require evaluation (reference NUREG-0938), continue sampling as long as necessary to ensure that appreciable exposures to these other compartments do not go undetected and to provide estimates of total dose commitments.

APPENDIX F

APPLICATION OF BIOASSAY FOR I-125 AND I-131

A. CONDITIONS UNDER WHICH BIOASSAY IS NECESSARY

1. Routine bioassay is necessary when an individual handles in open form, unsealed quantities of radioactive iodine that exceed those shown in Table 1. The quantities shown in Table 1 apply to both the quantity handled at any one time or integrated as the total amount of activity handled by an individual over a one month period.
2. Bioassay is not required, but recommended, when process quantities handled by an individual are less than those in Table 1.

B. PARTICIPATION

All individuals handling radioactive iodine or sufficiently close to the process so that intake is possible (i.e., within a few meters and in the same room as the individual handling the material), should participate in bioassay programs.

C. TYPES OF BIOASSAY THAT SHOULD BE PERFORMED

1. Baseline
A baseline bioassay should be conducted prior to beginning work with radioactive iodine in amounts that would require participation in the bioassay program.
2. Routine
Regular bioassay should be conducted to monitor routine operations at the frequency specified in Section D.
3. Emergency
A bioassay should be performed as soon as possible after any incident that might cause thyroid uptakes to exceed burdens given in Section E.1.b so that actions recommended in Section E.1.b.(3) can be most effective.
4. Post-Operational and Termination of Usage
A bioassay should be performed within 2 weeks of the last possible exposure to I-125 or I-131, when operations are being discontinued or when the individual is terminating activities with potential exposure to these radionuclides.
5. Diagnostic

Follow-up bioassay should be performed within 2 weeks of any measurements exceeding levels given as action points in Section E. in order to confirm the initial results and in the case of a single intake, to allow an estimate of the effective half-life of radioiodine in the thyroid.

D. FREQUENCY

Initial Routine

A bioassay sample or measurement should be obtained within 72 hours following entry of an individual into an area where bioassay is performed in accordance with Sections A and B and every 4 weeks or more frequently thereafter, as long as the conditions described in Sections A and B exist. When work with radioactive iodine is on an infrequent basis, (less frequently than every 4 weeks), bioassay should be performed within 10 days of the end of the work period during which radioactive iodine was handled, unless emergency action is appropriate.

E. ACTION POINTS AND CORRESPONDING ACTIONS

1. Monthly and Other Measurements

a. Whenever the thyroid burden at the time of measurement exceeds 0.12 μCi (4.4 kBq) of I-125 or 0.04 μCi (1.5 kBq) of I-131, the following actions will be taken:

- (1) An investigation of the operations involved, including air and other in-house surveys, will be carried out to determine the causes of exposure and to evaluate the potential for further exposures or for the possible involvement of other individuals.
- (2) Any evidence indicating that further work in the area might result in an individual receiving a dose commitment in excess of the limits established in 64E-5.304 F.A.C., should serve as cause to remove the individual from work in this operation until the sources of exposure is discovered and corrected.

- (3) Reports or notification must be provided as required by 64E-5.344 F.A.C. and 64E-5.345 F.A.C. or as required by conditions of the license.
 - (4) Corrective actions that will eliminate or lower the potential for further exposures should be implemented.
 - (5) A repeat bioassay should be taken within 2 weeks of the previous measurement and should be evaluated within 24 hours after measurement in order to confirm the presence of internal radioiodine and to obtain an estimate of effective half-life for use in estimating dose commitment.
- b. If the thyroid burden at any time exceeds 0.5 μCi (18.5 kBq) of I-125 or 0.14 μCi (5.2 kBq) of I-131, the following actions shall be taken:
- (1) Carry out all steps in item a. of this regulatory position.
 - (2) If the projected dose commitment exceeds levels for whole body as provided in 64E-5.304 F.A.C., provide appropriate notification to FLDOH.
 - (3) As soon as possible, the case shall be referred to appropriate medical consultation for recommendations regarding therapeutic procedures that may be carried out to accelerate removal of radioiodine from the body. This shall be done within 2-3 hours after exposure when the time of exposure is known so that any prescribed thyroid blocking agent would be effective.

- (4) Carry out repeated measurements at approximately 1 week intervals at least until the thyroid burden is less than 0.12 μCi (4.4 kBq) of I-125 or 0.04 μCi (1.5 kBq) of I-131.

TABLE 1

ACTIVITY LEVELS ABOVE WHICH BIOASSAY FOR I-125 OR I-131 IS REQUIRED

Type of Operation	Activity Handled in Unsealed Form Making Bioassay Necessary*	
	Volatile or Dispersible*	Bound to Nonvolatile Agent
Processes in open room or bench, with possible escape of iodine from process vessels	1.0 mCi (37 MBq)	1.0 mCi (37 MBq)
Processes with possible escape of iodine carried out within a fume hood of adequate design, face velocity, and performance reliability	1.0 mCi (37 MBq)	10.0 mCi (370 MBq)
Processed carried out within gloveboxes, ordinarily closed, but with possible release of iodine from process and occasional exposure to contaminated box and box leakage	10.0 mCi (370 MBq)	100.0 mCi (3700 MBq)

*Quantities may be considered the cumulative amount in process handled by an individual during a 1-month period; e.g., the total quantity introduced into a chemical or physical process over a 1 month period, or on one or more occasions in that period, by opening stock reagent containers from which radioactive iodine may escape. Quantities in the right-hand column may be used when it can be shown that activity in process is always chemically bound and processed in such a manner that I-125 and I-131 will remain in nonvolatile form and diluted to concentrations less than 0.1 mCi/mg (3.7 MBq/mg) of nonvolatile agent. Capsules (such as gelatin capsules given to patients for diagnostic test), may be considered to contain the radioiodine in non-free form, and bioassay would not be necessary unless a capsule were inadvertently opened (e.g., dropped and crushed). However, certain compounds where radioiodine is normally bound are known to release radioiodine when the material is in process, and the left-hand column may then be applicable. In

those laboratories working only with I-125 in radioimmunoassay (RIA) kits, the quantities of I-125 are very small and in less volatile forms; thus, bioassay requirements may be judged from the right-hand column. In field operations, where reagent containers are opened outdoors for simple operations such as pouring liquid solutions, the above table does not apply; bioassay should be performed whenever an individual handles in open form (e.g., an open bottle or container) more than 50 mCi (1850 MBq) at any one time.

Operations involving the routine use of I-125 or I-131 in an open room or bench are discouraged. Whenever practicable, sealed bottles or containers holding more than 0.1 mCi (3.7 MBq) of I-125 or I-131 should be opened at least initially within hoods having adequate face velocities of 100 lf/min or more.

APPENDIX G**INVENTORY REPORTING INSTRUCTIONS**

A CONDITION of the radioactive material license requires Principal Investigators submit quarterly inventory reports of radioactive materials to the Radiation Safety Officer (RSO). To ensure compliance with this license condition, the Radiation Control Committee has agreed that Principal Investigators who are delinquent or neglect submitting their inventory reports are subject to enforcement actions.

"Quarterly Radioactive Materials Inventory" forms are provided for use when reporting inventories. These inventory forms are for reporting the amount of activity "On Hand" at the end of the reporting quarter. Maintenance of the laboratory's utilization forms will facilitate the completion of the quarterly inventory form.

See "QUARTERLY RADIOACTIVE MATERIAL INVENTORY" form. The following is an explanation of each column.

<u>Radionuclide</u>	Radionuclide listed (self-explanatory). List radionuclides not already listed.
<u>Present Inventory (mCi)</u>	List in this column, beside the listed radionuclides, the amount of activity in stock solutions or vials that are on hand at the end of the reporting quarter.
<u>Location</u>	Use this column to record the room location of the listed activity.
<u>Remarks</u>	Any additional pertinent information we need to know (i.e., waste material).

UTILIZATION FORM INSTRUCTIONS

Accountability of radioactive material is of great importance in maintaining compliance with license requirements. See Radionuclide Utilization Form.

1. A Utilization Form must be initiated and maintained for each separate shipment of radioactive material received.
2. An entry must be made on this form each time there is radionuclide usage by the receiving Principal Investigator in his or her lab.
3. An entry must be made on this form each time radioactive materials are transferred to another Principal Investigator.
4. Each Principal Investigator who receives radioactive material via on-campus transfers must keep and maintain a Radionuclide Utilization Form. All Transfers must be approved by the Radiation Safety Office prior to the Transfer.
5. An entry must be made on this form when radioactive materials are received via transfer or shipment and each time those radioactive materials are used.
5. Accurate and regular use of the Utilization Forms facilitate the completion of the Quarterly Radioactive Material Inventory Form.

**University of Florida
Radiation Control and Radiological Services Department
Quarterly Radioactive Material Inventory**

PI: _____ Date: _____

 (signature)
 Department: _____ Building: _____ Room: _____

Inventory Date: _____

Radionuclide	Present Inventory (mCi)	Location	Remarks
³ H			
¹⁴ C			
¹²⁵ I			
³² P			
³³ P			
³⁵ S			
⁵¹ Cr			
⁴⁵ Ca			
⁶⁰ Co			
¹³⁷ Cs			
⁶⁵ Zn			
²² Na			
³⁶ Cl			
⁶³ Ni			
¹⁹² Ir			
⁹⁰ Sr			

Equipment Containing Radioactive Material.

	Manufacturer	Location
Liquid Scintillation Counter	_____	_____
Gamma Counter	_____	_____
Portable Survey Meter	_____	_____
Gas Chromatograph w/ECD	_____	_____
Nuclear Gauge	_____	_____

U NO RADIOACTIVE MATERIAL IN MY POSSESSION
RETURN FORM TO: Radiation Safety, Box 118340, 212 Nuclear Sciences Center
RADIONUCLIDE UTILIZATION FORM

APPENDIX H

APPLICATION FOR THE NON-HUMAN USE OF RADIATION PRODUCING DEVICES TO THE RADIATION SAFETY OFFICE

1. Principal Investigator: _____
 Department: _____
 Office Room Number: _____ Phone Number: _____
 Lab Technician: _____ Phone Number: _____

2. Authorized user(s): _____ Job Title: _____

3. Information regarding the Principal Investigator and authorized user(s) basic training with the radiation producing device shall be forwarded to the Radiation Safety Office at the time this proposal is submitted. Forms for submitting this information (RC-1X) are available from the Radiation Safety Office, phone 392-7359.

4. Type of radiation producing device: _____ 5. Use of radiation producing device: _____
 _____a. Radioagraphic: max mA____ max kVp____ _____a. Veterinary medicine
 _____b. Fluoroscopic: max mA____ max kVp____ _____b. Research using animals
 _____c. Cabinet _____c. Diffraction analysis
 _____d. Diffraction: max mA____ max kVp____ _____d. Research other than above (explain)
 _____e. Other (explain)

6. Location of device:
 Bldg.: _____ Room(s)_____

7. Describe the procedures for which the device will be used. Submit any locally generated standard operating procedures and safety instructions and confirm that an operator’s manual is available at the unit. If factory installed safety interlocks must be bypassed during any use of the equipment, submit justification for bypassing the interlock.

8. Describe the facility in which the device will be used. Include shielding design for radiographic and fluoroscopic units and type of enclosure or shielding design for diffraction units. State if warning sign/lights are installed in or outside the facility and any protective equipment such as lead aprons or portable shielding.

9. Briefly describe personnel monitoring available.

Return original to the: RADIATION SAFETY OFFICE 212 Nuclear Sciences Center / Box 118340

**UNIVERSITY OF FLORIDA
RADIATION PRODUCING DEVICE OPERATOR
STATEMENT OF CERTIFICATION, TRAINING, AND EXPERIENCE**

(To be completed by ALL personnel who will be working with x-ray machines at the University of Florida and Shands Hospital)

NAME: _____ DEPARTMENT: _____

CLASSIFICATION (Faculty, Technician, Student, etc.) _____

SUPERVISOR: _____ PHONE: _____

TYPE OF X-RAY MACHINE TO BE USED:

_____ Medical - Fluoroscopic	_____ Dental
_____ Medical - Radiographic	_____ Diffraction
_____ Industrial	_____ Analytical
_____ Veterinary	_____ Other _____

CERTIFICATION/LICENSURE (State of Florida):

_____ Basic X-ray Machine Operator	_____ Dental Hygienist
_____ CRT-Radiographer	_____ Dental Radiographer
_____ CRT-Computed Tomography	_____ CRT-Therapy
_____ CRT-Nuclear Medicine	_____ Other _____

Certificate/License Number: _____

Expiration Date: _____

NON-CERTIFIED/LICENSED INDIVIDUALS MUST COMPLETE THE REMAINDER OF THE FORM

RADIATION SAFETY AND X-RAY MACHINE OPERATION TRAINING			
SUBJECT	LOCATION	DATES	HOURS
Principles and Operation of X-ray machines _____ Preceptor _____ Formal			
Biological Effects of Radiation Exposure _____ Preceptor _____ Formal			
Radiation Safety _____ Preceptor _____ Formal			

X-RAY MACHINE OPERATING EXPERIENCE			
TYPE OF MACHINE	LOCATION	DATES	USAGE

Have radiation exposure records been maintained for you at another institution? YES NO

SIGNATURE _____ DATE _____

Return original to the: RADIATION SAFETY OFFICE, 212 Nuclear Sciences Center /
Box 118340

**DOCUMENTATION OF TRAINING FOR
RADIATION PRODUCING DEVICE OPERATOR**

NAME _____ DEPARTMENT _____

CLASSIFICATION (*Faculty, Technician, Student, etc.*) _____

TYPE OF X-RAY EQUIPMENT TO BE USED _____

PRINCIPAL INVESTIGATOR _____ PHONE _____

Check appropriate response:

_____ **Option 1: Radiation Safety Training Provided by Principal Investigator.**

<i>TYPE OF TRAINING</i>	<i>WHERE TRAINED</i>	<i>DATES AND DURATION TRAINING</i>	<i>TRAINING PROVIDER</i>
A. <i>Principles and practices of radiation protection</i>			
B. <i>Significance of the radiation warning and safety devices incorporated into the equipment</i>			
C. <i>Operating and Emergency procedures</i>			
D. <i>Biological effects of radiation exposure</i>			
E. <i>Practical experience with the x-ray equipment to be used</i>			

_____ **Option 2: Radiation Safety Training provided by Radiation Safety.**

I have contacted the Radiation Safety Office and have scheduled an in-service for the above individual.

_____ **Option 3: Radiation Safety Training provided by outside service.**

I will assure that the above individual will enroll in and attend the following course:

PI Signature _____ Date

Return original to the:

*RADIATION SAFETY DEPARTMENT - 212 Nuclear Sciences Center
Box 118340*