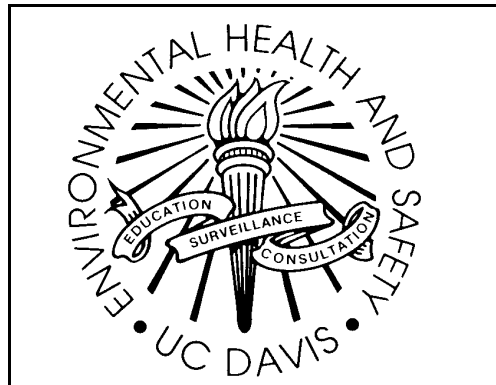



**RADIATION SAFETY MANUAL**



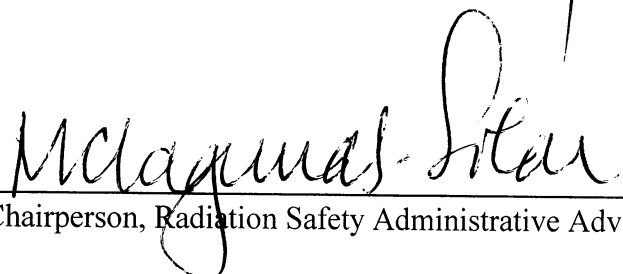
**UNIVERSITY OF CALIFORNIA, DAVIS**

**ENVIRONMENTAL HEALTH AND SAFETY, HEALTH PHYSICS**

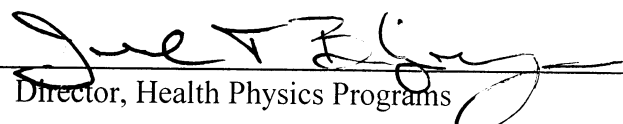
**<http://ehs.ucdavis.edu/>**

Approved by:   
Director, Office of Environmental Health and Safety

Date: 4-9-09

Approved by:   
Chairperson, Radiation Safety Administrative Advisory Committee

Date: 4/16/09

Approved by:   
Director, Health Physics Programs

Date: 4/3/09

The above approval signatures apply to the January 2009 revision of the UC Davis Radiation Safety Manual. Subsequent revisions to individual pages of this manual shall be approved by the UC Davis Radiation Safety Administrative Advisory Committee and distributed to the principal investigators for inclusion and update of their manuals. The Revision History on the next page provides information on the latest revision and previous revisions subsequent to November 1994.



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**DEFINITIONS**

**Absorbed Dose**

The energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the international unit, gray (Gy) or the rad.

Quantity	Name	Symbol	Units	Conversions
Absorbed Dose	gray <i>rad (old unit)</i>	Gy <i>rad</i>	J Kg <sup>-1</sup> <i>100 ergs/gram</i>	1 Gy = 100 rads 1 cGy = 1 rad

**Activation**

The process of making a material radioactive by bombardment with neutrons, protons, or other nuclear radiation.

**Activity**

The rate of disintegration per (second = dps, minute = dpm) or decay of radioactive material. The units of activity are the international unit, Becquerel (Bq) or the Curie (Ci).

Quantity	Name	Symbol	Unit	Conversions
Activity	Becquerel <i>Curie (old unit)</i>	Bq <i>Ci</i>	dps <i>3.7 × 10<sup>10</sup> dps</i>	1 Ci = 3.7 x 10 <sup>10</sup> Bq

Sub units of the Curie are:

millicurie (mCi)	=	3.7 × 10 <sup>7</sup> dps
microcurie(μCi)	=	3.7 × 10 <sup>4</sup> dps
nanocurie (nCi)	=	3.7 × 10 <sup>1</sup> dps
picocurie (pCi)	=	3.7 × 10 <sup>-2</sup> dps

**ALARA**

(acronym for **A**s **L**ow **A**s **R**easonably **A**chievable) Making every reasonable effort to maintain exposures to radiation as far below the dose limits as practical and consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations.

**Analytical X-ray System**

A group of components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials.

**Application for Use of Radionuclides or Radiation-producing Machines**

An application that precedes the issuance of a Radiation Use Authorization (RUA) or Machine Use Authorization (MUA). Separate applications are required for non-human research use, non-human classroom use, human use, and radiation-producing machines.

### **Authorized User**

For purposes of this manual, an authorized user is a person who has fulfilled the training requirements and has through the amendment process been added to a Radiation Use Authorization (RUA). The term does not imply the individual has met the requirements of 10 CFR 35.2.

### **Bioassay**

The determination of kinds, quantities, or concentrations, and in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body.

### **Brachytherapy**

A method of radiation therapy that uses sealed sources to deliver a therapeutic dose at a distance up to a few centimeters from the source.

### **Cabinet X-ray System**

An x-ray system with the x-ray tube installed in an enclosure independent of existing architectural structures except the floor that it stands on. The cabinet x-ray system is intended to contain the material being irradiated, provide radiation attenuation, and exclude personnel from its interior.

### **California Code of Regulations (CCR), Title 17**

California State Regulations, also known as Title 17, which govern the use of ionizing radiation and radioactive materials at locations where the State of California has jurisdiction.

### **Contamination**

Deposition of radioactive material in any place where it is not desired.

### **Contamination Control Zone**

A section of the restricted area which has been set up to control the potential spread of contamination from the use of unsealed radioactive materials. A contamination control zone can cover as small of an area as a portion of a laboratory bench top or in rare cases can encompass an entire room. Contamination control zone guidance is in section V. D. of this manual.

### **Curie**

See "Activity."

### **Deterministic Effect**

A deterministic effect is a health effect whose severity increases with increasing dose and that has a threshold dose below which the effect will not occur (e.g. skin burns).

### **Diagnostic X-ray System**

An x-ray system designed for irradiation of any part of the human or animal body for diagnostic purposes.

### **Dose Equivalent**

The product of the absorbed dose in tissue, quality factor (i.e.,  $\text{rad} \times Q = \text{rem}$ ) or organ dose weighting factors (i.e.,  $\text{Gy} \times w_T = \text{Sv}$ ), and all the necessary modifying factors at the location of interest. The units of dose equivalent are the international unit, Sievert (Sv) or the rem.

Quantity	Name	Symbol	Unit	Conversions
Dose Equivalent	Sievert <i>rem (old unit)</i>	Sv <i>rem</i>	$J\ kg^{-1}$ $10^{-2}\ Sv$	100 rem = 1 Sv 1 rem = 1 cSv

**Declared Pregnant Worker**

A woman who is occupationally exposed to ionizing radiation and who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception for the purpose of monitoring the radiation dose to the fetus.

**Deep Dose Equivalent**

External whole body exposure that is the dose equivalent at a tissue depth of 1 centimeter (1,000 mg/cm<sup>2</sup>).

**Environmental Health and Safety**

The Chancellor at UC Davis delegates the authority for promoting health and safety to the Office of Environmental Health and Safety (EH&S). The Health Physics section of UCDHS EH&S oversees the use of ionizing radiation at UCDHS. EH&S oversees the use of ionizing radiation at the UC Davis campus.

**Exposure**

A measure of the ionization produced in air by x- or gamma radiation. The sum of electric charges on all ions of one sign produced in air when all electrons liberated by photons in a volume of air are completely stopped in air, divided by the mass of the air in the volume. The units of exposure in air are the international unit, coulomb per kilogram or the Roentgen.

Quantity	Name	Symbol	Units
Exposure	Coulomb per Kilogram <i>Roentgen (old unit)</i>	X <i>R</i>	$C\ kg^{-1}$ $2.58 \times 10^{-4}\ C\ kg^{-1}$

**Eye Dose Equivalent**

External exposure of the lens of the eye that is the dose equivalent at a tissue depth of 0.3 centimeters (300 mg/cm<sup>2</sup>).

**Fluoroscopic X-ray System**

A system that uses x-ray photons to produce a fluoroscopic image. The system includes an image intensifier with spot film device and linkage between the image receptor and diagnostic source assembly.

**Health Physics**

The science concerned with recognition, evaluation, and control of health hazards associated with ionizing and non-ionizing radiation.

**High Radiation Area**

High radiation area means any area accessible to individuals, in which radiation exists at such levels that an individual could receive in any one hour, a dose equivalent in excess of 100 millirem (1.0 millisievert) at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

### **Ionizing Radiation**

Any electromagnetic or particulate radiation capable of producing ions directly or indirectly in its passage through matter. In general, it will refer to gamma rays and x-rays, alpha and beta particles, neutrons, protons, high speed electrons, and other nuclear particles. Ionizing radiation does not include radio waves, visible, infrared, or ultra-violet light (i.e., non-ionizing radiation).

### **Machine Use Authorization (MUA)**

An authorization issued by a Radiation Use Committee (if necessary), the Director of Health Physics Programs, or the appropriate Radiation Safety Officer to conduct specific research using ionizing radiation-producing machines.

### **Monitoring**

Checking for the presence of sources of radiation under a specific set of conditions. Monitoring includes measuring levels of radiation fields and determining contamination levels. Monitoring is performed both for health protection and for protection of future and current research.

### **NRC**

The Nuclear Regulatory Commission (NRC) is the primary federal agency charged with regulating the use of by-product radioactive and special nuclear materials. The NRC replaced regulatory functions of the Atomic Energy Commission (AEC). The NRC was established by the Energy Reorganization Act of 1974. This act abolished the Atomic Energy Commission and transferred to the NRC all the licensing and related regulatory functions.

### **Occupational Dose**

Occupational dose means the radiation dose received by an individual in the course of employment, education, training, or other activities, which involved exposure to ionizing radiation.

### **Personnel Dosimetry**

Devices that measure the cumulative dose of radiation to an individual. Types of dosimetry include film badges, thermoluminescence dosimeters (TLDs), finger rings, and albedo type dosimetry for neutron measurements.

### **Radiation Area**

An area accessible to individuals, in which radiation exists at such levels that an individual could receive, in any one hour, a dose equivalent to the whole body in excess of 5 mrem (.05 millisievert), at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

### **Radiation-producing Machine**

Any device capable of producing ionizing radiation when the associated control devices are operated, excluding devices that produce radiation only by the use of radioactive materials.

### **Radiation Safety Administrative Advisory Committee (Radiation Safety Committee)**

Members include researchers from the main campus, Health System, chairpersons of the Campus, Cyclotron, High Intensity Light Source and Laser and Health System Radiation Use Committees, Director of Health Physics Programs, and the Radiation Safety Officers, who are appointed by the Chancellor to fulfill the requirements of 17 CCR 30195.

### **Radiation Use Authorization (RUA)**

An authorization issued by a Radiation Use Committee (if necessary), the Director of Health Physics Programs, or the appropriate Radiation Safety Officer to conduct specific research using specific radionuclides.

**Radioactive Materials**

Any material, solid, liquid, or gas that emits ionizing radiation spontaneously.

**Restricted Area**

An area, access to which is limited by the Office of Environmental Health and Safety/UCDHS Health Physics for the purpose of protecting individuals against undue risk from exposure to radiation and radioactive material. Radiation areas, high radiation areas, and airborne radioactivity areas shall be considered restricted areas.

**Roentgen (R)**

A unit of exposure to ionizing radiation. It is the amount of gamma rays or x-rays required to produce ions carrying 1 electrostatic unit of electrical charge in 1 cubic centimeter of dry air under standard conditions. See "Exposure".

**Roentgen Equivalent Man (rem)**

The unit used to express human dose equivalence as a result of exposure to ionizing radiation. The relation of the rem to other dose units depends upon the biological effect of the radiation under consideration. For the purposes of this regulation, any of the following is considered to be equivalent to a dose of one rem:

Type of Radiation	Quality Factor (Q)	Absorbed dose in rad equal to a dose of 1 rem
X-, gamma, or beta radiation	1	1
Neutrons or high-energy protons	10	0.1
Alpha particles and heavy particles with energy to reach the lens of the eye	20	0.05

For neutrons, if the energy is not known, an exposure of  $25 \times 10^6$  neutrons per square centimeter is equivalent to one rem. If the neutron energy is known, use the following table to convert to rem (10 CFR 20.1004).

Neutron Energy (MeV)	Number of Neutrons Per Square Centimeter Equivalent to a dose of 1 rem.	Neutron Energy (MeV)	Number of Neutrons Per Square Centimeter Equivalent to a dose of 1 rem
Thermal	$980 \times 10^6$	1	$27 \times 10^6$
0.0001	$840 \times 10^6$	2.5	$29 \times 10^6$
0.001	$980 \times 10^6$	5	$23 \times 10^6$
0.01	$1010 \times 10^6$	7	$24 \times 10^6$
0.1	$170 \times 10^6$	10	$24 \times 10^6$
0.5	$39 \times 10^6$	40	$14 \times 10^6$

**Shall**

Used in laws, regulations, or directives to express what is mandatory.

**Shallow Dose Equivalent**

External exposure of the skin or an extremity that is the dose equivalent at a tissue depth of 0.007 centimeters ( $7 \text{ mg/cm}^2$ ) averaged over an area of 1 square centimeter.

### **Somatic Effects of Radiation**

Long term effects of radiation to the exposed individuals such as cancer as opposed to genetic effects to the next generation. However, somatic effects may also apply to subsequent unexposed generations beyond the first generation.

### **Source Materials**

Uranium or thorium or any combination thereof, in any physical or chemical form, or ores, which contain by weight 1/20th of 1% (0.05%) or more of uranium, thorium, or any combination thereof.

### **Special Nuclear Materials**

Plutonium, Uranium-233, Uranium enriched in the isotope 233 or in the isotope 235, or any other material so designated by the Nuclear Regulatory Commission, but not including source material. Any material artificially enriched by any of the foregoing but not including source material.

### **Stochastic Effect**

A stochastic effect is a health effect who's probability of occurrence increases with increasing dose (e.g. cancer)

### **Survey Meter**

Any portable radiation detection instrument designed to determine the presence of radioactive materials and/or ionizing radiation fields. Commonly used survey meters are of the types:

- a. Count rate meters (GM counters) that detect only the presence of radioactive material. Under certain conditions the survey meter's reading may be used to determine the exposure rate from a source of radioactive material.
- b. Dose rate meters (ion chambers) that are used to evaluate the intensity of radiation fields in units such as rem per hour, millirem per hour or Sievert per hour.

### **Teletherapy**

Therapeutic irradiation, in which the source of radiation is at a distance from the body.

### **University License**

A broad scope license issued to the Regents of the University of California for the Davis Campus, Health System, and specific off-site field locations for the use of radioactive materials.

### **Unrestricted Area**

Any area for which access is not limited by the Office of Environmental Health and Safety/UCDHS Health Physics for the purpose of protecting individuals from exposure to radiation and radioactive materials.

### **Wipe Test (Sample)**

A test (sample) made for the purpose of determining the presence of removable radioactive contamination on a surface. A piece of soft filter paper is wiped over 100 square centimeters of the area to be surveyed and counted for radioactivity with an appropriate instrument.

### **10 CFR 20**

Refers to the Code of Federal Regulations, Title 10, Part 20, "Standards for Protection Against Radiation". Other CFR parts are cited in the same manner.

Title 10 - "Energy" is composed of four volumes. The first volume, Parts 0-199, contains the regulations of the Nuclear Regulatory Commission (Chapter 1). The second, third and fourth volumes contain the regulations and rulings of the Department of Energy (Chapter 2, Chapter 3, Chapter 4).

## **17 CCR 30275**

Refers to the California Code of Regulations, Title 17, Section 30275, "Surveys and Tests". Other CCR sections are cited in the same manner.

Because the NRC made an effective arrangement with the state of California setting up regulations as exacting as Title 10, Chapter 1, an "Agreement State" status was established, which allows California to operate under their own guidelines. The following is an index of the California Code of Regulations.

### **Title 17. PUBLIC HEALTH**

Division 1. Department of Health Services,

Chapter 5. Sanitation,

Subchapter 4.0. Radiation, sections 30100-30397.

Subchapter 4.5. Radiologic Technology, sections 30400-30499.

Subchapter 4.6. Nuclear Medicine Technology, sections 30500-30570.

## **I. RESPONSIBILITIES**

The purpose of the University's Health Physics Program is to assure the safe use of ionizing radiation through training, consultation, and surveillance consistent with University, State, and Federal regulations.

The UC Davis Radiation Safety Manual describes the requirements for the use of ionizing radiation and the University's Health Physics Program. This guide is prepared for Principal Investigators as an aid in complying with the University's Broad scope license for use of radioactive materials as well as applicable state regulations for the use of radiation-producing machines.

### **A. CHANCELLOR**

The Chancellor of the University is responsible for the overall campus Environmental Health and Safety Program. The Health Physics Program ensures that all sources of ionizing radiation are handled in accordance with governmental agency requirements. These policies and procedures have been described in the UC Davis Campus Policy and Procedure Manual (290-75) and the UC Davis Radiation Safety Manual. The Chancellor is responsible for the development and interpretation of these policies.

The Chancellor has delegated his responsibility for the Health Physics Program to the Office of Environmental Health and Safety, the Radiation Safety and Use Committees, and specific individuals described below.

### **B. OFFICE OF ENVIRONMENTAL HEALTH AND SAFETY**

The Director of Environmental Health and Safety (EH&S) is assigned responsibility for surveillance of departmental activities and for providing services in radiation safety in conformity with policies and standards set forth in this manual. This responsibility is delegated to the Director of Health Physics Programs, campus Radiation Safety Officer, and UC Davis Health System Radiation Safety Officer as required by the UC Davis radioactive materials license. The Director of Health Physics Programs has the overall responsibility for all technical and administrative activities in the Health Physics Program and is the University's representative to outside regulatory agencies. The campus Radiation Safety Officer evaluates proposals for and maintains surveillance of all uses of ionizing radiation on the Davis campus and all sites authorized by the Davis Campus University License except Sacramento-based activities and human uses. The UC Davis Health System (UCDHS) Radiation Safety Officer is responsible for surveillance of radiation usage, including human use, at UCDHS and other departments based in Sacramento.

On initiation of a Radiation Use Authorization (RUA), the appropriate Radiation Safety Officer informs the Principal Investigator of the policies and procedures governing the handling/use of radioactive materials or radiation-producing machines.

### **C. RADIATION SAFETY ADMINISTRATIVE ADVISORY COMMITTEE (Radiation Safety Committee)**

The Radiation Safety Administrative Advisory Committee is responsible for developing policy, advising the Chancellor on all matters relating to health physics, and reviewing the functioning of the Radiation Use Committees. Committee approval provides the assurance to the Chancellor and to governmental officials that the kind and quantity of radionuclides requested, their proposed use, and the experience of the research personnel involved adhere to adequate health physics standards. The chairpersons of the Davis Campus, UC Davis Health System, the Cyclotron Radiation Use Committees, as well as the Director of Health Physics Programs, the campus Radiation Safety Officer, and the UCDHS Radiation Safety Officer shall be members of the Radiation Safety Administrative Advisory Committee.

### **D. UC DAVIS CAMPUS RADIATION USE COMMITTEE**

The UC Davis Campus Radiation Use Committee is responsible for reviewing all applications for the use of radionuclides at the UC Davis Campus locations except the cyclotron facilities, UCDHS, and projects involving the exposure of humans to radiation. The Committee authorizes use of radiation subject to review by the Radiation Safety Administrative Advisory Committee and recommends health physics policy to the Radiation Safety Administrative Advisory Committee. In addition, the committee reviews the compliance records of all radiation use authorizations and has the authority to mandate corrective actions for radiation events, incidents, and recurring non-compliance issues.

**E. UC DAVIS HEALTH SYSTEM RADIATION USE COMMITTEE**

The UC Davis Health System Radiation Use Committee is responsible for reviewing and authorizing all applications for the use of ionizing radiation at University facilities in Sacramento, off campus locations for the UCDHS, and in research projects involving the exposure of humans to radiation. The Committee authorizes the use of radiation, subject to compliance with the UC Davis Radiation Safety Manual and review by the Radiation Safety Administrative Advisory Committee. The Committee also recommends health physics policy to the Radiation Safety Administrative Advisory Committee.

**F. CYCLOTRON RADIATION USE COMMITTEE**

The Cyclotron Radiation Use Committee is responsible for reviewing all productions of radionuclides and all uses of the cyclotrons. The Committee authorizes the use of radiation, subject to compliance with the UC Davis Radiation Safety Manual and review by the Radiation Safety Administrative Advisory Committee. The Committee also recommends health physics policy to the Radiation Safety Administrative Advisory Committee.

**G. DEPARTMENTAL CHAIRPERSONS**

Department Chairpersons are responsible for review and approval of proposed uses of radionuclides and radiation-producing machines within their jurisdiction. Such approval demonstrates the department's willingness to assist in providing the resources necessary to control potential hazards and assist in the enforcement of University policies and procedures.

**H. PRINCIPAL INVESTIGATOR**

The Principal Investigator (PI) named on the Radiation Use Authorization (RUA) or Machine Use Authorization (MUA) shall be responsible for using the authorized radionuclides or radiation-producing machines in compliance with all applicable State of California, Nuclear Regulatory Commission, and University regulations.

The PI has the following responsibilities:

1. Instructing all co-workers listed on the RUA/MUA in good health physics practices including:
  - a. Control and measurement of contamination.
  - b. Use of protective clothing and equipment.
  - c. Operating and emergency procedures specific to the required tasks.
  - d. Maintenance of records on receipt, use, transfer, and disposal of radioactive material.
2. The Principal Investigator shall provide a copy of the safety protocol to each co-worker and confirm that each person attends an appropriate health physics seminar provided by the Office of Environmental Health and Safety/UCDHS Health Physics. See Section V. A. for training details. Refresher courses or exams are required every three years. The exams are available on the internet at <http://ehs.ucdavis.edu/> (Radiological, Radiation Exams & Quizzes). Temporary workers on an RUA (radiation work period less than or equal to 20 working days) are exempt from attending the seminar or taking the exam; however, direct supervision and documented training by the Principal Investigator is required. The Principal Investigator must assure that the appropriate chapters of the Radiation Safety Manual have been read by each authorized user on their respective RUA/MUA.
3. Ensuring that only work authorized by the approved RUA/MUA is carried out.
4. Ensuring operations involving radioactive materials or radiation-producing machines are performed by properly instructed and authorized personnel.
5. Maintaining records of receipt, transfer, current inventory, and disposal of all radioactive materials.
6. Maintaining records of radiation fields and contamination monitoring.

7. Posting warning labels, guidelines, and other appropriate posting as requested by the Office of Environmental Health and Safety/UCDHS Health Physics office or the State Department of Public Health.
8. Notifying the Office of Environmental Health and Safety/UCDHS Health Physics of all changes in the RUA/MUA, such as changes in location, personnel, experiments, etc.
9. Notifying the Office of Environmental Health and Safety/UCDHS Health Physics immediately in the case of an accident involving radiation or potential excessive exposure.
10. Ensuring the use of personnel dosimetry and survey instruments as applicable.
11. Assigning an alternate Principal Investigator to assume control of the use and storage of the radioactive material in the event of extended leave or absence.
12. Training provided by Principal Investigators for personnel named to their Use Authorizations with respect to radiation safety shall be conducted annually. Such training should cover specific hazards and protective measures, procedures and safety protocols for the Radiation Use Authorization. These training sessions shall be documented by the Principal Investigator. Such documentation shall include an outline of the subjects covered and personnel attending.

## **II. LICENSE REQUIREMENTS**

### **A. UNIVERSITY BROAD SCOPE RADIOACTIVE MATERIAL LICENSE**

The Regents of the University possess a broad scope license issued by the California Department of Public Health, Radiologic Health Branch, which authorizes the use of radioactive materials in research, teaching, and human use. The license can be reviewed at the campus Office of Environmental Health and Safety/UCDHS Health Physics office. The license describes the possession limits for each radionuclide and locations for use, and provides for the internal issuance of RUAs. Requests for amendments to the license shall be made by the Office of Environmental Health and Safety after approval by the Director of Health Physics Programs and/or the Radiation Safety Administrative Advisory Committee.

### **B. USE AUTHORIZATIONS**

Requests to use ionizing radiation are separated into the following categories:

- Non-Human Use Radiation Use Authorization (RUA) (Research and Classroom)
- Human Radiation Use Authorizations
- Radiation-producing Machines (also called Machine Use Authorizations or MUA)

Separate Radiation Use Applications are required for each category (see Section XI “Appendices” for a sample application). The Principal Investigator shall consult with the campus Radiation Safety Officer prior to completing the application for all non-human use and use of radiation-producing machine applications based in all locations other than Sacramento-based UCDHS departments. All human use applicants in Davis and/or Sacramento locations, and non-human use applicants and radiation-producing machine applicants in Sacramento locations, should consult with the UCDHS Radiation Safety Officer.

### **C. SPECIAL REQUIREMENTS FOR CLASSROOM RADIATION USE AUTHORIZATIONS**

The RUA for use of radioactive materials for teaching or demonstration in academic courses shall be submitted for review and approval to the campus Radiation Safety Officer/UCDHS Radiation Safety Officer, at least two weeks prior to the commencement of the scheduled quarter. An authorization may be renewed providing there is no change in the radionuclide, quantity, or procedures. A class roster must be sent to the appropriate Radiation Safety Officer for each quarter that the course is offered. The following information is required to supplement the standard RUA:

1. Names and history of experience for laboratory instructor in charge and/or teaching assistants involved in course.
2. Duration of course (e.g., 1 quarter, 1 year).
3. Number of students anticipated (forward the names, birth dates or social security numbers of the students immediately after quarter begins).
4. Number of laboratory groups and the number of students per group.
5. Number and type of monitoring instruments available for routine use in the laboratory.
6. Description of proposed use and procedures for each radionuclide stated on the application, including:
  - a. Radiation safety instruction for the students.
  - b. Extent that the students will be handling radiation sources.
7. The Principal Investigator must ensure that specific radionuclide and procedure specific awareness training is given to students. The Principal Investigator may provide the necessary training. The training outline to be used must be submitted as part of the protocol in the RUA. Alternatively, the Office of Environmental Health and Safety will, if requested by the Principal Investigator, provide the appropriate radiation safety instructions. Requests must be submitted at least one month prior to the beginning of the course to avoid scheduling conflicts.

#### **D. SPECIAL REQUIREMENTS FOR HUMAN USE RADIATION USE AUTHORIZATIONS**

All uses of ionizing radiation in humans for treatment, diagnosis, or research must be approved by the UCDHS Radiation Use Committee prior to such use. Diagnosis and treatment of humans with licensed radioactive materials or radiation-producing machines is controlled and approved by the issuance of a Radiation Use Authorization (RUA) or Machine Use Authorization (MUA). The RUA/MUA must be specifically approved for human use. Human research involving the use of ionizing radiation must also be approved by the UCD Institutional Review Board (IRB), with respect to requirements other than radiation use related concerns. The UCDHS Radiation Use Committee reviews research studies involving the use of ionizing radiation in humans and forwards their recommendations to the IRB.

1. Medical Diagnosis and Treatment With Radioactive Materials
  - a. A Human Use Radiation Use Authorization that is approved for medical diagnosis and treatment allows Medical Doctors licensed to practice medicine in the State of California and named in the Radiation Use Authorization to prescribe radioactive materials for the diagnosis and treatment of diseases in humans.
  - b. Physicians named to Radiation Use Authorizations approved for the treatment and/or diagnosis of humans with licensed radioactive materials should be board certified in their area of specialty practice. Board certification with the American Board of Nuclear Medicine, American Board of Radiology, American Board of Osteopathic Radiology, British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or Canadian Royal College of Physicians and Surgeons are considered acceptable certification organizations. Certificates from other organizations may be accepted provided that the above organizations recognize the certificate and the physician is authorized to practice medicine in the state of California.
  - c. Physicians without the above board certifications may be named as users for the treatment and diagnosis of humans on Radiation Use Authorizations provided that they meet the training and experience requirements described in the appropriate sections of 10 CFR 35.
  - d. Physicians who are in specialty training may work on Radiation Use Authorizations for the treatment of humans provided that they are under the direct supervision of a physician who is board certified in the specialty that the trainee physician is being trained in.
  - e. Direct supervision means that the supervisor must be in line of sight of the individual being supervised. The supervisor must be able to observe and assure that the individual being supervised is following directions and performing the task correctly. The supervisor must be able to immediately apply proper instruction and corrective actions.
  - f. Physicians who are in specialty training may work on Radiation Use Authorizations for the diagnosis of humans provided that they are under the general supervision of a physician who is board certified in the specialty that the trainee physician is being trained in.
  - g. General supervision means that the supervisor must be in the general area (e.g. the Department), or on the campus grounds and able to respond to any questions or problems that the supervised person may have.
  - h. Physicians who are authorized users may select radiopharmaceuticals in accordance with their professional judgement for the treatment and diagnosis of humans provided that the radiopharmaceutical is approved for use in humans by the FDA.
2. Research Uses in Humans
  - a. Research projects involving the exposure of human subjects to ionizing radiation requires UCDHS Radiation Use Committee review, as well as approval by the IRB. A Human Radiation Use Research Application form must be submitted for each study to the UCDHS

Radiation Use Committee. After approval by the UCDHS Radiation Use Committee, the UCDHS Radiation Safety Officer will assure that the RUC Notice of Action is forwarded to the PI. The research must be conducted under a Human Radiation Use/Machine Use Authorization. As part of the RUA/MUA, specific safety protocols for the procedures involving radiation work must be completed and on file prior to the start of the research project.

1. Informed consent forms

A signed, written consent is required from all research subjects who will receive radionuclides or be exposed to ionizing radiation. The method of obtaining informed consent must be submitted with the Human Radiation Use Research Application. Risk statements regarding the radiation exposure to the patient are provided to the Principal Investigator for the research protocol in the Human Radiation Use Research Application.

2. Records

Complete records of all administrations of radioactive materials to humans must be maintained. Records must include name, age, sex, date, prescribed dose, and total dose administered.

3. Instructions for Human Subjects

All human subjects who are to receive radioactive materials must be adequately informed about needed precautions, and where appropriate, possible risks.

b. The Radioactive Drug Research Committee (RDRC) is composed of members as stipulated in 21 CFR 361.1. The RDRC members shall be approved by the Food and Drug Administration. The RDRC reviews and oversees the use of radioactive substances which are used in research intended to obtain basic information about metabolism (including kinetics, distribution, and localization), human physiology, pathology or biochemistry.

c. Radiopharmaceuticals used in research must:

1. Be already approved by the FDA as a drug or;
2. Be under a manufacturer's sponsored IND program or;
3. Be under a Physician's sponsored IND program.

d. Radioactive materials which are not drugs (tracer studies) may be used provided that they are approved by the Radioactive Drug Research Committee.

e. Principal Investigators named on Radiation Use Authorizations requesting utilization of ionizing radiation in human research should have sufficient medical experience to assure that the medical aspects of the use of the radiation will not cause the human subject(s) undue harm. Generally this is evidenced by meeting the qualifications in sections II(D) 1.b and 1.c of this manual. However, the UCDHS Radiation Use Committee may approve other faculty to utilize radionuclides on humans for research, provided that the committee determines that the principal investigator has the necessary skills to perform the research in a safe and effective manner. There must be at least one physician licensed to practice medicine in the State of California identified to be responsible for the medical aspects of the research protocol.

- f. Radiation-producing machines used in research must be registered with the State. The individual who operates or supervises the operation of the radiation-producing machine shall be appropriately certified by the State CDPH.
  - g. The expected exposure (doses) from ionizing radiation to human subjects shall be maintained at levels which are as low as reasonably achievable consistent with research objectives, costs and the expected benefits of the research being conducted.
3. Use of Radiation-producing Machines in Diagnosis and Treatment.
- a. Radiation-producing machines for diagnosis and treatment of humans must be approved through a Machine Use Authorization.
  - b. Determination of the specifications (e.g., kVp, mA, type of machine, etc.) shall be made at the direction of a physician who is board certified as a Radiologist or in the specialty area in which the machine is being used. For diagnostic X-ray and fluoroscopy equipment, the physician who specifies the operating procedures or operates the equipment must be certified by the State of California to do so. Section VI provides further details on training and approval for use.

#### **E. SUBMISSION OF RUA/MUA APPLICATIONS AND APPROVAL**

A completed application packet includes a use application, statement(s) of experience, safety protocol(s), and laboratory diagram(s). Once the RUA/MUA application is complete, including the chairperson signature, mail it to the Office of Environmental Health and Safety (campus) or the UCDHS Health Physics office. The appropriate RSO or their designee will review the information and then contact the applicant for an appointment. During the appointment the following will be discussed:

- content of safety protocol
- room posting
- bioassay requirements
- purchasing of radioactive material
- safety training
- recharge rates
- EH&S Safety Nets
- Radiation Safety Manual.
- adequate work area
- required laboratory monitoring including survey meter
- EH&S Health Physics inspections including hazard rating
- waste disposal, including minimization
- RUA renewal requirements
- responsibility of PI
- appointment of an alternate PI

The appropriate Radiation Safety Officer will process the application for the approval.

#### **F. APPROVAL OF APPLICATIONS**

Prior to use of radionuclides or radiation-producing machines, all applications must be approved as required by the Hazard Rating Category (see Section II.G.). Hazard Rating Categories are calculated for non-human and human use applications based on the criteria listed in section II.G. The Radiation Use Committee may, however, require a higher or lower hazard rating level for special cases at their discretion. Upon approval of the application, the appropriate Radiation Safety Officer will issue an RUA/MUA. A service fee that covers a fraction of the Health Physics processing fee and monitoring costs, will be required at the time of authorization and annually thereafter. All health and safety costs, not covered by the service fee, will be borne by the Principal Investigator. Such costs may include:

1. New construction or major alterations.
2. Acquisition of special monitoring equipment and shielding.
3. Waste disposal.

4. Salaries of extra health physics personnel as required (i.e., incident response, extensive use of radiation material or radiation sources, probation [see Section V.L.9]).

**G. METHODS OF COMPUTING HAZARD RATING**

Hazard Ratings are computed by the following summation formula:

$$HR = R \sum ( (Q_i \times U_i \times A) \div T_i )$$

where:  $Q_i$  = Quantity of  $i^{th}$  radionuclide in microcurie  
 $U_i$  = Use Factor for the  $i^{th}$  radionuclide  
 $A$  = Assessment Factor  
 $T_i$  = Tolerance Factor for the  $i^{th}$  radionuclide  
 $R$  = Number of radiation users

**Hazard Rating Table**

Hazard Rating (HR)	HR Category	Level of Review Required
600 or less	1A	CRSO or UCDHS RSO or Director of Health Physics
600 or less	1B	CRSO or UCDHS RSO or Director of Health Physics (Sealed Source Only)
601 to 6000	2	CRSO or UCDHS RSO or Director of Health Physics
6001 to 600000	3	Full Radiation Use Committee
over 600000	4	Full Radiation Use Committee

1. Quantity (Q)

The quantity of the radionuclide is expressed in microcuries ( $10^{-6}$  curies). A microcurie is defined as that quantity of radionuclide that decays at a rate of  $3.7 \times 10^4$  disintegrations per second.

2. Use Factor (U)

The use factor is based on the type of experimental procedures that will be involved in the proposed use of the radionuclide(s). Consideration is given to the probability of:

- a. Release of the radionuclide to the environment
- b. Contamination of personnel engaged in the operation
- c. Contamination of equipment and facilities
- d. External radiation hazard potential.

Examples of use factors are shown in the table below:

Operation	Use Factor, (U)
Moisture Density Probes	0.0001
Sealed Sources	0.001
Storage of Radioactive Materials	0.01
Simple Wet Operations (i.e., RIA Kits, Electrophoresis, Nick Translation, Chromatography)	0.1
Simple Dry Operations (i.e., Transfer of Dry Precipitates)	1.0
In vivo Work, Radiolabelling, Work with Volatile Components	1.0 - 5.0
Complex Wet Operations (i.e., Evaporation to Dryness, Aerosols)	5.0 - 10.0
Complex Dry Operations (i.e., Crushing, Mixing, Sieving)	10.0 - 100.0

3. Assessment Factor (A)

The assessment factor may range from 0.1 to 10.0 depending on investigation of the protocols and review of the compliance record. The value will be recommended by the appropriate Radiation Safety Officer prior to submission to the Director, Health Physics Programs or the appropriate Radiation Use Committee. Normally, all new RUA's start with an assessment factor of 1.0. After one year and on an annual basis thereafter the Radiation Use Committees review all RUA compliance records. The assessment factors listed below are assigned based on the compliance point total at the time of the committee's annual review.

Status	Compliance Point Total	Assessment factor
Perfect Laboratory	0.0	0.1
Good Laboratory	1.0 - 10.0	0.5
Average Laboratory	11.0 - 24.0	1.0
Poor Laboratory	≥ 50	>1.0

Perfect and good laboratory status may result in a lower hazard rating category (see Section V. L.). Poor laboratory performance may result in a higher hazard rating category.

4. Tolerance Factor (T)

The tolerance factor is based on the microcurie amounts established for each radionuclide listed in 10 CFR 30.71, Schedule B. For radionuclides not listed, the tolerance factor shall be determined by the Director, Health Physics Programs or the appropriate Radiation Safety Officer. (See section XI, Appendices)

**H. RENEWAL OF RADIATION USE AUTHORIZATIONS**

Radiation Use Authorizations with a hazard rating of 3 or 4 are approved for a maximum of one year.

RUA's with a hazard rating of 1A, 1B or 2, are approved for a maximum of two years.

1. The RUA must be renewed if:
  - a. Work with radionuclides is to continue.
  - b. Any radionuclides are to remain in possession of the Principal Investigator.
2. Renewals can be accomplished without amendment provided:
  - a. There are no major changes in the scope, location, or procedures of the project that would require a change in radiation safety measures (e.g. increased shielding, changes in monitoring, etc.).
  - b. All pertinent regulatory requirements have been met.
  - c. The total quantity of radionuclides acquired under the applications does not exceed the amount authorized.
  - d. The Principal Investigator remains the same.
  - e. For a class application, a class roster is submitted as soon as the class roll has been established.
  - f. If items a. through e. above cannot be met, an amendment to the RUA may be issued. The renewal process will be initiated by the campus Radiation Safety Officer/UCDHS Radiation Safety Officer or their alternate prior to the expiration date of the application. During the renewal process, RUA's are bound to existing conditions of the Radiation Use Authorization.

## **I. AMENDMENTS TO RADIATION USE AUTHORIZATIONS**

All amendment requests must be submitted in writing on a Radiation Use Authorization Amendment Request Form.

### **1. Amendments Requiring Approvals by Radiation Safety Officers**

Except as noted above, the campus Radiation Safety Officer/UCDHS Radiation Safety Officer, or a designated member of the Health Physics technical staff, may authorize amendments to existing use authorizations. Such amendments will be limited to increases in possession or experimental amounts of already authorized materials, chemical forms of authorized materials, locations, or techniques, provided such changes do not increase the overall authorized Hazard Rating Category (HRC) above an HRC-2 level. Amendments involving the addition of new radionuclides may be approved by the appropriate Radiation Safety Officer, providing the amounts, use, and toxicity of the radionuclides to be added does not increase the Hazard Rating Category above the criteria specified for the Director, Health Physics Programs, or committee approval.

### **2. Amendments Requiring Approval by the Director, Health Physics Programs**

Existing HRC- 3 or HRC-4 authorizations requesting amendments shall require Director of Health Physics Programs review if the total hazard rating increase for the addition of new radionuclides is between 1000 and 2500, or 5000 and 7500 for existing radionuclides.

### **3. Amendments Requiring Approval by Radiation Use Committees**

Existing HRC-3 or HRC-4 authorizations requesting amendments shall require appropriate Radiation Use Committee review if the total hazard rating increase for the addition of new radionuclides is >2500 or >7500 for existing radionuclides.

**J. CEASE AND DESIST / TERMINATION OF RADIATION USE AUTHORIZATIONS**

The Director of Health Physics Programs and the RSOs have the authority to issue a Cease and Desist order if any person is found to be willfully or negligently violating any of the University, State, or NRC regulations governing the use of radiation sources. This may lead to a PI having their Radiation Use Authorization placed on probation, suspended, or revoked by the Director of Health Physics Programs with the concurrence of the appropriate Radiation Use Committee. Any radionuclides in the Principal Investigators possession will be impounded. The applicant has the right to appeal this decision to the Radiation Safety Administrative Advisory Committee.

Radiation Use Authorizations will ordinarily be terminated upon:

1. Completion of the project.
2. Expiration of the application without renewal.
3. Failure to comply with the University and license commitments for re-training or radioactive materials inventory control.

Upon termination of a RUA, all radioactive material must be accounted for to the appropriate Radiation Safety Officer. Unused amounts must either be transferred to another active RUA, which is authorized for the material, or disposed of as radioactive waste. The campus Radiation Safety Officer/UCDHS Radiation Safety Officer, shall be notified of the termination of projects using radionuclides in sufficient time to permit scheduling of any necessary medical examination and/or bioassay for personnel engaged in the project.

All costs associated with the suspension or termination of an RUA (including disposal of radioactive materials and radiologically associated decommissioning costs) will be the responsibility of the Principal Investigator or the Departmental Chairperson.

**K. EXTENDED LEAVE BY A PRINCIPAL INVESTIGATOR**

An applicant leaving the campus/UCDHS for an extended period of time (greater than 30 days) must terminate their RUA and dispose of the radionuclides under their control and have an exit inspection, or request an amendment to the RUA to allow a responsible person to assume authority (i.e., alternate Principal Investigator).

**L. EQUIPMENT AND FACILITIES**

The quantity of radioactive material permitted in the laboratory is based on the hazard rating of each RUA, the nature of the containment facilities, and the overall laboratory design. In some instances, specialized equipment is necessary to assure a safe operation. UC Davis has established a laboratory classification system based on the RUA Hazard Rating Criteria that outlines minimum facility requirements. The following criteria will be used to determine the laboratory assignment:

<u>Hazard Rating of Radionuclides*</u>	<u>Laboratory Classification</u>
100 or less	Class A
101 to 50,000	Class B
50,001 to 100,000	Class C
over 100,000	Class D

\*In this case, the Hazard Rating is applied to each individual radionuclide, not the cumulative rating of all radionuclides authorized, unless the radionuclides are used in combination for a specific experiment.

Class **A** laboratories shall meet the following requirements:

- a. Ten air changes per hour.
- b. One hundred percent exhaust.
- c. Smooth floors and work surfaces, which can be decontaminated.
- d. Plastic backed absorbent coverage of all work areas.
- e. Doors must have a lock.
- f. Available portable survey instrument or counting device.
- g. Appropriate waste storage area.

Class **B** laboratories shall be equipped with:

- a. All items listed in "Class A" above.
- b. An approved fume hood, minimum face velocity of 100 linear feet per minute and a maximum of 150 linear feet per minute.
- c. Assigned portable survey meter or counting device.

Class **C** laboratories shall be equipped with:

- a. All items listed in "Class A and B" above.
- b. An approved glove box maintained under negative pressure with appropriate filtration.

Class **D** laboratories shall be equipped with:

- a. All items listed in "Class A, B and C" above.
- b. An approved shielded glove box with remote manipulators and appropriate filtration.
- c. Exhaust stack monitor.
- d. Lead glass shields.
- e. Floors that can be stripped.
- f. Air monitoring capability.
- g. Hand and foot counters.
- h. Separate waste storage area.
- i. Continuous background monitor.

#### **M. EXCEPTIONS TO FACILITIES CRITERIA**

Exceptions to the above requirement can be granted by the Director of Health Physics Programs or a majority vote of a quorum of the appropriate Radiation Use Committee.

#### **N. BUILDING PLANS**

Plans for new buildings or for alterations in existing buildings, where provisions are made for use or possible use of radioactive materials or radiation-producing machines, shall be reviewed by the appropriate Radiation Safety Officer or designee. The Office of Environmental Health and Safety is responsible for obtaining further review and approval by the Radiation Safety Administrative Advisory Committee and others, as circumstances dictate.

#### **O. RELOCATIONS**

Radioactive materials shall not be moved to locations other than those expressly stated in the Radiation Use Authorization. A change in the location for the use and storage of radioactive material must be done only after an amendment to Radiation Use Authorization has been approved in accordance with section II.I. of this manual. The ability to use temporary locations must be approved as part of the Radiation Use Authorization's "Conditions and Restrictions."

### **III. ACQUISITION, TRANSFERS, AND DISPOSAL**

#### **A. PROCUREMENT POLICY**

All purchases of radioactive materials shall be accomplished through established campus or Health System purchasing channels and with the approval of the Office of Environmental Health and Safety/UCDHS Health Physics.

#### **B. PURCHASING PROCEDURE**

1. Campus purchases must be requested on standard purchase requisition forms in one or both of the following manners:

a. DM3 Supply Agreement Purchases

All purchases of radioactive material covered by the supply agreements that are designated DM3 (see P&PM Section 350-21), can be made directly by the departments with current RUAs. Purchases must be initiated directly to the radioactive material vendor identifying the type and amount of radioactive material desired, the RUA number, the University supply agreement number, and any special instructions for shipping and handling. The material is to be delivered to EH&S, 2201 Environmental Services Lane, Davis, CA 95616 (for on-campus/Research Park orders). The exceptions to the central delivery point are orders initiated by and for Bodega Bay Marine Laboratory and others approved by EH&S. Additional information on DM3 supply agreements can be obtained by contacting the Purchasing Department, Planned Purchasing Program Assistant at 530-757-8716.

b. Non-Supply Agreement Purchases

All purchases of radioactive materials from non-agreement vendors (suppliers not having a negotiated agreement with UC) must be placed through the campus Purchasing Department. A signed Health Physics approval is not needed. Purchases must be requested through the standard campus purchase requisition processes identifying the type and amount of radioactive material desired, the RUA number, and any special instructions for the shipping and handling. The material is to be delivered to EH&S, 2201 Environmental Services Lane, Davis, CA 95616 (for on-campus/Research Park orders). The only exception to the central delivery point are orders initiated by and for Bodega Bay Marine Laboratory.

2. UCDHS purchases must be requested on standard purchase requisition forms in one of the following manners:

a. Requisition process

1. Indicate the identity, catalog number, and amount of radioactive material desired.
2. Indicate the RUA number.
3. Indicate that material is to be delivered to the UCDHS Health Physics office unless otherwise approved in the Radiation Use Authorization.
4. Call, mail or walk the requisition to the UCDHS Health Physics office for approval and forwarding to the Purchasing Department.

b. Blanket Orders

Blanket orders can be used to purchase radioactive materials. Requisition forms are completed only once, in the same manner as Section III, (B), 2,a., except that all intended purchases from the vendor are listed separately. Once completed, send the requisition to UCDHS Health Physics. Health Physics will forward orders to the Purchasing Department. The Purchasing Department will assign a Purchase Order Number, which can then be used to call the vendor directly.

c. Standing Orders

Standing order requisitions are completed in the same manner as blanket orders. The only difference is that a specific shipment of radioactive material will be received at an established frequency (e.g., every two weeks).

Requisitions will not be approved if the requested radionuclides and amounts are not identified on the purchase order, or the amounts exceed the possession limit, or are in a chemical form other than those listed on the RUA.

**C. DELIVERY OF RADIONUCLIDES**

1. All deliveries of radioactive materials to the University of California, Davis are made through the Office of Environmental Health and Safety/UCDHS Health Physics. Exceptions must be specifically authorized by the campus Radiation Safety Officer/UCDHS Radiation Safety Officer.
2. Inspection of incoming packages of radioactive materials by the Office of Environmental Health and Safety/UCDHS Health Physics shall assure that material acquired by the researcher is a) material authorized by the RUA both in form and amount; b) material that was ordered; and c) properly contained and not contaminated by loose radioactive material.

**D. CUSTODY OF RADIOACTIVE MATERIALS**

The Principal Investigator named on a RUA shall be continuously responsible for the custody of any radioactive material acquired. They shall be responsible for the proper storage, labeling, inventory, use, transfer, monitoring, and disposal.

**E. TRANSPORTATION OF RADIOACTIVE MATERIALS**

1. All transportation of radioactive materials must be specifically approved by either the campus EH&S or UCDHS Health Physics Offices. This included transportation on campus by means other than walking.
2. All packaging and labeling of shipping containers must conform to Department of Transportation (DOT) regulations and any other appropriate regulations. The Office of Environmental Health and Safety/UCDHS Health Physics must be consulted prior to transportation.
3. The EH&S/ Health Physics Office shall be responsible for determining if the recipient is authorized to receive and possess the material to be shipped and for securing a copy of the recipient's license.
4. After proper packaging and approval, shipments leaving campus will be made through the Receiving Department, the Mail Division, or the carrier.
5. Special arrangements may be made with the campus Radiation Safety Officer/UCDHS Radiation Safety Officer, for frequent, routine shipments such as nuclear medicine radiopharmaceuticals or cyclotron produced radionuclides. Anyone who prepares packages for shipment must be specifically trained and certified by the Office of Environmental Health and Safety/UCDHS Health Physics to do so.

6. Improper packaging, labeling and certification can result in a monetary fine from Department of Transportation (DOT) or other regulatory agencies as well as a citation from the State Radiologic Health Branch.
7. Export of any radioactive materials shall have prior approval of the appropriate Radiation Safety Officer. Shipping procedures shall comply with DOT and international shipping regulations.

#### **F. TRANSFER OF RADIOACTIVE MATERIALS**

1. The appropriate health physics office must be notified prior to transferring radioactive materials from the RUA to a person, department, or project. Unauthorized transfer of radioactive materials may result in the revoking of the RUA and the impounding of the material. Radioactive Material Transfer forms shall accompany all transfers and one copy must be sent to the appropriate Radiation Safety Officer. The transfer form requires a signature from both RUA authorized users. The transfer forms are available on the EH&S website.

2. Transfer of Radioactive Material Between UC Campuses

Transfer of radioactive materials to another campus of the University system shall have prior approval of the campus Radiation Safety Officer/UCDHS Radiation Safety Officer. The Radiation Safety Officer on the campus that the radioactive material is transferred to will be notified. Shipping procedures shall comply with DOT regulations.

3. Transfers between Campus and UCDHS.

Prior to departure, the integrity of the vial and package must first be checked by the Office of Environmental Health and Safety/UCDHS Health Physics to make sure the transferee has swiped the package/primary vial for contamination, the package is properly prepared and the shipping documents are correct.

4. Transfer to a Nuclear Regulatory Commission (NRC) Licensee or State Licensee

An individual desiring to transfer radioactive materials to another NRC or State licensee must have prior approval from the appropriate Radiation Safety Officer. The Radiation Safety Officer shall be responsible for determining if the recipient is authorized to receive and possess the material to be shipped and for securing a copy of the recipient's license. The shipping procedures shall comply with DOT regulations.

#### **G. QUARTERLY RADIOACTIVE MATERIAL INVENTORY**

1. Campus

Quarterly, the campus Radiation Safety Officer will e-mail an inventory notice to each Principal Investigator possessing an RUA. The notice will instruct the Principal Investigator to access their on-line quarterly inventory report, to review the last calendar quarter receipts, transfers, and disposals and to enter the current amount of on-hand and waste activities. It is the responsibility of each Principal Investigator to complete the quarterly inventory report within thirty days. All radioactive material, including sealed sources and "in-storage" material must be accounted for each quarter. Compliance with the requirement is critical; non-compliance is sufficient grounds for suspension of radioactive material delivery or suspension of the RUA.

2. UC Davis Health System

- a. Each time a UCDHS RUA is audited, the person performing the audit will perform a sight inventory of the radioactive material. When radioactive material is received at the UCDHS Health Physics Laboratory, a form is generated. This form is used to document the receipt survey. The form also documents receipt of the material at the RUA location, a running inventory of that material, and the material's usage.

- b. The UCDHS Health Physics office keeps a copy of the form, which documents the receipt survey and receipt of the material by the RUA. When all the radioactive material is used, the Principal Investigator for the RUA ensures that the original form is returned to the UCDHS Health Physics office while keeping a copy for their records. Receipt of the form by the Health Physics office indicates that all of the radioactive material in that shipment has been used or disposed as radioactive waste. Until the form is received, it is presumed that all of the material is present at the location of the RUA or has been documented as disposed of in an authorized manner.
- c. This system effectively maintains a running inventory of radioactive materials present at the UCDHS units. Laboratories that have the authority to receive radioactive materials at the location of the RUA must maintain a radioactive materials receipt log and a running inventory. Compliance with the requirement is critical; non-compliance is sufficient grounds for suspension of radioactive material delivery or suspension of the RUA.

## **H. RADIOACTIVE WASTE DISPOSAL POLICY**

- 1. All contaminated and potentially contaminated material must be disposed of as radioactive waste. Radioactive waste must be stored in approved containers and sealed prior to pickup by the Office of Environmental Health and Safety/UCDHS Health Physics. All containers must be labeled with a "Caution - Radioactive Materials" label indicating the radionuclides(s), amount, and date of assay. Liquid waste containers shall identify the percent chemical composition. The user is responsible for verifying the chemical compatibility of all solutions placed in the 5 gallon waste container. (see Section XI for link to Safety Net #9)
- 2. Excreta and body fluids from humans receiving diagnostic or therapeutic radiopharmaceuticals may be discharged in the sewer system. Exceptions to this policy can be made by the appropriate Radiation Use Committee.

## **I. RADIOACTIVE WASTE CONTAINERS**

All radioactive waste material shall be contained as follows:

### **1. Dry Waste**

All dry waste must be deposited in a two-cubic-foot box furnished by the Office of Environmental Health and Safety/UCDHS Health Physics or another container approved by that office. Each box must be lined with a 4 mil or greater, clear plastic bag. Vials containing liquid are not to be discarded in the dry waste. Needles should be placed in a hard walled small container prior to being placed in dry waste. Dry waste must be separated into the following categories:

- a. Long-lived dry (radionuclides with half-life greater than or equal to 120 days)
- b. Short-lived dry (radionuclides with half -life less than 120 days)

### **2. Liquid Waste**

- a. The Office of Environmental Health and Safety will provide appropriate containers for liquid waste. The use of other containers than the aforementioned must have the approval of the appropriate Radiation Safety Officer. Aqueous solutions with pH between 2.1 and 5 or 10 and 12.4 should be normalized prior to placement in the approved Office of Environmental Health and Safety/UCDHS Health Physics waste jug. For aqueous solutions with pH less than or equal to 2 or greater than or equal to 12.5 or that contain regulated hazardous chemicals, contact EH&S/Health Physics Office for disposal instructions.

The following liquids classified as aqueous are: water, detergent, ethyl alcohol, buffers,

salts, acetic acid and mild acids such as TCA. Liquids must be separated into the following categories:

- i. Long-lived aqueous (radionuclides with half-life greater than or equal to 120 days)
  - ii. Short-lived aqueous (radionuclides with half-life less than 120 days)
- b. Each 5-gallon jug shall be stored in a secondary container.
3. Scintillation Vials
- a. Full vials are to be placed in the original honeycomb containers. If the honeycomb containers are not available, request empty containers from the Office of Environmental Health and Safety/UCDHS Health Physics. Vials must be separated into the following categories:

- i. Exempt vials (H-3 and C-14 in concentration less than 0.05 microcurie/ml)
- ii. Regulated vials (i.e., anything other than exempt vials described above)

4. Biological Waste

a. Individual researchers must have access to freezer storage for animal carcasses until the scheduled waste collection date. Notify the Office of Environmental Health and Safety/UCDHS Health Physics prior to the time animal carcasses are ready for disposal.

b. Radioactive biologicals must be separated into the following categories:

- i. Long-lived biological (radionuclides with half-life greater than or equal to 120 days)
- ii. Short-lived biological (radionuclides with half-life less than 120 days)

c. Special arrangements for disposal of large animal carcasses must be made with the Office of Environmental Health and Safety/UCDHS Health Physics prior to administering radioactive materials.

5. Sharps

Sharps are defined as syringe needles, broken glassware, or other items, which have a sharp edge or point that might penetrate the human skin. These items must be disposed of in an approved hard-walled container. For waste pick-up the hard wall container is placed in the dry trash box.

6. Non-compactable Dry Waste

Non-compactable dry waste is defined as dry waste with a half-life greater than 120 days that can not be compacted into a 55 gallon drum.

**J. DISPOSITION OF RADIOACTIVE WASTE**

1. All waste will be picked up by a staff member of the Office of Environmental Health and Safety/UCDHS Health Physics. The containers must be properly labeled and sealed. Twenty-four hour to forty-eight hour notification should be given to allow time for pickup and replacement of containers. For campus pick up requests, use the EH&S website (<http://ehs.ucdavis.edu>). For UCDHS pick ups, call 916-734-3355 to schedule a waste pickup.

2. Disposal Through the Sanitary Sewer

Disposal of liquid radioactive waste through the sanitary sewer system is prohibited unless

specifically approved on the RUA.

3. Disposal by Burial

Disposal by burial is prohibited, except when specifically authorized and directly supervised by the campus/UCDHS Radiation Safety Officer.

4. Unusual Radioactive Waste Disposal Problems

The campus/UCDHS Radiation Safety Officer will assist in the development of a method of disposal for unusual waste problems (e.g., radioactive infectious waste). A method must be developed and defined as a "Condition and Restriction" on the RUA.

**K. WASTE MINIMIZATION**

1. All radioactive material users should develop and implement source reduction and waste minimization programs. Work with unsealed radioactive materials must be performed such that contamination is minimized. Waste minimization begins by first determining the causes of potential contamination and then reducing or eliminating them. After work is completed, a thorough check of all items used for radioactivity should be made. Only those items which are radioactive and considered waste should be disposed of as radioactive waste. Other items which can either be decontaminated or are not radioactive should be recovered, or sent to their normal non-radioactive waste stream.
2. The use of unsealed radioactive materials should be minimized consistent with the objectives for which the material was obtained. Items which are not radioactive, but have been marked as radioactive must have the radiation symbols removed or defaced prior to their being released as non-radioactive materials. For more information on source reduction and waste minimization, contact the Office of Environmental Health and Safety 530-752-1493/UCDHS Health Physics 916-734-3355.

#### IV. EXPOSURE STANDARDS AND DOSIMETRY

##### A. RADIATION DOSE LIMITS

1. In accordance with state law, every effort shall be made to maintain radiation doses by humans to levels that are as far below the appropriate regulatory limits as is reasonably achievable (ALARA). As a guide to assist in maintaining radiation doses ALARA, the following UC Davis administrative guidelines should not be exceeded.

During a calendar year either a or b will be effective - whichever is most limiting.

- a. Total Effective Dose Equivalent. 2.5 rem per calendar year (25 mSv).
  - b. Committed Dose Equivalent to any organ other than the skin of the whole body or the lens of the eye. 25 rem per calendar year (250 mSv)
  - c. A dose to the lens of the eye. 7.5 rem per calendar year (75 mSv).
  - d. Shallow dose equivalent to the skin of the whole body. 25 rem per calendar year (250 mSv).
  - e. Shallow dose equivalent to any extremity. 25 rem per calendar year (250 mSv).
  - f. The radiation dose to a minor (under 18 years of age) shall be less than 10% of the above guidelines.
2. In a situation where the above administrative guidelines have been or are about to be exceeded:
    - a. The appropriate Health Physics office will immediately begin investigating the circumstances by which the radiation dose was received or is about to be received.
    - b. The Director, Health Physics Programs or designee must immediately determine the need to issue a "cease and desist order" to prevent an unnecessary radiation dose or the possibility of exceeding of 10 CFR 20 limits (as referenced by Title 17 CCR).
    - c. Except where such action may cause injury to another human being or reduce the effectiveness of essential medical care, individual users of radiation sources are required to stop work whenever they have good reason to believe that the dose designated in the UC Davis dose guidelines may have been or will be exceeded. Individual users must notify the Office of Environmental Health and Safety/UCDHS Health Physics immediately. After hours call 911, or if at the Medical Center, call the Hospital Operator or page the Safety Officer at 916-762-1994.
    - d. Before work continues, the appropriate health physics office, the principal investigator, and the individual workers involved will establish a written plan of action such that:
      1. Radiation doses can be reasonably maintained ALARA.
      2. The appropriate regulatory limits will not be exceeded.
    - e. An event report shall be written and reviewed by the appropriate Radiation Use Committee for each action required under a. through d. above.
  3. An authorized user who becomes pregnant is encouraged to notify her supervisor of her pregnancy. Upon notification, the appropriate Health Physics office will implement lower dose limits to protect the embryo/fetus.

A "declared pregnant woman" is a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception. The radiation dose limits for the fetus of a declared pregnant radiation worker is 500 mrem over the period of pregnancy not to substantially exceed a rate of 50 millirem per month (see Section XI for link to Safety Net #54).

4. Radiation fields outside restricted areas shall be controlled such that for all uses of ionizing radiation, no one member of the public can be reasonably expected to receive a radiation dose greater than 2 millirem in any one hour or more than 100 millirem in any one calendar year.
5. Occupancy factors, machine use factors, and other such factors that account for the time radiation fields are present or the time a member of the public is present in the radiation field, may be used in determining compliance with the 100 millirem standard in section 4 above.

## **B. DOSIMETRY**

The campus Radiation Safety Officer/UCDHS Radiation Safety Officer shall provide dosimetry to certain personnel to aid in the assessment of radiation exposure. Dosimetry will be issued only when careful evaluation establishes a need for the use of this monitoring technique. These devices provide legal records of radiation exposure; therefore, it is imperative that they only be used as prescribed. When prescribed, they must be worn at all times while working with radionuclides or radiation-producing machines. They must be stored away from radiation sources and protected against heat, moisture, or contamination. Personnel must return their dosimetry to the appropriate Health Physics office for processing at the intervals set by health physics. Lost dosimetry must be immediately reported to the appropriate health physics office. If the dosimetry is later recovered, it must immediately be sent to the appropriate health physics office for processing. Any information concerning expected exposure of the person the lost/recovered dosimeter was assigned to, or suspected exposure of the lost/recovered dosimeter itself must be reported immediately.

## **C. PERSONNEL EXPOSURE RECORDS**

Personnel exposure data shall be part of the permanent records maintained at the Office of Environmental Health and Safety/UCDHS Health Physics. Upon written request by an employee or student, the Office of Environmental Health and Safety/UCDHS Health Physics will provide a copy of the individual's exposure history.

It is the responsibility of staff who concurrently work at other facilities where dosimetry is issued to provide the Health Physics Office with their exposure reports so that accurate annual radiation doses can be calculated.

## **D. RECORDS OF PRIOR EXPOSURE**

Employees or students requiring personnel dosimetry will be required to complete a "Statement of Experience" form indicating all locations where previous radiation exposures may have occurred. With the signed consent of the employee, a letter will be sent to the indicated facility requesting the current calendar year exposure history. A reasonable effort will be made to obtain the individual's prior lifetime exposure levels.

## **E. BIOASSAY REQUIREMENTS**

1. Conditions Requiring Participation in the Thyroid Bioassay Program
  - a. Personnel with prior exposure history to radioactive iodine should have a baseline bioassay performed prior to beginning any laboratory use of radioiodine. A termination bioassay should be performed within one month of the last possible exposure to radioiodine(s) (when operations are discontinued, or when employment at UC Davis is discontinued).
  - b. Any individual who works with or opens a primary vial containing a quantity of radioiodine in a volatile or nonvolatile form that meets or exceeds the following

quantities, must be monitored by the Office of Environmental Health and Safety/UCDHS Health Physics within the specified time periods for the radioiodine involved.

Volatile Radioiodine	Primary Vial Amount	Time Frame for Bioassay
I-125	≥ 10 mCi	24 - 72 hours
I-131	≥ 1 mCi	24 - 72 hours
I-123	≥ 5 mCi	6 - 24 hours
Nonvolatile	≥ 50 mCi	24 - 72 hours

NOTE: When using radioiodine in human therapy applications, personnel preparing therapeutic quantities in liquid form containing more than 30 mCi shall have a bioassay within 24 - 72 hours. Individuals who administer therapeutic quantities of radioiodine in bound form are not required to receive a bioassay. Doctors, nurses, and maintenance staff working with radioiodine therapy patients are exempt from bioassay requirements under normal circumstances.

- c. When laboratory monitoring results indicate the possibility of internal contamination.
- d. At the discretion of a Health Physicist:  
Special monitoring schedules (i.e., monthly, weekly) and methods (i.e., whole body counts, urinalysis, air sampling, tracking DAC-hours, etc.) may be established for frequent high activity users or special projects. All monitoring programs specific to a project should be included as a condition of the RUA.
- e. Upon the request of the Principal Investigator or the radioiodine user.

2. Conditions Requiring Participation in the Tritium Bioassay Program

- a. Personnel with prior exposure history to tritium should have a baseline bioassay performed prior to beginning any laboratory use of tritium. Personnel who will be working with tritium at the levels described in 2.b. below should have a baseline bioassay prior to the start of work and a termination bioassay upon completion of work with tritium or removal from the RUA.
- b. Any individual who introduces into a physical or chemical process at any one time a quantity of tritium greater than or equal to 100 mCi on a bench top or 1 Ci in a fume hood must be monitored by the Office of Environmental Health and Safety/UCDHS Health Physics.
- c. When laboratory monitoring results indicate the possibility of internal contamination.
- d. At the discretion of a health physicist.

**F. MEDICAL SURVEILLANCE POLICY**

Personnel will be placed under medical surveillance when their potential exposure to ionizing radiation is such that somatic biological effects susceptible to detection by medical evaluation could occur. This situation will only occur for individuals who have exceeded or are likely to have received a radiation dose in excess of 100 rem to any part of their body. Such appraisal will include an acute and chronic exposure evaluation and will consider many variables (duration, source, type of potential exposure, etc.). Personnel will be referred as follows:

1. Employees

Employees requiring medical surveillance will be referred to the examining physician by the campus Radiation Safety Officer/UCDHS Radiation Safety Officer.

2. Students

Students requiring medical surveillance during academic pursuits will be referred to the Student Health Center.

**G. MEDICAL RECORDS AND EXAMINATIONS**

1. Medical records will consist of the following:

- a. Any measurement made to detect internally deposited radionuclides.
- b. Information necessary to assess exposure.
- c. Personnel dosimetry records.

2. It is the policy of the UC Davis to qualitatively and quantitatively determine internally deposited radionuclides.

3. Examinations will be performed on any student or employee who is suspected of ingesting, inhaling, or absorbing radionuclides at defined levels of activity. Urinalysis, thyroid counting, whole body counting, and eye examinations may be included. Radiation workers must be scheduled to appear at a prearranged time for the measurement. Failure to appear may result in suspension of the RUA.

4. Copies of examination records will be maintained in the Office of Environmental Health and Safety/UCDHS Health Physics and coordinated with one's personal dosimetry data.

**H. EXCESSIVE RADIATION EXPOSURES**

The Director, Health Physics Programs, the campus Radiation Safety Officer, or the UCDHS Radiation Safety Officer must be notified immediately if any person is known or suspected of receiving internal or external exposure to radiation above the State mandated limits. These limits are twice the UC Davis administrative limits delineated in Part A.1. of this section of the Radiation Safety Manual. Such personnel will cease and desist all activities involving work with radiation. If any uptake is suspected, an appropriate bioassay will be required by the Office of Environmental Health and Safety/UCDHS Health Physics. When exposure of an individual to radiation must be reported to the State Radiologic Health Branch pursuant to regulations, such individuals will be notified in writing of the nature and extent of their exposure. If the individual has or is suspected to have an exposure greater than 100 rem to any part of the body, they shall be placed under medical surveillance as defined above (F.).

## V. HANDLING REQUIREMENTS

### A. TRAINING

All radiation workers planning work with ionizing radiation for a time period greater than 20 working days in a calendar year shall meet one of the following requirements:

1. Radiation Workers with Approved Previous Experience

a. Campus

All individuals planning work with ionizing radiation, and have previous experience working with radiation, must attend the Laboratory Radiation Safety class within 30 days of being added to the RUA.

b. UCDHS

All researchers planning work with ionizing radiation, and have previous experience working with radiation, must attend the Laboratory Radiation Safety class and complete the intranet radiation safety exam within 30 days of being added to the RUA. (This exam is available on the internet at <http://ehs.ucdavis.edu/>, Radiological, Radiological Exams & Quizzes. Take the Laboratory Radiation Safety examination.)

2. Radiation Workers with No Previous Experience

a. Campus

All individuals planning work with ionizing radiation, and have no previous experience, must attend the Laboratory Radiation Safety class before commencement of radiation work and being added to a RUA.

b. UCDHS

All researchers planning work with ionizing radiation, and have no previous experience, must attend the Laboratory Radiation Safety class and complete the intranet radiation safety exam before commencement of radiation work and being added to the RUA. (This exam is available on the internet at <http://ehs.ucdavis.edu/>, Radiological, Radiological Exams & Quizzes. Take the Laboratory Radiation Safety examination.)

3. Radiation Workers' Re-training

Retraining is required every three years. Nurses radiation safety training is required every two years. Retraining requirements can be fulfilled by either attending a radiation safety seminar or completing the intranet radiation safety exam. This exam is available on the internet at <http://ehs.ucdavis.edu/>, Radiological, Radiological Exams & Quizzes. Take the Laboratory Radiation Safety examination. Failure to meet the above requirements after two notifications will result in a loss of radiation use privileges, termination from the RUA(s), and possibly confiscation of radioactive materials.

4. Classroom Use

Training requirements for ionizing radiation can be met by either the instructor or a member of the Office of Environmental Health and Safety/UCDHS Health Physics presenting a summary of radiation safety guidelines prior to radiation work. If the instructor provides the training, the lesson plan must be approved by the Health Physics office. If the appropriate Health Physics office will be providing the training, they must be notified 30 days in advance to prevent scheduling conflicts and to allow time for lesson plan preparation.

5. Exceptions to the above policy are as follows:

- a. Temporary radiation workers (i.e., radiation work period less than or equal to 20 working days per year) must be trained by their supervisor (who is an authorized user on the RUA) in good health physics practices and policies, and must be directly supervised. Radiation safety exams or attendance at a Radiation safety seminar are recommended, but not mandatory. The Principal Investigator must document the radiation safety training that they provide.
  - b. Radiation workers may be exempt from this policy if, in the professional judgement of the Director of Health Physic Programs, this training is unnecessary. Documentation of the justification for this exemption will be maintained on file in the Office of Environmental Health and Safety/UCDHS Health Physics.
6. Attendance at a radiation safety class and receipt of a passing score on a radiation safety exam may both be required at the discretion of the Director of Health Physics Programs, appropriate Radiation Safety Officer, or Radiation Use Committee, based on a prior compliance history of the user or RUA. These cases will be reported at the appropriate Radiation Use Committee meeting.
  7. New employees working with a moisture density gauge (hydroprobe) must attend the Hydroprobe Safety class prior to working with the gauge.
  8. New users working with Analytical x-ray machines must attend the Analytical X-Ray Safety class.
  9. New users working with radiation-producing machines used for diagnostic or clinical type purposes must take the on-line diagnostic x-ray exam. This training requirement for users of radiation-producing machines in the healing arts is satisfied by the appropriate State certificate or permit. The Director of Health Physics, the UCDHS Radiation Safety Officer, the Health System Radiation Use Committee, or the Radiation Safety Committee may require additional training.
  10. Training provided by the PI or their designee for personnel named to their RUA with respect to radiation safety shall be conducted annually in accordance with the Injury Illness Prevention Program (IIPP). Such training should cover specific hazards and protective measures, procedures and safety protocols for the RUA.

## **B. STORAGE OF RADIOACTIVE MATERIALS**

Radioactive materials shall be stored to prevent unauthorized access or removal. The storage area must be correctly posted (See Section C. below). The storage area must not create a "radiation area" and must be shielded or sealed to keep exposures as low as reasonably achievable.

## **C. POSTING AND USE OF SIGNS**

1. Posting of signs, caution warning, labels, and so forth are used to advise personnel of potential hazards with respect to radiation and radioactive materials. The standard radiation symbol, warning signs, labels, and other such items shall only be used to provide information and warnings to personnel. Any other use is prohibited.
2. Radioactive Materials Posting.
  - a. An area or room which has radioactive materials in excess of 10 times the quantities in Appendix C to 10 CFR 20.1001-20.2401, shall be posted with a sign bearing the radiation symbol and the words "Caution, Radioactive Materials" or "Danger, Radioactive Materials".
  - b. Containers of radioactive materials must be identified by a label, tape, or tag. At a minimum, a trefoil and the words, "Caution, Radioactive Material", shall be used. Where practicable, the radionuclide and quantity of material in curies or its sub units, or becquerels shall be noted. If the container will be used for the storage of radioactive materials for more than 24 hours, it must be labeled or have written on the container tag

- the radionuclide(s) and quantity of material in curies or its sub units, or becquerels in addition to the trefoil and words "Caution, Radioactive Material".
- c. The physical boundaries of the rooms, buildings, or areas used by a Radiation Use Authorization set up on a permanent basis shall be considered Restricted Areas as defined in this manual. There shall be at least one copy of DHS Form RH 2364, "Notice to Employees" conspicuously posted in the restricted area. Every room or separate area within the restricted area shall have at least one copy of the UC Davis "Guidelines for Radioactive Material" form posted conspicuously.
3. Radiation Use Authorizations which are authorized to have temporary locations (e.g. Nuclear Medicine, Health Physics, etc.) need only provide the appropriate warning signs and postings such as radioactive materials, radiation area signs and so forth. A temporary location shall be authorized for no more than 30 days.
  4. Contamination Control Zones
    - a. Contamination control zones are established in accordance with section V.D., "Contamination Control", of this manual. The contamination control zone markings are used to define the zone's boundaries and provide warnings to personnel of the potential radiation risks involved. Contamination control zone markings may consist of tape, barrier rope, signs, postings or a combination of the above.
    - b. Small contamination control zones are small defined work areas such as laboratory bench tops, sections of floor, etc. which are delineated by using:
      1. Yellow tape with or without the radiation symbol, and the words "Radioactive Materials", "Caution Radioactive Materials", "Danger Radioactive Materials", "Contamination" or Contaminated Area" or;
      2. Tape with yellow and magenta alternating stripes.
    - c. Large contamination control zones such as rooms or large areas must be posted with a caution sign which has the radiation symbol, the words "Contamination" or "Contaminated Area", and a brief set of instructions for entry requirements. For large areas, barrier rope or tape must be used.
    - d. Large contamination control zones must have controlled entrances and exits. The major control measure is a "Step Off Pad". The step off pad may be made of paper or plastic. The final step off pad used for exiting a large contamination control zone is a neutral zone that is maintained at less than 220 dpm/100 cm<sup>2</sup> for beta-gamma emitters and less than 22 dpm/100 cm<sup>2</sup> for alpha. This final step off pad must bear the words "Contamination Area" or "Entering Contaminated Area" or equivalent language which an individual will read upon entering the large contamination control zone. As a person exits a contamination control zone, there should be brief instructions as to what items to remove before the individual steps on to the step off pad. Self-monitoring is required prior to stepping off the step off pad.
  5. Radiation Areas
    - a. A radiation area is defined as a room or area where radiation levels are such that an individual could receive in excess of 5 millirem in one hour at 30 centimeters from the nearest accessible surface of a radiation source.
    - b. The area shall be posted with a sign bearing the radiation symbol and the words, "Caution Radiation Area".

6. High Radiation Areas

- a. A high radiation area is defined as a room or area where radiation levels are such that an individual could receive in excess of 100 millirem in one hour at 30 centimeters from the nearest accessible surface of a radiation source.
- b. The area shall be posted with a sign bearing the radiation symbol and the words, "Caution High Radiation Area", or "Danger, High Radiation Area".
- c. For high radiation areas that are temporary and will only exist for periods of less than one week or patient rooms, the following controls in lieu of the controls specified in 10 CFR 20.1601 may be used:
  1. Posting of the high radiation area caution signs.
  2. A door or other means of securing the area such that entry by unauthorized personnel is not likely or;
  3. An individual who is in attendance and can assure that unauthorized personnel do not enter the high radiation area.
  4. For rooms that hold patients treated with radioactive materials, the nursing staff assigned to the patient will satisfy conditions 2 and 3 above; provided that the nursing staff members have received radiation safety training.
- d. For rooms or areas other than patient rooms that hold patients treated with radioactive materials, if no one is physically present in the room or at the entrance to assure that no unauthorized personnel enter the area, then the room or area must be locked or otherwise secured against unauthorized entry.

7. Very High Radiation Areas

- a. A very high radiation area is defined as a room or area where radiation levels are such that an individual could receive in excess of 500 rem in one hour at one meter from the nearest accessible surface of a radiation source.
- b. The area shall be posted with a sign bearing the radiation symbol and the words, "Grave Danger, Very High Radiation Area".
- c. The precautions listed in 10 CFR 20.1602 shall be followed.

8. Airborne Radioactivity Areas

- a. Areas, rooms or enclosures which meet the conditions as defined in 10 CFR 20.1003, "Airborne Radioactivity Area" are considered airborne radioactivity areas.
- b. These areas shall be posted with signs which have the radiation symbol and the words, "Caution, Airborne Radioactivity Area" or "Danger, Airborne Radioactivity Area".
- c. Areas which may be airborne radioactivity areas due to the presence of an inert gas such as Xenon-133 or short-lived materials due to accelerator production (half-life of less than 2 hours) and do not have airborne radioactivity for more than 24 hours do not require posting as airborne radioactivity areas.

**D. CONTAMINATION CONTROL**

1. Control Levels

- a. Radioactive contamination controls are normally prescribed through the RUA process.

However, controls may also be posted through the use of signs, written procedures, and verbal instructions by health physics personnel.

2. The meaning of the term "restricted area" is the meaning used in 10 CFR 20.1003 (See Definitions).
3. Within the laboratory, contamination control will be required. Consequently, the following types of areas and limits are established:
  - a. Controlled Areas: Controlled areas are areas where radioactive material is used or stored. The contamination limits for a controlled area are as follows:
    1.  $\leq 60$  cpm/100 cm<sup>2</sup> above background for beta-gamma emitters.
    2.  $\leq 18$  cpm/100 cm<sup>2</sup> above background for alpha emitters.OR
    3.  $\leq 220$  dpm/100 cm<sup>2</sup> above background for beta-gamma emitters.
    4.  $\leq 22$  dpm/100 cm<sup>2</sup> above background for alpha emitters.
  - b. Small Contamination Control Zone: A small contamination control zone (defined work area) is a small area where unsealed radioactive materials may be used. The contamination limits for this type of area are as follows:
    1.  $\leq 300$  cpm/100 cm<sup>2</sup> above background for beta-gamma emitters.
    2.  $\leq 88$  cpm/100 cm<sup>2</sup> above background for alpha emitters.OR
    3.  $\leq 1100$  dpm/100 cm<sup>2</sup> above background for beta-gamma emitters.
    4.  $\leq 110$  dpm/100 cm<sup>2</sup> above background for alpha emitters.
  - c. Large Contamination Control Zone: A large contamination control zone is a large area, typically an entire room or laboratory with a "step-off pad", where unsealed radioactive material may be used. The contamination limits for this type of area are as follows:
    1.  $\leq 300$  cpm/100 cm<sup>2</sup> above background for beta-gamma emitters.
    2.  $\leq 88$  cpm/100 cm<sup>2</sup> above background for alpha emitters.OR
    3.  $\leq 1100$  dpm/100 cm<sup>2</sup> above background for beta-gamma emitters.
    4.  $\leq 110$  dpm/100 cm<sup>2</sup> above background for alpha emitters.

Small contamination control zones may be established in a large contamination control zone. These are specifically defined and stated in the "Conditions and Restrictions" of the RUA. These small areas may have contamination levels as follows:

1.  $\leq 600$  cpm/100 cm<sup>2</sup> above background for beta-gamma emitters.
2.  $\leq 176$  cpm/100 cm<sup>2</sup> above background for alpha emitters.

OR

3.  $\leq 2200$  dpm/100 cm<sup>2</sup> above background for beta-gamma emitters.
  4.  $\leq 220$  dpm/100 cm<sup>2</sup> above background for alpha emitters.
- d. Unrestricted areas are areas in which no radiological safety controls are instituted, e.g., offices, hallways, etc. The contamination limits for an unrestricted area are the same as a controlled area.
  - e. The contamination limits for contamination control zones are intended to apply upon the completion of work with radioactive materials or at the end of the work day, whichever occurs first.
  - f. Where it is not practicable to achieve the above limits (for example, the interior of a glove box or the storage of contaminated equipment), appropriate contamination controls and postings shall be utilized. For articles such as small tools, pieces of equipment and so forth, the item should be placed in a plastic bag or container and sealed. The bag or container must be labeled with a radioactive materials tape or sticker, the count (dose) rate of the item, radionuclide, date the item was placed in the bag, and the initials of the person placing the item in the bag. Items exhibiting readings greater than 2 mR/hr or 10,000 cpm on a GM survey meter at one foot must be placed in a shielded area.

3. Work Involving Unsealed Radioactive Materials

- a. The use of radioactive materials in liquid, gaseous, or aerosol form must be planned so as to maintain contamination levels from such activities as low as reasonably achievable. Such planning must include a written safety protocol which takes into account appropriate contamination control measures.
- b. Prior to the start of work with unsealed radioactive material, a contamination control zone (defined work area) shall be established. This zone will be defined by markings, the use of surface coverings, signs and other contamination control measures. These zones are determined by the levels of anticipated contamination during work in the control zone:

<b>Zone Class</b>	<b>Beta-Gamma Emitter Limits (Averaged over 1 square meter)</b>	<b>Alpha Emitter Limits (Averaged over 1 square meter)</b>
1	$\leq 20,000$ dpm/100 cm <sup>2</sup>	$\leq 2,000$ dpm/100 cm <sup>2</sup>
2	$> 20,000$ dpm/100 cm <sup>2</sup> $\leq 50,000$ dpm/100 cm <sup>2</sup>	$> 2,000$ dpm/100 cm <sup>2</sup> $\leq 5,000$ dpm/100 cm <sup>2</sup>
3	$> 50,000$ dpm/100 cm <sup>2</sup>	$> 5,000$ dpm/100 cm <sup>2</sup>

- c. As a minimum, a contamination control zone for work with unsealed radioactive materials shall:
  1. Have surfaces covered with plastic backed absorbent paper or equivalent material.
  2. Have an approved safety protocol on file which specifies the contamination control measures to be taken in addition to other radiation safety measures.

- d. The individuals who are working with the radioactive material will wear as a minimum laboratory coats and one pair of disposable plastic gloves (preferably two pairs of disposable plastic gloves). Safety glasses are recommended.
- e. If it is determined that contamination levels will be no greater than 20,000 dpm/100 cm<sup>2</sup> from beta-gamma emitters or 2,000 dpm/100 cm<sup>2</sup> from alpha emitters averaged over one square meter work can be performed with the requirements of sections V.D.3. If contamination levels in excess of these limits are anticipated, the control measures specified in section V.D.3.f. must be implemented. If contamination is expected to be present on floors, then individuals working in the area must wear shoe covers and use a step-off pad or equivalent control measure instituted at the entrance and exit point of the control zone.
- f. If it is determined that contamination levels will be greater than 20,000, but less than or equal to 50,000 dpm/100 cm<sup>2</sup> from beta-gamma emitters, or greater than 2,000, but less than or equal to 5,000 dpm/100 cm<sup>2</sup> from alpha emitters averaged over one square meter work can be performed with the following requirements:
  - 1. Work surfaces and the floors of the area where the work is to be done must be covered with protective coverings such as plastic, plastic backed absorbent paper, etc.
  - 2. Personnel must wear cotton or paper coveralls, plastic high top shoe covers, two pair of plastic gloves and a surgeon's cap or equivalent. The gloves must be taped to the coverall, the front opening of the coverall taped and the area where the shoe covers meet the coveralls must be taped.
  - 3. A step-off pad or equivalent control measure must be instituted at the egress and exit points for the control zone.
  - 4. Personnel must remove their protective clothing prior to leaving the contamination control zone. They then must monitor their entire body focusing close attention to their hands, feet, and face using a "pancake" type GM survey meter or equivalent. For alpha emitters, use an alpha probe and for I-125, use a thin crystal NaI detector. This monitoring must be done in a area where the background is less than 300 cpm and the monitoring must be done as soon as possible after exiting the contamination control zone.
  - 5. The contamination control zone must be posted as a "Contaminated Area" in addition to other necessary postings.
- g. Work which involves probable contamination levels greater than 50,000 dpm/100 cm<sup>2</sup> from beta-gamma emitters or greater than 5,000 dpm/100 cm<sup>2</sup> from alpha emitters averaged over one square meter must either be done in a glove box or fume hood. Projects which involve the above expected levels of contamination may only start after a review of the task by the appropriate EH&S Health Physics Office. The review must determine the potential for emission of radioactive materials into the environment and other areas within the restricted area. Consideration must be given to air sampling or other evaluation measures for airborne radioactivity. Work involving the above levels of contamination outside of a glove box or fume hood may only be performed with the approval of the appropriate Radiation Safety Officer, the Director, Health Physics Programs, and the appropriate Radiation Use Committee.
- h. If it is determined at any time that the contamination control measures being used are inadequate, the work area shall be placed in a radiologically safe condition and work with unsealed radioactive materials must cease until such time as proper contamination control measures are instituted.
- i. Whenever individuals who are working with unsealed radioactive materials leave the

work area for the purposes of temporally stopping work (e.g., coffee breaks, lunch, etc.), or they are finishing work for the day, the individual and the work area must be monitored for contamination.

- j. Any contamination which is found shall be decontaminated to levels which are as low as reasonably achievable and the proper contamination controls instituted.
- k. In cases of frequent contamination problems, the appropriate health physics office shall investigate and document the apparent causes of failure by the authorized users of radioactive materials to detect, control, clean or report the contamination. If one of the causes of failure to detect contamination appears to inadequate sensitivity of portable survey instruments used for direct contamination monitoring or inadequate sensitivity of instruments used for counting wipe samples, the authorized user(s) shall be required to obtain and utilize more sensitive survey/counting instruments as specified by the appropriate Health Physics Office.

#### **E. PROTECTIVE CLOTHING**

- 1. Personnel working with unsealed radioactive material must wear protective garments. Open-toed shoes and sandals are not permitted. The usual laboratory coat and disposable gloves (preferably double gloves) are considered as the minimum fulfillment of this requirement. Safety glasses are recommended.
- 2. Personnel working with more than 1 mCi of unsealed radioactive material must cover their legs with pants, or an extra long laboratory coat, or a long skirt to protect them against absorption of radioactivity in the case of a spill.
- 3. Additional protective garments may be required by the campus Radiation Safety Officer/UCDHS Radiation Safety Officer. Exceptions may be granted by the appropriate Radiation Safety Officer.

#### **F. STORAGE AND CONSUMPTION OF FOOD**

- 1. The storage and consumption of food are prohibited in laboratories and other locations authorized for the storage and use of radioactive materials.
- 2. Refrigerators/freezers used for storage of radioactive materials must not be used for storage of food and beverages.

#### **G. PERSONAL HYGIENE**

Mouth pipetting is not permitted while working with radioactive materials. After working with radioactive material all personnel must wash their hands thoroughly.

#### **H. GENERAL MONITORING**

- 1. Immediately following the use of radioactive materials, the area and equipment used must be monitored for contamination and radiation fields by those directly involved with the project. At a minimum, wipe test results must be documented once every two weeks if work with radioactive materials has occurred. Unless the RUA has more restrictive requirements, monitoring results must be kept for inspection by the Office of Environmental Health and Safety/UCDHS Health Physics office and by the State Radiologic Health Branch. Documented monitoring results may be required more frequently at the discretion of the appropriate Radiation Safety Officer or Radiation Use Committee.
- 2. Each department that uses radioactive materials must have in its possession, or have access to, a survey instrument(s) capable of detecting low levels of radiation. These instruments must be immediately available for routine monitoring and for hazard surveys following a radiation incident. All survey instruments shall have a calibration check at least yearly by the Office of Environmental Health and Safety/UCDHS Health Physics.

**I. MONITORING BY THE OFFICE OF ENVIRONMENTAL HEALTH AND SAFETY/UCDHS HEALTH PHYSICS**

The Office of Environmental Health and Safety/UCDHS Health Physics will conduct periodic surveys of all areas that have significant radiation present, and institute or recommend appropriate corrective measures in cases where contamination or other sources of potential hazard are detected. Radioactive sealed sources in excess of exempt quantities (greater than 100  $\mu\text{Ci}$  for beta or gamma emitters or 10  $\mu\text{Ci}$  for alpha emitters) shall be tested for external contamination/leakage twice yearly, unless they are "storage only" sources or sources certified for longer testing periods. Sealed sources shall not remain in service if their leak test yields a level greater than or equal to 0.005  $\mu\text{Ci}$ .

**J. ANIMAL USE**

1. Caging and Labeling

Small animals given radioactive materials shall be caged separately from non-radioactive animals. Cages shall be labeled with appropriate radiation warning signs. Information on the label must include the name of the person responsible for the experiment, a contact phone number, the radionuclide, quantity, and date of administration. Special arrangements through the Office of Environmental Health and Safety/UCDHS Health Physics Office must be made prior to administering radioactive materials to large animals. Animals that receive radionuclides and are not sacrificed at the end of the project must be properly identified and controlled. Approval from the Office of Environmental Health and Safety/UCDHS Health Physics will be required prior to relocation of any such animals.

2. Contamination Control

Radioactive excreta, animal carcasses and tissues, contaminated cage bedding, etc., must be handled in accordance with radioactive waste disposal procedures. Projects likely to produce large quantities of waste or involving unusual contamination potentials will be reviewed by the campus Radiation Safety Officer/UCDHS Radiation Safety Officer prior to the start of work to assure that facilities are adequate.

3. Training of Caretakers

Principal Investigators are responsible for assuring that animal caretakers and custodians are aware of potential hazards and are adequately trained and supervised in the observance of necessary precautions.

4. Sale of Experimental Animals

The appropriate Radiation Safety Officer and the Institutional Animal Care and Use Committee (IACUC) must approve the sale of animals containing radionuclides. To arrange for sale, contact the Office of Environmental Health and Safety/UCDHS Health Physics. All costs will be borne by the researcher.

5. Release of Animals Containing Radioactive Material

Animals that have received radionuclides for therapeutic or diagnostic purposes shall not be released unless:

- a. The external radiation dose level is such that if a person were in contact with the animal for 1 hour per day they would receive less than 100 mrem per year as computed from the following formula:  $1.44 (T_{e\ 1/2}) (\text{surface dose rate}) < 100 \text{ mrem}$ . Where,  $T_{e\ 1/2}$  is the effective half life in hours.

- b. The level of activity per day in the excreta does not exceed 10 times the values listed in the Tolerance Factor table given in Section XI, "Appendices" of this Manual.
- c. A consent form explaining the hazards and precautions must be given to the owner of the animal. The owner must understand the warning, instructions, and sign a form prior to the therapy dose being administered which provides the owner with instructions concerning radiation safety precautions. This form will be part of the "Safety Protocol" for the therapy and maintained by the Principal Investigator.

**K. SAFE WORK PRACTICES**

1. Good housekeeping is required where radioactive materials are used. Work areas must be clearly defined at the borders, uncluttered, and recognizable as distinct from non-radioactive work areas.
2. Work surfaces must be covered with absorbent paper to facilitate decontamination. Bench coverings must be changed frequently and clearly defined with "Caution-Radioactive Material" tape.
3. Work areas must be located away from heavy traffic or doorways.
4. When moving any radioactive solution between approved locations, place the material in a sealed container within a sturdy secondary container.
5. Laboratory coats, gloves, closed-toed shoes, dosimetry (when required), and any additional required protective clothing must be worn.
6. Monitor yourself and your laboratory coat for radioactive contamination before leaving the work area.
7. Do not eat or drink in the laboratory where radioactive materials are used or stored.
8. Do not store food or drink in the laboratory.
9. Do not handle doorknobs, drawer pulls, elevator buttons, etc., with gloves on.

**L. AUDIT POINT SYSTEM**

1. System Application

- a. The audit point system provides a consistent tracking method of non-compliance with the investigator's Radiation Use Authorizations and provides principal investigators with a current compliance status report. The system is based on points assigned to individual compliance issues (Section V.L.4) during the authorization performance index time period (PITP).
- b. The Director of Health Physics Programs and the appropriate Radiation Use Committee will evaluate and assign points in those circumstances that may range from zero (e.g., an accident that did not violate any safety protocol) up to 100 depending on the severity of the violation.

2. Primary Audit Points

All points assigned to an RUA are based on the following rolling performance index time period (PITP) of the authorization:

<u>HR</u>	<u>PITP</u>	<u># Audits During PITP</u>
1	4 years	4
2	2 years	8
3	1 years	12
4	1 years	12

All points assessed during the primary audits that are performed during the performance index time period are totaled.

3. Follow-up Audit Points

Follow-up audits are required for certain non-compliance issues (see table in section V.L.7.). Failure to correct an identified deficiency in a timely manner is considered a serious violation of the safety conditions of the RUA.

If an RUA follow-up audit confirms that a non-compliance issue has not been corrected, the points per issue is multiplied by 1.5 and added to the primary audit total.

Example: RUA #0001 has accumulated 30 points during 3 primary audits in the first nine months of the performance index time period. During the next primary audit the RUA was observed to be in non-compliance for having personal items in a radioactive material work area, which has an individual point assignment of 50. At this point, the RUA point total is 80. At this time, a warning letter will be sent to the PI. Two weeks later, at the required follow-up audit, the issue is found to be uncorrected. The authorization's point total is now  $80 + 75 = 155$ . This will result in the RUA being placed on probation and two more audits being performed within the next 30 days. For further explanation of the compliance review system, see the flow diagram in section V.L.8. or contact the appropriate Radiation Safety Officer.

## 4. Individual Compliance Issues

<b>Audit Sheet Code No.</b>	<b>Non-Compliance Issue Description</b>	<b>Points Per Issue</b>
003	Laboratory cluttered/messy	5
007	Notice to Employees not posted	5
009	Handling Guidelines not posted	5
010	Laboratory/room not posted	5
020	Clean Areas not identified	5
021	Storage of food/drink in the laboratory	50
022	Mouth pipetting	50
023	Marked RAM/Equipment in clean area	50
024	Smoking/eating/drinking in the laboratory	50
025	Laboratory coat not worn	5
026	Gloves not worn	5
031	Protective clothing/materials in public areas	10
032	Radioactive material work areas not defined	5
033	Absorbent paper not used or ineffective	5
034	Radioactive material container not identified	5
037	Personal Items in radioactive material work area	50
038	Annual fume hood check not performed	5
039	Fume hood used with inadequate face velocity	5
040	No flow indicator on fume hood	5
042	Fume hood overloaded/overcrowded	5
055	Emergency eyewash/shower	5
088	Radioactive material work areas not monitored	10
089	Equipment used not monitored	10
090	Inadequate monitoring frequency per occurrence	50
091	Decontamination results not recorded	10
092	Inadequate radiation detection instrumentation	10
093	Loss of Control/Radioactive material in common trash	100
094	Contamination	see Table 5 below
095	Work area shielding not adequate	25
096	Radioactive material inventory incomplete	5

<b>Audit Sheet Code No.</b>	<b>Non-Compliance Issue Description</b>	<b>Points Per Issue</b>
103	Waste storage area shielding inadequate	15
104	Waste packaging inadequate	5
105	Waste containers not properly labeled	5
106	Secondary containers for liquid waste not used	5
107	Waste not properly segregated	15
108	Storage area not secured	15
112	Sharps in the dry waste	25
115	Insufficient storage space for waste	15
123	Personnel working with RAM not on RUA	33
124	Personnel not wearing assigned dosimetry	10
125	Bioassay not performed	33
126	Personnel training not in compliance	33
127	Inadequate or not following the Safety Protocol	25
128	Inappropriate footwear	5
129	Accumulation of radioactive waste	25
130	Radioactive material/item in unsecured control area	50
131	Violation of Safety Protocol	50
132	Events and Incidents	100
140	Conditions and Restrictions not met	50
141	Hood used without annual check	5
142	Other fume hood issues (e.g. sash missing/damaged)	5
143	Other (violation of Radiation Safety Manual)	100

5. Contamination Found in the Laboratory\*

Type of Area	Contamination Level (counts above background)		Points per Contaminated Area
	$\beta, \gamma$	$\alpha$	
Controlled or Unrestricted Area	61 - 120	19 - 35	15
	121 - 180	36 - 53	18
	181 - 240	54 - 71	21
	241 - 300	72 - 88	24
	> 300	>88	45
Small or Large Contamination Control Zone	301 - 600	89 - 176	10
	601 - 900	177 - 265	14
	901 - 1200	266 - 353	16
	> 1200	>354	30
Small Contamination Control Zone within a Large Contamination Control Zone	601 - 1200	177 - 354	5
	1201 - 1500	355 - 441	7
	1501 - 1800	442 - 529	8
	> 1800	>529	15

\*The contamination level for the above areas apply after work with unsealed radioactive materials has been completed, the after work surveys and monitoring has been completed and any necessary decontamination efforts applied.

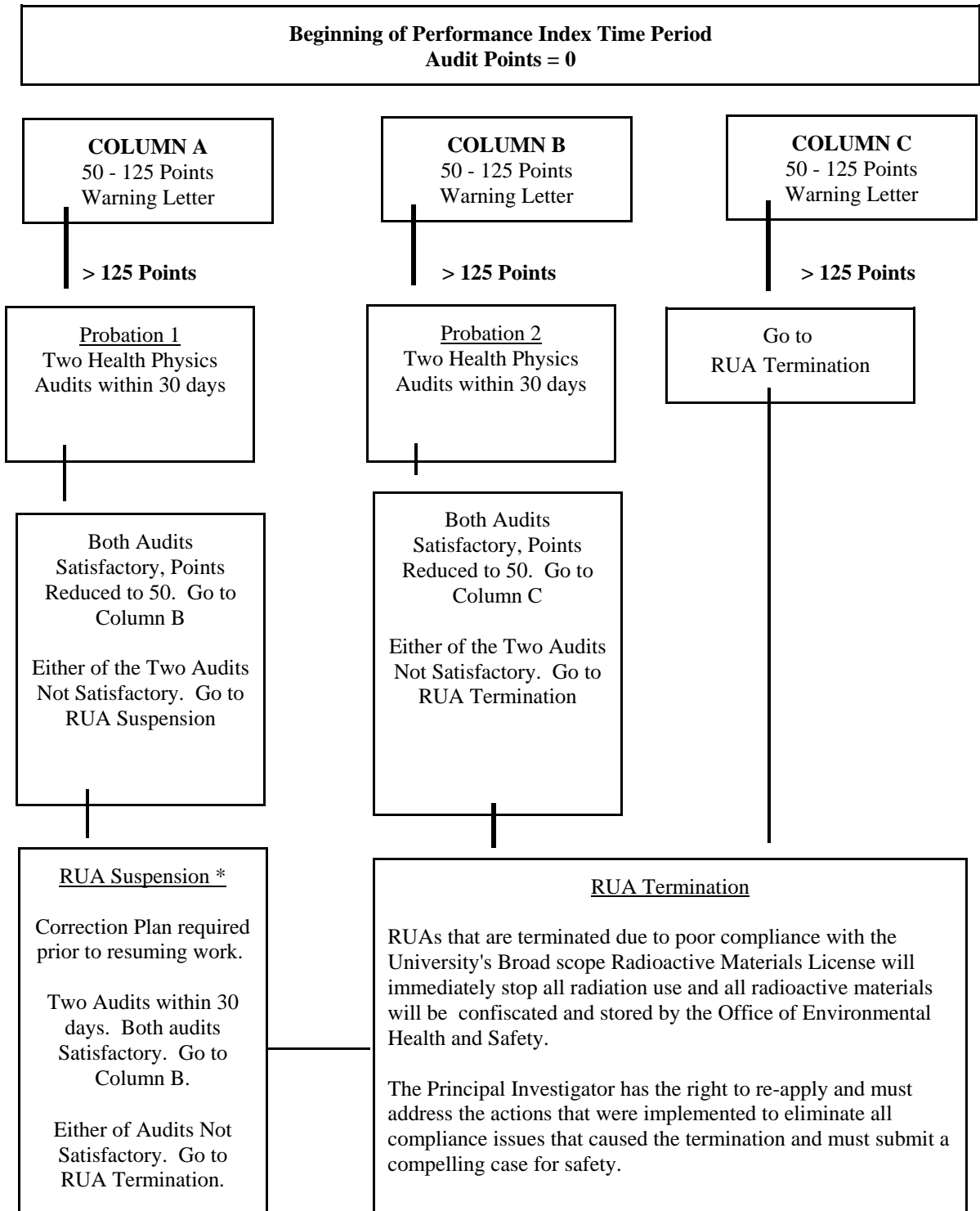
6. Principal Investigator Notification

After each audit the Principal Investigator will be informed of all recorded non-compliance issues and current point total. Recommendations will be provided as necessary or when requested by the Principal Investigator.

7. Time Table for a scheduled Follow-up

<b>Audit Code #</b>	<b>Non-Compliance Issue Description</b>	<b>Time Frame for Follow-up Audit</b>
021 or 024	Storage of food or Eating/Drinking in laboratory	14 Days
090	Inadequate monitoring frequency of laboratory	14 Days
092	Inadequate instrumentation	28 Days
093	Loss of Control/Radioactivity in common trash	14 Days
094	Contamination	2 Days
095	Inadequate shielding of work area	14 Days
103	Inadequate shielding for waste	14 Days
129	Accumulation of radioactive waste	28 Days
130	Radioactivity in unrestricted area	7 Days

8. Compliance Review System Flow Diagram +



\* Minimum suspension time: 30 days

+ The RUC reserves the right to take more or less restrictive action depending upon extenuating or exacerbating circumstances that may apply.

9. Warning Letter

If an RUA accumulates 50 points or more during its PITP, the Principal Investigator will receive a Warning letter. The purpose of this letter, from the RSO, is to inform the Principal Investigator of the status of the RUA and caution them to be aware of the point total with regards to possible probation. A response from the Principal Investigator with a corrective action to prevent recurrence is required.

10. Probation Level 1 and 2

If an RUA accumulates 125 points during its performance index time period, the RUA will be placed on Probation 1 or 2, as appropriate. During the probation status, two health physics audits will be performed within 30 days. If both audits are satisfactory, the RUA's point total will be reduced to 50. If either of the audits are not satisfactory, the RUA will be suspended until a correction plan is received, reviewed and approved by the appropriate Radiation Use Committee. Upon committee approval, two health physics audits will be performed within 30 days. If both audits prove that the corrective actions taken have been successful, the RUA's point total will be reduced to 50. If either of the audits are unsatisfactory, the RUA will be terminated by the appropriate Radiation Use Committee.

11. Radiation Use Authorization Evaluation for "Perfect" and "Good" Compliance Status

All RUAs are reviewed annually for compliance with the University's radioactive materials license by the appropriate Radiation Use Committee, which directly effects the RUA Assessment Factor (see Section II.G.3). The RUA may then be awarded a perfect or good compliance status. This may result in a reduction of the Radiation Use Authorization's hazard rating and hence, the annual RUA fees.

## **VI. RADIATION-PRODUCING MACHINES (X-RAY)**

### **A. APPROVAL FOR ACQUISITION**

Departments that would like to use a radiation-producing machine shall obtain the approval of the Office of Environmental Health and Safety/UCDHS Health Physics prior to acquisition. This must be done in order to assure that the machine is registered with the State, appropriate safety protocols are written, and necessary shielding will be in place.

### **B. PROPOSAL FOR USE**

Departments preparing to purchase or acquire radiation-producing machine(s) must submit their application for use to the Office of Environmental Health and Safety/UCDHS Health Physics for review. The application must include the following information:

1. Name of the Principal Investigator and extent of experience (see Section IX for link to "Statement of Experience" form) with radiation-producing machines. For clinical use, the primary supervisor/operator shall furnish this information.
2. Names of other personnel who will use the machine and their "Statements of Experience".
3. Description of the machine and its proposed use.
4. Health and safety provisions must also be provided, these include such items as shielding and monitoring devices. The Office of Environmental Health and Safety/UCDHS Health Physics is available to provide assistance for any shielding calculation.
5. Approval of departmental chairperson or dean.
6. A "Safety Protocol" specifically designed for the particular radiation-producing machine will be on file with the Office of Environmental Health and Safety/UCDHS Health Physics. (General Safety Protocols are found at: <http://ehs.ucdavis.edu>, Radiological, Forms/Manuals/Plans, Radiation Safety Manual Forms, Forms 37-41.) Each individual assigned responsibility for operating the machine shall be thoroughly familiar with the safety protocol prior to assuming his/her duties as an operator.

### **C. PURCHASE**

All purchases of radiation-producing machines shall be made through the normal procedures of the Purchasing Department after approval from the Office of Environmental Health and Safety/UCDHS Health Physics. After the machine is purchased and becomes operable, an annual or biennial inspection fee is paid to the Office of Environmental Health and Safety. This fee only applies to machines which are not owned by UCDHS. UCDHS pays machine registration fees which are recharged to departments that operate x-ray machines.

### **D. SURVEY OF INSTALLATION**

Unless otherwise specified, the Office of Environmental Health and Safety/UCDHS Health Physics must survey, prior to use, the installation of radiation-producing machine(s), whether newly acquired, relocated, modified, or repaired to determine the effectiveness of health and safety hazard controls. For new installations or modifications of existing sites, a Request for Shielding Design form must be submitted to the Office of Environmental Health and Safety/UCDHS Health Physics. All radiation-producing machines must be inspected to assure compliance with 17 CCR 30305.

### **E. WARNING SIGNS AND SIGNALS**

All devices and equipment capable of producing radiation when operated shall be appropriately labeled to caution individuals that such devices or equipment produce radiation. Each area where ionizing radiation exists shall be posted in accordance with 17 CCR. Rooms or areas that contain permanently installed x-ray

machines as the only source of radiation shall be posted with a sign or signs that bear the words, "CAUTION X-RAY." The standard UCD X-Ray safety protocol for a given type of radiation-producing machine shall be posted in each room containing that particular type of machine.

**F. OPERATION SIGNALS**

Any radiation-producing machine that is located in an area accessible to individuals and is capable of producing a dose rate in excess of 100 millirem per hour, shall be provided with conspicuous visible or audible alarm signal so that any individual at or approaching the tube head or radiation port is aware that the machine is producing radiation. This alarm signal shall be activated automatically only when radiation is produced and is not required for radiographic and fluoroscopic machines used solely in the healing arts.

**G. CHANGES IN LOCATION AND DISPOSITION**

1. Changes in the location or disposition of radiation-producing machines must have prior approval of the Office of Environmental Health and Safety/UCDHS Health Physics.
2. The Office of Environmental Health and Safety/UCDHS Health Physics must be given notice of intent to dispose or transfer the radiation-producing machine to another user in order to notify the State of the transfer or disposal of the radiation-producing machine.
3. If the radiation-producing machine is to be disposed of, all radiation-producing parts (e.g., X-ray tube) must be destroyed.

**H. STATE RADIOLOGIC HEALTH BRANCH NOTIFICATION**

All radiation-producing machines shall be registered with the State of California, Department of Public Health, Radiologic Health Branch . Each Radiation Safety Officer is responsible for assuring that the State is notified of the total number of radiation-producing machines under their jurisdiction including the type, location, and use.

**I. GENERAL REQUIREMENTS FOR THE OPERATION OF RADIATION-PRODUCING MACHINES**

1. Only personnel who are named as authorized users on the Machine Use Authorization or hold a valid permit or certificate to operate such machines from the State shall operate or supervise the operation of a radiation-producing machine.
2. When required, dosimetry shall be worn whenever the machine is producing ionizing radiation. This dosimetry shall be supplied by and returned to the appropriate Health Physics Office in accordance with the time table established.
3. Personnel who are required to wear lead aprons or other similar radiation protection devices should visually inspect these devices prior to each use for obvious signs of damage. If there appears to be any damage, the device should be taken out of service immediately. All lead clothing at UCDHS shall be inspected annually in accordance with UCDHS P&P 1728.
4. All individuals are responsible for using the radiation-producing machine that they are operating:
  - a. In a safe manner.
  - b. In accordance with the written protocols and the UCD safety protocol (see Section IX) for the machine.
  - c. In such a manner that their exposure, their fellow workers, and the patient's exposure is as low as is reasonably achievable.
5. Personnel who supervise or operate radiation-producing machines are responsible for notifying their

fellow workers and their supervision of any unsafe operating conditions and failures of the machine to operate according to specifications.

6. The appropriate department head is responsible for assuring that radiation-producing machines are kept in a good state of repair, safety systems are functioning, and the equipment meets specifications.
7. Records of the use of the radiation-producing machine shall be kept. The records shall as a minimum:
  - a. Record the kVp, mA, and if applicable, mA-sec used for each use of the equipment.
  - b. Names of operators.
  - c. Patient name or identification in cases of medical or veterinary use.
  - d. Equipment failures.
  - e. Failure of any safety system (e.g., interlocks, warning lights, etc.).
8. Technique charts and safety procedures should be available at all locations where x-ray machines are used.
9. All radiation-producing machines shall have periodic Quality Assurance inspections. The purpose of these inspections is to assure that the equipment is operating in a safe manner, in accordance with specifications, and where applicable, in accordance with State mandated standards. These inspections will only be performed by the appropriate health physics office or personnel designated by the appropriate health physics office. The following general inspection table applies. More frequent inspections may carried out as necessary.

Category of Machine	Inspection Interval
X-ray and Fluoroscopic Equipment Used for Humans	Once every year
X-ray and Fluoroscopic Equipment Used in Veterinary Medicine	Once every 2 years
Veterinary Dental X-ray equipment	Once every 2 years
Other Radiation-producing Equipment	As specified in the MUA

**J. TRAINING**

1. Anyone authorized to use a radiation-producing machine (diagnostic or analytical) shall either attend a training course taught by the Office of Environmental Health and Safety/UCDHS Health Physics on the safe use of x-ray machines or pass a Radiation X-ray Safety exam. Refresher courses or exams will also be required every three years. Exceptions to this training requirement may be given to those holding state issued permits or certificates (e.g., certified x-ray technologists, X-ray Supervisor and Operators, etc).
2. Exemptions for diagnostic x-ray training may be given to Veterinary Medicine Radiologists if they are board certified.
3. State regulations require that anyone operating x-ray machines in the healing arts obtain a certificate or permit from the state if they do any of the following:
  - a. Activate an x-ray generator (machine).
  - b. Use fluoroscopy.

- c. Perform functions of a radiologist.
  - d. Supervise one or more certified radiologic technologists, or students of radiologic technology.
4. Exemptions: A physician is not required to obtain a certificate or permit from the State if that physician:
  - a. Requests an x-ray examination through a certified supervisor and operator.
  - b. Performs radiology only in the course of employment by an agency of the Federal government and only at a Federal facility.
5. Applicants who are certified by the American Board of Radiology (ABR) must apply for and obtain a certificate.
6. All applicable continuing education credits as mandated by the state and outlined in Title 17 are the responsibility of the permit holder.
7. Applicants can obtain study materials and State application(s) for certification from the State Radiologic Health Branch. Physicians who pass the examination, and ABR-certified physicians must forward copies of their X-ray Supervisor and Operator permit(s) to the Medical Staff Office upon initial receipt and at the time of each renewal.

#### **K. RESTRAINT/MANIPULATION OF PATIENTS DURING EXAMINATIONS**

No individual shall be regularly employed to hold or support humans or animals during radiation exposures. Operating personnel shall not perform this service except infrequently and then only in cases where no other method is available.

Any individual holding or supporting a person or animal during radiation exposure should wear protective gloves and apron with a lead equivalent of not less than 0.25 millimeters. Under no circumstances shall individuals holding or supporting a person or animal place part of their body directly in the primary beam.

#### **L. SOURCES OF INCIDENTAL X-RAYS**

Some electrical equipment operating at potentials of 20 kVp and above is capable of producing x-rays. Generally, only equipment operating at potentials of 30 kVp and above is capable of producing x-rays of biological significance. Anyone acquiring or constructing equipment operating at or above 30 kVp, or employing cathode-ray tubes, rectifier tubes, klystrons or magnetrons must contact the appropriate Radiation Safety Officer so that the machine may be checked under operating conditions to insure that no significant exposures will occur to operating personnel.

#### **M. SPECIAL REQUIREMENTS FOR THE USE OF FLUOROSCOPY IN THE HEALING ARTS INCLUDING VETERINARY MEDICINE**

When personnel use fluoroscopy equipment for treatment and diagnosis, the following special requirements must be met:

1. Whenever practical, shielding (e.g., drapes, screens, etc.) of 0.25 mm lead equivalent thickness should be interposed between the operator and the patient so as to reduce the exposure from scattered radiation. This shielding will not be substituted for the use of leaded aprons and gloves.
2. Aprons must be worn when the fluoroscopy machine is producing radiation. These aprons must have a lead equivalent thickness of at least 0.25 mm. However, a 0.5 mm lead equivalent thickness apron is recommended.

**N. SPECIAL REQUIREMENTS FOR RADIOGRAPHIC INSTALLATIONS IN VETERINARY MEDICINE**

When personnel use radiographic equipment for the diagnosis of animals, the following special requirements must be met:

1. The user must stand well away from the tube housing and the animal during the exposure.
2. The user must not stand in the useful beam.
3. If the film must be held, it must be held by individuals not occupationally exposed to radiation.
4. Hand-held fluoroscopic screens must not be used.
5. The tube housings must not be held by the user.
6. No individuals other than the operator should be in the x-ray room while exposures are being made unless such person's assistance is required. Health physics personnel, at their discretion, may be present in the x-ray room while exposures are being made (e.g. surveys, observation for compliance with safety issues, etc.)
7. In any application in which the user is not located behind a protective barrier, protective aprons having a lead equivalent of not less than 0.25 millimeters must be worn by the user and any other individual in the room during the exposure.
8. No individual must be regularly employed to hold or support animals during radiation exposures. Operating personnel must not perform this service except very infrequently and then only in cases in which no other method is available. Any individual holding or supporting an animal during radiation exposure must wear protective gloves and apron having a lead equivalent of not less than 0.25 millimeters.

**O. SPECIAL REQUIREMENTS FOR VETERINARY MEDICINE DENTAL RADIOGRAPHIC INSTALLATIONS**

When personnel use dental radiographic equipment for the diagnosis of animals, the following special requirements must be met:

1. No individual occupationally exposed to radiation is permitted to hold patients or films during exposure, nor must any individual be regularly used for this service.
2. During each exposure, the operator must stand a least 6 feet from the patient or behind a protective barrier.
3. Only the animal must be in the useful beam.
4. Neither the tube housing nor the position indicating device (cone, cylinder) must be hand held during the exposure.
5. Fluoroscopy must not be used in dental examinations.
6. Only persons required for the radiographic procedure shall be in the radiographic room during the exposure.

**VII. INTENTIONALLY LEFT BLANK**

## **VIII. USE OF RADIOACTIVE MATERIALS AND RADIATION-PRODUCING MACHINES IN THE HEALING ARTS**

Radioactive materials and radiation-producing machines are used for the diagnosis and treatment of patients and in human research so as to provide the maximum benefit to patients while minimizing exposure to the public and UCDHS personnel. The UCDHS Health Physics Program's mission is to assure that appropriate radiation safety practices are implemented while providing consultative services to enhance education, public service, research and patient care.

### **A. CONTROL OF RADIOACTIVE MATERIALS AND RADIATION-PRODUCING MACHINES IN MEDICINE AND HUMAN RESEARCH**

1. All uses of radioactive materials or radiation-producing machines that will be used for the treatment, diagnosis, or human research must be approved by the UCDHS Health Physics Office.
  - a. Diagnosis and treatment of patients with radioactive materials or machine produced radiations (e.g., radiography, fluoroscopy, etc.) is controlled and approved by the issuance of a Human Use Radiation Use Authorization or Human Use Machine Use Authorization.
  - b. Human research involving the use of ionizing radiation is controlled by the approval of the research protocols by the UCDHS Radiation Use Committee. The research must then be conducted under a Human Use Radiation Use Authorization or Human Use Machine Use Authorization.
  - c. Human research involving the use of ionizing radiation must also be approved by the UCD IRB.
2. The physician's responsibility is to assure that radioactive material and radiation-producing machines are used in a medically responsible manner. In addition, physicians are required to coordinate with the UCDHS Health Physics office in order to assure that radiation safety measures are designed and implemented which will not compromise the patient's or human subject's medical condition. For campus based human research, coordination with the campus Health Physics section must also be done.
3. A written directive is an authorized user's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject as specified by 10 CFR 35.40.
4. The UCDHS Radiation Safety Officer is responsible for assuring that radiation safety measures are implemented and followed which will protect both the public and radiation workers, while at the same time fostering good medical practice. This is achieved by a coordinated effort with the appropriate physicians and medical staff.
5. The UCDHS Radiation Use Committee also acts as a peer review committee with respect to the medical use of ionizing radiations. The UCDHS Radiation Use Committee has the authority to review both radiological safety and medical aspects of radioactive materials and machine produced radiation use in humans. The UCDHS Radiation Use Committee's scope of authority extends to UCDHS activities.

### **B. APPROVAL OF HUMAN RESEARCH WITH IONIZING RADIATION**

1. Approval for the use of ionizing radiation in a research project by the Health System Radiation Use Committee is required whenever:
  - a. The proposed use of the ionizing radiation is for human research.
  - b. The proposed use of the ionizing radiation is not considered to be a standard treatment or

diagnostic that would have been performed even if the research was not performed.

2. Request for approval of human research with ionizing radiation shall be submitted to the Health System Radiation Use Committee prior to such research commencing. No human research with ionizing radiation shall be performed without the approval of the UCD Institutional Review Board (IRB) and the Health System Radiation Use Committee.
3. The UCDHS Radiation Safety Officer shall assure that a suitable application form is developed and maintained for the submission of requests for human research with ionizing radiation to the Health System Radiation Use Committee.
4. The Health System Radiation Use Committee shall review the application for human research with ionizing radiation for:
  - a. Medical and research issues.
  - b. Radioactive Drug Research Issues (see section E, Radioactive Drug Research Committee, below).
  - c. Qualifications of personnel to perform research and workers who will be assisting in the research.
  - d. Radiological safety issues.
  - e. Patient care issues.
5. The Health System Radiation Use Committee shall only approve a human research application when the Committee is reasonably certain:
  - a. That the research will be effective.
  - b. That the radiation doses to the human subjects and staff will be as low as reasonably achievable while providing for the maximum benefit from the human research.
  - c. That the human subjects will be given a reasonable standard of care.
6. Self Subject Policy
  - a. Principal Investigators and their staff will only be allowed to use themselves as the subject in a radiation human use research protocol when they adhere to current policies established by the UCD IRB.
7. Use of Staff for Human Radiation Research
  - a. UC Davis staff members (campus or Health System) may only be used as subjects in human radiation research under conditions in which the staff members participation is voluntary.
  - b. Coercion of any kind, retaliatory measures, or punitive actions to force staff to volunteer as subjects for human radiation research is strictly prohibited.

**C. SELECTION OF PHYSICIANS TO USE RADIOACTIVE MATERIAL FOR HUMAN TREATMENT AND DIAGNOSIS**

1. Physicians named to a Radiation Use Authorization approved for human treatment and/or diagnosis with radioactive materials should be board certified in their area of specialty practice. Board certification with the American Board of Nuclear Medicine, American Board of Radiology, American Board of Osteopathic Radiology, British "Fellow of the Faculty of Radiology" or "Fellow of the Royal

College of Radiology", or Canadian Royal College of Physicians and Surgeons are considered acceptable certification organizations. The physician must also be authorized to practice medicine in the state of California.

2. Physicians without the above board certifications may be named as users for human treatment and diagnosis with radioactive materials on Radiation Use Authorizations provided that they meet the appropriate training and experience requirements described in 10 CFR 35.
3. Physicians who are in specialty training (i.e., residents and fellows) may work on Radiation Use Authorizations for human treatment and diagnosis provided that they are under the general supervision of a physician who is board certified in the specialty area that the resident physician is being trained in. Residents and fellows performing therapy must be under the direct supervision of a board certified physician.
  - a. Direct supervision means that the supervisor must be in line of sight of the individual being supervised. The supervisor must be able to observe and assure that the individual being supervised is following directions and performing the task correctly. The supervisor must be able to immediately apply proper instruction and corrective actions.
  - b. General supervision means that the supervisor must be in the general area, or on the campus grounds and able to respond to any questions or problems that the supervised person may have.
4. Physicians conducting human research with ionizing radiation should have sufficient medical experience to assure that the medical aspects of the use of the ionizing radiation will not cause the human subject(s) undue harm. Generally, this is evidenced by meeting the qualifications stated in preceding sections. However, the Health System Radiation Use Committee may approve other physicians to conduct human research with ionizing radiation, provided that the committee determines that the physician has the necessary skills to perform the research in a safe and effective manner.

#### **D. SELECTION OF RADIOPHARMACEUTICALS AND RADIONUCLIDES FOR HUMAN USE**

1. Physicians who are authorized users may select radiopharmaceuticals in accordance with their professional judgement for the treatment and diagnosis of human beings provided that the radiopharmaceutical is approved for human use by the FDA.
2. Radioactive materials used in human research must be part of an approved UCD Human Subjects research study and:
  - a. Be already approved by the FDA as a drug or;
  - b. Be under a manufacturer's sponsored IND program;
  - c. Be under a physician's sponsored IND program or;
  - d. Be radioactive materials which are not drugs (tracer studies) and are approved by the Radioactive Drug Research Committee (See section VIII.E. of this manual).

#### **E. RADIOACTIVE DRUG RESEARCH COMMITTEE (RDRC)**

1. The RDRC is typically composed of the members of the UCDHS Radiation Use Committee. The RDRC approves the use radioactive substances which are used in research intended to obtain basic information regarding metabolism (including kinetics, distribution, and localization), human physiology, pathophysiology, or biochemistry. The RDRC does not approve or convene concerning the use of radioactive materials intended for immediate therapeutic, diagnostic, or similar purposes, or to determine the safety and effectiveness of the radioactive materials in humans.

2. The committee conducts business as specified in 21 CFR 361, Prescription Drugs For Human Use Generally Recognized as Safe and Effective and Not Misbranded: Drugs Used in Research. Research requirements are contained in the instruction section of Form 5, Human Radiation Use Research Application.
3. If the number of subjects exceeds 30 per year or the subjects will be under the age of 18, a special summary must be submitted to the FDA. This special summary shall be of the form specified in 21 CFR 361.1 (b) (3).
4. The RDRC annual report is compiled by the UCDHS Health Physics Department and presented for review by the RDRC chairperson and the Director, UCD Health Physics Programs prior to its submission to the Food and Drug Administration (FDA). Each PI shall complete the forms provided to them by the UCDHS Health Physics Office by January 15. This report must be transmitted to the FDA on or before January 31 of each year.

**F. EXEMPTION FROM FULL RADIATION USE COMMITTEE REVIEW FOR HUMAN RESEARCH STUDIES**

1. Human research studies involving the use of ionizing radiation may be exempt from full review by the UCDHS Radiation Use Committee, provided that:
  - a. The protocol has received national multi-center review by the FDA or SWOG (Southwest Oncology Group), POG (Pediatric Oncology Group) or similar review group. Attach a copy of the review or other evidence of external review and approval. Other than for cancer therapy, the total effective dose equivalent for each subject can not exceed 5 rem. This exemption does not apply for studies involving the therapeutic application of radioactive materials.
  - b. The patients would receive the diagnostic procedure or therapeutic treatment whether or not enrolled in the protocol.
  - c. The protocol involves the performance of diagnostic imaging exams on cancer patients who are already receiving or will be receiving radiation therapy and the diagnostic exams are a small fraction of the therapeutic dose.
  - d. The protocol involves the performance of diagnostic imaging exams on cancer patients who are already receiving or will be receiving chemotherapy.
  - e. The protocol involves performing DEXA scans on human subjects and the total effective dose equivalent does not exceed 5 mrem per subject for the entire study.
  - f. Other criteria as approved by the UCDHS Radiation Use Committee.
2. Whenever the research meets one of the above criteria, then the use of the ionizing radiation only requires that Form 35, *Protocol Exemption from Full Radiation Use Committee Review*, be complete and signed by the Principal Investigator. The consent forms are reviewed for accuracy and inclusion of UCDHS radiation risk language by the UCDHS Health Physics Office. The Director of Health Physics Programs or designated alternate approves the consent form.

**G. SELECTION AND USE OF RADIATION-PRODUCING MACHINES**

1. Radiation-producing machines used for the treatment and diagnosis of humans must be approved and registered with the State Radiologic Health Branch. The machines must be in a good state of repair and meet the State Quality Assurance standards for the type of machine.
2. Radiation-producing machines used in human research must meet the same standards as the same type

of machine used for treatment or diagnosis of humans. If a radiation-producing machine is of an experimental design, or involves a modality which is not covered by State regulations, then its use must be specifically approved by the UCDHS Radiation Use Committee.

3. Personnel who use radiation-producing machines for the treatment and diagnosis of humans must be qualified in accordance with the conditions of Section VI of this manual. No requirement herein shall be interpreted in such a way so as to restrict the ability of physicians to request diagnosis and therapeutic procedures in accordance with their medical judgement. However, the physician who actually directs the use of the radiation-producing equipment (i.e., determines machine settings such as kVp, mA, mAs, etc.) must be fully qualified in accordance with section VI of this manual. Personnel who operate or manipulate the controls of a radiation-producing machine at the direction of a physician for the purposes of treatment and diagnosis of humans (e.g., Radiology and Radiation Therapy Technologist), must be fully qualified in accordance with State law.

## **H. MEDICAL EVENTS AND SENTINEL EVENTS**

1. The provisions in 10 CFR 35.3045 apply to the medical events of radiation to human beings during both clinical and research procedures.
2. In summary, medical events are defined as a dose of 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ, tissue or shallow dose equivalent to the skin in association with one of the following:
  - a. The total dose delivered differs from the prescribed dose by 20 percent or more or falls outside the prescribed dose range.
  - b. The fractionated dose delivered differs from the prescribed dose for a single fraction by 50 percent or more.
  - c. The administration of the wrong radiopharmaceutical.
  - d. The administration of a radiopharmaceutical by the wrong route.
  - e. The administration of a radiopharmaceutical or radiation to the wrong individual.
  - f. The administration of a dose by the wrong mode.
  - g. A leaking sealed source.
  - h. Other criteria as defined in 10 CFR 35.3045.
3. In order to comply with the provisions of 10 CFR 35.3045, records must be maintained for 10 years for any medical events which occur.
4. All medical events shall be verbally reported to the UCDHS RSO or one of the UCDHS Health Physicists within 4 hours of the medical event being determined. Under no circumstances are the Principal Investigator or other Departments to directly report medical event(s) to the State Radiologic Health Branch. Within 12 hours of the medical event being determined, a written report:
  - a. Shall be provided to the UCDHS Health Physics Office.
  - b. The following data must be reported utilizing the State Radiologic Health Branch form, DHS 8453:
    - i. Names of all individuals involved in the event including:

- (a). The supervising staff physician at the time of the medical event.
    - (b). The certified medical technologist (e.g., Nuclear Medicine, Radiation Therapist, etc.) at the time of the medical event.
    - (c). Any involved allied health personnel.
    - (d). The patient.
    - (e). The patient's referring physician.
  - ii. The Medical Record Number for the patient.
  - iii. A brief description of the event.
  - iv. The effect on the patient.
  - v. Dose in rem or millirem to the patient and the amount of radiopharmaceutical used in millicuries.
  - vi. Actions, if any, taken to prevent a reoccurrence.
5. The physician administering the radiopharmaceutical and/or radiotherapy shall be responsible for notifying the referring physician of the medical event within 24 hours.
  6. The patient involved in the medical event or the patient's responsible relative or guardian should be notified within 24 hours of the medical event. This notification should be made after conferring with the referring physician. In general, the referring physician should make the initial notification of the patient. However, if based on medical judgement, it is determined that such a notification will be harmful to the patient who received the medical event or the patient's responsible relative or guardian, then notification to these parties shall not be made. If the patient or the patient's responsible relative or guardian cannot be located within 24 hours, then the notification of medical event shall be made as soon as practicable.
  7. The UCDHS RSO or designee is responsible for assuring that a notification is made to the State Radiologic Health Branch within 24 hours of determining that a medical event has occurred.
  - 8.. The UCDHS RSO or designee is responsible for assuring that a written report is furnished to the State Radiologic Health Branch and the referring physician within 15 days of the initial medical event report.
  9. Upon request, a copy of this report will be furnished to the patient or the patient's responsible relative or guardian.
  10. Reports of medical events involving ionizing radiation shall be investigated by the UCDHS RSO or designee.
  11. Records of medical events shall be maintained for a minimum of 10 years.
  12. The following are reviewable events under the Joint Commissions Sentinel Event Policy. In either case, an Incident Report should be filed by the Department and a root cause analysis performed by the UCDHS Health Physics Office.
    - a. Prolonged fluoroscopy with cumulative dose greater than 1500 rads to a single field.
    - b. Any delivery of radiotherapy to the wrong body region or greater than 25% above the planned dose.

## **I. BRACHYTHERAPY**

1. Brachytherapy is performed in two basic modalities. Sealed sources are placed in the patient's body in close proximity to or within the tumor volume and left for several hours or days. This is known as low dose rate brachytherapy. In the second modality, a sealed source is delivered from a machine via a tube to a catheter in the patient's body. The sealed source remains in the vicinity of the tumor for a given period of time at given positions. This treatment typically requires less than one hour. This modality is referred to as high dose brachytherapy or high dose rate after loader (HDR) brachytherapy. Low dose rate brachytherapy typically requires the patient to be hospitalized for several days. High dose rate brachytherapy is typically done on an outpatient basis.
2. Radiation Use Authorizations that are authorized for human use brachytherapy must have a source custodian and at least one alternate source custodian named on the RUA. The source custodian is responsible for assuring that they or their alternates:
  - a. Maintain a written, running inventory of the brachytherapy sources which reflects the status of each sealed source.
  - b. Performs an inventory of sealed sources used in implants immediately after their return to the source storage room.
3. The UCDHS Health Physics Office is responsible for performing a quarterly inventory of the brachytherapy sealed sources and their leak testing.
4. For sealed sources used in low dose rate brachytherapy, a sealed source storage room shall be maintained. The room must be capable of being locked. Storage containers within the room should be shielded such that dose rates within the room are less than 5 millirem per hour at 30 cm (1 foot) from any one storage container with all sources in their containers.
5. All brachytherapy treatments must have a written treatment plan which is prepared in accordance with the treating physician's written directive. This treatment plan shall be prepared under the supervision of a medical physicist who is certified by the American Board of Radiology or other organization acceptable to the State of California. The treatment plan must be independently verified by an individual qualified to prepare a written treatment plan. This individual shall verify that:
  - a. The dose and dose rate calculations conform to the physician's written directive.
  - b. Placement and types of sources used are correct.
  - c. Identity of the patient is correct.
  - d. For the HDR, that the machine settings are correct and that the equipment to be used is in calibration. Prior to all treatments, the identity of the patient shall be independently verified.
6. For low dose rate brachytherapy, the following conditions shall be adhered to:
  - a. The UCDHS Radiation Safety Officer shall assure that provisions are made for determining levels of activity that may signal the need for extraordinary radiation safety precautions (e.g., adjacent room clearances, potential nursing stay time problems, etc.). When this situation occurs, both the medical personnel and the health physics staff must work together to determine the best radiation safety precautions that will result in good patient care as well as adherence to the provisions of State and Federal law.
  - b. A health physics staff member or an individual who has received special training in the radiation safety issues involved and is listed on the RUA as approved for this responsibility will observe and provide direction for radiation safety issues during the implantation of the radiation sources in the patient.

- c. A survey shall be taken of the room and its adjacent surroundings immediately after the sources are loaded into the patient. Appropriate radiation safety precautions (e.g., portable shielding) shall be taken to assure that radiation levels in the adjacent areas to the patient's room meet the following requirements:
    - i. No one individual could receive 2 millirem in any one hour.
    - ii. No one individual could receive 100 millirem over the course of the patient's expected stay. Occupancy factors may be used in determining compliance with this standard. Typically, factors of 0.25 will be used for halls, bathrooms, and other low occupancy areas. Patient beds that are occupied shall have an occupancy factor of one.
  - d. The room shall be posted as a radioactive materials area and with the necessary radiation area warning sign(s). If the dose rate at one foot from the brachytherapy patient is greater than 100 millirem per hour, then:
    - i. The nursing staff shall be provided with appropriate instructions by a member of the health physics staff.
    - ii. The room shall be posted as a high radiation area.
    - iii. Medical staff shall be reminded to minimize their time next to the patient, consistent with good medical practice.
  - e. The nursing staff shall be provided with instructions concerning radiation safety issues and stay times by a member of the health physics staff. These instructions are intended to be specific guidance given immediately after the source is in place and is not a substitute for the training requirements given in section V.A of this manual. Stay times shall be calculated to provide reasonable assurance that the UCD Dose Guidelines will be adhered to (see section VIII. M. of this manual).
  - f. Upon removal of the sources from the patient, a survey of the patient, the patient's room and bedding shall be made to assure that no sources were left in the patient or the patient's room. All surveys must be documented by the person performing the survey.
  - g. Upon removal from the patient, the sources will be immediately transported to the sealed source storage area and inventoried by the source custodian or alternate source custodian. The inventory shall be performed prior to discharge of the patient. If a source is missing or unaccounted for, the UCDHS Health Physics Office shall be notified immediately.
7. High Dose Rate Brachytherapy
- a. Radiation Use Authorizations which are authorized to use HDR machines shall have written policies and procedures for the use of these machines.
  - b. The HDR machine shall meet the following calibration requirements:
    - i. Dwell time checked each treatment day.
    - ii. Travel distance of the source each treatment day.
    - iii. Delivered dose (dose rate) at a given distance whenever a new source is loaded into the machine.

- c. Ion chambers used for the calibration of the HDR must be calibrated at least once every two years.
- d. The HDR machine must be tested at least once each month:
  - i. For Source Travel Time Error.
  - ii. Dose accuracy to within  $\pm 5\%$  and upon installation.
- e. The HDR treatment room must be shielded such that when the source is fully out of the machine, dose rates outside of the room will be such that no one individual could receive 2 millirem in one hour, or 100 millirem in any one year. Occupancy factors may be taken into consideration for the 100 millirem in any one year standard.
- f. The HDR treatment room shall have a door which can be kept locked whenever no one is in attendance. The door shall also have an interlock which will cause the HDR to retract its source should the door be opened whenever the HDR source is out of the machine (e.g., patient treatments, machine calibrations, etc.). The interlock shall be tested monthly.
- g. The HDR treatment room shall have an area radiation monitor which provides a visual indication inside and outside the treatment room whenever the HDR source is outside of the HDR machine. The visual alarm shall be configured such that when a patient treatment is in progress, the alarm is visible at the control console and in the patient treatment room.
- h. The HDR machine shall have an emergency "off" button. There shall also be an emergency "off" button within the treatment room close to the device. This emergency off system shall be tested monthly.
- i. During patient treatments, only the patient shall be in the HDR treatment room. The HDR treatment room shall have the means to maintain visual and audio contact with the patient or other personnel that may be in the treatment room. Normally, these means shall be by the use of remote video cameras, microphones, and speakers.
- j. An emergency plan shall be in effect. Elements of this plan shall include:
  - i. Provisions for actions during a medical emergency involving the patient.
  - ii. Actions to take should the source fail to retract fully into the HDR machine housing.
- k. Annual training shall be conducted for individuals authorized to provide treatment or operate the HDR machine. This training shall cover the following topics:
  - i. Principles of Radiation Protection
  - ii. Configuration and Conditions of the Treatment Room.
  - iii. Location and Operation of Safety Devices.
  - iv. Dry Runs of Emergency Procedures.
  - v. Emergency Notification(s).
  - vi. ALARA Policy.
- l. Prior to initiation of a treatment program (not individual treatments) and subsequent to each source exchange for a HDR machine, radiation surveys shall:

- i. Be made of the irradiator source housing with the source inside. If an exposure (dose) rate greater than 3 mR/hr at 20 centimeters from the housing is found, then treatments shall not proceed until the problem is found and corrected.
    - ii. With the source in the irradiate position, all areas adjacent to the HDR machine room shall be surveyed for radiation levels. If the criteria in section VIII.I.7.e. of this manual are exceeded, then treatments shall not proceed until the problem is found and corrected. After the initial loading, this survey is only required if the HDR is moved to a new location (e.g., another room), loaded with a higher than previous amount of activity, or a change in the room shielding configuration has occurred.
  - m. Repair, maintenance and source change out of the HDR shall be performed in accordance with the manufacturer's instructions and manuals. Personnel who perform such maintenance or source change outs shall either be the manufacturer's representative or trained in accordance with a manufacturer approved course for the repair and maintenance of the HDR.
8. Permanent Implants of Sealed Sources.
  - a. A health physics staff member or an individual who has received special training in the radiation safety issues involved and listed on the RUA as an approved user will observe and provide direction for radiation safety issues during the implantation of the radiation sources in the patient. (See link to Form 23 in Section IX of this manual.)
  - b. A radiation survey of the room where the implant was performed, surgical instruments, and waste shall be performed after the implant is completed. The purpose of this survey is to assure that no radioactive sources were inadvertently lost or misplaced.
  - c. A survey of the patient shall be performed. This survey is made to assess radiation safety guidelines for nursing staff and to assure that the dose to members of the public, other than the patient, can reasonably be expected to be less than 100 millirem in one year.
  - d. The patient's room shall be posted in accordance with section VIII.I.6.d. of this manual. The nursing staff shall be given instructions concerning radiation safety issues and stay times (Form 24) by a member of the health physics staff. Stay times shall be determined to provide guidance that will assist the nursing staff in maintaining their dose limits with the UCD Dose Guidelines.
  - e. Upon discharge, the patient shall be given instructions concerning actions to take which will maintain the exposure of others near them at a reasonably low level (Form 25). Directions shall also be given, requesting the patient to inform or notify the treating department and the UCDHS Health Physics Office if the patient is again hospitalized within a period equal to 10 times the radioactive implant's half life.
  - f. Immediately after the patient leaves the hospital room, a survey shall be made of the room, all bedding, bandages, and other materials that may contain a dislodged source.

#### **J. USE OF UNSEALED RADIOACTIVE MATERIALS FOR THERAPY**

1. Use of radioactive sources in liquid or in capsule form used for therapy may require the hospitalization of patients for radiation safety purposes. If the amount of radioactive material administered is such that a member of the general public is likely to receive greater than 500 millirem then the patient shall be hospitalized for radiation safety purposes. The current guidelines for release of patients administered radioactive materials will be used. Patients treated with I-131 in amounts of 33 millicuries or less do not require hospitalization. If the patient is treated with greater than 33 millicuries of I-131 or any other radionuclide, determination of the need for hospitalization is based on the potential for a member of the public to exceed 500 mrem due to radiation from the patient. The following steps will be performed.

- a. A nuclear medicine physician will assess the factors which may cause a member of the public to exceed the 500 mrem limit. This assessment includes, but is not limited to, the following factors:
    - i. Number, ages and relationship of persons living in the patient's home.
    - ii. Individuals who may be in proximity to the patient and their potential for exposure to radiation from the patient.
  - b. Calculation of the expected dose to a member of the public from the patient by the UCDHS Health Physics staff.
  - c. A set of written instructions provided to the patient by the nuclear medicine physician detailing any restrictions of the patient's normal activities.
  - d. The nuclear medicine physician's judgement that the patient will be compliant with instructions.
  - e. Concurrence by the nuclear medicine physician and the UCDHS Health Physics Section that any radiation dose to a member of the public can reasonably expected to be less than 500 mrem.
2. Whenever patients treated with radioactive materials for therapy purposes are hospitalized, whether or not for radiation safety purposes, appropriate contamination controls shall be instituted until the patient reaches 10 mCi of I-131 or its equivalent. At this point, the room will be decontaminated and the only contamination controls required will be the use of disposable eating utensils and place settings, and the collection of waste (e.g., trash) and used linens by the UCDHS Health Physics Office. These contamination controls will continue until such time as the items being collected exhibit count rates indistinguishable from background.
  3. After the radionuclide is administered and the patient is in their room, a radiation survey shall be performed to determine radiation levels for radiation safety purposes and visitor stay times. In addition, the adjacent areas of the room shall be surveyed. This is performed in order to assure that no member of the public will receive greater than 100 millirem in any one year or greater 2 millirem in any one hour due to radiation from the patient. Appropriate radiation safety measures (e.g., use of portable shielding) shall be taken to assure that those standards are met. Exception to these measurements may be granted by location and activity at the discretion of the UCDHS Radiation Safety Officer or the Director, Health Physics Programs when previous data exists to presume that the above referenced exposure limits will not be exceeded. This exception will be specified in the applicable RUA.
  4. The room shall be posted as a radioactive materials area and with the necessary radiation area warning sign(s) and contaminated area signs as required. If the dose rate at one foot from the patient is greater than 100 millirem per hour:
    - a. The nursing staff shall be provided with appropriate instructions by the health physics office.
    - b. The room shall be posted as a high radiation area.
    - c. Medical staff shall be reminded to minimize their time next to the patient, consistent with good medical practice.
  5. The nursing staff shall be provided with instructions concerning radiation safety issues and stay times by a member of the health physics staff. Stay times shall be calculated to provide reasonable assurance that the UCD Dose Guidelines will be adhered to.
  6. Patients who have been administered radioactivity lower than the amounts specified in section VIII.J.1. of this manual may be released as outpatients. They shall be given instructions concerning actions to take which will maintain the exposure of others near them at a reasonably low level.

Directions shall also be given, requesting the patient to inform or notify the treating department and the UCDHS Health Physics Office if the patient is again hospitalized within a period equal to 10 times the radionuclides' effective half life or two weeks, whichever is shorter (See link to Forms 9 & 10 in Section IX).

7. For unconditional release, the patient's room will be surveyed and decontaminated to a level of less than 220 dpm/100 cm<sup>2</sup> for loose surface contamination. Also for unconditional release, fixed contamination should be no more than 500 CPM above background, except for plumbing.
  - a. Plumbing for sinks, toilets, and so forth shall be marked with a radioactive materials symbol on a tag stating the plumbing is potentially contaminated.
  - b. Fixed contamination on items other than plumbing for sinks, toilets and so forth which exhibits an exposure rate of more than 0.1 mR/hr at six inches, or is greater than 10 times the exempt quantity for the radioisotope shall either be removed or covered and posted as radioactive materials. Fixed contamination below these levels shall be covered and monitored as necessary.

#### **K. RADIOTHERAPY PATIENT BODY FLUIDS**

1. Patient body fluids can represent a hazard due to possible contamination problems that are associated with handling fluids, such as blood or urine. When it is necessary to perform blood or urine tests on a patient containing radioactive materials used for therapeutic purposes (e.g., I-131), the following safety measures must be utilized:
  - a. Universal precautions must always be observed.
  - b. When a blood or urine sample must be obtained and sent to Clinical Laboratory for analysis, the nurse or the individual sending it to the lab is to:
    - i. Label the test tube with a sticker that has the words "Caution: Radioactive Material."
    - ii. Place the sample in a secondary container (i.e., a plastic bag), and seal it.
  - c. The specimen should be tested in a manner so as to minimize exposure to lab personnel. The following methods are recommended:
    - i. Minimize time spent with the radioactive specimen.
    - ii. Maximize the distance from the radioactive specimen.
  - d. 10 CFR 20.2003 (b) states that excreta and body fluids from people receiving diagnostic or therapeutic radiopharmaceuticals may be discharged directly into the sewage system. Accordingly, when clinical laboratory has finished analyzing the specimens, they are to:
    - i. Segregate all waste products (i.e., gloves, test tubes, etc.) and dispose of these items in the radioactive dry waste receptacles. These dry waste receptacles should be placed such that time spent near the receptacles is minimized and the distance to work stations is as far as practicable.
    - ii. Dispose of all urine specimens in the sink specifically approved for this purpose by the UCDHS Health Physics Office. Dispose of blood specimens in the same sink or in the dry waste container as appropriate. The sink must be rinsed with an ample amount of water to reduce contamination levels to indistinguishable from background.

- e. Exceptions to any of the above mentioned requirements must be approved by the UCDHS Health Physics Office.
- f. Each RUA that is authorized to perform therapeutic treatments of humans with unsealed radioactive materials must have a safety protocol on file which reflects the above provisions.

**L. DIAGNOSTIC AND THERAPEUTIC TREATMENTS IN RADIOACTIVE PATIENT ROOMS**

1. Hospitalized patients that have been given therapy with sealed or unsealed sources of radioactivity (radioactive patients) may need other diagnostic and therapeutic procedures. If these procedures are done in the patient's room the following requirements must be complied with. If the procedures are to be done in another area of the hospital, then the requirements of section VIII.O of this manual shall be followed.
2. The radiation precautions for the patient's room must be followed.
3. The nursing staff for the patient's unit must notify the UCDHS Health Physics Office in advance of the diagnosis or treatment being performed. This notification should be at least one working day prior to the scheduled treatment.
4. The UCDHS Health Physics Office shall assure that necessary safety briefings and radiation safety precautions are taken. If necessary, a technical staff member will be available during the procedure to provide radiation safety consultation.

**M. NURSING STAFF AND VISITORS STAY TIME GUIDELINES**

The following tables provide guidance for the maximum daily stay time for nurses caring for patients therapeutically treated with radioactive materials and visitors for such patients.

**NOTE:** This table is based on the following assumptions:

- a. University yearly guidelines are 2500 mrem/yr for occupationally exposed workers and 100 mrem/yr for non-occupationally exposed individuals.
- b. A nurse would provide care for two patients per month, 2 days per patient.

$$\text{THEN } \frac{2500 \text{ mrem/yr}}{24 \text{ patients/yr}} = 104 \text{ mrem/patient}$$

$$\text{AND } \frac{104 \text{ mrem/patient}}{2 \text{ days/patient}} = \text{Approximately 50 mrem/day for nurses is the maximum allowable dose at 1 meter from source.}$$

1. Nursing Stay Time Guidance (Not including MICU)

<b>EXPOSURE RATE (mR/hr)@ 1 Meter From Source</b>	<b>DAILY NURSING TIMES (Time @ 1 Meter)</b>
100.0	30 minutes
90.0	30 minutes
80.0	35 minutes
70.0	40 minutes
60.0	50 minutes

50.0	60 minutes
40.0	75 minutes
30.0	100 minutes
20.0	150 minutes
10.0	300 minutes
5.0	Unlimited
2.0	Unlimited

2. Visitors Stay Time Guidance

<b>EXPOSURE RATE (mR/hr)@ 2 Meters From Source</b>	<b>DAILY VISITOR TIMES (Time @ 2 Meters)</b>
25.0	20 minutes
22.5	20 minutes
17.5	25 minutes
15.0	30 minutes
12.5	40 minutes
10.0	50 minutes
7.5	65 minutes
5.0	100 minutes
2.5	200 minutes
1.25	400 minutes
0.5	Unlimited

- a. A visitor comes to the hospital for four days per patient stay and visits 3 times per year, for a total of 12 days. (I-131 patients are often admitted more than once).

$$\frac{100 \text{ mrem/yr}}{12 \text{ days/yr}} = 8.3 \text{ mrem/day}$$

8.3 mrem/day is the maximum allowable dose at 2 meters from the source.

3. MICU Nursing Stay Time Guidelines

Intensive Care exposure limits are based on a distance of one foot from the patient and the University goal of 2500 mrem/yr for occupationally exposed workers. Exposure times are also based on the following assumptions: a nurse may provide care for 5 patients per year and spend 10 hours with each patient at an exposure rate of 50 mR/hr at one foot. (50 mR/hr is based on patient data soon after receiving 150 mCi of I-131).

$$50 \frac{\text{mrem}}{\text{hour}} \times 10 \frac{\text{hour}}{\text{patient}} \times 5 \frac{\text{patients}}{\text{year}} = 2500 \frac{\text{mrem}}{\text{year}}$$

If the exposure rate is less than 50 mrem/hr at one foot, time spent with the patient may be increased. UCDHS Health Physics will post exposure rates daily and advise MICU on exposure times.

**N. DIAGNOSTIC PATIENTS**

Patients given radioactive materials for diagnostic purposes do not require any further radiation safety precautions beyond what is expected from "universal precautions" against contact with bodily fluids.

**O. TRANSPORT OF RADIOACTIVE PATIENTS**

1. Patients which require contamination controls (see section J) or have received sealed source implants (see section I) must be transported with appropriate radiation safety precautions.
2. UCDHS Patient Escort personnel shall receive training from the UCDHS Health Physics Office on an as needed basis concerning the radiation safety precautions and hazards for these types of patients.
3. Whenever a patient is to be taken to a clinic or for treatment or a diagnostic procedure, the UCDHS Health Physics Office shall be notified, unless the patient is being taken to a restricted area (e.g., nuclear medicine). A member of the UCDHS Health Physics Office shall assure that appropriate radiation safety precautions are taken.

**P. USE OF INERT GASES IN NUCLEAR MEDICINE**

1. Inert gases (Xe-133) in nuclear medicine should be used in such a manner that no individual, other than the patient, is likely to receive a submersion dose greater than 2500 mrem (see section IV., Exposure Standards and Dosimetry) over the course of one year. Inert gases shall be used in such a manner that the instantaneous levels of airborne radioactivity should not exceed 5 times the inhalation derived air concentration (DAC) listed in 10 CFR 20, appendix B (such as  $5 \times 10^{-4} \mu\text{Ci}/\text{cm}^3$  for Xe-133). This should provide reasonable assurance that the average effluent concentration fraction remains less than one for a calendar year. If the instantaneous levels of airborne radioactivity exceeds 5 times the inhalation derived air concentration level (DAC) listed in 10 CFR 20, then the patient procedure shall be concluded and no further uses of inert gases for that particular protocol shall be performed until corrective actions are determined and implemented.
2. The room where the inert radioactive gas is used must be under negative pressure. The exhaust from the room where the inert gas is used shall be directly vented to the environment. Fresh air may be mixed with the exhaust stream so as to reduce the concentration of radioactive inert gas. In no case shall a protocol be used which could result in the venting of inert radioactive gases which exceeds the effluent release concentrations in 10 CFR 20 when averaged over the course of one year or exceed an instantaneous level of 5 times the effluent release concentration (such as  $5 \times 10^{-7} \mu\text{Ci}/\text{cm}^3$  for Xe-133). Five times the effluent release concentration is one-half of the reporting level per 10 CFR 20. A report to the State RHB shall only be required when 10 times the applicable effluent release concentration is reached.
3. The UCDHS Health Physics Office will assure that appropriate technical assistance and guidance is provided for achieving compliance with the above.
4. The UCDHS Health Physics Office shall approve of machines used for the administration of radioactive inert gases to patients. The machines must feature:
  - a. A rebreathing system.
  - b. A charcoal filtered exhaust trap which will trap or hold most of the radioactive gases such that airborne radioactivity levels are not likely to exceed one DAC fraction at 1 meter from the machine's exhaust.

- c. A radiation monitor or other alarm system which indicates that the trap has failed or reached its maximum loading.
5. In the event the patient experiences breathing difficulties or other medical problems, the patient will be immediately disconnected from the machine. Appropriate first aid measures shall be conducted. As soon as practicable, the machine shall be shut off with the priority directed towards the well-being of the patient.

**Q. CARE OF HUMAN SUBJECTS**

Human subjects which are given diagnosis or treatment as part of the research in which they participate shall fall under the restrictions and controls outlined in sections VIII. H. through VIII. P. of this manual.

**R. CERTIFICATION OF MEDICAL TECHNOLOGISTS**

1. Nuclear Medicine technologist, radiation therapists, and other medical technician and technologists level staff shall be certified in accordance with State law prior to their administering physician directed procedures for the treatment and diagnosis of patients.
2. Individuals who provide the same type of services as nuclear medicine technologists for human research subjects do not need to be certified by the State of California. However, the principal investigator must assure that the individuals have the training and experience to perform the procedures being done.

**S. EMERGENCY ACTIONS FOR PATIENTS**

1. Whenever a patient or human research subject is in a condition that requires immediate medical treatment, which if not given will result in death or serious medical harm to the patient, that treatment shall take precedence over radiation safety measures designed to prevent infractions of State or Federal law.
2. Intensive care units shall be trained in the necessary radiation safety measures as needed. The best room for the patient shall be used on the basis of patient care needs and radiation safety issues.
3. The UCDHS Health Physics Office shall provide support as necessary to assure that medical support personnel can enter the patient's room or area. Support will also be provided in the area of contamination control, advice on radiation safety, and related matters.
4. If an emergency procedure must be performed that requires transporting the patient to another area (e.g., surgery), then the patient shall immediately be transported to the necessary location. The UCDHS Health Physics Office shall be notified immediately. The UCDHS Health Physics Office shall then assure that appropriate health physics support is provided.
5. If a patient dies with internally deposited radioactive material from a therapeutic treatment:
  - a. If the radioactivity in the patient is a temporary sealed source implant, the sources shall be removed prior to the decedent being transported to the hospital morgue. A survey by the medical physicist or UCDHS Health Physics shall be done to assure that no sources remain in the body or in the room.
  - b. If the radioactive material is in an unsealed form or a permanent sealed source implant, the attending physician shall tag the body with a radioactive materials tag stating the estimated amount and type of radionuclide in the body. The UCDHS Health Physics Office shall provide the necessary radiation safety consultation. Form 27 provides information to be given to the Funeral Directors.
  - c. An autopsy or other invasive procedure shall not be performed until the UCDHS Radiation

Safety Officer or designated representative has met with the appropriate physician(s) and determined the best radiation safety procedures and contamination control measures.

## IX. FORMS

The following forms are available on the web at <http://ehs.ucdavis.edu> , Radiological, Forms/Manuals/Plans, Radiation Safety Manual Forms.

1. Radiation Use Authorization Application Instructions
2. Radiation Use Authorization (RUA) Application
3. Radiation Use Authorization - Statement of Experience
- 3A. Machine Use Authorization - Statement of Experience
4. Safety Protocol
5. Human Radiation Use Research Application
6. Guidelines for Completing Amendment/Renewal Request Form
7. Radiation Use Authorization Amendment/Renewal Request Form
8. Radioactive Materials Transfer Form
9. General Safety Guide for Outpatients Receiving Radioiodine Therapy :10-33 mCi
10. General Safety Guide for Outpatients Receiving Radioiodine Therapy: Less than 10 mCi
11. Safety Guidelines for I-131 Therapy
12. Checklist for I-131 Therapy Room Preparation and Clean-up
13. Doctor's Orders for I-131 Therapy
14. Nursing Care for Patients Receiving Iodine-131 Therapy
15. Doctor's Orders for Patients Who Have Received P-32 Radionuclide Therapy
16. Checklist for P-32 Colloid Therapy
17. General Safety Guide for Outpatients Receiving Radionuclide Therapy (other than I-131)
18. Checklist for Cs-137, Ir-192 Brachytherapy
19. Doctor's Orders for Cesium-137, Iridium-192 or Iodine-125 Therapy
20. Uncontrolled Area Survey for Patients Treated with Cs-137, Ir-192 or I-131
21. Nursing Care for Patients Receiving Cesium-137 or Iridium-192 Therapy
22. Guidelines for Receiving Ir-192 at UC Davis Health System
23. Checklist for I-125 Seed Brachytherapy
24. Nursing Care for Patients Receiving I-125 Therapy
25. Recommendations for Patients with Radioactive Iodine Implants
26. Procedures for Receiving I-125 Seeds at UC Davis Health System
27. Report on Radioactivity to the Funeral Director from the Radiation Safety Officer
29. MICU Exposure Time Guidelines
30. Radiation-Producing Machine (MUA) Application
31. Request for Shielding Design
32. Radiation-Producing Machine Amendment Form
33. Health Physics Event Form
35. Protocol Exemption from Radiation Use Committee Review
36. Diffraction/Fluorescence X-Ray Safety Protocol
37. Cabinet X-Ray Safety Protocol
38. Portable Radiography X-Ray Safety Protocol
39. Radiography X-Ray Safety Protocol
40. Fluoroscopic Safety Protocol

## **X. EMERGENCIES**

### **A. EMERGENCY TRAINING**

All individuals who work with radioactive materials at UC Davis will be trained in the appropriate emergency actions (see section V.A., "Training"). Emergency actions are considered as actions taken to mitigate or resolve the consequences of an unforeseen occurrence involving radioactive materials that have the potential to seriously degrade radiation safety or effect the health and human welfare. Emergencies involving radioactive materials are considered radiation emergencies. Radiation emergencies may be involved with other life threatening events such as fire, accidental injury, and so forth.

### **B. PRIORITIES DURING RADIATION EMERGENCIES**

When a radiation emergency occurs, the following priorities must be observed:

1. Actions to save lives and provide appropriate first aid to injured individuals.
2. Actions to reduce the damage to equipment, which if further damaged, could cause harm to individuals.
3. Actions to place the accident site in a radiologically safe condition (e.g., stop or contain spills, shield sources of radiation, etc.).
4. Actions to save expensive equipment, important records, etc.
5. Cleanup and other actions to return the area into normal operating condition.

### **C. NOTIFICATIONS AND REPORTS**

1. If the radiation emergency involves other types of emergencies such as fire, police activities, health threatening injuries, etc., call 911.
2. For radiation emergencies that do not involve other non-radiological emergency actions, the appropriate office must be notified.

Campus: Office of Environmental Health and Safety:	530-752-1493
After hours pager	530-752-1230
UCDHS: Health Physics Office:	916-734-3355
After hours pager	916-762-1994

3. In all cases, the appropriate health physics office must be notified as soon as possible.
4. All radiation emergencies, except minor contamination emergencies, will be documented as a radiation event or if appropriate, a radiation incident. All Principal Investigators involved in the emergency will receive a copy of the report for review prior to review by the UC Davis Radiation Safety Administrative Advisory Committee and if applicable, prior to submission to the State Radiologic Health Branch.

### **D. CONTAMINATION EMERGENCY**

1. A contamination emergency is one that:
  - a. Causes the evacuation of a room, several rooms in a building, or a building for more than 24 hours.
  - b. Causes a room or building to be restricted from access for more than 24 hours.
  - c. Causes airborne radioactivity in excess of 10 Derived Air Concentration (DAC) as determined by the appropriate Radiation Safety Officer.
  - d. Causes the release of either airborne or liquid radioactive material into the environment that is outside of the restricted area in excess of an effluent release concentration fraction of one as determined by the appropriate Radiation Safety Officer.

- e. Causes radiation levels outside of a restricted area such that a member of the general public could exceed 2 millirem in any one hour or 100 millirem in any one year.
  - f. Is of such magnitude, that the personnel involved are unable to contain or mitigate the spill.
2. For a contamination emergency, non-health physics personnel must take actions as are necessary to save human life, provide first aid, and seal off the contaminated area. The appropriate health physics office will respond and provide technical assistance and direction as necessary.

#### **E. MINOR CONTAMINATION EMERGENCY**

1. A minor contamination emergency is one which does not meet the requirements of section X.D.1. of this manual and one such that personnel on the Radiation Use Authorization at the scene can contain and clean up with their resources.
2. The appropriate health physics office may provide assistance in the form of consultation or resources.
3. The appropriate health physics office should be notified of the minor contamination emergency as soon as possible.
4. A survey of the contamination site shall be performed after it has been decontaminated.
5. The Principal Investigator of the involved Radiation Use Authorization shall assure that a memorandum for record is written which briefly states what occurred, any radiation measurements taken, actions taken, and probable causes of the minor contamination spill. A copy of the survey and decontamination results required in section X.E.4. of this manual shall be attached to the memorandum and maintained in the laboratory's radiation monitoring log book.
6. Records for minor contaminated area emergencies must be retained and available for inspection by the appropriate health physics personnel as well as the State Radiologic Health Branch inspectors for a period of 3 years or from the date of the last State inspection, whichever is longer.

#### **F. CONTAMINATION OF PERSONNEL**

1. An individual is considered to be contaminated whenever radioactive material is present on their personal clothing or any part of their body such that the appropriate count rate survey meter reads above background at ½ inch from the surface of the clothing or individual's body. The background count rate of the instrument shall be less than 300 counts per minute.
2. The individual who is contaminated must assure that they take steps to reduce the spread of contamination. They must also assure that the appropriate health physics office is notified as soon as possible.
3. During decontamination of the individual's skin, no actions shall be taken that may abrade the skin of the individual, unless such action is specifically approved by a medical doctor after consultation with the appropriate Radiation Safety Officer and/or Director, Health Physics Programs.
4. Prior to starting decontamination, the personnel involved shall measure and record the dose rate or count rate of the contaminated areas.
5. If the individual can easily remove the contamination, they should proceed to do so.
6. If the contamination is not easily removable, then the decontamination must proceed under the direction of the appropriate health physics office personnel.
7. Personal items of clothing which are not readily decontaminated may be held for decay, if the half life of the radionuclide(s) involved is less than 120 days. Otherwise, the clothing will be disposed of as radioactive waste.
8. When decontamination efforts reach the point where there is less than a 10% reduction in cpm of the contaminated area between efforts, the individual shall be released without any additional restrictions provided that the count rate is less than 1000 counts per minute above background.

9. If the count rate is greater than 1000 counts per minute above background on the appropriate count rate instrument after decontamination efforts, the individual will be released with the following instructions:
  - a. To cover the contaminated area with a bandage or appropriate dressing which would contain any contamination given off by the skin.
  - b. Report to the appropriate health physics office for evaluation each working day until such time as the contamination level is reduced to less than 1000 counts above background.
10. If, because of skin contamination, there is good reason to believe that the skin dose to an individual is greater than five rem when averaged over one square centimeter, then:
  - a. The dose to the individual's skin shall be evaluated by the appropriate health physics office.
  - b. The dose evaluation results shall be transmitted to the individual and retained in the individual's dosimetry records.
  - c. Copies of the dose evaluations will be submitted to the individual(s) involved, the Principal Investigator, and the UC Davis Radiation Safety Administrative Advisory Committee for review.
11. In all cases of skin contamination, the appropriate Radiation Safety Officer will determine the need to perform a bioassay in order to determine whether an internal uptake has resulted from the absorption, ingestion, or inhalation of the radioactive material.

## **XI. APPENDICES**

- A. SAFETYNETS** - available on the web at: <http://ehs.ucdavis.edu/>
- B. TOLERANCE FACTOR TABLE** - 10 CFR 30.71, Schedule B, available on the web at: [http://edocket.access.gpo.gov/cfr\\_2008/janqtr/pdf/10cfr30.71.pdf](http://edocket.access.gpo.gov/cfr_2008/janqtr/pdf/10cfr30.71.pdf)  
Any alpha radionuclide not listed in Schedule B or mixtures of alpha emitters of unknown composition - **0.01**  $\mu\text{Ci}$ .  
Any radionuclide other than alpha emitting radionuclides not listed or mixtures of beta emitters of unknown composition - **0.1**  $\mu\text{Ci}$
- C. EXAMPLE RUA APPLICATION AND AMENDMENT REQUEST**

Proposed RUA# \_\_\_\_\_

Recharge Number \_\_\_\_\_

## RADIATION USE AUTHORIZATION (RUA) APPLICATION

**A. Applicant (Submit Statement of Experience)**

Name: Jane Doe, Ph.D. Date: 10-13-94  
 Department: Environmental Health and Safety Office phone: 752-0123  
 Mailing address: TB-30 Laboratory phone: 2-4567

**B. Co-Workers (Submit Statement of Experience for each worker)**

Hilary Davis Dana Woodland Lauren S. Tahoe  
John Doe\* \_\_\_\_\_  
 \_\_\_\_\_

Designate an alternate principal investigator with an asterisk (\*)

**C. Locations for Use of Radioactivity**

Locations: TB 31 100 & 101 103 (counting only)  
105 (storage only) 110 (darkroom)

Please attach a diagram of each laboratory and clearly mark the areas of your laboratory where radioactivity will be stored or utilized.

**D. Radionuclides Requested**

Radionuclides	Chemical Form	Physical Form	Possession Limit	Experimental Limit
H-3	Thymidine	Liquid	5.0 mCi	1.0 mCi
P-32	Nucleotides	Liquid	3.0 mCi	1.0 mCi
I-125	NaI & Proteins	Liquid	7.0 mCi	5.0 mCi

**E. Protocol**

Submit a Safety Protocol for each proposed procedure that uses radioactive materials.

**F. Will this RUA involve use of radiation on humans as patients or research subjects?** Yes  No  (If no, you may submit an amendment in future for human use.)

**G. Signatures**

\_\_\_\_\_  
Principal Investigator Date

\_\_\_\_\_  
Department Chairperson Date

\_\_\_\_\_  
Radiation Safety Officer Date

**FORM 3**  
 University of California, Davis  
 Environmental Health & Safety, Health Physics

Date Received: \_\_\_\_\_

RUA	Date Added	Date Term.

**RADIATION USE AUTHORIZATION - STATEMENT OF EXPERIENCE**

FIRST NAME: Hilary LAST NAME: Davis PHONE (work): 2-8901  
 LAST 5 DIGITS SOC SEC #: 33333 DATE OF BIRTH: 02/11/1970  
 DEPARTMENT: EH&S RUA & PI YOU ARE WORKING WITH : J. Doe RUA 1766  
 STATUS: STUDENT  VISITOR \_\_\_\_\_ EMPLOYEE \_\_\_\_\_ E-MAIL ADDRESS: \_\_\_\_\_

**A. PREVIOUS EXPERIENCE**

Have you had previous experience working with ionizing radiation? yes  no \_\_\_\_\_  
 If yes, then indicate the institution, date(s) and type of work.  
 Institution UCLA Date 2000 Type of work DNA Sequencing  
 Address: \_\_\_\_\_  
 Institution \_\_\_\_\_ Date \_\_\_\_\_ Type of work \_\_\_\_\_  
 Address: \_\_\_\_\_

**B. PREVIOUS DOSIMETRY ISSUANCE**

Has an institution(s) issued you radiation dosimetry for the **current calendar year**? yes \_\_\_\_\_ no   
 If yes, then indicate the institution, address and duration.  
 Institution \_\_\_\_\_ Address \_\_\_\_\_  
 City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_ Duration \_\_\_\_\_

Are you presently issued dosimetry at another institution? yes \_\_\_\_\_ no  It is your responsibility to inform EH&S!

Have you ever used a Planned Special Exposure (>5 rem/year)? yes \_\_\_\_\_ no ; If yes, attach statement with details.

**C. PLANNED IONIZING RADIATION WORK**

List radionuclide(s), experimental quantities, and chemical form.  
 Radionuclide H-3 Quantity 1 mCi Form Thymidine  
 Radionuclide P-32 Quantity 0.25 mCi Form Nucleotides

**D. TRAINING**

Indicate if you have ever received ionizing radiation safety training.  
 UC Davis EH&S radiation class lecture or test? yes  no \_\_\_\_\_ If yes, approximate date 7/10/2007  
 List any other radiation safety training you have received:  
 Topic \_\_\_\_\_ Location \_\_\_\_\_ Duration (hrs) \_\_\_\_\_  
 I will or have read the appropriate EH&S radiation safety training booklet.  
 I will or have read the Safety Protocol(s) which correspond with my job assignment for RUA 1766.  
 I have been made aware of the UC Davis Radiation Safety Manual, which contains emergency information.  
 I will follow the safety procedures necessary to work with radioactive material and minimize my exposure to radiation.  
 I hereby authorize UC Davis, Environmental Health and Safety/Health Physics to obtain information on the nature and amount of occupational radiation exposure that I received in the past.

\_\_\_\_\_  
 Signature

\_\_\_\_\_  
 Date

University of California, Davis  
Environmental Health & Safety, Health Physics

RUA Number: \_\_\_\_\_

**SAFETY PROTOCOL**

Provide a copy of this protocol to each co-worker participating in the experiment.

Title of project: Detection of DNA Sequences by Filter Hybridization

Purpose: To detect DNA sequences of nucleic acid of interest

Radionuclide(s): P-32

Chemical Form: Nucleotides

A. What personnel protection methods will be used to prevent contamination and internal exposures to radiation?

Disposable gloves X Disposable shoe covers \_\_\_\_\_ Laboratory coat or coveralls X Glove box \_\_\_\_\_

Fume hood \_\_\_\_\_ (Flow rate: \_\_\_\_\_ FPM) Absorbent paper X

Other: (explain) \_\_\_\_\_

\_\_\_\_\_

B. How will you detect radioactive contamination and/or radiation fields?

Wipes and liquid scintillation counting/or gamma well counting: Liquid Scintillation

G.M. Survey Meter Model: Bicron Surveyor 50

Ionization Chamber Model: \_\_\_\_\_

Other (explain): \_\_\_\_\_

\_\_\_\_\_

C. Radiation work areas must be surveyed at the end of each experiment. At what frequency will you check the rest of the laboratory for contamination?

After each experiment X Daily \_\_\_\_\_ Weekly \_\_\_\_\_ Biweekly X

Other (explain): Whenever the radioactive work area is left during an experiment for an extended period of time, (e.g. lunch break etc.)

\_\_\_\_\_

D. Explain your method for decontamination of nondisposable objects contaminated with the radioactivity:

A decontamination solution will be used (e.g. detergent & water or commercial solution to clean all non-disposable items. All items will be verified to be indistinguishable from background. A re-wash may be needed. A 1 ml aliquot of wash water will be taken and mixed with 9 ml of scintillation cocktail. A background sample will be prepared with 1 ml of the decon solution and 9 ml of scintillation cocktail. Both samples will be analyzed using an LSC. If the wash water sample is less than the background counts plus  $3\sqrt{\text{Background counts}}$ , the water will be poured in the lab sink. If not, the water will be collected as liquid radioactive waste.

**FORM 4 CONTINUED:**

E. What personnel protection methods will be used to prevent external exposures?

Shielding (explain): At least 1/4 inch of plexiglass for work, storage and waste area.

Distance: Distance from the source will always be taken into consideration and utilized.

Devices (e.g., long-handled tongs, etc.) explain: Long handled tongs will be used when handling primary vials.

Time in the work area: The time in the work area will be kept to a minimum.

F. List the types of radioactive waste you will have and where you will store each form of waste until EH&S picks it up. Estimate the volume per month:

	Expected Disposal (Yes/No)?	Storage Location	Quantity/Month
Dry	yes	TB 30	1 (cubic feet)
Liquid	yes	TB 30	1 (gallons)
Biological	no		(pounds)
Scintillation vials	yes	TB 30	2 (flats [100 vials/flat])
What type of liquid chemical form will be generated ? (i.e., H <sub>2</sub> O, ethanol, etc.)			Aqueous

G. Protocol

Describe your protocol for the use of each radionuclide emphasizing radiation safety procedures below. INDICATE LABORATORY PROCEDURES, THE SEQUENCE IN WHICH THEY ARE PERFORMED, PERSONNEL PROTECTION METHODS AS THEY ARE USED, AND DISPOSITION OF WASTE AS IT IS PRODUCED. The scientific basis of the protocol should not be addressed. Attach additional pages if necessary. (Do not submit reprints.)

All work areas and equipment used will be defined/labeled with tape marked "Caution - Radioactive Material." Personnel will wear lab coats, close toed shoes and disposable gloves. During the experiment, a count rate meter will be accessible to confirm that the shielding used is effective and to check gloves and work area for contamination.

General description of experiment: Include the frequent changing of disposable gloves, monitoring of the work area prior to extended leaves during the experiment, types of operations (e.g. crushing, incubation, use of centrifuges, trapping of volatile radioactivity, etc.), monitoring work area and protective clothing after the experiment. Also include the waste minimization techniques such as segregation of organic liquids from aqueous liquids, using the count rate meter to determine whether the absorbent paper is contaminated, etc. Include details for the disposition of radioactive waste: packaging, labelling, segregation, etc. See Safety Net #9.