

Radiation Safety Manual 2016



Environmental Health and Safety

UNIVERSITY OF COLORADO
DENVER | ANSCHUTZ MEDICAL CAMPUS

EMERGENCY TELEPHONE NUMBERS

| Where to call for: | Weekdays 8 a.m. – 5 p.m. | After Hours, Weekends, & Holidays |
|--|---|---|
| CU Police – Anschutz Campus | 911(from campus phone) 303-724-4444 (any phone) | 911 (from campus phone) 303-724-4444 (any phone) |
| Auraria Police – CU Denver Campus | 911 (AHEC campus phone) 303-556-5000 (any phone) | 911 (AHEC campus phone) 303-556-5000 (any phone) |
| Fire | 911 | 911 |
| Medical Emergencies | 911 | 911 |
| Hazardous Materials Spills (Chem/Bio/Rad) | 303-724-0345 | 911 |
| | | |
| | | |
| Research Safety & Industrial Hygiene | 303-724-0345 | 911 |
| Other | 303-724-0345 | 911 |
| Colorado Department of Public Health and Environment | (303) 692-3320 (303) 692-3300 <i>Toll Free (888) 569-1831</i> | (303) 877-9757 |

RADIATION SAFETY ROUTINE TELEPHONE NUMBERS

| Where to call for: | Weekdays 8 a.m. – 5 p.m. | After Hours, Weekends, & Holidays |
|--|--|---|
| Radiation Safety Officer (RSO) | 303-724-0234 | 911 (from campus phone) 303-724-4444 (any phone) |
| Alternate RSO | 303-724-0128 | |
| Radioactive Waste Pickups | 303-724-0109 (<i>or On Line</i>) | ***** |
| Radioactive Materials Inventory and Paperwork | 303-724-0109 or 303-724-0345 | ***** |
| General Questions | 303-724-0345 | 911 |
| Personal Dosimeters | 303-724-0345 | ***** |

Incidents Requiring Reporting to Environmental Health and Safety

With the exception of performing the initial emergency actions described in the emergency procedures located on the following two pages of this manual, **any person involved in any of the following types of incidents must ensure that Environmental Health and Safety is informed immediately by telephone:**

- **any incident involving possible contamination of an individual's person (any part of the body, including contamination of clothing that may transfer to the body),**
- **any incident involving disappearance or loss of control of radioactive material, including improper disposal,**
- **any incident involving known or suspected contamination of floors, and**
- **any incident involving radioactive contamination that cannot be immediately and completely contained and controlled.**

Contact telephone numbers are listed on the first page of this Manual. When calling Environmental Health and Safety, you will be asked:

- your name,
- names of potentially affected individuals,
- location of the incident,
- type and amount of radioactive material involved and
- a description of the incident

Emergency Procedure for Personal Contamination

- **If the exposure involves a liquid containing chemicals that are caustic to the skin or a solution of radioactive iodine as sodium iodide (NaI) flushing with water must begin IMMEDIATELY.**

Use:

- a safety shower for large areas of the body,
 - an eyewash for the eyes, or
 - a laboratory water tap for small areas of the body.
- **Ask a nearby person to call Environmental Health and Safety (303-724-0345 or 911).**
 - Place any contaminated clothing into a sealed plastic bag for later survey and disposition.
 - **DO NOT use chemical or mechanical methods that may damage the skin, which will worsen the situation.** Use only mild soap or detergent and warm water. Wash water may be disposed down the drain if it is not practical to contain it in the sink.
 - **DO NOT leave the area until Environmental Health and Safety has addressed the situation.**

Emergency Procedure for Radioactive Spills

If the spill involves:

- a portion of the floor that cannot be quickly and completely contained and cordoned off, or
- volatile forms of radioactive material (e.g., radioactive iodine in sodium iodide solution, tritiated water in milliCurie-or-greater quantities),

YOU MUST EVACUATE the laboratory and close the doors BUT DO NOT allow any persons who were in the laboratory to leave the area.

- Address any contamination of persons according to the Emergency Response Procedure for Personal Contamination (*found on the previous page of this manual*).
- Call Environmental Health and Safety (303-724-0345 or 911).
- All persons who were in the laboratory must remove any potentially contaminated footwear and place them in a secure area.
- If the spill did not require evacuation of the laboratory by the above criteria, then you may begin decontamination operations:
 - don your lab coat, gloves, and eye protection,
 - cordon off an area that is certain to contain the spill so that no other person will enter,
 - use disposable paper towels or pads to absorb any liquid and place into a radioactive waste liner, changing gloves frequently,
 - decontaminate the spill with a detergent solution or a commercial preparation intended for radioactive decontamination, by soaking paper towels in the solution, wiping toward the center of the spill, and placing the towels into the radioactive waste liner,
 - survey the area after each such effort to determine residual contamination levels, and attempt to remove all detectable contamination by continuing such efforts until no removable contamination appears on swipe samples.

Table of Contents

| | |
|--|-----------|
| EMERGENCY TELEPHONE NUMBERS | II |
| RADIATION SAFETY ROUTINE TELEPHONE NUMBERS | III |
| INCIDENTS REQUIRING REPORTING TO ENVIRONMENTAL HEALTH AND SAFETY | IV |
| EMERGENCY PROCEDURE FOR PERSONAL CONTAMINATION | V |
| EMERGENCY PROCEDURE FOR RADIOACTIVE SPILLS | VI |
| PART I: PURPOSE AND INTENDED USE OF THE RADIATION SAFETY MANUAL | 11 |
| HSC 1.1 PURPOSE | 11 |
| HSC 1.2 ISSUANCE OF THE MANUAL | 11 |
| HSC 1.3 AVAILABILITY OF THE RADIATION SAFETY MANUAL IN THE LABORATORY | 12 |
| HSC 1.4 SALE OF ADDITIONAL COPIES OF THE MANUAL | 12 |
| HSC 1.5 REVISION OF THE MANUAL | 12 |
| PART II: AUTHORITY AND RESPONSIBILITY IN THE RADIATION SAFETY PROGRAM | 13 |
| HSC 2.1 PROGRAM INTRODUCTION | 13 |
| HSC 2.2 PROGRAM AUTHORITY | 14 |
| 2.2.1 BROAD SCOPE LICENSE | 14 |
| 2.2.2 INSPECTIONS OF UNIVERSITY LICENSES BY CDPHE | 14 |
| 2.2.3 UNIVERSITY OF COLORADO HOSPITAL (UCH) LICENSE | 14 |
| 2.2.4 CU DENVER ANSCHUTZ OFF CAMPUS FACILITIES AND CU DENVER ANSCHUTZ ADMINISTERED GRANTS' FUNDING OF OFF CAMPUS ACTIVITIES | 15 |
| 2.2.5 GENERALLY-LICENSED RADIOACTIVE MATERIALS | 15 |
| HSC 2.3 PROGRAM RESPONSIBILITIES | 16 |
| HSC 2.4 COMMITTEE ON IONIZING RADIATION (CIR) | 17 |
| 2.4.1 AUTHORITY AND RESPONSIBILITIES OF THE COMMITTEE | 17 |
| 2.4.2 AUTHORITY OF ENVIRONMENTAL HEALTH AND SAFETY DEPARTMENT ADMINISTRATORS | 17 |
| 2.4.3 COMMITTEE MEMBERSHIP | 18 |

| | | |
|--------|--|----|
| 2.4.4 | COMMITTEE’S ESTABLISHMENT AND STAFFING OF A RADIATION SAFETY PROGRAM | 18 |
| 2.4.5 | COMMITTEE MEETINGS | 18 |
| 2.4.6 | CIR REVIEW OF APPLICATIONS FOR AUTHORIZATION TO PROCURE AND USE RADIOACTIVE MATERIALS | 18 |
| 2.4.7 | CIR REVIEW OF QUALIFICATIONS FOR PRINCIPAL INVESTIGATOR STATUS | 20 |
| 2.4.8 | PRINCIPAL INVESTIGATOR’S REGISTRATION OF AUTHORIZED COINVESTIGATORS AND RADIATION WORKERS WITH EHS | 20 |
| 2.4.9 | CONDITIONS REQUIRING A NEW APPLICATION TO THE COMMITTEE | 21 |
| 2.4.10 | TRANSFER OF AUTHORIZATION | 22 |
| 2.4.11 | CIR REQUIREMENTS FOR CERTIFICATION AS AUTHORIZED PRINCIPAL INVESTIGATOR, AUTHORIZED USER, OR COINVESTIGATOR/RADIATION WORKER | 22 |
| 2.4.12 | INFORMATIONAL RESPONSIBILITY OF CIR MEMBERS | 22 |
| 2.4.13 | | 22 |
| 2.4.14 | SIGNIFICANCE OF THE TERMS “PRINCIPAL INVESTIGATOR,” “COINVESTIGATOR,” AND “RADIATION WORKER” | 23 |
| 2.4.15 | AUDITS OF AUTHORIZED PRINCIPAL INVESTIGATORS’ LABORATORIES BY ENVIRONMENTAL HEALTH AND SAFETY DEPARTMENT | 24 |
| 2.4.16 | RULINGS AND ACTIONS BY THE COMMITTEE | 24 |
| 2.4.17 | TERMS AND EXPIRATION OF AUTHORIZATIONS FOR RADIOACTIVE MATERIALS | 24 |
| 2.4.18 | PROTECTION OF HUMAN RESEARCH SUBJECTS | 25 |

HSC 2.5 PROGRAM ORGANIZATION 26

HSC 2.6 COMPLIANCE WITH REGULATIONS AND ADVISORY GUIDANCE 27

| | | |
|-------|---|----|
| 2.6.1 | PRINCIPAL INVESTIGATORS’ KNOWLEDGE AND UNDERSTANDING OF REGULATIONS AND ADVISORY PUBLICATIONS | 27 |
|-------|---|----|

HSC 2.7 THE UNIVERSITY AS LOW AS REASONABLY ACHIEVABLE (ALARA) PROGRAM 27

| | | |
|-------|---|----|
| 2.7.1 | RADIATION SAFETY OFFICER’S REVIEW OF DOSIMETRY AND BIOASSAY RESULTS | 28 |
| 2.7.2 | COMMITTEE’S QUARTERLY REVIEW OF DOSIMETRY AND BIOASSAY RESULTS | 30 |
| 2.7.3 | RESPONSIBILITY OF AUTHORIZED PRINCIPAL INVESTIGATORS | 30 |
| 2.7.4 | RESPONSIBILITY OF ALL PERSONS WORKING WITH RADIOACTIVE MATERIALS | 30 |

PART III: ADMINISTRATION OF THE MEDICAL BROAD SCOPE RADIOACTIVE MATERIALS LICENSE 31

HSC 3.1 THE UNIVERSITY MEDICAL BROAD SCOPE LICENSE 31

| | | |
|-------|--|----|
| 3.1.1 | FEATURES OF THE MEDICAL BROAD SCOPE LICENSE AND TYPES OF RESEARCH PROJECTS THAT MAY REQUIRE EXTRA LEAD TIME FOR AMENDING THE LICENSE | 31 |
| 3.1.2 | OBTAINING COPIES OF THE LICENSE OR OTHER LICENSE INFORMATION | 32 |
| 3.1.3 | AMENDMENTS TO THE LICENSE | 32 |
| 3.1.4 | RENEWAL OF THE LICENSE | 33 |

HSC 3.2 SERVICES PROVIDED BY THE ENVIRONMENTAL HEALTH AND SAFETY DEPARTMENT (EHS) 33

| | | |
|-------|--|----|
| 3.2.1 | PERSONNEL MONITORING AND BIOASSAY | 33 |
| 3.2.2 | RADIOACTIVE PACKAGE RECEIVING PROCEDURES | 34 |
| 3.2.3 | RADIOACTIVE MATERIALS INVENTORY CONTROL AND TRACKING | 34 |
| 3.2.4 | CALIBRATION OF RADIATION SURVEY INSTRUMENTS | 35 |
| 3.2.5 | LEAK TESTING OF SEALED SOURCES | 35 |
| 3.2.6 | RADIATION PROTECTION SURVEYS | 35 |
| 3.2.7 | EVALUATIONS OF FUME HOOD FUNCTION | 36 |

| | | |
|----------------|--|-----------|
| 3.2.8 | DISPOSAL OF RADIOACTIVE WASTES AND SALE OF WASTE CONTAINERS | 36 |
| 3.2.9 | ASSISTANCE IN PREPARING OUTGOING SHIPMENTS OF RADIOACTIVE MATERIALS | 36 |
| 3.2.10 | TRAINING AND TESTING OF WORKERS | 36 |
| 3.2.11 | ADVICE AND CONSULTATION | 37 |
| 3.2.12 | EMERGENCY RESPONSE | 37 |
| HSC 3.3 | SERVICES PROVIDED TO RADIOACTIVE MATERIALS LABORATORIES BY THE CLEANING SERVICES STAFF | 37 |
| HSC 3.4 | REQUIREMENTS TO BE MET BY AUTHORIZED PRINCIPAL INVESTIGATORS | 38 |
| 3.4.1 | TRAINING AND QUALIFICATIONS | 38 |
| 3.4.2 | CONSTRAINTS ON ACQUISITION, DISPOSITION, AND TRANSPORTATION OF RADIOACTIVE MATERIALS | 39 |
| 3.4.3 | CONTROLLING POTENTIAL INTERNAL EXPOSURE TO RADIATION | 46 |
| 3.4.4 | CONTROLLING POTENTIAL EXTERNAL EXPOSURE TO RADIATION | 56 |
| 3.4.5 | POTENTIAL ENVIRONMENTAL RELEASES AND CONTROL OF RADIOACTIVE MATERIALS IN AIR AND WATER EFFLUENTS | 59 |
| 3.4.6 | DISPOSAL OF RADIOACTIVE AND MIXED WASTES | 62 |
| 3.4.7 | DESIGNATION AND DECOMMISSIONING OF AREAS WHERE RADIOACTIVE MATERIALS ARE STORED OR USED | 65 |
| 3.4.8 | REQUIRED SIGNS, LABELS, AND OTHER POSTINGS | 68 |
| 3.4.9 | EMERGENCY PROCEDURES AND REPORTING OF INCIDENTS | 71 |
| | RADIATION SAFETY MANUAL APPENDICES | 74 |
| I | BROAD SCOPE RADIOACTIVE MATERIALS LICENSE AND COVER LETTER | 75 |
| II | LIST OF GOVERNMENT REGULATORY AGENCIES | 85 |
| III | ENVIRONMENTAL HEALTH AND SAFETY RECEIVING PROCEDURE FOR RADIOACTIVE MATERIALS PACKAGES | 87 |
| IV | ENVIRONMENTAL HEALTH AND SAFETY RADIOACTIVE MATERIALS INVENTORY SYSTEM | 90 |
| V | PERMISSION FORM FOR MINORS | 92 |
| VI | APPROVAL FOR NON-PURCHASE-ORDERED ACQUISITIONS OF RADIOACTIVE MATERIALS | 94 |
| VII | CHANCELLOR'S MEMORANDUM | 96 |
| VIII | RADIOACTIVE ANIMAL CAGE TAG | 99 |
| IX | GAMMA RAY SPREADSHEETS AND SHIELDING GUIDELINES | 101 |

| | | |
|-------------|---|------------|
| X | PERSONAL DOSIMETER INFORMATION | 115 |
| XI | RADIOIODINE BULLETIN AND IODINATION SUITE GUIDANCE NOTE | 119 |
| XII | ENVIRONMENTAL HEALTH AND SAFETY GREEN TAG | 123 |
| XIII | TABLE OF QUANTITIES FOR POSTING AND LABELING | 125 |
| XIV | PRINCIPAL INVESTIGATOR'S POSTING | 127 |
| XV | TRI-LEVEL HAZARD CLASSIFICATION SYSTEM FOR RADIOACTIVE MATERIALS LABORATORIES AT CU DENVER ANSCHUTZ | 129 |
| XVI | FACTORS TO BE CONSIDERED WHEN PROPOSING USE OF RADIOACTIVE MATERIALS IN FACILITIES NOT PREVIOUSLY SO AUTHORIZED | 132 |
| XVII | GENERAL CRITERIA FOR TRAINING AND EXPERIENCE OF PRINCIPAL INVESTIGATORS TO BE AUTHORIZED FOR RADIOACTIVE MATERIALS | 134 |
| XVIII | CDPHE NOTICE TO EMPLOYEES | 136 |

Environmental Health and Safety Department
Office of the Assistant Vice Chancellor for Regulatory Compliance

2016 RADIATION SAFETY MANUAL

PART I: PURPOSE AND INTENDED USE OF THE RADIATION SAFETY MANUAL

HSC 1.1 PURPOSE

The university *Radiation Safety Manual* establishes and defines the university's Radiation Safety Program, and serves as the principal document submitted in support of the university's applications for radioactive materials licenses. The *Manual* serves as an institutional policy document, and the policies and procedures set forth herein are imbued with the authority of both:

- the Office of the Chancellor, through the offices of the university CIR (radiation safety committee), and
- the CDPHE, through that Department's licensing of CU Denver | Anschutz.

This *Manual*, along with its appendices and supplements, is intended to serve as a comprehensive reference document for all persons using or regulating the use of radioactive materials at CU Denver | Anschutz, including

- authorized Principal Investigators and all persons using radioactive materials under the auspices of their authorizations from the university CIR,
- authorized users and all persons using radioactive materials under the auspices of their authorizations from the university HuCIR
- members of the university CIR, and
- staff of the university Environmental Health and Safety Department.

Where applicable distinction between Principal Investigator (PI) and Authorized User (AU) is made; otherwise, all conditions in this manual apply to both PI's and AU's.

HSC 1.2 ISSUANCE OF THE MANUAL

This manual, along with its revisions and supplements as published, will be available to each principal investigator, radiation worker, CIR member, Environmental Health and Safety staff, and any other

person interested in the Radiation Safety Program through the Radiation Safety website. Communication of revisions, updates and changes will be sent to the university community via a listserv or other electronic mail message. Hard copies of this manual will be maintained in the Radiation Safety office of the Environmental Health and Safety Department and are available for review during normal business hours.

HSC 1.3 AVAILABILITY OF THE RADIATION SAFETY MANUAL IN THE LABORATORY

It is expected that each authorized Principal Investigator will post the location of this *Manual*, along with the location of copies of the Principal Investigator's authorizations for radioactive materials. The Principal Investigator's authorizations must be available in a designated and accessible location in the Principal Investigator's laboratories, so that these materials will be readily available to all persons working in that Principal Investigator's laboratories. These documents are public records and should be made available to *all* persons who are authorized to be present in the Principal Investigator's laboratories, regardless of the reason for their presence.

HSC 1.4 SALE OF ADDITIONAL COPIES OF THE MANUAL

Due to the considerable cost of producing the *Manual*, hard copies of the manual will be sold by EHS at cost to those who request, in writing, to obtain a copy of the *Manual* through EHS.

HSC 1.5 REVISION OF THE MANUAL

Because the *Radiation Safety Manual* proper contains policies and procedures on which the issuance of the university's radioactive materials license is predicated, the revision of the manual is a major undertaking. Correspondingly, those items likely to change on a fairly frequent basis are placed into the appendices and supplements to the *Manual*.

- The year of publication of the *Manual* proper is indicated on the cover, on the first page of every section and included in the footer of each page.
- The appendices and supplements to the *Manual* are annotated to indicate their individual dates of original publication or revision.

Environmental Health and Safety Department
Office of the Assistant Vice Chancellor for Regulatory Compliance

2016 RADIATION SAFETY MANUAL

PART II: AUTHORITY AND RESPONSIBILITY IN THE RADIATION SAFETY PROGRAM

HSC 2.1 PROGRAM INTRODUCTION

Ionizing radiation is among the most versatile and useful tools of modern medicine and biomedical research. Like many other instrumentalities of medicine and research, ionizing radiation is potentially hazardous unless used with strict adherence to safety rules and procedures.

But unlike most other such hazards, the risk of unguarded exposure to ionizing radiation includes the possibility of damage to future generations. Thus the safety rules which govern all uses of ionizing radiation are as concerned with preventing genetic damage as with protecting the health of the exposed individual. When followed faithfully, these rules limit exposures of radiation workers to levels far below those which might cause any adverse *somatic* (to the health of the exposed individual) or *genetic* (heritable defects affecting offspring of the exposed individual) effects. The general operating philosophy of maintaining radiation exposures as far below applicable limits as possible, consistent with efficient use of resources, is referred to as ALARA (As Low As Reasonably Achievable).

The university has been issued a medical broad-scope license by the CDPHE, which allows the university a prodigious breadth of discretion in the use of radioactive materials. Among other things, the university is licensed for a great variety of radioactive materials (wide variety of radionuclides and chemical and physical forms of those radionuclides), and is given the discretion to internally review and approve

- new users of radioactive materials (authorized Principal Investigators and Radiation Workers),
- new uses of radioactive materials (highly variable types of experiments, including use in animals and administration to human research subjects), and
- new facilities and equipment for the use of radioactive materials at the university's authorized locations of use.

The issuance of such a license is predicated on the idea that the university, as a sophisticated biomedical research institution, has available among its staff and faculty the appropriate expertise, and has created appropriate administrative mechanisms in its institutional structure, to assure the licensing agencies that radioactive materials will be procured, used, and disposed of in a safe and proper manner that complies with all applicable regulatory requirements.

HSC 2.2 PROGRAM AUTHORITY

Radioactive materials in Colorado are controlled and licensed by the **Colorado Department of Public Health and Environment (CDPHE)**, which derives its licensing authority from an agreement with the **U. S. Nuclear Regulatory Commission**.

2.2.1 BROAD SCOPE LICENSE

Pursuant to the *Radiation Control Act Title 25, Article 11, CRS 1989*, Replacement Volume, as amended, and the *Colorado Rules and Regulations Pertaining to Radiation Control*, Part 3, and in reliance on statements and representations heretofore made by the University of Colorado Denver as license applicant, the university has been licensed by the CDPHE to receive, possess, use, and transfer radioactive materials as designated by license No. Colo-835-01; and to use such radioactive materials for the purposes and at the locations specified in the license, which includes locations of use at our two main campuses (CU Denver Campus in Denver and the CU Anschutz Medical Campus in Aurora) and at several satellite locations. This license is subject to all applicable rules, regulations, and orders now or hereafter in effect of the CDPHE, and to all conditions specified in the license document. A copy of the medical broad-scope license is provided as Appendix I or through the Environmental Health and Safety office at 303-724-0345.)

2.2.2 INSPECTIONS OF UNIVERSITY LICENSES BY CDPHE

The university is subject to inspections every other year by the **Radiation Control Division of the CDPHE**, to ensure that all requirements of the license are being met. These inspections are very thorough, including monitoring checks of laboratory areas, inspection of procurement and disposition records, inspection of records of laboratory monitoring by the principal investigator, inspection of records of the qualifications of individual users, review of records of personnel monitoring and records of administrations to patients. Violations of license requirements can result in a variety of enforcement actions, including fines and suspension or revocation of the license.

2.2.3 UNIVERSITY OF COLORADO HOSPITAL (UCH) LICENSE

In 1991, subsequent to University of Colorado Hospital's separation from the University of Colorado Denver and the creation of the University Hospital Authority as a separately-governed institution, a separate radioactive materials license, No. Colo-828-01, was issued to University Hospital by CDPHE. University Hospital maintains a completely separate radiation safety program

from CU Denver | Anschutz, including a separate Radiation Safety Committee and Radiation Safety Officer.

2.2.3.1 Geographical Boundaries of CU Anschutz and UCH Licenses

On the CU Anschutz campus at the Anschutz Medical Campus, which includes University of Colorado Hospital's main facilities, the UCH license governs all activities taking place in the UCH main building. Activities taking place in all other buildings on the CU Anschutz campus, including buildings contiguous with the UCH buildings, are governed by the University of Colorado license, No. Colo-835-01. Each institution maintains off-campus satellite facilities, which are governed by the licenses of the respective institutions.

2.2.3.2 Joint Projects Involving UCH and CU Anschutz

Research or other projects that involve activities both within the UCH buildings and elsewhere on campus will typically require approvals from both institutions' radiation safety committees, and may require that radioactive materials be transferred from one license to the other by appropriate paperwork when they pass across the geographical boundaries between the UCH buildings and the rest of campus. EHS should be consulted as far in advance as possible when such projects or transfers of radioactive materials are contemplated.

2.2.4 CU DENVER | ANSCHUTZ OFF CAMPUS FACILITIES AND CU DENVER | ANSCHUTZ ADMINISTERED GRANTS' FUNDING OF OFF CAMPUS ACTIVITIES

The university maintains both authority and responsibility for oversight of regulatory compliance in all activities funded by CU Denver | Anschutz-administered grants and monies, including those taking place at off-campus locations. In some cases, the off-campus activities take place under the authority of the radioactive materials license of the host institution, subject to the immediate oversight of the host institution's Radiation Safety Committee and RSO. In other cases, the facility in question is considered a satellite of CU Denver | Anschutz, and is listed as an off-campus location of use for the university's license; hence, the university's CIR and EHS department exert direct oversight of the activities occurring at the off-campus location. EHS should be consulted whenever questions arise.

2.2.5 GENERALLY-LICENSED RADIOACTIVE MATERIALS

In some specific cases, state and federal regulations allow the manufacture and distribution of specific items containing radioactive materials, without requiring that the party acquiring such materials be the holder of a specific license for radioactive materials. Such cases, typically involving very small amounts of radioactive material, are referred to as "general licenses." The improper use or disposal of radioactive materials can create serious problems for the university, regardless how small or insignificant the amount of radioactivity or what its regulatory status. All persons at the university who propose to acquire radioactive materials, regardless of the particular

circumstances, should check first with EHS. Some specific cases of interest are discussed in more detail in sections [2.2.5.1](#) through [2.2.5.3](#) below.

2.2.5.1 Kits for *in vitro* Assays

Some small kits for radioimmunoassays or other *in vitro* clinical-type assays are allowed to be distributed to small, free-standing laboratories, physicians' offices, etc., who hold a "General License Certificate" from CDPHE. CDPHE does not issue such certificates to individual persons or units at the university; rather, they require that such items be controlled under the usual mechanisms of its medical broad-scope license. Consequently, such kits can be used at the university only by authorized Principal Investigators.

2.2.5.2 Liquid Scintillation Counters, Static Eliminators, Electron-capture Detectors, and Other Devices

Several types of devices in common use at the university are manufactured and supplied with generally-licensed radioactive sources. Liquid scintillation counters typically contain small gamma sources as external standards for quench monitoring, and gas chromatographs with electron-capture detectors contain weak beta sources. Static-elimination devices containing alpha sources are sometimes associated with photographic equipment, scales and balances, and other instruments. All such sources should be registered with EHS, and investigators must be aware that the transfer or disposal of such equipment must be communicated to EHS. CDPHE has imposed requirements of this type on the university in license inspections, due to the public concern that arises when such items are used or disposed improperly and appear inappropriately in some public area.

2.2.5.3 Uranium (Uranyl Acetate, Uranyl Nitrate)

Natural or depleted uranium is not controlled by the licensing agencies in the same manner as most radioactive materials, as it is regarded as "source material" that is mined directly from the earth. Materials such as uranyl acetate and uranyl nitrate can be purchased under a general license. Due to the serious waste-disposal problems associated with such materials, investigators utilizing them are strongly urged to consult with EHS regarding the management of the wastes that will be generated.

HSC 2.3 PROGRAM RESPONSIBILITIES

The CU Denver | Anschutz license is contingent upon the existence of a radiation safety committee, the **Committee on Ionizing Radiation (CIR and HuCIR)** and a radiation safety organization which shall consist of a **Radiation Safety Officer (RSO)** and an **Environmental Health and Safety Department (EHS)** which, among other requirements, must:

- assure that any authorized Principal Investigator and Authorized Users using radioactive materials is qualified by training, board certifications and experience, has the facilities and equipment to handle the materials safely, and proposes a use which is safe to all concerned, with the word “use” to be construed as including all of the physical and chemical handling steps involving the radioactive material and all of the safety practices and precautions involved therein,
- assure observance of all safety standards established or regulated by the CDPHE Division of Radiation Control, the U.S. Nuclear Regulatory Commission (NRC), and other regulatory or standards-setting agencies,
- exert *a priori* control over all acquisitions of radioactive materials to ensure compliance with the CU Denver | Anschutz license, and keep records of the receipt, storage, use, transfer and ultimate disposal of all radioactive materials used at the university, and
- keep records of the monitoring of
 - personnel,
 - effluents of air and water, and
 - areas potentially affected by the use of radionuclides and other sources of ionizing radiation such as x-ray tubes.

HSC 2.4 COMMITTEE ON IONIZING RADIATION (CIR)

The **Committee on Ionizing Radiation** shall supervise the radiation health and safety of university personnel and patients and provide for the facile intramural use of radiation sources by maintaining and administering a broad-scope institutional license for the use of radioactive materials.

2.4.1 AUTHORITY AND RESPONSIBILITIES OF THE COMMITTEE

The CIR is established by the institution, under the authority of the Office of Vice Chancellor for Research. The CIR, as the institutional radiation safety committee, must conform to RH 3.11.2 of the *Colorado Rules and Regulations Pertaining to Radiation Control*, which describes the requirements for a Type A license of broad scope, and RH 7.8 and 7.9 of the same regulations, which describe the requirements for a medical license. Based on a majority vote of its membership, the Committee is empowered to approve or deny applications for individual authorization to procure radioactive materials and to warn or suspend temporarily or permanently the authorizations of individuals found to be in violation of its rules.

2.4.2 AUTHORITY OF ENVIRONMENTAL HEALTH AND SAFETY DEPARTMENT ADMINISTRATORS

The Committee grants to the Environmental Health and Safety Department administrators (Radiation Safety Officer, Alternate Radiation Safety Officers, Director of Environmental Health and Safety Department) the authority to prevent any unsafe practice and the authority to communicate promptly with an appropriate level of management as necessary to halt any operation they deem unsafe.

2.4.3 COMMITTEE MEMBERSHIP

The Chancellor, Vice Chancellor for Research, or Dean of the School of Medicine shall appoint no fewer than three but no more than nine members from the Executive Faculty, and shall designate a Chairperson. Preferably the latter shall have served previously a minimum of one year on the Committee. No division shall be represented by more than two Committee members. When possible, one-half of the membership of the Committee shall be basic scientists and the other half clinicians. The normal term of appointment shall be for three years. Reappointment shall not be made until at least two years have elapsed. Consistent with RH 7.8. of the *Colorado Rules and Regulations Pertaining to Radiation Control*, the Chancellor, Vice Chancellor for Research, Associate Vice Chancellor for Regulatory Compliance or Dean of the School of Medicine appoints an official, such as the Associate Dean for Research Affairs, to serve as the management representative to the Committee, in an *ex officio* capacity.

2.4.4 COMMITTEE'S ESTABLISHMENT AND STAFFING OF A RADIATION SAFETY PROGRAM

Through the Chancellor's office the Committee shall arrange for the hiring of such personnel as may be necessary for efficient operation of a radiation safety program. A consultant skilled in matters of radiation protection shall be designated by the Committee to supervise its employees on a day-to-day basis and to assist users who require advice on matters of protection, exposure calculations, etc. This individual shall be an *ex officio* member of the committee.

2.4.5 COMMITTEE MEETINGS

The Committee shall formally meet as often as required, but not less than 4 times every calendar year. Minutes will be maintained and filed in the Office for Research Committees Support. The Committee shall, by e-mail, review all electronic applications from Principal Investigators for authorizations for the procurement of radioactive materials weekly (or as required). All requests for additional application information and recommended changes, prior to Committee approval, will be initiated through EHS.

2.4.6 CIR REVIEW OF APPLICATIONS FOR AUTHORIZATION TO PROCURE AND USE RADIOACTIVE MATERIALS

2.4.6.1 Initial Review of Applications by EHS

EHS will provide an initial review of each application to assess its basic conformance to Committee requirements. The application must be submitted electronically and must contain all of the information required in the current version of the appropriate application form. In communicating the resulting recommendations to the applicant, the EHS reviewer will also supply such specific technical and regulatory reference information and calculations as may be pertinent to a health physics evaluation of the proposed use, for the information of both the applicant and the Committee. If no response to the initial review and any subsequent communication is received by EHS within 45 days of the last communication the application will be inactivated, archived, and a new application will be required.

2.4.6.2 Submission of Copies of an Application by the Applicant

After the applicant has had an opportunity to consider the EHS reviewer's remarks and has submitted a final version electronically, EHS will circulate the applications and EHS reviewer's comments to Committee reviewers via email. Each applicant must also submit one original signed copy of the application for EHS's records. Approved electronic signatures are accepted. Please contact EHS for additional information.

2.4.6.3 Actions to Be Taken by Reviewers

Members shall vote on each application via electronic mail or committee meeting by approving (e.g. yes, approve, ok), disapproving (e.g. no, disapprove,) or conditionally approving (e.g. maybe, yes provided that) with appropriate comments, **WITHIN TEN BUSINESS DAYS**, to EHS. The Committee may authorize the RSO to determine the adequacy of applicants' responses to *conditional approvals* (maybe) if the Committee specifically determines that the RSO is qualified to assume this role, but responses to *disapprovals* must be resubmitted in writing (via e-mail) to the appropriate reviewer(s).

2.4.6.4 Handling of Time Deadlines

EHS will process the application at any time after the ten-business-day deadline has passed, as soon as EHS can obtain responses from a majority of the reviewers, and will proceed on the basis of the reviewers' remarks that have been received as of that time. A reviewer's remarks that are received after such processing time will be duly considered and every attempt made by EHS to reconcile any concerns or objections raised, but the absence of one or more reviewers' responses will not be allowed to further delay the processing of the application if the above conditions have been met.

2.4.6.5 Establishing the Committee's Approval of an Application

Upon initiation of processing of the reviewers' remarks by EHS, if questions are raised, approval will be withheld until all questions have been answered satisfactorily by communications between the applicant and Committee reviewers, with said communications to be facilitated by EHS staff, who will safeguard the confidentiality of reviewers. The CIR

chairperson will have the responsibility of facilitating resolutions to issues that have not been satisfactorily resolved by the communications facilitated by EHS. A meeting of the Committee will be called if necessary to evaluate an application; final action at the Committee meeting will be by majority vote. If response to a reviewer's remark or any subsequent communication is not received by EHS within 45 days of the last communication the application will be inactivated, archived, and a new application will be required to be submitted to resume the application and approval process.

2.4.6.6 Issuance of Authorization to the Applicant

Upon establishing that approval has been granted, EHS staff will email the authorization electronically to the PI and issue a written authorization to the applicant, which will be signed by the chairperson, and which will summarize for the applicant's reference the relevant constraints and conditions on the applicant's use of the specified radioactive materials, as determined by the Committee's review process.

2.4.7 CIR REVIEW OF QUALIFICATIONS FOR PRINCIPAL INVESTIGATOR STATUS

In order to be credentialed as a "user" of radioactive materials under the university's license ("user" meaning a principal user listed on the radioactive materials license, as the term is commonly employed in radioactive materials licensing, and not referring to all persons who actually physically use the material), an applicant must meet the criteria established herein and be authorized as a Principal Investigator by the CIR. A Principal Investigator must be a faculty member with training and/or experience appropriate to the type of investigative procedure involving radioactive materials as requested on the application and must complete the required training administered by the Environmental Health and Safety Department, as specified in section [2.4.11](#) below. Additional guidance is provided in [Appendix XVII](#) to this *Manual*.

A faculty member who, in the Committee's judgment, does not meet all of the appropriate qualifications of training and experience in the relevant uses of radioactive materials must first complete the university's training requirements for PI's ([2.4.11](#)) and may then be issued a provisional authorization under the supervision of an authorized Principal Investigator, who shall serve as a preceptor, for a period to be determined by the Committee. After the prescribed period has elapsed, a formal request for review can be initiated by the faculty member desiring the autonomous status of "authorized Principal Investigator."

2.4.8 PRINCIPAL INVESTIGATOR'S REGISTRATION OF AUTHORIZED COINVESTIGATORS AND RADIATION WORKERS WITH EHS

The Principal Investigator must be able, upon request, to provide EHS with a list of laboratory personnel that are authorized to work with radioactive materials under each of the PI's authorizations, as "coinvestigators" and "radiation workers," This list must be provided at the time of audits by the RSO, and on the application form for new authorizations. The PI must

ensure that certification testing (section [2.4.11](#) below) is completed by each such person, prior to allowing said person's involvement on any project utilizing radioactive materials, wherein that person may use or affect the use of such materials. Failure to comply with this requirement will result in action by the CIR.

2.4.9 CONDITIONS REQUIRING A NEW APPLICATION TO THE COMMITTEE

There are various situations that occur in practice, in which a new application to the Committee is required. Sections (2.4.9.1 through 2.4.9.3) below list three common situations in which it must be understood that a new application is required. This list is not necessarily exhaustive with respect to situations in which the Committee may decide that a new application is required. Consult EHS for advice when you are unclear if a new application is required.

2.4.9.1 Operations Not Within the Scope of an Authorized Principal Investigator's Usual Personnel or Facilities

An authorized Principal Investigator who allows the acquisition of radioactive materials under his or her authorization must have control of the use of those materials, as described in ([2.4.13](#)) below. If the authorized Principal Investigator allows use of the materials in locations that are not under the authorized PI's direct administrative control, then the overall situation, including the location of such use in geographical relationship to the location of the authorized PI's own laboratories and offices, must be such as to provide the Committee with a reasonable assurance that effective oversight and control is being exercised by the authorized PI. In addition, the radioactive materials must be used in a manner consistent with the authorized PI's approved uses. Failure to meet these conditions constitutes a clear indication that a new application must be filed by an investigator who will exercise such control over the use in question.

2.4.9.2 New Type of Experiment

If an authorized PI proposes a new use of radioactive materials (i.e., a new type of experiment) that is significantly different than the use(s) for which that PI has previously been authorized by the Committee, then a complete new application is required. Investigators who have questions about specific situations should consult EHS to determine when a complete new application is required, in contrast to a less extensive and rigorous communication to the Committee, or none at all.

2.4.9.3 Previous Authorization Expired

Once an authorization has passed its expiration date no materials may be procured under that authorization and any continuance of previously authorized work requires submittal of a new full application rather than a short renewal application. Principal Investigator's should make note of this when considering renewal and when tracking expiration dates of currently held authorizations.

2.4.10 TRANSFER OF AUTHORIZATION

No existing authorization may be transferred to another Principal Investigator or Authorized User except by the submission and approval of a new and complete application on the current version of the application form, signed by the PI or AU who will hold the authorization.

2.4.11 CIR REQUIREMENTS FOR CERTIFICATION AS AUTHORIZED PRINCIPAL INVESTIGATOR, AUTHORIZED USER, OR COINVESTIGATOR/RADIATION WORKER

All persons at the university are required to complete specific mandatory training requirements at CU Denver | Anschutz before receiving authorization as “Principal Investigators” or “radiation workers” working unsupervised with radioactive materials. CU Denver | Anschutz does not accept training received at other institutions in lieu of the university’s mandatory minimum requirements. This policy is compelled by the university’s institution-specific requirements, by periodic changes in state and federal regulations, and by the impracticalities of determining the adequacy of other institutions’ training programs. Current details of the training program are available from Environmental Health and Safety.

Authorized User (AU)

Credentialed physicians granted authorization in writing by the Committee on Ionizing Radiation as Authorized Users of radioactive materials are responsible for the safe use of these materials by workers under their supervision. These individuals must meet the criteria listed in 6 CCR 1007-1 Part 07 appendices 7D or 7E. All medical use of radioactive materials is under the supervision of an AU. The AU is fully responsible for the acts and omissions of supervised individuals.

2.4.12 INFORMATIONAL RESPONSIBILITY OF CIR MEMBERS

All Committee members should review and become familiar with the contents of this *Manual* and the other program documents provided by EHS, in order to responsibly and effectively discharge their duties.

2.4.13

RESPONSIBILITIES OF AUTHORIZED PRINCIPAL INVESTIGATORS

The only administrative function of a radioactive materials authorization is to assign the responsibility and authority for assuring the safe and proper use and disposal of all radioactive materials procured under said authorization. There may be but one authorized PI for a given authorization, who shall be a qualified faculty member, and who shall be charged with this authority and responsibility. The responsibility created by the radioactive materials authorization may not be shifted from the authorized PI onto others by delegation of work or other functions. All persons named as coinvestigators or radiation workers are subject to the authority of the authorized PI in matters pertaining to 1) the procurement of radioactive materials under the authorization and 2) the safe and proper use and disposal of those materials.

In a practical sense, the PI named on a particular authorization for procurement of radioactive materials is the person responsible for assuring the safe and proper use and disposal of all materials obtained under the auspices of that authorization. In a regulatory sense, the authorized PI is responsible to assure compliance with all of the requirements of this *Manual* and other institutional policies and procedures documented in EHS publications, with which the PI should have become familiar in the course of completing the required training and certification testing. In addition, the authorized PI is bound by the terms and conditions of the authorization as issued and administered by EHS under the CIR's authority, and by all of the representations and commitments that were made to the CIR in order to obtain the authorization.

RESPONSIBILITIES OF AUTHORIZED USERS

Provide proper instructions in all policies, regulations, and license conditions to individuals authorized to use RAM under the AU authorization. AU must ensure compliance with the CDPHE rules and regulations pertaining to radiation control, UC Denver policies and procedures, and the conditions of the UC Denver Radioactive Materials License. If required, AU must be physically present; otherwise, AU must be available by phone within ten (10) minutes to communicate with the supervised individual. AU is responsible for reporting to the Radiation Safety Officer any unusual incidents including theft or loss of radioactive materials, major spills, or misadministrations as outlined in 6 CCR 1007 Part 7.21.

2.4.14 SIGNIFICANCE OF THE TERMS “PRINCIPAL INVESTIGATOR,” “COINVESTIGATOR,” AND “RADIATION WORKER”

It should be understood that the terms “coinvestigator” and “radiation worker,” as used in the present context, are specific to a particular authorization for procurement of radioactive materials, and may apply to any person, other than the authorized PI, who will work with or direct work with radioactive materials that are procured under the auspices of that authorization. Coinvestigators must be faculty and are expected to complete the radiation safety certification testing ([2.4.11](#)) at the “Investigator Level.” The term “coinvestigator” is otherwise indistinct from “radiation worker” for the purposes of the radioactive materials authorization, in that it does not *per se* confer any unique authority or responsibility: coinvestigators do not have the authority and responsibility that are assigned to authorized PIs ([2.4.13](#)).

Apart from the authority issues defined above in ([2.4.13](#)), and any such distinctions as may be defined by the Chancellor or the Dean, the terms “Principal Investigator,” “coinvestigator” and “radiation worker” shall not be construed to imply any other distinctions related to administrative reporting relationships, grant awards and other sources of funding, publications, or other matters affecting pay, status, tenure, etc.

2.4.15 AUDITS OF AUTHORIZED PRINCIPAL INVESTIGATORS' LABORATORIES BY ENVIRONMENTAL HEALTH AND SAFETY DEPARTMENT

The authorized PI's assurance of compliance with the specific requirements described in section [2.4.13](#) above, at the level of the individual authorization, is a key link in establishing the institution's overall compliance with state and federal regulations and the terms and conditions of the institution's license. The authorized PI's laboratories and operations are subject to regular audits by EHS, which are conducted under the authority of the CIR, to establish and document this regulatory compliance. The basic guidelines used by the Committee for assigning audit frequency to approved uses of radioactive materials and corresponding authorizations are found in [Appendix XV](#) of this *Manual*.

2.4.16 RULINGS AND ACTIONS BY THE COMMITTEE

The CIR shall have the authority to make final judgments and take actions relative to any situation involving ionizing radiation. Reports by the RSO or other employees of the Environmental Health and Safety Department will be forwarded to the Committee with recommendations. In addition to program policy and procedural issues, the Committee may consider problems relating to applications, rule infractions and disciplinary actions. The Committee shall have the authority to revoke or suspend any authorization for cause, and the authority to change the conditions of existing authorizations at any time, based on any new information that may come to the Committee's attention.

The Committee will take action against violators of rules of the Committee in as objective a manner as possible, preferably by letter to the individual concerned from the Committee as a whole.

2.4.17 TERMS AND EXPIRATION OF AUTHORIZATIONS FOR RADIOACTIVE MATERIALS

Radioactive materials authorizations issued to PIs by the CIR carry maximum terms of two years for High hazard level, four years for Medium hazard level, and six years for Low hazard level. Any authorization that has exceeded this term requires a short renewal application to the CIR, to be processed in the same manner as all other applications, as described elsewhere in this *Manual*. Authorizations due to expire will typically be identified and brought to the PI's attention via e-mail approximately 90 days prior to the authorization expiration date. The RSO will suspend any authorization if a renewal application has not been submitted by the expiration date.

If a laboratory is in possession of radioactive materials obtained under the expired authorization they will be contacted to schedule disposal of that material. **NO RADIOACTIVE MATERIALS** may be held at CU Denver | Anschutz without a current and active authorization approved by the CIR. A 30-day grace period may be granted to the PI in order to prepare a new application for authorization and retain the materials. Once that grace period has lapsed the RSO will confiscate the materials under authority of the CIR. If no application is received within 30 days of confiscation the material will be properly disposed.

2.4.18 PROTECTION OF HUMAN RESEARCH SUBJECTS

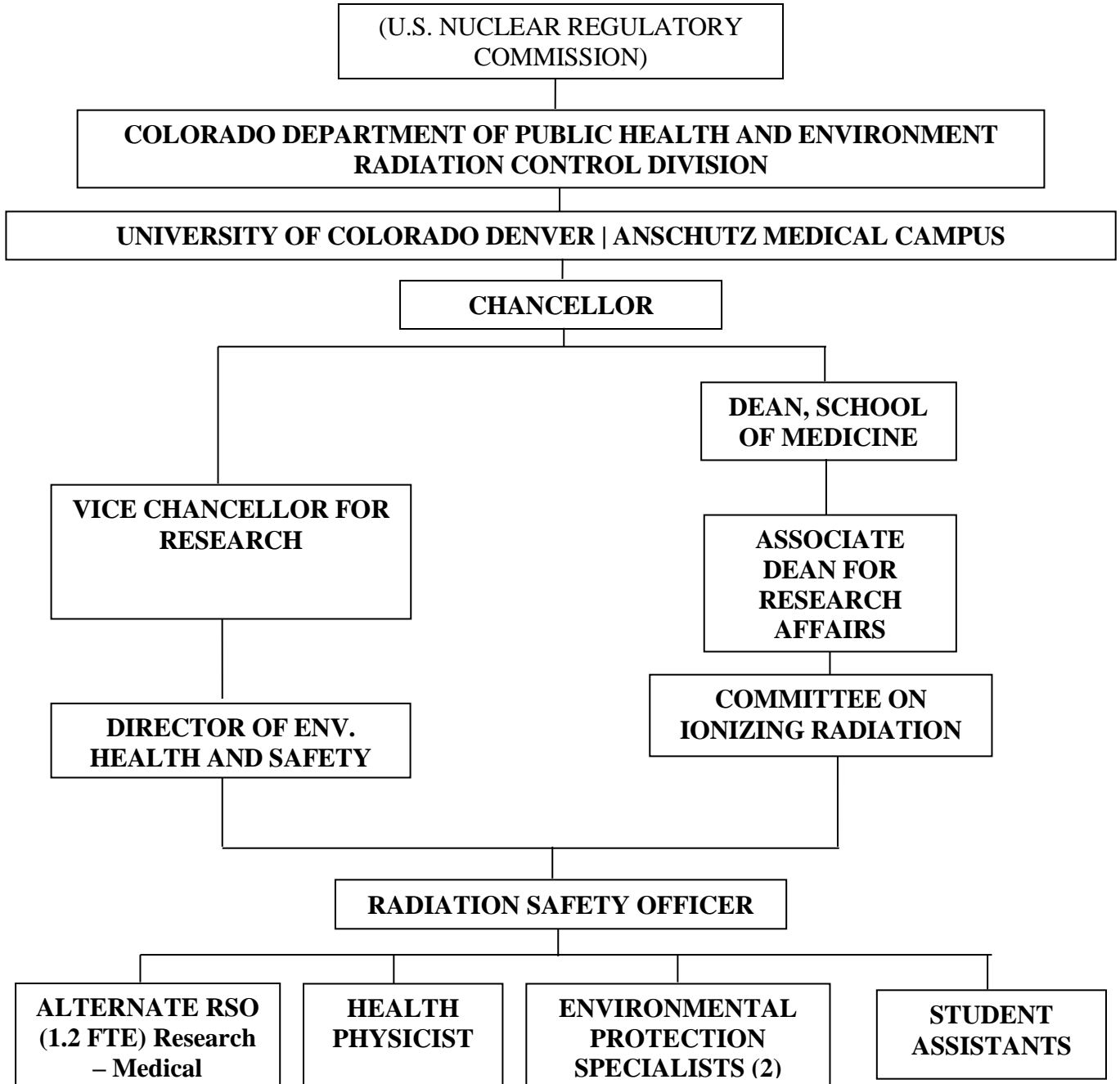
Before a research protocol application involving the administration of ionizing radiation and/or radioactive materials to human research subjects can be considered by the CIR or HuCIR, a corresponding protocol must have been either approved or concurrently being considered for approval by the Colorado Multiple Institutional Review Board (COMIRB). Such research protocols may also be subject to the authority of the CU Denver | Anschutz Radioactive Drug Research Committee (RDRC) if they involve basic human research (use of radioactive materials as tracers to study human metabolism, etc.) Under no circumstances will the CIR issue a final authorization to use radioactive materials for human research unless the Principal Investigator or the Authorized User possesses current COMIRB and RDRC approval letters.

For applications involving human use, the CIR will primarily consider issues associated with protection of persons other than the patient/subject, such as faculty, staff, and visitors, and the environment. In relation to issues of patient/subject dose and dosimetry, the CIR will generally seek only to obtain an assurance that COMIRB and RDRC requirements have been met through the processes of those committees.

Human subjects that need to be hospitalized, whether for regulatory reasons deriving from the administered radioactive materials or for other reasons, must be hospitalized in University of Colorado Hospital. Such studies therefore occur at least partly under the University of Colorado Hospital radioactive materials license, and require application to the University of Colorado Hospital Radiation Safety Committee. The CU Denver | Anschutz RSO can help the PI to determine whether human subjects to be administered radioactive materials are strictly required to be hospitalized by state and federal regulations, or likely to be required to be hospitalized by the university CIR, and therefore to which committee(s) application(s) must be made.

HSC 2.5 PROGRAM ORGANIZATION

UNIVERSITY OF COLORADO DENVER



HSC 2.6 COMPLIANCE WITH REGULATIONS AND ADVISORY GUIDANCE

Radioactive materials and other sources of ionizing radiations are subject to a wide array of *regulations* enforced by federal, state, regional, and local government agencies. These agencies and their regulations are listed in [Appendix II](#) to this *Manual*. In addition, voluminous *advisory guidance* is published by these agencies and by various standards-setting bodies, such as the National Council on Radiation Protection and Measurements, which is chartered by Congress. Although the *advisory guidance* does not have the direct regulatory authority of coded regulations, published *advisory guidance* is often included by reference in radioactive materials licenses or otherwise used as a standard by the licensing agencies. In addition, published *advisory guidance* creates community standards of practice that have considerable legal significance with regard to establishing whether due diligence was observed in the protection of personnel and the environment.

2.6.1 PRINCIPAL INVESTIGATORS' KNOWLEDGE AND UNDERSTANDING OF REGULATIONS AND ADVISORY PUBLICATIONS

Authorized PIs are expected to attain an understanding of general regulatory requirements through their training and experience in safe use of radioactive materials, including their completion of the radiation safety certification exam administered by EHS as stipulated in [\(2.4.11\)](#) above. However, authorized PIs are not expected to have a complete command of the regulations and advisory guidance that affect their use of radiation sources and radioactive materials. It is the duty of staff professionals (e.g., health physicists) in the EHS Department to maintain a current knowledge of the appropriate regulations and advisory guidance and to create CU Denver | Anschutz-specific program documents, beginning with this *Manual* and including the documentation produced in EHS staff's assistance to the CIR in its review of applications and issuance of authorizations as described in [\(2.4.6.1\)](#) and [2.4.6.6\)](#) above, that serve to provide detailed guidance to authorized PIs and their personnel, in order to facilitate compliance.

HSC 2.7 THE UNIVERSITY AS LOW AS REASONABLY ACHIEVABLE (ALARA) PROGRAM

Persons working with sources of ionizing radiations should be aware that the Colorado Maximum Permissible Doses (MPD) for occupational exposures to ionizing radiation are maximum legal limits and not generally practical working guidelines for acceptable levels of radiation exposure. CU Denver | Anschutz is committed to maintaining employees' radiation exposures As Low As Reasonably Achievable (ALARA), under the MPD. radiation workers are expected to take an active role in maintaining their exposures ALARA.

The potential adverse health effects of low level radiation exposure, specifically, increased risk of carcinogenesis and/or genetic defects in future generations, is considered by the regulatory agencies to be non-threshold phenomena. MPD does not provide a simple line of demarcation between “safe” and “unsafe” or “harmless” and “harmful” radiation doses. The risk of any radiation exposure, including those less than the MPD, decreases with the magnitude of the exposure. Doses less than the MPD carry risks that are considered for purposes of regulatory policy to be very small but NOT

nonexistent. These considerations define the rationale for maintaining radiation exposures ALARA, so as to avoid any unnecessary risk, no matter how small.

Biomedical research, in contrast to clinical radiology, rarely involves working with sources of penetrating radiations that are likely to deliver doses that exceed the ALARA limits. That is, the hazard of significant *external* doses from *direct irradiation*, which are the doses reported on personal monitors is minimal. Correspondingly, very few such reports are seen, and dose reports substantially exceeding the ALARA limits are usually attributable to a misuse of the dosimeter or an artifact of the reporting process. The emphasis in the university's program is placed upon:

- thoroughly investigating those few dose reports that *do* exceed ALARA levels, and
- promoting informational and educational communications to radioactive materials users in order to minimize the likelihood that a significant dose will be received by self-contamination (*internal* dose), which is the greater hazard in the biomedical research setting.

2.7.1 RADIATION SAFETY OFFICER'S REVIEW OF DOSIMETRY AND BIOASSAY RESULTS

Maximum Permissible Dose (MPD) limits were published by the CDPHE, effective on January 1, 1994, under RH 4.6, "Occupational Dose Limits for Adults", in the *Colorado Rules and Regulations Pertaining to Radiation Control*. These limits are all in the form of annual, rather than quarterly, limits, and they require summation of dose from both internal and external sources.

- Doses from *external* sources are taken directly from the reported doses on personal monitors.
- Doses from *internal* sources are calculated when bioassay measurements indicate the presence of some measurable amount of a radionuclide in a worker's body.

The RSO reviews each monthly or quarterly dosimetry report as it comes in from the vendor, in order to evaluate radiation exposure from *external* sources, and performs comparisons for the ALARA Program simultaneously. Monthly dosimeters use comparisons based on the cumulative *quarterly* totals that have been reported to date. That is, each time a monthly report is reviewed, the cumulative quarterly dose equivalents in mrems that have been reported for a worker for the calendar quarter to the date of the monthly report, where the complete calendar quarters are Jan-Mar, Apr-Jun, Jul-Sep, Oct-Dec, are compared to the ALARA limits. Results reported for quarterly dosimeters are simply compared directly to the quarterly limits.

The ALARA limits are defined by

(I) **one tenth** of one quarter of the applicable annual MPD (**ALARA Level I**), and

(II) **three tenths** of one quarter of the applicable annual MPD (**ALARA Level II**).

Table: Applied Annual Occupational* Dose Limits for Adults and Related ALARA Reporting Levels for Cumulative Quarterly Totals (mrems)**

| Part of Body Affected | Applicable Annual Occupational MPD | Quarterly ALARA Level I Limit | Quarterly ALARA Level II Limit |
|---------------------------------|---|--------------------------------------|---------------------------------------|
| Whole Body ¹ | 5,000 | 125 | 375 |
| Skin of Whole Body ² | 50,000 | 1,250 | 3,750 |
| Extremity ³ | 50,000 | 1,250 | 3,750 |
| Lens of Eye ⁴ | 15,000 | 375 | 1,125 |

*These limits apply to *radiation workers* who are trained, have passed the Radiation Safety Certification Examination administered by EHS, and are being regularly monitored with a whole body/TLD dosimeter. *Persons who do not meet these criteria must be considered members of the public*, and much stricter criteria (e.g., an annual Maximum Permissible Dose of 100 mrems' total effective whole-body dose equivalent) are applicable.

**These limits apply to ADULTS ONLY - *the limits for minors are one tenth of those shown* in the table. The Maximum Permissible Dose for fetal dose to *declared-pregnant workers* is "500 mrems over the full term of gestation, acquired at a more or less steady rate," and reported fetal doses in excess of 10 mrems in any month are generally reported to the declared-pregnant worker and investigated by the RSO.

¹e.g., deep dose reported on the whole-body dosimeter

²e.g., shallow dose reported on the whole-body dosimeter

³e.g., finger dose reported on a ring dosimeter

⁴e.g., eye dose when reported separately on an eyeglass dosimeter

ALARA limits are operational action levels, set at a fraction of the legal MPDs that trigger notification of the individual dosimeter wearer and investigation by the RSO. The use of quarterly ALARA limits allows more flexibility in accommodating month-to-month variations and small anomalies, than would be the case if each individual monthly dose were compared to one tenth of *one twelfth* of the annual limit for ALARA Level I, etc.; yet it still meets the ALARA Program requirements of the licensing agencies. The limits for reporting ALARA overexposures and initiating related correspondence from the RSO to notify the affected individual, are therefore as shown in the table above.

All reports of doses exceeding ALARA limits, both Level I and Level II,

- are reported to the affected individual in writing, along with explanatory information, and
- are investigated by the RSO, who seeks to determine their seriousness, depending on magnitude and cause.

For Level II dose reports, the affected individual is required to reply in writing to the RSO regarding the circumstances that may have created the dose report.

The RSO may also seek to determine whether, in cases of concern, the worker's exposure could be reduced by reasonable and economical changes in procedures, facilities, or equipment, and may make corresponding recommendations to the CIR.

2.7.2 COMMITTEE'S QUARTERLY REVIEW OF DOSIMETRY AND BIOASSAY RESULTS

All reported doses exceeding ALARA levels are reported to the CIR by the RSO, and are discussed at the CIR's quarterly meetings. At its discretion, the CIR may choose to address problem situations individually and/or at the program level, by correspondence or other actions.

2.7.3 RESPONSIBILITY OF AUTHORIZED PRINCIPAL INVESTIGATORS

In addition to their responsibilities as defined elsewhere in this *Manual*, authorized PIs are responsible for the implementation of any controls required by the CIR as a result of reported doses exceeding ALARA levels.

2.7.4 RESPONSIBILITY OF ALL PERSONS WORKING WITH RADIOACTIVE MATERIALS

The individual working directly with radioactive materials bears a major responsibility in maintaining doses ALARA. This is especially so in the biomedical research setting, where most doses of concern are likely to result from incorrect actions of the affected individual(s), rather than being a necessary or likely concomitant of the activity being performed.

Environmental Health and Safety Department
Office of Vice Chancellor for Research

2016 RADIATION SAFETY MANUAL

PART III: ADMINISTRATION OF THE MEDICAL BROAD SCOPE RADIOACTIVE MATERIALS LICENSE

In addition to the administrative controls explicitly described in the previous section on Authority and Responsibility, an extensive program of services and record-keeping systems is necessary to maintain the radioactive materials license. This program, which is described below, is administered by the RSO and the Environmental Health and Safety Department of the Office of the Vice Chancellor for Research.

HSC 3.1 THE UNIVERSITY MEDICAL BROAD SCOPE LICENSE

The university's medical broad scope radioactive materials license and all files pertaining to it are maintained by the university's RSO in the offices of the Environmental Health and Safety Department.

3.1.1 FEATURES OF THE MEDICAL BROAD SCOPE LICENSE AND TYPES OF RESEARCH PROJECTS THAT MAY REQUIRE EXTRA LEAD TIME FOR AMENDING THE LICENSE

A hard copy of the university's medical broad scope radioactive materials license is maintained at the Environmental Health and Safety Office. The license allows the university to acquire, possess, use, and transfer specified radionuclides in specified chemical and physical forms, for specified "uses." The salient features of the license are described in the following subsections. Any research project that has the unusual characteristics described in any of the below subsections will require the RSO to consult the CIR and obtain an amendment to the institutional license, which requires at least *two months* to obtain from the CDPHE. This must be completed before the Principal Investigator can be authorized for such research by the CIR.

3.1.1.1 Radioactive material (element and mass no.)

The license specifies the radionuclides that the university may acquire. Because the license is a "broad scope" license, the university is licensed for all radionuclides with atomic numbers 1 through 85 (elements hydrogen through astatine), in a specified amount. In addition, certain specific radionuclides are allowed to be possessed in larger amounts, or in specified sealed

sources for use in certain devices. Any investigator proposing to use a radionuclide not listed must be aware that such an authorization would require amendment of the institutional license.

3.1.1.2 Chemical and/or physical form

Because the license is broad scope, most of the radionuclides may be acquired in “Any” chemical or physical form.

3.1.1.3 Maximum quantity licensee may possess at any one time

For each specific listing, the university is licensed for an overall “institutional” possession limit that limits the entire sum of all materials in the possession of the university, including those materials in the possession of individual PIs and those in the possession of EHS (packages awaiting distribution and wastes being decayed or awaiting final disposal). Due to the nature of the license, this quantity is set at 50 Curies. Any investigator proposing to use a radionuclide in quantities that represent a substantial fraction of the possession limits for the entire institution, as listed on the license, must be aware that such an authorization would require amendment of the institutional license.

3.1.1.4 Authorized uses

The medical broad scope license allows CU Denver | Anschutz to use most of its radioactive materials for a variety of “uses” described as “demonstration, teaching, and research including administration to animals and administration to human subjects for basic human research and for radiopharmaceutical preparation and development.”

3.1.1.5 Locations of use

The license allows the university to possess its radioactive materials at specified locations, identified by street addresses, including CU Denver, CU Anschutz in Aurora, as well as several off-campus satellite locations. Any investigator proposing to use radioactive materials at an off-campus location not listed on the current license must be aware that such an authorization would require amendment of the institutional license.

3.1.2 OBTAINING COPIES OF THE LICENSE OR OTHER LICENSE INFORMATION

Copies of the license and related information are available by calling EHS. Vendors and collaborating institutions supplying radioactive materials to CU Denver | Anschutz are required by law to maintain a copy of the license. EHS provides copies to known suppliers as appropriate and will arrange to provide copies to new suppliers or other interested parties whenever they are identified.

3.1.3 AMENDMENTS TO THE LICENSE

Whenever a need to amend the license is identified and verified by the CIR and the RSO, the RSO will prepare a request for amendment and file it with the Radiation Services Program of the CDPHE.

3.1.4 RENEWAL OF THE LICENSE

The RSO and the EHS Department are responsible for preparing license renewal applications under the authority of the CIR and filing the applications with the Radiation Control Division of the CDPHE prior to the expiration date.

HSC 3.2 SERVICES PROVIDED BY THE ENVIRONMENTAL HEALTH AND SAFETY DEPARTMENT (EHS)

The EHS Department provides a number of services to Principal Investigators in order to assist them in meeting the requirements of the radioactive materials license.

3.2.1 PERSONNEL MONITORING AND BIOASSAY

EHS provides dosimeters to measure total integrated *external* radiation dose to the whole body and/or designated extremities. These dosimeters are obtained from a properly-accredited commercial supplier. As required by the Radiation Control Division of the CDPHE, no personal dosimeter will be issued by EHS until the wearer has completed the applicable training and testing requirements described in section 2.4.11 of this Manual. Under very limited circumstances, the RSO may issue a dosimeter to individuals occupying spaces surrounding areas where large amounts of radioactive materials are being used. These badges are issued on a case by case basis and only the RSO can exempt these individuals from completing the training.

EHS has in-house capability to provide all routine types of bioassay measurements that are required by the license, in order to assess intakes of radioactive material and resulting *internal* radiation doses. This capability includes urine bioassay and direct *in vivo* measurement of gamma and x rays emitted by radioiodine in the thyroid. Rarely, it may be necessary to obtain bioassay from a commercial firm, due to the limitations of EHS's capability. It shall be the duty of the RSO to identify such cases when they occur, and to make appropriate arrangements to obtain the necessary bioassay information.

Through its radioactive materials inventory system, EHS identifies those PIs' authorizations that have the potential to require bioassay, based on forms and amounts of radioactive materials acquired, and performs follow-up to ensure that effected personnel complete the applicable bioassay requirements. The RSO can provide further information on procedures and equipment used, minimum detection limits, or other concerns.

All records pertaining to personnel dosimetry and bioassay are maintained by EHS, and EHS responds to requests for exposure histories from employers of former university personnel, upon submission of a signed release from the effected individual.

3.2.2 RADIOACTIVE PACKAGE RECEIVING PROCEDURES

EHS performs package receiving procedures on all packages of radioactive materials coming onto campus, in order to accomplish the following functions:

- check if the package is damaged or leaking, and
- perform appropriate notifications if indicated, as required by regulations,
- including notification to the delivering airfreight carrier or other transporter,
- measure the radiation exposure rates due to penetrating (x and gamma) radiations emitted by the package and
- ensure that they are within the limits set by the U.S. Department of Transportation marking and labeling on the package,
- provide appropriate information about measured exposure rates to persons who will handle the package, and
- perform appropriate notifications if indicated, as required by regulations, including notification to the delivering airfreight carrier or other transporter,
- ensure that the outside surfaces of the package are free of radioactive contamination, and that the package is otherwise suitable for transfer to the laboratory staff on campus, and
- record all necessary initial information into the EHS radioactive materials inventory system.

3.2.3 RADIOACTIVE MATERIALS INVENTORY CONTROL AND TRACKING

EHS maintains a centralized radioactive materials inventory system as required by many aspects of the radioactive materials license. This system allows the RSO to exercise the required *a priori* approval authority over all acquisitions of radioactive material, so as to ensure that the type and amount of radioactive material to be acquired is consistent with the institutional license and the PI's authorizations from the CIR.

Incoming packages of radioactive materials are logged into EHS's system at the time of the package-receiving procedure performed by EHS. Radioactive waste accounting information is provided to EHS by laboratories using the coded radioactive waste tickets that EHS provides, which must be affixed to the actual items of waste as presented to EHS for disposal. More information about the inventory system is provided in [Appendix IV](#).

3.2.4 CALIBRATION OF RADIATION SURVEY INSTRUMENTS

EHS maintains a moderate-sized gamma ray source and a number of other radioactive check sources and electronic pulse-generating devices, and is capable of providing almost all calibrations of portable radiation survey instruments that are required by the institutional license. One exception involves some high-range calibrations of radiation exposure rate at exposure rates in the hundreds of milliRoentgens per hour, which are obtained from a commercial provider. EHS also maintains a set of instruments that can be provided to laboratories on a loan basis while an instrument is in the process of being calibrated. More information about the technical details of EHS's calibration services is available from the RSO.

3.2.5 LEAK TESTING OF SEALED SOURCES

EHS maintains a detection capability for sub-nanoCurie (Becquerel-sized) quantities of all beta and gamma-emitting radionuclides used on campus, and is correspondingly capable of providing leak testing of sealed radioactive sources. EHS maintains a complete inventory of specifically-licensed sources on campus that require such testing, and performs the required tests. In addition, some generally-licensed sources (see section [2.2.5](#)) may require such testing, which can be performed by EHS.

3.2.6 RADIATION PROTECTION SURVEYS

EHS has the complete capability of performing radiation protection surveys to evaluate contamination of laboratory surfaces and dose rates due to sources of penetrating ionizing radiations.

Laboratories are encouraged to request *dose rate* measurements from EHS whenever they feel they are necessary, as such measurements are typically beyond the capability of laboratory personnel and equipment to properly perform and interpret.

Contamination surveys are typically performed by EHS for the following:

- when laboratory areas or major items of laboratory equipment are being moved, or decommissioned and returned to general use not including radioactive materials,
- during routine laboratory audits
- as a follow-up to a radioactive spill or contamination incident, or
- as part of a spot check program as directed by the CIR

In all cases, EHS's contamination surveys are confirmatory in nature and do not replace or lessen the need for the contamination surveys that are required to be performed by Principal Investigators (see section [3.4.3.2](#) below).

3.2.7 EVALUATIONS OF FUME HOOD FUNCTION

EHS provides face velocity measurements and other testing to establish the proper operation of fume hoods. Routine face velocity measurements are recorded on a label that EHS places on the hood at the side of the cabinet, with an arrow indicating a specified sash position, when the measurements are made. Hoods that have not been tested less than one year prior to a proposed use should not be used for experiments involving volatile forms of radioactive material (e.g., iodination labeling) until a test has been obtained. More information about fume hood testing is available by calling Environmental Health and Safety.

3.2.8 DISPOSAL OF RADIOACTIVE WASTES AND SALE OF WASTE CONTAINERS

EHS provides complete disposal services for all radioactive and mixed wastes generated by research laboratories on the CU Denver | Anschutz campuses and at some satellite locations. EHS picks up wastes at the point of generation (at the laboratory). Contact EHS by calling 303-724-0109 or by completing the waste pickup request form. EHS also offers for sale, at its cost of procurement, containers, liners, and other packaging materials for radioactive wastes, including the standard items required by university policy. Additional requirements are described briefly in section 3.4.6 below, and are completely documented in the university's *Radioactive Waste Disposal Manual*.

3.2.9 ASSISTANCE IN PREPARING OUTGOING SHIPMENTS OF RADIOACTIVE MATERIALS

State and federal regulations require a complex set of specific packaging, labeling, marking, shipping papers, radiation measurements, and other precautions, which are described in more detail in section [3.4.2.7](#) below. EHS should be contacted as soon as possible at when plans are being made to ship RAM to off-campus locations.

3.2.10 TRAINING AND TESTING OF WORKERS

EHS provides the testing required by section [2.4.11](#) above, for Principal Investigators and other persons who will work with radioactive materials. The *Radiation Safety Training Manual* provides study material to supplement the initial Radiation Worker training and is available on the EHS Department website. Some additional personalized instruction may be available from EHS, depending on the staff resources available. The training and testing provided by EHS does not replace or lessen the need for the specific job-related instruction that Principal Investigators are required to provide, as discussed in section [3.4.1](#) below.

EHS also provides online refresher training for Principal Investigators and Radiation Workers. Radiation Safety refresher training is required annually for all Principal Investigators and Radiation Workers actively possessing and using radioactive materials. **If any PI or Radiation Worker is found to be delinquent in this requirement, the RSO will suspend all of the associated PI's**

authorizations until the refresher training course is completed. EHS will send announcements concerning the refresher training routinely via email.

As described in [2.4.13](#), Principal Investigators are responsible for ensuring that all members of their staff working with materials under their authorizations are in compliance with the university's policies and procedures.

3.2.11 ADVICE AND CONSULTATION

EHS staff professionals are always available to researchers for advice and consultation in matters related to radiation safety. EHS maintains access to a variety of printed and electronic resources that may be helpful to researchers. EHS's staff time may need to be scheduled in accordance with other workload priorities, especially in matters requiring extensive effort, such as assistance in preparing applications for complicated or unusual experimental protocols.

3.2.12 EMERGENCY RESPONSE

EHS responds to all emergencies and incidents involving radioactive materials used by researchers. Due to limited staff resources, EHS's involvement must be limited to advice, oversight, bioassay and similar measurements, and confirmatory surveys, except in situations that require equipment or expertise that is not available in the Principal Investigator's laboratory.

EHS maintains shower areas at the EHS Support Facility located on the Anschutz Medical campus, which can be made available as a decontamination area for cases of skin contamination that the RSO determines to be suitable for such use.

HSC 3.3 SERVICES PROVIDED TO RADIOACTIVE MATERIALS LABORATORIES BY THE CLEANING SERVICES STAFF

The contracted cleaning services staff provides ONLY the following routine services in laboratory areas:

- removal of regular trash, and
- sweeping and mopping of floors.

The contracted cleaning staff also performs routine removal and replacement of the sealer on tile floors at approximately annual intervals. When this function is performed, the responsible Principal Investigator must assure that all physical, chemical, radioactive, and biological hazards are removed from the floor and from adjacent benchtops and similar locations where they might endanger the workers.

Contracted cleaning staff are not allowed to become involved in the cleaning of benchtops, sinks, or laboratory equipment of any type without clearance from EHS (see section [3.4.7.4](#) below for information about Green Tags).

Contracted cleaning staff must NEVER be involved in the cleanup of spills or other incidents involving research materials that may be radioactive.

Laboratory personnel must be aware that they must take every reasonable precaution to avoid inappropriate actions by the contracted cleaning staff, including but not limited to the following precautions:

- use of properly-marked standard-type containers for radioactive wastes,
- immediate securing of incoming radioactive materials packages within the laboratory by placement of the radioactive materials into a refrigerator, freezer, or other appropriate storage receptacle, and
- contamination survey and removal of all radioactive materials-related symbols and markings from empty radioactive materials packaging that will be discarded as regular trash.

HSC 3.4 REQUIREMENTS TO BE MET BY AUTHORIZED PRINCIPAL INVESTIGATORS

3.4.1 TRAINING AND QUALIFICATIONS

In addition to the training and testing requirement set forth in section [2.4.11](#) and [3.2.10](#) above, authorized Principal Investigators have the responsibility to provide and document additional training and instruction, especially in regard to the details of the actual types of experiments to be performed, that will allow the work to be performed safely and in a manner that complies with applicable regulations. EHS will provide an “On The Job” training form that covers general radiation safety topics for use in documenting each lab workers progress in regard to lab specific information knowledge. In addition, the Principal Investigator’s authorizations for use of radioactive materials should be readily accessible at a designated location in the PI’s laboratories, and all persons working with radioactive materials should be aware of the conditions and requirements contained in the corresponding authorization documents.

3.4.1.1 Use of Radioactive Materials by Minors

Any minor (person of age less than eighteen years) who will work directly with radioactive materials, or whose activities might be reasonably expected to present a possibility of contact with potentially-contaminated surfaces or other radiation-related hazards, must complete the permission form shown at [Appendix V](#) before commencing such activities.

The use of radioactive materials by minors is generally discouraged, even if such use occurs in the context of a designed educational experience that involves only small amounts of radioactivity. Such minors must certainly meet the training and testing requirement set forth in section [2.4.11](#), and they are deserving of more supervisory attention than older persons. In

addition, extremely restrictive Maximum Permissible Dose guidelines are stipulated by the state and federal regulations for minors.

Individual cases of prospective work by minors should be discussed with the RSO to minimize the likelihood of problems.

3.4.1.2 Issues Related to Pregnancy and Fertility

Issues related to pregnancy and fertility are complicated and fraught with legal implications, and should be understood by all persons involved in working with radiation or radioactive materials, both male and female. These issues are treated at length in the EHS Radiation Safety Initial Training.

3.4.2 CONSTRAINTS ON ACQUISITION, DISPOSITION, AND TRANSPORTATION OF RADIOACTIVE MATERIALS

Radioactive materials obtained under the university license are strictly controlled, as they are under all specific licenses. Users should understand the concept of the audit trail, by which the university, as a licensee, is responsible for tracking the fate of each microCurie (or kiloBecquerel) of radioactive material from “cradle to grave”: from the time of its initial arrival on campus until its ultimate disposal, transfer, or disappearance due to decay is properly documented. As discussed in more detail below, radioactive materials acquired under the license can leave the Principal Investigator’s possession legally by one of only five routes:

- disposal of waste through EHS,
- disposal via sanitary sewage that is reported to EHS (^3H only),
- disposal via a registered, EHS-authorized program of decay-in-storage conducted autonomously in the PI’s laboratory,
- transfer to the authorization of another university Principal Investigator who has an acceptable authorization for the material in question, or
- transfer to the radioactive materials license of another institution, corporation, or individual, arranged through EHS.

Radiation Safety provides accounting sheets to assist lab personnel in tracking their radioactive materials use. Pre-coded radioactive waste tickets are also provided to assist in tracking how much activity is attributed to a specific waste stream.

3.4.2.1 Obtaining Prior Approval from Environmental Health and Safety for All Acquisitions

ALL acquisitions of radioactive materials at the university require the PRIOR approval of the RSO, as stipulated by the license. Regular purchase requests, including blanket and standing orders, must be approved by the Radiation Safety office prior to their being submitted to Grants and Contracts, Purchasing, or Finance. Non-purchase-ordered acquisitions, such as credit card

orders, free samples from vendors or materials supplied by collaborating investigators at other institutions, also require prior approval, as described in more detail in [Appendix VI](#).

- The exact same approval process is required for materials that will be delivered directly to a satellite location off campus for use under the university's license, except that the Purchase Request will have a satellite location delivery address.
- When the University of Colorado Hospital's purchasing system is used to acquire RAM that will be used on the CU Anschutz campus, the same approval by Radiation Safety is required.
- When CU Denver | Anschutz-administered grant funds are used to purchase RAM through the university purchasing system for use at another institution under the other institution's radioactive materials license (e.g., University Hospital, the Veterans Administration Hospital, or Children's Hospital Colorado), the same approval by Radiation Safety is required, but is granted automatically on the authority of the host institution's RSO, and therefore should be signed off by that officer before being submitted to Radiation Safety. (This requirement is necessary for two reasons: to avoid intractable problems for the CU Denver | Anschutz Purchasing Agent, tracking purposes, and to assist the RSO of the host institution in exercising the control that that institution's license requires.)

NO PROCUREMENT OR RECEIPT of radioactive materials will be permitted unless all staff members designated as radiation workers on any of the Principal Investigator's authorizations is current on the training requirements set forth by the CIR as described in 2.4.11. This includes completion of a refresher training course annually.

3.4.2.2 The Principal Investigator's On-hand Possession Limit

For each individual *authorization*, the Principal Investigator is authorized a specific on-hand possession limit by the CIR, which is a subdivision of the university's overall institutional possession limit and functions in the same manner. That is, the possession limit is the maximum amount that the PI may possess at any one time, including all waste materials that have not yet been properly disposed. The RSO may grant increases in possession limit to any amount less than or equal to the PI's current yearly limit, based on a brief written request from the Principal Investigator, or may refer the matter to the Committee for review. The RAM Authorization Update form, available on the EHS website, may be submitted to Radiation Safety to request changes to the possession limit.

3.4.2.3 The Principal Investigator's Yearly Acquisition Limit

For each individual *authorization*, the Principal Investigator is authorized a specific yearly acquisition limit by the CIR. That is, the yearly limit is the maximum amount that the PI may acquire in the calendar year; January 1 through December 31. The RSO may grant increases in annual limit based on a brief written request from the Principal Investigator, or may refer the

matter to the Committee for review in the event that the increase would require an increase in the institutional license. The RAM Authorization Update form, available on the EHS website, may be submitted to Radiation Safety to request changes to the annual limit.

3.4.2.4 Delivery of Radioactive Materials to CU Denver | Anschutz

ALL radioactive materials that arrive on campus from other locations (delivery over a roadway or public thoroughfare) must arrive initially at the EHS Support Facility so that package receiving procedures required by the radioactive materials license can be performed as described in section [3.2.2](#).

Dedicated EHS Package Receipt Addresses:

EHS Support Facility
13178 E. 19th Ave.
Aurora, CO 80045

- Any incoming RAM package that arrives at an on-campus laboratory without passing through the dedicated EHS package receipt location, for whatever reason, must be brought to the attention of Radiation Safety immediately.
- Collaborating investigators at other institutions, or their campus RSOs, that may make radioactive shipments to CU Denver | Anschutz investigators should be informed about this requirement and directed to contact the CU Denver | Anschutz RSO.
- Direct deliveries to listed off-campus satellite locations require specific arrangements with Radiation Safety, to ensure that package receiving procedures and RAM inventory system data entry will be properly completed.

3.4.2.5 Removal of Radioactive Materials from Authorized Locations of Use: Departing Investigators

In the case of investigators who are departing from CU Denver | Anschutz and will no longer conduct operations on campus under their radioactive materials authorizations, Radiation Safety should be contacted as soon as possible if there are RAM that the PI wishes to transport to a new location at another institution. CU Denver | Anschutz Radiation Safety will contact the RSO of the new institution to obtain a copy of that institution's radioactive materials license and to obtain appropriate shipping instructions, and will assist the PI in preparing the shipment in conformance with the applicable regulations of the U.S. Department of Transportation (U.S. DOT), the International Air Transport Association (IATA), or other governing agencies as applicable. In such cases, CU Denver | Anschutz MUST obtain a copy of the destination institution's radioactive materials license and properly document the transfer between institutional licenses of the radioactive materials involved.

Departing Principal Investigators are responsible for returning all radioactive wastes to Radiation Safety and arranging for decommissioning of their authorized locations of use, including the performance of final contamination surveys on all equipment used with RAM as well as all work area and other potentially contaminated surfaces within those locations.

3.4.2.6 Transportation of Radioactive Materials on Campus

Transportation on campus does not require the extensive packaging, labeling, marking, shipping papers, and other regulatory items that are required for over-the-road transport. However, as documented below,

- NO transportation over or along public thoroughfares may be performed, and
- materials must be transported carefully in CLOSED, DURABLE CONTAINERS with due precautions against spillage or leakage such as secondary containment for any liquids.

When new stock radioactive materials are received by the laboratory, they must be immediately secured within a refrigerator, freezer, or other appropriate storage receptacle, in order to avoid their being misplaced or improperly removed by contracted cleaning staff.

Radiation Safety takes extensive precautions in its on-campus transport of radioactive waste materials.

Other transport on campus by laboratory personnel is strongly discouraged and should be avoided whenever possible, due to the extensive problems that may ensue if there is an incident of any kind in which there is a possibility of contamination of floors, elevators, or other surfaces in public areas.

3.4.2.6.1 Contamination Status of Transported Packages and Prohibition Against Wearing Gloves When Transporting Packages in Public Areas

A consistent application of radiologic hygiene principles will show that the only proper way to transport items containing RAM, in areas outside the laboratory proper, is to first ensure that their exterior surfaces are free of radioactive contamination that could be transferred to the transporter's person and thence to surfaces in public areas. If this requirement is met, then the person transporting the item is protected and gloves are not needed.

Radiation Safety tests the exterior surface of every incoming radioactive materials package for contamination, so that persons accepting those packages in the laboratory may be assured that this requirement has been met.

Persons observed wearing gloves to transport radioactive materials in public areas on campus will be warned by the RSO, and recurring instances of this behavior will be referred to the responsible Principal Investigator for action.

3.4.2.7 Transportation of Radioactive Materials To and From Off-Campus Locations

Transportation of radioactive material to off-campus locations necessarily requires transport over public roadways, which invokes the regulations of the U.S. Department of Transportation (U.S. DOT) and comparable regulations of the Colorado Department of Public Health and Environment (CDPHE) and the U.S. Nuclear Regulatory Commission (U.S. NRC). Basic regulatory requirements include, but are not limited to, the following:

- These regulations require *specific types of packaging* along with *specific markings and labels*.
- If the package is to be transported by a commercial carrier, *DOT shipping papers* must be prepared and other requirements (e.g., security seals) may apply.
- Individuals offering radioactive material for domestic ground shipments must have current DOT shipper training, as outlined in 49 CFR 172, Subpart H.

Investigators contemplating shipments of radioactive material of any type to colleagues at other institutions should contact EHS as early as possible for assistance in meeting the applicable requirements. Radiation Safety will then

- contact the RSO of the receiving institution to obtain a copy of that institution's radioactive materials license as required by law and to obtain appropriate shipping instructions,
- assist the Principal Investigator in preparing the shipment in conformance with the applicable regulations, and
- properly document the transfer of radioactive material from the CU Denver | Anschutz license to the receiving institution's license.

International shipments are especially difficult to arrange. International freight forwarders have often shown reluctance to work with packages prepared by academic and research institutions, as opposed to commercial firms that regularly ship large quantities of such items. In some such cases in the past, it has ultimately been necessary to have the radiolabeled materials shipped directly by a manufacturer to the international destination.

Any accident involving the transportation of radioactive materials on public roadways or any other location not completely on CU Denver | Anschutz property must be reported IMMEDIATELY to the Colorado Department of Public Health and Environment.

3.4.2.8 Security of Radioactive Materials

The *Colorado Rules and Regulations Pertaining to Radiation Control* require that areas where radioactive materials are *used* must be controlled as

- “restricted areas,” where “restricted area” means “an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risk from exposure to sources of radiation” (6 CCR 1007-1, 1.2.2), or
- “unrestricted areas,” whereby “The licensee shall control and maintain constant surveillance of licensed or registered radioactive material that is in an unrestricted area and that is not in storage or in a patient.” (6 CCR 1007-1, 4.26)

Areas where radioactive materials are in *storage* must be controlled such that “The licensee shall secure from unauthorized removal or access licensed or registered sources of radiation that are stored in unrestricted areas.” (6 CCR 1007-1, 4.25)

Because it is generally not practical for institutions like CU Denver | Anschutz to restrict access to laboratories, those university laboratory areas that are authorized as locations of use for RAM must be controlled as *unrestricted areas*, and the applicable security requirements are the underlined ones in the previous paragraphs.

Thus, areas where radioactive materials are *used* must either be:

- locked to prevent access to members of the public (including untrained workers), or
- under constant surveillance by trained radiation workers who will protect others from the associated hazards.

Areas where radioactive materials (including waste containers) are *stored* but are *never opened or used* must:

- be locked, or
- be under constant surveillance by trained radiation workers who will prevent unauthorized “removal [of] or access [to]” the stored materials, or
- have those materials stored in strong, locked, immovable containers that will prevent unauthorized “removal [of] or access [to]” the stored materials.

The following points should receive careful consideration from Principal Investigators authorized for radioactive materials:

- Security improvements for campus buildings, including access control and “ID badges”, are clearly helpful, but do not obviate the need for security of individual laboratory areas.
- The operational criterion used by inspectors from the CDPHE is as follows: **if an inspector can at any time (usually during business hours, and with the assumption that the inspector has already gained access to the building in question) gain access to a radioactive materials laboratory and discover radioactive materials in any form, without being confronted and asked for identification, etc.**, then a violation has occurred.
- Some enhancement of security is provided by locking the refrigerators, freezers, and other storage units used for storing radioactive materials, particularly concentrated stock materials not yet used.
- Some advantage is also gained by storing radioactive wastes, as much as possible, in a locked centralized area.
- The two previous considerations are not exhaustive with respect to the situations that need to be controlled, especially in the case of a laboratory currently using radioactive materials. For instance, they do not consider radioactive materials that may be in process on the benchtop or in appliances such as centrifuges and incubators, and they do not consider small quantities of waste that may be in the process of being accumulated near the area of use. Due to the open lab setting in many of the labs at CU Denver | Anschutz these situations are particularly important to be aware of. In regard to waste, EHS requires that all temporary waste receptacles be either secured with or emptied into the main waste container before the area is left unoccupied by the radiation workers involved with a particular experiment. When stock or working materials must be present in reaction mixtures or analogous situations where ongoing experimentation *cannot* be either secured or constantly monitored due to logistical constraints EHS requires that these materials be the very minimum activity that each experiment requires and that these items are only left unattended in a properly labeled area for the minimum time period required for the experiment to be completed.
- Any person who is not a fully-trained and certified radiation worker is, by definition, a member of the public. The regulatory and liability issues surrounding potential exposures to members of the public are serious. Prudence dictates that areas where radioactive materials are used must have adequate supervision by trained and qualified radiation workers to prevent inadvertent exposures to such persons, such as by the possibility of contact with laboratory surfaces that are subject to becoming contaminated during operations.

Most importantly, for operating laboratories utilizing unsealed sources of radioactive material in research or clinical assays, the only generally-acceptable solution to the security issue is to emphasize the discipline of requiring that **the last person who leaves a given laboratory area at any time must either lock the doors to that area or, in the case of an open setting, ensure that all lockable storage areas are secured.**

Principal Investigators' laboratories are subject to unannounced spot checks of security by Environmental Health and Safety Department staff, the results of which are reported to the CIR.

3.4.3 CONTROLLING POTENTIAL INTERNAL EXPOSURE TO RADIATION

This section describes the specific precautions that Principal Investigators must follow in order to protect laboratory occupants and the public from the possibility of internal exposure to radioactive material, which may occur if the radioactive material enters the exposed person's body by inhalation, ingestion, absorption across the skin, or other means.

3.4.3.1 Principal Investigator's Radiation Survey Instruments

Each Principal Investigator who is authorized for any radionuclide other than tritium (^3H) MUST possess at least one functional portable survey instrument that will detect the radionuclides other than tritium that are in use, for use in surveys to detect contamination.

3.4.3.1.1 Type of Instrument Required

Generally, the portable survey instrument should include a *thin-window* Geiger-Mueller-type detector with a window whose mass thickness is on the order of 1 to 2 mg/cm², so that the weak beta emitters (^{14}C and ^{35}S) can be detected. This type of detector is typically configured as a "pancake probe" or a "thin end window" cylindrical design. If the PI possesses only one type of portable detector, this is the type that should be available. Other types of Geiger-Mueller detectors are far less useful in detecting contamination and should generally be avoided.

Laboratories using gamma emitting radionuclides are strongly encouraged and in some cases may be required to possess a portable scintillation detector specifically designed for low-energy gamma and x rays, when ^{125}I or ^{51}Cr is in use.

Additional technical information about portable survey instruments is given in the *Radiation Safety Training Manual*.

3.4.3.1.2 Availability of a Designated Backup Instrument

Each Principal Investigator subject to this requirement, and who possesses only one portable survey instrument, should also be prepared to designate a neighbor whose instrument will be available immediately as a *backup instrument* if the PI's own sole instrument becomes non-

functional. In some cases, a PI may be allowed to designate Environmental Health and Safety for this purpose, with the CIR's approval, but this is generally discouraged.

3.4.3.1.3 Sharing of an Instrument by Two or More Principal Investigators

Principal Investigators may request permission from the CIR for two or more PI's to share one or more survey instruments. In such cases, the applicants must be prepared to convince the Committee that:

- the designated locations of use for all of the PI's involved are so co-located or in such proximity that it is reasonable to assert that the shared instrument(s) will always be available for immediate use in any part of those areas, and
- there is a backup instrument readily available as described above.

3.4.3.1.4 Exemption for Infrequent Uses of Short Duration

A Principal Investigator whose only use of radioactive materials other than tritium involves infrequent periods of very short duration, such that it would be practicable and reasonable for the Principal Investigator to borrow a portable survey instrument from Environmental Health and Safety for the duration of each such use, may request the Committee to allow this alternative to the possession of a survey instrument.

3.4.3.2 Performance of Surveys for Radioactive Contamination

All Principal Investigators authorized for the use of radioactive materials are required to perform regular surveys during and after periods of use, as detailed below, in order to demonstrate that all potentially-contaminated laboratory surfaces are being maintained free of contamination. Additional guidance about survey technique and other related subjects is given in the *Radiation Safety Training Manual*.

3.4.3.2.1 Frequency and Scheduling of Surveys

During periods of continuous or frequent use of radioactive materials, surveys must be performed daily in areas authorized for uses carrying a HIGH hazard level, weekly, in areas for which the most hazardous authorized use carries a hazard level of MEDIUM, or monthly, in areas authorized only for uses carrying a hazard level of LOW. Information concerning the laboratory hazard classification system can be found in [Appendix XV](#).

Survey frequency requirements are detailed on each PI's Radioactive Materials Authorization documents for the specific material authorized.

Surveys are not required to be performed during periods when radioactive materials are not being used, if a survey was performed *after* the last use of radioactive materials.

Copies of the latest contamination surveys must be examined by the Environmental Health and Safety worker picking up radioactive wastes, for the authorized areas of each Principal Investigator whose waste is being removed. These surveys must be *current*, viz., within the last day, week, or month, depending on the hazard class assigned to the laboratory's authorization.

Any waiver of the requirement for the availability of a *current* survey at the time of a given waste pickup, on the premise that radioactive materials have not been used but radioactive wastes have remained in the laboratory, is subject to the judgment of the RSO and the ultimate authority of the CIR. In such cases, the RSO will review the Principal Investigator's records of the surveys that *have* been performed and consider the elapsed time since the last documented survey, in light of such information as:

- the EHS inventory system's information on the PI's acquisitions of radioactive materials during the period in question,
- EHS's records of the PI's disposals of the resulting wastes, and
- EHS's records of any contamination found on the PI's waste containers at times of waste pickups.

Most cases of a PI's personnel arranging a disposal of radioactive wastes after an *extended* period of no use of radioactive materials involve changes in personnel or responsibilities, and the simplest and most appropriate approach is for the person(s) assuming such responsibility to perform a confirmatory contamination survey of the authorized areas involved.

When it is known that radioactive materials will not be used for an extended period of time in a particular authorized area, the Principal Investigator's personnel should arrange disposal of any radioactive wastes, perform surveys and decontamination as appropriate, and remove any unnecessary labeling on benchtops and appliances.

3.4.3.2.2 Areas to Be Surveyed

Each room in which radioactive materials are used must be surveyed. All potentially-contaminated surfaces should be included in each survey, including

- fume hoods and benchtop areas where radioactive materials are manipulated,
- floors and sinks near fume hoods and benchtop areas where radioactive materials are manipulated,
- exterior *and* interior surfaces of centrifuges, incubators, ovens, water baths, gel dryers, refrigerators, freezers, and other laboratory appliances in which radioactive materials are used or stored,
- exterior surfaces of radioactive waste containers, and
- light switches, doorknobs, and other similar objects *throughout the room* being surveyed that are subject to being contaminated by touching.

All surfaces should be surveyed in their entirety with a portable survey instrument by sweeping over the surface in a slow, methodical manner. Consider that radionuclides other than soft beta emitters will produce interference due to radiation arising from within the container. Unless the material can be temporarily removed, the instrument survey must defer to swipe testing.

It is also recommended to spot check the household trash receptacles and desks during routine surveys. All spots of apparent contamination detected with the portable survey instrument, along with a reasonably representative sample of the other surfaces surveyed with the portable instrument, should be sampled with a swipe test for removable contamination.

3.4.3.2.3 Type of Survey (Portable Instrument vs. Swipe Survey) and Records Required

Both portable instrument surveys and swipe surveys must be performed, as they serve different and complementary purposes.

If ^3H is the only radionuclide in use, then portable instrument surveys are not required; however, swipe surveys should be correspondingly more thorough (numbers of swipe locations) in order to provide a proper coverage of the surface areas being surveyed.

Swipe Surveys:

Although swipe surveys only reveal removable contamination from the limited areas covered by the swipes, it has considerably better detection efficiency in all cases than *in situ* survey with a portable instrument. Swipe surveys will therefore give a more sensitive indication of the accumulation of diffuse contamination, and will reveal small areas of contamination with a certain probability. This probability is improved if the areas being swiped are properly selected, such as by targeting areas that are likely to become contaminated by touching or by spillage during liquids transfers. Swipe survey results, i.e. detector computer printouts, annotated in some manner to indicate the origin of each sample in terms of location in the laboratory must be retained as record of formal survey. A drawing of the laboratory, with numerically-keyed indications of areas surveyed, is a useful device to minimize the amount of effort required to record the necessary information, as it may be used repeatedly to indicate the areas surveyed. These surveys must be performed at the frequency required by the hazard class assigned to the laboratory's authorization at the very least.

Portable Instrument Surveys:

Portable instrument surveys are required in addition to the swipe surveys. Portable instrument surveys must be performed both before and after use of radioactive materials.

A survey performed on a labeled work area before work commences assures the user that the area is free of contamination that may have been either left or missed by the worker who last used the area. This is particularly appropriate considering the open lab setting as well as the fact that many radioactive materials use areas are used by different lab personnel at different times of the day.

A post manipulation survey is also required to reduce the chance of spreading any contamination that may be on your person as well as eliminating the chance of anyone else becoming contaminated by operating in the work area at a later time.

All results, including negative ones not differing significantly from background, must be retained.

Upon request, EHS will provide a form for recording the results of portable instrument surveys.

Survey results that differ significantly from background, based on appropriate criteria, must be recorded in true units of radioactivity, of which the most practical unit is DPM (Disintegrations Per Minute). This requires that the counting efficiency of the instrument in use must be known, for the radionuclide(s) that might be present. Further guidance is given in the *Radiation Safety Training Manual*.

3.4.3.2.4 Decontamination and Other Required Actions when Contamination Is Detected

Principal Investigators must ensure that any area indicating contamination, based on a comparison of the survey result to background count rates, is properly decontaminated. Additional information about how to make this determination is given in the *Radiation Safety Training Manual*. The Radiation Safety Office should be consulted if additional explanation or information is desired, or if problems arise.

Any contaminated area must be resurveyed by both the portable instrument (detects fixed plus removable contamination) and swipe survey (detects removable contamination only) after decontamination is attempted. If any area yields results that indicate persistent contamination from either or both types of survey, despite repeated and diligent efforts at decontamination, the RSO must be informed.

In some cases involving persistent contamination that defies repeated efforts at removal, the RSO *may* be able to verify by appropriate calculations that the contamination present is within the strict numerical maxima published by the U.S. Nuclear Regulatory Commission in *Regulatory Guide 8.23, Radiation Safety Surveys at Medical Institutions*, and that no further action is necessary. If this is not successful, the RSO *may* be able to devise a means of removing the contamination, or, for reasonably short-lived radionuclides, a means of controlling the contamination until it decays to acceptably low levels.

Records of both Portable and Swipe Surveys for prior, during, and post decontamination efforts must be annotated and retained along with the routine formal survey records. This is required as record that the contamination was removed and the area was left free of detectable contamination.

3.4.3.3 Practice of Radiologic Hygiene

All Principal Investigators are expected to require the practice of good hygiene in all operations involving radioactive materials. The ways that radioactive materials are used in biomedical research, and the types of materials used, are such that the greatest hazard of

receiving a significant radiation dose is typically the one associated with internal dose from self-contamination due to inadequate hygienic practices.

The only way to detect internal contamination is by bioassay measurements, and the usage levels above which bioassay is required for personnel, as stipulated by the CIR, are predicated on the assumption that good hygienic practices are being followed.

Finally, poor hygiene can result in the spread of contamination to public areas and/or individuals who are not radiation workers, and contamination may be transported to homes and other uncontrolled environments by contaminated individuals if proper practices are not observed. The U.S. Nuclear Regulatory Commission (USNRC), Inspection and Enforcement Division, publishes bulletins on a regular basis, detailing the extremely aggressive enforcement actions taken by the NRC in response to such transport of contamination into the larger outside community, providing a palpable indication of the regulatory agencies' particular sensitivity to this issue, which is capable of arousing great public sentiment.

3.4.3.3.1 Control of Contamination

A detailed guidance on controlling contamination is given in the *Radiation Safety Training Manual*. Almost all contamination problems arise from one or both of two initial mechanisms:

- spills of liquid, however small, which occur mostly during operations transferring the liquid from one vessel to another, or
- transfer by touching with the hands.

Persons working with radioactive materials should have an awareness and understanding of the principles in contamination surveys, and should appreciate the need for proper surveys of themselves (after each use and before exiting the laboratory) *and* laboratory surfaces (periodically according to the guidelines in section [3.4.3.2](#) *and* whenever a spill or other source of contamination is suspected).

3.4.3.3.2 Protective Apparel

Persons handling radioactive materials **MUST**, without exception, wear

- eye protection,
- double gloves, and
- lab coats.

Eye protection is especially crucial and is required for all laboratory operations involving *any* type of eye hazard, not just radioactive materials, as stipulated in EHS Policies.

Closed-toe shoes and long trousers should be worn when handling radioactive materials. In some cases, additional protective apparel, beyond the items noted above, may be advisable. The RSO should be consulted when questions arise.

3.4.3.3.3 Safe Practices

The safe practices discussed in previous sections should be followed as applicable. Most importantly, two egregiously *unsafe* practices must be avoided:

- mouth pipetting, and
- eating and drinking in areas where radioactive materials are used.

The latter prohibition is discussed at length in the Chancellor’s memorandum included in [Appendix VII](#).

3.4.3.3.4 Control of Equipment Used with Radioactive Materials

No item of equipment used with radioactive materials, from small items such as mechanical pipetting devices to large appliances such as centrifuges, should leave the laboratory for any reason, including maintenance, repair, calibration, moving of the laboratory, or sale or transfer to another user, until it has been properly tested for contamination and a documented survey recorded by the Principal Investigator’s personnel. In the case of larger items of equipment, EHS may choose to perform confirmatory surveys before appending a “Green Tag” to release the equipment.

3.4.3.3.5 Contamination Status of Radioactive Liquid Waste Containers

Containers used for radioactive liquid waste are notable as being particularly susceptible to contamination of their exterior surfaces due to dripping or spillage during the transfer of liquid into the container. The CDPHE has required the university to implement specific controls to address this issue, and these containers are regularly tested for external contamination by EHS personnel at the time of waste pickup. Containers found to be contaminated must be cleaned by laboratory personnel before they will be accepted by EHS.

3.4.3.4 Ventilation Controls and Respiratory Protection

Ventilation controls are the usual means of protecting personnel against the hazard of inhaling airborne radioactive materials. Depending on the type and degree of hazard, a specific type of control will generally be specified during the CIR’s review of applications for operations that present such a hazard.

3.4.3.4.1 General Ventilation

The general-purpose ventilation that exists in a specific area, as opposed to completely stagnant air with no exchange to outside air, may sometimes be used in calculations to demonstrate that some potential releases are not sufficient to approach maximum permissible levels for members of the public. It is not the responsibility of the Principal

Investigator to control general building ventilation, but it is prudent to contact campus Facilities Services when there appears to be a sudden lack of general ventilation in a radioactive materials laboratory.

3.4.3.4.2 Fume Hoods

Fume hoods must be used *exactly* as specified in the Principal Investigator's radioactive materials authorizations. The use of specific hoods for certain operations is determined in the review process of the CIR. In some cases, very specific controls on the content of fume hood effluent air and its dispersal after leaving the duct system are either engineered into the hood system or are required to be performed by the Principal Investigator's personnel for certain operations, as described below in section [3.4.5.2](#).

In general, fume hoods should *always* be used for the following types of operations:

- opening sealed containers of liquid radioactive materials, especially stock vials of material that will typically have been sealed by the manufacturer at sea-level atmospheric pressures and will be capable of ejecting a jet of material that can create an aerosol when first opened,
- performing sonication, homogenization, or other forms of mechanical agitation of a radioactive sample that may disperse material into the air,
- operations involving volatile forms of radioactive materials, most notably
 - radioiodine labeling reactions,
 - P-32 labeled unbound orthophosphate,
 - use of tritiated water or volatile tritiated organic compounds, including acetate, and
 - use of sulfur-labeled methionine and or cysteine in some circumstances.

Fume hoods *may* be used for operations that do not present a hazard of releasing radioactive materials into the air, in order to take advantage of the confinement that a fume hood cabinet can afford, for such things as splashes that may occur during liquids transfers.

Fume hoods *should not* be used as storage areas for materials that do not require local exhaust ventilation and should be kept as free of obstructions as possible.

Fume hoods *must not* be used for extended storage of plastic scintillation vials containing volatile solvents such as toluene and xylene.

Fume hoods *may* be used for drying or other processing involving evaporation of *water*, if no volatile forms of radioactive material are present, but *must not* be used to dispose of volatile organic solvents by evaporation.

3.4.3.4.3 Glove Boxes and Other Special Systems

Glove boxes or other special systems affording complete containment of airborne radioactive materials may be specified by the CIR for certain types of radioactive materials and operations involving a particularly high hazard of airborne radioactive materials, although such cases are rare in modern biomedical research.

3.4.3.4.4 Respirators

Respirators, regardless of type, are almost never specified by the CIR, for two compelling reasons:

- engineering controls such as the ventilation controls described in the previous section are generally considered preferable to respirators by safety professionals and standards-setting organizations, due to their lesser degree of reliance on an individual worker’s performance and other variable individual-specific factors that affect the efficacy of respirators; and current Colorado regulations specifically require engineering controls such as fume hoods to be used whenever feasible, and
- laboratories where radioactive materials are used are generally not classifiable as isolated and strictly controlled “restricted areas” where entry is restricted to selected, specially-trained individuals wearing respiratory protection.

Individuals who choose to attempt some form of individual respiratory protection for personal reasons must be aware that respirators require careful selection and maintenance, and usually require individual fit-testing to be effective, and that many respirators require medical qualification of the individual wearer because of the cardiopulmonary stresses of breathing through the respirator. Such individual choices must never be relied upon to provide protection in a situation that would otherwise be deemed unsafe or inconsistent with the specific requirements of the Principal Investigator’s authorizations for radioactive materials.

3.4.3.5 Bioassay Requirements

For laboratory procedures conforming to the training and hygiene requirements of this *Manual* and not involving volatile forms of radioactive material, bioassay for a given radionuclide is required for any person who uses, in any one month, more than ten times the most restrictive Ingestion Annual Limit on Intake (ALI) that is specified for that radionuclide in Table 4B1 of Part 4 appendix B of the *Colorado Rules and Regulations Pertaining to Radiation Control*. The resulting monthly usage limits above which bioassay is required is shown in the table below. In this context, the word “usage” shall be construed to include total amounts contained in any vessels (e.g., stock vials) that the worker opens for the purpose of removing smaller quantities.

Table of Usage Limits Requiring Bioassay

| Radionuclide | Monthly Usage Limit Requiring Bioassay (mCi) |
|-----------------|--|
| ³ H | 800 |
| ¹⁴ C | 20 |

| | |
|-------------------|----------------|
| ²² Na | 4 |
| ³² P | ** 6 ** |
| ³³ P | 60 |
| ³⁵ S | 60 |
| ³⁶ Cl | 20 |
| ⁴⁵ Ca | 20 |
| ⁴⁶ Sc | 9 |
| ⁵¹ Cr | 400 |
| ⁵⁷ Co | 40 |
| ⁵⁹ Fe | 8 |
| ⁶⁵ Zn | 4 |
| ⁸⁵ Sr | 30 |
| ⁸⁶ Rb | 5 |
| ⁹⁰ Y | 4 |
| ¹¹¹ In | 40 |
| ¹¹³ Sn | 20 |
| ¹²⁵ I | 0.4 |
| ¹³¹ I | 0.3 |

As the statutory requirement for bioassay states that bioassay is required for “adults likely to receive, in one year, an intake in excess of 10 percent of the applicable ALI...” this criterion amounts to equating 120 ALI’s of usage (per year) with one tenth of an ALI of intake. This is equivalent to assuming that trained laboratory workers using good hygienic practices and working with non-volatile forms of radioactive materials do not take into their bodies more than 1/1200 of the radioactive material with which they work. The CIR has determined that this assumption is appropriately conservative for the stated conditions.

Bioassay is required after each labeling for all persons performing radioiodine labeling reactions, regardless of the milliCurie amounts involved.

For all situations involving volatile forms of radioactive material, other than radioiodine labeling reactions, the requirement for bioassay will be determined by the CIR on a case-by-case basis.

Apart from the specific requirement for radioiodine labeling, the scheduling of bioassay measurements will be determined individually on a case-by-case basis by the RSO in consultation with the Principal Investigator, the affected individual, and, if appropriate, the CIR and Occupational Health Program.

3.4.3.6 Housing and Care of Animals Containing Radioactive Materials

The contamination hazards associated with animals to which radioactive materials have been administered are evaluated by the CIR for each specific proposed protocol, during the application review process. The precautions stipulated by the CIR must be followed and clearly communicated to all persons who may become involved in care of the animals. Any

change in procedure, including a change in the location of the animals' housing, must be approved by the CIR.

Cage cards displayed in [Appendix VIII](#) must be completed by the Principal Investigator's personnel and attached to each cage until its removal is authorized by the RSO or as stated in the authorization document, regardless where the animals are housed, unless the animals containing the radioactive material are housed for only a few hours after the administration of the radioactive material and are continuously under the care and supervision of the Principal Investigator's personnel. If animals are to be housed in the Center For Comparative Medicine (CCM), it shall be the Principal Investigator's responsibility to make appropriate prior arrangements with the CCM and to ensure that the cages are labeled with the required cards as soon as the animals are administered radioactive materials.

Issues related to animal excreta, bedding, and other aspects of waste disposal are discussed below in section [3.4.5.5](#), with respect to potential releases to the environment, and section [3.4.6.6](#), with respect to waste disposal.

3.4.4 CONTROLLING POTENTIAL EXTERNAL EXPOSURE TO RADIATION

Persons who are not trained and monitored (e.g. receiving personal dosimeters) as radiation workers are by definition members of the *general public* for radiation protection purposes. Because it is not feasible to control access to laboratories and nearby areas to exclude such persons, the radiation dose limits prescribed for the general public must be generally observed throughout CU Denver | Anschutz facilities.

This means that:

- **Overall limiting dose guideline:** sources of penetrating radiations must be controlled so that any person who is not a trained and monitored radiation worker could not receive more than 100 mrem (1 mSv) in an entire calendar year;
- **Dose guideline for short time periods:** in addition, no source of radiation must ever create a condition whereby a dose rate exceeding two mrem (20 μ Sv) in any one hour could ever be received in any area accessible to any person who is not a trained and monitored radiation worker.

Radiation Safety has prepared spreadsheets that display the minimum allowable distances from occupied areas to unshielded containers of various amounts of several radionuclides typically used at CU Denver | Anschutz. The spreadsheets, along with instructions for using them, are included in [Appendix IX](#). The appropriate "occupancy factors" should be carefully chosen for areas under consideration (additional information on occupancy factors accepted by CDPHE is available from Environmental Health and Safety). All areas in all directions, including areas on the floors below and overhead, and without regard to the presence of walls and other structural barriers, should be considered.

When a completely conservative use of the appropriate spreadsheet(s), with no assumptions about the shielding afforded by walls, floors and other structural barriers, indicates a possible need to shield or relocate an item of radioactive material, Environmental Health and Safety should be

consulted for further advice. [Appendix IX](#) also includes generally-applicable shielding guidelines for the most common radionuclides that emit penetrating radiations.

3.4.4.1 Location of Storage Areas

Storage areas should be chosen to be as well-secured and as far away from frequently-occupied areas, especially office areas, as possible. Locations of waste storage areas are usually more critical than locations of areas where stock materials are stored, because the small size of stock vials generally makes them easy to shield, even when considerable thickness of lead is necessary; whereas wastes typically involve much larger volumes.

3.4.4.2 Use of Shielding

3.4.4.2.1 Stock Vials and Wastes

When a need for shielding of *wastes or stock quantities* is indicated by the calculations implicit in the spreadsheets in [Appendix IX](#), EHS should be consulted to determine the appropriate type of shielding and the minimum thickness required.

3.4.4.2.2 Materials in Process during Experiments

Materials in process in the laboratory, or contained in animals, are generally much more difficult to shield because of the size of the source(s) and other considerations.

Fortunately, the quantities involved are usually low enough that shielding of such materials is not required. Distance and its consideration in facility layout will generally provide a more practicable alternative than shielding in such cases.

3.4.4.2.3 Benchtop Shields

Benchtop shields made of plastic are very useful in handling high-energy beta emitters such as ^{32}P , and provide the added advantage of splash protection. They are generally required by the CIR in its review of applications for the use of high-energy beta emitters.

Benchtop shields made of leaded plastic are available; however

- they are expensive,
- they provide significant protection only for a few radionuclides whose primary x and gamma ray emissions are low in energy, most notably ^{125}I , and
- the dose avoided by using such shields is minimal for quantities less than about one mCi (37 Mbq).

A good practical alternative to the use of leaded plastic shields for ^{125}I , which should be considered in applications for use of larger amounts, is the use of lead foil to shield items such as reaction vessels and purification columns.

3.4.4.2.4 Eye Protection

Eye protection that suffices for general safety purposes will also provide considerable protection against high-energy betas, and must *always* be worn when handling radioactive materials of *any* kind.

3.4.4.3 Measurements of Dose Rates from Sources of Penetrating Radiations

Most radiation survey instruments possessed by principal investigators are appropriate for measuring surface contamination, but are not appropriate for measuring radiation exposure rates from gamma rays and x rays. The measurement of skin dose rates from high-energy beta particles is also beyond the capability of most laboratory personnel. Some additional information is given in the *Radiation Safety Training Manual*. Environmental Health and Safety can make or assist in making such measurements when they are required.

3.4.4.4 Personnel Monitoring Devices

A personal dosimeter for external whole-body exposure to penetrating radiations, with the specified type of device to be determined by the RSO and the CIR for specified classes of potentially-exposed individuals, is required for

- Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the annual dose limits,
- any minor for whom a permission form is required under section 3.4.1.1 above, and
- any other person designated by the CIR.

A thermoluminescent dosimeter (TLD) finger ring badge or other similar extremity monitor is required for

- any person who will directly handle vessels containing more than 1 mCi (37 Mbq) of beta-emitting radionuclides with a maximum energy above 500 keV, and
- any person who will directly handle vessels containing more than 5 mCi (185 Mbq) of any radionuclide that emits gamma rays and/or x rays, unless that person is specifically exempted by the RSO.

Any person who is issued a personal dosimeter for work at CU Denver | Anschutz shall wear that badge or device ONLY while working under the university's radioactive materials license. Work at University of Colorado Hospital, Veterans Administration Medical Center, or any other institution should be monitored by that institution. Any person who is being monitored by both the university and another employer or institution must notify the CU Denver | Anschutz RSO at the time when such conditions take effect, so that information may be exchanged appropriately to control the individual's total radiation dose.

Environmental Health and Safety may impose additional requirements on the issuance, wearing, and exchange for personal monitoring devices, subject to the approval of the CIR. The EHS personal monitoring device application as well as additional information on personal dosimeters is provided in [Appendix X](#).

3.4.4.5 Housing of Animals Containing Radioactive Materials

As with all other sources of penetrating radiations, the dose guidelines set forth in section [3.4.4](#) above are applicable to animals containing radioactive materials. The types and amounts of radioactive materials administered to animals are such that beta particles are almost completely absorbed and typically do not represent a significant direct exposure hazard due to betas escaping the animal's body, and photon (gamma and x) dose rates due to radiations emitted by experimental animals are typically a minor hazard at most; however, some controls may be required in some cases. Precautions are specified during the CIR's review of specific applications for the use of radioactive materials, and any change in procedure, including a change in the location of the animals' housing, must be approved by the CIR.

3.4.5 POTENTIAL ENVIRONMENTAL RELEASES AND CONTROL OF RADIOACTIVE MATERIALS IN AIR AND WATER EFFLUENTS

The possibility of improper or illegal releases of radioactive materials to the larger environment in the surrounding community, especially improper disposal or loss of control of identifiable items of radioactive materials, represents one of the most potentially damaging and sensitive types of incidents that can occur in the institutional setting.

Other potential types of releases, associated with effluents of air (from fume hoods and ventilation systems) and water (sanitary sewage, runoff and storm sewer drainage) are discussed specifically in the sections below.

3.4.5.1 Improper Disposal or Other Loss of Control of Radioactive Materials

The improper disposal or loss of control (theft or disappearance) of radioactive materials, which may occur accidentally through a failure of controls such as the securing and proper labeling of containers of various types, is by far the greatest risk of an illegal release of radioactive materials. Incidents of this type must be reported immediately to Environmental Health and Safety.

The importance of prominent labeling and proper securing of radioactive materials, and the proper disposal of wastes that are known or suspected to contain licensed radioactive materials, cannot be overemphasized. These subjects are treated at length in other sections of this *Manual*.

3.4.5.2 Utilization of Fume Hoods

As a form of local exhaust ventilation, fume hoods are intended to remove airborne contaminants from the work area and disperse them into the air outside the building. Modern systems are specifically designed to eject the plume of exhaust air away from the building at the location of discharge, which is usually on the rooftop, with particular attention to

- minimizing the amounts of contaminant that could be accumulated in breathing zones near the rooftop, as these areas may be occupied by maintenance workers, and

- minimizing the amounts of contaminant that could be re-entrained in intake air coming into the building's ventilation systems.

Uses of radioactive materials that present a significant hazard of airborne materials must be evaluated carefully by EHS during the CIR review process, and appropriate supporting calculations must be produced by EHS reviewers for the Committee's information, to demonstrate that regulatory limits will not be exceeded in discharged air. Two specific cases of interest are discussed in the sections below.

Researchers must make every reasonable effort to minimize the actual amounts of radioactive material that become airborne, especially regarding the techniques discussed in the section below on iodination labeling reactions. This affords additional protection to those working with the radioactive materials in case there should be a less-than-perfect removal of airborne contaminants from the work area, and it also serves the purpose of protecting the larger environment.

3.4.5.2.1 Iodine Labeling Reactions

Radioiodination of proteins is notorious in the biomedical research arena because of the unusual radiotoxicity of the radioiodines (^{125}I , ^{131}I) and their potential volatility. Researchers performing these labelings are required to follow a number of precautions, especially those related to maintaining all liquids at appropriately basic pH in tightly-sealed containers, and initially drawing off the air in stock vials through a charcoal-filled syringe. More detail is given in [Appendix XI](#).

3.4.5.2.2 Volatile Tritiated Compounds

Although tritium is one of the least radiotoxic radionuclides used in biomedical research, some uses employ such large quantities (stock quantities of one Curie or more in some cases) and some compounds used are so volatile (especially tritiated water) that potential releases are a serious concern. Uses involving milliCurie (37 MBq) or larger quantities of tritiated water or other volatile tritiated organics, including acetate, should be discussed with EHS as early as possible in the planning stages of the proposed research.

3.4.5.3 Sewage Effluents

CU Denver | Anschutz has historically followed a restrictive policy on disposal of radioactive materials by sanitary sewage. The university does not generally allow sink disposal of radionuclides other than ^3H by laboratory personnel. ^3H must be diluted to concentrations less than 10 microCuries (370 kBq) per liter of liquid *before* being poured into the sink drain. For all other radionuclides, aqueous wastes containing more than the extremely low trace quantity limits stipulated by university policy are collected by EHS, which holds about two thousand gallons of such wastes for decay for periods up to 30 months. No aqueous waste is discharged

by EHS unless it meets the state and federal concentration limits for sewage disposal, as it sits in the storage container, with no credit assumed for the prodigious dilution afforded by the volume of sewage entering the campus system.

The wisdom of the university's policy has been demonstrated in many ways, such as

- by incidents involving exposure of maintenance workers to sewage from sewer line breaks,
- by the tightening of federal regulations pursuant to concerns about reconcentration of radioactive materials in sludges at community sewage treatment plants, and
- by the problems that other institutions have encountered in dealing with local authorities governing sanitary sewer systems.

Due to the nature of the radioactive materials usage at CU Denver | Anschutz, there is no expectation that any accidental release will affect soils, ground water, or runoff into storm sewers. Environmental Health and Safety's handling and storage of all liquid radioactive wastes is done with extensive controls providing a minimum of two levels of containment against possible leakage or spillage. Spills occurring in laboratories, even those involving several liters of liquid waste, would be extremely unlikely to escape the containment of the building. Furthermore, all spills of radioactive materials that may occur on campus are required to be reported to EHS for other reasons, as discussed in section [3.4.9](#) below.

Disposal of liquid wastes by sanitary sewage is discussed below in section [3.4.6](#).

3.4.5.4 Vacuum Systems

Operations involving the use of "house vacuum" (vacuum from lines installed in the building), if they involve radioactive materials, **MUST** utilize appropriate filters and/or traps to avoid contamination of the vacuum lines, mechanical equipment, and areas where the mechanical equipment providing the vacuum is located and the evacuated air is discharged.

Vacuum pumps used in the laboratory with radioactive materials should be similarly protected by traps and/or filters, and it may be advisable to vent them into a properly-operating fume hood as an additional precaution.

All procedures involving the use of vacuum with radioactive materials must be clearly described in applications to the CIR, so that appropriate precautions can be specified.

More information about traps, filters, and other safety concerns related to the use of vacuum is available from EHS.

3.4.5.5 Releases from Animals Containing Radioactive Materials

An obvious result of administering radioactive materials to animals is that the radionuclide involved is usually subject to being excreted in various ways, usually after some metabolic

transformation(s) of the original chemical and physical form in which the radioactive material was administered. For any use involving the administration of radioactive materials to animals that will be housed after the radioactive material has been administered, the Principal Investigator's application to the CIR must include the PI's careful and conservative estimates of the amounts of radioactivity that may appear in:

- urine,
- feces,
- exhaled breath if applicable (e.g., $^3\text{H}_2\text{O}$, $^{14}\text{CO}_2$), and
- any other pathway that may be of concern with respect to controlling contamination and potential releases to the environment.

The precautions stipulated by the CIR must be followed and clearly communicated to all persons who may become involved in care of the animals. Any change in procedure, including a change in the location of the animals' housing, must be approved by the CIR.

3.4.6 DISPOSAL OF RADIOACTIVE AND MIXED WASTES

Any waste that is known or suspected to contain licensed radioactive materials must be managed in accordance with the provisions of this section and the *Radioactive Waste Disposal Manual*. Radioactive wastes that are also classifiable as hazardous wastes, based on their chemical composition or physical and chemical attributes (ignitability, corrosivity, reactivity) are classified as *mixed wastes* and require special segregation and preparation.

This section of the *Radiation Safety Manual* covers only selected items of major regulatory significance. All persons involved in the generation of radioactive wastes must be familiar with the *Radioactive Waste Disposal Manual*, which is a separate document.

3.4.6.1 Disposal through Environmental Health and Safety Department

At CU Denver | Anschutz, almost all disposals of radioactive and mixed wastes is performed by EHS, which picks up wastes at the point of generation (laboratory) and transports them to a campus processing facility. The only allowable exceptions are those explicitly discussed in the following sections.

3.4.6.2 Disposal of Materials into Sanitary Sewage

At CU Denver | Anschutz, Principal Investigators' personnel are allowed to perform only the extremely limited disposal by sanitary sewage that is explicitly described in sections [3.4.6.2.1](#) and [3.4.6.2.2](#) below, for the reasons set forth in section [3.4.5.3](#) above. All other disposal of aqueous wastes is performed by EHS after extensive decay and testing.

3.4.6.2.1 ^3H

Radioactive aqueous wastes containing only ^3H may be sink disposed in laboratories, if they are diluted to radioactivity concentrations less than 10 microCuries (370 kBq) per liter *before* they are poured into the drain and the other requirements stated in the *Radioactive Waste Disposal Manual* are met.

Disposal of more concentrated materials by pouring them directly into the drain and allowing the water to flow is NOT an acceptable method.

3.4.6.2.2 Trace Amounts of Radionuclides Other Than ^3H

The CIR has recognized that a quantitative limit is the only defensible regulatory position for aqueous wastes containing traces of radionuclides other than ^3H . A strict prohibition stating that absolutely no radioactive material may be sink disposed is not logically consistent with

- the finite and limited detection capability of any method used to determine the presence or “absence” of radioactivity, which will depend on the equipment and procedures in use, and
- the unavoidable presence of naturally-occurring radioactivity in the environment at extremely low levels, including the same radionuclides that are used at the university as licensed radioactive materials.

Therefore, the CIR has decided to use the strictest water concentration limits published by the state and federal agencies: the limits for water effluents to unrestricted areas. These limits are predicated on the assumption that such water effluents are subject to being directly consumed by members of the public, and are therefore extremely low. However, they can be measured and quantified in most cases, without extreme effort.

Assumptions that are not supported by measurements are NOT acceptable. Consult the *Radioactive Waste Disposal Manual* for other limits and suggested methods of measuring the radioactivity concentration of aqueous liquid wastes. A simple but conservative statistical formulation for establishing the lower limit of detection (LLD) of an assay is given in Radiation Safety Training Manual.

3.4.6.3 Disposal by Decay-in-Storage in the Laboratory

Autonomous disposal by decay-in-storage in the Principal Investigator’s laboratory is discouraged by the CIR and may not be practiced without filing a form with EHS (consult the *Radioactive Waste Disposal Manual*) and approval from the RSO.

3.4.6.4 Disposal of “Deregulated” Radioactive Wastes

State and federal regulations provide a regulatory exemption for liquid scintillation wastes and animal tissue that contain only ^3H and/or ^{14}C at concentrations less than 0.05 microCuries (1.85 kBq) per gram. These wastes are commonly called “deregulated” wastes. At CU Denver | Anschutz, although deregulated wastes are classified as such by EHS, all “deregulated” wastes

are required to be disposed through EHS unless a specific arrangement to the contrary is established with the RSO.

3.4.6.5 Disposal of Empty, Non-contaminated Packaging Materials from Radioactive Materials Shipments

After radioactive materials packages are received by the laboratory and the actual stock vials are properly secured in a storage unit, the carton or other shipping container and all associated packing materials must be carefully surveyed for contamination and all labels and markings with the words “radioactive” or the trifoil symbol must be obliterated before these items may be discarded in regular trash.

Environmental Health and Safety should be contacted for current information about the status of recycling programs for expanded plastic (e.g., “styrofoamTM”) shippers, which must not be shipped by laboratory personnel without a contamination survey to demonstrate that they do not exceed contamination levels allowable by the regulations of the U.S. Department of Transportation.

3.4.6.6 Disposal of Bedding, Excreta, Carcasses and Other Materials Deriving from Animals Containing Radioactive Materials

Disposal of all materials deriving from animals to which radioactive materials have been administered must comply with the specifications in the Principal Investigator’s authorization from the CIR. The precautions stipulated by the CIR must be followed and clearly communicated to all persons who may become involved in care of the animals. Any change in procedure, including a change in the location of the animals’ housing, must be approved by the CIR.

Animal tissue and other materials (e.g., bedding) that are “deregulated” must be disposed through EHS unless specific arrangements for other disposal procedures have been approved by the RSO, for the reasons explained in section 3.4.6.4 above.

3.4.6.7 The *Radioactive Waste Disposal Manual*

The *Radioactive Waste Disposal Manual* contains current information about disposal of radioactive wastes, including details about

- segregating wastes by specific forms,
- for some forms, segregating wastes by radionuclides or specific classes of radionuclides (e.g., long-lived vs. short-lived radionuclides according to a specific limit on half-life), and
- preparation of wastes, required labels and documentation, and allowable containers for storage of each form in the laboratory.

3.4.6.8 Provision of Radioactive Waste Information and Contamination Survey Records to the Environmental Health and Safety Department

At the time when custody of an incoming package of radioactive material is transferred to the Principal Investigator or the Principal Investigator's laboratory personnel, EHS provides

- a pre-printed *User's Radioactive Material Accounting Sheet* to be used for the Principal Investigator's own record-keeping, and
- a pre-printed, pre-coded set of Radioactive Waste Tickets, by which the Principal Investigator may simultaneously
- identify the contents of an item of radioactive waste in terms of radionuclide(s) and amount(s), and
- report the corresponding radioactive materials accounting information to EHS's inventory system.

Timely and properly-documented disposal of wastes is an important obligation of authorized Principal Investigators.

All disposal must be reported to EHS on the pre-coded waste tickets, including those forms of disposal for which wastes are not physically presented to EHS, i.e. sink disposed ^3H , as well as materials that are administered to human subjects and not recovered as samples, or other patient wastes.

In addition, any transfer of radioactive material, to another investigator at CU Denver | Anschutz or to another party operating under a different radioactive materials license, must be reported to EHS before transporting the material, and the additional requirements of sections [3.4.2.5 through 3.4.2.8](#) must be met.

At the time of each waste pickup, as required by the CIR, copies of the latest contamination surveys must be examined by the EHS worker picking up radioactive wastes, for the authorized areas of each Principal Investigator whose waste is being removed. These surveys must be current, viz., within the last day, week, or month, depending on the hazard class assigned to the laboratory's authorization as described in Section [3.4.3.2.1](#). Additionally, the EHS representative will perform a spot check of the waste container exterior for removable contamination. If evidence of contamination is present, laboratory personnel will need to decontaminate the waste container exterior prior to EHS removing the waste.

3.4.7 DESIGNATION AND DECOMMISSIONING OF AREAS WHERE RADIOACTIVE MATERIALS ARE STORED OR USED

Each Principal Investigator that is authorized for use of radioactive materials is responsible for the conditions in one or more areas ("areas" as defined in section [3.4.7.1](#) below) where those

materials may be used or stored, including responsibility for matters such as control of contamination and control of dose rates from penetrating radiations.

Radioactive materials may be stored or used only in the responsible Principal Investigator's authorized areas that have been registered with EHS as described below, so that EHS's emergency response and other institutional responsibilities under the radioactive materials license may be effectively discharged. **Principal Investigators considering use of radioactive materials in facilities not previously so authorized should consult the RSO as early as possible in the planning process, to review all of the considerations listed in [Appendix XVI](#) to this Manual.**

3.4.7.1 Boundaries of a Designated Area (Definition)

An area designated for radioactive materials may be defined by any combination of walls and doors that clearly demarcate a contiguous space, such that access to the entire space can be controlled in some fashion and the entrances to the space can be clearly defined and posted as required in section [3.4.8.1](#) below. In the case of the open laboratory design an area designated for radioactive materials may be defined by the designated module space (up to but not including the main aisle way), such that access to the main entry point(s) to the open laboratory can be controlled by card access or a key and the module, alcove, procedure room space can be clearly posted as required in section [3.4.8.1](#)

3.4.7.2 Designation of Laboratory Areas Authorized for a Principal Investigator's Use

Areas to be authorized for the use or storage of radioactive materials are normally designated by laboratory room numbers on a Principal Investigator's application to the CIR. Any addition or deletion of rooms that is not contained on an application to the CIR must be reported to the RSO by submitting the *Authorization Update Form*. For such cases, the RSO will determine whether any communication with the CIR is necessary. In addition, deletion of an authorized Principal Investigator's responsibility for a given space requires that the conditions in section [3.4.7.4](#) below be met.

3.4.7.3 Common Areas Shared by Two or More Principal Investigators

Common areas, such as rooms that are dedicated to radioactivity counting machines, will be shown by EHS as being authorized to all of the Principal Investigators who may use them. Environmental Health and Safety will not become involved in disputes about conditions such as contamination that may arise in such areas; it will be left to Departments or Divisions to resolve such matters when necessary.

3.4.7.4 Decommissioning of Areas Prior to Renovation, Reassignment to Another Authorized Principal Investigator, or Return to General Use (EHS "Green Tags")

Environmental Health and Safety must be notified whenever any particular authorized Principal Investigator will no longer use any particular area for radioactive materials, regardless whether

- the space is being transferred to another authorized CU Denver | Anschutz Principal Investigator, or
- other Principal Investigators previously authorized for common use of the area remain authorized and responsible, or
- the area is being returned to general use, such that radioactive materials will no longer be used in the space.

Upon such notification, EHS will review the contamination surveys of the appropriate authorized Principal Investigator(s) and may elect to perform additional confirmatory surveys for contamination. If the space is being returned to general use, EHS will verify that all radioactive materials including wastes have been removed. After these actions are complete, if appropriate, EHS will attach a “Green Tag” ([Appendix XII](#)) to the entrance to the area.

In addition to situations involving a change in the responsible Principal Investigator, areas authorized for radioactive materials *always* require a Green Tag for certain types of services performed by workers from outside the laboratory. A Green Tag from EHS is required for

- renovation (painting, etc.),
- various other maintenance and repair services from the Facilities Department that require contact with laboratory surfaces such as laboratory benches, casework, sinks, and fume hoods,
- cleaning of laboratory benches, casework, sinks, and fume hoods; and
- other non-routine services provided by cleaning services.

Environmental Health and Safety should be contacted for guidance in specific cases.

3.4.7.5 Storage in Hallways and Corridors

Storage of radioactive materials in hallways, corridors, and other public areas is strongly discouraged because

- only small amounts of radioactive material can legally be stored in such areas, due to the fact that these public areas are not and cannot be posted as “Caution: Radioactive Materials” areas,
- security of materials in such locations is of greater concern than in laboratories, and
- storing radioactive materials in such areas increases the risk of contamination in public areas, which is an extremely sensitive issue.

Radioactive materials stored in hallways, corridors, and other public areas must meet the following criteria:

- storage must be in a strong, securely-locked container that cannot be removed by an individual without mechanical assistance (e.g., a freezer, refrigerator, heavy steel box),
- the total quantity stored must not exceed the amounts specified in [Appendix XIII](#) (e.g., 100 microCuries of ^{32}P or 1 milliCurie of ^{35}S), and
- any storage unit containing more than one tenth (1/10) of the amounts specified in [Appendix XIII](#) must bear the “Caution: Radioactive Materials” label on the exterior surface of the unit in a prominent location.

Each such instance of storage in a hallway, corridor, or other public area is subject to the explicit approval of the CIR. Investigators who have a particular storage problem because they do not have the space or other necessities inside their laboratories for the appropriate freezer or other storage unit, but cannot meet the above requirements for storage in an adjacent public area, may need to store their materials in another nearby Principal Investigator’s laboratory.

3.4.8 REQUIRED SIGNS, LABELS, AND OTHER POSTINGS

Signs, labels, and other postings perform a particularly valuable function in the university setting, as a means of communicating information to the diverse array of persons who may frequent areas where radioactive materials are stored or used. Many of these persons will not be trained radiation workers, or may not be familiar with the operations in a particular laboratory in which they are performing some activity. Proper signs, labels, and postings are an important indication of diligence and good practice on the part of the authorized Principal Investigator.

3.4.8.1 *Radioactive Materials Caution Signs*

Any space, as defined in section [3.4.7.1](#) above, that is subject to containing radioactive materials exceeding the quantities in [Appendix XIII](#) (based on the combined authorizations of the Principal Investigators to whom the space is authorized) is required by state regulations to be posted with the standard yellow-and-magenta sign bearing the trifoil symbol and the words “Caution: Radioactive Materials.” At CU Denver | Anschutz, ALL rooms authorized by the CIR for use or storage of radioactive materials must be so posted, unless a specific exemption is granted (Contact EHS for more information on exemptions).

Standard laboratory hazard signs provided by EHS are mounted at the corridor entrance(s) to laboratories and include the “Caution: Radioactive Materials” sign when appropriate. These signs may be supplemented on an interim basis by stickers available from EHS. In some cases, additional signs at entrances from adjacent areas other than the corridor or hallway may be needed - EHS should be consulted in specific cases.

3.4.8.2 *Radiation Area Caution Signs*

Signs bearing the words “Caution: Radiation Area” are generically different than “Caution: Radioactive Materials” signs, under state and federal regulations. “Caution: Radiation Area” signs are to be used to warn of the presence of substantial sources of penetrating photon radiations (gamma and x rays).

The definition of a “Radiation Area” is

“any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 5 mrem (0.05 mSv) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates” (*Colorado Rules and Regulations Pertaining to Radiation Control*).

Such areas should be relatively rare in modern biomedical research, except for some special areas where devices such as irradiators may be housed.

Any area requiring designation as a “Radiation Area” clearly requires special controls on access (control as a “restricted area” in the sense described in section [3.4.2.8](#) above), in order to demonstrate compliance with the allowable dose limits affecting members of the public (section 3.4.4). Principal investigators are encouraged to contact EHS early in the planning stages if non-routine or large quantities of radionuclides are anticipated so that proper posting and area controls may be evaluated, in addition to provisions listed under section [3.1.1](#) above.

3.4.8.3 The CDPHE Notice to Workers

The CDPHE publishes a poster entitled “Notice to Workers” that contains legally-required information that licensees must post in “a sufficient number of locations to permit individuals engaged in work under the license to observe them on the way to or from any particular work location” where the radioactive materials will be used. These postings, along with information about where individuals can review copies of the radioactive materials license and related documents (the offices of EHS) are posted in public areas of buildings on campus that contain areas authorized for radioactive materials. Individual PIs are encouraged to post these items in their own areas (contact EHS). The “Notice to Workers” is also included in the introduction section of the *Radiation Safety Training Manual* and in [Appendix XVIII](#).

3.4.8.4 The Principal Investigator’s Authorization Postings

Each Principal Investigator authorized for radioactive materials must maintain, in some accessible area in or near the area(s) authorized for radioactive materials, all of the PI’s authorizations and supporting applications.

The location of this area must be known, and the indicated documents readily available, to ALL persons who will frequent the PI’s authorized area(s), *including persons who will not work directly with the radioactive materials*.

3.4.8.5 Labeling of Laboratory Appliances and Bench Areas Used for Radioactive Materials

Specific, designated areas within the laboratory that will be used in any manipulation or processing of radioactive materials should be marked with tape bearing the “Caution: Radioactive Materials” warning. These areas must be treated as being potentially-contaminated during periods of use of radioactive materials, even when regular surveys are being performed in accordance with the requirements of section [3.4.3.2](#) above. During extended periods of NO use of radioactive materials, subsequent to a thorough contamination survey demonstrating that these surfaces are not contaminated, the labeling may be removed until the use of radioactive materials is resumed.

Types of areas to be labeled include

- designated portions of benchtops,
- fume hoods,
- centrifuges, water baths, hybridization ovens, incubators, and other laboratory appliances, and
- refrigerators, freezers, and other storage units.

The extent of these areas should be minimized as a fundamental method of limiting the potential for persons in the laboratory to become contaminated and spread contamination; therefore, the representation that *every* surface in the PI’s authorized area(s) is subject to such use

- is generally *not* defensible, and
- does not eliminate the requirement to mark such areas as described in this section.

It should also be noted that clear and prominent marking is required for sinks used for disposal of ³H (see the *Radioactive Waste Disposal Manual*), but that sinks should otherwise *not* be suspect of significant contamination, due to the restrictions on disposal by sewage.

3.4.8.6 Labeling of Containers

The appearance of containers used for radioactive materials, particularly waste containers that will sit on the floor, is critical to minimizing the potential for problems such as improper disposal actions by cleaning services employees (see sections [3.3](#) and [3.4.5.1](#) above).

All radioactive trash cans and liquid waste collection containers absolutely must be labeled conspicuously on at least two sides with standard yellow-and-magenta “Caution:

Radioactive Materials” warning labels that are at least 3x5 inches in size, available from EHS. Principal Investigators are urged to use the standard containers that are sold at cost by EHS, which are pre-labeled and are chosen and standardized to further minimize the potential of their being confused with other waste containers. Additional details are given in the *Radioactive Waste Disposal Manual*.

In addition, any container of any type that may contain more than one tenth (1/10) of the amounts of radioactive materials in [Appendix XIII](#), and is not *continuously* in the control of a trained radiation worker during the performance of an experiment, must be labeled, at least with tape bearing the “Caution: Radioactive Materials” warning.

3.4.9 EMERGENCY PROCEDURES AND REPORTING OF INCIDENTS

All significant incidents involving radioactive materials should be reported to EHS as soon as possible. Environmental Health and Safety seeks to respond in ways that are supportive rather than punitive. Proper actions and documentation at the outset of an incident will generally save effort overall, and reporting incidents initially through proper channels is likely to have less serious consequences than having the incident come to light at some later time, when damage to personnel or facilities may be more difficult to assess and/or ameliorate, and far greater liabilities may have been created.

3.4.9.1 Incidents Requiring Reporting to Environmental Health and Safety

With the exception of performing the initial emergency actions described in the emergency procedures, **any person involved in any of the following types of incidents must ensure that EHS is informed immediately by telephone:**

- **any incident involving possible contamination of an individual’s person (any part of the body, including contamination of clothing that may transfer to the body),**
- **any incident involving disappearance or loss of control of radioactive material, including improper disposal,**
- **any incident involving known or suspected contamination of floors, and**
- **any incident involving radioactive contamination that cannot be immediately and completely contained and controlled.**

Contact telephone numbers are listed on the first page of this Manual. When calling EHS, you will be asked to give your name and the names of other potentially-affected individuals, the location of the incident, the type and amount of radioactive material involved, and a description of the incident.

3.4.9.2 Emergency Procedure for Personal Contamination

- **If the exposure involves a liquid containing chemicals that are caustic to the skin or a solution of radioactive iodine as sodium iodide (NaI) flushing with water must begin IMMEDIATELY.** Use
 - a safety shower for large areas of the body,
 - an eyewash for the eyes, or
 - a laboratory water tap for small areas of the body.
- **Ask a nearby person to call Environmental Health and Safety**
- Place any contaminated clothing into a sealed plastic bag for later survey and disposition.
- **DO NOT use chemical or mechanical methods that may damage the skin, which will worsen the situation.** Use only mild soap or detergent and warm water. Wash water may be disposed down the drain if it is not practical to contain it in the sink.
- **DO NOT leave the area until Environmental Health and Safety has addressed the situation.**

3.4.9.3 Emergency Procedure for Radioactive Spills

- **If the spill involves**
 - a portion of the floor that cannot be quickly and completely contained and cordoned off, or
 - volatile forms of radioactive material (e.g., radioactive iodine in sodium iodide solution, tritiated water in milliCurie-or-greater quantities),
 - **YOU MUST EVACUATE the laboratory and close the doors BUT DO NOT allow any persons who were in the laboratory to leave the area.**
- **Address any contamination of persons according to the Emergency Response Procedure for Personal Contamination.**
- **Call Environmental Health and Safety.**
- **All persons who were in the laboratory must remove any potentially-contaminated footwear and place them in a secure area.**

- If the spill did not require evacuation of the laboratory by the above criteria, then you may begin decontamination operations:
 - don your lab coat, gloves, and eye protection,
 - cordon off an area that is certain to contain the spill so that no other person will enter,
 - use disposable paper towels or pads to absorb any liquid and place into a radioactive waste liner, changing gloves frequently,
 - decontaminate the spill with a detergent solution or a commercial preparation intended for radioactive decontamination, by soaking paper towels in the solution, wiping toward the center of the spill, and placing the towels into the radioactive waste liner,
 - survey the area after each such effort to determine residual contamination levels, and attempt to remove all detectable contamination by continuing such efforts until no removable contamination appears on swipe samples.

Radiation Safety Manual **Appendices**

I

Broad Scope Radioactive Materials License and Cover Letter



Pursuant to the *Colorado Radiation Control Act*, Title 25, Article 11, *Colorado Revised Statutes*, and the *State of Colorado Rules and Regulations Pertaining to Radiation Control* (the Regulations) and in reliance on statements and representations heretofore made by the licensee designated below; a license is hereby issued authorizing such licensee to transfer, receive, possess and use the radioactive material(s) designated below; and to use such radioactive material(s) for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders now or hereafter in effect of the Colorado Department of Public Health and Environment and to any conditions specified below.

1. Licensee: University of Colorado Denver
2. Mailing Address: Environmental Health and Safety, Mail Stop F484, 1784 Racine Street, Room 212, Aurora, Colorado 80045
3. License Number: CO 835-01, Amendment Number: 46
4. Expiration date: November 30, 2016
5. Authorized Storage/Use Location: Facilities Specifically listed in Condition 14.A
6. Designated Radiation Safety Officer(s): Riad Safadi
Designated Alternate Radiation Safety Officer(s): Jeremy Byble (for all radioactive material use authorized in License Condition 10 except 10.J and 10.K);
Dr. Philip Koo, M.D. (for radioactive material use authorized in License Conditions 10.J and 10.K only)
7. Radiation Safety Officer Contact Number: (303) 724-0345
8. Fee Category: 7.B, 3.C, and 3.N
9. Reference Number: PET, NSTS, Cat 1

CONDITIONS

10. Authorized Radioactive Material and Uses:
 - A. The licensee is authorized to possess and use any radioactive materials with atomic numbers 1-85 (inclusive) in any form, with the total activity not to exceed 1.85 TBq (50 Ci). These materials may be used in research and development activities (as defined in Section 1.2 of the Regulations), for teaching and instructional purposes, for administration to animals, and for radiopharmaceutical preparation and development.

- B. The licensee is authorized to possess 1 sealed source containing not more than 45.38 TBq (1226 Ci) of Cesium-137 to be used in a CIS-US model IBL-437C Irradiator for research.
- C. The licensee is authorized to possess sealed sources containing not more than a total of 40.7 MBq (1.1 mCi) of Germanium-68 and 370 MBq (10 mCi) of Cobalt-57 for calibration of the Inveon PET System.
- D. The licensee is authorized to possess 1 sealed source containing not more than 3.7 GBq (100 mCi) of Cesium-137 to be used in a Technical Operations Model 726 Instrument Calibrator for the calibration of survey instruments.
- E. The licensee is authorized to possess 1 sealed source containing not more than 6.11 GBq (165 mCi) of Cesium-137 to be used in a Technical Operations Model 733 Instrument Calibrator for the calibration of survey instruments.
- F. The licensee is authorized to possess 1 sealed source containing not more than 7.4 GBq (200 mCi) of Cesium-137 to be used in a Technical Operations Model 773 Instrument Calibrator for the calibration of survey instruments.
- G. The licensee is authorized to possess sealed sources containing a total of not more than 3.7 MBq (0.1 mCi) of Radium-226 for use as check sources.
- H. The licensee is authorized to possess sealed sources containing a total of not more than 3.7 MBq (0.1 mCi) of Americium-241 for use as check sources.
- I. The licensee is authorized to possess and use not more than 1 source of Cesium-137 as a J.L. Shepherd & Associates Model 6810 sealed source, to be used in a J.L. Shepherd & Associates Model 81-14 Irradiator for research. The total activity shall not exceed 148.15 TBq (4000 Ci).
- J. The licensee is authorized to possess and use not more than 50 mCi of Carbon-14 and 50 mCi of Hydrogen-3 in any form for use in in vivo clinical or laboratory tests involving the internal administration of byproduct material to human beings. No single administration to an individual shall exceed 40 µCi of Carbon-14 or 200 µCi of Hydrogen-3.
- K. The licensee is authorized to possess and use any unsealed radioactive material for imaging and localization studies which has been prepared for medical use in accordance with the requirements of Section 7.32 of the Regulations. The licensee shall not possess more than 370 GBq (10 Ci) of these materials at any one time.
 - i. This authorization includes positron-emitting isotopes
- L. The licensee is authorized to possess and use any radioactive materials specified in Section 7.19 of the Regulations for check, calibration, and reference use.

- M. The licensee is authorized to possess sealed sources containing not more than 7.4 GBq (200 mCi) of Cobalt-57 and 7.4 GBq (200 mCi) of Cadmium-109 in a mobile van custom ABIOMED Bone Lead Analyzer to be held in storage for disposal in accordance with Section 3.22 of the Regulations.
- N. The licensee is authorized to possess and use any radioactive materials with atomic numbers 6 through 9 inclusive, in any form, for the development, production, use, and distribution or transfer of PET drugs. These materials may be distributed or transferred to licensed recipients for non-human research only. The total activity of materials shall not exceed 1073 GBq (29 Ci).
- O. The licensee is authorized to possess and use any radioactive materials with atomic numbers 3 through 83 inclusive, in any sealed source manufactured in accordance with a U.S. Nuclear Regulatory Commission or Agreement State license. The licensee may use the sources for instrument calibration. The total activity of all sealed sources in the possession of the licensee shall not exceed 222 MBq (6 mCi) and no single source shall exceed 92.5 MBq (2.5 mCi).
- P. The licensee is authorized to possess and use any radioactive materials with atomic numbers 3 through 83 inclusive, in activation products in targets, foils and cyclotron parts which may result from operation of the cyclotron. The total activity of all activation products in the possession of the licensee shall not exceed 20.5 GBq (550 mCi).
- Q. The licensee is authorized to receive from the University of Colorado Hospital, Colorado radioactive materials license number CO 828-01, Iodine-125 and Palladium-103 in the form of brachytherapy seeds. These materials are to be possessed and stored as waste only until they are lawfully disposed of in accord with the Regulations. The total activity of the material received shall not exceed 22.2 GBq (600 mCi).
- R. The licensee is authorized to receive from the University of Colorado Hospital, Colorado radioactive materials license number CO 828-01, Iodine-131 in the form of nuclear medicine waste. These materials are to be possessed and stored as waste only until they are lawfully disposed of in accord with the Regulations. The total activity of the material received shall not exceed 9.25 GBq (250 mCi).

11. Authorized Radioactive Material Users:

- A. Radioactive materials authorized in Items 10.A through 10.C shall be used by or under the supervision of individuals who have been designated as Principal Investigators by the Committee on Ionizing Radiation
- B. Radioactive materials authorized in Items 10.D through 10.H, 10.Q, and 10.R shall be used by or under the supervision of the individual designated as the Radiation Safety Officer.

- C. Radioactive materials authorized in Item 10.I shall be used by individuals who have satisfied the requirements of the irradiator training program, as detailed in the license correspondence and attachments dated October 2, 2008, and have been designated as an approved user by the Radiation Safety Officer.
- D. Radioactive materials authorized in Item 10.J, which will be administered to human subjects or used to intentionally expose human subjects to radiation, shall be used by or under the supervision of individuals who have been designated as Principal Investigators by the Committee on Ionizing Radiation after research protocols have been approved by the Combined Multiple Institutional Review Board and, where applicable, the UCHSC Radioactive Drug Research Committee, and prior informed consent from the human subjects has been obtained.
- E. Radioactive materials authorized in Item 10.K shall be used by or under the supervision of Phillip J. Koo, M.D., or individuals designated as Authorized Users (AUs), as defined in Part 7 of the Regulations, in writing by the Committee on Ionizing Radiation.
- F. Radioactive materials authorized in Item 10.K, which will be administered to human subjects or used to intentionally expose human subjects to radiation, shall be used by or under the supervision of individuals who have been designated as Authorized Users by the Committee on Ionizing Radiation after research protocols have been approved by the Combined Multiple Institutional Review Board and, where applicable, the UCHSC Radioactive Drug Research Committee, and prior informed consent from the human subjects has been obtained.
- G. Physicians designated in writing as Authorized Users to use licensed material in or on humans shall meet the training criteria established in Appendix 7 of the Regulations and shall be designated by the Committee on Ionizing Radiations.
- H. Radioactive material authorized in Item 10.L may be used by or under the supervision of Phillip J. Koo, M.D., individuals designated as Authorized Users in writing by the Committee on Ionizing Radiation, and by the designated Radiation Safety Officer and alternate RSO listed on this license.
- I. The Radiation Safety Officer shall maintain written records indicating the date and basis of approval of designated users for Items 10.A through 10.J.
- J. The Radiation Safety Officer shall maintain documentation of the training and experience for each Authorized User of radioactive materials authorized in Item 10.K. This documentation shall include for each user: a copy of the applicable board certifications, preceptor statements, and any other relevant training documents.
- K. Radioactive material, authorized by Item 10.N, shall be used by or under the supervision of the following individuals: Phillip J. Koo, M.D.

- L. Radioactive material authorized in Items 10.N through 10.P may also be used by, or under the supervision of the following persons named as Cyclotron Engineers for cyclotron operation and maintenance only: Michael Mueller.

12. General Requirements:

- A. Radioactive material authorized in Items 10.J and 10.K shall be used for medical diagnosis and research in humans in accordance with any applicable Food and Drug Administration (FDA) requirements.
- B. The licensee shall comply with the provisions of the State of Colorado Rules and Regulations Pertaining to Radiation Control: Part 1, "General Provisions"; Part 3, "Licensing of Radioactive Material"; Part 4, "Standards for Protection Against Radiation"; Part 7, "Use of Radionuclides in the Healing Arts"; Part 10, "Notices, Instructions and Reports to Workers; Inspections"; Part 17, "Transportation of Radioactive Material"; Part 19, "Licenses and Radiation Safety Requirements for Irradiators"; and Part 22, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Materials".
- C. The Radiation Safety Officer shall maintain documentation of the training and experience for each person who uses radioactive materials under the supervision of an Authorized User.
- D. Each person who uses radioactive material under the supervision of an Authorized User shall meet the requirements of Appendix 7N and be supervised and receive instruction in accordance with the requirements of Section 7.10 and Section 10.3 of the Regulations.
- E. The licensee shall not transfer possession and/or control of radioactive materials or items contaminated with radioactive material except: by transfer of waste to an authorized recipient; by transfer to a specifically licensed recipient; or, as provided otherwise by specific condition of this license pursuant to the requirements of Part 3, Section 3.22 of the Regulations.
- F. Radioactive material authorized by Condition 10 of this license shall be stored and used in a manner that will preclude use by unauthorized personnel.
- G. The licensee shall ensure that information listed in this license is correct and accurate. The licensee shall notify the Department in writing within ten (10) days whenever the information contained in Items 1 through 7 above is no longer current or determined to be incorrect.
- H. The licensee may transport radioactive material or deliver radioactive material to a carrier for transport in accordance with the provisions of Part 17 of the Regulations and the requirements of U.S. Department of Transportation (49 CFR).

- I. The licensee shall not make any false statement, representation, or certification in any application, record, report, plan, or other document regarding radiation levels, tests performed or radiation safety conditions or practices.
- J. Prior to the use of licensed materials outside the State of Colorado, or at any facility under exclusive federal jurisdiction including a facility within the State of Colorado, the Licensee shall comply with the applicable provisions of 10 CFR 150.20 or if the use shall take place in an Agreement State the licensee shall comply with the applicable provisions of that State's reciprocity requirements.

13. Occupational Dose Monitoring:

- A. All users of radioactive material authorized in Item 10 who are likely to receive an occupational dose exceeding 10% of any applicable limit specified in Part 4 of the Regulations must be equipped with personnel monitoring devices capable of detecting the applicable radiation of interest.
- B. If personnel monitoring devices will not be used, the Radiation Safety Officer must maintain written records demonstrating that personnel dose monitoring was not required pursuant to Section 4.18 of the Regulations.
- C. The licensee shall implement and maintain a bioassay program sufficient to meet the requirements of Part 4 of the Regulations.

14. Specific Radiation Safety Requirements:

- A. Radioactive material shall be used and stored only at the following locations:
 - i. AMC Cancer Research Center, Diamond Building, 1600 Pierce Street, Denver, CO 80214;
 - ii. Anschutz Health and Wellness Center (AHWC), 13001 East 17th Place, Aurora, CO 80045;
 - iii. Anschutz Inpatient Pavilion, 12605 East 16th Avenue, Aurora, Colorado 80045;
 - iv. Anschutz Outpatient Pavilion, Room 1405, 1675 Aurora Court, Aurora, Colorado 80045;
 - v. Auraria Higher Education Center, Science Building, 1151 Arapahoe Street, Denver, CO 80204.
 - vi. Barbara Davis Center for Childhood Diabetes Building, 1775 North Aurora Court, Aurora, CO 80010;
 - vii. Children's Hospital, 13123 East 16th Ave., Aurora, Colorado 80045;
 - viii. Fitzsimons Building 500, 13001 East 17th Place, Aurora, CO 80045 0508;
 - ix. Fitzsimons Environmental Health and Safety Support facility, 13178 East 19th Ave., Aurora, CO 80045;
 - x. FRA Biosciences Research Center, 12635 East Montview Blvd., Aurora, CO 80045;
 - xi. Human Imaging Core - PET/CT Facility, Building 400, 12469 East 17th Place, Aurora, CO 80045;

- xii. Leprino Office Building, 12401 East 17th Ave., Aurora, CO 80262;
 - xiii. Research Complex 1 (North Bldg), 12800 East 19th Ave., Aurora, CO 80045;
 - xiv. Research Complex 1 (South Bldg), 12801 East 17th Ave., Aurora, CO 80045;
 - xv. Research Complex 2, 12700 East 19th Ave., Aurora, CO 80045;
 - xvi. School of Pharmacy, 12850 East Montview Boulevard, Aurora, CO 80045;
 - xvii. UCHSC Perinatal Research Center, 13243 E. 23rd Ave., Fitzsimons Army Medical Center, Aurora, CO 80010; and
 - xviii. University of Colorado Denver, Downtown Campus, 1200 Larimer Street;
- B. Each sealed source authorized in Item 10 of this license shall be tested for leakage in accordance with the requirements of Section 4.16 of the Regulations. For those sealed sources authorized an alternative leak test interval in the applicable device registry sheets, the leak test interval shall not exceed the interval specified in the applicable device registry sheet.
- C. The licensee is authorized to make minor modification to the training materials, procedure manuals and guidance documents referenced in License Condition 16 of this license. Substantial changes in the content of these documents must be approved in writing by the Department.
- D. The licensee shall acquire and maintain a current copy of the applicable Sealed Source and Device Registry Evaluation for each device/source in use by the licensee. Unless alternative operating procedures are specifically authorized by this license, the licensee shall comply with the safety precautions and limitations established in the applicable device registry evaluation.
- E. Installation, relocation, maintenance, repair, leak testing and initial survey of devices that contain radioactive material and replacement, and disposal of sealed sources that contain radioactive material that is used in devices shall be performed only by the manufacturer, or by other persons who are specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State having jurisdiction over the possession and use of accelerator produced radioactive material.

15. Special License Requirements:

- A. The licensee shall immediately notify the Colorado Department of Public Health and Environment in the event of an emergency condition resulting from cyclotron operation or a release of radioactive materials. During normal business hours the Department number is (303) 692-3300. After hours and on weekends the 24 hour number is (303) 877-9757.

- B. A physical inventory of each sealed source possessed by the license shall be conducted at intervals not to exceed 6 months or an alternate frequency specifically approved by the Department. The licensee shall retain each inventory record for 5 years. The inventory records shall contain the date of the inventory, the model number of each sealed source, the serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each sealed source, and the name of the individual who performed the inventory.
- C. The licensee shall maintain in effect the following financial warranty acceptable to the Department in accordance with the requirements of Part 3, Section 3.9.5, of the Regulations: financial assurance warranty letter for \$850,000 signed by Richard J. Traystman, Ph.D., Vice Chancellor for Research, dated May 24, 2012.
- D. The licensee shall maintain sufficient Department approved Assistant RSO(s) on this license for all modalities and activities authorized by this license.
- E. The licensee shall establish, implement, and maintain provisions as necessary to comply with Part 22, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Materials," of the Regulations.
- F. Notification and submission of reviewing official (RO) certifications to the Department, in accordance with Section 22.9.2(B) of the Regulations, are required within thirty (30) days of naming a new or additional individual as a reviewing official, or revoking an RO certification from a previously named individual.
- G. Security plans and corresponding implementation procedures may be revised as necessary to ensure the effective implementation of the Department requirements in accordance with Section 22.16 of the Regulations. Written records of all revisions shall be maintained for a period of 3 years and made available for Department review.
- H. The licensee shall make reports regarding nationally tracked sources in accordance with Section 4.55 of the Regulations.

16. Licensee Commitments and Reference Documents:

The State of Colorado *Rules and Regulations Pertaining to Radiation Control* shall govern unless the licensee's statements, representations, and procedures contained in the application and correspondence are more restrictive than the Regulations. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Condition 10 of this license in accordance with the statements, representations, and procedures contained in:

- A. the application and attachments dated October 27, 2011; and
- B. the license correspondence and attachments dated August 15, 2011; September 9, 2011 (email); November 29, 2011 (email); December 1, 2011; December 8, 2011 (email); December 21, 2011 (email); March 27, 2012; April 18, 2012 (email); June 28, 2012 (email); July 9, 2012 (email); July 24, 2012 (email); August 1, 2012 (email); August 8, 2012; November 6, 2012; February 13, 2013; June 10, 2013; June 14, 2013; June 20, 2013 (email); June 28, 2013; and August 2, 2013; February 25, 2014; April 9, 2014; April 24, 2014; August 1, 2014; September 16, 2014; September 17, 2014; September 19, 2014; October 02, 2014; November 25, 2014; February 6, 2015; February 9, 2015; February 19, 2015; and May 19, 2015.
- C. the 2011 University of Colorado at Denver and Health Sciences Center Radiation Safety Manual; the 2011 University of Colorado at Denver and Health Sciences Center Radioactive Waste Disposal Manual; the 2015 Memorandum of Understanding; the 2015 University of Colorado Denver Anschutz Medical Campus Nuclear Medicine Waste Pickup and Processing Radiation Safety.

FOR THE COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT



Digitally signed by James Grice
DN: dc=local, dc=dphe,
ou=Divisions, ou=HMD,
ou=Users, cn=James Grice,
email=james.grice@state.co.us
Date: 2016.03.08 13:56:43 -07'00'

Date: 03/08/2016

By: _____

II

List of Government Regulatory Agencies

Government Regulatory Agencies Affecting Radioactive Materials

Federal

U.S. Nuclear Regulatory Commission - licensing at federal facilities, general regulatory literature used by the Colorado Department of Public Health and Environment

U.S. Environmental Protection Agency - offsite releases, regulatory precedents affecting mixed radioactive/hazardous wastes

U.S. Food and Drug Administration - all administration of radioactive materials to patients and human research subjects

U.S. Department of Transportation - all off-campus transportation of radioactive materials by air or highway (public roadways)

Regional

Rocky Mountain Low-Level Radioactive Waste Board - all disposal of radioactive wastes generated in Colorado, Nevada, and New Mexico

State

Colorado Department of Public Health and Environment - licensing of radioactive materials, registration of radiation-producing machines/devices, all matters affecting radioactive and mixed radioactive/hazardous wastes

Colorado State Patrol - transportation of radioactive materials by highway (public roadways)

Washington Department of Ecology - disposal of radioactive wastes at the Benton County, Washington, commercial low-level radioactive waste disposal site required to be used by all Colorado generators

Local

City and County government, especially local fire departments and or emergency planning committees - reporting of inventories of materials

Sewer Authority - disposal by sanitary sewer

III

Environmental Health and Safety Receiving Procedure for Radioactive Materials Packages

ENVIRONMENTAL HEALTH & SAFETY

EHS RADIOACTIVE MATERIALS PACKAGE RECEIVING PROCEDURES

Why we do it:

State and federal regulations require a number of procedures to be performed when radioactive materials packages are received in order to minimize the potential for problems in the licensee's facility, and to insure that vendors are shipping properly packaged materials and that carriers are transporting them safely. In a large institution like the University of Colorado Denver | Anschutz Medical Campus, the licensing agency always requires these procedures to be performed at a central location by specially trained staff, usually in the "Radiation Safety Office."

What we do:

We inspect packages for visible evidence of damage or leakage, except for that which is obscured by inner containers that we do not open. When we open the package to check its contents and fill out radioactive materials inventory paperwork, we open the inner containers until we find a container label that contains all of the required information (radionuclide, compound, amount, assay date, lot #).

We check the outside of the package for contamination. We take a swipe of the package outer surface and check it briefly for contamination with the GM. We then verify the contents of the swipe by screening it with our liquid scintillation counter.

We check the radiation exposure rates on the exterior surface of the package (the dose rates that you could receive from gamma and x rays that are being emitted by the material inside the package). For packages classified as DOT Yellow II or Yellow III, we make actual measurements to determine maximum readings at the surface and at a distance of one meter. For other packages, we screen for unusual exposure rates with the GM.

What we do NOT do:

We do not open the package any further than is necessary to find the first container label that contains the required information described above. We never open the actual source vial itself.

We also do not test the containers inside the package for contamination. We regard these as potentially contaminated and handle them with gloves. We do not have nearly enough time to test all of these inner containers for contamination. Furthermore, we expect the package to be delivered to the lab intact, so that nothing will be in contact with potential contamination on these inner containers.)

What YOU should do:

You should immediately secure the package within the lab upon delivery and, if you are transporting the material from one location to another NEVER leave it unattended in a public area.

You should NOT wear gloves when transporting the packages within the lab. As noted above, we check the package to make sure its outer surfaces are free of contamination. If you are wearing gloves because your hands may be contaminated, then you cannot touch doorknobs, elevator buttons, and other surfaces in public areas. This practice has generated complaints from the public on campus, and will be strongly discouraged by the RSO.

You should consider the information that we provide about the gamma/x-ray exposure rates produced by the package. In some cases, it may be well worth your while to use a lab cart or hand truck to transport the package, in order to reduce your exposure.

You should regard the inner containers as being potentially contaminated, and handle them with gloves. It is not practical for EHS to attempt to guarantee that these items are free of contamination. Moreover, they are subject to being contaminated after they are opened, and it is a matter of good radiological hygiene to treat them, in a generic sense, as being potentially contaminated. All inner packaging items must be surveyed while unpacking the material.

You should not discard empty packaging without first surveying them to ensure that they are free of radioactive contamination and then obliterating all Radioactive Materials Markings. Survey must include a swipe sample and liquid scintillation counting. Survey records must be maintained at the laboratory for three years for inspection by EHS.

IV

Environmental Health and Safety Radioactive Materials Inventory System

Using the EHS Radioactive Waste Accounting System (Pre-coded Waste Tickets)

- Each time that you withdraw/aliquot an amount from a stock vial of radioactive material for use, write down an entry in the top section of the corresponding *User's Radioactive Material Accounting Sheet*, or similar accounting sheet approved by EHS.
- Each time that you place an item into a radioactive waste container at the end of an experiment,
 - fill out one or more of the pre-coded waste tickets that were supplied with the stock vial from which the radioactive material was taken for the experiment (one ticket for each waste form that was created, e.g., dry trash, aqueous liquid, etc.), and
 - make corresponding entries on the bottom section of the corresponding *User's Radioactive Material Accounting Sheet*, or similar accounting sheet approved by EHS.

NOTES:

- **Maintain your copy of the inventory sheet at the lab**- the only paperwork required for waste pickup is the pre-coded radioactive waste tickets (except for mixed waste, which requires a request form for pickup). **Call x40109 or email the online form to radwaste@ucdenver.edu to request a waste pickup.**
- **You can use as many tickets as you like, and each waste container may have many tickets attached** by the time it is picked up by EHS. You can photocopy more for any specific order, or request new originals from EHS at x40109 if someone used the last one and didn't tell you, **BUT DO NOT use tickets** on which the pre-printed information has been altered.
- **You may add up all the waste amounts that have been produced** from a particular order to provide a single waste ticket for the waste stream (e.g. dry, aqueous, etc.) provided all waste activity reported for the container is accounted for. If multiple RSO#s are included in the same waste container, a minimum of one waste ticket per RSO# is required.
- **EHS can help with information about how much of your radioactivity is expected to end up in which waste form (partitioning fractions).** PI's have been required to submit this information on their applications to the CIR for more than ten years.

V

Permission Form for Minors

Minor's Permission to Work in CU Denver | Anschutz Radioactive Materials Laboratory

During the period from _____ to _____ (enter dates), the undersigned minor student will perform educational activities in the laboratories of the undersigned Principal Investigator. These activities will be such that (check as applicable):

___the minor student will work directly with small quantities of radioactive material under appropriate supervision.

___the minor student will not work directly with radioactive materials but will be present in areas where radioactive materials are used or stored, under circumstances such that appropriate training and supervision is advisable to protect against unnecessary exposure to radiation or contact with radioactive materials, including possible contact with potentially-contaminated surfaces.

In preparation for the minor's participation in the activities described above, the minor

- has completed the university Radiation Safety Certification examination to demonstrate basic competence in the safe handling of radioactive materials in biomedical research laboratories on _____ (enter date),
- will be issued a personal radiation dosimeter if appropriate, and
- will be provided with appropriate additional instruction and supervision by the Principal Investigator or the Principal Investigator's staff, to ensure that all activities will be conducted safely.

| | Minor's Employee or Student ID Number | Date |
|--|---------------------------------------|-----------|
| Authorized Principal Investigator | Name (print) | Signature |
| Minor Student | Name (print) | Signature |
| Parent or Legal Guardian | Name (print) | Signature |

VI

Approval for Non-purchase-ordered Acquisitions of Radioactive Materials



Environmental Health and Safety

UNIVERSITY OF COLORADO
DENVER | ANSCHUTZ MEDICAL CAMPUS

INTEROFFICE MEMO

TO: Principal Investigators Authorized for Radioactive Materials

FROM: Riad Safadi, Radiation Safety Officer

SUBJECT: EHS Approval for Obtaining Radioactive Materials

DATE: October 31, 2016

The university radioactive materials license requires that the Radiation Safety Officer exercise a *priori* approval authority for all acquisitions of radioactive materials. This includes those that are obtained without a university Purchase Order, such as free samples from vendors, materials supplied by collaborating investigators in other institutions (including the VAH), and materials being paid for by third-party contractors or sponsoring agencies.

A *priori* approval consists of obtaining a reference number from EHS. To make this as easy as possible, EHS has a RAM Purchase Approval Request form online form available at <http://www.ucdenver.edu/research/EHS/Forms/Pages/default.aspx> which must be completed and approved prior to ordering radioactive material.

All Radioactive materials used at the CU Anschutz campus must be delivered to the following address:

**Environmental Health & Safety Support Facility
13178 E. 19th Ave.
Aurora, CO 80045**

Delivery of radioactive material to a satellite facility must be approved by the Radiation Safety Officer. Thank you for cooperating in this important license requirement. This will also help EHS to provide the fastest possible service on package receiving.

VII

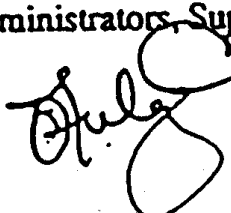
Chancellor's Memorandum

MEMORANDUM

DATE : October 10, 1995

TO : Deans, Department Chairpersons, Department Heads, Division Heads,
Principal Investigators, Administrators, Supervisors

FROM : Vincent A. Fulginiti, M.D.
Chancellor



SUBJECT : Safety Issues

The campus Environmental Health and Safety Committee has recommended three safety policies be formally stated and fully implemented at the Health Sciences Center. These policies were drafted by the Department of Environmental Health and Safety and presented to administrators for the School of Medicine, the School of Pharmacy, the School of Dentistry, and the School of Nursing for comment.

EYE PROTECTION

Strong acids, bases, and other materials that may be corrosive, toxic, or infectious are in widespread use at the Health Sciences Center and some activities have the potential of generating dangerous projectiles. There is a very real risk that employees, students, or visitors may be injured by these materials coming in contact with their eyes. In fact, eye injuries represent a significant percentage of our workplace injuries. Moreover, Colorado law requires "the governing board of every school district, university, college, or other institution of higher learning...to provide eye protective devices for the use of all students, teachers, and visitors" and requiring supervisors of activities involving "working with hot liquids, solids, or chemicals which are flammable, toxic, corrosive to living tissues, irritating, sensitizing, radioactive, or which generate pressure through heat, decomposition or other means" to "require such eye protective devices be worn by students, teachers and visitors." The requirements for providing appropriate eye protection also applies to all UCD employees, students and visitors engaged in research.

It is the policy of the Health Sciences Center that full compliance with the provisions of this law in accordance with DEHS guidelines is the responsibility of managers, principal investigators, supervisors and employees for all teaching, research, and maintenance activities.

EATING AND DRINKING IN HAZARDOUS AREAS

Eating, drinking, applying cosmetics, and smoking in areas where toxic, radioactive, or infectious materials are used increase the risk of harmful exposure by ingestion and are prohibited by regulations and standards adopted by Centers for Disease Control/National Institutes of Health, Colorado Department of Health/Nuclear Regulatory Commission, and other governmental and standards setting organizations.

Eating, drinking, applying cosmetics, or any other extraneous activities that increase the risk of ingestion of hazardous chemical, radioactive, or infectious materials are prohibited in areas where these materials are used. Areas where food and beverages may be consumed must be separated by a physical barrier from work areas where hazardous materials are used. Food and beverages may not be consumed in areas where hazardous materials may be deposited from airborne contamination. Departments, schools, or other work units shall designate appropriate areas for lunches and breaks where eating and drinking are permitted and no hazardous materials are present. The supervisor of an employee or student area or activity shall be responsible for assessing the potential exposure for an area or activity in accordance with DEHS guidelines.

CHILDREN IN HAZARDOUS AREAS

Hazardous materials are stored and used in many areas of the Health Sciences Center, including most laboratories. The presence of children in any of these areas unnecessarily exposes the children and the other occupants of these areas to risks of accident, injury or a release of hazardous materials. Recent accidents and injuries at other institutions underscore the need for a clear policy limited the conditions under which children can be brought into a potentially hazardous work place.

Children under the age of 18 are prohibited from entering laboratory areas or other areas where hazardous materials or conditions may be present unless such entry is in the context of a scheduled, approved, and properly supervised departmental activity, such as an open house or tour, or the potential exposure to hazardous materials or conditions is in the context of the normal duties of a student, student worker or intern and the minor has been trained in the hazards of the work and deemed competent to handle those risks by his or her supervisor. Children shall not be brought to work areas where hazardous materials are used or stored or hazardous conditions may exist. Children may be escorted through potentially hazardous areas to reach office areas, waiting rooms, or other non-hazardous areas if they are in the presence of and under the close supervision of an adult cognizant of the hazards of the area. Children shall not be left unattended in areas where hazardous materials are used or stored or hazardous conditions may exist. The supervisor of an employee or student area or activity shall be responsible for assessing the potential hazards of an area or activity in accordance with DEHS guidelines.

VIII

Radioactive Animal Cage Tag

NOTE: EHS recommends photocopying this sheet onto purple paper and then cutting down the middle to produce two cage tags.

| Cage Tag for Radioactive Animals | |
|---|---------------------------------------|
| Name of Principal Investigator Authorized for Radioactive Materials: | |
| In case of problems, contact: | |
| Name: | Phone: |
| Name: | Phone: |
| Animal type and number: | Radioisotope: |
| Amount (mCi) administered to each animal: | Date administered: |
| Animal housing (bldg. and room no.): | Do not remove this tag until*: |
| Required Precautions* | |
| Personal monitoring device ___ are ___ are not required for attending personnel. | |
| Collect (check as applicable) ___ urine ___ feces ___ bedding. | |
| Disposal of collected excreta and bedding by: carcasses by: other materials (specify) by: | |
| Cleaning of cage requires (fill out completely): | |
| Other required precautions (fill out completely): | |

| Cage Tag for Radioactive Animals | |
|---|---------------------------------------|
| Name of Principal Investigator Authorized for Radioactive Materials: | |
| In case of problems, contact: | |
| Name: | Phone: |
| Name: | Phone: |
| Animal type and number: | Radioisotope: |
| Amount (mCi) administered to each animal: | Date administered: |
| Animal housing (bldg. and room no.): | Do not remove this tag until*: |
| Required Precautions* | |
| Personal monitoring device ___ are ___ are not required for attending personnel. | |
| Collect (check as applicable) ___ urine ___ feces ___ bedding. | |
| Disposal of collected excreta and bedding by: carcasses by: other materials (specify) by: | |
| Cleaning of cage requires (fill out completely): | |
| Other required precautions (fill out completely): | |



**CAUTION:
RADIOACTIVE
MATERIALS**

*This tag must remain affixed to the cage until all required precautions are completed. All precautions stipulated in the Principal Investigator's authorization from the CIR must be fully listed on this tag. In case of problems, if the listed contact persons cannot be reached, call EHS at x40345 (after hours, 911).



**CAUTION:
RADIOACTIVE
MATERIALS**

*This tag must remain affixed to the cage until all required precautions are completed. All precautions stipulated in the Principal Investigator's authorization from the CIR must be fully listed on this tag. In case of problems, if the listed contact persons cannot be reached, call EHS at x40345 (after hours, 911).

IX

Gamma Ray Spreadsheets And Shielding Guidelines

Using the Gamma Ray Spreadsheets

The spreadsheets in this section may be used to screen for situations that *might* require specification of shielding or changes in location of proposed storage or usage areas. To use the spreadsheet for a given radionuclide,

- from among the limiting quantities on the spreadsheet, choose a quantity that will not be exceeded by the total amount to be stored and/or used in a given location, then
- consider all areas near the projected location where the radioactive material will be stored or used - in doing so,
 - choose the most applicable occupancy factor for each area based on its nature and utilization as defined in the legend on the spreadsheet,
 - consider all areas, including areas on floors below and above the location of interest, (**the utilization of areas within the laboratory MUST be considered under these criteria unless the laboratory will be controlled as a restricted area with explicit approval of the CIR, such that no personnel other than the PI's trained, film-badged radiation workers will ever be able to enter the area**), and
 - do NOT adjust the numbers in any way to account for assumed attenuation due to floors, walls, or other structural barriers that would attenuate gamma and x rays.
- If any area so considered lies within the minimum compliance radius shown on the spreadsheet for the occupancy factor appropriate to that area, then the source will need to be shielded or moved until these criteria can be met by repeating the above process for all adjacent areas.

For cases involving:

- multiple radionuclides,
- multiple storage/usage areas that lie within five meters of each other,
- quantities that are not shown on the spreadsheet, or
- other complications,

Contact Environmental Health and Safety

For areas that do not meet the above criteria but are separated from the radioactive materials storage area by walls or floors, Environmental Health and Safety should be consulted for

advice about the shielding that will be afforded by those structural barriers, before plans are made that will incur expense or inconvenience in operations.

Example (refer to spreadsheet for I-125):

An area in Room 8888 SOM is being considered for storage of I-125 wastes. The most that will ever be accumulated in this area, consistent with the PI's requested possession limit, is 10 milliCuries. Shielding of the waste or relocation of the waste storage area MAY be required, and Environmental Health and Safety should be consulted in completing the application for authorization to use I-125, if

- any desk or frequently-used workstation (Occupancy factor = 1) within the laboratory or adjacent laboratories is located within 4.6 m = 15 feet of the waste location, or
- any office area (Occupancy factor = 1) is located within 4.6 m = 15 feet of the waste location, or
- any corridor (Occupancy factor = 1/4) is within 1.9 m = 6.2 feet of the waste location, or
- any area on the floor above, directly above the waste storage area, or any area directly below the waste storage area on the floor below, includes
 - an office area (Occupancy factor = 1), or
 - a portion of a laboratory area that will be frequently occupied (Occupancy factor = 1).

Note also that, if the waste is NOT to be shielded, the laboratory room containing the waste storage area would have to be posted as a "Radiation Area" and correspondingly controlled as a *restricted area* such that no person who is not a trained, monitored radiation worker could enter the area. (Strictly speaking, if any quantity of I-125 exceeding 6.4 mCi is ever to be unshielded for time periods approaching one hour, then the laboratory area would have to be posted as a "Radiation Area.")

Furthermore, because 2.574 mCi of unshielded I-125 produces a dose rate of 2 mrem/hour at one foot, **if any quantity of I-125 exceeding 2.574 mCi is ever to be unshielded for time periods approaching one hour, then the laboratory area must still be controlled as a *restricted area*,** although it may not require posting as a Radiation Area.

Shielding Guidelines for Iodine 125

I-125 has a low gamma constant of 0.07 mR/hr per milliCurie at one meter.

The gamma ray and x rays of I-125 have energies in the range of 0.027 to 0.035 MeV (low photon energy).

The shielding half-value layer of I-125 (thickness of absorber required to reduce the gamma ray exposure rate to one half of its unattenuated value) is **about 0.04 mm of lead**. Therefore, **minimal thicknesses of lead, which may even be obtained with lead foils, are sufficient to obtain significant attenuation of the gamma rays and x rays.**

Stock quantities of I-125 as supplied by the vendor should always be stored in lead shipping “pigs.”

Quantities in process in the open laboratory are typically less than one milliCurie and do not require shielding.

Waste storage areas that may contain quantities of I-125 that approach five to ten milliCuries in the aggregate should not be located within 4.5 meters of offices and other continuously-occupied areas that are frequented by persons who do not wear personal monitoring devices, OR within 2 meters of corridors and other occasionally-occupied areas accessible to the public, unless proper shielding is in place.

EHS has an assortment of lead shielding available to labs. Leaded acrylic benchtop shields are available, although expensive, and they do contain enough lead to significantly attenuate the gamma rays and x rays of I-125. Lead foils and other I-125 shielding items are available from Research Products International (RPI), <http://www.rpicorp.com/>.

Shielding Guidelines for Chromium 51

Cr-51 has a very low gamma constant of 0.016 mR/hr per milliCurie at one meter, because only a small fraction of its atomic disintegrations result in the emission of a gamma ray.

The gamma ray of Cr-51 has an energy of 0.32 MeV (moderate photon energy).

The shielding half-value layer of Cr-51 (thickness of absorber required to reduce the gamma ray exposure rate to one half of its unattenuated value) is **3 mm of lead**. Therefore, **substantial thicknesses of lead, approximating one quarter inch or more, are required to obtain significant attenuation of the gamma rays.**

Stock quantities of Cr-51 as supplied by the vendor should always be stored in lead shipping “pigs.”

Quantities in process in the open laboratory are typically less than one milliCurie and do not require shielding.

Waste storage areas that may contain quantities of Cr-51 that approach five to ten milliCuries in the aggregate should not be located within 2 meters of offices and other continuously-occupied areas that are frequented by persons who do not wear personal monitoring devices, unless proper shielding is in place.

EHS has an assortment of lead shielding available to labs. Leaded acrylic benchtop shields are available, but are expensive, and do not contain enough lead to significantly attenuate the gamma rays of Cr-51.

| Radionuclide | Gamma or X Constant (mR/hr/mCi @ 1 m) | Amount (mCi) | X @ 1 m (mR/hr) | Unshielded compliance radii (m) | | |
|--------------|--|--------------|-----------------|---------------------------------|---------|----------|
| | | | | T = 1 | T = 1/4 | T = 1/16 |
| I-125 | 0.07 | 10 | 0.7 | 4.5826 | 1.8708 | 0.9354 |
| | 0.07 | 5 | 0.35 | 3.2404 | 1.3229 | 0.6614 |
| | 0.07 | 2 | 0.14 | 2.0494 | 0.8367 | 0.4183 |
| | 0.07 | 1 | 0.07 | 1.4491 | 0.5916 | 0.2958 |
| | 0.07 | 0.5 | 0.035 | 1.0247 | 0.4183 | 0.2092 |

2.574 mCi creates 2 mrems/hour at one foot. No quantity exceeding this amount may remain unshielded and unattended except in special restricted areas.

6.43501 mCi may require posting of the laboratory as a Radiation Area.**

*Note: the unshielded compliance radii indicate the MINIMUM allowable distances to areas that may be occupied by the general public, including all occupancy by non-radiation-workers, where "T = 1" applies to fully-occupied spaces such as offices, "T = 1/4" applies to partly-occupied spaces such as hallways, and "T = 1/16" applies to infrequently-occupied areas such as stairwells and toilets.

FOR THE PURPOSES OF THIS CALCULATION, THE FACILITY WAS ASSUMED TO BE OPEN AND SUBJECT TO OCCUPANCY BY THE SAME PERSONS **60 HOURS PER WEEK.**

**If any quantity exceeding the noted amount will be unshielded for periods approaching one hour, then the area must be posted and controlled as a restricted Radiation Area.

| Radionuclide | Gamma or X Constant (mR/hr/mCi @ 1 m) | Amount (mCi) | X @ 1 m (mR/hr) | Unshielded compliance radii (m) | | |
|--------------|--|--------------|-----------------|---------------------------------|---------|----------|
| | | | | T = 1 | T = 1/4 | T = 1/16 |
| Cr-51 | 0.016 | 40 | 0.64 | 4.3818 | 2.1909 | 1.0954 |
| | 0.016 | 20 | 0.32 | 3.0984 | 1.5492 | 0.7746 |
| | 0.016 | 10 | 0.16 | 2.1909 | 1.0954 | 0.5477 |
| | 0.016 | 5 | 0.08 | 1.5492 | 0.7746 | 0.3873 |
| | 0.016 | 2 | 0.032 | 0.9798 | 0.4899 | 0.2449 |

11.2613 mCi creates 2 mrems/hour at one foot. No quantity exceeding this amount may remain unshielded and unattended except in special restricted areas.

28.1532 mCi may require posting of the laboratory as a Radiation Area.**

*Note: the unshielded compliance radii indicate the MINIMUM allowable distances to areas that may be occupied by the general public, including all occupancy by non-radiation-workers, where "T = 1" applies to fully-occupied spaces such as offices, "T = 1/4" applies to partly-occupied spaces such as hallways, and "T = 1/16" applies to infrequently-occupied areas such as stairwells and toilets.

FOR THE PURPOSES OF THIS CALCULATION, THE FACILITY WAS ASSUMED TO BE OPEN AND SUBJECT TO OCCUPANCY BY THE SAME PERSONS **60 HOURS PER WEEK.**

**If any quantity exceeding the noted amount will be unshielded for periods approaching one hour, then the area must be posted and controlled as a restricted Radiation Area.

| Radionuclide | Gamma or X Constant (mR/hr/mCi @ 1 m) | Amount (mCi) | X @ 1 m (mR/hr) | Unshielded compliance radii (m) | | |
|--------------|---|-----------------|-----------------|------------------------------------|---------|----------|
| | | | | T = 1 | T = 1/4 | T = 1/16 |
| I-131 | 0.22 | 10 | 2.2 | 6.63325 | 3.31662 | 1.65831 |
| | 0.22 | 5 | 1.1 | 4.69042 | 2.34521 | 1.1726 |
| | 0.22 | 2 | 0.44 | 2.96648 | 1.48324 | 0.74162 |
| | 0.22 | 1 | 0.22 | 2.09762 | 1.04881 | 0.5244 |

0.819 mCi creates 2 mrems/hour at one foot. No quantity exceeding this amount may remain unshielded and unattended except in special restricted areas.

2.0475 mCi may require posting of the laboratory as a Radiation Area.**

*Note: the unshielded compliance radii indicate the MINIMUM allowable distances to areas that may be occupied by the general public, including all occupancy by non-radiation-workers, where "T = 1" applies to fully-occupied spaces such as offices, "T = 1/4" applies to partly-occupied spaces such as hallways, and "T = 1/16" applies to infrequently-occupied areas such as stairwells and toilets.

FOR THE PURPOSES OF THIS CALCULATION, THE FACILITY WAS ASSUMED TO BE OPEN AND SUBJECT TO OCCUPANCY BY THE SAME PERSONS **60 HOURS PER WEEK**.

**If any quantity exceeding the noted amount will be unshielded for periods approaching one hour, then the area must be posted and controlled as a restricted Radiation Area.

| Radionuclide | Gamma or X Constant (mR/hr/mCi @ 1 m) | Amount (mCi) | X @ 1 m (mR/hr) | Unshielded compliance radii (m) | | |
|---------------|---|--------------|-----------------|------------------------------------|---------|----------|
| | | | | T = 1 | T = 1/4 | T = 1/16 |
| In-111 | 0.34 | 10 | 3.4 | 8.24621 | 4.12311 | 2.06155 |
| | 0.34 | 5 | 1.7 | 5.83095 | 2.91548 | 1.45774 |
| | 0.34 | 2 | 0.68 | 3.68782 | 1.84391 | 0.92195 |
| | 0.34 | 1 | 0.34 | 2.60768 | 1.30384 | 0.65192 |

0.5299 mCi creates 2 mrems/hour at one foot. No quantity exceeding this amount may remain unshielded and unattended except in special restricted areas.

1.32485 mCi may require posting of the laboratory as a Radiation Area.**

*Note: the unshielded compliance radii indicate the MINIMUM allowable distances to areas that may be occupied by the general public, including all occupancy by non-radiation-workers, where "T = 1" applies to fully-occupied spaces such as offices, "T = 1/4" applies to partly-occupied spaces such as hallways, and "T = 1/16" applies to infrequently-occupied areas such as stairwells and toilets.

FOR THE PURPOSES OF THIS CALCULATION, THE FACILITY WAS ASSUMED TO BE OPEN AND SUBJECT TO OCCUPANCY BY THE SAME PERSONS **60 HOURS PER WEEK.**

**If any quantity exceeding the noted amount will be unshielded for periods approaching one hour, then the area must be posted and controlled as a restricted Radiation Area.

| Radionuclide | Gamma or X Constant (mR/hr/mCi @ 1 m) | Amount (mCi) | X @ 1 m (mR/hr) | Unshielded compliance radii (m)* | | |
|--------------|---|-----------------|-----------------|-------------------------------------|---------|----------|
| | | | | T = 1 | T = 1/4 | T = 1/16 |
| Na-22 | 1.2 | 1 | 1.2 | 6 | 3 | 2.12132 |
| | 1.2 | 0.5 | 0.6 | 4.24264 | 2.12132 | 1.5 |
| | 1.2 | 0.25 | 0.3 | 3 | 1.5 | 1.06066 |

0.15015 mCi creates 2 mrems/hour at one foot. No quantity exceeding this amount may remain unshielded and unattended except in special restricted areas.

0.37538 mCi may require posting of the laboratory as a Radiation Area.**

*Note: the unshielded compliance radii indicate the MINIMUM allowable distances to areas that may be occupied by the general public, including all occupancy by non-radiation-workers, where "T = 1" applies to fully-occupied spaces such as offices, "T = 1/4" applies to partly-occupied spaces such as hallways, and "T = 1/16" applies to infrequently-occupied areas such as stairwells and toilets.

FOR THE PURPOSES OF THIS CALCULATION, THE FACILITY WAS ASSUMED TO BE OPEN AND SUBJECT TO OCCUPANCY BY THE SAME PERSONS **60 HOURS PER WEEK.**

**If any quantity exceeding the noted amount will be unshielded for periods approaching one hour, then the area must be posted and controlled as a restricted Radiation Area.

| Radionuclide | Gamma or X Constant (mR/hr/mCi @ 1 m) | Amount (mCi) | X @ 1 m (mR/hr) | Unshielded compliance radii (m) | | |
|--------------|--|--------------|-----------------|---------------------------------|---------|----------|
| | | | | T = 1 | T = 1/4 | T = 1/16 |
| P-32 | 0.004 | 100 | 0.4 | 2.8284 | 1.4142 | 0.7071 |
| | 0.004 | 50 | 0.2 | 2 | 1 | 0.5 |
| | 0.004 | 25 | 0.1 | 1.4142 | 0.7071 | 0.3536 |
| | 0.004 | 5 | 0.02 | 0.6325 | 0.3162 | 0.1581 |
| | 0.004 | 1 | 0.004 | 0.2828 | 0.1414 | 0.0707 |

45.05 mCi creates 2 mrems/hour at one foot. No quantity exceeding this amount may remain unshielded and unattended except in special restricted areas.

112.613 mCi may require posting of the laboratory as a Radiation Area.**

*Note: the unshielded compliance radii indicate the MINIMUM allowable distances to areas that may be occupied by the general public, including all occupancy by non-radiation-workers, where "T = 1" applies to fully-occupied spaces such as offices, "T = 1/4" applies to partly-occupied spaces such as hallways, and "T = 1/16" applies to infrequently-occupied areas such as stairwells and toilets.

FOR THE PURPOSES OF THIS CALCULATION, THE FACILITY WAS ASSUMED TO BE OPEN AND SUBJECT TO OCCUPANCY BY THE SAME PERSONS **60 HOURS PER WEEK.**

**If any quantity exceeding the noted amount will be unshielded for periods approaching one hour, then the area must be posted and controlled as a restricted Radiation Area.

THIS SHEET APPLIES TO BREMSSTRAHLUNG X RAYS ONLY AND IS BASED ON EMPIRICAL DATA OBTAINED AT CU Denver | Anschutz

| Radionuclide | Gamma or X Constant (mR/hr/mCi @ 1 m) | Amount (mCi) | X @ 1 m (mR/hr) | Unshielded compliance radii (m)* | | |
|--------------|--|--------------|-----------------|----------------------------------|---------|----------|
| | | | | T = 1 | T = 1/4 | T = 1/16 |
| Rb-86 | 0.05 | 10 | 0.5 | 3.873 | 1.9365 | 1.3693 |
| | 0.05 | 5 | 0.25 | 2.7386 | 1.3693 | 0.9682 |
| | 0.05 | 2 | 0.1 | 1.7321 | 0.866 | 0.6124 |
| | 0.05 | 1 | 0.05 | 1.2247 | 0.6124 | 0.433 |
| | 0.05 | 0.5 | 0.025 | 0.866 | 0.433 | 0.3062 |
| | 0.05 | 0.25 | 0.0125 | 0.6124 | 0.3062 | 0.2165 |

3.604 mCi creates 2 mrems/hour at one foot. No quantity exceeding this amount may remain unshielded and unattended except in special restricted areas.

9.00901 mCi may require posting of the laboratory as a Radiation Area.**

*Note: the unshielded compliance radii indicate the MINIMUM allowable distances to areas that may be occupied by the general public, including all occupancy by non-radiation-workers, where "T = 1" applies to fully-occupied spaces such as offices, "T = 1/4" applies to partly-occupied spaces such as hallways, and "T = 1/16" applies to infrequently-occupied areas such as stairwells and toilets.

FOR THE PURPOSES OF THIS CALCULATION, THE FACILITY WAS ASSUMED TO BE OPEN AND SUBJECT TO OCCUPANCY BY THE SAME PERSONS **60 HOURS PER WEEK.**

**If any quantity exceeding the noted amount will be unshielded for periods approaching one hour, then the area must be posted and controlled as a restricted Radiation Area.

| Radionuclide | Gamma or X Constant (mR/hr/mCi @ 1 m) | Amount (mCi) | X @ 1 m (mR/hr) | Unshielded compliance radii (m) | | |
|--------------|--|--------------|-----------------|---------------------------------|---------|----------|
| | | | | T = 1 | T = 1/4 | T = 1/16 |
| Zn-65 | 0.27 | 5 | 1.35 | 6.364 | 3.182 | 1.591 |
| | 0.27 | 2 | 0.54 | 4.0249 | 2.0125 | 1.0062 |
| | 0.27 | 1 | 0.27 | 2.846 | 1.423 | 0.7115 |
| | 0.27 | 0.5 | 0.135 | 2.0125 | 1.0062 | 0.5031 |
| | 0.27 | 0.1 | 0.027 | 0.9 | 0.45 | 0.225 |

0.667 mCi creates 2 mrems/hour at one foot. No quantity exceeding this amount may remain unshielded and unattended except in special restricted areas.

1.66834 mCi may require posting of the laboratory as a Radiation Area.**

*Note: the unshielded compliance radii indicate the MINIMUM allowable distances to areas that may be occupied by the general public, including all occupancy by non-radiation-workers, where "T = 1" applies to fully-occupied spaces such as offices, "T = 1/4" applies to partly-occupied spaces such as hallways, and "T = 1/16" applies to infrequently-occupied areas such as stairwells and toilets.

FOR THE PURPOSES OF THIS CALCULATION, THE FACILITY WAS ASSUMED TO BE OPEN AND SUBJECT TO OCCUPANCY BY THE SAME PERSONS **60 HOURS PER WEEK.**

**If any quantity exceeding the noted amount will be unshielded for periods approaching one hour, then the area must be posted and controlled as a restricted Radiation Area.

| Radionuclide | Gamma or X Constant (mR/hr/mCi @ 1 m) | Amount (mCi) | X @ 1 m (mR/hr) | Unshielded compliance radii (m) | | |
|--------------|--|--------------|-----------------|---------------------------------|---------|----------|
| | | | | T = 1 | T = 1/4 | T = 1/16 |
| Fe-59 | 0.64 | 2 | 1.28 | 6.1968 | 3.0984 | 1.5492 |
| | 0.64 | 1 | 0.64 | 4.3818 | 2.1909 | 1.0954 |
| | 0.64 | 0.5 | 0.32 | 3.0984 | 1.5492 | 0.7746 |
| | 0.64 | 0.25 | 0.16 | 2.1909 | 1.0954 | 0.5477 |
| | 0.64 | 0.1 | 0.064 | 1.3856 | 0.6928 | 0.3464 |

0.282 mCi creates 2 mrems/hour at one foot. No quantity exceeding this amount may remain unshielded and unattended except in special restricted areas.

0.70383 mCi may require posting of the laboratory as a Radiation Area.**

*Note: the unshielded compliance radii indicate the MINIMUM allowable distances to areas that may be occupied by the general public, including all occupancy by non-radiation-workers, where "T = 1" applies to fully-occupied spaces such as offices, "T = 1/4" applies to partly-occupied spaces such as hallways, and "T = 1/16" applies to infrequently-occupied areas such as stairwells and toilets.

FOR THE PURPOSES OF THIS CALCULATION, THE FACILITY WAS ASSUMED TO BE OPEN AND SUBJECT TO OCCUPANCY BY THE SAME PERSONS **60 HOURS PER WEEK.**

**If any quantity exceeding the noted amount will be unshielded for periods approaching one hour, then the area must be posted and controlled as a restricted Radiation Area.

X

Personal Dosimeter Information

Dosimetry Service Request

Complete each field. Contact EHS at 303-724-0345 if you have questions about this form. Upon completion, print the form, sign page 2 (and 3 if necessary) and send to Mail Stop F484, or fax to 303-724-0388.

I. Personal Information

| | | | |
|---------------|--|-------------|--------|
| Employee ID#: | | Date: | |
| Last Name: | | First Name: | M.I.: |
| Birth Date: | Sex: <input type="checkbox"/> F <input type="checkbox"/> M | Dept: | Phone: |
| PI: | Campus Box: | Email: | |

II. Dosimetry Information

- Type of Service Needed: Whole Body Extremity Fetal* Other: _____
 Date Dosimetry Service Needed: _____
 *Please complete RSF-040 "Declaration of Pregnancy" if requesting a fetal badge
- Regarding the use of radioactive materials or devices, I am considered:
 Radiation Worker Principal Investigator Device Operator (e.g. irradiator, DEXA)
- Please check the completed University of Colorado Denver | Anschutz Medical Campus Radiation Safety Training:
 Rad Worker – Part I Rad Worker – Part II Mod 5 Other: _____
- Radiation Sources that you will use:
 Isotopes used on lab bench (list): _____
 Sealed sources (e.g. irradiator) Other (e.g. DEXA, x-ray): _____
- Have you ever been issued a dosimetry badge (e.g. film, TLD) at this institution? Yes No
 If "Yes" please complete: PI: _____ Department: _____
- Are you currently monitored for occupational radiation exposure at another institution? Yes No
 If "Yes" which institution: _____
- Have you ever been issued a dosimetry device (e.g. film, TLD) at another institution? Yes No

****IF YES TO #7, YOU MUST COMPLETE THE RECORDS RELEASE ON PAGE 3****
OBTAINING PAST RADIATION HISTORY IS REQUIRED BY LAW
 (Complete a separate form for each employer)

| FOR EHS USE ONLY | | | |
|--------------------|-------------------------|-------------------------|-------------|
| Perm. ID#: | Series: | Temp WB Badge#: | Temp Ring#: |
| _____ | _____ | _____ | _____ |
| Date Temps Issued: | Date Entered in Mirion: | Date Records Requested: | _____ |
| _____ | _____ | _____ | _____ |

Proper Use of Dosimetry Badges

In order for your dosimetry badge to provide proper monitoring results, you MUST:

Wear the badge at all times when you are working in any area that is a controlled area for protection purposes.

Leave the badge in a secure, non-radioactive area whenever you are not wearing it.

Wear only the badge that is designated for you by Environmental Health and Safety.

Always wear the badge in the proper holder supplied by EHS. Failure to do so may result in seriously erroneous estimates of dose.

Ensure that the badge is returned in a timely manner to EHS at the beginning of the monitoring period.

You MUST NOT:

Wear or use a badge that has been issued to someone else.

Write on the badge or do anything that may destroy the holder.

Use the badge to monitor areas when you are not present or place it in any radiation exposure situation that does not reflect the dose that you are receiving.

Expose the badge to excessive heat or immerse in water.

I have read and understand the above information and the “Information for Personal Dosimeter Badge Applicants”, as published by the Environmental Health and Safety Department.

Signature: _____

Date: _____

Information for Personal Dosimeter Badge Applicants

The Thermoluminescent Dosimeter (TLD) badge is a device that is used to evaluate your personal exposure to radiation over a period of time. It measures your external exposure to radiation arising from sources outside your body, such as x-ray machines and radioactive materials. It cannot generally be relied upon to provide an indication of any radiation dose that you might receive if the radioactive materials themselves were introduced into your body, by being inhaled, ingested, or absorbed through your skin. The badge is returned after the monitoring period to the dosimetry vendor to be read by computerized equipment.

The university Committee on Ionizing Radiation mandates dosimetry badges for all persons who will work with sources of penetrating radiation (typically x-rays and gamma rays). Persons working with high energy beta particles with an activity of 1 milliCurie or more are also required to wear dosimetry badges. This does not mean that you are expected to be exposed to significant amounts of radiation. The requirement is imposed for medico-legal purposes and for your peace of mind. In fact, most of the persons who wear dosimetry badges at this institution do not work in situations in which they would normally be exposed to any level of radiation dose that significantly exceeds background.

In order for EHS to fulfill its legal requirements in the dosimetry program, we must obtain certain private information (e.g., birth date and employee ID number) on your application. We safeguard this information, along with your dosimetry results on our program, and release them outside the university only with your permission.

You have a legal right to be informed of your monitoring results and you may request this information from us at any time. These records are maintained indefinitely. The results are reported by the vendor for shallow (i.e., skin) and deep (i.e., whole body) dose estimates, for the monitoring period in question, with cumulative totals for calendar quarter, year, and the entire time you have been on the system. Dose is reported in millirem (mrem). The minimal detectable dose with the current TLD is 1 mrem. A dose report with “ND” would indicate “non-detectable, below minimal reportable dose,” or less than 1 mrem.

Because the detection limit is very low, it is natural to expect that reports of 10 or even 20 mrem may occasionally occur due to statistical fluctuation alone. (The average monthly background that people receive in Colorado is in the vicinity of 15 mrem.) Occasional reports of 10 or 20 mrem should not be a cause of concern. Reports of whole body dose over 125 mrem will be specifically brought to your attention by a notice from our As Low As Reasonably Achievable (ALARA) Program.

We can provide a great deal of additional information about the dosimetry program, and you should feel free to direct questions to us at any time.

XI

Radioiodine Bulletin And Iodination Suite Guidance Note

RADIATION SAFETY BULLETIN

Special Precautions for Unbound Forms of the Radioiodines

Radioactive iodines (most notably I-125 and I-131, but also including I-123) are vastly more hazardous in unbound form than in those forms in which the iodine is covalently bound to proteins or other large molecules. For this reason, iodine labeling reactions and other uses involving sodium iodide or other unbound forms, including radiothyroidectomy of experimental animals, require special precautions.

The following precautions should be followed by all users of unbound radioiodines:

1. When opening stock vials or preparing to withdraw aliquots with a syringe, **all vials of iodine radioisotopes, even bound forms, should be vented to atmospheric pressure in a certified fume hood. Any quantity of 100 microCuries or more of unbound radioiodine should initially be vented through a charcoal-filled syringe** to trap volatile iodine. Even NaI shipped in solution at appropriately basic pH has been demonstrated to have considerable gaseous radioactive iodine in the air in the stock vial (typical values of .1 to .2% and extreme values up to 2% of the total radioactivity in the vial).
2. **All vials of NaI or other unbound forms should be stored in a certified hood and kept tightly capped.** When NaI solution is left open to the atmosphere and allowed to dry out, the radioactive iodine will volatilize. The release of substantial fractions of a milliCurie or more into air in this way, even in a properly-operating fume hood, could result in a serious license violation.
3. **Iodinations should, of course, be carried out in a certified hood.**
 - Reaction systems, in which the labeling reaction can be confined to a closed vial, by introducing reagents via needles inserted through a septum, are most preferable.
 - Columns, after removal of all liquid content, should be wrapped in parafilm or another airtight seal before being discarded as dry solid radioactive waste.
 - **All liquids containing radioiodine in unbound forms, including wastes, should be kept at basic pH and stored in tightly-capped containers in a fume hood.**
4. **Protective apparel, especially double or triple gloves, should be worn during handling, and great care should be taken to avoid any contamination of skin or clothing.** Past incidents have indicated that the predominant mechanism of self-contamination resulting in thyroid uptake has been inadvertent skin contamination of the hands by touching items contaminated with unbound radionuclide. Some unbound forms are highly mobile in regard to percutaneous uptake (across intact skin) into the underlying tissues, after which they are transported by systemic circulation and deposited in thyroid.
5. **All persons performing iodinations or handling unbound forms in other ways must notify EHS so that we can schedule a thyroid bioassay after each labeling or other use** (call 4-0345 to schedule a bioassay approximately 48 to 72 hours after using the material).
 - Persons possessing sensitive scintillation detectors appropriate for the radioactive iodine isotope in use are encouraged to survey themselves after use; however, a neck measurement by Environmental Health and Safety is required. The equipment used by Environmental Health and Safety is specially calibrated with a thyroid neck phantom, and the procedures used are designed to obtain accurate and reproducible results in terms of thyroid radioactivity content.
 - Bioassay measurements should be made within two to three days after the affected individual's use of the unbound material.
 - These measurements require only about five minutes to perform, and can typically be scheduled at the requester's convenience; however, an appointment should be made by calling Environmental Health and Safety beforehand, to ensure that a health physicist will be present to perform and interpret the measurement.

6. **ALL Iodinations and Iodine labeling experiments at the CU Anschutz campus are to be performed in one of the designated Radioiodination Suites.** These spaces are controlled by EHS and you may call 4-0234 for scheduling and access to these spaces. Each Suite has a fume hood specially calibrated and filtered to best capture any volatile iodine. Please see Radiation Safety Guidance Note RSG-002 for more details.

Iodination Suite Guidance Note

This document is informational, to ensure procedural consistency. No response is required.

Iodination

Researchers performing iodination at RC1 and RC2 must perform procedures in the designated iodination laboratory for each building. To schedule the laboratory, call Environmental Health and Safety at (303) 724-0345 as soon as the date and time for performing the procedure is determined. At least two days' notice is required to schedule the room, otherwise EHS cannot guarantee availability of the laboratory.

Follow these procedures:

1. Transport experimental material in secondary containment to the iodination laboratory. In addition, transport any needed equipment, including an appropriate portable survey instrument (i.e. low energy gamma detector).
2. Survey yourself and the work area with a portable survey instrument. Record survey results on the Portable Instrument Survey Log (RSF-002).
3. Contact EHS at 4-0345 if any contamination is found (twice background).
4. Ensure that the fume hood is operating properly by checking that air flow is between 85 and 115 linear feet per minute. If flow rate is not within these parameters or the red light is on, call EHS at 4-0345 and do not perform experiment.
5. Perform the experiment. ALL WORK MUST BE PERFORMED IN HOOD.
6. Place all waste material in the appropriate waste containers provided by EHS.
7. Survey yourself and the work area with a portable survey instrument. Record survey results on the Portable Instrument Survey Log (RSF-002).
8. If any contamination is found (twice background), call EHS at 4-0345.
9. Perform a swipe survey for Liquid Scintillation or Gamma Counter analysis for, at minimum, each location marked on the provided area map.
10. Return material to a secure location in the laboratory.
11. Count swipe samples and fax survey results to EHS at 4-0388. If any contamination is found, call EHS at 4-0345.

XII

Environmental Health and Safety Green Tag

The EHS Green Tag Program

Before any equipment in a lab can be moved to another lab, disposed of or serviced, it must be cleaned and disinfected by lab personnel, then inspected by EHS. This process is also followed for lab space to be vacated. These steps ensure equipment and spaces do not present an exposure hazard to new occupants, housekeeping staff or maintenance personnel. Complete details on how to green tag equipment or spaces can be found on the EHS website (<http://www.ucdenver.edu/research/EHS/hazmat/Pages/greentag.aspx>).

XIII

Table of Quantities For Posting and Labeling

Table of Quantities for Labeling and Posting

| Radionuclide..... | Amount (mCi) |
|-------------------------|--------------|
| ¹⁴ C | 10 |
| ⁴⁵ Ca | 1 |
| ¹⁰⁹ Cd..... | 0.01 |
| ³⁶ Cl | 0.1 |
| ⁵⁷ Co | 1 |
| ⁵¹ Cr..... | 10 |
| ⁵⁹ Fe..... | 0.1 |
| ¹⁵³ Gd..... | 0.1 |
| ³ H | 10 |
| ¹²⁵ I | 0.01 |
| ¹³¹ I | 0.01 |
| ²² Na | 0.1 |
| ⁹⁵ Nb | 1 |
| ⁶³ Ni..... | 1 |
| ³² P..... | 0.1 |
| ³³ P..... | 1 |
| ⁸⁶ Rb | 1 |
| ¹⁰³ Ru..... | 1 |
| ³⁵ S..... | 1 |
| ⁴⁶ Sc..... | 0.1 |
| ¹¹³ Sn | 1 |
| ⁸⁵ Sr | 1 |
| ⁶⁵ Zn | 0.1 |

Note: this table is for reference as specified in sections 3.4.7.5, 3.4.8.1, and 3.4.8.6 of the Radiation Safety Manual.

XIV

Principal Investigator's Posting

Authorized Laboratory for Radioactive Materials

Dr. _____ Lab

Radiation Safety Publications Posting

The Radiation Safety Manual, Radioactive Waste Disposal Manual, and Radiation Safety Training Manual are online:

<http://www.ucdenver.edu/research/EHS/Radiation/Pages/Guidelines.aspx>.

The CDPHE “Notice to Employees” is posted near laboratory exits into the main elevator lobby. The posting is also contained in the Radiation Safety Training Manual.

Radioactive Materials Authorization # _____ for _____, and related radiation safety documentation located in lab: _____.

XV

Tri-Level Hazard Classification System For Radioactive Materials Laboratories At CU Denver | Anschutz

Tri-Level Hazard Classification System for Radioactive Materials Laboratories at CU Denver | Anschutz

The classification system shown here was adopted by the CIR on December 18, 1997, and is based on federal and state regulatory guidance¹. This system is intended by the Committee to create distinctions that are orderly and meaningful in the context of the particular radionuclides and ranges of amounts that are used in biomedical research environments, to serve as a qualitative index of the relative hazard of a particular authorized use of radioactive materials. The Committee *may* assign a different hazard rating to a particular authorized use than is indicated in the table, based on the details of the use in question.

The hazard rating for a given laboratory room or suite authorized for radioactive materials is the highest rating associated with any authorization that is currently in force for that area, which will *usually* be the highest rating among the authorizations held by some single specific PI to whom that area is assigned. The hazard ratings of a PI's authorizations will also be used to determine frequencies of radiation safety audits, frequencies of contamination surveys that the PI is required to perform, and similar parameters. **As such, this classification scheme will be of interest to PI's preparing applications for radioactive materials.**

I. Classification of Radionuclides by Radiotoxicity and Gamma Ray Production:

High: Na-22, P-32, Sc-46, Fe-59, Zn-65, Rb-86, Y-90, I-125, I-131

Medium: C-14, S-35, P-33, Cl-36, Ca-45, Co-57, In-111, Sn-113

Low: H-3, Cr-51, Tc-99m

II. Hazard Level Classification by On-Hand Possession Limit in mCi for Radionuclide Authorized:

| Radiotoxicity ↓ | Laboratory Hazard Level | | |
|-----------------|-------------------------|--------------|-------|
| | Low | Medium | High |
| High | ≤ 0.2* | > 0.2 & ≤ 5 | > 5 |
| Medium | ≤ 2 | > 2 & ≤ 50 | > 50 |
| Low | ≤ 20 | > 20 & ≤ 100 | > 100 |

*Activity unit is mCi

¹ Draft Regulatory Guide DG-0005 (Second Proposed Revision 2 to Regulatory Guide 10.5): *Applications for Licenses of Broad Scope*. U.S. Nuclear Regulatory Commission, October 1994.

| Hazard Classification of Authorization | Required Frequency of PI's Contamination Surveys | Frequency of RSO's Audits |
|---|---|----------------------------------|
| Low | Monthly | Every 2 years |
| Medium | Weekly | Every 2 years |
| High | Daily | Every 1 year |

XVI

Factors to Be Considered When Proposing Use of Radioactive Materials in Facilities Not Previously So Authorized

Factors to Be Considered When Proposing Use of Radioactive Materials in Facilities Not Previously So Authorized

Principal Investigators and other persons planning for laboratory space involving the use of radioactive materials in facilities not previously so authorized should consider the following factors, as explicated in the indicated sections of the *Radiation Safety Manual*, and should consult the RSO as early as possible in the planning process to review these considerations:

- facility location and layout with respect to transportation of radioactive materials (sections [3.4.2.6](#) and [3.4.2.7](#)),
- facility layout with respect to posting and access control (sections [3.4.7](#) and [3.4.8](#)),
- facility layout and structural shielding with respect to protection of persons from gamma rays and/or x rays (section [3.4.4](#)),
- facility ventilation with respect to protection of persons working with radioactive materials (section [3.4.3.4](#)), and
- facility ventilation with respect to control of air effluents to uncontrolled areas (section [3.4.5](#)).

XVII

General Criteria for Training and Experience of Principal Investigators to Be Authorized for Radioactive Materials

General Criteria for Training and Experience of Principal Investigators to Be Authorized for Radioactive Materials

All PIs to be authorized for radioactive materials, as members of the executive faculty, will be expected to have completed a college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences, or engineering, prior to their appointment as faculty. Faculty members not meeting these criteria will not be authorized for radioactive materials without special consideration of their qualifications.

In connection with a recommendation from the most recent inspection by CDPHE, a laboratory classification scheme has been developed to classify laboratories, based on the PI's authorizations, as low, medium, and high hazard level laboratories. In addition to the completion of university specific Radiation Safety Training requirements for new PI's, the Committee may specifically consider the need for additional training for uses that qualify as "high" hazard, and may consider a requirement for additional training for some uses that qualify as "medium" hazard.

XVIII

CDPHE Notice to Employees



Colorado Department
of Public Health
and Environment

COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT
Hazardous Materials and Waste Management Division
Radiation Management Program

NOTICE TO EMPLOYEES

**STANDARDS FOR PROTECTION AGAINST RADIATION (PART 4); NOTICES, INSTRUCTIONS
AND REPORTS TO WORKERS; INSPECTIONS (PART 10); EMPLOYEE PROTECTION**

To report radiation safety
concerns or violations by your
employer, **Telephone:**
303-692-3300 (daytime)
303-877-9757 (after hours)

**HAZARDOUS MATERIALS AND WASTE MANAGEMENT
DIVISION**

**COLORADO DEPARTMENT OF PUBLIC HEALTH AND
ENVIRONMENT**

Within Colorado, the Radiation Management Program of the Hazardous Materials and Waste Management Division (the Division) is the regulatory agency responsible for licensing and inspecting the use of radioactive materials and registering and inspecting radiation producing machines.

**HAZARDOUS MATERIALS AND WASTE MANAGEMENT
DIVISION'S RESPONSIBILITIES**

The Division's primary responsibility is to ensure that workers and the public are protected from unnecessary or excessive exposure to radiation. The Division does this by establishing requirements in the State of Colorado Rules and Regulations pertaining to Radiation Control, 6 Code of Colorado Regulations (CCR) 1007-1 (Regulations).

EMPLOYER RESPONSIBILITIES

Any individual conducting activities licensed or registered by the Colorado Department of Public Health and Environment (Department), Hazardous Materials and Waste Management Division, must comply with the Department's requirements. If a violation of the Department's requirements occurs, the license or registration can be modified, suspended or revoked and/or the licensee or registrant can be fined.

Your employer must post or make available Department radiation regulations and must post Department Notices of Violation involving radiological working conditions.

EMPLOYEE RESPONSIBILITY

For your own protection and the protection of your co-workers, you should know how Department requirements relate to your work and should obey them. If you observe violations of the requirements, you should report them.

REPORTING VIOLATIONS

If you believe that violations of the Department rules or of the terms of the license have occurred, you should report them immediately to your employer. If you believe that adequate corrective action is not being taken, you may report this to a Department inspector or to the Division.

WORKING IN A RADIATION AREA

If you work with or in the vicinity of radioactive materials or radiation producing machines, the amount of radiation exposure that you may receive is limited by the Regulations. The limits on your exposure, as well as limits for an embryo/fetus, are contained in Part 4 of the Regulations. While those are the maximum allowable limits, your employer should also keep radiation exposure as far below those limits as is "reasonably achievable".

**OBTAINING A RECORD OF WORKER RADIATION
EXPOSURE**

If the Regulations require that your radiation exposure be monitored, your employer is required to advise you annually of your dose. In addition, if you terminate employment with the licensee or registrant, you may request that your employer provide, at termination, a report of your radiation exposure during the current year.

**IDENTIFYING VIOLATIONS OF DEPARTMENT
REQUIREMENTS**

The Department conducts regular inspections at licensed and registered facilities to assure compliance with Department requirements. In addition, licensees and registrants are required to perform audits, surveys and/or measurements to assure compliance.

CONTACTING A DEPARTMENT INSPECTOR

Your employer may not prevent you from talking with a Department inspector and you may talk privately with an inspector and request that your identity remain confidential.

REQUESTING AN INSPECTION

If you believe that your employer has not corrected violations involving radiological working conditions, you may request an inspection. Your request should be addressed to the Hazardous Materials and Waste Management Division, Colorado Department of Public Health and Environment, and must describe the alleged violation in detail. You or your representative must sign the request.

CONTACTING THE DEPARTMENT

Call the Division. Department Staff would like to talk to you if you are worried about radiation safety or other aspects of licensed or registered activities.

CAN I BE FIRED FOR RAISING A SAFETY ISSUE?

Federal law prohibits an employer from firing or otherwise discriminating against you for bringing safety concerns regarding radioactive material to the attention of your employer or the Department. You may not be fired or discriminated against because you:

- ask the Department to enforce its rules against your employer;
- refuse to engage in activities which violate Department requirements;
- provide information or are about to provide information to the Department or your employer about violations of requirements or safety concerns;
- are about to ask for, or testify, help or take part in, a Department, Congressional, or any Federal or State proceedings.

*NOTE: Federal Law Provisions do not apply to workers using only radiation producing machines (x-ray machines).

WHAT FORMS OF DISCRIMINATION ARE PROHIBITED?

It is unlawful for an employer to fire you or to discriminate against you with respect to pay, benefits, or working conditions because you help the Department or raise a safety issue.

HOW AM I PROTECTED FROM DISCRIMINATION?

If you believe that you have been discriminated against for bringing violations or safety concerns to the Department or your employer, you may file a complaint with the U.S. Department of Labor, Section 211 of the Energy Reorganization Act of 1974 (42 U.S.C. 5865) or to go to you may directly contact the Occupational Safety and Health Administration (OSHA) Regional Office to receive your complaint. Your complaint must describe the firing or discrimination and must be filed within 180 days of the occurrence.

Send complaints to:

Department of Labor/OSHA
1999 Broadway, Suite 169C
P. O. Box 46550
Denver, Colorado 80201-6550

or contact OSHA office by telephone at (720) 264-6550 or by fax at (720) 264-6585.

WHAT CAN THE DEPARTMENT OF LABOR DO?

The Department of Labor (DOL) will notify the employer that a complaint has been filed and will investigate the case.

If the DOL finds that your employer has unlawfully discriminated against you, it may order that you be reinstated, receive back pay, or be compensated for any injury suffered as a result of the discrimination.

WHAT CAN THE RADIATION MANAGEMENT PROGRAM DO?

If DOL or the Division finds that unlawful discrimination has occurred, the Division may issue a Notice of Violation to your employer, impose a fine, or suspend, modify or revoke your employer's license or registration.

OR-RH-15 (9/05, previous editions are obsolete) Radiation Management Program, Hazardous Materials and Waste Management Division, Colorado Department of Public Health and Environment, 4300 Cherry Creek Dr. S., Denver, CO 80246-1530

The Colorado Rules and Regulations Pertaining to Radiation Control, the UCD Radioactive Materials License, and the UCD Radiation Safety Manual are located in Bldg. 401, RM 202, 1784 Racine St., Aurora, CO 80045.
For radioactive materials emergencies, contact the Radiation Safety Office at 303-724-0345 during business hours or the Campus Police at 911 after hours and on weekends.

INDEX

- Accounting Sheet, 65
- ALARA
 - CIR review of dose, 30
 - dose limits, 29
 - Maximum Permissible Dose (MPD), 28
 - program, 27
 - worker responsibilities, 30
- Animals, 56
 - housing, 59
 - RAM releases from, 62
- Annual Limit**, 41
- Authorizations**
 - approval, 20
 - audits, 24
 - hazard classification, 127
 - issuance, 20
 - spot checks, 46
 - terms and expiration, 24
 - transfer of authority, 22
- Authorized RAM Laboratories, 67
- Bioassay, 28, 33, 54
 - usage requiring, 55
- Broad Scope License, 14, 31
 - amendments, 33
 - copies, 32
 - renewal, 33
- Calibration of Survey Instruments, 35
- CDPHE
 - inspections, 14
 - operational criteria, 45
- CIR
 - authority, 17
 - conditions for new applications, 21
 - meetings, 18
 - membership, 18
 - RAM use, 19
 - review of PI qualification, 20
 - reviewer actions, 19
- Cleaning Services Staff, 37
- Coinvestigator, 23
- Colorado Multiple Institution Review Board
 - human research. *See* COMIRB
- Committee on Ionizing Radiation. *See* CIR
- Contamination Control, 51
- Decommissioning, 66
- Dosimetry, 28
 - devices, 58
 - personnel monitoring, 33
- EHS
 - authority, 18
 - delivery address for RAM packages, 41
 - services, 33
- Emergency Procedure for Personal Contamination, v
- Emergency Procedure for Radioactive Spills, vi
- Emergency Procedures, 71
- EMERGENCY TELEPHONE NUMBERS, ii
- Environmental Health and Safety.** *See* EHS
- Exposure Control, 46
- Fume Hood
 - evaluation, 36
- Fume Hoods, 53, 60
- Generally licensed RAM, 15
 - instruments and devices, 16
 - in-vitro kits, 16
 - uranium, 16
- Green Tags, 67
- Improper disposal, 59
- Incident Reporting, 71
- Incident Reporting Requirements, iv
- Instrumentation, 46
- Iodine Labeling, 60
- Labeling, 70, 71
- Leak Test, 35
- Maximum Permissible Dose, 28
- Minors, 38
- Personal Protective Equipment, 51
- Possession Limit**, 40
- Postings, 69
 - CDPHE Notice to Workers, 70
 - PI's documents, 70
 - Radiation Area, 69
 - Radioactive Materials, 69
- Pregnancy and RAM use, 39
- Principal Investigator
 - audits of lab, 24
 - certification, 22
 - defined, 23
 - radiation survey instruments, 46
 - responsibilities, 23, 38
- RAD SAFETY ROUTINE PHONE NUMBERS, iii
- Radiation Protection Program
 - organization chart, 26

INDEX

- regulatory compliance, 27
- Radiation Safety
 - consultation, 37
 - surveys, 35
 - worker training, 36
- Radiation Safety Manual
 - copy locations, 12
 - manual revisions, 12
 - sale of copies, 12
- Radioactive Material.** *See* RAM
- Radioactive Waste Disposal, 62
 - decay in storage, 64
 - deregulated wastes, 64
 - lab personnel responsibilities, 66
 - sanitary sewage, 63
 - trace amounts, 63
- Radioactive Waste Disposal Manual, 65
- Radiological Hygiene, 51
- RAM**
 - accounting, 65
 - animal releases, 62
 - annual (yearly) limit, 41
 - control of releases, 59
 - decay in storage, 64
 - deliveries to UCD, 41
 - disposal, 62
 - disposition and transportation, 39
 - forms, uses, limits, 32
 - inventory and control, 34
 - off-campus transport, 43
 - on campus transport, 42
 - package receipt, 34
 - possession limit, 40
 - postings and labels, 69
 - pre-approval, 40
 - security, 44
 - shipments, 36
 - volatile forms, controlling, 53
 - waste, 62
 - waste disposal, 36
 - waste tickets, 65
- Reporting Incidents, 71
- Respiratory Protection, 54
- Restricted Area, 44
- Sewage Effluents, 61
- Shielding
 - benchtop, 57
 - uses, 57
- Surveys, 47
 - decontamination, 50
 - documentation, 49, 50
 - frequency, 48
 - locations of, 48
 - types of, 49
- Thermoluminescent Dosimeter. *See* TLD
- TLD, 58
- Tritiated Compounds, 60
- UCD-UCH Joint Projects**, 15
- Unrestricted Area, 44
- Vacuum Systems, 61
- Ventilation Controls, 52
- Volatile Forms, 53
- Waste Tickets, 65