

RADIATION SAFETY MANUAL

For
Columbia University
New York-Presbyterian Hospital
New York State Psychiatric Institute
Barnard College

June 2016

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INTRODUCTION

This Columbia Radiation Safety Program Manual (this **Manual**) was approved by the Radiation Safety Committee of Columbia University, Lamont-Doherty Earth Observatory, Nevis Laboratories and Barnard College, and the Joint Radiation Safety Committee of Columbia University, New York-Presbyterian Hospital and New York State Psychiatric Institute (the foregoing institutions being referred to collectively as the **Program Institutions**) and supersedes all other manuals, memoranda or notices relating to radiation safety issued prior to the date of this Manual.

This Manual includes the policies and procedures of the Radiation Safety Program of the Program Institutions that govern all work involving the use of radionuclides, radiation-generating equipment and other sources of ionizing radiation.

These radiation policies and procedures meet all regulatory requirements of the New York City Department of Health and Mental Hygiene, the New York State Department of Health, the New York State Department of Environmental Conservation and the federal Nuclear Regulatory Commission. These policies and procedures apply to all personnel working with radiation or radioactive materials at the facilities or campuses described below and/or any off-site location where the Columbia University Chief Radiation Safety Officer has cognizance under radioactive materials licenses or permits granted to Columbia University.

To the extent that this Manual relates to use of radiation in research, it may be read with its companion Research Radiation Safety Handbook available on the website of the Columbia University Executive Vice President for Research.

Chapter I: Radiation Safety Program

A. Program Structure and Jurisdiction

The Columbia Radiation Safety Program (the **Radiation Safety Program**) is responsible for assisting its constituent communities in the safe use of ionizing radiation, including radioactive materials and x rays. The Radiation Safety Program is designed to protect users, staff, patients, the general public and the environment from radiation exposure and to ensure the safe receipt, handling, use and storage of radioactive materials. The mission of the Radiation Safety Program is to facilitate safe conditions for the proper use of radiation, to maintain radiation exposures As Low as Reasonably Achievable (**ALARA**) and to ensure that operations are in compliance with applicable city, state and federal regulations.

The Radiation Safety Program is integrated, but has two components. One component includes:

- the Morningside Heights campus (**Morningside**) of Columbia University (**Columbia** or the **University**),
- the Manhattanville campus
- the Lamont-Doherty Earth Observatory (**Lamont**),
- Nevis Laboratories (**Nevis**) and
- Barnard College (**Barnard**).

The other component includes the following schools constituting the Columbia University Medical Center (**CUMC**):

- College of Physicians and Surgeons,
- Mailman School of Public Health,
- College of Dental Medicine, and
- School of Nursing

and also includes

- New-York Presbyterian Hospital/Columbia (**NYP**), and
- New York State Psychiatric Institute (**NYSPI**).

In addition, the Radiation Safety Program includes any offsite location covered by radioactive materials licenses or permits granted to the University. The Radiation Safety Program is operated under the University's Office of Environmental Health and Safety (**EH&S**) in the Office of the Executive Vice President for Research (**EVPR**), as a single Radiation Safety Program headed by a Chief Radiation Safety Officer.

For purposes of describing those aspects of the Radiation Safety Program that differ between the two components, the part of the Radiation Safety Program that covers Morningside, Lamont, Nevis, Barnard and any related off-site location is called the **Morningside Program** and the part of the Radiation Safety Program that covers CUMC, NYP, NYSPI and any related off-site location is called the **Joint Program**.

Management's ALARA Statement

The University strongly endorses and adopts the principle of keeping exposures to ionizing radiation **As Low As Reasonably Achievable (ALARA)**. ALARA means making every reasonable effort to maintain exposures to radiation as far below the dose limits set by City, State and Federal regulations as practical, taking into consideration technical, economic and

social considerations. (NRC 10 CFR 20)

All radiation safety programs and radiation use projects are designed with ALARA as a governing principle. Procedures, equipment and facilities are designed such that exposures are minimized to the extent that the overall benefits justify the measures taken.

The University provides technically qualified personnel and resources to implement this policy. See [Chapter III – ALARA Program](#).

B. Roles and Responsibilities

Ultimate responsibility for the implementation and governance of the Radiation Safety Program lies with (1) the President of the University, with respect to those aspects of the Radiation Safety Program that relate to Columbia, (2) the President of Barnard, with respect to those aspects that relate to Barnard, (3) the President of NYP, with respect to those aspects that relate to NYP, and (4) the Director of NYSPI, with respect to those aspects that relate to NYSPI. The President of the University has delegated his authority to the EVPR, with respect to those aspects of the Radiation Safety Program that relate to the use of radiation sources and radioactive materials in research, and to the Executive Vice President for Health and Biomedical Sciences (**EVPHBS**), with respect to those aspects that relate to the clinical use of radiation sources and radioactive materials.

The primary oversight responsibilities within the Radiation Safety Program rest with the **Radiation Safety Committees (RSC)**, the **Radiation Safety Officers (RSO)** and the **Radiation Safety Program personnel (RSP)**. The **Radiation Safety Officers** shall be delegated the authority to ensure the implementation of the radiation protection programs described in Section 175.103(b)(1) of Title 24 Article 175 of the Rules of the City of New York. Together the RSC, RSO, and RSP establish policies and procedures, oversee regulatory compliance, monitor the Radiation Safety Program performance and support the highest quality research and clinical use of radiation. **Authorized Users** and **Principal Investigators (PIs)** (who may or may not be Authorized Users) also have responsibilities under the Radiation Safety Program. The following briefly describes their roles and responsibilities.

1. Radiation Safety Committees

Federal, New York and New York City radiation control regulations require institutions that receive, possess or transfer radioactive materials to obtain a specific license and to establish a radiation safety committee. There are two radiation safety committees at the University: (a) the Radiation Safety Committee (**RSC**) for the Morningside Program and (b) the Joint Radiation Safety Committee (**JRSC**) for the Joint Program. (The RSC and JRSC are referred to collectively as the **RS Committees**.)

2. Membership

The composition of each RS Committee must meet the requirements set forth in Section 175.103(b)(3) of Title 24 of the Rules of the City of New York, Article 175 Radiation (**Article 175**). The membership must include, but is not limited to, for the RSC, representatives from the management of the University and Barnard, departments where radiation sources are used and the Radiation Safety Officer, and for the JRSC, in addition to representative from such departments and the Radiation Safety Officer, representatives from the management of NYP and NYSPI and the NYP nursing service.

The members and Chair of the RSC are appointed by the EVPR and the President of Barnard College. The members and Chair of the JRSC are appointed by the EVPR, the EVPHBS, the President of NYP

and the Director of NYSPI.

Subcommittees are comprised of members of the full RS Committee and members are appointed by the Chair of the full Committee. Ad-hoc committees may be established at the request of the Chair and/or the Radiation Safety Officer. Other individuals who are not members of the JRSC may be appointed to subcommittees at the discretion of the Chair of the RS Committee.

The JRSC has a Human Use Subcommittee (**HUS**) that is responsible for reviewing and approving or disapproving all applications for the use of radiation in studies involving human subjects and a Radiation Quality Assurance Subcommittee (**RQAS**) that is responsible for overseeing the administration of a quality assurance program required by Article 175.

3. Meeting Requirements

The RS Committees meet as often as necessary to conduct business, but not less than once in each calendar quarter. At least one-half of the applicable RS Committee must be present, including the Chief Radiation Safety Officer and a representative of management, to establish a quorum and conduct business. Minutes of the proceedings are recorded and include the meeting date, members present and absent, a summary of deliberations, discussions and recommendations, and a record of the ALARA program reviews undertaken.

Each of the HUS and the RQAS meets once a month.

4. Committee Duties

The RS Committees are responsible for the following, to the extent covered by the jurisdiction of the RSC or the JRSC:

- Being familiar with all pertinent laws and regulations and the terms of all licenses and amendments, license applications and permits;
- Overseeing all uses of radioactive material and radiation producing equipment;
- Monitoring the Radiation Safety Program to maintain individual and collective doses ALARA;
- Reviewing, on the basis of safety and with regard to training and experience, and approving or disapproving any proposed user, the Radiation Safety Officers or any radiation physicist;
- Reviewing and approving or disapproving each proposed use of radioactive materials and/or radiation using currently acceptable radiation safety practices as the basis for the decision.
- Ensuring that radiation generating equipment is used only for those procedures for which it is designed;
- Reviewing and approving or disapproving any changes to the Radiation Safety Program;
- Reviewing quarterly occupational radiation exposure records of all personnel working with radioactive materials, and giving attention to individuals or groups of workers whose occupational exposure seems excessive;
- Establishing investigational levels for occupational doses that, when exceeded, would initiate an investigation;
- Reviewing quarterly all incidents involving radioactive materials with respect to cause and subsequent actions taken;
- Reviewing the Radiation Safety Program content and implementation annually, including an examination of records, reports from the Radiation Safety Officers, written safety procedures and the adequacy of management control systems;

- Recommending remedial actions to correct any deficiencies identified in the Radiation Safety Program and all incidents involving radioactive material;
- Providing a quality assurance program for diagnostic and therapeutic use of radiation generating equipment and radioactive materials;
- Ensuring that all personnel involved in planning for or administering radiation doses to humans, or in the use of radiation generating equipment or radioactive materials for other purposes, are supervised, instructed and competent;
- Evaluating the adequacy of facilities and equipment for specific radionuclide applications and ensuring that any such equipment is used safely;
- Ensuring that the appropriate committee Chair co-signs license amendment requests if required prior to any changes in facilities, equipment policies, procedures and personnel; and
- Establishing a program to ensure that all individuals who work with or in the vicinity of radioactive materials are properly instructed as required by all applicable laws, regulations and licenses.

C. Radioactive Drug Research Committee

The Radioactive Drug Research Committee (**RDRC**) is chartered by the FDA under the provisions of 21 CFR 361.1. The RDRC reviews and approves certain basic research using radioactive drugs in humans without an Investigational New Drug Application (**IND**). The only research that the RDRC is permitted to approve are studies “intended to obtain basic information regarding the metabolism (including kinetics, distribution and localization) of a radioactively labeled drug or regarding human physiology, pathophysiology or biochemistry, but not intended for immediate therapeutic, diagnostic or similar purposes or to determine the safety and effectiveness of a drug in humans for such purposes (i.e., to carry out a clinical trial)”.

The members of the RDRC are appointed by the EVPR and the EVPHBS. The Chair is elected by the RDRC.

As required by the FDA, the membership of the RDRC must include (1) a physician recognized as a specialist in nuclear medicine, (2) a person qualified by training and experience to formulate radioactive drugs, (3) a person with special competence in radiation safety and radiation dosimetry and (4) other individuals qualified in various disciplines pertinent to the field of nuclear medicine. The RDRC meets once a month.

D. Radiation Safety Officers

The Radiation Safety Program is managed by the Executive Director of Radiation Protection Services/Chief Radiation Safety Officer (the **Chief RSO**), who oversees all aspects of the Radiation Safety Program (including the use of radioactive materials in research) under the supervision of the RS Committees. The Chief RSO is assisted by a Radiation Safety Officer for Clinical Programs (**RSO(C)**), who oversees clinical uses of radioactive material (either of the Chief RSO and the RSO(C) being referred to as a **Radiation Safety Officer**). The Chief RSO reports to the Associate Vice President for EH&S for administrative purposes and to the Chair of the RSC and the JRSC for technical matters and with respect to those areas that are within the purview of the RS Committees.

The Radiation Safety Officers are responsible for the following:

- Ensuring that all radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the Radiation Safety Program;

- Investigating overexposures, misadministrations, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers and disposals, and other deviations from approved radiation safety practice and implementing corrective actions as necessary;
- Establishing, implementing and maintaining written policies and procedures for:
 - authorizing the purchase of radioactive materials;
 - receiving and acceptance testing packages of radioactive materials;
 - storing radioactive materials;
 - keeping an inventory record of radioactive materials;
 - using radioactive materials safely;
 - taking appropriate action if control of radioactive materials is lost;
 - performing periodic radiation surveys;
 - performing checks of survey instruments and other safety equipment;
 - disposing of radioactive materials;
 - using radiation-generating equipment safely;
 - training personnel who work in or frequent areas where radioactive materials and radiation-generating equipment are used or stored; and
 - keeping copies of all records and reports required by Article 175, each license and amendments and the written policies and procedures required by Article 175;
- Briefing the RS Committees at least once each year on the Radiation Safety Program;
- Assisting the RS Committees in the performance of their duties;
- Approving or disapproving the Radiation Safety Program changes with the advice and consent of the RS Committees; and
- Reviewing applications for the possession and/or use of radioactive materials and protocols for human or animal studies using radioactive materials and making recommendations to the RS Committees for approval or disapproval.

E. Authorized Users

Under Article 175.02(a)(18), an Authorized User is an individual who is identified as an authorized user on a New York City Department of Health and Hygiene – Bureau of Radiological Health (the **City DOH**), New York State Department of Health, Bureau of Environmental Radiation Protection (the **State DOH**) or a federal Nuclear Regulatory Commission (**NRC**) license that authorizes the use of radioactive material or who is named as an authorized user on a certified registration issued by the City DOH. There are two types of Authorized Users in the Radiation Safety Program: **Non-Clinical Authorized Users** and **Clinical Authorized Users**. In either case, the Authorized User (who may or may not be the PI of the study) is responsible for overseeing the use of radiation in a research study.

In general, an Authorized User is responsible for:

- Maintaining an up-to-date listing with the Radiation Safety Program of radiation-generating devices, rooms where radioactive materials or radiation generating devices are used or stored and names of personnel who may use these devices and materials;
- Allowing only personnel who are trained to use radioactive materials or radiation generating devices and ensuring that such personnel follow applicable safety practices;
- Understanding the ALARA concept and the need to maintain exposures ALARA to all supervised individuals;
- Minimizing radiation exposures to users, the University community, the environment and the general public;
- Ensuring that dosimetry is used and dosimeters are returned on time;

- Controlling the purchase, possession, use, transfer and/or disposal of radioactive materials or radiation generating devices in his or her possession, including security for radioactive material stocks;
- Maintaining records of purchase, receipt, use, surveys and disposal of radioactive materials;
- Minimizing and properly packaging radioactive wastes;
- Notifying Radiation Safety Program personnel immediately in the event of any radiological emergency; and
- Complying with University policies governing the use of radioactive materials and radiation generating devices and with applicable laws, regulations and licenses.

A **Non-Clinical Authorized User** holds a permit for the use of radiation or radioactive materials in research that does not involve human subjects. Upon application and approval by a Radiation Safety Officer and the Chair of the applicable RS Committee, a permit is granted for specific uses of radiation or radioactive materials.

A **Clinical Authorized User** is a physician who is an expert in the clinical use of radiation or radioactive materials, has the requisite training and qualifications for such use and has been authorized by the JRSC to prescribe the administration of radiopharmaceuticals to humans. There are three categories of expertise in the Radiation Safety Program:

- Imaging, localization studies, uptake, dilution and excretion;
- Uptake, dilution, excretion, imaging, localization studies and therapeutic use of radiopharmaceuticals; and
- Therapeutic use of brachytherapy sources.

A Clinical Authorized User has the following special responsibilities:

- Examination of the subject and relevant medical records to determine if a radiation procedure is appropriate;
- Prescription of the radiation dose and how it to be administered;
- Actual use of, or direction of other medical personnel in the use of, radioactive material; and
- Interpretation and evaluation of the results of any procedures involving the administration of radiopharmaceuticals.

If the PI of a study is using radiation involving human subjects is not him/herself a Clinical Authorized User, the personnel on such study must include a Clinical Authorized User to carry out the foregoing responsibilities.

Any physician wishes to become a Clinical Authorized User should forward to the CUMC Radiation Safety Program Office for review:

- A letter from his/her department chair requesting specific privileges;
- His/her current New York State medical license; and
- A Curriculum Vitae

Physicians who are board certified in an appropriate medical discipline must also submit documentation of certification. A written application must also be submitted.

If a physician has been previously authorized for medical use and wants to use only material permitted by a previous license, a copy of the license on which the physician was specifically named as a Clinical Authorized User should be submitted.

Physicians not previously authorized *and* not board certified must submit a complete description of their training and experience using a written application.

The RSO will review the application materials submitted and will make a recommendation to the Chair of the JRSC regarding approval of the application. The Chair will submit the physician's credentials to the JRSC for approval.

If a research study involves the use of radiographic procedures and the PI is not a licensed physician, a physician must be selected to order such procedures.

Note: An individual whose only contact with a radiation source involves the use of radiation-generating equipment (e.g., an individual who operates an x-ray machine) is not required to obtain a permit as an Authorized User. However, the acquisition and use of the radiation-generating equipment itself must be approved by a Radiation Safety Officer. **See Chapter X(B): Safe Use of Radioactive Materials and Radiation-Generating Equipment: Radiation-Generating Equipment.**

Chapter II: Radiation Safety Codes and Standards

The following regulations constitute the basis for the policies and procedures set forth in this Manual:

- Title 24 Rules of The City of New York, Article 175 – Radiation Control
- Title 10 New York Code of Rules and Regulations, Part 16 – Ionizing Radiation
- Title 6 New York Code of Rules and Regulations, Part 380 - Prevention and Control of Environmental Pollution by Radioactive Materials
- Title 10 Code of Federal Regulations, Part 19 – Notices, Instructions, and Reports to Workers; Part 20 – Standards for Protection Against Radiation; Part 35 – Medical Use of Byproduct Material

These policies and procedures are also derived from the specific requirements set forth in the following guides:

- City of New York Department of Health and Mental Hygiene, Bureau of Radiological Health License Guide 10.8, rev. 2, Guide for Preparations of Application for Medical Programs
- New York State Department of Health, Bureau of Environmental Radiation Protection, Radiation Guide 10.5, rev 1, Guide for the Preparations of Applications for Type A Broad Scope Licenses
- U.S. Nuclear Regulatory Commission, NUREG 1556, Consolidated Guidance About Materials Licenses

Chapter III: ALARA Program

A. Management Commitment

The Program Institutions are committed to the maintenance of individual and collective exposure to radiation ALARA. There are many aspects of the Radiation Safety Program that support the ALARA philosophy and include commitments by the RS Committees, the Radiation Safety Officers, other Radiation Safety Program personnel and Authorized Users. The major elements of the ALARA program are described as follows.

B. Training

All Authorized Users and other research personnel who use radioactive material and/or may be exposed to radiation are required to obtain training in radiation safety, the ALARA philosophy, the Program Institutions' commitment to ALARA and the University's specific procedures and policies by attending training provided by EH&S. Authorized Users are the "front line" in training as they have the most contact with personnel using radiation and therefore bear much of the responsibility for training.

Authorized Users are required to provide specific training and set expectations for the proper use of radiation and radioactive materials in their laboratories.

C. Monitoring of Individual Radiation Exposures

The Program Institutions have established investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by a Radiation Safety Officer and/or the RS Committees. There are three levels of personnel doses used:

Personnel dose less than Notification Level I

Except when deemed appropriate by a Radiation Safety Officer, no action is required if an individual's exposure is less than the notification levels set forth in the following Table:

Exposure Type	QUARTERLY ALARA LEVELS (mrem)		ANNUAL REGULATORY LIMIT (mrem)
	ALARA Level I Notification Level	ALARA Level II Investigation Level	
Whole Body Deep (DDE)	125	375	5,000
Lens of Eye (LDE)	375	750	15,000
Skin and Extremities (SDE)	1,875	5,625	50,000
Organ	1,250	3,750	50,000

DDE (Deep Dose Equivalent) applies to external whole body exposure; dose equivalent at a tissue depth of 1.0 cm.

LDE (Lens Dose Equivalent) applies to the external exposure of the lens of the eye; dose equivalent at a tissue depth of 0.3 cm.

SDE (Shallow Dose Equivalent) applies to the external exposure of the skin or extremities; dose equivalent at a tissue depth of 0.007 cm averaged over one square cm.

Personnel dose equal to or greater than Notification Level I but less than Investigation Level II

A Radiation Safety Officer will review the dose of each individual whose quarterly dose equals or exceeds ALARA Level I (Notification Level) shown above and report the results at the first meeting of the applicable RS Committee following the quarter when the dose was recorded. The individual will be notified in writing. If the dose does not equal or exceed ALARA Level II (Investigation Level), no further action is required unless deemed appropriate by the applicable RS Committee.

Personnel dose equal to or greater than Investigation Level II

A Radiation Safety Officer must investigate in a timely manner the causes of all doses equal to or exceeding Investigational Level II and, if warranted, take action. First, an ALARA Level II Notification is sent to each individual with more than ALARA Level II exposure. Each ALARA II report will be investigated, even if the investigation leads to the conclusion that the individual did everything reasonable to minimize radiation exposure. A report of this investigation, actions taken and the individual's exposure record is reported to the applicable Department Administrator, Department Chair and RS Committee.

Personnel dosimeter reading equal to or greater than 4,500 mrem (DDE)

The Radiation Safety Officer shall issue a stop work order any time an individual's dosimeter readings show a Deep Dose Equivalent (DDE) equal to or greater than 4,500 mrem. The individual shall cease all work which might cause exposure to ionizing radiation in excess of background levels. The Radiation Safety Officer shall conduct an immediate investigation to determine the cause of the exposure readings and recommend appropriate corrective and preventative actions.

Personnel dose equal to or greater than Annual Regulatory Limit

A Radiation Safety Officer must immediately investigate the cause of any cumulative exposure that exceeds the annual regulatory limit set forth in **Chapter VI(A): Occupational Exposure to Radiation, Personal Monitoring and Bioassay Program: Occupational Exposure** and, if warranted, take immediate corrective actions to prevent additional exposure. In addition to the ALARA actions described above, a report of the investigation, actions taken and the individual's exposure record will be reported to the appropriate regulatory agency as described in the applicable regulations.

D. Program Reviews

1. Annual Reviews

A Radiation Safety Officer and the applicable RS Committee must perform an annual review of the Radiation Safety Program and its adherence to ALARA principles. This will include reviews of operating procedures, dose records, inspections and consultations with Radiation Safety Program personnel. The principal purpose of the annual review is to assess trends in occupational exposure as evidence of the ALARA program quality.

2. Quarterly Reviews

A Radiation Safety Officer will review the external radiation doses of Authorized Users and other research personnel and will report to the applicable RS Committee on at least a quarterly basis. In addition, a Radiation Safety Officer will review radiation surveys to determine if dose rates and amounts of contamination were at ALARA levels.

3. Review of Proposed Users and Uses

When approving an Authorized User or the use of radiation or radiation-generating equipment, the RSO and the RS Committees must ensure that the applicant will take appropriate measures to maintain exposure ALARA. Modifications to research protocols, maintenance procedures and equipment and facilities will be made if they reduce exposure unless the burden outweighs the potential for dose reduction.

Chapter IV: Approval of the Use of Radiation

A. Research Applications

Any individual at the Program Institutions who wishes to purchase, use or work with radioactive materials or radiation-generating devices requires written authorization from the applicable RS Committee (or designee thereof) or the RDRC prior to any such activity. The purpose of such authorization process is to assure the applicable RS Committee or RDRC that the individual has the appropriate experience and training for the intended activity. Once approved, the individual is issued a permit as an Authorized User and is responsible for controlling all radioactive materials and radiation generating devices covered by the permit from the time of receipt until transfer to the applicable Radiation Safety Program office as waste, shipment to another location or transfer to another Authorized User.

The authorization that you must obtain depends on the nature of research that you are intending to conduct. There are four categories of use: **non-human use**, **animal use**, **use off campus or at sea** and **human use**.

1. Non-Clinical (Non-Human Use)

An individual who wishes to use radioactive materials in research that does not involve human subjects must apply for a permit (a **Non-Human Use Permit**). A Permit Application for Non-Human Use of Radioactive Materials should be completed and submitted to the applicable Radiation Safety Program office before any radioactive material can be acquired by purchase, transfer, loan or otherwise. This Application gives information relating to the intended use of the material, the locations of use and storage, protective equipment and facilities available, and plans for the disposal of radioactive wastes.

The application will be reviewed by a Radiation Safety Officer. Once the Radiation Safety Officer and the Chair of the RSC (or the JRSC) approve the Application, it is effective and the applicant receives a Non-Human Use Permit as a Non-Clinical Authorized User. Notice of the Permit's effectiveness is given to the applicable RS Committee at its next meeting.

Permits expire after a period of five years. Non-Human Use Authorized Users may request renewal of a Permit by written application to the applicable Radiation Safety Program office prior to expiration. Approval of the renewal will be reported at the next scheduled meeting of the applicable RS Committee.

The quantity of radioactive materials allowed under all permits for non-human use should be consistent with the actual needs of the laboratory. A Radiation Safety Officer will verify that the requested quantities are consistent with the University's applicable radioactive materials licenses. Based on a review of the proposed use(s), the reviewing Radiation Safety Officer may require special equipment, shielding or facilities or that a special laboratory be used.

At a minimum, the permit will list

- The Non-Clinical Authorized User as the permit holder;
- Room(s) where the radioactive material will be used or stored;
- The permitted use(s) of the radioactive material or radiation;
- Type, form and quantity of radioactive materials that can be acquired; and
- Limits on the amount of radioactive materials that may be purchased or acquired at any one time and the maximum possession limits.

The permit may also impose additional restrictions or requirements such as bioassays when radioiodine or tritium is used.

Requests for modifications of a Non-Human Use Permit should be made by the Non-Clinical Authorized User submitting the same Application form as is used for initial Permit application to the applicable Radiation Safety Program office, together with a cover letter indicating the changes in the Application and the rationale for each change. The Application relating to the amendment will be reviewed by a Radiation Safety Officer and once the Radiation Safety Officer and the Chair of the applicable RS Committee has approved it, it is effective.

A Non-clinical Authorized User may request that his/her Non-Human Use Permit be inactivated or terminated by written application submitted to the applicable Radiation Safety Program office and a Permit is automatically terminated when a Non-Clinical Authorized User is no longer at a Program Institution. If a permit is inactivated or terminated, all radioactive materials must be surrendered and laboratories and/or facilities cleared of all waste and contamination by EH&S personnel. Secure storage of radioactive materials may be granted on a case-by-case basis by a Radiation Safety Officer. However in no case will the materials be removed from storage without the consent of a Radiation Safety Officer. Inactivations will be reported at the next scheduled meeting of the applicable RS Committee.

Inactive Non-Human Use Permits may be reactivated at any time by written application submitted to the applicable Radiation Safety Program office and approval by a Radiation Safety Officer. Reactivations will be reported at the next scheduled meeting of the applicable RS Committee.

Inactive permits will not be renewed upon expiration unless the Non-Clinical Authorized User requests renewal in writing.

Any Radiation Safety Officer may add conditions, suspend or cancel a permit at any time based on lack of compliance with safety or regulatory requirements, subject to subsequent ratification by the applicable RS Committee.

The above requirements also apply to the use of radioactive materials in animals and off campus or at sea.

2. Animal Use

An investigator who wishes to use radioactive materials must hold a Non-Human Use Permit. An additional authorization is required for the use of ionizing radiation or radioactive materials in animal studies. Applicants for this use of radioactive materials or ionizing radiation submit an Application for Use of Radiation Involving Animals as Appendix G to the Institutional Animal Care and Use Committee (IACUC) protocol in Rascal. The Application is completed online and is filed with the protocol. The Animal Use Application is not reviewed by a RS Committee, but the Chief RSO sits on the IACUC and reviews the protocol and Application for issues involving radiation.

3. Use Off Campus or At Sea

Use of radioactive materials off campus or at sea is governed by the same policies described above. The investigator must hold a Non-Human Use Permit and must make written application to the Radiation Safety Officer for each proposed use. The RSO will review the protocol to ensure compliance with appropriate local, state and federal laws, rules and applicable licenses issued to the University. Such activities include, but may not be limited to:

- Transportation to and from, and use of radioactive materials at sea aboard, research vessels owned or operated by the University;
- Transportation to and from, and use of radioactive materials at sea aboard, any other vessel;
- Transportation to and from and use of radioactive materials at a site within the United States; and
- Transportation to and from and use of radioactive materials at a site outside of the United States.

4. Human Use

A human use authorization permits the use of radiation or radioactive materials or radiation in studies with human subjects. Radiation exposure can come from a number of sources, from x rays to PET scans to radioactive drugs. The great majority of human use authorizations come through the JRSC. Applicants who wish to use radiation or radioactive materials must submit a JRSC Application for Use of Radiation Involving Human Subjects (the **JRSC Application**) in Rascal as Hazardous Materials Appendix H to the related IRB protocol. The JRSC Application will first be reviewed by a Radiation Safety Officer and then submitted to the HUS for a final vote of approval or disapproval.

Requests for modification of a JRSC Application must be submitted in Rascal at the same time that the related IRB Protocol Modification is submitted to the IRB. The amendment Application will be reviewed by a Radiation Safety Officer and the Chair and/or the HUS and once approved, it is effective.

If the study is to be approved by the RDRC, preliminary approval of the RDRC study must be obtained from the Radiochemistry and Radiopharmaceutical Laboratory (the **Laboratory**) at the University's Kreitchman PET Center (the **PET Center**). The Director of the Laboratory will determine whether the study should be conducted under an IND or with RDRC approval. If the Director believes that the study is appropriate for the RDRC, a RDRC Application for Use of Radiopharmaceuticals in Certain Basic Research Studies must be submitted in Rascal as Hazardous Materials Appendix H to the related IRB protocol.

As further described in [Chapter I\(E\): Radiation Safety Program: Authorized Users](#), any investigator who intends to prescribe the administration of radiopharmaceuticals in a research study involving human subjects must do so under the supervision of a Clinical Authorized User.

B. Non-Human Use Permit States and Actions

Depending on the needs of the laboratory, Non-Human Use Permits may have one of the following four statuses:

1. **ACTIVE** – the laboratory is currently using radioactive materials or has stocks, samples, waste or other materials in use. Monthly surveys are required, inventory records must be kept up to date, and retraining is required annually. All requirements in this Radiation Safety Manual must be maintained and all labeled rooms/areas are to be controlled as radiation use areas.

2. **ACTIVE WITH ZERO INVENTORY** – the laboratory will not be using radioactive materials for a period of less than approximately 6 months and has no stocks, waste or other permitted radioactive materials in use. All waste has been removed and all inventory sheets have been accounted for. The Permit holder is relieved of the responsibility of performing and recording monthly surveys and record-keeping duties. However, all other requirements in this Radiation Safety Manual must be maintained: refresher training is required annually and all labeled areas are to be controlled as radiation use areas (i.e., no eating

or drinking, etc.) The Permit and laboratories are maintained so that work with radioactive materials may start with the next receipt of radioactive materials.

3. **INACTIVE** –the laboratory will not be using radioactive materials for a period of more than 6 months. The Authorized User is strongly encouraged to make the permit inactive. Essentially this is a “temporary termination” whereby the laboratory is permitted to do work not involving radiation, and the Authorized User may re-activate the permit by contacting EH&S. Generally a laboratory will be ready for work involving radiation within 2 weeks of EH&S receiving the reactivation request. All the requirements for termination must be met (e.g., no stock vials in the laboratory, all waste has been removed and a termination survey has been completed). See **Section D: Non-Human Use Permit Termination** below. Once inactive, there are no restrictions on laboratories and no paperwork or retraining requirements. A Permit may be inactive for 3 to 5 years after which radiation safety retraining may be required or the Permit may be terminated.

4. **TERMINATED** – see **Section D: Non-Human Use Permit Termination** below. Depending on the amount of time elapsed since termination, a terminated Permit may be reactivated or a new application may be required. Radiation safety retraining may also be required.

When an Authorized User is expected to be away for up to six weeks, the Authorized User must designate another Authorized User to act in his/her place. The **Alternate Contact** will be in charge of the laboratory work involving radiation on behalf of the Authorized User. The Alternate Contact will be contacted for Permit-related issues and will perform most of the Authorized User’s responsibilities and functions, including minor requests for Permit amendments such as adding/deleting users or rooms. The Authorized User will, upon return, countersign those items that required signatures during his/her absence. When the Authorized User and the Alternate Contact are expected to be away at the same time, the Permit holder must advise a Radiation Safety Officer of an alternate arrangement.

When an Authorized User is expected to be away for six weeks or more, a Radiation Safety Officer should be notified in writing. Another Authorized User should be named and agree in writing to accept the responsibility for the Permit for the duration of the leave. Approval of the arrangement will be made by a Radiation Safety Officer. A Permit amendment is issued to reflect the change. The acting Authorized User must hold a currently active Permit.

C. Non-Human Use Permit Termination

When a Non-Human Use Permit is expected to be terminated, the Authorized User must notify a Radiation Safety Officer as far in advance as possible. This is particularly important when the termination is due to the Permit holder’s leaving the University. The Authorized User will assist Radiation Safety Program personnel to ensure that:

- All radioactive materials still in the possession of the Permit holder are properly transferred, or disposed of;
- Personnel monitoring is discontinued, where applicable;
- The laboratory area is free of radioactive contamination and radiation caution signs, labels and other postings are removed. EH&S will perform an exit survey of the laboratory and equipment to ensure that all spaces and items are free of contamination.

D. Clinical Applications

As further described in [Chapter I\(E\): Radiation Safety Program: Authorized Users](#), any person who intends to use or prescribe radioactive materials for diagnosis or therapy must submit credentials and an application for review and approval by the JRSC. Permits are not issued for clinical (i.e., non-research) use of radioactive materials. However, the physician will receive a letter of approval from the Chairman of the JRSC.

Chapter V: Procurement of Radioisotopes and Other Sources of Ionizing Radiation

A. Research Applications

All purchases of radioactive materials or radiation-generating equipment must be approved by a Radiation Safety Officer, or designee, in advance. Normally, orders will be entered electronically and automatically forwarded to the applicable Radiation Safety Program office for review and approval. It is the responsibility of the Authorized User to ensure that the order is correct in all particulars – i.e. units, catalog number, type, form and activity of radioactive materials, product description, etc. The order will be reviewed for completeness and to ensure that the Authorized User is allowed under his/her Permit to purchase the requested radionuclide and/or perform the requested activity. Standing orders may be established with the approval of a Radiation Safety Officer.

Unless otherwise specifically authorized by a Radiation Safety Officer, shipments of radioactive material must be delivered to the applicable Radiation Safety Program office. Other suitable arrangements for delivery or shipments can be made for Nevis and/or Lamont. A properly trained member of the Radiation Safety Program office will inspect the package and complete an inventory record sheet, which is retained by the laboratory for updating.

Departments planning to install or make changes in radiation-generating equipment (such as x-ray machines, accelerators, reactors and irradiation units) should obtain approval of the plans by a Radiation Safety Officer. The term "change" is meant to include, but is not limited to, replacement of source slugs or x-ray tubes, structural alterations in the equipment or its housing, and alterations in shielding and/or interlocks. Early consultation with a Radiation Safety Officer will facilitate planning of the installation.

B. Clinical Applications

Radioactive materials intended for human diagnosis or therapy may be ordered as necessary provided the type, form and quantity conform to the provisions of the University licenses. The department/division of the Clinical Authorized User who orders the radioactive material is responsible for maintaining appropriate records of receipt surveys, inventory, use and disposal. A Radiation Safety Officer will audit these records at least annually to ensure that these requirements are met.

New radionuclides or novel uses of a currently authorized radionuclide may require amendment of a University license. Contact a Radiation Safety Officer for assistance.

C. Loans and Transfers of Radioactive Materials

An Authorized User may not, without the approval of a Radiation Safety Officer, lend or transfer radioactive material to any person or place outside the location specified for the use of such radioactive material. Approval for such a loan or transfer may be sought by submitting a request in writing to the applicable Radiation Safety Program office. The Authorized User should provide the name and address of the recipient and a copy of the recipient's radioactive materials license prior to the date of the loan or transfer.

An Authorized User may neither transfer nor loan materials to an unauthorized person under any circumstances.

All transfers of radioactive materials will be carried out by a properly trained individual with the

knowledge and approval of a Radiation Safety Officer. To the extent applicable, City, State and Federal DOT rules will be followed for the packaging, labeling and shipping of all radioactive materials.

Chapter VI: Occupational Exposure to Radiation, Personal Monitoring and Bioassay Program

A. Occupational Exposure

Any person who is exposed to ionizing radiation as a direct or necessary condition of his/her occupation, business or employment is “occupationally exposed” and is subject to the dose limits set forth in the table below. The purpose of a system of dose limits is to ensure that the radiation dose received by any person is such that:

- The dose is below the threshold for any biological effect (non-stochastic or deterministic) that requires a minimum dose for expression; and
- The probability of any effect of the all-or-nothing (stochastic) type is small enough to be acceptable to the individual and to society.

Exposure Type	Annual Regulatory Limit (mrem)
Whole Body Deep (DDE)	5,000
Lens of Eye (LDE)	15,000
Whole Body Shallow (SDE)	50,000
Extremity	50,000
Organ	50,000

B. Monitoring of External Exposure

Columbia manages the dosimetry badge program for the Program Institutions. Badges are issued to assess occupational radiation exposure and to help develop strategies to reduce doses.

More specifically, personal dosimeters for monitoring whole body and/or extremity radiation doses are issued to the individuals specified below:

- Individuals assigned to work in, or frequent, a restricted area where a source of penetrating radiation is present, and who may be exposed under circumstances where they likely receive a whole body radiation dose in excess of 500 mrem (5 mSv) in one year;
- Individuals entering a high radiation area;
- Minors who may enter a restricted area;
- Visitors who enter an area posted with a “CAUTION – RADIATION AREA” sign;
- Any Program Institution employee who sincerely believes that he/she is being exposed to radiation levels that are significantly above background;
- Individuals assigned to handle sources of penetrating radiation such that the dose to their extremities may exceed 10% of the permissible dose established in Article 175 shall be issued finger monitors to determine the absorbed dose to the hands; and/or
- Individuals involved in other uses deemed by a Radiation Safety Officer to warrant the wearing of a dosimeter (e.g., using high activity levels of P-32, using gamma emitters such as Cr-51, etc.)

Because it is the responsibility of the Radiation Safety Officers to maintain radiation doses ALARA and below the maximum limits specified by City, State and/or Federal regulations, regardless of where the exposure may occur, separate dosimeters will not normally be issued to individuals working in

separate locations (“double badging”).

Personal dosimeters are issued to determine an individual’s occupational exposure only. Monitors should not be worn by an employee receiving a radiographic or nuclear medicine examination or procedure or treatment involving ionizing radiation.

Auxiliary monitoring devices, including direct reading dosimeters, can be provided to any individual where the absorbed dose to a body part may not be adequately defined by the readings obtained with other dosimeters.

Other individuals who are exposed to radiation on an occasional basis such as Public Safety personnel, office workers or Facilities personnel will not normally be issued exposure monitors.

Personal dosimeters intended to measure whole body exposure are to be worn on the trunk of the body (e.g., on the collar, chest pocket or belt loop). Extremity dosimeters (i.e., finger rings) are to be worn on the finger (under a protective glove) of the hand most frequently used to handle radioactive material.

Individuals may wear only dosimeters assigned by a Radiation Safety Officer. Dosimeters must be returned as soon as possible following the end of the monitoring period, but in no case more than 22 business days after the end of such period. Missing, damaged or contaminated dosimeters must be reported to a Radiation Safety Program staff member immediately. Dosimeters should not be removed from an individual’s work areas. However, dosimeters should be kept away from sources of radiation when not in use.

The Radiation Safety Officers will monitor the occupational exposure of declared pregnant women likely to receive during their pregnancy, a dose in excess of 0.05rem (0.5mSv). See also **Chapter VII: Radiation Protection of the Pregnant Worker**.

It is the responsibility of each PI, supervisor or Authorized User to ensure that individuals under his/her supervision are provided with dosimeters, that these dosimeters are worn properly and returned promptly, and that routine dosimetry reports are made available to monitored workers.

For those individuals for whom dosimetry is required, determination of prior exposure at other facilities must be documented. In order to do this, the individual must complete and sign the Radiation Safety Program Previous Radiation Exposure Release Form.

C. Monitoring of Internal Exposure

Monitoring of ingestion or inhalation of radioactive materials is required for the potentially volatile radioisotopes listed below. Individuals initiating work with one of these radioisotopes should have a baseline measurement prior to using the material.

- **Tritium:** Individuals involved in operations that utilize, at any one time, more than 3.7 GBq (100 mCi) of H-3 in a dispersible or unsealed form (other than metallic foil) must submit a urine sample and have a bioassay performed within one week following a single operation and at weekly intervals for continuing operations. An individual should not receive an exposure to tritium such that the urinary excretion rate exceeds 740 KBq (20 µCi) of tritium per liter when averaged over a quarter.

A written report of an average concentration in excess of these limits for any individual must

be filed by a Radiation Safety Officer within 30 days of the end of the applicable calendar quarter with the City DOH. The report will contain the results of all urinalyses for the individual during the calendar quarter, the cause of the excessive concentration and the corrective steps taken or planned to assure against recurrence.

Any single urinalysis that shows a concentration greater than 1.85 GBq (50 mCi) per liter shall be reported in writing by a Radiation Safety Officer within 7 days of receipt of the results, as described above.

- **Na [125]-I and Na [131]-I:** Each individual who handles 37 MBq (1 mCi) or more of radioiodine in a dispersible form must receive a thyroid bioassay within 3 days of administration. The individual should bring a Radiation Safety Program Iodination Bioassay Report with him/her when he/she reports for the bioassay.
- **Na [131]-I radiopharmaceutical therapy:** Individuals who helped prepare or administer a dosage of I-131 must have a bioassay within 3 days of administration.

In each case, contact the applicable Radiation Safety Program office to schedule an appointment for the bioassay.

When an uptake measurement yields positive results, a Radiation Safety Officer will calculate the dose and initiate an investigation to determine the route of internalization, as appropriate.

D. Summation of External and Internal Doses

A Radiation Safety Officer will demonstrate compliance with radiation dose limits by summing the external and internal doses received by individuals who wear personal dosimeters and who participate in the bioassay program described above.

E. Reports and Notices to Workers

Following review by a Radiation Safety Officer, routine dosimetry reports will be provided to supervisors of those individuals who wear dosimeters. These reports must be posted or otherwise made readily available for inspection and review. An Occupation Dose Record for a Monitoring Period (NRC Form 5 or equivalent) will be provided to each individual annually or upon request.

F. Minors

Individuals under the age of eighteen are considered minors for the purposes of New York State law. The following provisions apply to short-term research participants who are minors (http://evpr.columbia.edu/files/evpr/pdf/Guidelines_for_Short-term_Visitors.pdf)

- No one under the age of fourteen is allowed in any University laboratory (except if present on an organized tour or field trip for strictly observational purposes, provided hazards are minimized).
- Minors between ages 14 and 18 may participate in certain research-related activities in a laboratory, so long as they have completed applicable safety training and they are directly supervised by the PI, sponsor or his or her designee.
- No one under the age of 18 is allowed to be alone in a laboratory.
- Minors may not handle radioactive materials.

Matriculated students under the age of eighteen may participate in research-related activities without restrictions, so long as they have completed applicable safety training. However, radiation dose limits are restricted to 10% of the limits specified in **Section A: Occupational Exposure** above.

G. Planned Special Exposures

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

Chapter VII: Radiation Protection of the Pregnant Worker

Under Article 175, and other applicable state and federal regulations, it is the University's policy to limit the radiation dose to the embryo/fetus of a declared pregnant woman to 5 mSv (0.5 rem) over the entire gestation period. Radiation Safety Program personnel will review the exposure history of the declared pregnant woman and require the adjustment of working conditions so as to avoid a monthly exposure of more than 0.5 mSv (0.05 rem). The radiation dose to the embryo/fetus is defined as the sum of the deep dose equivalent to the declared pregnant woman from external sources of radiation, such as x rays and gamma rays and the internal dose to the embryo/fetus from the uptake of radionuclide by the declared pregnant woman and by the embryo/fetus.

Further, it is the policy of the University to provide counseling and education to the declared pregnant woman with regard to the risks of radiation exposure and to consult with her regarding recommendations for maintaining the radiation dose to the embryo/fetus within the above limits and ALARA. Declarations and records under this policy are confidential. The declared pregnant woman is specifically protected from discharge or discrimination by her employer resulting from her pregnancy.

The RS Committees are responsible for administering this policy. The RS Committees have been provided sufficient authority and organizational freedom to identify radiation safety problems, initiate, recommend, or provide corrective actions and verify implementation of corrective actions. Day to day implementation of this policy has been delegated to the Radiation Safety Officers.

As part of their initial employee orientation, all radiation workers will receive instructions in radiation protection from Radiation Safety Program personnel. These instructions may be given at a new employee orientation or at a scheduled radiation safety lecture for new employees. These instructions should include; the effects of radiation to the embryo/fetus, a statement of the special limit for protection of the embryo/fetus of a declared pregnant woman, the responsibility of the pregnant woman to declare her condition to Radiation Safety Program personnel and the importance of her doing so. At the time of her Declaration of Pregnancy, the declared pregnant woman will receive individual counseling from Radiation Safety Program personnel.

Copies of this policy, the U.S.N.R.C. Regulatory Guide 8.13, Instruction Concerning Prenatal Radiation Exposure, and the Declaration of Pregnancy Form are available upon request at the applicable Radiation Safety Program Office.

Federal regulations (10 CFR 20) state that; *"It is the fundamental responsibility of the pregnant worker to decide when or whether she will formally declare her condition to her employer"*. Formal declaration is defined as filing a completed, signed and dated Declaration of Pregnancy form with the applicable Radiation Safety Program office. If a worker chooses not to declare her pregnancy, the applicable Radiation Safety Program personnel will continue to ensure that she receives all normal occupational protections; the annual occupational dose limit of 50 mSv (5.0 rem) and all ALARA requirements will be in effect. All rights of declaration rest with the pregnant woman. The declaration of pregnancy may be withdrawn at any time by a signed, dated, written statement of withdrawal filed with the applicable Radiation Safety Program office.

Upon declaration of her pregnancy, a Radiation Safety Officer, or designee, will review the present and/or anticipated job duties and responsibilities and exposure history with the worker. If this review indicates that the anticipated monthly fetal dose could exceed 0.5 mSv (0.05 rem) or the total dose could exceed 5 mSv (0.5 rem), the Radiation Safety Officer will recommend appropriate adjustments in assigned duties. For example, the worker may be expected to wear an additional personnel radiation

dosimeter as an assigned fetal monitor, wear protective lead aprons, and/or be prohibited from participating in certain procedures.

If, by the time the pregnant worker declares her pregnancy the dose to the embryo/fetus has exceeded 4.5 mSv (0.45 rem), Radiation Safety Office personnel will ensure that additional occupational dose to the embryo/fetus does not exceed 0.5 mSv (50 mrem) during the remainder of the pregnancy.

Due to privacy provisions noted in the following paragraph, if an adjustment of working conditions is necessary, a Radiation Safety Officer, or designee, will consult with the declared pregnant woman; discuss with her any adjustment of working conditions that may be required and obtain her written authorization prior to discussing such adjustments with her supervisor.

The employment status of the declared pregnant woman is explicitly protected. Article 175 states that: *“No licensee, registrant, or contractor or subcontractor of a licensee or registrant shall discharge or in any manner discriminate against any worker because...of the exercise by such worker on behalf of such worker or others of any option afforded by this Code”*. A notice of alleged violation of this or any other requirement of Article 175 may be filed in writing with the City DOH, which is empowered to inspect the licensee and levy penalties if a violation is determined to exist.

ALARA review of the declared pregnant woman’s Personal Radiation Dosimetry Report will be performed on a monthly basis to avoid a monthly exposure of more than 0.5 mSv (0.05 rem). Records will be kept in the form specified above. The declared pregnant woman will be notified in writing if her monthly radiation dose exceeds the 0.05 rem (0.5 mSv) ALARA level and an appropriate ALARA investigation will be performed.

A Radiation Safety Officer will advise each pregnant worker annually of the worker’s exposure to radiation and will furnish a report of the worker’s (or former worker’s) exposure to sources of radiation at any time upon written request. This report will include fetal exposure if the worker has been issued a separate dosimeter.

Chapter VIII: Receipt of Packages Containing Radioactive Materials

A. Packages Delivered to a Radiation Safety Program Office

Packages containing radioactive materials received at a Radiation Safety Program office will be surveyed by Radiation Safety Program personnel as described in Article 175.03(j). Briefly, the external surfaces of the packages will be monitored for radiation levels and the exterior surfaces and interior packing wiped for removable contamination. The package will also be inspected for damage or evidence of leakage. A Radiation Safety Officer will be notified immediately if one or more of the following conditions are noted:

- Damage to the package;
- Radiation levels at 1 meter exceed 10 mR/hr or 200 mR/hr at the surface; or
- Removable contamination exceeds 22,000 **disintegrations** per minute (dpm)/100 cm²

This survey will be completed as soon as possible after receipt, but no later than three hours of initial receipt of the package.

B. Packages Received by Other Recipients

Packages not received by applicable Radiation Safety Program office must be surveyed as described above and the results either recorded in a log for later review or directly communicated to a Radiation Safety Program office. Records must be maintained and are subject to audit by Radiation Safety Program personnel.

Chapter IX: Safe Use of Radioactive Material and Radiation-Generating Equipment

A. Radioactive Materials

- Prior to performing an operation with quantities of radioactive material that may produce significant external or internal exposure, the user must consider using precautionary measures such as remote handling devices, hoods, shielding, interlocks, etc. A Radiation Safety Officer must be consulted before beginning any new use of radioactive material.
- Eating, drinking, smoking, application of cosmetics, manipulation of contact lenses or storage or preparation of food in any location where radioactive materials are used or stored is prohibited.
- Food, drink or personal effects may not be stored with radioactive materials.
- Pipetting of radioactive materials by mouth is prohibited.
- Eye protection, lab coats and disposable gloves, as well as long pants or long skirts or dresses and closed-toe shoes, must be worn during operations involving the handling of unsealed sources of radioactive material. The lab coat and gloves should be removed before leaving the laboratory. Care must be taken such that other items (i.e., pens, pencils, notebooks, doorknobs, telephones, etc.) are not handled with gloves used during work with radioactive materials.
- Work that may result in contamination of work surfaces should be performed in such a manner so as to minimize the generation of any low-level radioactive waste and still provide for ease of decontamination. Trays made of impervious material (i.e., stainless steel, porcelain-coated, etc.) as well as plastic-backed absorbent paper provide excellent work arrangements to help prevent the spread of contamination.
- Work surfaces and personnel should be monitored for contamination before, during and after working with radioactive materials.
- Where there has been a spill of radioactive material that may have produced personal contamination or contamination of clothing, both the person and the clothing must be monitored and decontaminated as soon as possible.
- When contamination above 200 dpm/100 sq cm is discovered, decontamination must be initiated immediately by the user. See [Chapter XVII: Emergency Spill Procedures](#).
- After working with unsealed sources of radioactive material, hands should be monitored and washed before leaving the laboratory, eating or smoking.
- Objects and equipment that may have been contaminated with radioactive material must be surveyed and demonstrated to be free of contamination prior to their removal from the laboratory, or transferred to other laboratories, repair shops, surplus, etc. If found to be contaminated, such items must be decontaminated as soon as practical.
- All equipment and radioactive material use areas to be repaired, maintained, or visited by a vendor, supplier, or other non-Columbia personnel shall be surveyed and decontaminated as needed to below 200 dpm/100 sq cm PRIOR to allowing the non-Columbia personnel access. This survey shall be documented by the laboratory and kept in the lab's yellow Radiation Safety binder for inspection by Radiation Safety Program personnel or inspecting agencies.
- Radioactive waste may be disposed of only in the manner designated by Radiation Safety Program personnel and records maintained as instructed.
- Radioactive materials should be stored in covered containers plainly identified and labeled with the name of the compound, radionuclide, date, activity and radiation level (if applicable).

- When transporting radioactive materials between laboratories or buildings, use strong and tight shielded containers.
- Transport of radioactive materials in your personal vehicle or on public transportation is prohibited.

B. Radiation-Generating Equipment

1. Types of Equipment:

Radiation-generating equipment includes the following:

- X-ray machines or any other device designed to accelerate particles through an electric field or by means of a radiofrequency oscillator. These include:
 - Linear accelerators
 - Diffractometers, x-ray crystallography devices, or x-ray fluorescence equipment
 - Transmission electron microscopes
 - Cyclotrons
 - X-ray irradiators
- Devices containing sealed sources of radioactive materials. These include:
 - Radioisotope irradiators
 - Sources containing alpha-emitting radionuclides (i.e., Am-241 or Pu-238) mixed with beryllium to produce neutrons
 - Cf-252 sealed sources designed to produce neutrons
 - Gas chromatograph/mass spectrometers containing radioactive sources (i.e. Ni-63)
 - X-ray fluorescence devices
 - Mossbauer spectrometers
 - Neutron generators

2. Purchase and Installation of Equipment

All purchases of radiation-generating equipment and all changes in such equipment must be approved by a Radiation Safety Officer in advance.

For such equipment, the Radiation Safety Officer will, prior to installation, determine if and how much shielding is required and prior to putting the equipment into service, the Radiation Safety Officer must conduct an evaluation to determine if limits on operations and/or personal dosimetry is required.

All personnel must receive training specific to the equipment to be used prior to use. It is the responsibility of the owner/operator of the equipment to provide this training. At a minimum, the training should include:

- Theory of operations;
- Normal and emergency operating procedures;
- Function of installed safety devices such as interlocks;
- Requirements for personal protective equipment and radiation dosimeters, if applicable;
- and
- Any routine maintenance suggested or required by the manufacturer.

Chapter X: Clinical Radiation Safety

In addition to the policies and procedures described above, the safe use of radioactive materials and radiation-generating equipment for clinical use is governed by the following policies and procedures.

A. Safe Use of Radioactive Materials for Clinical Use

Individuals working with radiopharmaceuticals have a responsibility to take all reasonable precautions to protect patients, members of the general public, their colleagues and themselves from unnecessary exposure to ionizing radiation. The guidelines listed below represent general guidance for individuals using radiopharmaceuticals at Columbia, NYP and NYSPI.

- Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used;
- Wear disposable gloves at all times while handling radioactive materials;
- Either after each procedure or before leaving the area, monitor hands and feet for contamination in a low-background area using an appropriate survey instrument;
- Use syringe shields for reconstitution of radiopharmaceutical kits and administration of radiopharmaceuticals to patients, except when their use is contraindicated (e.g., recessed veins, infants). In these and other exceptional cases, use other protective methods, such as remote delivery of the dose (e.g., use a butterfly needle);
- Use appropriate shielding to reduce exposure to staff, patients and visitors;
- Do not eat, store food, drink, smoke, manipulate contact lenses or apply cosmetics in any area where radioactive material is stored or used;
- Do not bring anything you intend to eat, drink, smoke or apply as a cosmetic into an area where radioactive material is stored or used;
- Wear personnel monitoring devices, if required, at all times while in areas where radioactive materials are used or stored. These devices shall be worn as prescribed by a Radiation Safety Officer. When not being worn to monitor occupational exposures, personnel monitoring devices shall be stored in the work place in a designated low-background area;
- Wear extremity dosimeters, if required, when handling radioactive material;
- Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles;
- Never pipette by mouth;
- All areas where unsealed radionuclides are being received, handled or stored must be surveyed daily. The following surveys must be performed:
 - Wipes for removable contamination;
 - Meter surveys for fixed contamination; and
 - Area surveys in mR/hr for gamma radiation levels;
- Radiopharmaceutical multi-dose diagnostic and therapy vials must be properly labeled;
- Syringes and unit dosages must be labeled. Mark the label with the radionuclide, the activity, the date for which the activity is estimated, and the kind of materials (i.e., radiopharmaceutical). To avoid mistaking patient dosages, label the syringe with the type of study and the patient's name;
- For prepared dosages, assay each patient dosage in the dose calibrator (or instrument) before administration;
- Do not use a dosage if it does not fall within the prescribed dosage range or if it varies more than $\pm 10\%$ from the prescribed dosage, except as approved by a Clinical Authorized User;

- When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle;
- Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering;
- Check that the physician ordering administration of the radiopharmaceutical is a Clinical Authorized User. A list of Clinical Authorized Users is posted on the Radiation Safety web site at <http://www.ehs.columbia.edu/RadiationPhsicians.html>;
- Always keep radioactive solutions, flood sources, syringes, waste, and other radioactive material in shielded containers that are clearly labeled; and
- Secure all licensed material when not under constant surveillance and immediate control.

B. Safe Use of Sealed Sources

Radioactive material is often used in the form of a sealed source. These sources are used as both therapeutic agents and as calibration tools. These sources are employed in Nuclear Medicine, Nuclear Cardiology, Positron Emission Tomography, Radiation Oncology, Transfusion Services and Radiation Safety.

The risk of exposure to radiation is still present with sealed sources. Individuals handling sealed sources must wear finger ring dosimeters in addition to whole body dosimeters.

Sealed sources must be secured against theft or loss when not in use. If you see a sealed source where it does not belong, contact the applicable Radiation Safety Program office immediately.

C. Safe Use of Radiation-Generating Equipment

Radiation-generating equipment is any piece of equipment which can produce ionizing radiation. Examples include radiography and mammography equipment, CT scanners, fluoroscopy equipment and linear accelerators. This equipment can produce x rays for diagnosis or therapy. Linear accelerators also produce high energy electrons for therapy.

Regardless of the type or use of this radiation-generating equipment, basic radiation safety principles apply:

- Operators must be trained and certified to use radiation producing equipment;
- The principles of time, distance and shielding apply to operation of radiation producing equipment: (i) reduce the time the equipment is energized and producing x rays; (ii) move as far away from the source of the radiation as possible during operation; and (iii) employ shielding;
- Personal protective equipment (PPE) should be utilized, including lead aprons and lead safety glasses, as appropriate. Lead aprons must be worn when standing within six feet of radiation producing equipment when in use. Within three feet, a thyroid shield is required. It is the responsibility of the individual department to maintain an adequate supply of PPE;
- Fixed shielding shall be provided prior to installation or initial operation of radiation-generating equipment when the need is documented by a Radiation Safety Officer; and
- Portable shields may also be used to provide local protection.

D. Quality Assurance

Departments or divisions conducting medical imaging procedures using radiation-generating equipment or radioactive materials or using radiation-generating equipment or radioactive materials for therapeutic

purposes shall adopt written quality assurance procedures in accordance with the requirements of Article 175 and applicable local, state and federal regulations. These procedures are contained in the New York Presbyterian Hospital Radiation Quality Assurance Manual. The goal of these procedures is to ensure the equipment provides quality images and to ensure radiation doses to patients and staff are maintained ALARA at all times.

Testing and inspections required by these procedures may be overseen by a medical physicist licensed in the appropriate discipline by the State of New York under the provisions of Article 166 of the New York State Education Law.

E. Radiation Safety Compliance Audits

A Radiation Safety Officer will conduct routine audits of clinical departments, facilities or groups covered by this Manual to ensure compliance with its provisions.

F. Radioactive Waste

Most radioactive waste generated from clinical imaging or therapy is short-lived (i.e., less than 90 day half-life) and can be held for decay in storage. Containers and bags should be surveyed for detectable activity with an appropriate survey instrument prior to disposal. See **Chapter XII(C)(3): Radioactive Waste Disposal: Radioactive Waste Guidelines: Decay-in-Storage Guidelines.**

If the material cannot be held for decay in storage at the point of generation, contact the applicable Radiation Safety Program office for assistance.

G. Death or Surgery of a Patient Containing Radioactive Material

In the case of the death of a patient who has been administered radioactive material, a distinction is made between radioactive material administered for diagnostic studies and patients who have been administered radioactive material for therapeutic purposes.

1. Death

a. Diagnostic Amounts of Radionuclides

- There are no special precautions beyond standard precautions for the handling of a deceased patient with residual radioactivity from a diagnostic study.
- Individuals handling the body should protect themselves from exposure to body fluids by wearing disposable gloves and an outer garment such as a laboratory coat or an isolation gown.
- The body may be released to the family or funeral home without restrictions

b. Therapeutic Amounts of Radionuclides

- The Clinical Authorized User, the physician in charge of a patient and a Radiation Safety Officer must be notified immediately upon death.
- An autopsy will be performed only after consultation and permission from a Radiation Safety Officer. The Radiation Safety Officer will evaluate the radiation hazard(s), direct personnel in safety and protection, and suggest suitable procedures in order to keep doses ALARA during the autopsy.

- Protective eye wear should be worn by the pathologist and assisting staff for protection from possible splashing of radioactive material. Consider the need for protection against exposure from high-energy beta particles in cases involving therapy with P-32, Y-90 and Sm-153.
- Remove tissues containing large activities early to help reduce exposure of autopsy personnel. Shield and dispose of contaminated tissues in accord with license conditions. In some cases, exposure reduction may be accomplished by removing tissues for dissection to a location where the exposure rate is lower.
- If an injury occurs during the autopsy that results in a cut or tear in the glove, monitor the wound and decontaminate as appropriate to the situation; inform a Radiation Safety Program staff member.
- The body will be released to the family after consultation with a Radiation Safety Officer. Written instructions from the Radiation Safety Officer may be necessary to ensure the safety of funeral home personnel.
- If more than 5 mCi of radioactive materials remains in the body, the New York City Health Department must be notified immediately.

2. Surgery

For a patient who has been administered radioactive material who requires surgery, there is an important distinction between radioactive material administered for diagnostic studies and patients who have been administered radioactive material for therapeutic purposes.

a. Diagnostic Amounts of Radionuclides

- There are no special precautions beyond standard precautions for the handling of a patient with residual radioactivity from a diagnostic study.
- Individuals involved in the surgical procedure should protect themselves from exposure to body fluids by wearing disposable gloves and an outer garment such as a surgical gown, laboratory coat or an isolation gown.
- Bodily fluids should all be handled in a routine manner – i.e. blood-soaked pads should be disposed in red bags, urine may be flushed down the toilet.

b. Therapeutic Amounts of Radionuclides

- A Radiation Safety Officer, the Clinical Authorized User and the referring physician should be notified as soon as possible.
- If emergency surgery is performed within the first 24 hours following the administration of Iodine-131 sodium iodide, fluids (e.g., blood, urine) should be carefully removed and contained in a closed system.
- Protective eye wear must be worn by the surgeon and any personnel involved in the surgical procedure for protection of the eyes from possible splashing of radioactive material and exposure from beta radiation (if applicable).
- The Radiation Safety Program staff will direct personnel in methods to keep doses ALARA during surgical procedures.
- If an injury occurs during surgery that results in a cut or tear in the glove used, the individual involved will be monitored to determine if radioactive material was introduced into the wound. Inform a Radiation Safety Program staff member of any possible radiation hazard.
- In the case of brachytherapy, the radioactive sources should be removed from the patient prior to surgery by the Clinical Authorized User.
- If the brachytherapy sources cannot be removed, a Radiation Safety Officer must be consulted.

H. Medical Events

It is the goal of the University to maintain the highest possible standards in the protection of patients from improper application of radiation or radioactive material. A medical event can occur when a patient is administered a radiopharmaceutical or radiobiologic. An event can also occur during the performance of external beam treatments or brachytherapy procedures.

A medical event can take many different forms. The following scenarios are considered medical misadministrations:

- A radiopharmaceutical, radiobiologic or radiation from a source other than the one ordered;
- A radiopharmaceutical, radiobiologic or radiation to the wrong person; or
- A radiopharmaceutical, radiobiologic or radiation administered by a route other than the route prescribed by the authorized physician; or
- A radiopharmaceutical, radiobiologic or radiation administered to a part of the body other than the part of the body specified by the authorized physician; or
- An activity of a diagnostic radiopharmaceutical or radiobiologic differing from the prescribed activity by more than 50%; or
- An activity of a therapeutic radiopharmaceutical or radiobiologic differing from the prescribed activity by more than 10%; or
- A therapeutic radiation dose from any source other than a radiopharmaceutical, radiobiologic or brachytherapy source such that errors in computation, calibration, time of exposure, treatment geometry or equipment malfunction result in a calculated total treatment dose differing from the final prescribed total treatment dose ordered by more than 10%; or
- A therapeutic radiation dose from a brachytherapy source such that errors in computation, calibration, treatment time, source activity, source placement or equipment malfunction result in a calculated total treatment dose differing from the final prescribed total treatment dose ordered by more than 10%; or
- A therapeutic radiation dose in any fraction of a fractionated treatment such that the administered dose in the individual treatment or fraction differs from the dose ordered for that individual treatment or fraction by more than 50%.

A Radiation Safety Officer must be notified immediately when a medical event is known or suspected. The Radiation Safety Officer will conduct an investigation, determine a root cause if possible and recommend corrective and preventative actions necessary to prevent a reoccurrence. The Radiation Safety Officer is responsible for informing appropriate regulatory agencies.

Chapter XI: Contamination and Radiation Surveys of Laboratories Using Radioactive Materials

All laboratories where radionuclides are used in unsealed form must be surveyed and documented by laboratory personnel every month when radioactive materials are used during such month. Clinical areas such as Nuclear Medicine, Nuclear Cardiology and the PET Center must be surveyed and documented on a weekly basis.

Surveys during and following each use of radioactive materials are required as stated in **Chapter X(A)**. These surveys should concentrate on the areas and equipment in which radioactive materials were used, as well as surveying hands and body. Note that these surveys need not be documented, but serve to provide early detection of contamination.

Monthly surveys performed by the laboratory will be specific to that laboratory as listed in the special conditions of the Authorized User's permit. In addition to radioactive material work areas, the survey should include a sampling of areas throughout the laboratory or area where radioactive materials are used or stored, including waste areas. Negative results should be clearly indicated. These surveys must be documented by indicating the sample locations on an accurate map of the laboratory.

Surveys need not be performed when radioactive materials in unsealed form have not been used in a calendar month. However, documentation should be provided stating that a survey was not required. Acceptable documentation includes written log book entries or written notation on the lab map "No RAM used this month." Each such entry should be signed and dated by the person making the "no use" statement.

A. Surveys

The following surveys are to be performed monthly. Note that a fixed contamination survey should be performed first to determine if wipe testing is needed for certain isotopes:

- 1. Fixed contamination surveys:** For isotopes that emit medium to high energy betas during decay (i.e., P-32, P-33, Sr-90, etc.), a survey with a Geiger Mueller (**GM**) detector should be performed first. If contamination is detected at 200 dpm per 100cm² or more above levels, the area should be wiped clean, or the item disposed of as radioactive waste. [**Handbook requires decontamination**] If no contamination at 200 dpm or more above background is found then a wipe survey is NOT required. [**Note: GM detectors are not suitable for H-3, C-14, or S-35 because of low detection efficiency (< 10%).**] Isotopes emitting gamma or x rays (F-18, Na-22, Cr-51, I-125, I-131, Cs-137, etc.) require the use of a NaI(Tl) detector. Record readings in dpm using the appropriate correction factor(s) found on the calibration sticker for each instrument.
- 2. Wipe tests:** All areas should be surveyed for removable contamination by wiping sample locations with a small piece of filter paper, Q-tip or other suitable material. For H-3, it is required that these wipes be counted on a liquid scintillation counter (**LSC**). For C-14, S-35 or other low energy beta emitters, either a LSC or a low energy beta solid state scintillator detector should be used for counting. Record the results in dpm using the efficiency for your particular detector.
- 3. Radiation field surveys:** Laboratories using gamma-emitting isotopes must conduct surveys for ambient radiation level. An ion chamber survey meter with a sensitivity to detect 0.1 mR/hr is the appropriate instrument for these surveys. Readings should be recorded in mR/hr or mrem/hr. [**Note: Do not use GM detectors for these surveys – they are not calibrated for accurate mR/hr readings**]

B. Action Levels

Small amounts of contamination will be unavoidable at times, but the degree of such contamination should be kept as low as possible. Laboratory personnel should take immediate action when removable contamination is detected at 200 dpm or more above background levels or a GM meter scan indicates levels more than 2 times background.

Ambient radiation levels above 1 mR/hr or 1 mrem/hr (0.01 mSv/hr) should be addressed by adding appropriate shielding. Any area where radiation levels meet or exceed 5 mR/or 5 mrem/hr (0.05 mSv/hr) at one foot from the source must be posted with a “CAUTION – RADIATION AREA” sign.

C. Record Retention

Monthly survey reports must be retained for a period of three years. These reports are subject to inspection by Radiation Safety Program personnel during laboratory or clinical area audits as well as by regulatory inspectors.

Chapter XII: Radioactive Waste Disposal

A. Waste Minimization

The University is committed to public health and safety and the environment by ensuring that radioactive material users avail themselves of all opportunities to produce the least amount of radioactive waste. The goal is accomplished by minimizing the use of radioactive sources, reducing the amount of waste requiring treatment, storage and disposal, avoiding unnecessary uses of radioactive materials, and considering non-radioactive alternatives when available. The waste minimization program is consistent with the promotion of responsible research and innovation.

Radioactive waste material is characterized so as to reduce disposal liabilities and conserve disposal capacity. Opportunities will be identified to achieve source minimization, volume minimization and storage for decay. These opportunities include avoiding unnecessarily contaminating items while using radioactive materials, segregating radioactive waste from non-radioactive trash, avoiding generating mixed waste and identifying the objective of substituting short-lived radionuclides or non-radioactive materials for long-lived radionuclides, where possible.

B. No Drain Disposal

To minimize the effect on the environment, radioactive materials used in laboratories should never be disposed of by release to a sanitary sewer.

Exceptions to this rule include patient excreta containing radioactive materials administered for diagnosis or therapy. Other exceptions may be made by the Radiation Safety Officer on a case-by-case basis in a document signed by the Radiation Safety Officer. Any exceptions may be amended or revoked at any time for cause.

With the exception of the patient excreta exemption, records must be maintained for all discharges.

C. Radioactive Waste Guidelines

Only radioactive materials that are on an Authorized User's permit may be discarded through EH&S. If the material is not listed, the applicable Radiation Safety Program office should be contacted. Radioactive wastes must be segregated by Authorized User, isotope, and type of radioactive waste. All radioactive waste must be labeled upon collection of the first item. Liquid constituents must be listed on the label (e.g., type of liquid scintillation fluid used or components of aqueous or mixed wastes).

1. By Authorized User:

Radioactive isotope usage is tracked by an Authorized User. Therefore, in common-use rooms, radioactive wastes must be kept separated from other Authorized Users' wastes, even if they are of the same type.

2. By Isotope:

Long-lived isotopes (ex. H-3 and C-14) may be consolidated in the same collection container provided they are the same type of waste and generated under the same Authorized User. EH&S should be consulted for guidance regarding other long-lived isotopes.

Short-lived isotopes, including any material with a half-life or less than 90 days, must be:

- Separated from each other whenever possible;
- Segregated from long-lived isotopes; and
- Held for decay-in-storage by the lab or EH&S. After decay and clearance, all radioactive labels and markings must be completely defaced or removed prior to disposal in the waste collection container.

3. Decay-in-storage guidelines:

A log with collection dates, activities, and isotopes must be maintained by the Authorized User.

EH&S can provide space for decay-in-storage upon request, if necessary. A request is made by submitting a [radioactive waste pickup request](#).

The radioisotopes must have a half-life of less than 90 days. The minimum required storage time is 10 half-lives of the isotope being decayed. The amount of activity remaining after ten half-lives is approximately 1/1000 of the original amount.

If more than one isotope is commingled in the waste, it must be stored for a minimum of 10 half-lives of the slowest decaying component. After the waste has been stored for at least 10 half-lives, the waste must be checked for any radioactivity using the appropriate survey device at the lowest scale. The reading must be the same as the background level and all results must be recorded.

After decay, the waste should be disposed of as non-radioactive waste through EH&S. All radioactive labels must be removed or destroyed before discarding the items. Final clearance must be completed by EH&S.

4. By Radioactive Waste Type:

Every effort must be made to minimize waste volumes. Accordingly, each type of radioactive waste must be separated. Animal/biological, beta plates/96-well plates, dry solid waste, liquid scintillation vials, liquid waste must be separated from each other. See the following guidelines for disposal of several common radioactive waste streams.

a. Animal /Biological

- EH&S arranges periodic shipments of radioactive animal carcasses through an email communication to Authorized Users. Additionally, if a lab generates radioactive animal carcasses, advance notification may be made by submitting a [radioactive waste pickup request](#).
- Radioactive carcasses must be frozen prior to pick-up by EH&S.
- Radioactive carcasses containing isotopes with half-lives of less than 90 days must be held for a minimum of 10 half-lives by the lab for decay-in-storage (see **Section 3: Decay-in-Storage Guidelines** above). After decay, the lab should submit a request for clearance by emailing rsotech@columbia.edu.
- Radioactive carcasses with half-lives of greater than 90 days with an activity of greater than or equal to 0.05 uCi/g averaged over the weight of the animal must be arranged for disposal by EH&S by submitting a [radioactive waste pickup request](#).
- Animal bedding and feces may be disposed of as biological radioactive waste by submitting a [radioactive waste pickup request](#).

- Red bags must only be used for potentially infectious materials, and not as a general liner for a radioactive waste container or for radioactive spill debris.

b. Beta Plates/96-well Plates

- Beta Plates/96-well plates may be contained in 5, 14 or 30 gallon containers supplied by EH&S. Additional containers, and container removal can be arranged by submitting a [radioactive waste pickup request](#).
- Waste collection containers must be closed when not actively adding radioactive waste to the container.
- Scintillation fluids with a pH ≤ 2 or ≥ 12.5 or with a flash point $< 140^\circ\text{F}$ generate potentially mixed wastes and must be avoided whenever possible. Contact EH&S for guidance prior to using corrosive or low flash point scintillation cocktails.

c. Dry Solid Waste

- No bulk liquids (i.e. more than incidental remaining liquids or liquids over 5 ml), sharps, radioactive standards or sources are permitted.
- Radioactive sharps (pipette tips, needles etc.) must be discarded in a rigid, puncture resistant container. The outer container must be marked “SHARPS” in addition to the completed radioactive waste label.
- Plastic pigs that previously contained radioactive materials may be placed in dry solid waste containers. Any markings or labels indicating the presence of radioactivity must be removed or defaced prior to disposal. Lead pigs must be collected for recycling separately from all other radioactive waste types and may not be placed in dry solid waste containers. Please contact hazmat@columbia.edu for additional guidance on lead pigs.

d. Liquid Scintillation Vials (LSV)

- LSV waste may be contained in 5 gallon or 30 gallon containers supplied by EH&S. Additional containers and container removal can be arranged by submitting a [radioactive waste pickup request](#).
- Waste collection containers must be closed when not actively adding liquid to the container.
- The liquid scintillation fluid must be listed on the label.
- Liquid scintillation standards must not be placed in radioactive waste collection containers. A completed radioactive waste label must be affixed to a clear plastic bag and a [radioactive waste pickup request](#) submitted for disposal.
- Vials must be intact with caps securely in place.
- Scintillation fluids with a pH less than or equal to 2 or greater than or equal to 12.5 or with a flash point less than 140°F generate mixed wastes and must be avoided whenever possible. Contact EH&S for guidance prior to using corrosive or low flash point scintillation cocktails.

e. Liquid Waste

- Liquid waste may be contained in 10- or 20-liter carboy containers supplied by EH&S. Additional containers and container removal can be arranged by submitting a [radioactive waste pickup request](#).
- Waste collection containers must be closed when not actively adding liquid to the container.
- List the pH of the radioactive liquid waste on the radioactive waste label, if available.

- Secondary containment trays must be used.
- All chemical components, including the type of buffer, must be listed on the **chemical constituents** section of the radioactive waste label.
- Hazardous Waste must **not** be mixed with radioactive liquid waste, whenever possible. (Examples: tritiated benzopyrene in ethyl acetate, P-32-labeled GTP in chloroform, etc.)
 - There should be no generation of mixed waste without the prior notification to EH&S and the applicable Radiation Safety Program personnel.
 - Do not mix iodine waste with acids or oxidizers.
- See the No Drain Disposal policy above.

Chapter XIII: Security of Radioactive Materials

A. General Statement

Radioactive materials must be secured when not in use or otherwise left unattended. Because radioactive material stock bottles/vials represent the greatest concentration of radioactive material, these materials must be properly stored in a locked container, cabinet, freezer or refrigerator, room or other secure location to prevent unauthorized access or removal. Radioactive material aliquoted from a stock vial into an experiment represents much less of a hazard and is exempt from the security requirements.

B. Radioactive Materials in Quantities of Concern

The NRC has determined that certain radionuclides pose a threat to the health and safety of the public if deliberately released. Therefore, heightened oversight to better control these sources has been ordered by the NRC and the New York City Commissioner of Public Health.

The following radionuclides and/or sources are subject to this Order:

Radionuclide	Quantity of Concern (TBq)	Quantity of Concern (Ci)
Am-241	0.6	16
Am-241-Be	0.6	16
Cf-252	0.2	5.4
Cm-244	0.5	14
Co-60	0.3	8.1
Cs-137	1	27
Gd-153	10	270
Ir-192	0.8	22
Pm-147	400	11,000
Pu-238	0.6	16
Pu-239/Be	0.6	16
Ra-226	0.4	11
Se-75	2	54
Sr-90 (Y-90)	10	270
Ym-170	200	5,400
Yb-169	3	81

Pursuant to the provisions of this order, the following policies have been developed and implemented:

1. Limited Access

Only trustworthy and reliable individuals who have a job-related need may have unescorted access to radioactive materials in quantities of concern. Individuals without such approval may only access the restricted areas if accompanied by someone who has unescorted access. An individual's trustworthiness and reliability may be established by verifying employment history, education and personal references. Unescorted access may be granted to employees with more than three years employment with the licensee.

The basis for concluding that there is a reasonable assurance that an individual granted unescorted access is trustworthy and reliable should be documented in writing. Lists of personnel who have been approved for unescorted access must be maintained. These lists will be modified as appropriate when personnel are either added or removed.

Individuals granted unescorted access privileges are required to complete annual refresher training in Rascal. The TC2500 course, *Increased Control of Radioactive Materials and Unescorted Access*, should be completed every 12 months. Failure to renew this training in a timely fashion will result in termination of access privileges until the training has been completed.

Employees of manufacturing and distribution licensee service providers should be escorted unless determined to be trustworthy and reliable by a NRC or City DOH required background investigation and written verification attesting to or certifying the person's trustworthiness and reliability should be obtained from the manufacturing and distribution licensee providing the service.

Security devices should be changed out as quickly as practical when their physical security may be subject to compromise.

2. Monitoring

Appropriate physical security equipment, devices and procedures should be purchased, developed and deployed to monitor access, detect unauthorized individuals attempting to gain access to these materials, and initiate the appropriate response.

Each time unauthorized access to radioactive material is detected, the incident must be documented, including the details of the unauthorized access event as well as the corrective action taken to prevent recurrence in the future. These records should be maintained for inspection for a minimum of three years.

3. Record Retention

The following documentation should be retained for three years:

- Documentation regarding trustworthiness and reliability
- Purchase and transfer of irradiators with high energy sources
- Any maintenance done on any irradiators
- Calibration and isodose curves

4. Information Protection

Each individual who produces, receives, or acquires the licensee's sensitive information should be notified of the need to protect the information from unauthorized disclosure. Special care should be taken to ensure the protection of sensitive information during use, storage and transit. Unnecessary documents with sensitive information should be shredded. Integrity of electronic documents should be maintained and purged from computer systems before being discarded.

Chapter XIV: Audit and Enforcement of Regulations, Policies and Procedures

A. Audits

Radiation Safety Program personnel or any city, state or federal agency charged with regulation of radioactive material or radiation-generating equipment may, at any time, inspect the facilities and activities covered by the Radiation Safety Program.

The Radiation Safety Officers are responsible for monitoring each Authorized User. For Non-Clinical Authorized Users, monitoring includes but is not limited to: quarterly audits of laboratory activities to review lab practices, waste handling and storage, staff training, sealed source inventories and other relevant items. During these audits, the Authorized User should make available all required records and documents and should assist the Radiation Safety Officer or designated inspector as necessary. Audits may be scheduled in advance, but a Radiation Safety Officer may conduct unannounced inspections at any time.

For Clinical Authorized Users, monitoring includes but is not limited to: auditing of records of administration of radioactive materials for diagnostic or therapeutic purposes, quality assurance policies and procedures and checks of diagnostic imaging and therapy equipment, licenses and training records.

The Radiation Safety Program personnel conducting the audit should advise the Authorized User when an inspection determines that practices violate regulations or University policies.

The Authorized User must respond in writing within the time frame designated by the auditor. The response should describe the circumstances surrounding the violation and the corrective actions taken to prevent its reoccurrence.

Willful disregard or refusal to follow radiation safety regulations, policies or procedures will be reported by a Radiation Safety Officer to the applicable RS Committee for appropriate action. Accumulation of multiple violations may result in the Chief RSO placing the Authorized User on probation until satisfactory corrective actions are taken. Additional violations may result in suspension of radioactive materials use privileges by the applicable RS Committee.

The Chief RSO may suspend, modify or revoke any Authorized User's privileges to use radioactive material when the actions of the Authorized User or his/her subordinates present an unacceptable risk to the health or safety of faculty, students, staff or visitors, to University property or to the environment, or jeopardize the University's licenses.

An Authorized User who has been placed on probation or suspension or whose privileges are modified or revoked may appear at the next scheduled meeting of the applicable RS Committee to appeal the enforcement action or request an immediate special session of the of applicable RS Committee to consider such an appeal.

B. Violations

The following audit findings are serious deviations from regulations and/or policies or procedures and must be addressed immediately by the Authorized User:

- Lack of, or inappropriate security for, stock vials

- Eating, drinking, or food storage in radiologically posted laboratory space
- Use of radioactive materials by untrained personnel
- Use of radioactive materials in an unposted lab, room, or other unpermitted space
- Radioactive contamination in excess of 5,000 dpm/100 cm² in a posted area
- Radioactive contamination in excess of 1,000 dpm/100 cm² in any unposted area
- Unauthorized receipt, transfer or shipping of radioactive materials
- Loss of radioactive materials
- Evidence of internal exposure of radioactive materials resulting from abnormal incidents
- Failure to wear required radiation dosimetry
- Wearing a dosimeter assigned to another individual
- Radioactive materials in nonradioactive waste containers
- Evidence of liquid radioactive waste disposal into laboratory sinks
- Persons using radioactive materials while person or laboratory is under suspension
- Unlabeled contaminated laboratory equipment
- Failure to wear proper PPE
- Failure to participate in required bioassay programs (if appropriate)
- Failure to perform and document monthly radioactive contamination surveys during months in which radioactive materials were used
- Fume hood or other engineering controls not operational when required for protection of personnel during work with radioactive materials
- Pipetting by mouth

C. Deficiencies

The following audit findings represent problems that, if left unaddressed, could result in a violation:

- Evidence of eating or drinking in a radiologically posted room (i.e., presence of candy wrappers, soda cans, coffee-stained cups, etc.)
- Presence of radioactive contamination more than 1,000 dpm/100 cm² and less than 10,000 dpm/100 cm² in a **posted** room
- Presence of detectable radioactive contamination less than 200 dpm/100 cm² in any **unposted** area
- Survey meter out of calibration or use of inoperable survey meter
- Radioactive check source not available for contamination survey meter
- Incorrect documentation of radioactive materials inventory (i.e., no decay corrections; total activity present in waste plus stock vials does not agree with activity received and not disposed; failure to return inventory verification form)
- Dosimeters not returned in a timely fashion
- Dosimetry reports not available
- Dosimeters worn improperly
- Dosimeters stored improperly when not in use (e.g., in an area where radioactive materials are used or stored)
- Improper waste segregation
- Waste containers overfilled
- Waste containers not capped or sealed when not in use
- Improperly labeled waste containers
- Failure to demonstrate proper radiological survey techniques
- Poor radiological housekeeping

- Improper use of a fume hood, absorbent pads or bench covers not used in radiological work or storage areas
- Failure to post City, State or Federal information notices
- Failure to remove or obliterate radiological symbols from empty containers
- Failure to report a radiological incident (spill, skin contamination, loss of radioactive material, etc.) to Radiation Safety Program personnel within two hours of its occurrence
- Failure to take appropriate immediate actions in the event of radiological emergencies such as spills or skin contamination incidents
- Any other activities that violate City, State or Federal regulations.

Anyone may report to the Chief RSO any conditions or activities that he/she feels may present a risk to human health or the environment, or which may not be in full compliance with city, state or federal regulations. The Chief RSO will immediately initiate an investigation in response to such complaints or report of the misuse of radioactive material, of an unanticipated radiation exposure, or of an activity that is not in full regulatory compliance.

Chapter XV: Inventory Control of Unsealed Sources

The University Licenses specify the type, form (chemical or physical), and maximum possession limits for radioactive materials. It is the responsibility of the Radiation Safety Officers to ensure that these limits and restrictions are strictly adhered to at all times. The Radiation Safety Officers meet this obligation by:

- Reviewing all new requests for radioactive materials. If the type, form and/or quantity are not specified on a current University License, a Radiation Safety Officer, in consultation with the Chair of the applicable RS Committee, will request amendment of the license;
- For research applications, assigning appropriate possession limits to each Authorized User holding a permit to use radioactive materials. To set these limits, the Radiation Safety Officer will take into account the typical use pattern for the types of experiments expected to be performed; and/or
- For clinical applications, review of the use of radioactive materials at least quarterly.

A. Research Applications

The Radiation Safety Program staff member who receives radioactive material partially completes a Radioactive Use and Disposal Log identifying the Authorized User, isotope ordered, date received, amount and the lot number.

The Radiation Use and Disposal Log is the record for the laboratory to keep a running total of the use of the material. For any given isotope, the form permits the user to log in shipments, usage, waste and retained material. The Radioactive Use and Disposal Log must be updated to reflect any receipt or transfer of radioactive material.

Users are required to ensure that they document withdrawal and use of materials on the correct Radioactive Use and Disposal Log for the stock bottle being used. When a stock has been used up or disposed of, the use log is to be provided to the radioactive waste disposal pick-up staff at the time of waste removal.

B. Clinical applications

Departments or divisions authorized to purchase radioactive materials for clinical use must maintain receipt, use and disposal records. These records are subject to audits by Radiation Safety personnel.

Chapter XVI: Inventory and Leak Testing of Sealed Sources

A sealed source is radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions that are likely to be encountered in normal use and handling. Such sources have undergone rigorous testing by the manufacturer and the results have been reviewed and certified by the City DOH, State DOH or the NRC. Only a source that has been certified and issued a Seal Source and Device Registration (**SS&DR**) by one of these agencies is considered to be a sealed source. Without a SS&DR, a source is considered to be unsealed and must be treated as an unsealed source.

Sealed sources will be inventoried by Radiation Safety Program personnel each calendar quarter. Records are maintained by Radiation Safety Program personnel and the individual identified as responsible for the source.

Unless otherwise exempted from testing as described in Article 175.03(e) or 10 CFR, Part 39.35, wipe tests for leakage will be performed:

- Before the source is in placed into service;
- Every six months for sources not designed to emit alpha particles;
- Every three months for sources designed to emit alpha particles; and
- Any time there is reason to suspect that the source had been damaged or might be leaking

Sealed sources containing less than 3.7 MBq (100 uCi) of beta- or photon-emitting material, 370 kBq (10 uCi) or less of alpha-emitting material or only tritium (H-3) need not be leak tested.

Tests for leakage will be capable of detecting 185 Bq (0.005 uCi) of radioactive material in the test sample. The presence of 185 Bq (0.005 uCi) or more of removable contamination will be considered evidence that a sealed source is leaking. The source should immediately be withdrawn from service, stored in a secure location, and a Radiation Safety Officer should be notified immediately. A Radiation Safety Officer will notify the appropriate agency.

Chapter XVII: Emergency Spill Procedures

When a spill occurs, effort should be directed at minimizing personnel exposure and contamination and containing spread of contamination. When spills are associated with other events such as fire or explosion, the risks from radiation exposure may be minimal compared with the risk from other hazards and the need to care immediately for injured personnel.

The following procedures will be useful in the event of a spill or accident.

A. Priorities

- Save lives
- Control severe injuries
- Prevent spread of major fire
- Insure safety of personnel from radiation

B. Procedures (SWIMS)

- **S**top all work. Prevent the spread by covering the spill with absorbent paper;
- **W**arn persons in the area that a spill has occurred;
- **I**solate the area to prevent individuals from entering. Remove all personnel from immediate spill area to safe meeting area in or near the lab;
- **M**inimize further exposure by donning appropriate PPE including two layers of gloves and booties;
- **S**urvey spill area and mark contaminated areas with grease pencil or magic marker or CAUTION – RADIOACTIVE MATERIAL tape

Additional steps:

- Call a Radiation Safety Officer. Let him/her evaluate the spill and decide whether non-Radiation Safety Program personnel may conduct cleanup efforts. It may be necessary for the Radiation Safety Officer to notify and seek assistance from City or State radiation control officials;
- Shut off ventilation, close windows and doors, turn off hoods if possible. *Do not do this if radioactive gas is involved;*
- Begin decontamination efforts, starting with low-level contamination and working towards the center or high contamination areas. Clean up the spill using absorbent paper or pads with the clean side out and place in a plastic bag for transfer to radioactive waste container. For surface decontamination, use soap and water and cleansers appropriate to the compound spilled. Work slowly and deliberately, surveying continuously;
- Check all personnel for skin and/or clothing contamination with an operable survey instrument;
- Remove contaminated clothing;
- Decontaminate personnel and resurvey;
- Wear double gloves and protective clothing including protective shoe covers; and
- Perform a final survey to document that the area has been successfully decontaminated.

Chapter XVIII: Reports to Regulatory Agencies

The following reports are made by Radiation Safety Program personnel:

A. Routine Reports

1. New York State Department of Environmental Conservation

- Airborne emissions from cyclotron operations and clinical and research use of volatile radionuclides; and
- Discharges of radioactive materials to the sanitary sewer, if required

2. U.S. Nuclear Regulatory Commission National Source Tracking System

- Inventory of sources in quantities of concern.

B. As Required by Regulations

The following incidents must be reported by Radiation Safety Program personnel to the appropriate regulatory agency. The timeline for reporting and contents of the report are described in the applicable regulations.

- Medical events from diagnostic or therapeutic procedures involving radioactive materials or radiation-generating equipment;
- Lost, stolen or missing licensed radioactive material or registered radiation-generating equipment;
- Personnel exposure, radiation levels or concentrations of radioactive materials exceeding regulatory limits; and
- Death of a patient containing radioactive materials administered for therapeutic purposes;

Chapter XIX: Survey Instruments and Calibration

Survey instruments must be calibrated by a licensed outside vendor. Instruments requiring calibration should be delivered to the applicable Radiation Safety Program office. Meters are required to be calibrated at least annually and the calibration date and due date are on the label affixed to the meter. Always check that your meter is within the calibration due date prior to use.

If a laboratory GM meter becomes contaminated, contact the Radiation Safety Office to obtain a loaner meter.

If a GM meter becomes inoperable, perform the following:

- Inspect the detector and note if the grey window under the protective screen appears broken.
- If so, contact the applicable Radiation Safety Program Office for a replacement.
- If the detector appears functional, perform a battery check. If the batteries are dead, users may replace their own batteries. The meter does not need recalibration after a battery replacement.
- If the meter is still inoperable after steps 1 and 2, contact the Radiation Safety Program Office for a loaner meter.

For any questions about your survey equipment, contact the Radiation Safety Office.

Chapter XX: Airborne Effluents

Licensed activities that generate radioactive gases, aerosols, dusts or other airborne effluents should be conducted to maintain doses ALARA. In no case will effluents exceed the limits specified in Table 2 of Appendix B to Article 175.03.

Unless specific equipment has been installed to directly measure effluents, the estimates of effluents should be made by calculation. The total activity released to an unrestricted area (activity that is used each week that is released in an exhaust system) is divided by the total volume of air exhausted over the week ("on" time multiplied by measured air flow rate). The quotient must be less than the applicable maximum permissible value for an unrestricted area. If this is not the case, operations should be modified to bring effluent concentrations into conformance with the applicable regulations.

Radiation Safety Program personnel may choose to perform air monitoring inside hoods or at the release point as necessary to demonstrate compliance with limits to unrestricted areas. The instruments used for air sampling will be calibrated in accordance with the standards of general practice used in industrial hygiene air sampling programs.

Procedures involving radioactive gases, aerosols, dusts or other airborne effluents that might produce airborne contaminants must be conducted in a hood, dry box or other suitable closed system.

Hoods designated for radioactive materials use will be maintained in good working order. If the air flow is found to be outside of acceptable standards, the hood will be taken out of service and an appropriate sign affixed warning individuals not to use the hood until it has been repaired. Radioactive material use may not continue until the hood has been repaired or shown to be within proper specifications.

Revision History	
Date	Revisions
December 2012	<ol style="list-style-type: none"> 1. Consolidated Columbia University Medical Center and Morningside radiation safety policies and procedures
March 2015	<ol style="list-style-type: none"> 1. Added Radiation Quality Assurance Subcommittee (RQAS) to list of subcommittees supervised by the JRSC (Chapter I.B.2). 2. Clarified duties of RSO with respect to ALARA notifications and investigations and reporting of doses exceeding regulatory limits (Chapter III.C). 3. Added minors (Chapter VI.E). 4. Added use of RAM off campus and at sea (Chapter IV.A.3). 5. Clarified process for applying for a permit to conduct research involving human subjects exposed to ionizing radiation (Chapter X.H). 6. Added annual refresher training requirement for individuals granted unescorted access to irradiators (Chapter XIII.B.1). 7. Minor editorial and typographical changes.
August 2015	<ol style="list-style-type: none"> 1. Clarified role of RSO in managing radiation protection program in accordance with provisions of Article 175 (Chapter I.B). 2. Added statement that individual appointed to JRSC subcommittees need not be members of the JRSC (Chapter I.B.2). 3. Added statement clarifying that investigators wishing to use radioactive materials in animals and at sea or off campus must have a permit to use radioactive materials issued by the RSO (Chapter IV.A.1, 2 and 3) 4. Modified requirements for issuing dosimetry in accordance with changes in Article 175 – remove requirement for dosimetry if dose could exceed 25 mrem in seven days (Chapter VI.B). 5. Modified requirement for return of dosimeters to 22 business days (Chapter VI.B). 6. Added section on planned special exposures (Chapter VI.G). 7. Added requirement that RSO determine shielding requirements prior to installation of any radiation-generating equipment (Chapter IX.B.2). 8. Minor editorial and typographical changes. 9. Resequenced Chapter IV. , section B, C and D.
November 2015	<ol style="list-style-type: none"> 1. Added statement that RSO shall issue stop work order when DDE readings meet or exceed 4,500 mrem (Chapter III.C).
June 2016	<ol style="list-style-type: none"> 1. Modified lens of the eye dose (LDE) doses to 375 for ALARA I notification and and 750 for ALARA II investigation (Chapter III.C). 2. Deleted entry for extremity alone. Changed ALARA levels for skin and extremities to previous extremity dose.