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A. MEMORANDUM TO ALL RADIATION WORKERS

This fourth edition (July 12, 1996) of the Radiation Safety Code has been developed by the Joint Radiation Safety Committee of the Medical Center to advise all personnel using sources of ionizing radiation of the Medical Center rules and regulations governing their use. The Radiation Safety Code and Guide sets forth the function of the organizational structure for radiation protection and a set of regulations that must be observed by all radiation workers.

Most of the rules incorporated in the Code are restatements of those enacted by local and national government agencies for the control of the use of radioactive materials. The others are designed to facilitate control by the Radiation Safety Committee over activities involving possible radiation hazards. The Committee exercises this control in order to protect individuals and the population at large from radiation damage, both somatic and genetic. All radiation exposures should be kept as low as reasonably achievable (ALARA).

It is important that all personnel whose work involves the use of ionizing radiation familiarize themselves with the contents of this Code and maintain strict adherence to its provisions. Only in this way can we all be assured that each individual engaged in such work will have maximum protection against its hazards with the least interference with teaching, medical and research activities.

B. STAFF AND RAISON D'ETRE

By agreement between Presbyterian Hospital, New York State Psychiatric Institute (NYSPI) and the College of Physicians and Surgeons of Columbia University, an autonomous unit has been established at the Medical Center (CPMC) for the purpose of maintaining radiation safety. The Medical Board of the Hospital and administration of the Health Science Division has appointed the Joint Radiation Safety Committee (JRSC), with the responsibility to define and ensure the enforcement of proper safeguards in the use of sources of ionizing radiation. The Committee has developed this Radiation Safety Code and Guide, the administration of which is assigned to the Radiation Safety Officer.

THE JOINT RADIATION SAFETY COMMITTEE

Dr. Eric J. Hall, Chairman, JRSC, Professor of Radiation Oncology & Radiology
Dr. Philip Alderson, Deputy Chairman, Professor of Radiology
Dr. Howard Amols, Professor of Clinical Radiation Oncology
Dr. Rashid Fawwaz, Professor of Clinical Radiology
Ms. Marianne Glasel, Assistant Professor of Clinical Nursing
Dr. Daniel Goldberg, Professor of Pharmacology
Dr. Donald Kornfeld, Chairman, IRB, Professor of Psychiatry
C. DEFINITIONS

In this Code, the terms "shall" and "must" are used in the obligatory sense. "Should" is used in the permissible sense.

The term "RESPONSIBLE INVESTIGATOR" refers to one who has completed an application for use of radioactive material that has been approved by the Chairman of the Radiation Safety Committee, and who is immediately responsible for the conduct of a research project, teaching program, or clinical procedure involving the use of a source of ionizing radiation. In addition, this individual must attend the Radiation Safety Lecture.

The term "DIRECTOR OF AN INSTITUTE OR A LABORATORY" refers to one who is designated by the University or Hospital Administration as the individual who has immediate supervisory responsibility over all projects conducted within a unified framework or research.

The term "RESTRICTED AREA" means any area access which is controlled by a Responsible Investigator or Director of a Laboratory for purposes of radiation safety.

The term "RADIATION" and "IONIZING RADIATION" refer to the following: alpha and beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other atomic particles; but does not include radio waves, ultrasound, microwaves, visible, infrared or ultraviolet light.

The term "RADIATION WORKER" applies to any person who works with or in the immediate vicinity of a source of radiation. Doubtful cases will be resolved by the Radiation Safety Officer.
D. RESPONSIBILITY FOR RADIATION SAFETY

As indicated above, the legal responsibility for Radiation Safety rests with the corporate entities of the Presbyterian Hospital, New York State Psychiatric Institute and Columbia University. Principal responsibility for compliance with this Radiation Safety Code is with the Chairpersons of Departments, Directors of Services and Directors of Institutes or Laboratories. They must give initial approval for the acquisition and operation of radiation sources and endorse requests for Responsible Investigator status. In areas in which there is a significant level of radiation activities, the Section Head shall appoint a Radiation Safety Coordinator (RSC) who ensures compliance with the Radiation Code. Depending on the interaction between Responsible Investigators and especially their common use of radiation facilities, the Head of the Section may ask the RSC rather than the Responsible Investigators to carry out any of the procedures required. These include:

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The RSC should be familiar with all activities in his or her division that involve radiation, and should inform the RSO of any personnel that need, or no longer need badges. The RSC may be the primary contact between his or her division and the Radiation Safety Officer.

Heads of Sections or Responsible Investigators may develop a radiation safety manual for use with their own area of responsibility. Such a manual shall not be less restrictive than, or inconsistent with, this Radiation Safety Code and Guide, and shall be approved by the Radiation Safety Office.

The Radiation Safety Officer and the staff of the Radiation Safety Office are the executive arm of the JRSC. The responsibilities of the RSO include:

1. Surveillance of operations throughout the CPMC to ensure compliance with the CPMC Radiation Safety Code (hereafter termed "Code").
2. Maintenance of a roster of Responsible Investigators and Radiation Workers.
3. Operation of personnel monitoring (Badge) service and maintenance of bioassay program (thyroid uptake, urine samples, etc.)
4. Control of movement of radioactive sources into and out of the CPMC and of such movement between administrative units in the CPMC.
5. Operation of a centralized waste disposal system.
7. Liaison with regulatory agencies.
8. Advice and assistance in matters of radiation safety. However, this should not include service functions which any individual or group of individuals is required to perform under the terms of Code.
E. PROCUREMENT OF RADIONUCLIDES AND OTHER SOURCES OF IONIZING RADIATION

1. APPROVAL BY THE JOINT RADIATION SAFETY COMMITTEE

Approval by the JRSC is required for the use, acquisition, or manufacture of man-made or concentrated radioactive material and radiation-producing equipment.

2. LICENSES

Licenses issued by the New York City Bureau of Radiological Health are held by the College of Physicians and Surgeons, New York State Psychiatric Institute and Presbyterian Hospital for the purchase, possession, and use of radionuclides. Sources of ionizing radiation shall not be obtained under the authorization of individual licenses.

3. APPLICATION AND APPROVAL OF RESPONSIBLE INVESTIGATOR (R.I.) STATUS

a. Human Use
Complete the Human Use Application and attach copies of: your curriculum vitae, copy of Board Certification and copy of New York State Medical License. (Form #5) Submit Documents to the Radiation Safety Office. Notification of your approval will be sent to you.

b. Non-Human Use
Complete Non-Human Use Application (Form #6) and attach a copy of your curriculum vitae. Schedule a consultation with the Radiation Safety Office for review of your application and discussion of your R.I. responsibilities. Applicants must have a Ph.D. or M.D.

4. APPLICATION FOR PROCUREMENT

All radioactive material must be procured by an approved Responsible Investigator. Application for procurement shall be made through the Radiation Safety Office for any radioactive material to be acquired in any manner, including gift, loan, or transfer. Such application shall be made for any quantity, without regard to amount; there is no exempt quantity.

To add a radioisotope to your R.I. license, submit Radiation Safety Form Number 4 in duplicate. Upon approval of the application, one copy will be returned to the applicant. This document constitutes a license for the acquisition, possession, and use of the specified radionuclide only under the conditions expressed in the application. If the Responsible Investigator wishes to change the conditions (for example, by increasing the amount of activity authorized, or by significantly altering the experimental conditions) a request for appropriate modification of the license must be submitted (Form #16 or re-submit Form #4).
The Authorization ordinarily carries no restriction on the frequency with which a Responsible Investigator may acquire radionuclides under its conditions.

In cases where acquisition is by purchase, the requisition shall be submitted to the Radiation Safety Officer. The requisition must specify the radionuclide, and the activity, and bear the signature of an individual authorized by the Responsible Investigator. (The list of authorized signers is part of the Responsible Investigator's application.) This may be changed by re-submission of Form #15. Requisitions must be counter-signed by the Radiation Safety Officer before issuance of a purchase order number by the Purchasing Department.

In cases where acquisition is to be by Gift, Loan or Transfer an internal or external transfer form shall be submitted. (Forms #14 and #17) All applications for Procurement must bear the signature of the Responsible Investigator. Requisitions for purchase and transfer forms shall bear the signature of the Responsible Investigator or the signature of a person delegated by the Responsible Investigator, in consultation with the Radiation Safety Officer, with the authority to sign these documents.

5. PROCUREMENT OF OR CHANGES IN IRRADIATION UNITS AND RADIATION-PRODUCING EQUIPMENT

Departments planning to install or make changes in radiation-producing equipment (such as x-ray machines, x-ray diffraction units, electron microscopes, accelerators and multicurie irradiation units) shall obtain approval of the plans by the Joint Radiation Safety Committee prior to modification, construction, etc. The term "changes" is meant to include, but is not limited to, replacement of source slugs, structural alterations in the equipment or its housing, and alterations in shielding, including interlocks. Early consultation with the JRSC will facilitate the planning of the installation or changes therein.

The responsibility for presenting the proposal to the Joint Radiation Safety Committee, through the Radiation Safety Office, rests with the Chairman of the Department or the Director of the Laboratory.

6. HUMAN USE PROTOCOLS

Protocols in which radionuclides will be administered to human beings are subject to prior approval by the Joint Radiation Safety Committee (JRSC) if they are for the purposes of diagnosis or therapy of diseases. Approval by the Radioactive Drug Research Committee (RDRC) is required if the administration is planned in a research project; however, such studies must also be approved by the Institutional Review Board (IRB) of the CPMC. The Responsible Investigator shall submit to the Radiation Safety Officer an Application for Human Use (Form #9). The Radiation Safety Officer will transmit the Application for Human Use to the appropriate Committee. The Chairman of the Committee will inform the Applicant in writing of the action taken by the Committee.
Investigators should bear in mind that evaluation of an application for Human Use requires answers to all questions on the form. There should be sufficient information on the nature of the project to make it possible to balance the benefit to the patient or to medical science with the risk, however small, to persons to whom radioactive material is to be administered.

Please provide information to indicate whether the procedure is novel or has been used before, either here or in other institutions, including IND or NDA numbers. Literature references are useful to support your position. Their content should be summarized in order to avoid a delay in reviewing your application. In cases of inadequate information, delays in processing the application may occur because Committee members may request that you furnish additional data. The requirement that information be sufficient does not, however, necessarily mean that it needs to be extensive.

It should be noted that authorization for a human use study does not imply authorization for procurement and possession of radioactive material, which must still be handled in the manner described in Section IV.

7. ANIMAL USE PROTOCOLS

A Responsible Investigator approved for non-human use must submit a complete "Use of Radioactive Material in Animals" form (available from the Institutional Animal Care and Use Committee) to the Radiation Safety Officer for approval. The approved form must be submitted, with your protocol, to the IACUC for their review.

F. TRANSPORTATION OF RADIONUCLIDES:

The packaging and handling of radionuclides to be transported outside the Medical Center are subject to regulations of the U.S. Department of Transportation and other government agencies. These regulations are on file in the Radiation Safety Office. Packages must be inspected and handling procedures approved by the Radiation Safety Officer.

G. WASTE DISPOSAL

The radioactive waste area is located in P&S Basement Room 447. Investigators (except those located in HHSC, PI and PIA) may return 5-gallon cans and carboys between 11 a.m. and 12 p.m. on Tuesday and Thursday of each week. Requests for 30 gallon can pick-up or delivery may be obtained at any time by submitting a completed invoice to the Radiation Safety Office.

1. SEWAGE DISPOSAL

Sewage disposal of radioactive wastes is permitted only through Radiation Safety Office within the limitations established by the New York City Health Code Article 175.
2. COMMERCIAL SERVICE

The Radiation Safety Office maintains a supply of five-gallon steel cans, thirty-gallon steel cans, 10-liter plastic carboys and 20 liter plastic carboys that may be drawn upon by Investigators wishing to use this service. The following requirements must be met in the use of the cans:

1. The unshielded exposure rate at any surface of the can shall not exceed 2 mR/hr.

2. Solid Waste:
   a. Two can sizes are available, 5 gallon and 30 gallon.
   b. Absolutely no liquids in any form or in any type of container are allowed in "Solid Waste Cans." This includes even small quantities in test tubes or in company supplied stock bottles.
   c. Absolutely no liquid scintillation vials or caps, even if these do not or have never contained liquid scintillation fluid.
   d. Absolutely no animal carcasses.

3. Liquid Scintillation Vials:
   a. Two can sizes are available, 5 gallon and 30 gallon.
   b. Vials must be intact with tops securely in place. Separate caps or vial cannot be disposed of in any of our waste containers.
   c. Only liquid scintillation vials may be placed in these cans.

4. Animal Carcasses:
   a. Two sizes are available, 5 gallon and 30 gallon. Either size is available on request, but they will not be picked up nor accepted without prior arrangements with the Radiation Safety Office.
   b. Only the animal carcasses may be put in the can. The animal must not be in any kind of plastic bag, etc. No preservatives must be added, therefore all animal carcasses must be frozen.
   c. 30-gallon drums must be no more than 2/3 full and must allow passages of our packaging medium completely around the carcass.

5. Liquids:
   a. Carboys are available in two sizes 10 liters and 20 liters.
   b. Only aqueous liquids may be disposed of in this manner.
   c. The liquid must not be very acidic or basic.
   d. Absolutely nothing but liquid may be placed in these containers.

- For all pathogenic, infectious, pyrogenic, biological, explosive or any other radioactive waste not covered by the aforementioned, please contact the Radiation Safety Office, ext. 65672 for instructions.
- A radioactive waste log sheet shall be kept, on the label affixed to the can, of the principal contents and estimated amount of activity.
3. WASTES STORED PENDING DISPOSAL

Wastes stored pending disposal shall be kept in a manner approved by the Radiation Safety Officer. No waste shall be stored in hallways.

4. THE DISPOSITION OF UNUSED RADIONUCLIDES

The disposition of unused radionuclides remaining at the completion of an investigation shall be arranged by agreement with the Radiation Safety Officer.

G. PERSONNEL PROTECTION

1. HOW TO BECOME A RADIATION WORKER AT CPMC

Any person who works with ionizing radiation or works in the immediate vicinity of a radiation source and is likely to receive a dose in excess of 10 percent of the limits specified in the New York City Health Code Article 175 is required to become a radiation worker.

Personnel may become radiation workers by attending a Radiation Safety Lecture. Lectures for Hospital personnel and University laboratory workers are scheduled on a regular monthly basis. Additional lectures are scheduled as needed.

2. RADIATION BADGE REPORTS

The Radiation Safety Office will retain radiation badge reports and a copy will be sent to each area for posting. A radiation worker will receive an annual statement of his/her accumulated exposure as indicated by radiation badge records. A terminating radiation worker will receive, upon request, a statement of his/her exposure as indicated by radiation badge records. Such requests from former employees will also be honored, in accordance with the New York City Health Code, Article 175.

3. RADIATION SURVEYS

Routine radiation surveys will be performed by the Radiation Safety Office as required or on request in established radiation laboratories and clinical installations. An entry survey must be conducted by the Radiation Safety Office prior to use of radioactive material in a laboratory. An exit survey must be conducted by the Radiation Safety Office when the Responsible Investigator vacates the laboratory.

A copy of the Radiation Safety Officer's survey report will be provided to the Responsible Investigator. The latter shall forward to the Radiation Safety Officer, within a reasonable time, a statement of action taken to comply with recommendations made in the survey report and shall file a copy of this statement with his or her copy of the survey reports.
4. RESPONSIBLE INVESTIGATORS SHALL HAVE THE RESPONSIBILITY FOR ROUTINE SURVEILLANCE OF SOURCES AND PROCEDURES

Such surveillance shall include measurements of exposure rates, contamination checks, and assurance that good practices, as abstracted in Section VII.G&O, are observed. After any procedure in which the possibility of an incident exists wipes to check for contamination must be done.

Suitable instrumentation shall be used. In case of doubt, the Responsible Investigator shall consult the Radiation Safety Officer.

The Radiation Safety Officer will advise on, and at his own discretion will assist in, surveys of radiation-producing equipment.

5. RADIATION SURVEY INSTRUMENTS FOR SHORT-TERM LOAN

Radiation survey instruments are available in the Radiation Safety Office for short-term loan.

6. CALIBRATION OF SURVEY INSTRUMENTS

1. Laboratories' survey instruments shall be calibrated not less often than every twelve months by the Radiation Safety Office. Calibration records will be kept by the Radiation Safety Office.

2. A performance check must be done at the beginning of every day of radioactive material use. The result must be recorded on a log sheet.

7. INCIDENT PROCEDURE

In the event of the escape of a radioactive substance from its normal confines (spill, evaporation, vaporization, combustion, escape of a gas, liquid, solid, etc.) the Radiation Safety Officer shall be notified promptly. Pending arrival of the Radiation Safety Officer, take the following steps:

1. Where airborne contamination (from evaporation, vaporization, explosion, combustion, formation of a smoke, dust, spray, escape of a gas, etc.) may have occurred:
   a. Evacuate the laboratory immediately.
   b. Shut all doors to the laboratory.
   c. Post a guard to insure that no one re-enters the laboratory.
   d. Assemble all persons who were in the laboratory at the time of the incident. The place of assembly should be near the contaminated area, in order to reduce the spread of contamination.
   e. Monitor assembled personnel if an instrument is available, to determine whether contamination of the skin or clothing exists.
If such contamination is found, proceed as follows:

- Remove all contaminated clothing
- Flush contaminated cuts with running warm water
- Wash contaminated areas of skin with soap and warm water.

2. Where ingestion of a radionuclide may have occurred:
   a. Induce vomiting by placing a finger well back in the throat.
   b. Have the victim drink a pint of water and induce vomiting again. Check vomitus for contamination. Repeat until the vomitus is clear.

3. Where there is a spill of a substance that will not readily become airborne (such as a solid, not so finely divided that it may be carried about as a dust, or a liquid of relatively low volatility, such as an aqueous solution, provided spraying did not occur):
   a. Block off the area, using a rope barrier or items of furniture, to insure that others will not walk through the area.
   b. Monitor the skin and clothing of persons near the site of the spill. If contamination is found, proceed as in 1-e.
   c. The laboratory shall be decontaminated immediately.

A record shall be made of the incident on Form # 8, "Incident Report," which shall be submitted to the Radiation Safety Officer.

8. MAXIMUM PERMISSIBLE DOSE OF RADIATION

The maximum permissible dose of radiation for radiation workers shall be that specified in the New York City Health Code, Article 175. However, radiation exposures should always be kept As Low As Reasonable Achievable (ALARA).

9. EXPOSURES WARRANTING INVESTIGATION

In the event that a badge or other monitoring device indicates that an individual has received a whole body dose of 12.5 mSv (1250 mrem) or more in a calendar quarter, that person shall be suspended from further work with a source of radiation pending consideration of the situation by the Radiation Safety Officer. Written notification will be given to any person wearing a badge if the quarterly whole body exposure exceeds 1.25 mSv (125 mrem).
10. THEFT OR LOSS OF RADIOACTIVE MATERIAL

Theft or loss of radioactive material shall be reported immediately by the telephone to the Radiation Safety Officer. Radioactive materials shall be secured against theft in a manner approved by the Radiation Safety Officer.

11. UNAUTHORIZED ENTRY INTO RESTRICTED AREAS

Unauthorized entry must be discouraged. Authorized visitors should be supervised by a responsible member of the laboratory. Radioactive materials shall not be left unattended in places where unauthorized persons may handle them or take them. At the discretion of the Radiation Safety Officer, doors of unoccupied restricted areas shall be locked, as shall windows where ingress by this means is possible.

12. CAUTION SIGNS, LABELS AND SIGNALS

Caution signs, labels and signals shall be placed in accordance with the requirements of the New York City Health Code, Article 175.

13. INSTRUCTION OF NEW RADIATION WORKERS

Instruction of new radiation workers by the Responsible Investigator (or a designee) in the techniques and hazards of their work is required. Attendance of a Radiation Safety Lecture must precede any radiation work. This lecture covers the Columbia-Presbyterian Radiation Safety Program, general radiation safety procedure, maximum permissible doses, personnel monitoring and some information on risk evaluation.

14. RECORD OF ACCUMULATED DOSE

1. A record of the accumulated dose, in mSv (mrem), of individuals sufficiently exposed to a source of radiation to warrant the use of badges, will be maintained by the Radiation Safety Office. In order to determine the accumulated exposure, the radiation history of the individual prior to his employment by the Medical Center must be known (Form #7).

A "Pre-Employment History and Statement of Agreement" (Form # 1) shall be filed by a new radiation worker, giving information on past exposure to radiation, and certifying that he/she has read and will comply with the provisions and conditions of the applicable license.

2. Radiation workers who are occupationally exposed to radiation in a situation outside the control of the Medical Center (e.g., at another hospital, clinic or university) shall inform the Radiation Safety Officer of that fact. This information is required for the maintenance of cumulative exposure record.
15. STANDARD LABORATORY PRACTICES

1. Pipetting of radioactive solutions by mouth is prohibited.
2. All work with volatile or dust-forming radioactive material shall be confined to hoods. The minimum required airflow rate for procedures is 100 linear feet per minute with a sash opening of twelve inches. The maximum recommended airflow rate is 150 feet per minute. A hood that does not meet this requirement may not be used for procedures involving volatile or dust-forming radioactive material. A label shall be affixed to the window molding indicating measured airflow. Hoods used for iodination must be pre-approved (Form #18).
3. No extensive radiochemical work shall be performed with hazardous materials until the procedure has been tested by means of a "dummy" run.
4. Radiochemical procedures shall be performed on easily decontaminated or disposable surfaces such absorbent paper with plastic backing, stainless steel or plastic trays.
5. Anyone working with radioactive material must wear a lab coat and gloves. In special cases, it may be necessary to use dust filter masks, shoe covers, lead-impregnated gloves and aprons, etc.
6. No food or beverages shall be stored in any areas or refrigerators where radioactive materials are also stored or used. No foods or beverages shall be consumed in any areas where radioactive materials are stored or used. Smoking is also prohibited.
7. In the operation and use of x-ray equipment, the applicable recommendations of the NCRP Reports No. 49 & 102 shall be followed.

I. RECORDS AND REPORTS

1. RADIATION SAFETY OFFICE

The Radiation Safety Office maintains records of Responsible Investigator Applications, Personnel Rosters, Applications for Procurement of Radioactive Materials, Applications for Human Use, Reports of Survey, an inventory of acquisition orders, badge reports, and other data pertinent to the radiation safety program and a copy of the New York City Health Code, Article 175.

2. RESPONSIBLE INVESTIGATOR

The Responsible Investigator shall maintain a record book containing:

a) Reports of monthly laboratory wipes and monthly inventory records.
b) Copy of the Responsible Investigator's Application for Procurement of Radioactive Materials.
c) Copies of limit increases and additional radionuclide forms.
d) Record of performance checks.
e) Copies of survey reports made by the Radiation Safety Office.
f) Memoranda and notices distributed by the Radiation Safety Office.
g) A copy of the Radiation Safety Code of the Columbia-Presbyterian Medical Center.
3. RADIATION SAFETY RECORDS

All Radiation Safety records remain the property of the Radiation Safety Office, and shall be returned to the Radiation Safety Office upon termination of an individual's status as Responsible Investigator; unless the termination is effected by a transfer of responsibility. The new Responsible Investigator shall submit an R.I. application as in section IV.

4. MONTHLY REPORTS

a) Responsible Investigators shall submit to the Radiation Safety Office (by the 15th of the following month) inventory and wipe test reports, utilizing Forms No. 11 & 13 "Monthly Inventory of Radionuclide and Monthly Wipe Test Surveys."

b) Responsible Investigators who are authorized for Human Use shall submit, between January 1 and January 15 of each year, a summary of the year's work utilizing Form 12, enclosed, "Annual Report of Human Use." Failure to submit the summary automatically terminates the Responsible Investigator's Human Use Authorization.

5. FORMS

Forms for the required records and reports may be obtained from the Radiation Safety Office. The forms for records to be kept by the Responsible Investigators fit a standard three-holed loose-leaf binder. The forms are numbered as follows:

- Pre-Employment History and Statement of Agreement
- Report of Changes in Personnel
- Notice to Employees
- Application for Procurement of Radioactive Materials
- Application for Human Use
- Application for Non-Human Use
- Previous Exposure History Release Authorization
- Incident Report
- Human Use Protocol Application
- Personnel Roster
- Monthly Inventory of Radionuclides
- Annual Report of Human Use
- Monthly Wipe Test Survey
- Record of Disposition by Intramural Transfer
- Delegation of Authority to Sign Requisitions
- Limit Increase Request
- Authorization for Extramural Transfer
- Application for Iodination Hood Approval
J. COMPLIANCE WITH GOVERNMENTAL REGULATIONS

1) Laboratories situated within New York City are subject to provisions of the New York City Health Code, Article 175, "Radiation Control."
2) Certain radioactive materials are subject to regulations specified in the Code of Federal Regulations, Title 10, Chapter 1.
3) Copies of these codes may be consulted in the Radiation Safety Office.

K. DISPLAY OF RADIATION SAFETY REGULATIONS

1) The Radiation Safety Code shall be posted in all radionuclide laboratories and such other areas as the Radiation Safety Officer may direct.
2) Section VI-G (1,2,3) of the Code "Incident Procedure" shall be posted in laboratories.
3) A copy of Form #3 shall be posted in all radionuclide laboratories.

L. SELECTED SOURCES OF INFORMATION

- Introduction to Health Physics, Herman Cember; 3rd Edition
- The Physics of Radiology; Johns and Cunningham, 4th Edition
- Radiation Detection and Measurement; G.F. Knoll, 2nd Edition
- Radiation and Life; Eric J. Hall, 2nd Edition
- Radiation Protection, A Guide for Scientists and Physicians; Jacob Shapiro, 3rd Edition
- Radiobiology for the Radiobiologist; Eric J. Hall, 4th Edition
- Radiological Health Handbook; USHEW, 2nd Edition

National Council on Radiation Protection and Measurements Reports (NCRP). NCRP publications are distributed by the NCRP Publication Office. Information on prices and how to order may be obtained by directing an inquiry to:

NCRP Publication
7910 Woodmount Ave, Suite 800
Bethesda, MD 20814
Phone: (800) 229-2652
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ATTACHMENT I

Historical Overview of the Radiation Safety Office

On May 19, 1957, the President of Columbia University distributed a memo entitled ;Directive to All University Departments Having a Source of Ionizing Radiation,; advising all parties of the expanded function of the Radiation Safety Committee.

Later, a notice entitled ;Radiation Safety Guide for Columbia University,; dated February 10, 1959, named Philip M. Lorio as the Health Physics Officer for University Departments and Laboratories other than the College of Physician & Surgeons, where Dr. Edgar Watts was the named Health Physics Officer. The Chairman of the Radiation Safety Committee was Dr. Gioacchino Failla, who initiated the Radiological Research Laboratory in the Department of Radiology of Columbia-Presbyterian Medical Center (CPMC).

By agreement between The Presbyterian Hospital in the City of New York (PH) and Columbia University (CU), the Radiation Safety Office (RSO) was established as an autonomous unit in 1962 for the purpose of maintaining radiation safety. The Joint Radiation Safety Committee (JRSC), appointed by the Medical Board of CPMC and the Vice President for Health Sciences of Columbia University, is charged with the responsibility of defining and ensuring enforcement of proper safeguards in the use of sources of ionizing radiation.

Dr. Harald H. Rossi, Director of the Radiological Research Laboratories, was appointed Chairman of the JRSC. Under his direction, this committee developed a Radiation Safety Code and Guide, the administration of which is assigned to the Radiation Safety Officer. Dr. Eric J. Hall, the present Director of the Center for Radiological Research, now chairs the JRSC.

The present Radiation Safety Office came into existence through an agreement made on February 12, 1991 between New York State Psychiatric Institute (NYSPI), the College of Physicians and Surgeons of Columbia University (P&S), and The Presbyterian Hospital in the City of New York (PH). This agreement combined several overlapping clinical and educational programs, including all programs for ensuring radiation safety. On December 16, 1996, Mr. Salmen Loksen was appointed Director of the Radiation Safety Office and Radiation Safety Officer. The Radiation Safety Office reports to the Columbia-Presbyterian Medical Center and New York State Psychiatric Institute Joint Radiation Safety Committee. The Joint Radiation Safety Committee meets on a quarterly basis. For administrative purposes, the RSO reports to Dr. Richard Sohn, Associate Dean for Research Administration and Director of Grants and Contracts.
Radiation Safety Office staff are Columbia University employees. New York Presbyterian Hospital, Columbia University College of Physicians and Surgeons, and New York State Psychiatric Institute fund the RSO budget, via a cost sharing payback arrangement.

A full-asset merger between The Presbyterian Hospital in the City of New York and New York Hospital on December 1, 1997, created a single entity known as New York Presbyterian Hospital with facilities in two major Manhattan locations: Columbia Presbyterian Center at West 168th Street in Washington Heights and New York Weill Cornell Center at East 68th Street on the Upper East Side.
ATTACHMENT II

Services Provided by the Radiation Safety Office

The Radiation Safety Office advises CPMC and NYSPI through the JRSC, and also participates in the review of research protocols for the Radioactive Drug Research Committee under the jurisdiction of the U.S. Food and Drug Administration. The Radiation Safety Office is responsible for ensuring compliance with federal, state and city regulatory agencies. These regulatory agencies, which mandate rules, regulations, and guidelines, include:

- United States Food and Drug Administration
- United States Nuclear Regulatory Commission
- New York State Department of Environmental Conservation
- New York State Department of Health
- New York City Department of Health Bureau of Radiological Health.

The Radiation Safety Office also ensures compliance with the rules and regulations of the Radiation Code and Guide of Columbia-Presbyterian Medical Center and New York State Psychiatric Institute.

The **Radiation Safety Office provides the following primary services:**

- Radiation safety services to Columbia University.
- Radiation safety services to College of P& S of Columbia University.
- Radiation safety services to New York Presbyterian Hospital.
- Radiation safety services to New York State Psychiatric Institute.
- Radiation safety services to the Cyclotron Facility.
- Radiation safety services to Radioligand Laboratory.
- Radiation safety services to PET Net Pharmaceuticals, Inc.
- Radiation safety services to Audubon Biomedical Sci. & Tech. Park (Audubon I).
- Radiation safety services to the Russ Berrie Medical Science Pavilion (Audubon II).
- Reviewing and evaluating Human and Non-Human Use Protocols for the Joint Radiation Safety Committee and the Radioactive Drug Research Committee for compliance with federal, state and local regulatory requirements.
- Evaluation of education, training and experience of Responsible Investigators seeking to obtain radioactive materials and/or operate radiation-producing equipment for laboratory or hospital use.
- Initial and annual refresher training to personnel involved in handling radioactive materials or operating radiation-producing equipment.
- Personnel radiation dose monitoring and investigating reports of overexposure.
- Bioassay testing, including personnel thyroid uptake and urinalysis.
- Routine and specialized laboratory inspections for Human and Non-Human Use.
- Leak testing and inventory of sealed sources.
- Calibration of radiation survey instruments.
- Consultation for radiation shielding requirements.
- Emergency response, including weekends and after hours, in event of radiation accidents.
- Supervision and assistance with cleanup of contaminated-areas.
- Review and approval of the purchase of non-radiology dental and medical X-ray equipment.
- Monitoring and quality assurance testing of non-radiology dental and medical X-ray equipment.
- Radiation Safety support for clinical procedures performed at New York Presbyterian Hospital-Columbia-Presbyterian Center.
- Pick-up, storage and disposal of radioactive and mixed waste from laboratories and hospital facilities.
- Receiving, shipping and tracking of radioactive material packages, and wipe testing of packages for radioactive contamination.
- Monitoring and evaluating radioisotope effluent discharges to the atmosphere and the sewer system.

As a health sciences campus, Columbia-Presbyterian Medical Center has extensive teaching, research and clinical facilities in which sources of ionizing radiation are used. The goal of the Radiation Safety Office at Columbia-Presbyterian Medical Center is to provide adequate protective measures against exposure to these sources for patients, visitors, students, faculty and staff on campus, and for the community at large to ensure that the dose received by employees, patients and the general public from ionizing radiation is As Low As Reasonably Achievable (ALARA). The Radiation Safety Office ensures compliance with all regulatory requirements and guidelines for the use of radioactive material and radiation producing machines by means of training, education, consultation and a program of audits and inspections of facilities. These measures are required pursuant to CPMC Radioactive Materials License requirements and conditions.

The Radiation Safety Office is responsible for maintaining and updating licenses authorizing the use of radioactive materials and registrations of radiation producing equipment. Licenses include the New York City Department of Health, Bureau of Radiological Health, Broad Scope Research and Broad Scope Human-use licenses and specific licenses for a number of facilities, including the Cyclotron, the Gamma-Knife and the Cobalt-60 Teletherapy unit. Registrations include New York City Department of Health, registrations for X-ray equipment and the operation of medical accelerators. In addition the Radiation Safety Office maintains the New York State Department of Environmental Conservation Radiation Control Permit for the controlled discharge of radioisotopes to the environment.

Both the New York City Department of Health and the New York State Department of Environmental Conservation conduct periodic inspections and audits of the facilities at Columbia-Presbyterian Medical Center and New York State Psychiatric Institute operating under their licenses or permits. The Radiation Safety Office works continuously to ensure that regulatory violations are prevented and to ensure those that do occur are swiftly corrected.
ATTACHMENT III

NOTICE TO EMPLOYEES NSTANDARDS FOR PROTECTION AGAINST RADIATION

The transfer, receipt, possession or use of all sources of ionizing radiation in the City of New York is controlled by the applicable rules, regulations and orders of either the New York State Departments of Labor or the New York City Department of Health. These agencies require either the registration or licensing of all significant radiation sources and they require your employer to post or otherwise make available to you a copy of the applicable regulations, license and registration and the operating procedures applying to the work in which you are engaged and to explain relevant provisions to you. These documents are made available in the office of the Radiation Safety Officer or from the licensee.

R. S. 0. - Salmen Loksen
Licensee - Columbia Presbyterian Medical Center

The applicable regulation in this installation is 24 RC NY Article 175.
ATTACHMENT IV

YOUR RESPONSIBILITY AS A WORKER

You should familiarize yourself with the provisions of the New York City Health Code and your radioactive materials license and the operating procedures, which apply to the work in which you are engaged. You should observe these provisions for your own protection and the protection of your co-workers.

WHAT IS COVERED BY THESE REGULATIONS
1. Limits on exposure to radiation and radioactive material in controlled and uncontrolled areas;
2. Measures to be taken after accidental exposure;
3. Personnel monitoring, surveys and equipment;
4. Caution signs, labels, and safety interlock equipment
5. Exposure records and reports; and
6. Related matters.

REPORTS ON YOUR EXPOSURE TO RADIATION

If you work where personnel monitoring equipment is required the New York City Department of Health requires your employer to provide you, upon request, a written report of your exposure to radiation both annually and at the time that you terminate employment.

INSPECTIONS

All activities licensed or registered with the New York City Department of Health are subject to inspection. Any notice of violation involving radiological working conditions, any proposed imposition of civil penalty or order issued pursuant to the provisions of the New York City Health Code and any response from the licensee shall be posted within two (2) days after the receipt of the documents from the Department.

The licensee's response if any, shall be posted within two (2) working days after dispatch from the licensee. Such documents shall remain posted for a minimum of five (5) working days or until the action correcting the violation has been completed, whichever is later.

INQUIRIES

Inquiries dealing with matters outlined above can be directed to the:

Bureau of Radiological Health
2 Lafayette Street, 11th Floor
New York, New York 10007
Fax: (212) 676-1548
Telephone: (212) 676-1570
POLICY AND PROCEDURE MANUAL

TITLE: COLUMBIA-PRESBYTERIAN MEDICAL CENTER
RADIATION PROTECTION POLICY FOR PREGNANT WORKERS
VERSION 5

POLICY: Under applicable regulations of the Rules of the City of New York, Article 175, Radiation Control (1), and other applicable New York State and Federal statutes (2), it is the policy of the Columbia-Presbyterian Medical Center 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. The Medical Center shall review the exposure history of the declared pregnant woman and adjust working conditions so as to avoid a monthly exposure of more than 0.5 mSv (0.05 rem) to the declared pregnant woman (3).

Further, it is the policy of the Columbia Presbyterian Medical Center 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 As Low As Reasonably Achievable (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.

A copy of this policy shall be distributed to each department or laboratory at CPMC using radiation or radioactive materials. This policy shall be incorporated into their QA Manual and a copy of this policy prominently posted in each such department or laboratory.

RESPONSIBILITY: The CPMC Joint Radiation Safety Committee is responsible for administering the above policy at the Columbia-Presbyterian Medical Center and associated Columbia University facilities (4). In administering this and all other radiation safety policies the CPMC Joint Radiation Safety Committee shall be provided sufficient authority and organizational freedom to identify radiation safety problems, initiate, recommend, or provide corrective actions and verify implementation of corrective actions (5). Day to day implementation of this policy has been delegated to the CPMC Radiation Safety Office. This Office can be contacted at:

Radiation Safety Office
Columbia-Presbyterian Medical Center
650 West 168th Street
Black Research Building - Room B-06
Tel (212) 305-0303, Fax (212) 305-0318
PROCEDURE: The Columbia-Presbyterian Medical Center Radiation Protection Policy For Pregnant Workers shall be implemented as follows (6):

1. Method of instruction to workers:

As part of their initial employment (7), all radiation workers are required to receive from the Radiation Safety Office, instructions in radiation protection. 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 the Radiation Safety Office and the importance of her doing so. A copy of this policy should be distributed to each new radiation worker at his or her initial radiation safety orientation.

Instruction in the special limit for protection of the embryo/fetus of a declared pregnant woman and the CPMC pregnancy policy should be included in all annual refresher training. 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 shall be made available at all refresher training sessions and in the Radiation Safety Office.

At the time of her Declaration of Pregnancy, the declared pregnant woman will receive individual counseling from a Health Physicist or Medical Physicist on the staff of the Radiation Safety Office.

2. Responsibility of workers:

Federal statute (8) mandates that; "It is the fundamental responsibility of the pregnant worker to decide when or whether she will formally declare her condition to her employer". It is the policy of the Medical Center that formal declaration is defined as filing a completed, signed and dated Declaration of Pregnancy form with the Radiation Safety Office. A copy of the Declaration of Pregnancy Form is attached as APPENDIX A. If she chooses not to declare her pregnancy, the Radiation Safety Office will continue to ensure that she receives all normal occupational protections - the annual occupational dose limit of 50 mSv (5.0 rem) (9) and all ALARA (10) requirements will be in effect. All rights of declaration rest with the pregnant woman. The declaration of pregnancy may withdrawn at any time by a signed,, dated, written statement of withdrawal filed with the Radiation Safety Office.

In addition, all radiation workers have an individual responsibility to comply with RCNY Article 175 requirements. The Rules of the City of New York, Article 175 (11) states that "the supervised individual...shall follow the instructions of the supervising authorized user; follow the procedures established by the radiation safety officer; and comply with this Code and with the license conditions with respect to the use of radioactive material".
3. Regarding work assignments for pregnant workers:

In order to insure that the dose to an embryo/fetus (12) during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 5 mSv (0.5 rem), the Radiation Safety Office shall review the exposure history and the present job duties of the declared pregnant woman and require the adjustment in working conditions so as to avoid a monthly exposure of more than 0.5 mSv (0.05 rem) to a declared pregnant woman (13). This adjustment would range from requiring the wearing of a personnel radiation dosimeter as an assigned fetal monitor to a prohibition of participation in certain procedures.

If, by the time the pregnant worker declares pregnancy to the Radiation Safety Office, the dose to the embryo/fetus has exceeded 4.5 mSv (0.45 rem), the Radiation Safety Office shall ensure that additional occupational dose to the embryo/fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy (14). 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 radionuclides by the declared pregnant woman and by the embryo/fetus (15).

Due to privacy provisions noted in the following section, if an adjustment of working conditions is necessary, the Radiation Safety Office 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 or Responsible Investigator.

The employment status of the declared pregnant woman is explicitly protected. The Rules of the City of New York, Article 175 (16) 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 RCNY Article 175 may be filed in writing with the City of New York, Department of Health, Bureau of Radiological Health which is empowered to inspect the licensee and levy penalties if a violation is determined to exist.

4. Records, informing workers of exposure received during gestation, reports:

A) Records

Declarations and records required under this policy should be protected from public disclosure because of their personal privacy nature. These records are protected by New York State and Federal privacy statutes (17). The Declaration of Pregnancy Form, including the estimated date of conception will be maintained in a separate file from the dose records of the declared pregnant woman and the embryo/fetus (18). The Declaration of Pregnancy Form will be over-stamped or bear the prominent heading, CONFIDENTIAL". Such records shall be retained until the City of New York, Bureau of Radiological Health authorizes disposition (19).
B) Informing workers of exposure received during gestation

The Radiation Safety Office shall advise each worker annually of the worker’s exposure to radiation (20) and shall furnish a report of the worker’s (or former worker’s) exposure to sources of radiation at their request (21). If the Radiation Safety Office is required to report to the City of New York, Bureau of Radiological Health any exposure of an individual to radiation or radioactive material, the Radiation Safety Office shall also notify the individual at a time not later than the transmittal to the Bureau of Radiological Health (22).

Notification or report to a worker shall be in writing, shall include appropriate identification of the licensed institution, Columbia-Presbyterian Medical Center, the name and social security number of the individual worker, their exposure information and shall contain the statement, "This report is furnished to you under the provisions of Para.175.04 of the New York City Health Code. You should preserve this report for further reference." (23).

C) Reports

The Radiation Safety Office shall submit a written report to the City of New York Bureau of Radiological Health within thirty days after learning that the 5 mSv (0.5 rem) dose limit for an embryo/fetus of a declared pregnant woman has been exceeded (24). The report shall describe the extent of exposure of the embryo/fetus and the declared pregnant woman to radiation and radioactive materials and include as appropriate; estimates of each individual’s dose, the levels of radiation and concentrations of radioactive materials involved; the cause of the elevated exposures, dose rates and concentrations; and corrective steps taken or planned to ensure against a recurrence (25). This report shall be prepared so that identifiers such as name, social security number and date of birth are stated in a separate and detachable portion of the report in order to conform to privacy laws (26).

ALARA review (27) of the declared pregnant woman’s Personnel 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 ALARA level and an appropriate ALARA investigation will be performed. The CPMC Joint Radiation Safety Committee will receive ALARA reports for declared pregnant women with identifiers such as name, social security number and date of birth in a separate and detachable portion of the report.

5. Provision of further information:

Any individual or group having questions related to the radiation protection of the embryo/fetus is strongly encouraged to contact the Radiation Safety Office, telephone number (212) 305-0303, at the location cited above. The Radiation Safety Office will provide appropriate and confidential education and counseling.
Radioactive Materials Information

Radioactive Waste Guidelines
General guidelines for radioactive waste management

Waste Pickup Request
Form to submit a request for radioactive waste pickup. Note: 5 gal. cans and liquid carboys will only be picked up from the external buildings (Hammer Health, P.I., P.I. Annex)
ATTACHMENT VI

Radioactive Waste Management General Requirements

1. Laboratory permitees must ensure, prior to the procurement of radioactive materials, that a method of disposal for the materials presently exists or can be worked out to the satisfaction of Radiation Safety.

2. Each Radioisotope Laboratory must maintain accurate records of the types, quantities, and forms of radioisotopes which comprise the radioactive waste submitted from his/her laboratory to Radiation Safety (Completion of a Radioactive Waste Log Sheet fulfills this requirement).

3. It is the Responsible Investigator’s responsibility to secure proper storage for radioactive wastes generated in their laboratories.

4. Radioactive waste containers shall be stored as close to the work area as feasible to minimize the possibility of spillage during the transfer of waste to the containers.

5. Waste containers shall NOT be stored in hallways, stairwells or other uncontrolled areas.

6. Radioactive waste containers shall be kept closed at all times when not in use.

7. Regardless of content, each radioactive waste container shall be labeled with a "Caution Radioactive Materials" sticker.

8. When handling or transferring radioactive waste, the individual shall wear appropriate laboratory attire including lab coat, disposable gloves, protective eyewear and closed-toed shoes.

9. Radioactive wastes containing carcinogens, biohazards, or extremely hazardous chemicals must be handled separately and packaged in such a way that they present minimal hazards to people who handle the wastes. Contact Radiation Safety for specific requirements.

10. Do NOT combine different radioisotopes in the same waste container unless you have prior authorization from Radiation Safety to do so.

11. Under NO circumstance shall radioactive waste be released into the sewage disposal system.

12. Do NOT place any radioactive waste in regular trash receptacles.

13. Package the waste properly according to the attached instructions.
## Radiation Spill Response Guide

### Notes and Precautions

Spreading of radiation beyond the spill area can easily occur by the movement of personnel involved in the spill or cleanup effort. Prevent spread by confining movement of personnel until they have been monitored and found free of contamination. A minor radiation spill is one that the laboratory staff is capable of handling safely without the assistance of safety and emergency personnel. All other radiation spills are considered major.

### Minor Radiation Spill

1. Alert people in immediate area of spill.
2. Notify Radiation Safety Officer at (212) 305-0303.
3. Wear protective equipment, including safety goggles, disposable gloves, shoe covers, and long-sleeve lab coat.
4. Place absorbent paper towels over liquid spill. Place towels dampened with water over spills of solid materials.
6. Monitor area, hands, and shoes for contamination with an appropriate survey meter or method. Repeat cleanup until contamination is no longer detected.

### Major Radiation Spill

1. Attend to injured or contaminated persons and remove them from exposure.
2. Alert people in the laboratory to evacuate.
3. Have potentially contaminated personnel stay in one area until they have been monitored and shown to be free of contamination.
4. **Call Radiation Spill Emergency Response number.**
5. Close doors and prevent entrance into affected area.
6. Have person knowledgeable of incident and laboratory assist emergency personnel.
ATTACHMENT VIII

Waste Pick Up
If your lab is using 30 gallon waste drums we will pick up filled drums and replace them with an empty one. When this form is completed, you will be notified by e-mail or phone the day and approximate time the service will be performed.

Information Request Form

Select the items that apply, and then let us know how to contact you.

☐ Contact by e-mail

☐ Contact by phone

Your Name

Investigator’s Name

Department

Building

Floor

Room

E-mail

Phone

Comments

Send

Submit Request

Reset Form
ATTACHMENT IX

NOTICE TO RESPONSIBLE INVESTIGATORS AND RADIOACTIVE MATERIALS WORKERS

As part of the University and Medical Center recycling programs, all lead must be collected for recycling. No lead is to be disposed of with trash or other wastes.

All lead shipping and storage containers that previously contained radioactive materials must be sent to the Radiation Safety Office Waste Laboratory for recycling.

THE PROCEDURE IS AS FOLLOWS:

1. Survey the lead containers with your survey meter. There must be no activity detectable above background levels.

2. Wipe the lead containers, or a representative sample of the. Assay the wipes in your wipe count system. Removable activity must not exceed 1000 dpm/100 cm for beta or gamma emitters and must not exceed 200 dpm/100 cm for any isotopes of iodine.

3. Scrape off or deface with a permanent marker any labels bearing the yellow and magenta radioactive materials symbol or the words “radioactive materials”.

4. Place the lead in a sturdy box and attach a completed Lead Recycling Record Sheet with the results of your survey and wipe tests. Radiation Safety Technicians will not accept any lead for recycling without a completed record sheet.

5. The next time you bring radioactive waste to a can or are serviced by the radiation safety technicians, transfer your lead to them. At present, there is no additional charge for this service.

The Radiation Safety Waste Laboratory is located in the P&S Basement in Room B447. The Radiation Safety Waste Technicians can be reached at Ext. 5-8612.