Boston University / Boston Medical Center

# Radioisotope Use Manual

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# Radioisotope Use Manual

#### May 2020

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# **Emergency Contact Information**

Medical Physics and Radiation Safety:

Monday-Friday 8 AM-6PM: (617) 358-7688

# **After Hours:**

Incident Type	CRC	BUMC/BMC
HAZARDOUS MATERIALS SPILL Chemical, Biological, And Radioactive	(617) 353-2105	(617) 414-6666

See Environmental Health and Safety Emergency Response Flip Chart and Emergency Contact Numbers

# **PREFACE**

This Radioisotope Manual describes the radioisotope program at Boston University (BU Charles River and Medical Campuses) and Boston Medical Center (BMC) and defines internal procedures developed by the Radiation Safety Officer (RSO), Radiation Safety Committee (RSC), and Radioisotope Users, for the safe use of radioisotopes at BU and BMC. This manual shall be followed by all radioisotope users at BU/BMC. Any variance must be reviewed and approved by RSO. Overall responsibility for radiation safety rests with the University and hospital; however, primary responsibility for safety must be assumed by clinical and research permit holders, clinical authorized users, and individual users of radioactive material. Although every effort has been made to ensure that this manual reflects current federal and state regulations, and State License conditions, in case of any discrepancies the most current regulation and guidance document shall take precedence.

# Introduction

The use of radioactive materials is strictly regulated by federal, state and local agencies to ensure the safety of radiation users and the public. It is important for all individuals within BU/BMC who use radioactive materials to read and abide by the rules and practices documented within this manual.

# Section 1

Radioactive materials are valuable tools used in areas as diverse as medicine, biology, chemistry, engineering, and physics. Yet, if used improperly, they have the potential of being hazardous to people and the environment. Therefore, individuals using radioisotopes must understand the hazards and precautions associated with their use and are required to comply with relevant federal, state, local and institutional radiation safety regulations and standard practices.

Use of radioisotopes at BU and BMC is regulated by the Massachusetts Department of Public Health / Radiation Control Program (DPH RCP). Through this agency, BU/BMC has been granted a broad scope license to manage its use of radioactive material in BU laboratories and at BMC. This license offers the institutions the necessary degree of flexibility and autonomy to purchase, use, store, and dispose of radioactive materials, in research and clinical settings. In addition to ensuring compliance with all applicable regulations and adhering to applicable guidance documents and best practices, BU/BMC is required to appoint a Radiation Safety Officer (RSO) and Radiation Safety Committee (RSC) who together with institutional management are responsible for the radiation safety program. The program is subject to periodic audits by the DPH RCP and other regulatory agencies to verify regulatory compliance, which in turn demonstrates BU and BMC are conducting safe operations that protect personnel, the public, and the environment from any undue radiation risk.

This Radioisotope Manual describes the requirements applicable to all users of radioactive material. This Manual has been authored by a Board-Certified Radiation Safety Officer with input from Permit Holders and radioisotope users. It is consistent with conditions stipulated in the BU/BMC license, applicable federal and state regulations, and national radiation protection guides and standards.

#### How to Use This Manual

Radioactive materials are used at BU/BMC for human and non-human research purposes. Radioactive materials are also routinely used at BMC for diagnostic and therapeutic clinical purposes. The requirements for the use of radioactive materials for non-human research are very different from those for clinical purposes. This Manual describes the process that researchers and health care radiation users must follow when using radioactive materials in each of their respective settings.

# **ALARA Policy**

BU and BMC are committed to maintaining exposures <u>As Low as</u> <u>Reasonably Achievable (ALARA)</u>. Although current occupational radiation exposure limits present a very low risk of harm, it is prudent to practice radiation safety techniques and protocols to minimize unnecessary exposures.



The goal of an ALARA program is to make a reasonable effort to maintain exposures to radiation as far below dose limits as practical, consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of licensed materials in the public interest (105 CMR 120.005).

The ALARA program is implemented by a comprehensive radiation protection program that includes specific requirements and procedures for:

- A. <u>Training of Radiation Users</u>: Radioisotope safety training is provided by Environmental Health and Safety (EHS) through its Division of Medical Physics and Radiation Safety (DMPRS). The extent of the training is commensurate with the potential risk of radiation exposure to the individual. The goal of this program is to allow those individuals who may come in contact with radioactive materials or radiation generating equipment to recognize and protect themselves from sources of radiation.
- B. <u>Radiation Monitoring</u>: Dosimetry and bioassays are provided by the DMPRS to all individuals likely to receive a radiation exposure greater than 10% of the regulatory limits listed in <u>Table 1</u>: <u>Occupational Effective Dose Equivalents Limits (rem/year)</u> of this manual.
- C. <u>Investigating high radiation exposures</u>: The RSO investigates all radiation exposures that are greater than 7.5% of the regulatory limits listed in <u>Table 1</u>: <u>Occupational Effective Dose Equivalents Limits (rem/year)</u> of this manual. These exposures are reviewed along with investigation findings during RSC meetings.
- D. <u>Radiation Surveys</u>: DMPRS regularly surveys areas where radioisotopes are used for contamination and exposure rates. Unusual findings and corrective actions are documented to ensure radiation levels are maintained ALARA.
- E. <u>Safety Reviews</u>: The RSO and the RSC review and must approve all uses of radioactive material. Radioactive material users may be required to demonstrate how their proposed projects and/or radioisotopes meet ALARA principles.
- F. Review of the radiation safety program: The RSO conducts an annual program review, which is reviewed by the RSC, of the radioisotope safety program to verify compliance with federal and state regulations, regulatory guides and the BU/BMC license.

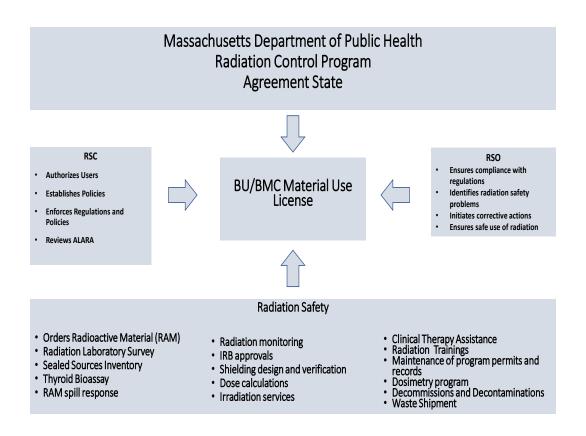
# Organization, Authority and Responsibility

The Radiation Safety Program applies to the use of radioactive materials and radiation generating devices at BU and BMC. Although the program spans across two institutions with separate management structures, both institutions are represented on the RSC, which jointly oversees uses of radiation.

Section 3

Executive management of BU/BMC has ultimate responsibility for the Radiation Safety Program. Executive management appoints a qualified individual to serve as RSO and also appoints the members of the RSC.

# **Program Functional Chart**



# **The Radiation Safety Officer**

The RSO is appointed by the institution (see page 11) and approved by the MA DPH RCP. The RSO is responsible for developing and maintaining the radioisotope radiation safety program within the limits set forth by federal and state regulations, license requirements and commitments, guiding documents and best practices. The RSO is responsible for ensuring compliance with relevant federal, state, and local regulations, license conditions and institutional policies. The RSO identifies radiation safety problems, initiates corrective actions and ensures safe use of radioisotopes.



Date: 4/11/2018

To: Alison Errico, MSc., CHP

From: Kathryn Mellouk,

Associate Vice President, Research Compliance

**Boston University** 

Subject: Delegation of Authority

This is to confirm that you have been appointed as Radiation Safety Officer (RSO) for material License 44-0062 in accordance with the provisions of the Massachusetts Department of Public Health's (MDPH) Radiation Control Program. In that capacity, your role is to ensure that the radiation safety program at Boston University is being performed in accordance with the license conditions, approved procedures and regulatory requirements.

As the RSO, you have the authority to:

- · Identify radiation safety problems;
- · Initiate, recommend, or provide solutions;
- · Verify implementation of corrective actions; and,
- Restrict or stop any activities involving use of radioactive materials, or sources of ionizing radiation, if such activities present a hazard to individuals or violate the regulations.

Your signature below confirms your acceptance of the appointment.

Kathryn Mellouk,

RSO Acceptance:

Associate Vice President, Research Compliance Boston University Alison Errico, MSc., CHP

A house

#### **Radiation Safety Committee (RSC)**

The Radiation Safety Committee oversees the use of radioisotopes and radiation generating devices at BU and BMC. The RSC Charter describes the role and responsibilities of the RSC.

#### Membership

The members of the RSC are appointed by the Boston University Designated Official, in consultation with Boston Medical Center.

# Committee Responsibilities, Delegation of Authority, and Subcommittees

The RSC oversees all uses of radioactive material within BU/BMC, authorizes radioisotope users, establishes policies, enforces regulations and policies, and reviews ALARA related reports and events. The RSC may delegate certain responsibilities to specific individuals, ad hoc and standing subcommittees.

# **Committee Meetings**

The RSC meets at least quarterly. Minutes of meetings will be documented and kept on file for review by committee members, regulatory agencies, and BU/BMC Management.

# The Division of Medical Physics and Radiation Safety (DMPRS)

The DMPRS maintains a professional staff of radiation safety professionals who ensure the safe receipt, use, surveillance, storage, and disposal of radioactive materials. The DMPRS is authorized to intervene to prevent hazardous conditions from developing, or to eliminate existing unsafe conditions related to radiation safety.

# **Permitting for Radioactive Material Use**

BU/BMC must ensure that all individuals who use radioisotopes are aware of and comply with regulatory requirements. The RSC, upon recommendation of the RSO, reviews and approves applicants seeking a radioisotope use permit, which authorizes the use of radioactive material. This section describes the eligibility requirements and the process for individuals applying for a radioisotope permit.

# Section \_\_\_\_\_\_

# **Applying for a Radioisotope Permit**

Radiation sources can only be used and stored by individuals issued a radioisotope use permit, or under the supervision of individuals issued a radioisotope permit (i.e., permit holder). There are two different types of radiation permits (1) Human-Use and (2) Non-Human Use. The process and eligibility for individuals requiring either type of radiation permit is set forth below.

Once a radioisotope permit application is determined to be complete by the RSO, it will be reviewed by the RSC for final approval. The RSO may provide provisional approval of permits prior to approval by the RSC.

# Eligibility & Process for becoming a Permit Holder

Application for Radioisotope Use Permit: Non-Human Use

The Permit Holder in the R&D setting is generally the Principal Investigator (PI).

- 1. The applicant must have a faculty/staff position within BU/BMC. Technically qualified individuals from outside BU/BMC may be given a temporary use authorization to carry out a relatively long-term or repetitive experiment; such authorizations are governed by the same requirements as any other permit holder.
- 2. The applicant must complete DMPRS-provided radiation safety training.
- 3. The applicant must submit the following to the DMPRS for review:
  - a. Resume or Curriculum Vitae (CV), which explicitly includes the applicant's radioisotope use history.
  - b. Radioactive Material Permit Application (Non-Human Use). This application should be completed online in BioRAFT or can be obtained from DMPRS.
  - c. Radioisotope work history attestation from a previous employer indicating that:
    - i. The applicant's use of radioactive material was safe and they have the ability to use radioisotopes independently.
    - ii. The applicant has a minimum of 6 months of radiation work experience using similar radionuclides and quantities as those being applied for. Otherwise, the applicant must work under the supervision of an existing permit holder using similar radionuclides and quantities for a minimum of 6 months before the application will be acted upon by the RSC.

- 4. The applicant must be familiar with the requirements of this Manual and have made adequate provisions for radiation safety and control within their lab.
- 5. The applicant must be able to secure the appropriate facilities and equipment to safely conduct permitted activities.
- 6. The use of radiation sources by minor undergraduate students for educational purposes requires approval of the RSO and the direct supervision of a PH or RSO-approved researcher. The Permit Holder must request permission from the RSO or designee to use radioisotopes with minor students. Each request will be handled on a case by case basis. The Permit Holder is required to submit a safety plan as part of their request. DMPRS will ensure that no minor student's exposure will exceed 10 mrem per year. The Permit Holder must meet appropriate BU/BMC policy requirements including the BU Policy on Minors in Laboratories.

#### Application for Radioisotope Use Permit: Human Use

Radioactive material involved in clinical trials must be used under the direct supervision of an approved permit holder with approved clinical privileges and through a protocol approved by the Institutional Review Board (IRB) and RSO. Human use (i.e., clinical) permit holders are referred to as 'Clinical Authorized Users'.

- 1. The applicant must be a Massachusetts licensed physician.
- 2. The applicant must acquire clinical privileges granted by the BMC Credentialing Committee.
- 3. The applicant must complete DMPRS-provided radiation safety orientation/training.
- 4. The applicant must submit the following to the DMPRS for review:
  - a. Appropriate Board Certification (or proof of eligibility to take the certification test).
  - b. Resume or Curriculum Vitae (CV), which explicitly includes the applicant's radioisotope use history.
  - c. Radioactive Material Permit Application (Human Use).
  - d. License from previous institution showing applicant's authorization for use of the requested isotope(s) OR signed attestation that the applicant has the required training and experience (as applicable in 105 CMR 120.500) and has achieved a level of competency to function independently as an authorized user for medical uses (sample attestations are available from the DMPRS upon request).

#### Application for Authorized and/or Qualified Medical Physicist

Machines which deliver therapeutic radiation are required to be calibrated and maintained by an 'Authorized Medical Physicist', for Ir-192 in HDR, or 'Qualified Medical Physicist' for radiation generating machines such as a linear accelerator.

Individuals requesting to become an authorized medical physicist and/or qualified medical physicist must supply the following to the DMPRS:

- 1. Appropriate Board Certification (or proof of eligibility to take the certification test).
- 2. Resume or Curriculum Vitae (CV), which explicitly includes the applicants' radioisotopes and/or linear accelerator use history.
- 3. License from previous institution showing applicant's authorization for use of the requested isotope(s) OR signed attestation that the applicant has the required training and experience (as applicable in 105 CMR 120.500) and has achieved a level of competency to function independently as an authorized and/or qualified medical physicist (sample attestations are available from the DMPRS upon request).

# Responsibilities of a Permit Holder

Permit holders (PH) are responsible for implementing radiation safety rules, regulations, and procedures and are directly responsible for laboratory safety. More specific responsibilities can be found in <u>APPENDIX II: PERMIT HOLDER RESPONSIBILITIES</u>, which a PH must sign prior to receiving their approved radioisotopes permit.

#### **Permit Status**

Permits may be considered either active, suspended or inactive. A permit holder's status may change from active to inactive or active/inactive to suspended by one of four methods:

- 1. The RSO will evaluate the status of all permit holders annually, and those who have not used or ordered radioactivity in one calendar year will be contacted. If their future use of radioactive materials is unknown or known to be not at all, the PH may request to change their status to "inactive" by removing all radioactive materials, radioactively contaminated items and objects, and waste. Removal of all radioactive materials and contamination will be verified by the RSO. Their status will then be changed to inactive.
- 2. The PH may request to change their permit status to "inactive" but maintain their permit for grant purposes. The request will be handled by the RSO as indicated above.
- 3. The RSO may change a permit holder's status to "inactive" due to other circumstances as considered appropriate after the conditions in No. 1 above have been satisfied.
- 4. The RSO and/or RSC may change a permit holder's status to "suspended" if radiation safety refresher training is overdue. Reinstatement of PH status to "active" will require completion of Basic Radiation Safety Training.

#### Suspended Status

A permit holder's status may become suspended if training requirements for the PH and/or users listed on the permit are not met. Once training has been completed, the DMPRS will confirm that training has been completed and reinstate active status.

#### **Inactive Status**

Inactive permit holders and individual users of radioactive materials whom they supervise must maintain all the conditions of their permit including completion of radiation safety refresher training every two years. Laboratories that apply or are designated for inactive status must meet the following requirements:

- 1. Inactive laboratories cannot possess radioactive material. All radioactive waste, samples, contaminated items, etc. must be properly removed and/or disposed of and disposition verified by the DMPRS.
- 2. A survey for "Release for Unrestricted Use" must be performed by the DMPRS and the change in use status approved by the RSO.
- 3. The ordering or transfer of radioactive material to a laboratory designated inactive must be approved by the DMPRS and the laboratory will be re-designated as an "Active" laboratory. In that regard, all labeling, posting, surveying, recordkeeping, etc. pertaining to an active status laboratory are applicable.
- 4. Inactive Use permit holders will be considered to possess a permit for grant purposes only. Inactive permit holders will not be required to perform the recordkeeping, surveys, inspections and other duties associated with possessing radioactive materials. Additionally, the RSO will not perform inspections of inactive permit holders until the status changes, but will maintain cognizance of their status.
- 5. Inactive permit holders and radioisotope users are required to perform Radiation Safety Refresher Training every two years.

# **Laboratory Supervisors**

In many instances, the PH will not always be available to provide direct supervision of radioactive material users. Therefore, the PH may designate a Laboratory Supervisor to act on their behalf. The ultimate responsibility for the use of radioactive materials, however, remains with the PH. The Laboratory Supervisor will be identified on the permit as the permit holder's designee.

# Research Radioisotope User

Research radioisotope users working under a PH must follow the policies and procedures outlined in this Manual. Use of radiation sources must be under the direct supervision of the PH and in the manner specified in the application for authorization to use such sources. The research radioisotope user must read and understand the laboratory permit prior to beginning work.

# **Becoming a Radioisotope User**

1. Individuals who work with radioisotopes are required to complete the Basic Radiation Safety training (both part 1 and 2) offered by the DMPRS. The training schedule and sign up is available in <a href="BioRAFT">BioRAFT</a>.

The goal of basic radiation protection training is to familiarize the radioisotope user with the following:

- Basic radiation science
- Radiation risk, biological effects, protection, and safety
- The concept of ALARA (As Low As Reasonably Achievable)
- Federal and state regulations and institutional policies
- The responsibilities of the radioisotope user, permit holder, and the BU/BMC radiation safety program
- Basic laboratory safety procedures
- Emergency response procedures
- 2. Before the radioisotope user is allowed to handle radioactive material, the user must undergo site-specific safety training provided by the permit holder or designee.
- 3. Laboratory personnel not specifically handling or working with radiation sources will receive radiation hazard awareness training as part of the introductory laboratory safety training that all users receive upon hire.
- 4. Clinical use of radioisotopes requires obtaining clinical privileges, which are granted by Trustees of BMC.

# Responsibilities of Radioisotope Users

Any individual at BU/BMC who works with radioisotopes is considered a radioisotope user. Radioisotope users at BU/BMC are responsible for:

- 1. Completing basic radiation safety training provided by the DMPRS prior to entering the designated radiation work site.
- 2. Completing training provided by the laboratory's PH (or designee) on specific radiation safety practices within the laboratory.
- 3. Following the BU/BMC ALARA program by keeping his/her radiation exposure As Low As Reasonable Achievable in addition to keeping his/her radiation exposure levels below the state and federal limits presented in <u>Table 1: Occupational Effective Dose Equivalents Limits (rem/year)</u>.
- 4. Participating in the whole body and/or ring dosimetry program if directed by the RSO.
- 5. Using standard laboratory protective measures when working with radioactive material. Such measures include, but are not limited to:
  - a. Wearing appropriate protective clothing (note: shorts and open toe shoes are not appropriate clothing).
  - b. Using appropriate radiation shielding.
  - c. When possible and practical, using mechanical devices or remote handling tools to reduce radiation exposure to the extremities.
  - d. Whenever practical, minimizing the amount of time the user is exposed to radiation and performing experiments in an efficient, expeditious manner.
  - e. Performing work in an approved hood or glove box if it is possible that radioactive material may be released into the air.

- 6. Ensuring that no eating, drinking, smoking, or applying of cosmetics or lotions occur in areas where radioactive materials are present. Storage of food or beverages in a laboratory is prohibited.
- 7. Maintaining good work habits and safe laboratory techniques as specified in <u>APPENDIX</u> I: RADIOISOTOPE LABORATORY RULES.
- 8. Performing a radiation survey:
  - At the end of each day when radioactive materials have been used/accessed;
  - Following the transfer of radioactive materials from stock solutions; and
  - After each experimental run if there is a possibility of a change in radiation levels or contamination.
- 9. Immediately cleaning up contaminated areas and reporting spills and skin contamination to the DMPRS as soon as possible (see <u>Emergency Contact Information</u>).
- 10. Keeping the laboratory neat and organized.
- 11. Labeling and isolating radioactive sources, waste, and radiation emitting equipment.
- 12. Understanding how to procure/purchase radioactive materials as described in <u>Purchase of Radioactive Materials and Devices</u>.
- 13. Being familiar with the safe use and storage of radiation emitting materials and devices as described in Working with Radioactive Materials and Devices.
- 14. Properly storing and disposing of radioactive waste as described in <u>Radioactive Waste Management and Disposition of Radioactive Materials and Devices</u>.
- 15. Contacting the PH or a member of the DMPRS when unsure of how to handle a radiation safety related issue.

# Radioisotope Permit Deficiencies

The PH must correct all deficiencies identified by the DMPRS within two weeks of notification. If a corrective action cannot be completed within the two week time frame, the reason must be communicated to the RSO with an estimated time to completion. The RSO may grant a one-time extension or suspend the permit until the issue is resolved.

#### **Permit Reauthorization**

Permits are reauthorized/renewed by the RSC, at minimum, every two years. All permit amendments will be treated and reviewed as renewals. The DMPRS monitors permits monthly for issues of noncompliance. Permit holders will be notified by the DMPRS two (2) months prior to the expiration date of their permit. Permit holders must submit a renewal permit application to the DMPRS, ensuring that all radiation users have completed their radiation safety refresher training for radioisotope users.

Permit holders who do not complete the refresher training within two (2) months of their expiration date will be prevented from purchasing radioactive materials, the permit will be deemed suspended, and all radioactive work must stop until training is completed. In some instances, the DMPRS may confiscate all radioactive materials. After ninety (90) days, the PH will need to reapply for a new radioisotope permit with retraining of all users.

# Radioisotope Safety Regulations and Policies

This section describes fundamental regulations, policies, and procedures for the use of radioactive materials. These federal and state regulations are legally binding and require the maintenance of certain records and the fulfillment of certain obligations by all radioisotope users. Failure to meet

Section 5

these legal requirements could place the BU/BMC state license in jeopardy, and failure to comply with established policies and procedures could compromise radiation safety.

# Regulations

The Commonwealth of Massachusetts has established regulations to control the use and licensing of radioactive materials and nuclear facilities. The principal regulations on which this Manual is based are provided in 105 CMR 120.00, entitled "Massachusetts Regulations for the Control of Radiation" which are based on the federal regulations 10 CFR Part 20 "Standards for Protection Against Radiation". Institutions and individual radioisotope users must comply with the applicable requirements of the state regulations.

# **University and Hospital Policies and Procedures**

In addition to this Manual, BU and BMC (BU/BMC), as licensees for the possession and use of radiation sources, recognize their responsibility to evaluate, approve, and establish appropriate policies and procedures for the safe use of radioisotopes and radiation sources. To this end, both institutions appointed the RSO and RSC to evaluate new policies, procedures, or other proposed changes to the radioisotope program.

The guidance established in this Radioisotope Manual shall be followed by all radioisotope users at BU/BMC. Any variance must be reviewed and approved by the RSO.

#### **Definition of a Radiation Source**

A radiation source is any radionuclide, X-ray machine, accelerator or other device capable of emitting hazardous ionizing radiation and its use is subject to RSC oversight. Hazardous ionizing radiation is any particulate or electromagnetic radiation capable of producing biological damage through the ionization of an atom.

# **Occupational Radiation Exposure Limits**

BU/BMC users shall conform to the safety limits specified in Massachusetts regulation 105 CMR 120 regarding the total radiation exposure allowable in one calendar year. Here, a person's radiation exposure is referred to as the Total Effective Dose Equivalent (TEDE): the total external and internal doses to an individual, given in units of rem (a formal definition of TEDE is provided in 105 CMR 120.105). Often times a radiation exposure is small enough to be given in terms of millirem (mrem) where 1,000 mrem is equal to 1 rem. Table 1 below presents a

summary of the maximum radiation exposures (in units of rem/year) that a radiation user is allowed to receive in a single calendar year. While the exposures in Table 1 present the legal limit that a radiation user may receive, BU/BMC strictly adhere to the ALARA principle requiring users to minimize their radiation exposures (see <u>ALARA</u>, Section 2).

<u>Table 1: Occupational Effective Dose Equivalents Limits (rem/year)</u>

Total Effective Dose Equivalent (body)	5
Dose to Lens of the eye	15
Dose to Extremities and Organs	50
Dose to Embryo (Declared Pregnancy)	0.5/term

BU/BMC have set an administrative limit for the total effective dose equivalent at 375 mrem/quarter. Exemptions to this administrative limit may be granted by the RSO or their designee for specific projects on an as needed basis. Radiation sources normally encountered at BU/BMC are not expected to cause doses above this administrative limit. In fact, exposures are expected to be well below this limit. In addition, members of the public are limited to no more than 0.1 rem/year and 0.002 rem in any one hour from radiation related activities performed at BU/BMC.

#### **Regulations Regarding the Control of Radioisotopes**

To maintain public safety and meet relevant state and federal regulations, all radioisotopes are controlled for the lifetime of the source. Therefore, the BU/BMC Radiation Safety Program has set forth the following controls:

- 1. Any space or laboratory in which radioisotopes are to be used or stored must first be authorized by the DMPRS/RSO and RSC for the intended use and a PH must accept responsibility for implementing the requirements of this manual.
- 2. Ordering and purchasing radioisotopes is controlled through the DMPRS. Individuals wishing to purchase a radiation source must comply with <a href="Purchase of Radioactive">Purchase of Radioactive</a> Materials and Devices of this manual.
- 3. The use or storage of radioisotopes within a laboratory must comply with the conditions and standards presented in <u>Working with Radioactive Materials and Devices</u> of this manual.
- 4. Disposition of radioisotopes (shipping, or waste handling) must comply with the requirements of <u>Radioactive Waste Management and Disposition of Radioactive Materials</u> and <u>Devices</u> of this manual.

# Purchase of Radioactive Materials and **Devices**

purchases must be coordinated by the DMPRS.

BU and BMC Purchasing and DMPRS procedures have been established to prevent the unauthorized purchase and use of radioactive materials. All



# **Purchasing**

All radioactive material must first be approved by the laboratory's permit holder or designee and then approved by the DMPRS as described in this section.

All radioactive material purchase requests must be submitted online to the DMPRS. Accounting information included in the submission must be accurate and current. The DMPRS staff member will review the order and ensure the permit holder is active, the isotope may be possessed by the permit holder, and the amount requested is within their allowed possession limit. The DMPRS staff member places all orders of radioactive material directly with the vendor.

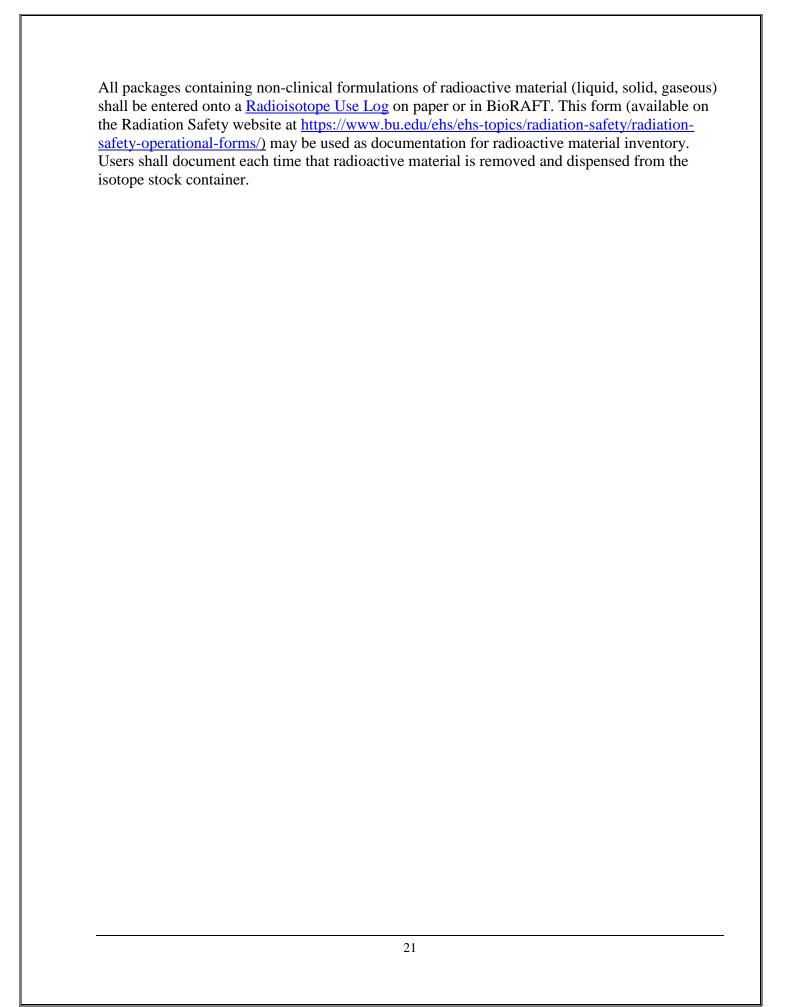
# **Package Receipt**

When a radioactive material package is shipped to BU/BMC, the DMPRS or authorized BMC receiving department (such as Nuclear Medicine) will receive, open, verify, inventory, and process the received radioactive materials shipment. After processing, a member of the DMPRS will deliver the package to the laboratory.

Radioactive materials ordered for clinical purposes may be delivered by a carrier directly to the license specified location in which they will be stored and used. The receiving department, (such as Nuclear Medicine) is responsible for receiving and opening the package according to established procedures. The receiving department is also responsible for performing the necessary surveys, documenting the results of the surveys, and providing the initial response if a package is found to possess contamination; departments receiving a package that exceeds 22 dpm/cm<sup>2</sup> for a beta gamma emitter, or 2.2 dpm/cm<sup>2</sup> for an alpha emitter, or whose transport index exceeds 10 millirem per hour at a distance of one meter must be placed in a safe isolated location, and the DMPRS must be contacted immediately.

The DMPRS will check all radioactive material packages it receives for contamination and verify that external dose rates agree with the values stated by the shipper. It is therefore not required for a laboratory to perform a radiation survey on a package received from the DMPRS but it is advisable to verify contamination levels or radiation field levels under the following conditions:

- The package is damaged, or its integrity compromised after receipt from the DMPRS;
- The radioactive material container is visibly damaged.



# Working with Radioactive Materials and Devices

Personnel using radioactive material must ensure that the location in which the material is used, and the equipment that may become contaminated during use, is strictly controlled. This section provides the guidance necessary to ensure such control is maintained.



# **Storage of Radioactive Material and Devices**

All radiation sources must be stored in a secure location (restricted access, minimum fire hazard, approved ventilation, sufficient shielding, and locked), labeled, and the location posted with a "Caution Radioactive Material" or "Caution Radiation Emitting Device" sign. The DMPRS will provide the laboratory with the proper signs and documentation to ensure compliance with the posting requirements of 105 CMR 120.

# **Inventory**

To maintain proper control of radiation sources and to comply with regulatory requirements a radiation laboratory must keep an inventory of all its radiation sources. This inventory shall include the following information:

- 1. Source description;
- 2. Original activity or radiation emission rate and date;
- 3. Record of usage and estimated remaining activity;
- 4. Physical location; and
- 5. Disposition of material and date.

The BioRAFT radioisotope inventory function allows authorized users to maintain and record the inventory requirements listed above. Also, the Radioactive Material Use Log is recommended for recording the above information and may be obtained from the DMPRS website.

# Labeling

Each individual radiation source (or container) shall be labeled with an identification tag clearly indicating the date, radionuclide, volume, and activity. Labels are available from the DMPRS. All tags or labels must be removed/replaced/defaced when the information on them is no longer current. Contact the DMPRS for questions on the labeling of radiation sources.

# **Personnel Radiation Monitoring (Dosimetry)**

Regulations require the licensee to provide radiation dosimetry (also called a radiation badge or ring) to any individual that may exceed ten percent of the applicable annual occupational dose limit (see Occupational Radiation Exposure Limits, Section 5). Operations in the laboratory and hospital were evaluated for the potential to exceed ten percent of the dose limit. Operations that

require a dosimeter were identified and the wearing of dosimeter by these individuals is considered mandatory. Operations that do not require a dosimeter were also identified and the wearing of dosimetry by these individuals is considered "optional," i.e., the individual may participate in the dosimetry program and can elect to wear a dosimeter if they so choose and must fully cooperate with the periodic change out of the dosimeter. Any changes to an individual's status with the program will be communicated with the individual.

#### Laboratory Operations

Most individuals working in research laboratories at BU/BMC will not require the use of radiation dosimetry, but may be provided dosimetry under specific circumstances as determined by the RSO. Radioisotope Users working with one millicurie or greater of a gamma or positron emitter, or highenergy beta emitter (e.g. P-32), in any one quarter will be issued dosimetry.

#### **Hospital Operations**

Individuals working directly with radiation sources, such as nuclear medicine isotopes, fluoroscopy, radiography, etc. do have the potential for approaching and exceeding ten percent of the applicable occupational dose limits. Therefore, individuals working directly with radiation sources in the hospital environment will require radiation dosimetry. Hospital employees that may inadvertently be exposed to radiation, such as through incidental contact with patients injected with nuclear medicine isotopes, or standing in the vicinity while a portable X-ray machine is used, receive very little exposure and do not require monitoring for radiation exposure. These individuals may be provided with dosimetry upon request. Note, there may be special cases when such individuals will require radiation monitoring. The DMPRS maintains awareness of radiation source use and will evaluate the need for monitoring in special cases.

#### **Contamination Control**

Radioactive contamination control is practiced through the proper handling of radioactive material, use of adequate protective clothing, and use of sealed containers for transfer and storage of such material. The following steps will help to control the creation and spread of contamination:

- 1. All areas in which radioactive material is used or stored will be posted as a "Radioactive Material Use" area.
- 2. Required protective clothing will be specified.
- 3. Wipe tests will be taken at routine intervals to evaluate the level of contamination.
- 4. Volatile radioactive compounds will be stored in sealed containers and vented prior to use in approved filtered hoods.
- 5. Eating and drinking is prohibited in all laboratories.
- 6. Air samples will be taken if significant airborne contamination is anticipated.
- 7. Leak tests will be performed on sealed sources.

#### **Controlled Areas**

Controlled areas will be established for controlling movement of radioisotopes and personnel. Segregating these areas will minimize the potential for accidental contamination and unnecessary radiation exposure. Every individual working or visiting such areas should observe signs and directions indicating actions to be taken in a specified area.

Controlled areas are designated as follows:

- 1. A controlled area is an area where access is controlled for purposes of personnel protection. State and federal regulations place the following restrictions on elevated radiation areas:
  - a. Radiation Area: A radiation area is defined as any area, accessible to personnel, in which radiation levels could result in an individual receiving a dose equivalent in excess of 5 millirem at a distance of 30 cm in one hour from a radiation source. These areas must be posted.



- b. <u>High Radiation Area</u>: This area is defined as any area, accessible to personnel when radiation levels could result in individuals receiving a dose equivalent in excess of 100 millirem in one hour at 30 cm from the radiation source or boundary. High Radiation Areas require access control measures to be instituted.
- c. <u>Contamination Area</u>: An area where controlled access is maintained for the purpose of contamination control. Persons should not enter such an area without authorization and proper personnel protection. Contamination areas may only be released for unrestricted use after evaluation and approval by DMPRS staff.

# **Radiation Monitoring**

Routine radiation and contamination monitoring surveys are conducted by the DMPRS as part of good radiation safety practice and to ensure compliance with radioactive material license requirements.

Surveys shall include a contamination survey and, if appropriate, an area radiation survey. Laboratories which use radioisotopes which do not pose an external radiation hazard (such as C-14 or H-3) are not required to perform radiation area surveys but are required to perform contamination surveys. Radiation users who wish to review proper radiation survey techniques may consult the <u>guide</u> on the DMPRS website or may contact a member of the DMPRS.

The following is a list of recommended laboratory radiation surveys:

- 1. Radiation and contamination surveys (as applicable) when a radioisotope is used, especially immediately following the transfer of radioactive materials from stock solutions.
- 2. After each experimental run if there is a possibility of a change in radiation levels or contamination.

3. After a radioactive material spill.

# **Survey Frequency**

Frequency of laboratory surveys will depend on the status of the radioisotope permit and hazards classification of the isotopes used and possession limits as outlined in the table below.

		Hazard classification			
		Low	Medium	High	Very High
nth	<0.1 mCi	Semi annual	Quarterly	Monthly	Weekly
n/ ie month	0.1-1 mCi	Semi annual	Quarterly	Monthly	Weekly
Possession/ Use in one	1-10 mCi	Quarterly	Monthly	Weekly	Daily
Poss Use	>10 mCi	Monthly	Weekly	Daily	Daily

Isotope (unsealed)	Hazard classification	Hazard class based on
H-3	Low	Internal
C-14	Medium	Skin dose
I-125	High	Internal
P-32	High	Skin dose
P-33	Medium	Skin dose
S-35	Medium	Skin dose
Cr-51	Medium	External
Ca-45	Medium	Skin dose
Nuclear	High	Internal
Medicine*		

<sup>\*</sup>Survey frequency dictated by regulation.

# Storage and Security of Radioactive Material

Radionuclides must be stored only in designated storage areas/containers, which are approved by the DMPRS. These areas and containers must be secured when unattended in a manner which prevents access and/or removal by unauthorized and untrained personnel. In practice, if access to the laboratory or storage area is limited only to radioisotope users (no ancillary or clerical staff has access), it is considered a sufficient security measure. If this is not possible, secure and lockable security freezers are acceptable. If neither of the previously mentioned security measures is available, affixed security boxes are a widely used solution throughout BU/BMC. The security of irradiators is addressed in Public Safety procedures and policies.

# Posting of Radioisotope Storage and Use Areas

Proper hazard communication is an integral part of the radiation safety program. All entryways to spaces permitted to use radioactive materials must display a radioactive materials sign on the posted BU HAZCOM sign. In addition, all entry ways must have emergency contact numbers visible detailing DMPRS contact information during business hours and Control Center contact information for 24 hour support.

Signs and labels are available from the DMPRS and must only be used to correctly communicate the presence of radioactive material, radiation hazards, or airborne radioactive contamination.

Depending on the nature of the area or laboratory the sign must bear the words:

• Caution Radioactive Material - This sign is required in areas where radioactive materials are used or stored.



#### Records

It is a legal requirement of our state radioactive material license that certain records be maintained and made available to the licensing agency. In accordance with this requirement and as part of good radiation safety program, the RSC requires that the following information be recorded:

- 1. The permit holder shall:
  - a. Keep an inventory of radioisotopes, on paper and in BioRAFT; and
  - b. Keep a record of all waste disposals of radioactive material.
- 2. The DMPRS shall maintain:
  - a. Up-to-date inventories of all radioisotopes;
  - b. Radiation surveys and monitoring records of a general and special nature;
  - c. Records of all incidents (spills, releases, contamination problems) involving radiation sources;
  - d. Leak test data on all radiation sources;
  - e. Personnel monitoring records;
  - f. Instrument calibration records;
  - g. Waste disposal records;
  - h. Licensing data;
  - i. Emergency equipment;
  - i. Minutes of RSC and subcommittee meetings;
  - k. Applications for authorization to use radiation sources;

- 1. Copies of authorizations and a list of all radioisotope users; and
- m. Decommissioning files in accordance with state regulations.

# **DMPRS** Release of Areas and Equipment for Unrestricted Use

Areas and equipment associated with the storage, use and disposal of radioactive materials that will be released for unrestricted use must meet the following criteria:

- 1. All radioactive material containers (including waste containers) must be removed.
- 2. All equipment associated with the processing, handling and storing of radioactive material must be surveyed on all accessible surface areas to ensure radioactive materials are below the limits defined in <a href="https://example.com/appendix iv: Boston University">APPENDIX IV: Boston University / Boston Medical CENTER</a>

#### **CONTAMINATION ACTION LIMITS FOR RELEASE**

3. Equipment that has the potential to become internally contaminated must be either surveyed to verify the absence of radioactivity or be disposed of as radioactively contaminated. Special consideration must be given for plumbing, air handling, and fume hoods.

# Radioactive Waste Management and Disposition of Radioactive Materials and Devices

Section 8

The transfer of radioactive material, whether in sample form, as waste, or as an unused compound, to another permit holder within the institution or to an organization outside the institution is subject to licensing and transportation regulations. No transfer may take place between campuses, within the same campus, or off campus unless it is approved by the DMPRS.

# **Shipping**

Transportation of radioactive materials is regulated by the Massachusetts DPH, U.S. Nuclear Regulatory Commission, U.S. Department of Transportation (DOT), and the U.S. Postal Service. These regulations require that BU/BMC maintain a central inventory of all radiation sources. Therefore, all radiation source shipments must be approved and documented by the DMPRS.

Radioactive materials may only be transferred to another PH, either at BU/BMC or at another institution, when pre-approved by the DMPRS (and as specified in the permit holder's permit). Only Radiation Safety staff may transfer radiological sources and products between buildings or campuses. If the transfer is to another institution, please allow enough time for DMPRS staff to work with the other institution's Radiation Safety Organization and complete the appropriate paperwork.

#### **Radioactive Waste**

BU/BMC are required under state law and municipal regulation to store all radioactive waste in approved containers using approved handling techniques and to maintain written records regarding the storage and disposal of radioactive waste. *It is a violation of federal, state, and municipal regulations and institutional policy to dispose of radioactive waste as normal trash.* The DMPRS must be contacted <u>immediately</u> (617-358-7688 or after hours via the Control Center at 617-414-4144) if it is found that radioactive waste has been disposed of improperly or if laboratory personnel are unsure of proper procedures for waste handling/disposal.

#### A. General Radioactive Waste Handling Rules Applicable to All Radioactive Waste

1. Radioactive waste is required to be segregated by <u>isotope</u>. NOTE: The laboratory may combine  ${}^{3}\text{H}$  and  ${}^{14}\text{C}$  into a single container or may combine short half-life ( $T_{1/2} \leq 120$  days) materials together. In all cases, materials added to a waste container shall be chemically non-reactive with both the container and its contents.

- 2. All radioactive waste shall be separated and stored into the following physical forms:
  - Solid waste
  - Liquid waste
  - Sharps waste
  - Animal carcasses
  - Lead (Pb) shipping containers

Detailed instructions on proper radioactive waste storage and handling for each physical waste form (also referred to as a "waste stream") are described below.

- 3. <u>Environmental and Waste Management</u> is available to assist in finding vendors of approved radioactive waste containers.
- 4. Regardless of the *type* of radioactive waste generated, <u>all</u> radioactive waste shall be assembled in designated restricted areas and stored in waste containers clearly labeled with the following: "RADIOACTIVE WASTE" or "CAUTION RADIOACTIVE MATERIAL." Environmental and Waste Management will not accept radioactive waste stored in improper waste containers.
- 5. Radioactive chemicals or powders, contaminated sharps, and radioactive animal carcasses are examples of a "mixed waste stream." All such waste shall meet the requirements for radioactive material waste handling documented here <u>and</u> the requirements for chemical/hazardous material waste handling as documented by EHS's Environmental and Waste Management division. Lead containers must <u>not</u> be placed in radioactive waste containers. Keep lead containers in a separate storage bin for pick up by Environmental and Waste Management.
- 6. Laboratories shall maintain a list containing the isotope and total activity present within each waste container generated or used by that laboratory. It is the responsibility of the PH to ensure that this list is up-to-date and accurate.
- 7. Radioactive labels must be removed or defaced prior to being placed in a radioactive waste container.
- 8. When in use, a radioactive waste container shall be labeled with the following information:
  - a. "RADIOACTIVE WASTE" or "CAUTION, RADIOACTIVE MATERIAL" warning sign;
  - b. A listing of the radioisotope(s) present within the container;
  - c. One (1) entry for each time waste is added to the container; and
  - d. The chemical form(s) of the radioisotope(s) present (if liquid).

- 9. When full, a radioactive waste container shall be labeled with the following information:
  - a. A listing of the radioisotope(s) present within the container;
  - b. A estimate of the activity present of each radioisotope (preferably in mCi);
  - c. The chemical form(s) of the radioisotope(s) present;
  - d. The permit holder's name;
  - e. The laboratory room number;
  - f. The name of person labeling the waste; and
  - g. The date that the waste was labeled.
- 10. All radioactive waste receptacles shall be kept in an approved area within the laboratory (not in the hall or other unsecured area). It is the responsibility of the PH to verify that the location of the waste receptacle within the laboratory does not present a health hazard.
- 11. When a radioactive waste container is full, a "Waste Pickup Request" must be submitted via BioRAFT. NOTE: Environmental and Waste Management will not accept any waste containing contaminated glass *unless* it is stored in a plastic lined rigid container (plastic or cardboard) or any other improperly stored waste.
- 12. It is the responsibility of the PH to verify that waste is properly contained and identified. The PH is also responsible for ensuring that any improperly stored waste (especially waste refused for pickup) is properly repackaged *as soon as possible*.
- 13. Short-lived waste may NOT be stored for decay (i.e., until the activity of the waste is indistinguishable from background) in the laboratory. The City of Boston Fire Department requirements preclude the storage of such waste in the laboratory for the purpose of decay in storage. The Boston Fire Department has permitted a specific area for this purpose.

#### **B. Solid Waste Handling Rules**

- 1. On the bench top, solid (dry) radioactive waste (gloves, absorbent material, etc.) shall be stored in clear Plexiglas containers lined with a clear plastic bag. All labels indicating radioactivity must be defaced prior to placing in the waste bin.
- 2. Bags from the bench top containers may be consolidated into larger containers; however, the containers must be the yellow five-gallon pails available from Environmental and Waste Management (at no charge).
- 3. Each radioactive waste container (bench top or floor pail) shall be identified with the magenta and yellow radiation symbol and the words: "RADIOACTIVE WASTE" or "CAUTION RADIOACTIVE MATERIAL."
- 4. Radioactive solid waste is required to be segregated by <u>isotope</u>. NOTE: The laboratory may combine <sup>3</sup>H and <sup>14</sup>C into a single container or may combine short

half-life ( $T_{1/2} \le 120$  days, i.e. P-32, S-35, Tc-99m, and I-131) materials together. In all cases, materials added to a waste container shall be chemically non-reactive with both the container and its contents.

- 5. The laboratory <u>shall</u> maintain a list of the isotope(s) and total activity present within each container. It is the responsibility of the PH to ensure that this list is up-to-date and accurate.
- 6. While in use, each radioactive waste container shall be clearly labeled with the information required above and this information shall be clearly visible.
- 7. Radioactive waste placed in containers shall NOT include any liquids, animal tissue, animal excreta, blood products, lead (Pb), or loose sharp objects likely to cause a laceration or puncture wound.
- 8. Radioactive material must not be put into a waste container if there is the possibility of a chemical reaction during storage that may cause a fire, explosion, or the release of radioactive material.
- 9. Special care must be taken in storing radioactive waste containing volatile isotopes such as iodine and some forms of Sulfur-35. It is suggested that these wastes be double bagged and tightly sealed. Charcoal felt must be used to assist with the control of iodine volatility. Please call Environmental and Waste Management (358-7840) with any questions on this matter.
- 10. When the container is full, the waste shall be labeled to clearly display the information required in <u>above</u>. Verify that the label is not obscured from view.
- 11. After labeling a full waste container, a "Waste Pickup Request" must be submitted online via BioRAFT. NOTE: Environmental and Waste Management will not accept any waste containing contaminated glass *unless* it is stored in a plastic lined rigid container (plastic or cardboard).

#### C. Liquid Waste Handling Rules

- 1. Liquid radioactive waste (including liquid scintillation fluid) shall be contained in plastic or glass sealable jugs. Call Environmental and Waste Management (617-358-7840) if special consideration must be given to another type of container due to chemical incompatibility with approved plastic or glass containers. NOTE: Liquid radioactive waste should be doubly protected; plastic storage bins are available from the Environmental and Waste Management Office.
- 2. Each radioactive liquid waste container shall be identified with the magenta and yellow radiation symbol and the words: "RADIOACTIVE WASTE."

- 3. Radioactive waste is required to be segregated by <u>isotope</u>. NOTE: The laboratory may combine  ${}^{3}H$  and  ${}^{14}C$  into a single container or may combine short half-life (typically  $T_{1/2} \le 90$  days, i.e. P-32, S-35, Tc-99m, and I-131) materials together. In all cases, materials added to a waste container shall be chemically non-reactive with both the container and its contents.
- 4. While in use, each liquid waste container shall be clearly labeled with the information required in <u>above</u>. Verify this information is not obscured from view.
- 5. The laboratory shall maintain a list of the isotope and total activity present within each container. It is the responsibility of the PH to ensure that this list is up-to-date and accurate.
- 6. When the liquid radioactive waste container is nearly full, a Radioactive Material Tag must be attached to the container including the information required in <u>above</u>. Verify that the label is not obscured from view.
- 7. A "Waste Pickup Request" shall be submitted online via BioRAFT.
- 8. Organic based Liquid Scintillation cocktails containing  $^3H$  or  $^{14}C$  at concentrations below 0.05  $\mu$ Ci/ml (1.11×10<sup>5</sup> dpm/ml) are disposed of as toxic waste <u>without</u> regard to radioactivity (that is, it is considered non-radioactive).
- 9. Disposal of *aqueous* liquids via a designated radioisotope laboratory sink may be performed only if the laboratory meets the following criteria:
  - a. The waste is an aqueous solution;
  - b. The isotope concentration falls within the limits specified in BU/BMC Sink Disposal Limits of Radioisotopes (available at <a href="https://www.bu.edu/ehs/ehs-topics/radiation-safety/radiation-safety-operational-forms/">https://www.bu.edu/ehs/ehs-topics/radiation-safety/radiation-safety-operational-forms/</a>); and
  - c. The PH has been approved by EHS for sink release for the specific chemical in question.

The PH is responsible for maintaining records which document the total activity disposed via the sink disposal route, the isotope disposed, and the date.

#### **D.** Animal Carcass Waste Handling Rules

- 1. All animal carcasses shall first be placed in a plastic bag and then in a brown paper biohazard material bag (e.g. a Kraft bag). Animal carcass, animal tissue/parts, and animal excreta/bedding may be placed together in the same bag for the same animal.
- 2. Animal carcass waste bags shall **NOT** contain:
  - a. Needles
  - b. Syringes

- c. Knives
- d. Blades
- e. Glass
- f. Sharps
- g. Scalpels
- h. Pipettes
- i. Ceramics.
- 3. Once the animal carcass has been double bagged, it must be frozen for at least twenty-four (24) hours prior to pick up by Environmental and Waste Management. Environmental and Waste Management will provide a container for the animal carcasses to ensure compatibility with waste vendor acceptance criteria.
- 4. A radioactive material tag (or sticker) must be placed on the outermost bag and must be fully labeled as described in <u>above</u>. To arrange pickup, an online request must be submitted via BioRAFT.

#### **E. Sharps Waste Handling Rules**

- 1. All sharps (needles, syringes, razor blades, scalpel blades, microtome blades, microscope slides/covers, pipette tips, Pasteur pipettes, broken glass, or any object likely to cause a laceration or puncture wound) contaminated with radioactive material shall be deposited into a sharps container marked for radioactive waste.
- 2. Radioactive sharps waste is required to be segregated by <u>isotope</u>. NOTE: The laboratory may combine  $^3H$  and  $^{14}C$  into a single container or may combine short half-life (typically  $T_{1/2} \le 90$  days) materials together. In all cases, materials added to a waste container shall be chemically non-reactive with both the container and its contents.
- 3. Each radioactive sharps container shall be identified with the magenta and yellow radiation symbol and the words: "RADIOACTIVE WASTE."
- 4. While in use, each sharps container shall be clearly labeled with the information required in above. Verify this information is not obscured from view.
- 5. The laboratory shall maintain a list of the isotope and total activity present within each container. It is the responsibility of the PH to ensure that this list is up-to-date and accurate.
- 6. When the sharps radioactive waste container is full, a Radioactive Material Tag must be attached to the container including the information documented in <u>above</u>. Verify that the label is not obscured from view.
- 7. Submit a request online via BioRAFT to arrange a pickup.

# F. Lead Shipping Containers

Many stock vials are shipped from vendors within lead (Pb) shielded containers. These containers shall be disposed of by EHS Environmental and Waste Management. Noncontaminated lead shields must be disposed of in accordance with applicable BU EHS procedures. Any lead shield contaminated with radioactive material shall be either labeled and stored as radioactive waste or labeled and given to the DMPRS.

# **APPENDICES**

**Appendix I: Radioisotope Laboratory Rules** 

**Appendix II: Permit Holder Responsibilities** 

**Appendix III: Research Radioisotope User Responsibilities** 

**Appendix IV: BU/BMC Contamination Action Limits for Release** 

**Appendix V: DPH Notice to Employees** 

#### APPENDIX I: RADIOISOTOPE LABORATORY RULES

These rules are designed to limit unnecessary radiation exposure and contamination of facilities and equipment, and to minimize the consequences of a radiation accident if one should occur. Copies of these rules should be posted in laboratories that use radioisotopes for reference.

#### **General Rules**

NO Eating, drinking, or smoking	Eating, drinking and smoking is prohibited in areas where radionuclides are being used or stored.
Frequent Hand Washing	Wash hands after handling any radioactive material and before going about any other work. Always wash hands before leaving the laboratory.
Proper Pipetting	Never pipette anything by mouth. Use filter tips when working with radioisotopes.
Protective Clothing	Always wear gloves, and consider using double gloves, when handling radioactive material. Lab coats must be worn in the laboratory and left in the laboratory.
Confine Activity	The spread of radioactive contamination may be minimized by working on a tray lined with absorbent material. Radioactive materials that are being transported within the laboratory or building should be transported in a closed lid secondary container which should be shatterproof.
Spill Notification	Notify the DMPRS of all spills. NOTE: Contamination surveys must be performed and documented even after a minor spill.
Proper Labeling	Label radioactive material samples with date of preparation, radionuclide, and quantity of radionuclide.
Proper Clean-Up	Before leaving the laboratory, clean up and monitor your work area and yourself using an appropriate radiation detection instrument. Remove your lab coat and wash your hands.

Proper Disposal of Liquid Radioactive Waste Liquid radioactive waste should be stored in plastic bottles whenever possible. The radionuclide, quantity, and date of disposal must be recorded on the waste container. Small amounts of nontoxic waste may be disposed of in the sanitary sewer as directed by the RSO.

Proper Disposal of Solid Radioactive Waste Solid radioactive waste must be placed in plastic-lined containers. The radionuclide, quantity, and date of disposal must be recorded on the waste container.

Proper Disposal of Liquid Scintillation Fluid Organic based Liquid Scintillation cocktails containing  $^3H$  or  $^{14}C$  at concentrations below 0.05  $\mu$ Ci/ml (1.11×10 $^5$  dpm/ml) are disposed of as toxic waste <u>without</u> regard to radioactivity (that is, it is considered non-radioactive). Disposal of scintillation fluid via laboratory sinks is NOT permitted unless approved by the RSO. Contact <u>Environmental and Waste Management</u> for more information.

Proper Use of Hoods

Hoods or glove boxes must be used when handling stock solutions of volatile radioactive materials.

#### APPENDIX II: PERMIT HOLDER RESPONSIBILITIES



Division of Medical Physics and Radiation Safety 80 East Concord Street Boston, Massachusetts 02118

Tel: 617.358.7688 Fax: 617.358.7686

# PERMIT HOLDER RESPONSIBILITIES

Permit Holders are approved by the Radiation Safety Committee to possess and use radioactive materials on the BU/BMC campuses. As a Permit Holder, your responsibilities include:

- 1. You are responsible for the practices and procedures implemented by all users of radioactive material listed on your permit.
- 2. You must attend the Basic Radiation Safety Training course and subsequent radiation safety refresher training every two years.
- 3. You must ensure that all individuals listed on your permit complete Basic Radiation Safety Training before using radioactive materials.
- 4. You must ensure that all users listed on your permit complete radiation safety refresher training every two years.
- 5. You <u>MUST NOT</u> allow untrained or unauthorized persons to use radioactive material in your possession, including individuals that have not completed radiation safety refresher training.
- 6. You must ensure that your permit is posted in an area generally accessed by users.
- 7. You must ensure that the name of the laboratory supervisor and all authorized users listed on your permit are accurate at all times.
- 8. You must seek Radiation Safety Officer (RSO) approval before making any changes to your permit (e.g., new users, adding locations, removing locations, etc.).
- 9. You must ensure that laboratory surveys and wipe tests are performed at the frequency specified by the DMPRS.
- 10. You must correct all deficiencies in your laboratory identified during DMPRS inspections within two (2) weeks of notification. If a corrective action cannot be completed within a two-week period, the RSO may grant a one-time extension or suspend the permit.
- 11. You must submit a renewal application for your permit at least every two years. (You will be notified approximately one month before your renewal date.)

#### APPENDIX III: RESEARCH RADIOISOTOPE USER RESPONSIBILITES



# RESEARCH RADIOISOTOPE USER RESPONSIBILITIES

Your responsibilities as a user of radioactive material are listed below:

- 1. You must complete Basic Radiation Safety Training and pass the quiz before using radioisotopes.
- 2. You must review and know where the permit(s) covering your use of radioisotopes are posted.
- 3. You must use only the radioisotopes listed on your permit.
- 4. You must use radioisotopes only in the locations listed on your permit.
- 5. You must only dispose of liquid radioactive waste down sinks designated for this purpose, and you must complete the sink disposal log.
- 6. You must know how to perform surveys for radioactive contamination.
- 7. You must wear a laboratory coat, safety glasses and protective gloves when working with radioactive materials.
- 8. You must know how to respond and who to contact in an emergency.
- 9. You must remove all radioactive symbols from labels prior to disposal.
- 10. You must participate in the whole body and ring radiation dosimetry program if you work with greater than 1 millicurie of gamma (Cr-51) or positron emitter or with 1 millicurie of greater than 500 keV maximum energy beta emitter (P-32) at one time.
- 11. You must read and understand protocol specific safety requirements and laboratory SOPs.
- 12. You must follow all laboratory safety procedures at all times.
- 13. You must report any accident, potential exposure, or safety concerns to your supervisor immediately.

Print Name	:		
Signature: _			
Date:		_	

# APPENDIX IV: BOSTON UNIVERSITY/BOSTON MEDICAL CENTER CONTAMINATION ACTION LIMITS FOR RELEASE

Surface Contamination Levels in Restricted Areas (dpm/100 cm <sup>2</sup> )		
Area, clothing	Restricted areas, protective clothing used only in	
	restricted area	
alpha emitters	200	
P-32, Co-58, Fe-59, Co-60, Se-75,	2000	
Sr-85, Y-90, In-111, I-123, I-125, I-131,		
Sm-153, Yb-169, Lu-177, Au-198		
Cr-51, Co-57, Ga-67, Tc-99m, Hg-197,	20000	
TI-201		

Surface Contamination Levels in Unrestricted Areas (dpm/100 cm <sup>2</sup> )			
Nuclide*	Average <sup>†,‡,§</sup>	Maximum† <sup>, ∥, §</sup>	Removable†,¶,§
I-123, I-125, I-129, Ra-223, Ra-224, Ra-226	100	300	20
I-126, I-131, I-133, Sr-90	1000	3000	200
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except those noted above.	5000	15000	1000

<sup>\*</sup>Where surface contamination by multiple nuclides exists, the limits established for each nuclide should apply independently.

The maximum contamination level applies to an area of not more than 100 cm<sup>2</sup>.

¶The amount of removable radioactive material per 100 cm² of surface area should be determined by swiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally, and the entire surface should be wiped.

<sup>&</sup>lt;sup>†</sup>As used in this table, dpm means the rate of emission by radioactive material, as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

<sup>&</sup>lt;sup>‡</sup>Measurements of average contaminants should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.

<sup>§</sup>The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 millirad/h at 1 cm and 1.0 millirad/h at 1 centimeter, respectively, measured through not more than 7 milligram/cm² of total absorber.

Action if > Release Limit		
Room	Equipment	
Hold for decay*	Hold for decay	
Clean	Hold for decay**	
Clean	Hold for decay	

<sup>\*</sup> CAUTION – The decision to prevent access to a room or area while waiting for alpha emitting isotopes to decay must be undertaken very carefully. Rooms or areas to which access is denied for greater than 8 working hours due to radioactive contamination will trigger an immediate report to the state Radiation Control Program. Alternate control strategies that will not trigger reporting requirements should be considered such as allowing access only by approved authorized users and implementing survey in and out protocols.

#### Most Commonly Used Radioisotopes at BU/BMC

Radioisotope	Half-Life in hours	Energy
F-18	1.8	633.2 keV (Positron)
		0.511 MeV x2 (gamma)
Tc-99m	6.0	140.5 keV (gamma)
I-123	13.2	158.9 keV (gamma)
Tl-201	72	167 keV (gamma)
Xe-133	124.8	81 keV (gamma)
P-32	343.2 (14.3 days)	1710 keV (Beta Max)
P-33	607.2 (25.3 days)	249 keV (Beta Max)
Cr-51	664.8 (27.7 days)	320 keV (gamma)
I-125	1430.4(59.6 days)	27 keV (X-ray)
		35 keV (gamma)
S-35	2097.6 (87.4 days)	166.7 keV (Beta Max)
Fe-55	23827.2 (2.72 years)	<10 keV (X-ray; Auger)
H-3	108186 (12.35 years)	18.6 keV (Beta Max)
Sr-90	249660 ( 28.5 years)	546.2 keV (Beta Max)
C-14	50194800 (5730 years)	156.5 keV (Beta Max)

<sup>\*</sup>Half-life and Energy from NCRP Report No. 58

<sup>\*\*</sup> Equipment such as refrigerators, centrifuges, etc., may be held for decay provided the half-life of the contaminating isotope does not require holding the item for extended periods. Depending on storage capability, equipment and items should not be held for more than 6 months for practicality purposes unless approved by the Executive Director of EHS.

# **APPENDIX V: DPH Notice to Employees**



#### MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH RADIATION CONTROL PROGRAM

#### NOTICE TO EMPLOYEES STANDARDS FOR PROTECTION AGAINST RADIATION; NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS

The Radiation Control Program (Agency) of Massachusetts Department of Public Health has adopted regulations in 105 CMR 120.200 which establish standards for your protection against radiation hazards. In 105 CMR 120.750, the Agency has also established certain provisions for the options of workers engaged in work under the Department license or registration

#### YOUR EMPLOYER'S RESPONSIBILITY

#### Your employer is required to -

- Apply these regulations to work involving sources of radiation.
- 2. Post or otherwise make available to you a copy of the Massachusetts Department of Public Health regulations for control of radiation, and the operating procedures which apply to work you are engaged in, and explain their provisions to you.

  3. Post Notice of Violation involving radiological working
- conditions, proposed imposition of civil penalties and

#### YOUR RESPONSIBILITY AS A WORKER

You should familiarize yourself with those provisions of the department regulations, and the operating procedures which apply to the work you are engaged in. You should observe their provisions for your own protection and protection of your co-workers.

#### WHAT IS COVERED BY THESE REGULATIONS

- 1. Limits on occupational exposure to radiation and radioactive material:
- 2. measures to be taken after accidental exposure;

- 2. Intessures to actar and a cancinate apposite,
  3. personnel monitoring, surveys, and equipment;
  4. caution signs, labels, and safety interlock equipment;
  5. exposure records and reports;
  6. options for workers regarding Agency inspections; and
  7. related matters.

#### REPORTS ON YOUR RADIATION EXPOSURE HISTORY

- 1. The Department of Public Health regulations require that your nue Department of Public Health regulations require that your employer give you a written report if you receive an exposure in excess of any applicable limit as set forth in the regulations or in the license. The basic limits for exposure to employees are set forth in 105 CMR 120.211 through 120.218 of the regulations. These sections specify limits on exposure to radiation and exposure to concentrations of radioactive material in air
- material in air.

  If you work where personnel monitoring is required:
  - (a) your employer must advise you of your occupational radiation dose each year, and (b) upon termination of employment, your employer must give you a written report of your dose if you request it.

#### INSPECTIONS

All licensed or registered activities are subject to inspection by representatives of the Department of Public Health, Radiation Control Program. In addition, any worker or representative of workers who believes that there is a violation of the M.G.L.c.111, the regulations issued thereunder, or the terms of the employer's the regulations issued increamer, or the terms of the employer's license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by sending a notice of the alleged violation to the Department of Public Health, Radiation Control Program. The request must set forth the specific grounds for the notice, and must be signed by the worker as the representative of the workers. During inspections, Department inspectors may confer privately with workers, and any worker may bring to the attention of the inspectors any past or present condition which he believes contributed to or caused any violation as described above.

Direct all inquiries on the matters outlined herein to:

Massachusetts Department of Public Health Radiation Control Program Schrafft Center, Suite 1M2A 529 Main Street Charlestown, MA 02129 Telephone: (617) 242-3035 Fax: (617) 242-3457 Emergency Phone: (617) 242-3453

#### POSTING REQUIREMENT

COPIES OF THIS NOTICE MUST BE POSTED IN A SUFFICIENT NUMBER OF PLACES IN EVERY ESTABLISHMENT WHERE EMPLOYEES ARE EMPLOYED IN ACTIVITIES LICENSED OR REGISTERED, PURSUANT TO 105 CMR 120.750, BY THE DEPARTMENT OF PUBLIC HEALTH, RADIATION CONTROL PROGRAM, TO PERMIT EMPLOYEES WORKING IN OR FREQUENTING ANY PORTION OF A RESTRICTED AREA TO OBSERVE A COPY ON THE WAY TO OR FROM THEIR PLACE OF EMPLOYMENT.

MRCP 120.750-1 January 2018