

EHS-500, Radiation Safety Manual

TABLE OF CONTENTS

| | |
|-----------------------------------------------------------------------------------|-----------|
| LIST OF TABLES..... | 5 |
| INTRODUCTION | 6 |
| 1. PURPOSE | 6 |
| 2. SCOPE | 6 |
| 3. REFERENCES | 6 |
| 4. RESPONSIBILITIES FOR USING RADIATION AT EMORY | 6 |
| 5. EMORY UNIVERSITY RESPONSIBILITIES | 10 |
| 6. ACCESS TO RADIATION SAFETY PROGRAM DOCUMENTS..... | 15 |
| RADIATION EXPOSURE LIMITS & MONITORING..... | 16 |
| 7. POLICY..... | 16 |
| 8. RADIATION EXPOSURE..... | 16 |
| TRAINING PROGRAM..... | 21 |
| 9. TRAINING REQUIREMENTS FOR ANCILLARY WORKERS | 21 |
| 10. TRAINING REQUIREMENTS FOR LABORATORY WORKERS USING RADIOACTIVE MATERIAL | 21 |
| 11. HOW DO I GET TRAINING? | 22 |
| 12. RETRAINING FREQUENCY..... | 22 |
| 13. TRAINING REQUIREMENTS FOR HEALTHCARE WORKERS USING RADIOACTIVE MATERIAL | 23 |
| 14. TRAINING REQUIREMENTS FOR X-RAY MACHINE OPERATORS..... | 24 |
| AUTHORIZATION TO USE RADIATION - HOW TO OBTAIN OR AMEND | 25 |
| 15. FOR NON-HUMAN USE OF RADIOACTIVE MATERIAL | 25 |
| 16. FOR HUMAN USE OF RADIOACTIVE MATERIALS | 27 |
| 17. FOR MACHINE-PRODUCED RADIATION IN RESEARCH | 29 |

EHS-500, Radiation Safety Manual

| | |
|------------------------------------------------------------------------|-----------|
| SAFE USE OF RADIOACTIVE MATERIAL | 31 |
| 18. GENERAL RULES FOR HANDLING RADIOACTIVE MATERIAL | 31 |
| 19. LABORATORY REQUIREMENTS..... | 32 |
| 20. GENERAL RULES FOR STORAGE & SECURITY OF RADIOACTIVE MATERIAL | 33 |
| 21. CLINICAL AREAS..... | 33 |
| 22. RADIOACTIVE VOLATILES AND GASES | 33 |
| 23. SIGNS & POSTINGS | 34 |
| 24. AREA SURVEYS AND WIPE TESTS..... | 35 |
| 25. SEALED SOURCES..... | 39 |
| ACCIDENTS / INCIDENTS / EMERGENCIES | 40 |
| 26. PERSONAL CONTAMINATION..... | 40 |
| 27. WHAT IF I HAVE A SPILL? | 41 |
| 28. OTHER INCIDENTS | 42 |
| PROCUREMENT OF RADIOACTIVE MATERIAL | 46 |
| 29. PROCUREMENT THROUGH EMORY EXPRESS | 46 |
| RECEIVING RADIOACTIVE MATERIAL | 48 |
| 30. RECEIVING PACKAGES OF RADIOACTIVE MATERIAL..... | 48 |
| MAINTENANCE OF RADIOACTIVE MATERIAL INVENTORY..... | 49 |
| 31. RADIOACTIVE MATERIAL INVENTORY | 49 |
| TRANSPORTING RADIOACTIVE MATERIAL | 50 |
| 32. TRANSPORTATION OF RADIOACTIVITY FROM EMORY | 50 |
| WASTE MANAGEMENT | 51 |
| 33. LABORATORY AREAS | 51 |
| 34. CLINICAL AREAS..... | 54 |

EHS-500, Radiation Safety Manual

| | |
|-------------------------------------------------------------------------------------------|-----------|
| USE OF RADIOACTIVE MATERIAL IN ANIMALS..... | 55 |
| 35. SAFE USE OF RADIOACTIVITY IN VIVO | 55 |
| 36. GUIDELINES FOR SELECTING PROPER ANIMAL CARE PROTOCOL | 57 |
| RADIATION INSTRUMENTATION | 59 |
| 37. GENERAL INFORMATION | 59 |
| USE OF RADIOACTIVE MATERIAL IN HUMANS | 62 |
| 38. WHO IS AUTHORIZED TO ADMINISTER RADIOACTIVE MATERIAL TO HUMANS? | 62 |
| 39. GENERAL REQUIREMENTS FOR CLINICAL USE OF RADIOACTIVE MATERIAL | 63 |
| 40. GUIDELINES FOR WRITTEN DIRECTIVES (PRESCRIPTIONS) | 65 |
| 41. BRACHYTHERAPY RULES | 67 |
| 42. HIGH DOSE RATE (HDR) AFTERLOADER RULES | 68 |
| 43. PATIENT CARE | 70 |
| 44. NURSING CARE OF PATIENTS CONTAINING THERAPEUTIC AMOUNTS OF RADIOACTIVE MATERIAL | 71 |
| 45. REPORTING PATIENT MEDICAL EVENTS | 72 |
| AUTHORIZATION INSPECTIONS | 73 |
| 46. LABORATORY AUDITS | 73 |
| 47. CLINICAL AUDITS | 74 |
| 48. RADIATION SAFETY AUDIT RECORDS | 75 |
| MACHINE-PRODUCED RADIATION | 76 |
| 49. REQUIREMENTS FOR POSSESSION OF RADIATION-PRODUCING EQUIPMENT | 76 |
| 50. POLICIES FOR STAFF | 77 |
| 51. PATIENT SAFETY GUIDELINES | 79 |
| 52. USING X-RAYS IN RESEARCH | 80 |
| 53. NON-HUMAN USE OF X-RAYS | 80 |
| APPENDIX A – INSPECTION ITEMS AND RECOMMENDATIONS | 82 |



EMORY
UNIVERSITY

Environmental Health and Safety Office
Research Administration

Effective Date:
09/10/2025

Version: 11

Page: 4 of 84

EHS-500, Radiation Safety Manual

APPENDIX B – VERSION HISTORY84

EHS-500, Radiation Safety Manual

LIST OF TABLES

| | |
|------------------------------------------------------------------------|----|
| Table 1, Exposure Limits for Adults | 16 |
| Table 2, ALARA Investigational Levels | 18 |
| Table 3, Job Functions at risk of exceeding ALARA 1 Level..... | 18 |
| Table 4, Action Level for Ambient Surveys | 38 |
| Table 5, Wipe Test Action Levels – Unrestricted/Restricted Areas | 38 |
| Table 6, Radionuclides Commonly Used in Research Laboratories | 45 |
| Table 7, Waste Containers | 52 |
| Table 8, Separation of Waste | 52 |
| Table 9, Radiotoxicity Classification..... | 57 |
| Table 10, Maximum Permitted Daily Activity Excretion | 57 |

EHS-500, Radiation Safety Manual

INTRODUCTION

1. PURPOSE

The Emory University Radiation Safety Manual is written for the purpose of administering the rules and regulations for facilities owned or controlled by the University by specifying the existing regulatory requirements that shall be adhered to by researchers and clinicians. This manual defines the level of compliance required of individuals who wish to utilize radiation or radioactive materials in their research, clinical practice, or teaching programs at Emory University and associated institutions. Further, this manual is written for the purpose of maintaining radiation exposure As Low As Reasonably Achievable.

The requirements of this Radiation Safety Manual are authorized by the Executive Radiation Control Council of Emory University.

All radioactive materials used at Emory University under these various licenses are under the jurisdiction of the State of Georgia Department of Natural Resources' Radioactive Materials Program.

2. SCOPE

This manual applies to all Emory University and Healthcare faculty, staff, students and volunteers at any of the facilities owned or controlled by the University.

3. REFERENCES

- 3.1. State of Georgia Rules and Regulations for X-Ray, Chapter 111-8-90
- 3.2. State of Georgia Rules and Regulations for Radioactive Materials, Chapter 391 3 17
- 3.3. FDA, 21 CFR 361.1, Radioactive Drugs for Certain Research Uses
- 3.4. OSHA, 29 CFR 1910.1096, Ionizing Radiation Standard
- 3.5. Emory University Radiation Control Council Charter
- 3.6. Emory University Broad Scope License GA 153-1
- 3.7. Emory Johns Creek Hospital License GA 203-1
- 3.8. Emory Decatur Hospital License GA 206-1
- 3.9. Emory Hospital Warner Robins License GA 260-1
- 3.10. Emory Saint Joseph's Hospital License GA 296-4
- 3.11. Emory Saint Joseph's Hospital License GA 296-6
- 3.12. Emory Southern Heart Specialists License GA 1359-1
- 3.13. Emory Heart Center License GA 1442-1
- 3.14. Emory Proton Therapy Center License GA 1661-1

4. RESPONSIBILITIES FOR USING RADIATION AT EMORY

- 4.1. General Policy

EHS-500, Radiation Safety Manual

All employees, students and volunteers are required to comply with the rules set forth by this Manual. All users of radioactive material (RAM) must be carried out in accordance with the State of Georgia Rules and Regulations for Radioactive Materials, Chapter 391-3-17, this Manual and written radiation safety procedures applicable to specific areas. All uses of radiation producing machines must be carried out in accordance with State of Georgia Rules and Regulations for X-Ray, Chapter 111-8-90, this Manual, and written radiation safety procedures applicable to specific areas.

- 4.1.1. All employees, students and volunteers are required to promptly report to Radiation Safety any condition which may cause unnecessary exposure to radiation or radioactive material; or may constitute, lead to, or cause Emory to be in violation of the rules and regulations for radioactive materials or conditions of the license.
- 4.1.2. All employees, students and volunteers are required to complete requisite Emory training before using radioactive material or radiation producing machines.
- 4.1.3. All RAM Users who fail to comply with these regulations may cause Emory to be subject to license revocation and/or other sanctions provided by law including monetary fines.

4.2. ALARA Principle

The fundamental objective of radiation protection is to keep all radiation exposures ALARA (As Low As Reasonably Achievable), consistent with the purpose for which the activity is undertaken. Exposures are maintained ALARA by following the basic principles of radiation protection: optimizing the amount of time of the exposure, distance from the source of the exposure, use of appropriate shielding and technology, and radioactive contamination control and prevention.

4.3. Authorized Users of Radioactive Material – Medical Treatment and Clinical Research

NOTE: Authorized Users who fail to comply with these regulations may cause Emory to be subject to license revocation and/or other sanctions provided by law including monetary fines.

Authorized Users are physicians who have been authorized by the State of Georgia or Radiation Safety Committee 1 (committee for human use) under the broad scope license to prescribe and direct the use of radiation and radioactive material to humans for clinical or research use and to perform the final interpretation of the results of the tests or studies. Their responsibilities include:

- 4.3.1. The health and safety of anyone using or affected by the use of radioactive materials under his/her direction or supervision;
- 4.3.2. Receiving initial training and ensuring that his/her staff receive appropriate training;
- 4.3.3. Ensuring that only those individuals trained and designated in writing by an Authorized User are permitted to administer radioactive material to patients or human research subjects;
- 4.3.4. Ensuring that his/her employees, staff, and visitors comply with relevant regulations, policies, and procedures;
- 4.3.5. Reviewing the work of the supervised individual(s) and their radioactive material records;

EHS-500, Radiation Safety Manual

- 4.3.6. Prescribing the radiopharmaceutical dosage to be administered by issuing a written directive or reference to the diagnostic clinical procedures manual;
- 4.3.7. Preparing and administering, or supervising the preparation and administration of radioactive material for medical use in accordance with applicable policies and regulations;
- 4.3.8. Being physically present for the administration of therapeutic doses;
- 4.3.9. Being immediately available to communicate with the supervised user(s);
- 4.3.10. Informing the Radiation Safety Officer of any changes to the authorization and written directive;
- 4.3.11. Reporting any medical events involving radioactive material, such as misadministration, unintended administrations to pregnant women, etc., to the Radiation Safety Officer.
- 4.3.12. Reporting to the Radiation Safety Officer any medical events involving external beam radiation therapy, including but not limited to:
 - 4.3.12.1. The total dose delivered differs from the prescribed dose by 20 percent or more;
 - 4.3.12.2. the fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more;
 - 4.3.12.3. an administration of a dose to the wrong individual or human research subject;
 - 4.3.12.4. an administration of a dose or dosage delivered by the wrong mode of treatment, i.e., photon vs. electron;
 - 4.3.12.5. administration to the wrong site.
- 4.4. Radiation Permit Holders – Non-Human Research

NOTE: Radiation Permit Holders who fail to comply with these regulations may cause Emory to be subject to license revocation and/or other sanctions provided by law including monetary fines.

The Radiation Permit Holder (RPH) is the researcher who has been authorized by the Radiation Safety Committee 2 (committee for non-human use) under the broad scope license to use radiation or radioactive material in research in vitro or in vivo. (See the section "[Authorization to Use Radiation](#)" for obtaining Authorization). The RPH's responsibilities include:

 - 4.4.1. Maintaining exposures ALARA to all laboratory personnel, both users of radioactive material and those who do not use radioactive material in their laboratory;
 - 4.4.2. Ensuring that only those individuals trained and approved on their Authorization are permitted to use radiation or radioactive material in their laboratories;
 - 4.4.3. Ensuring that laboratory personnel using radiation or radioactive material under their supervision are trained and educated in good radiation safety practices which contribute to maintaining exposures ALARA;
 - 4.4.4. Reviewing the supervised individual's use of radiation or radioactive material,

EHS-500, Radiation Safety Manual

providing reinstruction if needed, and reviewing records kept to reflect use;

4.4.5. Cooperating with Radiation Safety during investigations and audits;

4.4.6. Reporting promptly to Radiation Safety any condition which may cause unnecessary exposure to radiation or radioactive material; or may constitute, lead to, or cause Emory to be in violation of the rules and regulations for radioactive materials or the radioactive material license.

4.5. Radiation Workers

The responsibilities of the Radiation Worker include:

4.5.1. Following the instructions of the supervising RPH/Authorized User;

4.5.2. Following written radiation safety procedures or conditions established in the RPH/Clinical Authorization;

4.5.3. Maintaining their radiation exposures ALARA;

4.5.4. Properly wearing and returning in a timely manner any personnel monitoring badges issued;

4.5.5. Wearing appropriate protective clothing and personal protective equipment (PPE) and using proper shielding when indicated;

4.5.6. Reporting promptly to the Radiation Safety Office any accidents, incidents or condition which may cause unnecessary exposure to radiation or radioactive material; or may constitute, lead to, or cause Emory to be in violation of the rules and regulations for radioactive materials or the radioactive material license;

4.5.7. Completing training as assigned.

4.6. Authorized Diagnostic Medical Physicists (ADMP)

In addition to the responsibilities of the Radiation Worker in the section above, ADMPs' responsibilities include:

4.6.1. Fulfilling the Joint Commission (TJC) requirements to be completed by diagnostic medical physicist for diagnostic medical equipment, as outlined in TJC chapters (1) Environment of Care, (2) Provision of Care, Treatment, and Services, and (3) Performance Improvement;

4.6.2. ADMPs must meet regulatory requirements for training and experience prior to performing any of the above responsibilities.

4.7. Authorized Therapy Medical Physicists (ATMP)

In addition to the responsibilities of the Radiation Worker in the section above, ATMPs' responsibilities include:

4.7.1. Performing periodic full calibration measurements on the high-dose-rate afterloader (HDR).

4.7.2. Exchanging each source per regulatory requirements;

4.7.3. Verifying that Daily Spot-Checks were performed properly;

4.7.4. Performing radiation surveys of the HDR before and after use;

4.7.5. Performing independent output/activity measurements or calculations for any

EHS-500, Radiation Safety Manual

brachytherapy or HDR treatment plans. This check can be performed using software, spreadsheet or hand-calculation;

- 4.7.6. ATMPs must meet regulatory requirements for training and experience prior to performing any of the above responsibilities.

4.8. Nuclear Medicine Technologists (NMTs)

In addition to the responsibilities of the Radiation Worker in the section above, NMTs' responsibilities include:

- 4.8.1. Following requirements for procedures involving written directives or clinical procedures manual when preparing or administering radioactive materials to patients or human subjects (see the section "[Human Use of Radioactive Material](#)");
- 4.8.2. Performing and documenting measurements of radiopharmaceuticals for patients;
- 4.8.3. NMTs must meet regulatory requirements for training and experience prior to preparing radioactive material for human use;
- 4.8.4. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- 4.8.5. Quality Control checking of instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- 4.8.6. Calculating, measuring, and safely preparing patient or human research subject dosages;
- 4.8.7. Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
- 4.8.8. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
- 4.8.9. Administering dosages to patients or human research subjects.

4.9. Authorized Nuclear Pharmacists (ANP)

ANPs must meet regulatory requirements for training and experience prior to preparing radioactive material for human use, as reviewed and approved by Radiation Safety Committee 1 under the broad scope license.

4.10. X-Ray Users and Operators of Radiation-Producing Equipment

Operators of radiation-producing equipment must meet regulatory training requirements. Responsibilities of staff working with or around radiation-producing equipment are detailed in the [Machine-Produced Radiation](#) section of this Manual.

5. EMORY UNIVERSITY RESPONSIBILITIES

5.1. Emory University Management / Executive Oversight

Emory University Management is directly involved with the Radiation Safety Program. Management provides sufficient authority and organizational freedom to the Radiation Safety Officer and the Radiation Control Council to identify radiation safety problems, to initiate recommendations or provide solutions, and to verify implementation of corrective actions. Emory University Management at the level of Vice-President is represented on

EHS-500, Radiation Safety Manual

the Radiation Control Council. Members of the Radiation Control Council, Radiation Safety Committees 1 and 2 are appointed by Emory University administration. Members of the Radioactive Drug Research Committee (RDRC) are appointed by Emory University administration following approval by the US Food and Drug Administration's RDRC.

5.2. Radiation Control Council (RCC)

The RCC serves as the general policy-making and internal regulating body for activities at Emory University that involve the use of radiation and radioactive material. The Council delegates authority to the Radiation Safety Officer for enforcement of radiation safety policies and procedures. The Council meets periodically throughout the year to review and discuss matters relating to the use of radiation at Emory. Specific information about the membership and meetings of the Radiation Control Council can be found in the [Radiation Control Council Charter](#).

The duties and responsibilities of the Radiation Control Council include, but are not limited to:

- 5.2.1. Establishing University policies related to radiation safety;
- 5.2.2. Establishing training procedures and criteria;
- 5.2.3. Reviewing and approving, modifying or denying all proposals for ionizing radiation use and setting conditions of use for permits proposed by Radiation Safety;
- 5.2.4. Voting to approve, disapprove, or amend proposals;
- 5.2.5. Ensuring that only qualified individuals are permitted to use radiation sources, or to supervise such use by others;
- 5.2.6. Monitoring timely and effective resolution of corrective actions to assure the effectiveness of the radiation safety program;
- 5.2.7. Enforcing compliance with the program, including imposition of sanctions for noncompliance;
- 5.2.8. Voting to change service vendors as may be required by license, regulation, or commercial requirements;
- 5.2.9. Maintaining a list of the members and their appropriate training and experience;
- 5.2.10. Making recommendations to the University Vice President of Research Administration on risk management issues related to radiation safety.

5.3. Radiation Safety Committee 1

Radiation Safety Committee 1 reviews the human use of radioactive material and machine-produced radiation at Emory under the broad scope license. Specific information about the membership and meetings of the Radiation Safety Committee 1 can be found in [Radiation Safety Committees](#).

The duties and responsibilities of the Radiation Safety Committee 1 include:

- 5.3.1. Review, discuss, and approve or disapprove the annual report of the radiation safety program by the Radiation Safety Officer that includes a review of documentation and performance required to comply with license conditions, Nuclear Regulatory Commission and State of Georgia regulations, and Council and/or Radiation Safety Committee recommendations.

EHS-500, Radiation Safety Manual

- 5.3.2. Approve persons applying to function as Authorized Users, Authorized Medical Physicists, or Nuclear Medicine Technologists;
- 5.3.3. Review and approve the procedures, types and quantities of radioactive materials requested for human research or clinical use;
- 5.3.4. Review on the basis of safety and approve or disapprove each proposed method of machine-produced radiation on humans;
- 5.3.5. Review personnel dosimetry data at each Committee meeting for personnel exposures exceeding ALARA Level 1 and ALARA Level 2;
- 5.3.6. Review any significant incidents including spills, contamination, and misadministration with respect to cause and subsequent action taken;
- 5.3.7. Review and discuss the results of inspections by Radiation Safety;
- 5.3.8. Recommend or approve policy for the safe use of machine-produced radiation in human research;
- 5.3.9. Consider problems brought before it by the Radiation Safety Officer, faculty, medical staff, technical staff, or other interested parties, and give a prompt ruling in each case.

5.4. Radiation Safety Committee 2

Radiation Safety Committee 2 reviews applications and amendments for the non-human research use of radioactive material and machine-produced radiation under the broad scope license with respect to user qualifications, types and quantities of materials requested, and uses of materials and/or machines requested. Specific information about the membership and meetings of the Radiation Safety Committee 2 can be found in Radiation Safety Committees.

The duties and responsibilities of the Radiation Safety Committee 2 include:

- 5.4.1. Review and approve Non-Human radioactive material and machine-produced radiation use applications in accordance with Radiation Safety procedures and guidelines.
- 5.4.2. Address safety problems and concerns and provide prompt rulings.
- 5.4.3. Radioactive Drug Research Committee (RDRC)
- 5.4.4. The Emory University RDRC is charged by the Food and Drug Administration to approve and track research in humans using radioactive drugs generally recognized as safe and effective to obtain basic information regarding drug metabolism, human physiology, pathophysiology, or biochemistry. Specific information about the membership and meetings of the RDRC can be found in Radiation Safety Committees.

5.5. Radioactive Drug Research Committee (RDRC)

The Radioactive Drug Research Committee #0040 (RDRC) is charged by the FDA to approve and track research in humans using radioactive drugs generally recognized as safe and effective in order to obtain basic information regarding drug metabolism, human physiology, pathophysiology or biochemistry.

5.6. Facility Radiation Safety Committees

EHS-500, Radiation Safety Manual

Where required, each facility not included under the broad scope license maintains a separate Radiation Safety Committee to review the clinical use of radioactive material and machine-produced radiation at that facility.

The duties and responsibilities of the facility Radiation Safety Committees include:

- 5.6.1. Review, discuss, and approve or disapprove the results of the annual report of the Radiation Safety Program for the facility;
- 5.6.2. Review and discuss any significant incidents including spills, contamination, and misadministration with respect to cause and subsequent action taken;
- 5.6.3. Review and discuss personnel dosimetry data at each Committee meeting for personnel exposures exceeding ALARA Level 1 and ALARA Level 2;
- 5.6.4. Review and discuss the results of inspections by Radiation Safety.

5.7. Radiation Safety Officer

The Radiation Safety Officer is responsible for day-to-day oversight of the Radiation Safety Program. Duties and responsibilities include:

- 5.7.1. Develop, distribute, and implement current protection procedures in the daily operation of the Emory University radiation protection program;
- 5.7.2. Ensure that possession, use, and storage of radioactive materials are consistent with the limitations in each facility's license(s) and Georgia Rules and Regulations for Radioactive Materials, Chapter 391-3-17;
- 5.7.3. Ensure that personnel training is conducted and is commensurate with the individual's duties regarding radioactive material or radiation producing machines;
- 5.7.4. Maintain documentation to demonstrate, by measurement or calculation, that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits; or in the alternative, ensure that personnel monitoring devices are provided;
- 5.7.5. Establish and maintain a personnel monitoring program ensuring that dosimeters are appropriately provided, used, and exchanged, and that records of monitoring are maintained;
- 5.7.6. Ensure that radioactive material is properly secured;
- 5.7.7. Maintain documentation to demonstrate, by measurement or calculation, that the highest total effective dose equivalent to the non-occupationally exposed individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;
- 5.7.8. Notify proper authorities of incidents, such as loss or theft of radioactive material, damage to or malfunction of sealed sources, and fire involving radioactive materials;
- 5.7.9. Investigate and report to the State medical events and precursor events including cause, appropriate corrective actions identified, and timely corrective actions taken;
- 5.7.10. Participate in and document audits of the radiation protection program at least annually for adherence to ALARA concepts and seek to remedy any deficiencies

EHS-500, Radiation Safety Manual

noted;

- 5.7.11. Identify violations of regulations, license conditions, or program weaknesses and develop, implement and document effective corrective actions;
- 5.7.12. Ensure that radioactive material is transported, or offered for transport, in accordance with all applicable Department of Transportation (DOT) requirements;
- 5.7.13. Dispose of radioactive material properly;
- 5.7.14. Maintain an up-to-date license, and submit amendments and renewal requests in a timely manner;
- 5.7.15. Review quarterly radiation levels in restricted areas and adjacent non-restricted areas as indicated on staff surveys;
- 5.7.16. Review or develop shielding plans for new radiation areas;
- 5.7.17. Conduct annual surveys on X-Ray equipment and provide scatter and exposure charts to designated departments;
- 5.7.18. Audit all active radioactive material use and storage facilities quarterly and report any findings to the primary Radiation Permit Holder and the appropriate Radiation Safety Committee; and
- 5.7.19. Stop unsafe operations that come to the RSO's attention.

5.8. Associate Radiation Safety Officer

The Associate Radiation Safety Officer(s) operate under the direction of the Radiation Safety Officer and meet the training and experience criteria for medical Radiation Safety Officers per regulatory requirements and may participate in any role requiring the Radiation Safety Officer's authority.

5.9. Directors, Supervisors, and Managers

- 5.9.1. Directors, supervisors, and managers must have knowledge of the use of radioactive material or radiation producing machines in their areas.
- 5.9.2. They must understand that certain uses of ionizing radiation sources require specific training for the worker that might not be provided by EHSO (for example, certification training for nuclear medicine technologists or radiological technologists).
- 5.9.3. They must be aware that additions, removals, or alterations in the use of such radiation sources may require actions to be carried out by the Radiation Safety Officer for safety or regulatory purposes and must therefore keep the Radiation Safety Officer informed. Examples of actions that would require informing the Radiation Safety Officer include:
 - 5.9.3.1. Hiring persons to serve as Authorized Users (AUs), Authorized Medical Physicists (AMPs), or Nuclear Medicine Technologists (NMTs);
 - 5.9.3.2. Whenever an Authorized User, Authorized Medical Physicist, or Nuclear Medicine Technologist leaves the Emory system;
 - 5.9.3.3. Whenever a Radiation Permit Holder (RPH) leaves;
 - 5.9.3.4. Procuring new or disposal of old radiation-producing equipment;



EHS-500, Radiation Safety Manual

5.9.3.5. Relocating or reconstruction of radiation areas that alter or require radiation shielding.

5.9.4. Additionally, the Radiation Safety Officer may turn to the director, supervisor, or manager for assistance in the enforcement of the radiation protection program.

6. ACCESS TO RADIATION SAFETY PROGRAM DOCUMENTS

6.1. Location of Documents

All licenses and documents are available for inspection at the Emory University Environmental Health and Safety Office, 1599 Clifton Road, Fifth Floor, Atlanta, GA 30322.

EHS-500, Radiation Safety Manual

RADIATION EXPOSURE LIMITS & MONITORING

7. POLICY

Refer to [Occupational Exposure and Personnel Monitoring Program](#) for additional details on Emory's program for measuring, reporting, and investigating worker's exposure to radiation.

8. RADIATION EXPOSURE

8.1. How Is My Radiation Exposure Measured?

Exposure to ionizing radiation is measured using monitoring devices called dosimeters or radiation "badges". Badges measure external exposure to radiation. After the badges are worn for a specified period, they are sent for commercial processing. The amount of exposure to the badge is reported in units of millirem (mrem). Badges are worn on the part of the body most likely to receive radiation exposure. More information on badge placement is found in Section 8.9, [Rules for Wearing Badges](#).

Internal exposure to radiation, from inhalation, ingestion, or absorption, is unlikely to come from most forms of radioactive material used at Emory. However, some use of radioactive material requires monitoring of internal exposure to radiation. Tests used to determine internal exposure are called "bioassays". A list of those uses of radioactive material requiring bioassays and the type of bioassay is found in [Occupational Exposure and Personnel Monitoring Program](#).

8.2. How Much Radiation Can I Receive?

If you are an adult radiation worker, then your radiation exposure limits are listed in Table 1 below. Occupational exposure limits for minors are 10% of the corresponding limit for adults. If you exceed any annual limit, then you will not be allowed to work with or around radiation for the rest of the year.

Table 1, Exposure Limits for Adults

| Annual Occupational Exposure Limits (Radioactivity) | | Quarterly Limits for X-Ray |
|-----------------------------------------------------|-------------------------------------------------------------|-----------------------------------------------------------------------------------------------|
| Whole Body | 5 rem (0.05 Sv) | 1.25 rem/qtr (3 rem/qtr allowed if 5 rem/year not exceeded) |
| Lens of Eye | 15 rem (0.15 Sv) | 1.25 rem/qtr (3 rem/qtr allowed if 5 rem/year not exceeded) |
| Skin or any extremity | 50 rem (0.50 Sv) | 7.5 rem/qtr |
| Fetal exposure | 0.5 rem (5.0 mSv) during entire pregnancy after declaration | Not to exceed 0.05 rem per month, 0.5 rem (5.0 mSv) during entire pregnancy after declaration |

EHS-500, Radiation Safety Manual

8.3. Being Notified of High Exposure/ALARA Levels

To identify those workers at most risk of exceeding radiation exposure limits, quarterly investigational levels have been established. These levels are called “ALARA Levels”, named after the basic radiation safety principle, to always keep your exposure as low as reasonably achievable. There are two levels for each exposure limit; ALARA level 1 and ALARA level 2 (refer to Table 2). Radiation Safety will notify any worker who receives an exposure in excess of ALARA 1. If the exposure exceeds ALARA 2, then Radiation Safety will also investigate to determine whether additional measures can or should be taken to reduce the exposure.

8.4. Non-Radiation Worker’s Radiation Exposure

If you are not a radiation worker, then, by definition, your annual exposure from the use of radiation at Emory cannot exceed 100 mrem; exclusive of background, medical procedures or exposures from patients authorized for release or sewer disposal. There are many controls in place to keep radiation exposure within this limit for those who do not work with radiation. These include shielding x-ray rooms; documented daily and weekly surveys for contamination and measurements of radiation levels, establishing restricted areas; establishing safety procedures for receiving and disposing of radioactive material, establishing safety procedures for using x-ray equipment, etc.

8.5. How Do I Know What My Radiation Exposure Is?

All exposure reports are reviewed by members of Radiation Safety. As stated previously, if your exposure exceeds an ALARA level, you will be notified by Radiation Safety. Otherwise, your Radiation Exposure Reports are sent to the radiation safety contact in your department. You should make sure that you know where those reports are kept. Some departments require you to initial your exposure report to document that you are aware of your exposure.

Annual reports are also prepared by Radiation Safety for each monitored employee and are distributed according to the regulations. If you would like a copy of your annual dosimetry report, contact the Radiation Safety Group.

If you ever have any problems finding your radiation exposure reports, please contact Radiation Safety. Emory’s Radiation Safety maintains copies of all radiation exposure records.

8.6. Who Is Required to Wear Badges?

Regulations for both radioactive material and x-ray machines require that any person who is occupationally exposed to radiation at a level which is likely to exceed ten percent of any regulatory limit must be issued a radiation badge. ALARA Level 1 exposures, seen in Table 2, are set at ten percent of the regulatory limits.

EHS-500, Radiation Safety Manual

Table 2, ALARA Investigational Levels

| QUARTERLY ALARA INVESTIGATIONAL LEVELS | | |
|----------------------------------------|-------------|-----------------|
| | LEVEL 1 | LEVEL 2 |
| Whole Body | > 125 mrem | > 375 mrem |
| Lens of Eye | > 375 mrem | > 1125 mrem |
| Skin /Extremities | > 1250 mrem | > 3750 mrem |
| Fetal | none | > 50 mrem/month |

Table 3 lists job functions that are at the greatest risk for exceeding an ALARA 1 Level, and the type of badge(s) they will be assigned:

Table 3, Job Functions at risk of exceeding ALARA 1 Level

| If your job function involves... | Then you must wear* a ... |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|
| Working with large quantities of beta emitters | ring badge |
| Operating any type of x-ray equipment | body badge |
| Performing or assisting fluoroscopy procedures | collar badge only OR body and collar badge together** |
| Handling radiopharmaceuticals or brachytherapy sources for patients | body and ring badge |
| Performing HDR procedures | body badge |
| Nurses caring for patients containing radioactive material for therapy | body badge |
| <p>* see section below “Rules for Wearing Badges”</p> <p>** see section below “Rules for Wearing Badges” on how radiation exposure from two badges is calculated.</p> | |

8.7. What If I’m Not ‘Required’ to Wear a Badge, But I Think I’m Being Exposed to Radiation?

Any worker concerned about his or her exposure to radiation from radioactive materials, x-ray machines, or radioactive patients should consult Radiation Safety. Radiation Safety can determine, by your job responsibilities, if a radiation badge is necessary. If one is not necessary, Radiation Safety can explain why you are not likely to receive enough

EHS-500, Radiation Safety Manual

exposure to require monitoring. For example, if someone at your job was monitored previously, Radiation Safety can evaluate your potential exposure based on those exposure records. If you are still concerned about your exposure, then Radiation Safety can issue you a badge for an evaluation period, (typically six months) or until you don't wish to be monitored anymore.

8.8. How Do I Request A Badge?

You must complete an online form ([REDCap Request form](#)) and receive documented training (see Section "[Training](#)") in the proper use of a badge and basic radiation protection principles.

Once you have completed the request form for a dosimeter and your request has been reviewed and approved by EHSO, you will be issued a dosimeter. All workers issued radiation dosimeters are required to follow those rules and responsibilities stated in this Manual and to cooperate with the Radiation Safety Office in their efforts to maintain exposures ALARA.

8.9. Rules For Wearing Badges

- 8.9.1. Control badges assigned to a shipment must be kept in a low radiation background area. These control badges must be returned when the badges are collected for processing.
- 8.9.2. If you are issued a badge, you must wear it at all times while at work.
- 8.9.3. Badges must only be worn at work.
- 8.9.4. Badges are worn on the part of the body closest to the source of radiation. Whole body badges are to be worn on your front, on the torso, below the neck and above the hips. Ring badges are to be worn on your dominant hand, with the label facing the same direction as your palm.
- 8.9.5. For x-ray machine operators or staff issued a single whole-body badge, it must be worn unshielded on the collar or waist area. If a lead apron is worn, it must be worn on the outside of the apron at the collar. Assigned dose to Whole Body (WB) is 0.3 times the collar badge reading.
- 8.9.6. For x-ray machine operators or staff issued two badges, a designated chest badge must be worn on the torso, shielded underneath the lead vest. The designated collar badge must be worn unshielded at the collar. The collar badge will be used to evaluate the eye and skin exposure. The worker's whole-body dose (WB) will be calculated from the results of the two badges according to the following formula:
$$WB = (1.5 \times \text{Body Badge}) + (0.04 \times \text{Collar Badge})$$
- 8.9.7. Fetal monitors must be worn at the abdomen, under any protective lead.
- 8.9.8. Badges, when not worn, must not be stored near any radiation sources.
- 8.9.9. Badges are a legal record of your occupational radiation exposure. They are assigned to specific individuals and must never be shared.

8.10. When And Where Do I Return Badges?

Departments shall establish a Radiation Safety contact that is responsible for exchanging the old and new badges. The Radiation Safety Contact receives the new shipment of dosimeters and returns the worn dosimeters to the vendor for processing.

EHS-500, Radiation Safety Manual

Please make every effort to return your badges for processing by the 8th of the month following the wear period. Late badges generate unnecessary work effort and expense. Radiation Safety may request disciplinary advice from the supervisors of workers who chronically return badges late.

8.11. Lost Badges

Report all lost badges to Radiation Safety. If you need a replacement, one can be assigned. Radiation Safety staff may ask if you performed more, less or any unusual work with radiation during the wear period of the lost badge so that an exposure amount can be estimated and assigned to your history.

8.12. Pregnant Radiation Worker

Employees in the Emory community who work with radiation have the option and/or are encouraged to notify the Radiation Safety Officer (RSO) of suspected or confirmed pregnancies as soon as possible, so that the RSO can work with the employee and her supervisor to monitor the radiation exposure levels during the pregnancy and take measures, as appropriate, to maintain exposures as low as reasonably achievable and within regulatory limits.

All radiation workers will be informed of applicable state and federal regulations regarding occupational exposure to the fetus from ionizing radiation during their initial radiation safety training.

As soon as a radiation worker determines that she is pregnant, she should (unless privacy is desired) advise her supervisor and declare her pregnancy in writing to Radiation Safety using an online form ([REDCap Request form](#)). A professional from Radiation Safety will review the past radiation exposure history of the declared pregnant radiation worker and her job function and determine if radiation restrictions should be applied. If so, these restrictions will be discussed with the individual and her supervisor and will be provided to both in writing. A copy of the document "[Guide for Instruction Concerning Prenatal Radiation Exposure](#)" will be given to the declared pregnant radiation worker as required by the State, NRC and OSHA. The employee and supervisor (unless privacy is desired) will document that this information has been given. A radiation worker may, without declaring pregnancy, consult with Radiation Safety concerning issues relating to exposure of an embryo/fetus to radiation in the course of the employee's job.

Radiation Safety will issue a monthly fetal badge for the declared pregnant radiation worker to wear at the waist in addition to her regular badge.

All lead barriers in the university are designed so an individual, if she were behind the barrier for the full 40 hours of a week, would receive less than 10 mrem to the surface of her body and much less to the fetus. NCRP, NRC and the State of Georgia allow the fetus of a declared pregnant radiation worker to receive 500 mrem, sum of internal and external exposure, during the nine months of pregnancy.

It is recommended that pregnant nurses not care for patients containing therapeutic quantities of a radionuclide or brachytherapy sources.

EHS-500, Radiation Safety Manual

TRAINING PROGRAM

EHSO is responsible for ensuring that radiation safety training is provided to all Emory University employees who work with radioactive materials. You must complete training prior to beginning work with radioactive materials or radiation producing machines. Instructions are provided to those Emory University employees who work in close proximity to radioactive materials or equipment that produces radiation. Required training is dependent on the job functions performed and falls into four categories: 1) ancillary; 2) laboratories; 3) healthcare; or 4) machine-produced radiation. It is possible that an employee will be trained in more than one category. Training will include regulatory-required content based on the job function, as well as education topics identified by the department in which you work, and the radiation safety staff.

Online and classroom courses and self-study are described and can be accessed on the [training page of the EHSO website](#). Training completions shall be documented and retained by EHSO.

9. TRAINING REQUIREMENTS FOR ANCILLARY WORKERS

9.1. Training Content

9.1.1. Workers who enter radiation use areas to perform their duties with no direct use of radioactive material (whether escorted or not) or workers whose duties require them to work in the vicinity of radiation areas will receive instruction that includes the following topics:

- 9.1.1.1. Potential radiation hazards in each area where the employees will work
- 9.1.1.2. Posting requirements of areas where radioactive material /radiation is used and/or stored
- 9.1.1.3. Basic radiation protection principles which include the concepts of time, distance, and shielding

9.2. How Do I Get Training?

Training courses and instructions for accessing them are listed on the [training page of the EHSO Website](#). Instructions are provided in the new hire orientation, in the EHSO Research Safety Update newsletter and on the Policies and Procedures page of the EHSO website. You also can contact the research radiation safety liaison for your facility: <http://www.ehso.emory.edu/about/contact.html>.

9.3. Retraining Frequency

Retraining will be annually and whenever there is a significant change in duties or regulations.

10. TRAINING REQUIREMENTS FOR LABORATORY WORKERS USING RADIOACTIVE MATERIAL

10.1. Training Content

Training for laboratory workers will include the following topics:

- 10.1.1. Atomic Structure
- 10.1.2. Alpha, beta, and gamma radiation

EHS-500, Radiation Safety Manual

- 10.1.3. Radioactivity units
- 10.1.4. Radioactive decay
- 10.1.5. Biological effects
- 10.1.6. Background radiation
- 10.1.7. ALARA
- 10.1.8. Radiation protection principles
- 10.1.9. Radiation surveys
- 10.1.10. Radiation inventory
- 10.1.11. Recordkeeping
- 10.1.12. Personal protective equipment (PPE)
- 10.1.13. Waste disposal
- 10.1.14. Occupational dose limits and dosimetry
- 10.1.15. Policy on radiation and pregnancy
- 10.1.16. Purchase, receipt, and storage of radioactive material
- 10.1.17. Radiation instrumentation
- 10.1.18. Spill and contamination procedure (non-emergency)
- 10.1.19. Emergency response

11. HOW DO I GET TRAINING?

Training courses and instructions for accessing them are listed on the training page of the EHSO website. You also can contact the Radiation Safety health physicist for your facility: <http://www.ehso.emory.edu/about/contact.html>.

12. RETRAINING FREQUENCY

Retraining for laboratory workers using radioactive material is required at least every 3 years and is accomplished using one of several mechanisms:

- 12.1. You can repeat the Initial Training.
- 12.2. You will take the online Radiation Safety for Lab Workers Refresher Course, or
- 12.3. You can request an in-service presentation for a laboratory or division:
 - 12.3.1. The same general material is presented but is streamlined to meet the needs of the group;
 - 12.3.2. More hands-on practice time with survey meters and calculating efficiencies of liquid scintillation counters and dpm can be addressed in greater detail; and
 - 12.3.3. Other specific problems or incidents can be discussed in greater depth.
- 12.4. Significant or repeated inspection deficiencies may indicate the need for early retraining as part of corrective actions.

EHS-500, Radiation Safety Manual

13. TRAINING REQUIREMENTS FOR HEALTHCARE WORKERS USING RADIOACTIVE MATERIAL**13.1. Training Content**

Training for clinical workers will include the following topics:

- 13.1.1. Potential radiation hazards in each area where the employees will work
- 13.1.2. Posting requirements of areas where radioactive material and/or radiation is used and/or stored
- 13.1.3. Basic radiation protection principles which include the concepts of time, distance, and shielding
- 13.1.4. Basic radiation biology
- 13.1.5. Risk estimates, including comparison with other health risks
- 13.1.6. Proper use of personnel dosimetry and exposure reporting (when applicable)
- 13.1.7. Concept of maintaining exposure ALARA
- 13.1.8. Occupational dose limits and their significance
- 13.1.9. Dose limits to the embryo/fetus, including instruction on declaration of pregnancy
- 13.1.10. Dose to individual members of the public
- 13.1.11. Worker's right to be informed of occupational radiation exposure
- 13.1.12. Individual's obligation to report unsafe conditions to the Radiation Safety Office
- 13.1.13. Applicable regulations, license conditions, information notices, bulletins, etc.
- 13.1.14. Location of copies of the applicable regulations, the Radioactive Materials License, and its application are posted or made available for examination
- 13.1.15. Access control procedures
- 13.1.16. Proper use of radiation shielding, if used
- 13.1.17. Emergency procedures.

13.2. Additional training is designated for the following specific job function(s)

- 13.2.1. Authorized Users;
- 13.2.2. Authorized Medical Physicists;
- 13.2.3. Nuclear Medicine Technologists;
- 13.2.4. Nurses caring for patients containing radioactivity.

13.3. How Do I Get Training?

Training courses and instructions for accessing them are listed on the training page of the EHSO website. You also can contact the research radiation safety liaison for your facility: <http://www.ehso.emory.edu/about/contact.html>.

13.4. Retraining Frequency

Retraining will be conducted annually and whenever there is a significant change in

EHS-500, Radiation Safety Manual

duties or regulations. Refresher training frequency is determined by the terms of the license.

14. TRAINING REQUIREMENTS FOR X-RAY MACHINE OPERATORS

14.1. Training Content

Training for operators and support staff will include the following topics pertinent to their specific job function:

- 14.1.1. Applicable regulations
- 14.1.2. Operator responsibilities
- 14.1.3. Potential radiation hazards in work areas
- 14.1.4. Risk estimates, including comparison with other health risks
- 14.1.5. Basic radiation biology
- 14.1.6. Steps to minimize exposure to patients & staff
- 14.1.7. Patient safety
- 14.1.8. Radiation effects on skin
- 14.1.9. Pregnant patient precautions
- 14.1.10. Recording exposure information
- 14.1.11. Reporting high or accidental exposures
- 14.1.12. Proper use of personnel dosimetry
- 14.1.13. Department-specific work rules
- 14.1.14. Procedure risks

14.2. How Do I Get Training?

Training courses and instructions for accessing them are listed on the [training page of the EHSO website](#). Training requirements by job function are detailed in MCN policy "[Environmental Health and Safety \(EHSO\) Policy on Maintaining Quality and Safety in X-ray Imaging of Patients and Human Subjects](#)." You also can contact the research radiation safety liaison for your facility: <http://www.ehso.emory.edu/about/contact.html>.

14.3. Retraining Frequency

Retraining will be conducted whenever there is a significant change in duties or regulations. Refresher training frequency is detailed on the training page of the EHSO website.

EHS-500, Radiation Safety Manual

AUTHORIZATION TO USE RADIATION - HOW TO OBTAIN OR AMEND

15. FOR NON-HUMAN USE OF RADIOACTIVE MATERIAL

15.1. Application

- 15.1.1. You must be a faculty member of a division of Emory University with training and experience commensurate with the intended use.
- 15.1.2. You must complete a [Radiation Safety Committee 2 Application](#). Within this application, you must sign a statement indicating familiarity with the Emory University Radiation Safety Manual and acknowledging your commitment to keeping exposures as low as reasonably achievable.
- 15.1.3. Submit your signed original application to Radiation Safety.
- 15.1.4. After Radiation Safety checks the application for completeness, it is sent to Radiation Safety Committee 2 members where it is reviewed with respect to: training and experience presented by the Radiation Permit Holder in reference to proposed use; facilities and instrumentation available; and proposed techniques of safely using and disposing of radioactive material.
- 15.1.5. Approval is granted by unanimous vote by a convened quorum after resolution of any comment or questions.
- 15.1.6. Upon approval, a Radiation Safety staff member will deliver the Authorization (e.g. Permit), postings, and emergency procedures signs to the laboratory.
- 15.1.7. Laboratory personnel named on the authorization to use radioactive material must receive training prior to their first use of radioactive material.
- 15.1.8. Radiation Permit Holder (RPH) will evaluate all approved procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the applications of trial runs.

15.2. Amendments to Authorizations

- 15.2.1. Use the [Amendment to Authorization – Committee 2 form](#) to submit amendments involving the use of radioactive material. Amendments may include adding, removing, or changing protocols, or adding or removing labs. Personnel may be added or deleted from an authorization using EHSA.
- 15.2.2. An approval of changes of personnel to use isotopes, and addition and deletion of laboratory locations may be made at the discretion of Radiation Safety. Committee members receive a report of these administrative changes at each meeting.
- 15.2.3. Protocol amendments must include, at a minimum, the project title, the radionuclide and chemical form involved, an indication of any need to increase total possession limit or to add a chemical form, a detailed description of the portion(s) of the protocol dealing with the use of the radioactive material, the names and experience of any additional staff members who may be added due to the project, and Institutional Animal Care and Use Committee (IACUC) committee approvals where needed.
- 15.2.4. When additional isotopes or procedures are involved, the applicant must

EHS-500, Radiation Safety Manual

demonstrate appropriate knowledge and experience to ensure safety in carrying out the protocol.

- 15.2.5. The amendment will be circulated through the committee in the same manner as the original application. Approval is granted by unanimous vote by a convened quorum after resolution of any comments or questions.
- 15.2.6. For adding new personnel – all new personnel must receive preliminary training through EHSO before receiving approval.
- 15.2.7. For adding labs – laboratories will undergo a pre-occupancy contamination survey by Radiation Safety personnel if Radioactive Materials were previously used at the location and no prior contamination survey was completed for the laboratory location.
- 15.2.8. For removing labs – laboratories will undergo a post-occupancy contamination survey by Radiation Safety personnel.
 - 15.2.8.1. When adding a lab, Radiation Safety will add the room number(s) to the Authorization and post the lab accordingly. The RPH must then add the lab to the list of areas to be surveyed.
 - 15.2.8.2. When removing a lab, the RPH should follow lab decommissioning guidelines. The researcher is responsible for any radioactive material abandoned in a lab.

15.3. Renewals

The RPH must apply for renewal every three (3) years. Authorization renewal forms will be provided to the Radiation Permit Holders prior to expiration.

15.4. Active and Inactive Labs

- 15.4.1. When the RPH has not used radioactive material and has no radioactive materials inventory or waste for a period of one year, Inactive Status will be implemented.
 - 15.4.1.1. Authorizations approved for Inactive Status will not be inspected, personnel will not require refresher training, and survey instruments will be stored and will not require annual calibration.
 - 15.4.1.2. Reactivation of Inactive Labs: Reactivation will require the lab to submit correspondence to Radiation Safety in the form of a letter or e-mail. Radiation survey instruments must be calibrated and Radiation Safety Training completed by laboratory radiation workers prior to ordering or working with radioactive material.
 - 15.4.1.3. When the radiation safety staff receives an order or transfer to the laboratory, Radiation Safety will be notified and the Radiation Permit Holder will be returned to active status when training and survey instrument calibration requirements are satisfied.
- 15.4.2. Radiation Permit Holders will be notified when renewals are due. Any changes made during the review will be included in the renewal application. Labs with renewal applications received by the expiration date of the authorization will be considered active until Radiation Safety Committee 2 issues a new authorization.

EHS-500, Radiation Safety Manual

- 15.4.3. If the Radiation Permit Holder does not submit renewal materials by the expiration date, the authorization will be terminated.

15.5. Suspension

Radiation Safety Committee 2 and Radiation Safety have the right to suspend an authorization, in full or in part, following the discovery of violations or infractions of the authorization. The Committee may reinstate the authorization once the violations have been corrected and an increased surveillance program put into place.

16. FOR HUMAN USE OF RADIOACTIVE MATERIALS**16.1. Application**

- 16.1.1. Applicants must have faculty status (clinical instructor or above), must be experienced in the use of radioactive materials, and must be trained by EHSO prior to approval.
- 16.1.1.1. Applicants for the use of unsealed radionuclides in human research must be fully trained American Board of Nuclear Medicine or American Board of Radiology-Nuclear Medicine certified physicians.
- 16.1.1.2. Applicants for the use of sealed brachytherapy radionuclides in human research must be fully trained American Board of Radiology-Radiation Oncology certified physicians.
- 16.1.2. Researchers must apply to Radiation Safety Committee 1 for a Human Use Authorization to use radioactive materials in humans, in either research or clinical applications. [See the [Committee 1 Amendment to Authorization form](#) on the EHSO website].
- 16.1.3. Applications will require the description of personnel monitoring, protective clothing, shielding, and survey procedures designed to properly evaluate exposures and maintain them ALARA.
- 16.1.4. Submit completed application forms to the Radiation Safety Officer.
- 16.1.5. Approval is granted by unanimous vote by a convened quorum after resolution of any comments or questions.
- 16.1.5.1. If a member dissents or questions an application, the matter must be resolved to the member's satisfaction prior to approval.
- 16.1.5.2. Radiation Safety Committee 1 may require additional conditions under which the use of the material must be conducted.
- 16.1.6. Once approved, the Authorized User may then order, receive and use the requested materials, but must do so according to the statements and representations made in the application, and any conditions set forth by the safety committee and all applicable local, state and federal laws, regulations and license conditions. Violations or infractions of these conditions may result in suspension or termination of the approval to receive and use radioisotopes.
- 16.1.7. Approval will be given by the Committee for a period of three years.

16.2. Amendment

EHS-500, Radiation Safety Manual

- 16.2.1. Any changes to the authorization, such as additional personnel, new radionuclide(s), increased or decreased possession limits, changes in experimental procedures which have an impact on safety, addition or removal of areas of radioactive material use, changes to the number of subjects or controls, or changes in the chemical or physical form of a material previously approved must be submitted as a request for amendment. [See the [Committee 1 Amendment to Authorization form](#) on the EHSO website.] Submit completed amendment forms to the Radiation Safety Officer.
- 16.2.2. Approval is granted by unanimous vote by a convened quorum after resolution of any comments or questions.
 - 16.2.2.1. An administrative approval of changes of personnel to use isotopes, and addition or deletion of laboratory locations can be made at the discretion of the Radiation Safety Officer or designee.
 - 16.2.2.2. Committee members receive a list of these administrative changes at each meeting for final approval.
- 16.2.3. Radiation Safety Committee 1 may require additional conditions under which the use of radioactive material must be conducted.
- 16.2.4. Prior to using radioactive material in a clinical area, Radiation Safety will review the facility layout and proposed uses to determine if shielding is adequate to comply with exposure limits for the public in adjacent areas.
- 16.2.5. An amendment must be submitted and approved prior to allowing any person to assume the responsibilities of an Authorized User, Authorized Medical Physicist, or Nuclear Medicine Technologist, as stipulated in [section 4.3](#).

16.3. Renewal

EHSO will contact the Authorized User to review the authorization prior to renewal. Any changes made during the review will be included in the renewal application. Renewal applications received by the expiration date of the authorization will allow the work to continue in the interim until Radiation Safety Committee 1 issues a new authorization.

16.4. Suspension

Radiation Safety Committee 1 and/or the Radiation Safety Officer have the right to suspend an authorization, in full or in part, following the discovery of violations or infractions of the authorization. The Committee may reinstate the authorization once the violations have been corrected and an increased surveillance program put into place.

16.5. Closing/Terminating a Lab

- 16.5.1. The Radiation Permit Holder (RPH or Authorized User) may request assistance from Radiation Safety when leaving a lab. However, it is the responsibility of the permit holder when leaving a laboratory to properly dispose of or safely remove all hazardous materials, waste, and contaminated equipment in their lab. Work on all study protocols must cease. All laboratory spaces and equipment will be surveyed for radioactive contamination by EHSO. Guidelines can be found at Laboratory Decommissioning Guidelines.
- 16.5.2. The authorization may be terminated upon the following conditions:
 - 16.5.2.1. Written request of permit holder.

EHS-500, Radiation Safety Manual

16.5.2.2. Failure to renew authorization in a timely fashion.

16.5.2.3. Violations or infractions of the authorization that are not corrected.

17. FOR MACHINE-PRODUCED RADIATION IN RESEARCH

17.1. Human Use and Clinical Trials

17.1.1. The Radiation Safety Committee 1 reviews applications for research that involve exposure of research subjects to ionizing radiation. New applications that are submitted to the Institutional Review Board (IRB) are forwarded to Radiation Safety. Alternatively, the application may be provided directly to Radiation Safety.

17.1.2. The applicant should submit a copy of the research protocol, Informed Consent, a Lay Summary, if available, and a [Radiation Summary Form](#), and any other documentation subsequently requested by the committee, to Radiation Safety.

17.1.3. The Radiation Summary Form is a summary of radiological procedures that will be used in the research study. A copy of this form can be found on the website. The Radiation Permit Holder will indicate which procedures are research-driven and which are standard of care. The form also assists the RPH in estimating the total radiation dose likely to be given to the patient. This total dose is then categorized into Low Dose, Moderate Dose, or Significant Dose.

17.1.3.1. Standard of Care includes imaging that is normally performed as indicated by the subject's medical provider for diagnosis or treatment of a disease. The sole criteria when making a decision concerning performing these scans is the benefit of the patient. (Note, these scans may have research benefit but this must not be a factor when considering performing the scan.) Any other scans are considered beyond Standard of Care.

17.1.4. The Radiation Safety Committee 1 will also review the Informed Consent to determine if the research subject is appropriately notified of the risks from the radiation. The applicant should include radiation risk information in the Consent that provides the subject the following three pieces of information - which procedures involve ionizing radiation; if the radiation is necessary for their care or if it is being done only for the research purposes; and a comparative estimate of the risk of cancer from these procedures. Guidance for such language can be found at [Guideline for Radiation Safety Committee Review of Human Research Studies](#).

17.1.5. Once all documents are submitted, the Radiation Safety Office will review them for completeness and forward them to the Radiation Safety Committee 1. The Radiation Safety Committee 1 is given sufficient time to review and comment.

17.1.6. RPH is contacted to resolve any comments or questions.

17.1.7. Approval is granted by unanimous vote by a convened quorum after resolution of any comments or questions.

17.1.8. The approval document is either sent to the IRB or to the RPH or research coordinator.

17.2. Non-Human Use



EHS-500, Radiation Safety Manual

- 17.2.1. Any research use of machine-produced radiation on animals or samples requires an application to the Radiation Safety Committee 2. A copy of this application can be found at the [X-Ray Application Non-Human Use form](#).

EHS-500, Radiation Safety Manual

SAFE USE OF RADIOACTIVE MATERIAL

18. GENERAL RULES FOR HANDLING RADIOACTIVE MATERIAL

Do not allow children under 18 years of age in laboratories where radioactive materials are used or stored unless they are students or employees of the University who have been approved by Radiation Safety.

18.1. Personal Protective Equipment (PPE)

- 18.1.1. Wear a laboratory coat or other protective clothing, disposable gloves, close-toed shoes and eye protection at all times when using radioactive materials. [Also see EHSO PPE Guideline].
- 18.1.2. PPE such as lab coats and gloves should not be worn outside of the laboratory.
- 18.1.3. PPE that has been contaminated by any radioactive material in the lab must not leave the lab until it is decontaminated.

18.2. Contamination Control

- 18.2.1. All work bench areas must be covered with absorbent paper. Absorbent paper must be checked for contamination after each use. Work with large volumes of radioactive material must be done on a tray.
- 18.2.2. Monitor hands, shoes, and clothing for contamination after each procedure or before leaving the area.
- 18.2.3. Do not eat, drink, smoke, apply cosmetics or change contact lenses in any area where radioactive material is stored or used. [See also EHSO policy on food and drink in laboratories]
- 18.2.4. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.
- 18.2.5. Never pipette by mouth.
- 18.2.6. Dispose of radioactive waste only in designated, Emory approved, labeled, and properly shielded receptacles.

18.3. Exposure Control

- 18.3.1. Shielding materials must be available for specific isotopes used in the lab. Use lead shielding for gamma emitters; use Plexiglas for high energy beta emitters.
- 18.3.2. Wear personnel monitoring devices, if required, at all times while in areas where radioactive materials are used or stored.

18.4. Additional Precautions in Shared or Multi-User Labs

In large community laboratories shared by radiation users and non-radiation users, care will have to be exercised to limit both contamination events and exposure concerns. Quantities of and procedures with radioactive materials used in the open laboratory will be limited according to possible hazards connected with its use.

18.5. Recommended possession limits for RPH permits in shared labs:

- 18.5.1. 10 mCi limit for H-3, C-14, P-33, S-35, Cr-51, and Tc-99m.
- 18.5.2. 1 mCi limit for Na-22, Na-24, P-32, Cl-36, and Ca-45.

EHS-500, Radiation Safety Manual

- 18.5.3. 100 μ Ci limit for I-125 and I-131.
- 18.5.4. Approval may be granted for possession limits above those recommended on a case-by-case basis.
- 18.6. Radioactive materials must be adequately shielded on all sides to maintain exposures at less than 2 mR/hr at one foot from the highest point of the source.
- 18.7. Use enclosed labs with the doors closed or a chemical fume hood for:
 - 18.7.1. Amounts of stable, non-volatile radioactive materials which exceed the above recommended possession limits for RPH permits in shared labs.
 - 18.7.2. Procedures which may result in the production of small amounts of radioactive aerosols such as micro centrifuges and speed-vacs. Request specific approval if your equipment must be used in shared spaces.
 - 18.7.3. All unstable and/or volatile radioactive materials must be used in chemical fume hoods; preferably within an enclosed lab to restrict traffic.
- 18.8. Labeling
 - 18.8.1. All countertops where radioactive materials are used must be clearly defined and labeled with the radiation symbol.
 - 18.8.2. All hoods in which radioactive materials are used must be clearly labeled with the radiation symbol.
 - 18.8.3. All sinks in which radioactive material is introduced by disposal or by cleaning of contaminated lab ware must be clearly labeled with the radiation symbol.
 - 18.8.4. Centrifuges, incubators and speed-vacs and other multi-user equipment in which radioactive material is used must be clearly labeled with the radiation symbol.

19. LABORATORY REQUIREMENTS**19.1. Required Lab Features**

Basic construction of Emory laboratories is suitable for most combinations of radiotoxicity and possession limits requested. Laboratory use generally requires handling only low levels of non-volatile radioactive material. Laboratories where radioactive material is used or stored must possess the following features:

- 19.1.1. Smooth and nonabsorbent floors.
- 19.1.2. Countertops impervious to forms of radioisotope being used.
- 19.1.3. Hand washing sink with impermeable surface and drain set level with or below sink level to allow for complete draining.
- 19.1.4. Negative air pressure in laboratories with one-time pass-through ventilation.
- 19.1.5. Access to a GM Survey meter, unless only H-3 is used.
- 19.1.6. Access to a liquid scintillation counter and/or gamma counter.
- 19.1.7. Additional Features Dependent on Usage
- 19.1.8. Lab requirements may increase with higher possession limits or radiotoxicity of the material.

EHS-500, Radiation Safety Manual

- 19.1.9. Additional facilities, such as chemical fume hoods, portable or built-in shielding may be necessary for isotopes with higher radiotoxicity, such as Ca-45, I-125 or I-131.

20. GENERAL RULES FOR STORAGE & SECURITY OF RADIOACTIVE MATERIAL

Secure all radioactive materials when it is not under constant surveillance and immediate control of the user(s). Store all radioactive solutions in containers clearly labeled with the solution contents and the radiation trefoil symbol and/or a "Caution Radioactive Materials" label.. Areas where radioactive materials are stored need specific safeguards to prevent unauthorized removal or access. Radioactive material can be placed in a locked room by key or keypad code entrance or stored in a locked cabinet or closet. Also, the areas must be posted with "Caution Radioactive Material" signs.

20.1. Self-Contained Laboratories

Radiation Permit Holders who are in a self-contained laboratory area must choose a method of securing their stock solutions from the following options:

- 20.1.1. Secured in a locked refrigerator or freezer;
- 20.1.2. Keep lab locked when vacant, even for short periods of time;
- 20.1.3. Keep material in a lock box inside the refrigerator or freezer.
- 20.1.4. The RPH's choice will become an audit item. If material is found unsecured, use of a lock box will become mandatory.

20.2. Shared or Multi-User Labs

- 20.2.1. All stock material must be kept in a lock box inside refrigerator, freezer, or cabinet. The box must be secured to prevent easy removal. Refrigerators and freezers must be locked at the end of the day.
- 20.2.2. Radioactive samples may be stored in a locked refrigerator or freezer located in a hallway or alcove or in a locked box within. Refrigerators and freezers must be locked at the end of the day.

21. CLINICAL AREAS

Since clinical areas typically use much higher activities of radioactive material, additional safeguards should be in place. Consideration should be given to the location of flood sources and radioactive patients with respect to well-counters, dose calibrators and gamma cameras. Waste containers and sharps containers may also need added shielding to minimize exposure to staff. A spill kit should also be available, and its whereabouts known to all persons handling radioactivity. (See also "[Use of Protective Equipment](#)" in the Clinical Use section of this manual).

22. RADIOACTIVE VOLATILES AND GASES

- 22.1. All unstable and/or volatile radioactive materials (e.g., H-3 borohydride or C-14 methyl iodide) must be used in enclosed laboratories equipped with exhaust fume hoods.
- 22.2. Special Requirements for Users of Radioiodine-125 and -131

EHS-500, Radiation Safety Manual

- 22.2.1. Only Radiation Permit Holders and technicians with prior experience using large quantities (1 mCi or greater) of radioiodine will be authorized to perform iodinations.
- 22.2.2. Each lab in which an iodination is to be done will be cleared of all individuals except those actively participating in the procedure.
- 22.2.3. All work will be done in an approved hood with a minimum air flow of 100 linear feet per minute with a sash opening of one foot.
- 22.2.4. The hood will be exhausted to the outside. Laminar flow hoods recirculating air within the room will not be used.
- 22.2.5. Air samples will be taken in each lab during the use of 1 mCi or greater quantities of I-125 or I-131 until the research radiation safety liaison is satisfied that the vapors are contained during the procedure.
- 22.2.6. A mandatory radiation survey and wipe test for radioactive contamination is required after each use.
- 22.2.7. A baseline thyroid bioassay should be performed prior to an iodination. A thyroid bioassay is required within 24 to 72 hours following an iodination exceeding 1 mCi I-125 or I-131. These are scheduled by appointment with the research radiation safety liaison.

23. SIGNS & POSTINGS

23.1. What Signs Do I Need To Post And Where?

If you are in a laboratory at Emory University and need signs, EHSO will provide the required postings for all hazards. Refer to the Signage Program to request the signs. The following is a list of signs required for radioactive material use:

- 23.1.1. "Caution Radioactive Material" sign must be posted on the door of any area where radioactive material is used or stored.
- 23.1.2. "Restricted Area, Authorized Entrance Only", and "No Eating, Drinking or Smoking" signs may also be present, if available, depending on the building signage system.
- 23.1.3. "Notice to Employees" sign from the Georgia Department of Natural Resources must be posted in areas to permit employees working in or frequenting any portion of a controlled area to observe a copy on the way to or from the place of employment.
- 23.1.4. "Caution Radiation Area" sign must be posted at any area where a person may receive 5 mrem in an hour.
- 23.1.5. Other areas with higher radiation exposure rates or airborne radioactivity might require additional or different signage. Consult Radiation Safety if these situations apply.

23.2. Posting Exceptions

The following areas are exempted from posting requirements:

- 23.2.1. Areas where radioactive material is only present for less than 8 hours, provided

EHS-500, Radiation Safety Manual

that it is constantly attended by an individual who is taking measures to prevent exposure to other persons in excess of regulatory limits.

23.2.2. Hospital areas with radioactive patients, provided that the patients are authorized for release.

23.2.3. Areas where only a sealed source is stored, provided that the dose rate at 30 cm from the source (or source housing) is less than 5 mrem/hr.

23.3. Labeling Requirements

23.3.1. Stock containers of Radioactive Material shall bear a label displaying the radiation symbol and the words, "Caution, Radioactive Material", radionuclide, quantity of radioactivity and date of assay. Labeling of instruments, trays or racks containing samples is acceptable. Waste containers are labeled the same, except the date is added when the container is full.

23.3.2. Also, see additional labeling requirements for open laboratories in Laboratory Requirements.

24. AREA SURVEYS AND WIPE TESTS

Both area surveys and wipe tests are performed to demonstrate compliance with regulatory limits regarding keeping exposures ALARA to the general public as well as radiation workers.

24.1. Area Surveys

24.1.1. Geiger (GM) counters are portable instruments commonly referred to as survey meters used to detect ionizing radiation and can also be used to survey areas for ambient radiation dose rates and detect surface contamination providing the correct detector is used to survey areas and detect surface contamination.

24.1.2. The GM counter is the least expensive, fastest, and generally the most reliable means of detecting and measuring radioactive contamination. The beta pancake detector is used with the Geiger counter for finding and measuring beta radiation and will detect all beta radioisotopes used at Emory except H-3 and Ni-63. It does not detect those nuclides because their betas are too low in energy to penetrate the window of the detector. Radioisotopes which may be detected with the beta pancake are C-14, S-35, P-33, P-32, Ca-45, Cl-36 and other beta-emitting nuclides.

24.1.3. The low-energy gamma probe is used with the Geiger counter to detect and measure gamma radioisotopes of various energies. It is most efficient for I-125, but will perform adequately for Cr-51, In-111, Co-57 and other gamma emitting nuclides. These detectors will also detect low energy X-rays, such as those emitted by beta emitters producing Bremsstrahlung radiation.

24.1.4. When working with radioactive material, hands, lab coats (especially edge of sleeves), and shoes should be monitored before leaving the laboratory both during the workday and at the end of the workday before leaving the workplace.

24.1.5. Perform radiation level surveys with a survey meter sufficiently sensitive to detect 0.1 milliroentgen per hour (mR/hr) in the following areas, at the frequency specified:

EHS-500, Radiation Safety Manual

- 24.1.6. Survey at the end of each day of use all radiopharmaceutical elution, preparation, assay, and administration areas (except patient rooms, which will be surveyed at the end of the therapy instead of on the day of administration) when using radiopharmaceuticals requiring a written directive (e.g., all therapy dosages and any [I-131] sodium iodide dosage exceeding 30 μ Ci).
- 24.1.7. Survey weekly all radionuclide use, storage, and waste storage areas, including areas where radiopharmaceuticals with half-lives of less than 2 hours are eluted, prepared, assayed, or administered. If diagnostic administrations are occasionally made in patients' rooms (e.g., bone scan injections, Tc-99m heart agents) and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
- 24.1.8. Survey during the semi-annual inventory all sealed-source and brachytherapy-source storage areas.

24.2. Wipe Tests

- 24.2.1. Wipe tests are performed to detect and quantify radioactive contamination on surfaces of work areas, including floors, walls, laboratory furniture, and/or laboratory equipment. Removable contamination can be detected and measured through a wipe test of the surface, which is counted in an appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.
- 24.2.2. Perform removable contamination wipe tests daily:
- 24.2.3. In radiopharmaceutical elution, preparation, assay, and administration areas (except patient rooms, which will be surveyed at the end of the therapy instead of on the day of administration) when using radiopharmaceuticals requiring a written directive (e.g., all therapy dosages and any [I-131] sodium iodide dosage exceeding 30 μ Ci); and
- 24.2.4. In areas where generators and multi-use bulk vials of radiopharmaceuticals with half-lives of more than 2 hours are eluted, prepared, or assayed.
- 24.2.5. Perform removable contamination wipe tests weekly:
- 24.2.6. In radionuclide use, storage and radionuclide waste storage areas;
- 24.2.7. In laboratory areas where only small quantities (<1 millicurie at a time) of radioactive material are used, or
- 24.2.8. In areas where radiopharmaceuticals with half-lives of less than 2 hours are eluted, prepared, assayed, or administered.
- 24.2.9. If diagnostic administrations are occasionally made in patients' rooms (e.g., bone scan injections, Tc-99m heart agents), with special care taken to remove all paraphernalia, those rooms need not be surveyed.
- 24.2.10. Removable contamination wipe tests must additionally be performed in these instances:
- 24.2.11. After any spill or contamination event;
- 24.2.12. When procedures or processes have changed;
- 24.2.13. In areas adjacent to restricted areas and in all areas through which radioactive

EHS-500, Radiation Safety Manual

materials are transferred and temporarily stored before shipment;

24.2.14. Upon receipt of package deliveries to Radiation Safety;

24.2.15. Following the use of low-energy beta-emitters (for example H-3, C-14, P-33, I-125, S-35, etc.) since GMs are not useful;

24.2.16. During regular lab inspections performed by a Radiation Safety Inspector.

24.3. How to Perform

24.3.1. To ensure achieving the required sensitivity of measurements, wipe test samples will be analyzed in a low-background area.

24.3.2. A gamma counter system with a single or multi-channel analyzer can be used to count samples containing gamma-emitters (e.g., Cs-137, Co-60).

24.3.3. A liquid scintillation or gas-flow proportional counting system can be used to count samples containing beta-emitters and gamma-emitters. The instrument must be sufficiently sensitive to detect the presence of 200 dpm/100 cm² of removable contamination. Results must be documented in disintegrations per minute (dpm) on a facility diagram.

24.3.4. A radioactive source with a known amount of activity should be used to convert sample measurements usually in counts per minute (cpm) to dpm.

24.3.5. Each laboratory using gamma-emitting or high energy beta-emitting material must have a suitable survey meter available. The survey instrument must be checked for consistent response with a dedicated source before each use. Do not use an instrument that does not respond appropriately to the source. It is not necessary to keep records of these checks.

24.3.6. In addition to these instructions more information can be found on various online required trainings.

24.4. Action Levels – What Are They & What If They Are Exceeded

The tables below list the action levels for area surveys and wipe tests.

EHS-500, Radiation Safety Manual

Table 4, Action Level for Area Surveys

| Action Level for Area Surveys: | |
|--------------------------------|-----------------------------------------------------------------------|
| Unrestricted areas | 2 mR/hr @ 30 cm 2 mR/hr @ contact for personal clothing & skin |
| Restricted areas | 5 mR/hr @ 30 cm (protective clothing used only in restricted area) |

Table 5, Wipe Test Action Levels – Unrestricted/Restricted Areas

| Wipe Test Action Levels in Unrestricted Areas (dpm/100 cm ²) | | |
|--------------------------------------------------------------------------|----------------------------|------------------------------|
| Restrictions | Nuclide | Removable |
| Unrestricted areas | Any beta or gamma emitters | 200 dpm/100 cm ² |
| | Any alpha emitters | 20 dpm/100 cm ² |
| Restricted areas | Any beta or gamma emitters | 2000 dpm/100 cm ² |
| | Any alpha emitters | 200 dpm/100 cm ² |

- 24.4.1. If action levels for area surveys are exceeded, you must shield the source in order to reduce the dose rate to within the action level. You must notify Radiation Safety if you discover an unrestricted area has received more than 2 mrem in an hour.
- 24.4.2. If action levels for removable contamination are exceeded, then you must perform decontamination steps until the amount of contamination is below the action level. Contamination found in unrestricted areas and on personal clothing will be immediately decontaminated to background levels. The worker must retain a copy of the survey in the laboratory radiation records documenting that an effort was made to reduce ambient radiation levels through decontamination or shielding.
- 24.4.3. If the dose rates cannot be brought below the action levels:
 - 24.4.3.1. Shield the radiation.
 - 24.4.3.2. Post the area to restrict its access.
 - 24.4.3.3. Notify Radiation Safety Officer immediately.
 - 24.4.3.4. Assist in investigating what caused the action level to be exceeded.
 - 24.4.3.5. Records of dose-rate surveys and wipe tests must include the following:

EHS-500, Radiation Safety Manual

- 24.4.3.6. A diagram of the area surveyed or a list of items and equipment surveyed;
- 24.4.3.7. Specify locations on the survey diagram where wipe test was taken;
- 24.4.3.8. Measured dose rates in mR/hr and contamination levels in dpm/100 cm²;
- 24.4.3.9. Name or initials of the person who conducted the survey and the date;
- 24.4.3.10. Make and model number of equipment used;
- 24.4.3.11. Action taken in case of excessive dose rate or contamination, and follow-up survey information.

25. SEALED SOURCES

Sealed sources or source holders must identify isotope, activity and assay or reference date of the source. Sources shall be stored with sufficient shielding to ensure that the dose rates in the immediate area should not exceed 5 mR/hr at 30 cm from the storage area and efforts shall be made to reduce rates to the extent possible (ALARA). Additionally, the dose rates in adjacent unrestricted areas shall be evaluated carefully. Contact Radiation Safety if there are any measurable dose rates in locations adjacent to the storage location. The RSO will ensure that dose rates do not exceed 2 mR/hr in any one hour and that no personnel could receive more than 50 mrem in any one year.

25.1. Leak-Tests & Inventory of Sealed Sources

Any source of 100 μ Ci or more (or 10 μ Ci or more for sources designed to emit alpha particles) with a half-life greater than 30 days (excluding H-3) must be tested for leakage or contamination prior to initial use, any time there is reason to suspect that the source might be leaking, and at least every six months. Sealed sources will be leak-tested by Radiation Safety personnel. Leak tests are not required on sources that are stored and are not being used but are required 6 months before use or transfer.

25.2. The following are EXEMPT from leak testing:

- 25.2.1. Sources containing H-3;
- 25.2.2. Sources containing licensed material with a half-life < 30 days;
- 25.2.3. Sources containing licensed material in gaseous form (Xe, Kr);
- 25.2.4. Alpha or neutron-emitting radioactive material <10 μ Ci;
- 25.2.5. Beta or gamma-emitting radioactive material <100 μ Ci;
- 25.2.6. If license allows for sources designed to emit alpha radiation, please contact Radiation Safety.

25.3. All sealed sources will be inventoried by Radiation Safety per regulatory requirements.

EHS-500, Radiation Safety Manual

ACCIDENTS / INCIDENTS / EMERGENCIES

Emory Healthcare (EHC) personnel receive training in Emergency Preparedness and the use of the EHC Unified Emergency Codes. However, they should review the procedures below that are appropriate to their use of radioactive material.

26. PERSONAL CONTAMINATION

26.1. What If I Am Contaminated?

- 26.1.1. Any personal contamination must be reported to Radiation Safety immediately.
- 26.1.2. Contaminated skin should be washed with mild soap and water.
- 26.1.3. Contaminated clothing and shoes must be removed promptly. Fold the clothing inward to prevent the spread of contamination and place clothing and shoes in a plastic bag. Label the plastic bag with the time, date, and isotope (if known) for decay or disposal as radioactive waste by radiation safety.
- 26.1.4. Radiation Safety will record contamination levels observed and procedures followed for incidents involving contamination of individuals. An incident record will be documented that includes names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor's signature.

26.2. What If I Am Injured?

- 26.2.1. IN THE EVENT PERSONNEL ARE INJURED, SEEK MEDICAL ATTENTION IMMEDIATELY!
- 26.2.2. Employee incidents are reported to Employee Health. Inform your supervisor, staff leadership, or safety representative.
- 26.2.3. How Do I Reach Medical Help?
- 26.2.4. If this is an Emergency, call 911.
- 26.2.5. Page the on-call Employee Health/Occupational Injury Management Nurse Practitioner for further guidance at: 404-686-5500, PIC# 50464.
- 26.2.6. Notify the employee's supervisor or their designee within 24 hours of the incident.
- 26.2.7. Emory Healthcare
 - 26.2.7.1. Access the Emory Healthcare Intranet page and go to the Occupational Injury Management webpage
<https://www.hr.emory.edu/eu/wellness/general-health/occupational-injury-management/index.html>.
 - 26.2.7.2. Click on "Report a work-related accident, injury or illness" under Quick Links and Resources
 - 26.2.7.3. Click on "Protocols for Employee Incident: Work-Related Injury/Illness
https://www.hr.emory.edu/eu/_includes/documents/sections/wellness/protocol-incident.pdf.
- 26.2.8. Express Care Clinic

EHS-500, Radiation Safety Manual

- 26.2.8.1. The Express Care Clinic provides all Emory Healthcare and Emory University employees care for acute occupational accidents and exposures.
- 26.2.8.2. A SAFE Report must be completed within 24 hours of the incident. See next section.
- 26.2.9. How Do I Record Incidents and Exposures?
 - 26.2.9.1. Healthcare - EHC patient and visitor incidents and near misses are reported in the SAFE Event Reporting System. Access the Emory Healthcare Intranet page, <https://workspace.emory.org>. Click on SAFE event reporting under quick links, click submit a SAFE report, select employee injury, complete the report, and click submit.
 - 26.2.9.2. University event reporting system can be accessed through the 'How to Report an Accident' section on the Environmental, Health, and Safety Office (EHSO) website. If the employee is unable to complete the report, it should be completed by the supervisor.

27. WHAT IF I HAVE A SPILL?

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables, such as the number of individuals affected; other hazards present; the likelihood of spread of contamination; and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides, the best spill procedure may be restricted access pending complete decay.

As a general guideline, a spill involving more than one millicurie of radioactive material or more than one liter of radioactive liquid is a major spill which must be reported immediately to Radiation Safety. The initial responder can determine if the clean-up will require additional radiation safety assistance.

27.1. Minor Spills of Liquids and Solids

- 27.1.1. Notify persons in the area that a spill has occurred.
- 27.1.2. Prevent the spread of contamination by covering the spill with absorbent paper. (Paper should be dampened if solids are spilled.)
- 27.1.3. Clean up the spill, wearing disposable gloves and using absorbent paper.
- 27.1.4. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Put contaminated gloves and any other contaminated disposable material in the bag.
- 27.1.5. Survey the area with an appropriate radiation survey meter set on lower scale. Check the area around the spill for contamination. Also check hands, clothing, and shoes for contamination.
- 27.1.6. Report the incident to Radiation Safety promptly.
- 27.1.7. Cooperate with radiation safety personnel in discovering the root cause of the spill and in providing requested bioassay samples if indicated.

27.2. Major Spills of Liquids and Solids

- 27.2.1. Notify all persons not involved in the spill to clear the room, but to remain in the

EHS-500, Radiation Safety Manual

area to await survey.

- 27.2.2. Prevent the spread of contamination by covering the spill with absorbent paper (paper should be dampened if solids are spilled), but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.
- 27.2.3. Shield the source only if it can be done without further contamination or significant increase in radiation exposure.
- 27.2.4. Close the room and lock or otherwise secure the area to prevent entry. Post the room with a sign to warn anyone trying to enter that a spill of radioactive material has occurred.
- 27.2.5. Notify Radiation Safety immediately.
- 27.2.6. Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with a mild soap.
- 27.2.7. Allow no one to return to work in the area unless approved by radiation safety personnel.
- 27.2.8. Cooperate with radiation safety personnel in discovering the root cause of the spill and in providing requested bioassay samples if indicated.
- 27.2.9. Follow the instructions of the Radiation Safety staff concerning decontamination techniques, surveys, provision of bioassay samples, and requested documentation.

28. OTHER INCIDENTS

28.1. Incidents Involving Dust, Mist, Fumes, Organic Vapors or Gases

- 28.1.1. Notify all personnel to vacate the room immediately.
- 28.1.2. Shut down ventilation system, if possible, unless it is determined that the room ventilation system needs to be used to clear the air for access purposes.
- 28.1.3. Vacate the room. Seal the area, if possible.
- 28.1.4. Notify Radiation Safety immediately.
- 28.1.5. Ensure that all access doors to the area are closed and posted with radiation warning signs or post guards (trained) at all access doors to prevent accidental opening of the doors or entry to the area.
- 28.1.6. Survey all persons who could have possibly been contaminated. Decontaminate as directed by Radiation Safety personnel.
- 28.1.7. Promptly report suspected inhalation and ingestions of radioactive material to Radiation Safety.
- 28.1.8. Decontaminate the area only when advised and/or supervised by Radiation Safety.
- 28.1.9. Allow no one to return to work in the area unless approved by Radiation Safety.
- 28.1.10. Cooperate with radiation safety personnel in discovering the root cause of the

EHS-500, Radiation Safety Manual

incident and in providing requested bioassay samples if indicated.

- 28.1.11. Follow the instructions of Radiation Safety staff concerning decontamination techniques, provision and collection of bioassay samples, and providing requested documentation.

28.2. Minor Fires

- 28.2.1. Immediately attempt to put out the fire by approved methods (e.g., fire extinguisher) if other fire hazards or radiation hazards are not present.
- 28.2.2. Notify all persons present to vacate the area and have one individual immediately call the fire department and Radiation Safety.
- 28.2.3. Once the fire is out, isolate the area to prevent the spread of possible contamination.
- 28.2.4. Survey all persons involved in combating the fire for possible contamination.
- 28.2.5. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with a mild soap.
- 28.2.6. In consultation with Radiation Safety, determine a plan of decontamination and the types of protective devices and survey equipment that will be necessary to decontaminate the area.
- 28.2.7. Allow no one to return to work in the area unless approved by Radiation Safety.
- 28.2.8. Cooperate with radiation safety personnel in discovering the root cause of the incident and in providing requested bioassay samples if indicated.
- 28.2.9. Follow the instructions of Radiation Safety staff concerning decontamination techniques, provision and collection of bioassay samples, and providing requested documentation.

28.3. Major Fire, Explosion or Major Emergencies

- 28.3.1. Notify all persons to vacate the area immediately.
- 28.3.2. Notify the fire department.
- 28.3.3. Notify Radiation Safety and other facility safety personnel.
- 28.3.4. Upon arrival of firefighters, inform them where radioactive materials are stored or where radioisotopes were being used; inform them of the present location of the radioactive material and the best possible entrance route to the radiation area, as well as any precautions to avoid exposure or risk of creating radioactive contamination by use of high pressure water, etc.
- 28.3.5. Cooperate with radiation safety personnel in discovering the root cause of the incident and in providing requested bioassay samples if indicated.
- 28.3.6. Follow the instructions of Radiation Safety staff concerning decontamination techniques, provision and collection of bioassay samples, and providing requested documentation.
- 28.3.7. Allow no one to return to work in the area unless approved by Radiation Safety.

28.4. Release Into Environment

- 28.4.1. Immediately report to Radiation Safety any unplanned release of radioactive

EHS-500, Radiation Safety Manual

material into the environment. Radiation Safety will determine, based on the quantity released, if the event is required to be reported to the Georgia DNR.

28.5. What If Radioactive Material Is Missing?

28.5.1. Once a loss of radioactive material has been discovered, it must be immediately reported to Radiation Safety. Radiation Safety will:

28.5.1.1. Gather information regarding the disappearance of the radioactive material;

28.5.1.2. Initiate steps to locate and recover the material;

28.5.1.3. Determine if the loss is required to be reported to the Georgia DNR according to regulations, and

28.5.1.4. If required, report the loss in the required time frame.

EHS-500, Radiation Safety Manual

Table 6, Radionuclides Commonly Used in Research Laboratories

| Isotope | Beta/ Gamma | Personnel Monitoring | Shielding | GM Meter | Hazard | Laboratory |
|-------------------------|------------------|-------------------------|-----------|----------|----------|--------------------------|
| H-3 | Beta | None | None | No | Low | Up to 10 Ci |
| C-14 | Beta | None | None | Yes | Moderate | Up to 100 mCi |
| F-18 | Positron/Gamma | Yes | Lead | Yes | Moderate | Up to 100 mCi |
| Na-22 | Gamma | Yes | Lead | Yes | High | Up to 1 mCi, med-100 mCi |
| Na-24 | Gamma | Yes | Lead | Yes | Moderate | Up to 100 mCi |
| P-32 | Beta | wb>50 mCi ring >1mCi | Plexiglas | Yes | Moderate | Up to 100 mCi |
| P-33 | Beta | None | None | Yes | Moderate | Up to 100 mCi |
| S-35 | Beta | None | None | Yes | Moderate | Up to 100 mCi |
| Cl-36 | Beta | None | None | Yes | High | Up to 1 mCi, med-100 mCi |
| Ca-45 | Beta | None | None | Yes | High | Up to 1 mCi, med-100 mCi |
| Mn-54 | Gamma | Yes | Lead | Yes | Moderate | Up to 10 mCi |
| Fe-55 | Electron Capture | None | None | No | Low | Up to 10mCi |
| Rb-86 | Beta | Yes | Plexiglas | Yes | Moderate | Up to 100mCi |
| Cu-64 | Gamma | Yes | Lead | Yes | Moderate | Up to 100mCi |
| Y-90 | Beta | Yes | Plexiglas | Yes | Moderate | Up to 100 mCi |
| Cr-51 | Gamma | wb>10 mCi | Lead | Yes | Moderate | Up to 100 mCi |
| Tc-99m | Gamma | Yes | Lead | Yes | Low | Up to 10 Ci |
| In-111 | Gamma | Yes | Lead | Yes | Moderate | Up to 100 mCi |
| I-123 I-125 I-131 | Gamma | > 1 mCi | Lead | Yes | High | Up to 1 mCi, med-100 mCi |

H-3, S-35 and the radioiodines have some volatile forms.

Use of a chemical fume hood and bioassay may be required on a case-by-case basis

EHS-500, Radiation Safety Manual

PROCUREMENT OF RADIOACTIVE MATERIAL

29. PROCUREMENT THROUGH EMORY EXPRESS

Radioactive materials (RAM) shall be procured through Emory Express (with the exception of some clinical uses). All vendors/suppliers of radioactive materials must be appropriately licensed by the NRC or an Agreement State to manufacture and sell RAM. Vendors may request copies of the University Broad Scope license as part of their review process, refer these requests to Radiation Safety. If a copy is needed by a new or prospective supplier, the Radiation Permit Holder must advise Radiation Safety for a copy to be forwarded to the supplier.

29.1. How to Order Radioactive Material for Research Laboratories

- 29.1.1. A Radiation Permit Holder can request radioactive material from a hosted catalog or as a non-catalog item. Please see the [Ordering Radioactive Material \(RAM\) Guidelines](#) and follow the instructions given. All orders must be approved by EHSO prior to being processed by the Purchasing Department.
- 29.1.2. Orders cannot be placed directly with the vendor.
- 29.1.3. The Radiation Permit Holder must be authorized to use the isotopes and amounts prior to submitting an order.
- 29.1.4. Replacements for an incorrect order or unusable shipments must be negotiated by the Purchasing department with consent of EHSO.
- 29.1.5. The requisition must contain the name of the Radiation Permit Holder, the authorization number and the following product information:
 - 29.1.5.1. Vendor;
 - 29.1.5.2. Catalogue number;
 - 29.1.5.3. Isotope;
 - 29.1.5.4. Compound;
 - 29.1.5.5. Activity in μCi or mCi ;
 - 29.1.5.6. Quantity (number of units).
- 29.1.6. After verification by EHSO personnel that the Radiation Permit Holder is authorized to possess the material and that the order will not exceed the possession limit, the order will be transmitted to Purchasing by EHSO.

29.2. How to Transfer from Other Universities/ Vendor Replacements

- 29.2.1. If possible, a requisition with zero cost entered should be submitted via Emory Express. If this is not possible, a Non-Emory Express Acquisition Form must be completed by the receiving Radiation Permit Holder and submitted to EHSO for signature approval before the material is shipped.

29.3. How to Transfer Within the University to Another Lab

- 29.3.1. An Emory University Radioactive Material Transfer Form, completed and signed by both parties involved in the transfer, must be submitted to EHSO for signature approval before the material is transferred. Do NOT transfer radioactive materials prior to approval by RSO.

EHS-500, Radiation Safety Manual

- 29.3.2. Material must not be released until the transferor receives the transfer form approved by Radiation Safety personnel. Submit a completed and signed copy of the Emory University Radioactive Material Transfer Form to RSO.
 - 29.3.3. The transfer must be approved by Radiation Safety prior to transfer of the Material. To ensure with DOT/IATA regulations, Radiation Safety will review the contents, packaging and generate any required documentation. Do not offer any hazardous material including radioactive material for shipment without EHSO approval.
 - 29.3.4. Transport of Radioactive material must be in compliance with all DOT/IATA regulations. Contact Radiation Safety for information on assistance in hazardous materials transportation.
- 29.4. How to Order Sealed Sources
- 29.4.1. Sealed sources must be received and processed by Radiation Safety Office unless specifically approved for direct shipment to certain clinical areas.
 - 29.4.2. Order sources as outlined above in Item 29.
 - 29.4.3. Areas approved for direct receipt of sources shall notify RSO immediately upon receipt so Radiation Safety can add source information into database and prepare expired sources for return.
- 29.5. Ordering Radioactive Material for Clinical Departments
- 29.5.1. Routine orders for radiopharmaceuticals are placed by the Nuclear Medicine Technologist or Medical Physicist. Nuclear pharmacy personnel will deliver the radiopharmaceutical directly to the nuclear medicine hot lab which they are able to access and secure.
 - 29.5.2. When ordering radioactive materials for therapeutic uses, the person ordering the material will reference the Authorized User's written request when placing the order. The Authorized User's request will indicate the isotope, compound or physical form, and activity level.

EHS-500, Radiation Safety Manual

RECEIVING RADIOACTIVE MATERIAL

30. RECEIVING PACKAGES OF RADIOACTIVE MATERIAL

EHSO will receive packages for laboratories and check them for leakage and proper contents. EHSO will deliver the packages to the labs and will ask for a signature of receipt. For delivery of short-lived materials directly to the laboratory see below. All material procurement must be as described in Procurement.

30.1. Procedure for Receiving Packages

- 30.1.1. All personnel involved with the receipt of radioactive material shipments must be instructed in the proper procedures and precautions. Unpacking of Radioactive Materials must be done in accordance with established policy and procedures. See Procedure for Receiving and Opening Packages.
- 30.1.2. Appropriate information for packages processed by EHSO will be entered in the EHS Assistant database.
- 30.1.3. When material is delivered to a laboratory by Radiation Safety, a member of the laboratory must be present to sign for it. If no one is present in the preferred lab or another lab belonging to the same Radiation Permit Holder, the package is returned to Radiation Safety. An attempt will be made to deliver the package later in the day, or a voice-mail message will be left for the Radiation Permit Holder or laboratory personnel.
- 30.1.4. Ensure packaging is free of contamination prior to disposal. The lab needs to make the final assessment prior to disposal.
- 30.1.5. Labels (e.g., white I, yellow II) on shipping boxes used for receiving radioactive materials must be defaced prior to disposal through housekeeping.

30.2. Who Can Receive Radioactive Material Directly Without Going Through Radiation Safety?

- 30.2.1. Most laboratory authorizations are not approved to check-in packages containing radioactive material and must have all radioactive material shipments delivered to Radiation Safety for check-in and processing.
- 30.2.2. Researchers receiving time-sensitive material for animal use from a local radiopharmacy may receive it directly by special permission and instruction from Radiation Safety personnel. Laboratories must document the package receipt inspection and must maintain the documentation for inspection.
- 30.2.3. Shipments of Radioactive Materials for clinical human use may be shipped directly to clinical departments and received during working hours.
- 30.2.4. Due to the short half-life, isotopes produced in the Emory or PETNet cyclotron are transferred directly to Radiation Permit Holders without being routed to Radiation Safety.
- 30.2.5. The transfer of labeled compounds between laboratories can be made within the limits specified in the Authorization but must be approved by Radiation Safety and documented. (See "How To Transfer Radioactive Material within the University to Another Lab").

EHS-500, Radiation Safety Manual

MAINTENANCE OF RADIOACTIVE MATERIAL INVENTORY

31. RADIOACTIVE MATERIAL INVENTORY

Upon receipt of Radioactive Materials, the Authorized User/RPH is responsible for maintaining accurate inventory records for all Radioactive Materials possessed. Materials received in the lab must be recorded in online Inventory System. All laboratory radioactive material users must have training on how to use the EHS Assistant database. Contact Radiation Safety to schedule training. Clinical areas are responsible for maintaining their own inventory. When an order has been received by the EHSO staff, the radioactive stock vial information is added to the lab's inventory in the EHS Assistant database. The activity and the volume, among other items, are recorded. EHS Assistant thus enables the labs to track their use of radioactivity by date and volume, eliminating the need to calculate radioactive decay.

31.1. What Radioactive Material Am I Supposed to Track?

31.1.1. Each lab must keep track of any use of radioactive material. Use is tracked in the EHS Assistant database, which the lab accesses on-line. Specifically:

31.1.1.1. The date radioactive material is removed from a stock vial;

31.1.1.2. The amount of radioactivity used and;

31.1.1.3. The waste stream (dry, liquid, or mixed with liquid scintillation fluid) that it is destined for should be recorded.

31.2. How Do I Learn to Use EHS Assistant?

31.2.1. Database training is taught during Radiation Safety Training for Lab Workers;

31.2.2. The lab worker can also access a written tutorial at www.ehso.emory.edu.

31.2.3. The lab may contact Radiation Safety for assistance.

31.3. What If I Made a Mistake?

31.3.1. Anytime you are unable to correct a mistake yourself, please contact your Radiation Safety professional for assistance.

EHS-500, Radiation Safety Manual

TRANSPORTING RADIOACTIVE MATERIAL

32. TRANSPORTATION OF RADIOACTIVITY FROM EMORY

Radiation Safety must approve all radioactive material shipments prior to being offered for transportation. Only specific clinical staff with current DOT/IATA training certificates and approved by Radiation Safety are authorized to prepare radioactive material shipments.

32.1. Can I Drive Radioactive Material Around Myself?

32.1.1. No.

32.2. How Do I Ship Radioactive Material to Somewhere Else?

32.2.1. Submit a completed Transfer Form and wait for Radiation Safety approval.

32.2.2. Radiation Safety will review the request obtain necessary permission and documents (ex. current copy of recipient NRC or Agreement State license, Return Authorization number, etc.)

32.2.3. Radiation Safety will arrange for any required packaging and generate any required shipping paperwork.

32.3. Staff that have received the appropriate training (DOT/IATA) and have been approved by Radiation Safety may process routine shipments of radioactive material and shall maintain records in accordance with [Radiation Safety Office Record Keeping Guidelines](#).

EHS-500, Radiation Safety Manual

WASTE MANAGEMENT

Emory operations generate waste that is regulated by federal and state agencies, including the United States Environmental Protection Agency (EPA), Georgia Environmental Protection Department (GA EPD), and the Nuclear Regulatory Commission (NRC). The Environmental Health and Safety Office (EHSO) has developed guidelines for proper management of regulated waste and to ensure compliance with applicable regulations. Please refer to the Regulated Waste Guidelines document.

Radioactive waste is primarily generated by the routine use of radionuclides in life science research and human clinical applications. Most radioactive wastes tend to be dry solid materials contaminated by contact with RAM, liquid waste collected during experiments, scintillation vials used to count or analyze samples and empty or partially used stock vials.

Sealed radioactive sources may require disposal but constitute a special waste stream and need to be handled on a case-by-case basis. In general, sealed sources of radioactivity may NOT be disposed in categories outlined below. Contact EHSO if you have sealed sources for disposal.

When hazardous chemicals and radioactive materials are comingled, it is referred to as "Mixed Waste" and requires additional consideration prior to disposal. Minimization of these wastes is important because of the significantly higher disposal costs.

33. LABORATORY AREAS

- 33.1. EHSO provides appropriate containers for waste collection. The PI is responsible for ensuring the waste stream being generated is compatible with the container provided and to contact EHSO if an alternate container is needed. The containers shall be maintained in good condition to ensure waste is contained and there are no leaks.
- 33.2. Radioactive waste is segregated by waste type (dry solid, liquid, vial, etc.) and then further segregated by half-life. If you have questions about segregation or generation of mixed wastes with new research projects, contact EHSO for assistance at 404-712-6622.
- 33.3. EHSO provides containers and supplies for Dry, Liquid and Scintillation Vial Waste as well as Radioactive Waste Tags. Do not use alternate packaging unless specific approval has been obtained from EHSO beforehand.

EHS-500, Radiation Safety Manual

Table 7, Waste Containers

| Waste Stream | Container | Provided By |
|---------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Dry Solid Waste | 5-gallon plastic pail with plastic liner | EHSO |
| Liquid Waste | 1-gallon plastic jug with lid | EHSO |
| Scintillation Vials | 5-gallon plastic pail with vermiculite and plastic liner | EHSO |
| Sharps | Sharps container or another hard-sided container sufficient to prevent puncture. Sharps containers can be disposed into a dry solid waste container. | PI |
| Alternate containers for radioactive waste must be approved in advance by EHSO. | | |

33.4. Separate Radioactive Waste by Half-life

Each radioactive waste stream (dry, liquid, scintillation vials) is separated by half-life. If radionuclides must be comingled for an experiment, contact EHSO for additional guidance.

Table 8, Separation of Waste

| Group | Segregation | Examples |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|---------------------------|
| Half-life < 30 days | These isotopes may be comingled | Tc-99m, F-18, I-131, P-32 |
| Half-life > 30 days | Isotopes with half-lives greater than 15 days shall be collected in separate containers | I-125, S-35, H-3, C-14 |
| If radionuclides with half-lives greater than 30 days must be comingled for an experiment, contact EHSO for additional guidance. | | |

33.5. Animal Waste

Radioactive waste from animal research generates two primary waste streams: bedding waste from cages and pens and carcasses/tissue waste. Bedding waste will be processed through EHS Assistant database just as with other radioactive material uses. Carcass and tissue waste will be processed through EHS Assistant as either routine waste with a waste container number assigned or as deregulated waste (<0.05 uCi/g of animal tissue) and processed out through the container type "Deregulated Biological". Contact ESHO to

EHS-500, Radiation Safety Manual

determine how your waste stream should be processed.

33.6. Cage/Pen Waste

Cage/pen waste (i.e., other excreta and bedding) must be collected in appropriate biohazard bags, sealed with tape, and labeled with the following on a yellow radioactive waste tag and placed in designated storage area:

- 33.6.1. PI Name,
- 33.6.2. Container number (assigned by EHS Assistant database),
- 33.6.3. Isotope and activities and description of contents,
- 33.6.4. Date collected,
- 33.6.5. Survey Results,
- 33.6.6. Wipe test results of container exterior (top, bottom, and sides) recorded in dpm,
- 33.6.7. Meter survey results at contact and one meter recorded in mR/hr,
- 33.6.8. Enter the name of the person surveying the container,
- 33.6.9. Enter the date the survey was conducted,

33.7. Carcasses/Tissues Waste

Carcasses and tissues must be placed in appropriate biohazard bags (with double bagging for heavy carcasses), sealed with tape and labeled with the following on a yellow radioactive waste tag and placed in a designated freezer:

- 33.7.1. PI Name,
- 33.7.2. Isotope and activities and description of contents,
- 33.7.3. Date collected,
- 33.7.4. Survey Results,
- 33.7.5. Wipe test results of container exterior (top, bottom, and sides) recorded in dpm,
- 33.7.6. Meter survey results at contact and one meter recorded in mR/hr,
- 33.7.7. Enter the name of the person surveying the container,
- 33.7.8. Enter the date the survey was conducted,
- 33.7.9. Contact EHSO to determine how this waste should be processed out through EHS Assistant.
- 33.7.10. When double bagging is used, all labels must be on the outside of the outermost bag.
- 33.7.11. Carcasses and animal tissues must be frozen and stored in designated freezers until disposal can be arranged through EHSO.

33.8. Can I Pour Liquid Waste Down the Drain?

Sewer disposal of liquid radioactive wastes is generally prohibited. Radiation Safety can review and approve sink-disposal on a case-by-case basis. Contact Radiation Safety for specific approval. Procedures and documentation requirements will be provided upon approval.

EHS-500, Radiation Safety Manual

33.9. Can I Let My Waste Decay Away In My Lab?

All radioactive wastes must be processed through Radiation Safety and EHSO. Record keeping requirements must be maintained. Labs using short lived materials may request permission for decay-in-store and upon approval will be provided with the procedures and record keeping requirements.

34. CLINICAL AREAS

34.1. Clinical areas and PET Imaging areas using short-lived radioactive material are generally authorized to store, hold, decay, and dispose of their own waste. Waste disposal must be performed according to the [Clinical Radioactive Waste Disposal Procedure](#).

34.2. Clinical areas are encouraged to contact Radiation Safety if they need assistance with:

- 34.2.1. large quantities of radioactive waste;
- 34.2.2. waste with half-lives longer than ten days or therapeutic radioactive waste with long lived contaminants;
- 34.2.3. sealed sources for return or disposal.

EHS-500, Radiation Safety Manual

USE OF RADIOACTIVE MATERIAL IN ANIMALS

35. SAFE USE OF RADIOACTIVITY IN VIVO

35.1. General Guidance

- 35.1.1. An “Amendment to Non-Human Use Authorization-Committee II” form, “Radioactive Material in vivo” form, and an IACUC protocol must be submitted to Radiation Safety for approval by Committee II. IACUC has the prerogative to approve the use of animals.
- 35.1.2. Radiation Safety at Emory University performs quarterly radiation safety audits of all Animal Use areas. Records such as Animal Care Record Cards, Cage Cards, Survey Records, Waste Logs, and Training Records are checked during the Audit. The Radiation Safety staff also performs contamination and radiation level surveys if needed.
- 35.1.3. All use of radioactive material must be conducted under the supervision of a Radiation Permit Holder who has approval from Division of Animal Resources (DAR), Institutional Animal Care and Use Committee (IACUC), and Radiation Safety.
- 35.1.4. All investigators using radioisotopes in animals are required to design and perform their studies in a manner which prevents unnecessary exposure to radiation and keeps necessary exposure ALARA (As Low as Reasonably Achievable). This requirement applies to the use of all Animal Care Facilities.

35.2. Standard Procedures

- 35.2.1. All Animal Care Personnel and Research Staff must have current Radiation Safety Training on the safe use and sources of radiation. Personnel shall be aware of the significance of radioactive signs and labels and follow precautionary measures included on such signs.
- 35.2.2. Main entry doors of Animal Care Facilities where Radioactive Material is present must be posted with “CAUTION RADIOACTIVE MATERIAL” signs.
- 35.2.3. Primary enclosures containing live animals that have received Radioactive Material must be properly identified in the Animal Care Facility. Cage Cards must be attached to the cage in which Radioactive Animals are housed. See Section [“Guidelines for Selecting Proper Animal Care Protocol”](#) below for cage card selection.
- 35.2.4. Radioactive animals must be transported in such a manner to prevent contamination of hallways, elevators, etc. Solid bottomed transfer containers are mandatory.
- 35.2.5. The Radiation Permit Holder must evaluate the radiation dose in the workplace, the excretion rate of radioactive material, and any special hazard that may be associated with the radionuclide or its chemical form.
- 35.2.6. If routine animal care is handled by staff other than the Radiation Permit Holder’s Staff, specific instructions must be provided on animal care such as feeding, watering, cage and pen cleaning, and waste handling.
- 35.2.7. In the event animals undergo necropsy during the period of radioactivity, procedures for radiation protection, sample collection, and waste disposal must

EHS-500, Radiation Safety Manual

be specified to necropsy personnel prior to the beginning of procedures.

- 35.2.8. Rats and mice may be housed outside of a DAR facility for less than 24 hours but in accordance with the approved IACUC protocol. Carcasses and tissues must be collected and stored for decay by staff trained in Radiation Safety.
- 35.2.9. Waste logs must be maintained. Radiation survey must be conducted after 10 half-lives, and survey results must be documented in the waste log.
- 35.2.10. If animals are not sacrificed within 24 hours, animal housing must be done in accordance with the approved IACUC protocol and RSO restrictions for Radioactive Animals.

35.3. Standard Protocols for Care of Animals Containing Radioactivity

- 35.3.1. Authorized radioisotope users who require care for animals treated with radioactive materials must provide, by direct supervision and/or complete written instructions, the procedures which the animal caretakers must follow with respect to cage handling and collection and disposal of radioactive waste.
- 35.3.2. Investigators often house animals containing radioactive material in general animal care facilities which are used by several investigators at the same time. Such facilities, by necessity, are accessible to people with widely varying training in radiation safety.
- 35.3.3. All investigators using radioisotopes are required to design and perform their studies in a manner which prevents unnecessary exposures to radiation and keeps necessary exposures ALARA (as low as reasonably achievable). This requirement also applies to animal care and the use of animal care facilities.
- 35.3.4. To assist investigators who must maintain animals treated with radioactive material, a set of three standard protocols have been developed for animal care and specify the radiation conditions permitted for their use. Animal care protocols must be specified in the IACUC protocol.
- 35.3.5. Each protocol is designated by a specific color card.
- 35.3.6. The color alerts any person in the vicinity of the animal cage to the presence and degree of potential radiation hazard.
- 35.3.7. The decision on whether animals containing radioactive material may be housed in general care facilities or if they must be placed in isolation rooms depends in part on the radiotoxicity of the radionuclides being used and the maximum activity excreted daily per cage or room. Limits are based on the chemical and physical forms of the radionuclide and its excretion rate.
- 35.3.8. Radiotoxicity classifications and maximum daily excretion for commonly used radionuclides are as follows:

EHS-500, Radiation Safety Manual

Table 9, Radiotoxicity Classification

| Radiotoxicity Classification | |
|------------------------------|----------------------------------------|
| Hazardous | Ca-45, I-123, I-125, I-131 |
| Moderately Hazardous | Cu-64, F-18, P-32, S-35, Se-75, TI-201 |
| Slightly Hazardous | H-3, C-14, Tc-99m, In-111 |

Table 10, Maximum Permitted Daily Activity Excretion

| Maximum Permitted Daily Activity Excretion | | | |
|--------------------------------------------|----------------------------------------------------|---------------------------------------------------|---------------------------|
| Radiotoxicity Classification: | Housed in General Animal Facilities | | Housed in Isolation Rooms |
| | Care by Non-Radiation Workers | Care by Radiation Workers | Care by Radiation Workers |
| Hazardous | < 100 μ Ci / cage and < 500 μ Ci / room | > 100 μ Ci /cage and < 500 μ Ci / room | > 500 μ Ci / room |
| Moderately Hazardous | < 1 mCi / cage and < 5 mCi / room | > 1 mCi / cage or > 5 mCi / room | > 25 mCi / room |
| Slightly Hazardous | < 5 mCi / cage and < 10 mCi / room | > 5 mCi / cage or > 10 mCi / room | > 50 mCi / room |

36. GUIDELINES FOR SELECTING PROPER ANIMAL CARE PROTOCOL

Each of the standardized protocols for animal care is designated by a color-coded card. Selection of appropriate protocol (and hence the appropriate cage card) is essential to ensuring the safe handling of animals containing radioactive material. Animal care protocols are selected based on radiotoxicity, isotope half-life, dose rate, and likelihood of contaminated bedding. In order of increasing potential hazard, the color codes used are as follows: Blue - Yellow - Red.

36.1. Blue Protocol – Used only with short-lived isotopes (physical half-life < 10 hours) as long as the quantity does not exceed the limits established for non-radiation workers.

36.1.1. Radiation dose rate in normal workspace does not exceed 2 millirem/hour. Card may not be appropriate with animals requiring daily pen/cage cleaning unless the physical half-life of the radionuclide is less than 2.5 hours. Radiation dose rate in normal work space does not exceed 2 millirem/hour.

36.1.2. Researchers must complete the cage cards based on the information posted in the scan room. Cards will be returned to the Radiation Permit Holder's staff at the end of the study.

36.1.3. Cage room survey must be conducted and documented on the card by research staff. Radiation levels for animal bedding and waste must be checked at the end of the study. Radiation levels must not exceed background radiation levels.

36.2. Yellow Protocol – Used with any animal requiring care by radiation workers, but not

EHS-500, Radiation Safety Manual

requiring isolation.

- 36.2.1. Used for radioisotopes with a physical half-life >10 hours, as long as the quantity does not exceed the limits established for non-radiation workers. The radiation dose rate in the immediate work area may exceed 2 millirem/hour, but the radiation dose rate in adjacent work areas must not exceed 2 millirem/hour.
- 36.2.2. Animal litter is contaminated and must be collected and stored as radioactive waste. The Radiation Permit Holder or other trained radiation worker provides all routine care of animals as required by DAR for the designated care period.
- 36.2.3. Records must identify the persons who provide animal care. Animal litter and waste will be collected by trained radiation worker. Waste must be checked before regular disposal.
- 36.2.4. Cage must be checked for contamination at the end of the study. Cage cards must be returned to Radiation Permit Holder's staff assigned for the area.
- 36.3. Red Protocol – Used for any animal requiring isolation.
 - 36.3.1. The degree of hazard requires isolation of the treated animal(s).
 - 36.3.2. Access to the isolation room is restricted to necessary personnel.
 - 36.3.3. Arrangements for an isolation room must be made with DAR prior to the start of the experiment.
 - 36.3.4. The Radiation Permit Holder together with Radiation Safety and DAR will determine the duration of isolation and the specific procedures to maintain satisfactory animal care and radiation protection.
 - 36.3.5. The Radiation Permit Holder or another trained radiation worker provides all routine care of the feeding, water, cage washing, and room cleaning.
 - 36.3.6. Waste and contaminated equipment must be collected and stored for decay by the Radiation Permit Holder. The room must be checked by Radiation Safety staff before releasing room for general use.

EHS-500, Radiation Safety Manual

RADIATION INSTRUMENTATION

37. GENERAL INFORMATION

37.1. What Instruments Do I Need to Work with Radioactivity?

- 37.1.1. You are required to list the surveying and counting instrumentation available for use in your laboratory when applying for an authorization.
- 37.1.2. When an application enters the Radiation Safety Office, it is reviewed by a staff member who determines that the correct instrumentation is available to detect the radionuclides requested. Applications are reviewed by radiation safety to determine whether the correct counting instrument is available.
- 37.1.3. If a necessary piece of instrumentation is missing, the Radiation Permit Holder must purchase the equipment or receive permission from another Radiation Permit Holder to use their equipment.
- 37.1.4. Most laboratories purchase their own GM survey meter when needed, but liquid scintillation and gamma counters are often shared within departments.
- 37.1.5. The equipment must be ordered prior to submitting the application to the appropriate committee.

37.2. How Do I Obtain A GM Survey Meter?

- 37.2.1. A GM survey meter can be purchased from Ludlum Measurements, Johnson Nuclear, Thermo Scientific, or other major manufacturers of radiation detection equipment. The most commonly used GM survey meter at Emory is the Ludlum Model 3 with a Model 44-9 "pancake" probe.

37.3. What Are the Requirements of GM Survey Meter and Survey Instruments?

- 37.3.1. The survey meter must have an external detector for surveying surfaces for contamination and can read in either mR/hr, CPM, CPS or a combination of these units.
- 37.3.2. For Clinical Use:
 - 37.3.2.1. For uptake, dilution, and excretion studies for which a written directive is not required, a meter with a range of 0.1 to 50 mrem/hr is required;
 - 37.3.2.2. For procedures requiring a written directive, a meter with a range of 0.1 to 50 mrem/hr and a meter with a range of 1 mrem/hour to 1000 mrem/hour is required; and,
 - 37.3.2.3. There must be a dedicated check source available.

37.4. How Do I Get My GM Survey Meter Calibrated?

- 37.4.1. Survey meters must be calibrated by the Radiation Safety personnel before the first use (unless accompanied by a manufacturer's calibration certificate), annually, and after being repaired. The calibration sticker on the instrument will indicate the recalibration due date. The record of each meter calibration must be maintained by the Radiation Permit Holder for three years or per Emory Policy, whichever is longest. It is the responsibility of the Radiation Permit Holder to see that the instrument is free of contamination. Most laboratories can arrange to share an instrument with a neighboring lab while their instrument is being calibrated, but

EHS-500, Radiation Safety Manual

there are some “loaner” meters are available.

37.5. How Long Does Calibration Take?

37.5.1. Instrument calibration can take up to 2 weeks but may take longer if additional repairs are needed.

37.6. How Does the Meter Loaner Program Work?

37.6.1. The meter loaner program is a service provided in the event your meter is due for calibration and you are actively working with radioactivity. A loaner will be provided by Radiation Safety until calibration or repair of your meter is completed and must be returned after service is completed.

37.7. How Do I Get My GM Survey Meter Repaired?

37.7.1. If your survey meter needs repairs contact, Radiation Safety for an assessment. Radiation Safety may be able to perform minor repairs. Repairs outside the scope of our services must be completed by the instrument manufacturer at your expense. Instruments returned to the manufacturer must be wipe tested prior to shipment.

37.8. QC Requirements for Gamma Counters/Well Counters/Liquid Scintillation Counters/Thyroid Probes

37.8.1. Quality control checks for gamma counters, well counters, liquid scintillation counters, and thyroid probes must be performed as recommended by the manufacturer. These checks must include a background and constancy check each day the instrument is used for clinical purposes.

37.8.2. Periodic tests to assure proper performance of the instrument, such as a chi-square test, must be performed quarterly, or as recommended by the manufacturer.

37.8.3. The efficiency of the well counter for the isotopes of interest and the window of detection must be checked annually for non-human use, daily for human use.

37.8.4. Procedures and forms for the tests mentioned here are available from Radiation Safety.

37.8.5. Records must be kept according to [Radiation Safety Office Record Keeping Guidelines](#).

37.9. What Dose Calibrator QC is Required?

37.9.1. An Authorized User authorized to administer radiopharmaceuticals shall possess and use a dose calibrator to measure the activity of unsealed radioactive material prior to administration to each patient or human research subject.

37.9.2. The dose calibrator must be tested in accordance with nationally recognized standards or the manufacturer's instructions which shall include the following:

37.9.3. Constancy check each day of use with sealed source(s) of not less than 50 microcuries of a photon-emitting source, such as Cs-137.

37.9.4. Linearity check upon installation, and quarterly thereafter, and following adjustment or repairs.

37.9.5. Accuracy check annually and following adjustment or repair.

EHS-500, Radiation Safety Manual

- 37.9.6. Geometry dependence upon installation and following adjustment or repair.
- 37.9.7. Records must be kept according to [Radiation Safety Office Record Keeping Guidelines](#).
- 37.10. How Do I Dispose of Old Instruments such as a Liquid Scintillation Counter?
- 37.10.1. If you need to dispose of a liquid scintillation counter, gamma counter, or Geiger counter, contact Radiation Safety in order to test the instrument for contamination, check for internal radioactive sources, and properly dispose of the instrument.
- 37.10.2. Liquid scintillation counters contain Cs-137, Ba-133, or Ra-226. The instrument manufacturer must remove the radioactive source from the instrument before disposal.
- 37.11. How Do I Order Instrument QC Sources?
- 37.11.1. Order your instrument QC check sources using the [Ordering Radioactive Material \(RAM\) Guidelines](#).
- 37.12. What Should I Do If My Survey or Counting Instruments Fail?
- 37.12.1. If your survey or counting instrument fails and you are unable to survey for contamination, contact Radiation Safety to find a temporary replacement while your instruments are repaired.
- 37.13. Other Radiation Equipment
- 37.13.1. Area monitors, hand & foot monitors, and stack monitors must be calibrated on an annual basis.
- 37.13.2. Breathing zone monitors may be necessary if working with volatile radioactive compounds within a fume hood. The monitors will be calibrated annually and available upon request. A baseline bioassay may be necessary depending on the radioisotope of interest.

EHS-500, Radiation Safety Manual

USE OF RADIOACTIVE MATERIAL IN HUMANS

The use of radioactive material in humans is specifically regulated in Chapter .05 of the Georgia regulations for radioactive material use (391-3-17). The following sections summarize these regulations and any applicable license conditions.

The user should also familiarize themselves with the responsibilities of the Authorized User (AU), the Authorized Medical Physicist (AMP), and the Nuclear Medicine technologist (NMT) in section 4 of this Manual.

38. WHO IS AUTHORIZED TO ADMINISTER RADIOACTIVE MATERIAL TO HUMANS?

38.1. Can Any Physician Read Nuclear Studies or Prescribe Radioactive Material for Human Use?

No. Physicians wishing to prescribe, direct the use of, prepare or supervise the preparation of radioactive material for use in patients or research must first be approved by the State of Georgia or Radiation Safety Committee 1 for the broad scope license and designated on the Clinical Authorization as an Authorized User for the specific use of radioactive material.

38.2. The specific uses of radioactive material are categorized as follows:

- 38.2.1. Uptake, Dilution or Excretion Studies;
- 38.2.2. Imaging and Localization Studies;
- 38.2.3. Unsealed Use of Radioactive Material Requiring a Written Directive;
- 38.2.4. Manual Brachytherapy;
- 38.2.5. Ophthalmic Use of Sr-90;
- 38.2.6. Sealed Sources in a Remote Afterloader Unit.

38.3. How Do I Become an Authorized User?

Physicians wishing to be listed as Authorized Users:

- 38.3.1. Must be a faculty member of Emory University;
- 38.3.2. Must submit the following documentation to Radiation Safety:
 - 38.3.2.1. Current State of Georgia Medical License,
 - 38.3.2.2. CV,
 - 38.3.2.3. Copy or photo of original Board Certification(s), if applicable,
 - 38.3.2.4. Completed, Signed Committee I Amendment Form, and, either:
 - 38.3.2.4.1. A copy of a Radioactive Materials License from another institution that shows the physician listed as an Authorized User for the specific use of radioactive material for which a written directive is required; or
 - 38.3.2.4.2. A preceptor form signed by an Authorized User who supervised his or her training and experience.
 - 38.3.2.4.2.1. For Nuclear Cardiologists, use preceptor form NRC313A (AUD);

EHS-500, Radiation Safety Manual

38.3.2.4.2.2. For Nuclear Medicine, use preceptor form NRC313A (AUT);

38.3.2.4.2.3. For Radiation Oncology, use preceptor form NRC313A (AUS).

38.3.3. Applicants must receive documented training in applicable Emory Radiation Safety policies and procedures.

38.3.4. Once the required documents are received, they will be submitted to the State of Georgia or Radiation Safety Committee 1 for the broad scope license for review and approval. Once approved, the physician and their department will receive written notification that they may function as an Authorized User.

38.4. Who Else Is Authorized to Administer Radioactive Material to Patients or Research Subjects?

38.4.1. Only individuals designated in writing by an Authorized User and trained by Radiation Safety are permitted to prepare or administer radioactive material to patients. These individuals must be listed on the Clinical Radioactive Material Authorization.

38.4.2. Please contact Radiation Safety to schedule Radiation Safety training, or if you need assistance with the qualification documentation requirements.

38.5. New Nuclear Medicine Technologists

A staff member that wishes to function as a Nuclear Medicine Technologist, prior to their first use of radioactive material, must submit the following to the Radiation Safety Office:

38.5.1. Completed, Signed RSC1 Amendment Form from an Authorized User on the authorization; and

38.5.2. Copy of their Certification in Nuclear Medicine Technology (or documentation of other qualification as stipulated in Georgia rule 391-3-17.05(25)); and

38.5.3. Obtain written designation by an Authorized User that the person may procure and inject radiopharmaceuticals in patients or research subjects; and

38.5.4. Receive documented training in applicable Emory Radiation Safety policies and procedures.

38.6. New Authorized Medical Physicists

An Authorized Medical Physicist must be approved by the RSC1 and designated on the Clinical Authorization prior to their first use of radioactive material:

38.6.1. Submit the following to Radiation Safety:

38.6.1.1. Completed, Signed RSC 1 Amendment Form; and

38.6.1.2. Copy of their Board Certification (or documentation of other qualification as stipulated in Georgia rule 391-3-17.05(23) or (26)); and

38.6.2. Receive documented training in applicable Emory Radiation Safety policies and procedures.

39. GENERAL REQUIREMENTS FOR CLINICAL USE OF RADIOACTIVE MATERIAL

Since potential occupational exposure from radioactive material used in clinical settings are generally much greater than laboratory settings, the following rules are established to

EHS-500, Radiation Safety Manual

minimize occupational exposure.

- 39.1.1. Use syringe shields for reconstitution of radiopharmaceutical kits and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly needle.)
- 39.1.2. Always use vial shields when preparing or handling a vial that contains a radiopharmaceutical.
- 39.1.3. Syringes that contain radioactive material must be kept in shielded containers that are clearly labeled.
- 39.1.4. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
- 39.1.5. Consider using a cart to move flood sources, waste, and other radioactive material, since sources with even small amounts of radioactivity exhibit a high dose rate on contact.
- 39.1.6. Authorized users must secure radioactive material, both in storage and in use, from unauthorized removal or access.
- 39.1.7. Departments must possess appropriate survey instruments. (See "[What Are the Requirements of GM Survey Meter and Survey Instruments?](#)")

39.2. What are the Rules for Using Gases, Aerosols and Volatiles?

Clinical departments that administer radioactive aerosols or gases shall:

- 39.2.1. Store such volatile radioactive materials and radioactive gases in the shippers' radiation shield and container.
- 39.2.2. Use and store multi-dose containers in a properly functioning fume hood.
- 39.2.3. Administer the gas/aerosol/volatile with a system that will keep airborne concentrations within regulatory limits. The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.
- 39.2.4. Check the operation of collection systems monthly. Records must be kept according to [Radiation Safety Office Record Keeping Guidelines](#).

39.3. Rules for Safe Dose Administration

The following rules are established to ensure that radioactive material is administered to a patient as directed by the Authorized User:

- 39.3.1. Radiation may only be administered to patients according to a written directive or by reference to the diagnostic clinical procedures manual.
- 39.3.2. Radiopharmaceutical multi-dose diagnostic and therapy vials must be labeled with the radionuclide, the activity, the date for which the activity is calibrated, and the radiopharmaceutical.
- 39.3.3. NOTE: Radiopharmaceuticals used under RDRC require additional labeling. See RDRC Labeling SOP.
- 39.3.4. Syringes and unit doses must be labeled with the radioactive drug.

EHS-500, Radiation Safety Manual

- 39.3.5. For prepared doses, patient doses must be assayed before administration either in the dose calibrator or per manufacturer's instructions.
- 39.3.6. Do not use a dose that varies by greater than $\pm 20\%$ from the prescribed dose, except for prescribed doses of less than 30 microcuries or as approved by the authorized user.
- 39.3.7. When measuring the dose, the amount of radioactivity that adheres to the syringe wall or remains in the needle need not be considered.
- 39.3.8. Confirm the patient's name and identification number and the prescribed radionuclide, chemical form, and dose before administering.
- 39.3.9. In the event that a dose calibrator is malfunctioning, the manufacturer's assay can be used by decay correction and volumetric assay.
- 39.3.10. If the prescribed dose requires a written directive, the patient's identity must be verified and the administration must be in accordance with the written directive.
- 39.4. Special Consideration for the Pregnant or Breastfeeding Patient
 - 39.4.1. If the patient is pregnant or breastfeeding, then special considerations must be given regarding the necessity of the procedure and the radiation risk to the fetus or the nursing child. Any administration that results in a dose of 500 mrem to a fetus or nursing child must be specifically approved in advance by the Authorized User. Also see Release of Patients Containing Radioactive Material.
 - 39.4.2. Additional safety precautions may be instituted by Authorized User or Radiation Safety, as needed.
 - 39.4.3. Follow the rules in "[Patient Care](#)" for release of patients carrying radioactive material.
- 39.5. What Information Must Dose Administration Records Contain?
 - 39.5.1. For all administration records:
 - 39.5.1.1. the patient's name or identification number,
 - 39.5.1.2. prescribed dose (or procedure name in which the dose can be referenced from the Clinical Procedures Manual),
 - 39.5.1.3. the determined dose (if > 30 uCi),
 - 39.5.1.4. the date and time of dose determination, and
 - 39.5.1.5. the name of the individual who determined the dose.
 - 39.5.2. If any administration error is discovered, determine the patient's name, administered dose, pharmaceutical, date, time, and route of administration and report to the Authorized User and the Radiation Safety Office, and create a SAFE report.

40. GUIDELINES FOR WRITTEN DIRECTIVES (PRESCRIPTIONS)

A "written directive" is a written order by an Authorized User for the administration of radioactive material to a specific patient or human research subject.

40.1. Which Administrations Require a Written Directive?

EHS-500, Radiation Safety Manual

40.1.1. A written directive must be prepared for:

- 40.1.1.1. Any administration of I-131 sodium iodide greater than 1.11 MBq (30 uCi),
- 40.1.1.2. Any therapeutic dose of a radiopharmaceutical,
- 40.1.1.3. All therapeutic doses of radiation from byproduct material (e.g., manual and high dose rate remote afterloading brachytherapies),
- 40.1.1.4. Administrations of radioactive material or radiation from radioactive material using radioactive material approved for routine use by the FDA that are beyond standard of care, and
- 40.1.1.5. Administrations of radioactive material or radiation from radioactive material that use radioactive material approved under an Investigational New Drug or expedited Investigational New Drug (IND, eIND) or by the RDRC.

40.2. What Information Must Be On the Written Directive?

40.2.1. Written directives must contain the patient or research-subject's name and the following:

- 40.2.1.1. For an administration of a dosage of radioactive drug containing radioactive material, the radioactive drug containing radioactive material, dosage, and route of administration;
- 40.2.1.2. For high dose rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions, applicator used and total dose;
- 40.2.1.3. For all other brachytherapy:
 - 40.2.1.3.1. Prior to implantation: treatment site, the radionuclide, and dose; and
 - 40.2.1.3.2. After implantation but prior to completion of the procedure: the radioisotope, treatment site, number of sources, and total source strength and exposure time (or, the total dose).
- 40.2.1.4. Signature of an Authorized User approved for the modality of the administration.

40.3. Written Directive Procedures

40.3.1. Departments must develop, implement, and maintain written procedures for administrations requiring written directives that address, as applicable:

- 40.3.1.1. Verifying the identity of the patient or human research subject;
- 40.3.1.2. Verifying that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;
- 40.3.1.3. Checking both manual and computer-generated dose calculations;
- 40.3.1.4. Verifying that any computer-generated dose calculations are correctly transferred into the HDR console;
- 40.3.1.5. Any dose calculations are checked and verified;
- 40.3.1.6. Prior to administering a dose, the patient's or human research subject's identity will be verified as the individual named in the Written Directive. Examples of patient identity verification include the patient's I.D. bracelet,

EHS-500, Radiation Safety Manual

hospital I.D. card, driver's license or social security card; and

- 40.3.1.7. Components of the Written Directive (radionuclide, radiopharmaceutical, dosage, route of administration) will be confirmed by the person administering the dose to verify agreement with the Written Directive.
- 40.3.2. A Call to Order is required for all administrations to females requiring a written directive. The Call to Order consists of the verification of the results of a pregnancy test and must be included in the prescription checklist. The Call to Order must be conducted by:
 - 40.3.2.1. A technologist and an attending physician, or
 - 40.3.2.2. A resident and an attending physician.
- 40.3.3. Record the radiopharmaceutical dose or radiation dose actually administered.
 - 40.3.3.1. An Authorized User must date and sign a written directive prior to the administration of any dose,
 - 40.3.3.2. A prescription is required for administrations of radioactive material or radiation from radioactive material that are beyond standard of care, using radioactive material approved for routine use by the FDA. Any Authorized User approved for that modality may sign the prescription.
 - 40.3.3.3. A prescription is required for administrations of radioactive material or radiation from radioactive material that are beyond standard of care, that use radioactive material approved under an IND, eIND or by the RDRC. The prescription shall be signed by an Authorized User approved for that modality, who is listed on the IRB protocol.
 - 40.3.3.3.1. The PI will identify the Authorized Users listed on the protocol for each approved protocol in category.
 - 40.3.3.3.2. The PI will report any changes to the list to Radiation Safety.
 - 40.3.3.3.3. Copies of Written Directives shall be maintained for audit purposes.

41. BRACHYTHERAPY RULES

In this section and Section 45, references to "GA. Rule .05.55" refer to Georgia Department of Natural Resources' Rules and Regulations for the Use of Radioactive Materials in the Healing Arts, Chapter 391-3-17-.05.

41.1. Technical Requirements

- 41.1.1. Only sources approved in the Sealed Source Device Registry or with an Investigational Device Exemption can be used.
- 41.1.2. Must follow the manufacturer's safety & handling instructions.
- 41.1.3. Must have an appropriate survey instrument. (See Section "[What are the Requirements of GM Survey Meter and Survey Instruments?](#)")

41.2. Determining Brachytherapy Source Activity:

- 41.2.1. Source output/activity must be determined before first use using an acceptable dosimetry system (manufacturer's measurements are acceptable).

EHS-500, Radiation Safety Manual

41.2.2. Positioning accuracy must be determined within applicators.

41.2.3. Source activity must be decay corrected activity at 1% decay intervals.

41.2.4. Retain records of these calibrations and decay calculations according to [Radiation Safety Office Record Keeping Guidelines](#).

41.3. Acceptance Testing

Acceptance testing of computer systems must be performed in accordance with published protocols. At a minimum, testing should meet requirements in Georgia Rule .05(61).

41.4. Brachytherapy Procedures

41.4.1. Must follow Written Directive Procedures above,

41.4.2. Must maintain brachytherapy source accountability at all times (see Inventory below)

41.4.3. Patients must be surveyed after implant and removal of sources.

41.4.4. Department must take emergency response equipment to procedure room to respond to a source that becomes inadvertently dislodged from the patient.

41.5. Specific Nursing Precautions:

See also "[Patient Care](#)" Section.

41.5.1. For Cs-137 tandem and ovoid and Ir-192 interstitial implants:

41.5.1.1. Patients are not allowed to leave the room until cleared by the physicist;

41.5.1.2. Nothing leaves the room until cleared by the physicist;

41.5.1.3. Dietary and housekeeping are not allowed into the room.

41.5.1.4. Lab is not allowed in the room without consulting Radiation Oncology or Radiation Safety.

41.5.2. For patients receiving eye-plaques:

41.5.2.1. No additional precautions beyond normal nursing care procedures.

41.6. Brachytherapy Inventory

41.6.1. The department shall maintain accountability at all times for all brachytherapy sources in storage or use.

41.6.2. An inventory record must be maintained that includes all items required by GA Rule.05 (103).

41.6.3. Use the EHS Assistant database to account for any sources that are to be sent to the Radiation Safety for decay-in-storage.

42. HIGH DOSE RATE (HDR) AFTERLOADER RULES**42.1. Installation, Maintenance, Adjustment, & Repair**

42.1.1. For any source installation or any repair of the high dose rate afterloader (HDR) unit, follow GA Rule .05(69).

EHS-500, Radiation Safety Manual

- 42.1.2. Reciprocity of license must be in effect when handling radioactive sources at Emory locations.
- 42.1.3. Following any new source installation or unit repair, surveys must be performed according to GA Rule .05 (80).
- 42.1.4. The facility must meet the requirements for interlocks and monitoring systems in GA Rule .05(71).
- 42.1.5. Acceptance testing of the treatment planning system must meet the requirements of GA Rule .05(82).

42.2.HDR Procedures

- 42.2.1. Only procedures which allow for expeditious removal of a decoupled or jammed source are permitted.
- 42.2.2. An Authorized User and an Authorized Medical Physicist must be physically present during all patient treatments involving the unit. During continuation of treatment, a physician, under the supervision of an Authorized User, who has been trained in the operation and emergency response for the unit, may replace the Authorized User.
- 42.2.3. No person is allowed to be present in the room with the patient during treatment, unless approved by the Authorized User, Radiation Safety, or Authorized Medical Physicist.
- 42.2.4. Emergency equipment must be available to respond to an unshielded source or a source lodged in the patient.
- 42.2.5. The department shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 mrem/hr to 50 mrem/hr, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem/hr to 1,000 mrem/hr.

42.3.Safety Procedures

- 42.3.1. After the completion of a procedure, before they are released, the patient and the HDR unit must be surveyed with a portable radiation detection instrument to make sure that the source has returned safely to the unit.
- 42.3.2. HDR must be secured in a dedicated locked closet and/or the vault room must be locked and secured.
- 42.3.3. Any person entering the HDR room following a procedure is required to use radiation monitors to verify that the radiation levels are safe.
- 42.3.4. Only one radiation producing device may be operated at a time in the room.
- 42.3.5. The department must have written procedures available for responding to abnormal situations (e.g., equipment failures, unable to return the source, etc.). See GA Rule .05(70) for required content and posting of these procedures. Notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies.

42.4.Required Training

EHS-500, Radiation Safety Manual

42.4.1. All persons authorized to operate the unit must receive training in emergency situations (see previous rule above) and operating procedures.

42.4.2. AMPs, Authorized Users, and operators must participate in emergency drills initially and annually.

42.4.3. Training records will be kept by Radiation Oncology according to [Radiation Safety Office Record Keeping Guidelines](#).

42.4.4. Complete initial and annual refresher Radiation Oncology Radiation Safety Training.

42.5. Full-Calibration Measurements Requirements

42.5.1. The department must use a dosimetry system that meets the requirements in GA Rule .05(72).

42.5.2. Full-calibration measurements must be performed by an Authorized Medical Physicist on the HDR before first use, following replacement of the source, or repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly.

42.5.3. Full calibration measurements must be done once a quarter and must meet the requirements listed in GA Rule .05(74).

42.6. Spot Checks

42.6.1. Spot checks must be performed at the beginning of each day that the unit is used. The results must be documented.

42.6.2. The Authorized Medical Physicist must establish written procedures for the spot-checks. These procedures must meet the requirements in GA Rule .05(77)(d).

42.6.3. The Authorized Medical Physicist must review the results of the spot-checks within 15 days. Results only need to be reported to Radiation Safety if any spot-check fails.

42.6.4. If the spot-checks indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

43. PATIENT CARE

43.1. Release of Patients Containing Radioactive Material

43.1.1. Patients receiving diagnostic quantities of radioactive material are considered to be authorized for release. For patients receiving therapeutic amounts of radioactive material, the following rules apply:

43.1.2. An Authorized User may authorize the release of any individual who has received radioactive drugs or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).

43.1.3. Release of the patient must be approved by an individual listed as an Authorized User on the departmental authorization for the type of radioactive material use of which the patient being released has received. For radioiodine therapies, the final

EHS-500, Radiation Safety Manual

determination is based on responses to a patient questionnaire completed by the patient concerning his living conditions and other persons in the home, and on the opinion of the physician that the patient is competent to carry out instructions.

- 43.1.4. The released individual, or the individual's parent or guardian, will be provided with instructions, including oral and written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable.
- 43.1.5. If a breast-feeding infant or child could receive a radiation dose as a result of the release of the patient, the instructions shall include guidance on interruption or discontinuation of breast feeding and information of the potential consequences, if any, of failure to follow the guidance.
- 43.1.6. The Authorized User shall maintain a record of the basis for authorizing the release of an individual and of the instruction provided to breast-feeding women [Radiation Safety Office Record Keeping Guidelines](#).

44. NURSING CARE OF PATIENTS CONTAINING THERAPEUTIC AMOUNTS OF RADIOACTIVE MATERIAL

44.1. Instructions for Nurses:

- 44.1.1. Personnel caring for patients who are not authorized for release according to Release of Patients Containing Radioactive Material must receive radiation safety instruction initially, and at least annually which includes patient control, visitor control, contamination control, and waste control.
- 44.1.2. Specific Guidelines for Nurses caring for patients containing radioactive material can be found in the document "Radioactive Materials: Care for Patient Containing" which is available in Lotus Notes in the Emory Hospitals Policies database.

44.2. Inpatient Radiation Controls

- 44.2.1. The patient should be placed, on a nursing unit that has received radiation safety training.
 - 44.2.1.1. At Emory University Hospital, 6G and 7G are used for inpatient therapy, Tower 4th floor is used for Y90 clinical trials.
 - 44.2.1.2. At Emory University Hospital Midtown, Unit 71 is used for all radiation inpatients.
 - 44.2.1.3. At Winship Emory Midtown, the 17th Floor is used to house radioactive inpatients.
 - 44.2.1.4. Check with the Radiation Safety Officer for any changes or for other facilities.
- 44.2.2. The patient must be placed in a private room with a private bath.
- 44.2.3. All superfluous equipment and supplies must be removed from the patient room. Remaining items and portions of the floor must be covered with plastic or some other waterproof material to prevent surface contamination and spread of contamination.

EHS-500, Radiation Safety Manual

- 44.2.4. The patient's or human research subject's room shall be posted with a "Caution: Radioactive Material" sign and a note shall be posted on door or in patient's chart stating how long and where a staff member or a visitor may stay in the room.
- 44.2.5. The Radiation Safety Officer, or his/her designee and the Authorized User shall be notified immediately if the hospitalized patient dies or has a medical emergency.

45. REPORTING PATIENT MEDICAL EVENTS

Misadministrations are specifically defined in GA Rule 391-3-17-.05 (115). These definitions involve dose thresholds for whole body or organs. Instead of independently determining whether a misadministration has occurred, a department should report any unusual incident to Radiation Safety. Radiation Safety can then assist in determining if the incident qualifies as a reportable misadministration and, if so, reporting the incident to the proper agencies.

NOTE: Extravasated diagnostic doses are not considered misadministrations.

45.1. Incidents to Report

The following incidents shall be reported to the Authorized User and Radiation Safety immediately upon discovery:

45.1.1. Any administration of radioactive material to a patient that involves:

- 45.1.1.1. The wrong patient;
- 45.1.1.2. The wrong radiopharmaceutical;
- 45.1.1.3. An administered dose that is 20% or more different than the prescribed dose; or
- 45.1.1.4. An unintended dose to a pregnant or nursing patient; or

45.1.2. For therapies:

- 45.1.2.1. The wrong route of administration; or
- 45.1.2.2. The wrong mode of treatment; or

45.1.3. For brachytherapies:

- 45.1.3.1. A dose to tissue other than the treatment site that exceeds 50% of the expected dose defined in the written directive (excluding prostate seed migration), or
- 45.1.3.2. A leaking sealed source.

45.1.4. All such incidents will be investigated by Radiation Safety to determine the cause and any actions that can be taken to prevent a recurrence.**45.1.5. If an incident is determined to be a misadministration, the Authorized User will assist Radiation Safety in writing a description of the incident and in gathering the information required for notifying the DNR or any other agency. The referring physician must be contacted within 24 hours. Appropriate medical care, including remedial care from the misadministration, must not be delayed due to notification delays. The patient (or guardian) must be informed of the availability of the written description of the incident and provided a copy if requested. Reporting, patient notification and investigations must be in accordance with GA Rule .05 (115).**

EHS-500, Radiation Safety Manual

AUTHORIZATION INSPECTIONS

Radiation Safety visits each active area of radioactive material use quarterly in order to maintain safety and compliance with rules, regulations and license conditions. It is important for all users to understand that the ability to use radioactive material is a privilege and also a responsibility. The goal of Radiation Safety inspection is to maintain that privilege. Thus, the inspector makes an effort to discuss findings with the lab worker to elevate their understanding of those responsibilities.

46. LABORATORY AUDITS

46.1. Inspection Procedure

- 46.1.1. In preparation for inspecting a laboratory, the research radiation safety liaison reviews the authorization for laboratory location; name of laboratory contact; names and training status of laboratory employees; possession limits; amount of each radionuclide on hand with transaction histories; and manufacturer, model, and calibration due date of any survey meters.
- 46.1.2. The inspector uses the Emory Lab Safety Inspection criteria to determine laboratory compliance with applicable standards. Answers to checklist items are gathered through observation, conversation and review of records that are checked for presence and timely completion. Inspectors can provide performance-based instruction to users and technical level staff while observing their work practices.
- 46.1.3. GM surveys and wipe tests (as appropriate) are conducted in each laboratory facility in which radioactive material is used. These results are documented consistently with the requirements for survey records (see below). In addition to the surveys performed by Radiation Safety, each laboratory must be surveyed by the occupants each week that radioactive material is used in the laboratory.

46.2. Keys to a Successful Inspection:

- 46.2.1. Area surveys – GM survey and wipe tests performed within required time & recorded correctly;
- 46.2.2. Database – updates made as soon as possible but no later than within 2 weeks of isotope use, accurate records, use, and disposal data;
- 46.2.3. Isotope use – logs available, accurately maintained, kept on file;
- 46.2.4. Notebooks - organized, current, complete;
- 46.2.5. Authorization – all users authorized and trained, labs are listed on RAM Authorization;
- 46.2.6. Dosimetry – worn correctly, stored properly, returned timely, and reports posted;
- 46.2.7. Equipment – GM survey meters calibrated annually, and operational;
- 46.2.8. Attire – lab coats, disposable gloves, goggles available, closed toe shoes;
- 46.2.9. Laboratory – local shielding, no food or drink consumed or stored;
- 46.2.10. Storage – secure;

EHS-500, Radiation Safety Manual

46.2.11. Waste – proper containers, not overfilled, labeled, shielded if needed;

46.2.12. Postings – door postings, emergency procedures & phone numbers;

46.2.13. Animals – labeled, solid cage bottoms, appropriately color coded.

46.3.Repeat Violations

If serious deficiencies which have a high potential for resulting in excessive radiation exposure leading to possible personal injury are found, the Radiation Permit Holder is notified immediately of the situation. Lack of corrective action on the part of the Radiation Permit Holder can result in suspension of operation requiring action by the Radiation Control Council for reinstatement. Serious or repeated deficiencies may require the RPH to come before RSC2 and/or the Radiation Control Council to address the matter.

46.4.Corrective Actions

Radiation Permit Holders are required to take corrective actions and instruct lab personnel that they are aware of the deficiency and the actions being taken to correct the deficiency.

47. CLINICAL AUDITS**47.1.Inspection Procedure**

In preparation for inspecting a clinical department, the inspector reviews the Authorization for laboratory location; name of laboratory contact; names and training of employees authorized to handle radioactive material; history of inspection categories from previous inspections; authorized use of radioactive material; sealed source inventory and leak-test dates; and QC due dates of any survey meters, counters or other instruments used to detect or measure radioactive material. Most inspections are scheduled unless the department is off-site or seldom staffed or have demanding schedules.

The inspector uses the Emory Radiation Safety Inspection criteria appropriate for the type of clinical use of radioactive material to determine laboratory compliance with applicable standards. Answers to checklist items are gathered through observation, conversation and review of records that are checked for presence and timely completion. Any items of concern found during the inspection will be discussed during the inspection with the technologist and/or Authorized User, if available. Inspectors can provide performance-based instruction to users and technical level staff while observing their work practices.

G-M surveys (when appropriate) and wipe tests are conducted in areas where radioactive material is used or stored. These results are documented consistent with the requirements for survey records below.

47.2.Reports

The report is sent to both the responsible Authorized User, to whom the Authorization belongs, and the Chief Nuclear Medicine Technologist or Medical Physicist.

47.3.Corrective Actions

EHS-500, Radiation Safety Manual

For items of serious concern, a written Notice of Violation will be issued. Examples of such items include but are not limited to; incidents which are in direct violation of regulations or license conditions or acts or omissions that have a high potential for resulting in excessive radiation exposure leading to possible personal injury. The department in violation is then required to submit to Radiation Safety corrective actions in writing to correct the deficiency. If the violation continues to be repeated in subsequent inspections, the Radiation Safety may call the appropriate personnel in the department to come before Radiation Safety Committee 1 and/or the Radiation Control Council to address the matter.

47.4. Surveys by Radiation Safety

47.4.1. Quarterly dose rate measurements and surface contamination checks will be performed by research radiation safety liaison in labs with radioactive material inventory. The survey by Radiation Safety does not relieve the authorized individual from the responsibility of conducting and documenting their own surveys.

47.4.1.1. If all results are negative, report will be filed without notification of the laboratory.

47.4.1.2. Positive results initiate a phone call to the laboratory radiation safety representative or Radiation Permit Holder. The situation must be resolved by documented cleaning and confirmatory wipes.

48. RADIATION SAFETY AUDIT RECORDS

Records of all audit material will be maintained for inspection by the State Radioactive Materials Program according to [Radiation Safety Office Record Keeping Guidelines](#). The records will include the date of audit, name of person conducting the audit, persons contacted by the auditor, areas audited, audit findings and corrective actions.

EHS-500, Radiation Safety Manual

MACHINE-PRODUCED RADIATION

The term “radiation-producing machines” includes diagnostic x-ray machines, analytic x-ray machines, x-ray diffraction devices, DEXA machines, cabinet x-ray machines, cyclotrons, linear accelerators and electron microscopes. All radiation-producing machines operated at Emory University and associated institutions are operated under the jurisdiction of the State of Georgia, Department of Community Health. All uses of machine-generated radiation are to be carried out in accordance with the State of Georgia Rules and Regulations for X-Ray, Chapter 111-8-90.

49. REQUIREMENTS FOR POSSESSION OF RADIATION-PRODUCING EQUIPMENT

49.1. Registration

- 49.1.1. All machines and devices designed to produce x-rays or which produce x-rays incidental to their operation shall be registered with the State of Georgia Department of Community Health.
- 49.1.2. Notify Radiation Safety of the make, model, serial number, and location of any new radiation producing device.
- 49.1.3. Radiation Safety shall be notified when there is any change in the setup of the unit. Such changes include new equipment installed; changes in shielding of the surrounding walls; repair resulting in change in output of radiation; or change in usage of the unit.

49.2. Posting

- 49.2.1. Areas in which radiation-producing machines are located or are being used shall be posted with the characteristic "Caution Radiation" sign.
- 49.2.2. EXCEPTION: Diagnostic and patient treatment areas need not be so marked, provided that a person is charged with the responsibility for protection of employees, patients, and authorized visitors against unnecessary radiation and for the execution of Radiation Safety recommendations.
- 49.2.3. In addition, the controls shall bear a decal with the statement: "WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

49.3. Surveys

- 49.3.1. All protective devices that may become defective due to use or abuse, such as protective lead aprons, skirts, vests, thyroid collars, and gloves, should be inspected for radiation leakage at least annually, and whenever the integrity of the equipment is suspect.
- 49.3.2. An annual, scheduled survey of all radiation-producing equipment used on patients shall be made by Radiation Safety personnel or a qualified expert. In addition, radiation surveys will be made of all new installations and all existing installations after every change that might affect the radiation output (e.g., replacement of x-ray tube, changes of filtration in beam, etc.).
- 49.3.3. Entrance exposure rates for the beam shall be determined for all units used on human subjects and must be made available to the operator by posting this information on the equipment or in the control room.

EHS-500, Radiation Safety Manual

- 49.3.4. The faculty owners of radiation producing devices will ensure that each device under their control is surveyed annually by Radiation Safety personnel or a qualified expert to ensure that its performance is within legal requirements and that it is functioning correctly and safely.

49.4. Shielding for X-Ray Machines

- 49.4.1. Except for bone density devices, all X-Ray machines designated to be used within a specific location must have the walls of that location shielded to contain the radiation and reduce the exposure of those outside of the X-Ray room to within legally designated levels.
- 49.4.2. The structural shielding requirements of any new installation, or an existing one in which changes are contemplated, shall be approved by the Radiation Safety Office or a qualified expert and the Georgia Department of Community Health.
- 49.4.3. A radiation shielding integrity survey will be performed on all new or modified x-ray rooms by Radiation Safety personnel or a qualified expert.

50. POLICIES FOR STAFF**50.1. General Policies for Safe Use of X-Ray Equipment**

- 50.1.1. Workers who are likely to be exposed in one year to 10% of the occupational dose limits (see [Table 1](#)) must request and wear appropriate exposure monitoring devices.
- 50.1.2. Operators who are issued dual dosimeters must wear the body dosimeter beneath the lead apron at the waist or chest level and wear the collar dosimeter outside the lead apron.
- 50.1.3. Operators who are issued a single dosimeter must wear the dosimeter outside their lead apron, at the collar level.
- 50.1.4. The operator must keep exposures as low as reasonably achievable (ALARA) and must use minimum exposure factors necessary of the exam being performed. Fluoroscopic work shall be performed in the minimum time possible using the lowest dose rate and the lowest magnification consistent with clinical requirements.
- 50.1.5. The operator must never expose himself to the direct beam and must not stand within the exposure area (per the posted Scatter Radiation Diagram) of the tube or irradiation target while the unit is in operation unless adequately shielded. The operator must make full use of protective barriers, lead aprons, gloves, and goggles when practical.
- 50.1.6. The hand of the fluoroscopist should never be placed in the useful beam unless the beam is attenuated by the patient and a protective lead glove is worn.
- 50.1.7. During the operation of mobile and dental units, the operator should stand as far as possible from the tube and patient during exposure, and should wear a protective apron, or step behind an adequate shield. Rotation of operators or the use of portable shields is recommended for heavy workloads.

EHS-500, Radiation Safety Manual

- 50.1.8. Shutter mechanisms and interlocking devices should not be tampered with and must be inspected at frequent intervals to ensure proper operation.
- 50.1.9. The operator should insist that all nonessential personnel leave the exposure area before operating the unit and that all essential personnel be adequately shielded.
- 50.1.10. The operator must observe any restrictions in the use of the unit recommended by Radiation Safety staff.
- 50.1.11. The operator must notify their supervisor and the Radiation Safety Officer immediately of any accidental exposure to radiation to staff.
- 50.1.12. Use mechanical means to hold patients, animals, or image receptors when necessary. Only when mechanical means are unusable should an employee hold the patient, animal, or image receptor. No person shall be regularly employed to hold patients, animals, or image receptors during exposure. The person holding the patient, animal or image receptor shall wear protective gloves and a protective apron. No part of this person's body should be in the unattenuated useful beam.

50.2. Who Can Operate X-Ray Equipment?

- 50.2.1. Only physicians and other licensed practitioners of the Healing Arts (as defined in the Rules and Regulations of the State of Georgia 111-8-90-.01(ff) and registered radiologic technologists under the direction of a physician, or persons with training as described below under the direction of a physician, shall be allowed to apply x-rays from a machine to patients. Training courses and instructions for accessing them are listed on the training page of the EHSO website.
- 50.2.2. Physicians will receive a radiation safety training for X-Ray Operators at the time of requesting privileges, details described on the training page of the EHSO website and in section 51.2.4, unless a formal course in radiation physics and safety occurred during training (residency, fellowship or as a faculty member).
- 50.2.3. Radiologic technologists must be graduates of an accredited program in radiologic technology and must be a member in good standing of the American Registry of Radiologic Technologists or be Registry eligible.
 - 50.2.3.1. Radiologic technologists must comply with the Continuing Education Requirements for Renewal of Registration.
 - 50.2.3.2. Radiologic technologists will receive training provided by EHSO.

50.2.4. Fluoroscopy Use

- 50.2.4.1. Physicians will receive training in fluoroscopic safety provided by the Credentialing Modules at initial credentialing and recredentialing, orientation unless a formal course in radiation physics and safety occurred during training (residency, fellowship, or as a faculty member) (see <http://www.emoryhealthcare.org/for-physicians/index.html>). Physicians who regularly operate a fluoroscope at the time this policy is implemented receive the above course upon recredentialing and all subsequent recredentialing.

EHS-500, Radiation Safety Manual

- 50.2.4.2. Residents who are identified as fluoroscopy users will receive training in fluoroscopic safety provided by EHSO and should be directly supervised (i.e., available in adjacent area) by a physician credentialed to perform fluoroscopy.
- 50.2.4.3. Fellows who are identified as fluoroscopy users will receive training in fluoroscopic safety provided by EHSO.
- 50.2.4.4. Advanced Practice Professionals who perform fluoroscopy must be directly supervised by a physician credentialed to perform fluoroscopy and will receive training in fluoroscopic safety provided by EHSO.
- 50.2.4.5. The Radiation Control Council may recommend additional training if there are concerns about patient or employee radiation safety. Reasons for additional training could include, but are not limited to: (a) adoption of new fluoroscopic technology (b) high personal dosimetry badge readings that approach or exceed regulatory limits (c) observation of poor radiation protection practices or (d) resumption of fluoroscopic procedures after a long period of inactivity.
- 50.2.4.6. Other operators have courses available on the training page of the EHSO website specific to the hazards and regulations of their job function.
 - 50.2.4.6.1. DEXA operators must work at the direction of a physician and receive training specific to their job function.
 - 50.2.4.6.2. Dentists will receive training specific to their job function.
 - 50.2.4.6.3. Operators of dental units must work at the direction of a dentist and receive training specific to their job function.
 - 50.2.4.6.4. Veterinarians will receive training specific to their job function.
 - 50.2.4.6.5. Operators of veterinary units must work at the direction of a veterinarian and receive training specific to their job function.
 - 50.2.4.6.6. Researchers using x-rays for non-human use in-vivo or in vitro will receive training specific to their job function.

50.3. Can I Be In The Room During An X-Ray Procedure?

Only personnel essential to the procedure should be in the exposure area during operation of the unit. All essential personnel should be adequately shielded during fluoroscopic procedures.

50.4. Do I Have To Wear A Lead Apron?

During radiographic procedures, if you are not able to stand behind an operator's barrier, then you must wear a protective lead apron within the exposure area.

During fluoroscopic procedures, protective aprons shall be worn by the physician, nurse, technician, and all other persons within the exposure area.

51. PATIENT SAFETY GUIDELINES**51.1. Protocol Review**

EHS-500, Radiation Safety Manual

- 51.1.1. Appropriate radiation delivered for the medical information acquired requires a commitment from practitioners, administration, and medical directors.
- 51.1.2. All protocols should be reviewed for their potential to cause an injury to a patient. Protocols should be modified by the providers to optimize cumulative absorbed dose to any skin area.

51.2. Fluoroscopy Records

- 51.2.1. All fluoroscopy procedures shall have the cumulative air kerma or kerma area product documented in a retrievable format. If unavailable, the fluoroscopy time and number of images acquired are documented in a retrievable format.
- 51.2.2. For procedures in which anticipated fluoroscopy is in excess of 5000 mGy cumulative air kerma (or if cumulative air kerma is not available, 100 minutes of fluoroscopy time), the following actions should occur:
 - 51.2.2.1. Provide patients with the “Skin Injury Risk Information Sheet” (Appendix E of [Environmental Health and Safety \(EHSO\) Policy on Maintaining Quality and Safety in X-ray Imaging of Patients and Human Subjects](#)) advising the patient of skin injury risk from prolonged fluoroscopy.
 - 51.2.2.2. Identify areas of the patient’s skin that received the dose and note any specific dose information that is displayed by the machine (such as cumulative air kerma, dose area product, and total fluoroscopy time) in the patient’s chart.
 - 51.2.2.3. Submit the completed “Skin Injury Dose Risk Estimate” Form to Radiation Safety (Appendix F of [Environmental Health and Safety \(EHSO\) Policy on Maintaining Quality and Safety in X-ray Imaging of Patients and Human Subjects](#)). If Radiation Safety’s estimate of the peak skin dose exceeds 5000 mGy, Radiation Safety will notify physician of next steps, such as:
 - 51.2.2.3.1. Attending, consulting dermatologist or consulting radiation oncologist should see the patient initially at 2 weeks and followed (by either the dermatologist or interventional proceduralist) for several months. At this time, the skin should be evaluated, and its appearance documented in the patient’s record.
 - 51.2.2.3.2. Any fluoroscopy resulting in permanent tissue injury when clinical and technical optimization were not implemented and/or recognized practice parameters were not followed is considered a sentinel event and Radiation Safety will alert Risk Management.

52. USING X-RAYS IN RESEARCH

In order to obtain authorization to use x-rays on humans for research purposes (through the Institutional Review Board), see [Guideline for Radiation Safety Committee Review of Human Research Studies](#).

53. NON-HUMAN USE OF X-RAYS



EHS-500, Radiation Safety Manual

Any research use of machine-produced radiation on animals or samples requires an application to the Radiation Safety Committee 2 under the broad scope license. (See [Committee II Application for Machine-Produced Radiation Use](#)). General Guidelines for Safe Use of Non-Medical X-ray are available on the EHSO web page at http://www.ehso.emory.edu/content-guidelines/Non_Medical_Xray_Units.pdf.

EHS-500, Radiation Safety Manual

APPENDIX A – INSPECTION ITEMS AND RECOMMENDATIONS

| Category | Item | Recommendation |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Administrative Controls | 4.4 Personnel working with radioactive materials are identified on PI's authorization permit. | Radioactive materials must only be handled by authorized and trained personnel. |
| Administrative Controls | 4.6 The EHS Assistant database reflects current inventory of radioactive materials stock vials, including record of volumes withdrawn from each stock vial. | Any quantity of radioactivity used must be recorded in EHS Assistant. When a vial is empty, select 'totally disposed' to remove it from inventory. |
| Administrative Controls | 4.7 The EHS Assistant database reflects current inventory of radioactive waste containers, including record of activity discarded into each waste container. | Any quantity of radioactivity disposed of must be recorded in EHS Assistant. When waste container is full, seal the container and request a waste pick-up. |
| Administrative Controls | 4.9 Area Geiger meter surveys and wipe tests are performed during the work weeks that radioactive materials are used. | When radioactive materials are in use, Geiger meter surveys and wipe tests must be performed at least weekly in areas where radioactive material is used or stored. |
| Administrative Controls | 4.10 Documentation of Geiger meter surveys includes the Geiger meter's model, serial number and calibration due date, date of the survey, and the initials of the person who performed the survey. The results are recorded in units of mR/hr and include a background reading. | Complete documentation on the appropriate forms when the Geiger meter survey is performed. Documentation demonstrates that the survey has occurred within the required timeframe. |
| Administrative Controls | 4.11 Documentation of wipe tests include a list or map of areas surveyed, model and manufacturer of counter used, date of test, and the initials of the individual who performed the test. The results are either recorded in units of dpm or in cpm with counter efficiency and include a background reading. | Complete documentation on the appropriate forms when the wipe test is performed. Documentation demonstrates that the survey has occurred within the required timeframe. |
| Administrative Controls | 4.12 If removable contamination is found, lab attempts decontamination of contaminated | Area is considered decontaminated when liquid scintillation counter results are less than 200 dpm /100 |

EHS-500, Radiation Safety Manual

| | | |
|--------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | areas. Lab repeats the contamination survey and documents the clean-up effort. | cm2 and Geiger counter readings are less than 2 mR/hr. If lab is unable to decontaminate area, contact your research radiation safety liaison for assistance. |
| General Radiation Safety | 4.16 Use and storage of radioactive materials takes place in the authorized area. | Radioactive materials must be used and stored in authorized locations. Submit an amendment to add new locations. |
| Waste | 4.24 Radioactive waste is segregated by isotope and waste type (Dry, Liquid, or Liquid Scintillation Vial). | Identify isotopes present in laboratory and ensure that each isotope has at least one waste container for dry, liquid, and liquid scintillation vial waste. If lab does not use liquid scintillation vials except for wipe tests, lab may label liquid scintillation vial waste container as swipes only and does not have to distinguish between isotopes. |
| Waste | 4.26 All radioactive trefoils on vials or other containers are defaced prior to disposal into the radioactive waste container. | Check all waste for trefoils prior to disposing in radiation waste containers. |
| Waste | 4.28 Radioactive waste is not disposed of via sewer without authorization and documentation. Sewer disposal is not in excess of authorized limits. | Collect liquid radioactive waste in liquid radioactive waste containers unless specifically authorized to dispose of liquid radioactive waste via drain. |

EHS-500, Radiation Safety Manual

APPENDIX B – VERSION HISTORY**Change History**

| | |
|------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version 11 | Area surveys and wipe test |
| Version 10 | Faculty status for human use research authorizations; wipe test and removable contamination survey requirements. |
| Version 9 | Faculty status for human use authorizations; dosimetry issuance; NMT designation. |
| Version 8 | Removal of RSC Committee 3; Merged Restricted and Unrestricted tables; Added Authorized Diagnostic Medical Physicist; Added Version History, Added Appendix B; Removed White Protocol. |
| Version 7 | Unknown |
| Version 6 | Unknown. |
| Version 5 | Unknown. |
| Version 4 | Unknown. |
| Version 3 | Unknown. |
| Version 2 | Unknown. |
| Version 1 | Document creation. |