RADIATION SAFETY MANUAL
FOR USE OF RADIOACTIVE MATERIALS

Washington University in St. Louis and
Washington University Medical Center
St. Louis, Missouri

Locations of use include:
Barnes–Jewish Hospital
Heart & Vascular Center in South County
Heart & Vascular Center in West County
St. Louis Children's Hospital
Washington University in St. Louis – Danforth Campus
Washington University School of Medicine
Washington University in St. Louis – Tyson Research Facility

January 2017 Update
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INTRODUCTION

This web-based manual is designed to provide Authorized Users, Radiation Workers and other staff of Washington University in St. Louis and the affiliated institutions of the Washington University Medical Center (WU/WUMC) a convenient reference to the compliance requirements of the WU/WUMC Radiation Safety Program related to their use of radioactive materials.

ESTABLISHMENT OF WEB-BASED RADIATION SAFETY MANUAL

Previous to the February 2006 version of the WU/WUMC Radiation Safety Manual, the Radiation Safety Committee required that a paper-based version of the manual was the official copy and was to be provided to each Authorized User. As a result, updates to these paper-based manuals were difficult to accomplish in a timely manner, especially because historically different versions existed for research use or clinical use.

The Radiation Safety Committee approved establishing the web-based version of the WU/WUMC Radiation Safety Manual as the official version to:

- establish one official version of the manual;
- increase ease of use of the manual through the development of links to other parts of the manual, forms, regulations, and other references;
- increase access to official manual;
- improve the review and updating process for revisions; and
- provide better integration as the WU/WUMC Radiation Safety Program increases electronic data tracking and compliance reporting.

GENERAL RESPONSIBILITIES OF AUTHORIZED USERS

An Authorized User (AU) must be approved by the Radiation Safety Committee in order to use or supervise the use of radioactive materials under the Washington University in St. Louis Nuclear Regulatory Commission License. The AU’s primary responsibility is to ensure that radioactive materials used under their authorization are used safely and according to requirements of the WU/WUMC Radiation Safety Program and their authorization requirements. An AU is considered to be supervising the use of radioactive materials when directing personnel (Radiation Workers) in operations involving their authorized radioactive materials. Although the AU may delegate specific tasks to the AU’s Radiation Workers (e.g., conducting surveys, keeping records), the AU remains responsible for the safe use of radioactive material and compliance with the WU/WUMC Radiation Safety Program and their authorization requirements. The AU is also responsible to ensure that procedures and engineering controls are used by the AU’s Radiation Workers to keep occupational doses and doses to members of the public As Low As Reasonably Achievable (ALARA).
AUTHORIZED USER USE OF WEB-BASED RADIATION SAFETY MANUAL

In establishing authorization-specific radiation safety procedures, AUs should ensure access to, and encourage their Radiation Workers and other support staff to access, this web-based manual and the AUs’ current authorization amendment letter. AUs and their Radiation Workers may want to print out, or download for local access, certain parts of this web-based manual (e.g., opening radioactive packages, doing radiation surveys, managing radwaste, etc.) to ensure they have access if computer or web access are not readily available. However, the AU and Radiation Workers must ensure they are using the up-to-date version of any part of the web-based manual that they have downloaded or printed for reference.

UPDATES TO THE WEB-BASED RADIATION SAFETY MANUAL

In order to notify AUs, Radiation Workers and other staff of updates and changes to the WU/WUMC Radiation Safety Manual, the Radiation Safety Staff will:

- provide a version date on each section of the web-based manual;
- post a summary of recent changes made to the web-based manual;
- maintain an appendix to the web-based manual listing the history of changes; and
- notify each AU and his/her designated Lab Contact via e-mail of web-based manual changes that have immediate impact on the AU’s compliance responsibilities.

Some proposed changes to the web-based manual may be posted on the Radiation Safety website and AUs may be invited to comment prior to final approval.
1. ORGANIZATIONAL STRUCTURE AND AUTHORITY

1.1 RADIATION SAFETY PROGRAM ORGANIZATION

The organization of the Radiation Safety Program for NRC License No. 24-0167-11 is shown in Figure 1-1, Radiation Safety Organization. Use of all radioactive materials at Washington University and Washington University Medical Center (WU/WUMC) is governed by Executive Management, the Radiation Safety Officer and two safety committees:

1. The **Radiation Safety Committee** (RSC) has authority over all uses of radioactive materials at WU/WUMC except for the review of human research involving radioactive drugs. The current membership is given in the RSC Membership table.

2. The **Radioactive Drug Research Committee** (RDRC) has authority over human research involving radioactive drugs. Current RDRC membership and contact information is given in the RDRC Membership table.

In addition, the Radiation Safety Committee (RSC) has two active subcommittees that address specific issues.

1. The **RSC Authorizations Subcommittee** is scheduled to meet each week to review applications submitted by research faculty. The current membership is given in the Authorizations Subcommittee Membership table.

2. The **RSC Positron-Emitting Radionuclides and Cyclotron Safety Subcommittee** (PERCS Subcommittee) meets several times a year to review safety issues associated with the use of particle accelerators used for the on-site production of radioactive materials, and the use of positron-emitting radionuclides. The current membership is given in the PERCS Subcommittee Membership table.

1.2 RADIATION SAFETY OFFICER

The Radiation Safety Officer (RSO) is Maxwell Amurao, PhD, MBA, FAAPM

Phone: 314–362–2988
Email: maxwell.amurao@wustl.edu

The RSO is appointed by the Chancellor of the University and serves as Executive Secretary of the Radiation Safety Committee (RSC) and as a member of the Radioactive Drug Research Committee (RDRC). The RSO serves as director of the Radiation Safety Office, a division of the WU Environmental Health and Safety Department (EH&S). The RSO directs the radiation safety activities necessary to implement and enforce the safety program established by the RSC. The RSO is provided the administrative authority by the Chancellor to enforce procedures pertaining to the radiation safety program including the authority to temporarily suspend activities involving ionizing radiation deemed to be unsafe subject to review by the appropriate radiation committee.
Figure 1-1. Radiation Safety Organization
Washington University in St. Louis
Radiation Safety Organization
Effective May 2018

Radiation Safety Committee members are appointed by and the RSC reports to the Executive Vice Chancellor for Medical Affairs. The RSC oversees NRC licensed activities at Washington University in St. Louis Facilities and the Washington University Medical Center Facilities (includes Washington University Medical School, Barnes-Jewish Hospital, St. Louis Children’s Hospital, Howard Hughes Medical Institute, and St. Louis College of Pharmacy).

Radioactive Drug Research Committee members are appointed by and the RDRC reports to the Executive Vice Chancellor for Medical Affairs. The RDRC oversees the human research use of radioactive drugs specifically subject to the requirements of 21 CFR 361.1. It also oversees all other research protocols involving the administration of radioactive drugs to human subjects at Washington University and functions for this purpose as a subcommittee for both the RSC and the Human Research Protection Office.
2. INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM

2.1 EXECUTIVE MANAGEMENT

Executive responsibility and authority for administration of Washington University in St.
Louis is assigned to the Chancellor. The Chancellor has delegated responsibility and
authority to oversee the implementation and management of the Washington University
radioactive materials license to the Executive Vice Chancellor for Medical Affairs. This
individual appoints the Radiation Safety Committee (RSC) chairman, vice chairman, members
and any alternates for the members. The RSC membership meets the requirements of 10 CFR
35.24(f). The Executive Vice Chancellor for Medical Affairs also proposes to the Chancellor an
individual who meets the qualifications for the position of Radiation Safety Officer (RSO). The
Chancellor appoints the RSO. The management structure for the radiation safety program is
shown in Figure 1-1, Radiation Safety Organization.

2.2 RADIATION SAFETY COMMITTEE (RSC)

Duties and Responsibilities

1. Authorized by the Executive Management to oversee all uses of NRC-licensed and State
   of Missouri-registered radioactive materials and radiation-producing machines at
   Washington University and Washington University Medical Center (WU/WUMC).

2. Responsible for overseeing the receipt and handling of radioactive materials used in
   human research involving radioactive drugs. [NOTE: The Washington University
   Radioactive Drug Research Committee (RDRC) is responsible for overseeing all research
   protocols involving the administration of radioactive drugs to human subjects, and
   functions for this purpose as a subcommittee for both the RSC and the Washington
   University Human Studies Committee, which is our Institutional Review Board (IRB).
   For those research studies subject to the requirements of 21 CFR 361.1, the RDRC
   functions in accordance with the applicable Food and Drug Administration (FDA)
   regulations.]

3. Inform the Executive Vice Chancellor for Medical Affairs, and other WU/WUMC
   administrators as applicable, of the radiation safety program operations, changes,
   incidents and all situations that have or may result in regulatory intervention.

4. Establish the WU/WUMC policy on radiation protection matters that will ensure that
   radiation and radioactive materials are safely used. This includes review of training
   programs, equipment, facilities, supplies, procedures and the performance of individuals
   with radiation safety program responsibilities.

5. Be familiar with all pertinent regulations, license and registration conditions and
   commitments to regulatory agencies and ensure that radiation and radioactive materials
   are used in compliance with WU/WUMC obligations.
6. Ensure that radiation and radioactive materials are used consistent with the ALARA philosophy and program.

7. Review and approve or deny, on the basis of safety and the prior training and/or experience of the applicant, all requests to use radioactive materials within WU/WUMC.

8. Ensure that licenses or registrations are amended prior to implementing changes that require amendments.

9. Meet as often as necessary to conduct RSC business. Meeting quorum shall be half the membership, including a management representative and the RSO or their alternates.

10. Implement a mail ballot procedure, which includes electronic mail, when it is necessary to act on matters between Committee meetings. Decisions made via mail ballot shall be discussed and ratified during the next regular meeting. These mail ballot decisions do not constitute a meeting.

11. Maintain written minutes of all Committee meetings, including members in attendance and members absent, discussions, actions, recommendations, decisions and results of votes.

12. Empower subcommittee(s) and establish delegation of authority procedures to review and approve user authorizations in the name of the RSC.

13. Empower the RSO and establish delegation of authority procedures to review and issue interim authorizations, and to review and approve certain changes to authorizations in the name of the RSC. All interim authorizations issued by the RSO will be reviewed and approved at the next Committee/subcommittee meeting.

14. Appoint Temporary Radiation Safety Officer(s) and empower the individual(s) to function as the RSO over all or any portion of the radiation safety program as the individual is qualified and as the RSC deems is appropriate.

2.3 RADIATION SAFETY OFFICER AND STAFF

Responsibilities and Duties

1. Implement the radiation safety program, including policies and procedures of the RSC.

2. Review all applications for uses of radiation or radioactive material to ensure compliance with appropriate regulations and license or registration conditions.

3. Issue authorizations for the use of radioactive materials in the name of the RSC.

4. Restrict or suspend use and/or possession of radiation or radioactive materials whenever a significant deviation from established guidelines and procedures has occurred or there is threat to health or property.
5. Be the primary WU/WUMC liaison to the NRC and State of Missouri with regard to the radiation safety program and license or registrations.

6. Report incidents, as required, to the applicable regulatory agency and provide descriptions of these incidents to the RSC and to the Executive Management.

7. Regularly inspect the facilities of each Authorized User by the methods and frequency developed in collaboration with the RSC.

8. Supervise all ordering, receipt, survey, monitoring and delivery of all shipments of radioactive material arriving at WU/WUMC.

9. Personnel training is conducted as is commensurate with the individual’s duties regarding radioactive materials as required by 10 CFR 19.

10. Supervise and coordinate the radioactive waste storage and disposal program.

11. Maintain inventory of all licensed or registered materials or machines.

12. Supervise decontamination and recovery operations.

13. Perform or ensure performance of required leak tests on all sealed sources and calibration of radiation survey instruments.

14. Manage personnel dosimetry and ALARA programs.

15. Develop, distribute and implement up-to-date radiation protection procedures in the daily operation of the radiation safety program.

16. Ensure that individuals installing, relocating, maintaining, adjusting or repairing devices containing sealed sources are trained and authorized by NRC or Agreement State license.

17. Ensure radioactive material is properly secured.

18. Maintain documentation to demonstrate by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the applicable limit for members of the public.

19. Audit at least annually the radiation safety program, document findings and review with the RSC.

20. Ensure that effective corrective actions are developed, implemented, and documented if violations of regulations, or license or registration conditions, or program procedures are identified.

21. Ensure that radioactive material is transported, or offered for transport, in accordance with applicable DOT requirements.
22. Ensure the license and registrations remain up-to-date and submit to the NRC or State of Missouri, in a timely manner, all amendment and renewal applications.

23. Maintain appropriate license and registration records including minutes of all RSC meetings.
3. REQUIREMENTS FOR THE SAFE USE OF RADIOACTIVE MATERIALS

Most of the radioactive materials used at this institution are authorized by licenses issued by a federal agency, the US Nuclear Regulatory Commission (NRC). All licensees of the NRC are required to practice the standards for radiation protection established by the Commission. The NRC has many regulations that affect the research use of licensed materials, primarily those listed in Parts 19, 20, 30 and 33 of Title 10 of the Code of Federal Regulations. In addition, the NRC issues guidance for the safe use of radioactive materials in Regulatory guides that apply to our research use of radioactive materials. Finally, we make written commitments to the NRC about certain practices and procedures that will be used.

At our institution, most of the efforts required to fulfill the regulations and license conditions affecting the use of radioactive materials are performed by a support group funded by the School of Medicine, the Radiation Safety Office. However, the sheer size of our institution (the collective grouping of the Medical Center members and the University Danforth Campus involves more than 1300 personnel working in more than 650 approved areas under the responsibility delegated to approximately 300 faculty approved to use radioactive materials) precludes the Radiation Safety group from performing certain tasks required by the NRC. You should be aware of these requirements that are expected of research and laboratory medicine groups. They include the following:

3.1 RADIATION SAFETY EXAMINATION

All personnel, prior to working with radioactive materials, must pass the appropriate written examination(s) given by Radiation Safety. Refer to Chapter 4 for more information on the specific types of examinations provided.

3.2 RAM PACKAGE INSPECTION/SURVEY

A final inspection and a radiation survey are required for each package of radioactive materials. The required actions, documented in the lower portion of the Receipt Record form that accompanies each package, include (a) verification that the material (according to the label and packing slip) is what was ordered and (b) survey and proper disposal of the packaging materials. See Chapter 8 for detailed information.

3.3 ACCOUNTABILITY LOG

A record of the use and disposal of the activity must be kept for each lot or container of material. See Chapter 8 for detailed information.

3.4 ANNUAL RADIATION SAFETY TRAINING

Continuing training is annually provided by two separate mechanisms. Each research group must annually hold a training session to discuss how personnel exposures to radiation can be
maintained as low as reasonably achievable (ALARA) for the specific radioactivity work done by the group. In addition, Radiation Safety provides refresher training information that addresses certain generic safety issues. Authorized Users are asked to complete the lab-specific ALARA annual training component as a part of the online refresher training provided annually by Radiation Safety, and confirmation of completion of the lab-specific portion is affirmed by every radiation worker who completes the annual refresher training. Chapter 4 provides more information.

### 3.5 PERSONAL PRACTICES

Laboratory coats and disposable gloves must be worn at all times while handling unsealed radioactive materials. Gloves should be removed and disposed of before leaving the laboratory. Hands must be monitored with an appropriate survey instrument either after completing procedures involving radioactive materials or before leaving the area, e.g., at lunch and at the end of the workday. Lab coats must also be monitored before being worn outside the laboratory if they have been used for protection during radioactive material procedures. Face and/or eye protection should be worn if warranted by the type of procedure being performed.

### 3.6 PERSONNEL DOSIMETRY

Dosimeters for monitoring whole body radiation dose are provided to individuals conservatively evaluated by Radiation Safety as likely to incur more than 100 mrem of "deep" dose per year due to external radiation sources (The 100 mrem per year criterion is 20% of the level at which the USNRC requires dosimetry). Individuals who are expected to handle more than certain amounts of radioactivity (e.g., more than 100 mCi of $^{32}$P per year, or more than 2 mCi per experiment, or any positron-emitting isotope), are provided ring dosimeters to monitor radiation dose to the hands. If you are provided radiation dosimeters, it is very important that you wear them as intended and return them on time to Radiation Safety for processing. Any unusual incidents involving personnel radiation dosimeters should be reported promptly to the Radiation Safety Office e at 314−362−3476 or radsafety@wustl.edu. See Chapter 10 for more information.

### 3.7 BIOASSAYS

Individuals who handle more than 1 mCi of inorganic radioiodine in single operations or procedures should cooperate with Radiation Safety personnel who perform the required thyroid checks each calendar quarter. Personnel should provide urine samples to Radiation Safety for analysis when they handle sufficiently large activities to require bioassay (see Table 10-3, Chapter 10). Users are reminded of this rare urinalysis requirement via a notice that is attached to the package of materials that is delivered to the laboratory by Radiation Safety. Chapter 10 contains more information on bioassays.
3.8 PRENATAL MONITORING

All radiation workers should be aware and understand the special precautions concerning exposure during pregnancy, especially that the dose equivalent to the embryo or fetus from occupational exposure of the expectant mother should not exceed 0.5 rem (500 mrem) for the entire gestation period and the reasons for it. Personnel exposed to ionizing radiation are encouraged to disclose their pregnancy, in confidence and in writing, to the Radiation Safety Office. You also may call or email our main office at 314−362−3476 or radsafety@wustl.edu. After the formal declaration of pregnancy, women will be provided with supplementary monthly "fetal" dosimeter for the duration of pregnancy if their anticipated annual body dose is more than 50 mrem.

3.9 EMERGENCY ACTIONS

Laboratory personnel should be aware of the actions to take in case of an accident involving radioactive materials. The most common radiation emergency involves handling a spill of radioactive material. Emergency instructions are posted in all areas where unsealed radioactive materials are used or stored. These instructions (a) describe the immediate actions to be taken in order to prevent further contamination of personnel and work areas, (b) specify the names and telephone numbers of the responsible person to be notified in case of an emergency, (c) describe appropriate methods for reentering and decontaminating areas and (d) provide basic guidance for decontaminating personnel. Our 24-hour emergency cell phone number is 314−299−1322. You also may call or email our main office at 314−362−3476 or radsafety@wustl.edu

3.10 FOOD AND DRINK

Eating, drinking, smoking, gum chewing, the application of cosmetics, the storage of food and beverages or similar activities are not permitted in laboratories or other facilities where radioactive materials or radiation sources are used, handled or stored. Food waste, wrappers, containers, etc. must not be placed in laboratory trash cans as this is considered evidence of food or beverage consumption within the laboratory. Such activities are permitted in an area (defined as a room with floor to ceiling walls and a closed door) separated from the laboratory space – often referred to as a “break room”. This policy is consistent with the WUSTL policy Eating, Drinking and Related Activities in Laboratories, Revised April 30, 2010. Please refer to Chapter 9 for more information regarding the requirements for “break rooms”.

3.11 PERIODIC RADIATION SURVEYS

Periodic radiation surveys must be conducted and documented by any laboratory group whose authorization is on “active” status in all areas in which unsealed radioactive materials are approved for use or storage. The surveys are conducted once a week or once a month depending on quantities used in single operations. Each survey could include a test for removable contamination, the so−called "wipe test", and a survey instrument reading of the exposure rate level (mR/hr), depending on the kinds of isotopes present in the lab. A record of each survey and
of any corrective actions must be made and maintained. Refer to Chapter 12 for more detailed information.

3.12 SECURITY OF RADIOACTIVE MATERIALS

Our institution is very concerned about adequate security of radioactive materials when the materials are not in use or not under visual surveillance. Operational compliance with the regulations of the US Nuclear Regulatory Commission (NRC) requires that all rooms where RAM are used or stored must be attended or locked at all times. During use of the material (or during use of a laboratory containing radioactive materials that are not secured against access or removal) laboratory personnel must be present in order to maintain "constant surveillance" of the materials. If all personnel leave the laboratory, even for a brief time, the laboratory must be locked. As an alternative, locking the radioactive materials and wastes in non-removable storage containers may satisfy the NRC rules. If it is necessary for a laboratory to be kept unlocked when not attended, a “security exemption” may be requested. Under this exemption radioactive materials and wastes must be securely locked in a non-removable storage compartments or containers when not actively attended. If the requested exemption is approved, the laboratory will be posted with an “off hours security not required” sticker.

3.13 ANNUAL INVENTORY

An annual inventory of the radionuclides in the possession of each Authorized User must be prepared and submitted to Radiation Safety upon request.

3.14 RADIOACTIVE WASTE

Radioactive waste must be segregated according to waste category, appropriately stored and shielded and periodically transferred to Radiation Safety for disposal (there are a limited number of specifically approved exceptions). The disposal by drain of certain low levels of water soluble radioactivity can be permitted with prior written approval from the Radiation Safety Staff. Details are given in Chapter 14.

3.15 LABORATORY CLOSEOUT

Your laboratory’s Radiation Safety inspector should be notified when plans are made to discontinue the use of radioactive materials in one or more areas so that required "closeout" inspections and surveys can be coordinated by Radiation Safety Staff.
4. TRAINING PROGRAM

4.1 INITIAL TRAINING

4.1.1 Institutional Radiation Safety Examinations

Radiation Safety provides 3 different examinations, each designed to cover a specialized type of RAM usage:

- **Radiation Safety Examination (RSE)** is required of all users of by-product material, including positron-emitting (PET) isotopes, in a research or laboratory medicine area. The RSE is based on the material contained in the *Training Manual for Users of Radioactive Material*. More information is given on our Getting Started webpage.

- **PET Examination (PET)** is required of all users of PET material, including those in research, laboratory medicine & clinical areas. The PET is based on the material contained in *Radiation Safety Information for PET Laboratory Personnel*. More information is given on our Getting Started webpage.

- **Irradiator Examination (IRR)** is required of all individuals who need to use one of the gamma irradiators, whether it is for research or clinical applications. The IRR is based on the material contained in the “Training Manual for Users of Self-Shielded Gamma Irradiators”. Because of NRC regulations controlling access to certain radioactive sources, training for irradiator use is initiated only at the written request of an Irradiator Co-Authorized User. More information is given on our Getting Started webpage.

All of the study guides are also available on the Training Information page at the Radiation Safety website, [http://radsafety.wustl.edu](http://radsafety.wustl.edu). The exam schedule varies according to seasonal demand, but the RSE and PET exams are always on a Thursday between the hours of 1:15 – 2:45 pm at the Radiation Safety Office. More details, location information, and exam sign-up instructions are given on the Training Information page.

4.1.2 Lab-Specific Training

Prior to independently working with RAM, an individual must be provided training by the authorized user, or by a person designated by the authorized user, about the safety aspects of the specific procedures that will be performed by the individual.

The same kind of instruction must be provided by the authorized user or designate before radioactive materials are used for a new procedure that has significantly different radiation safety aspects.
4.2 CONTINUING TRAINING

4.2.1 Annual Refresher Training

Radiation Safety provides annual refresher training for personnel working with radioactive materials. The annual refresher information is provided as an on-line presentation with quiz questions. It includes:

- General information concerning radioactivity,
- Risks and biological effects of radiation exposure,
- Rules that apply to the use of RAM at this institution,
- Obligations of employees to report unsafe conditions,
- Employees' rights to be informed of their radiation exposure and bioassay results, and
- Locations where the licensee has posted or made available notices, copies of regulations, and copies of licenses and license conditions.

4.2.2 Lab Specific Training/ALARA Session

The authorized user directly responsible for personnel in a particular laboratory is required to hold an annual training/ALARA session, before September 30 of each year. The session must address the safety issues associated with the specific procedures conducted in the laboratory and ways to achieve ALARA. In addition, it is recommended that other radiation safety issues be reviewed at the time of the annual session, including the following:

- The ALARA concept and the ALARA program (refer to Section 11 of the institutional Radiation Safety Manual)
- The general rules for the safe–handling of RAM (refer to Sections 5 and 9 of the Radiation Safety Manual)
- The appropriate actions to take in case of a spill of radioactive materials (refer to Section 15 of the Radiation Safety Manual)

It is recommended that these two categories of instruction, i.e., the completion of the on-line refresher presentation/quiz and the ALARA session organized by the authorized user, be provided in conjunction with each other. Both categories of training must be provided each year during the training period from mid-April until September 30. Documentation must be provided to Radiation Safety verifying that the training requirements have been fulfilled. The on-line refresher training is automatically documented in our database. If you combine the two categories in a laboratory meeting without having each person take the on-line portion, a training documentation sign-up sheet to use is provided with the e-mailed training announcement.
5. INDIVIDUAL RESPONSIBILITIES

5.1 RESPONSIBILITIES OF AUTHORIZED USERS

Those faculty members who are granted authorization to use radioactive material are responsible for the safe use of the material by individuals working under their control. Authorized Users must

- Use radioactive materials consistent with the representations made in the application to become an authorized user or in subsequent amendment or renewal applications.
- Comply with the institutional policies pertaining to the use of radioactive materials.
- Instruct employees under their control regarding the ALARA philosophy as well as specific instructions pertinent to the procedures to be conducted.
- Assure that employees have passed the Radiation Safety Examination before they are assigned work that requires the handling of radioactive materials.
- Adequately plan experiments to assure that proper safety precautions are taken, including instructions regarding emergencies.
- Require personnel to comply with recommendations regarding personnel radiation monitors.
- Require personnel to comply with bioassay requirements.
- Maintain adequate records of (1) personnel training, (2) laboratory surveys, (3) package surveys, (4) radionuclide accountability and (5) radioactive waste disposal.
- Prepare annual inventories of radionuclides on hand as requested by the Radiation Safety Office.
- Assure that radiation survey instruments are calibrated as required.
- Notify the Radiation Safety staff of changes of location where RAM is used or stored by amending their authorization by calling 314–362–4966.

5.2 RESPONSIBILITIES OF INDIVIDUAL WORKERS

- Know and follow institutional policies pertaining to the use of radioactive materials.
- Be aware of the locations where radioactive materials are used or stored.
- Follow the radiation safety instructions that are provided by the responsible authorized user.
• Maintain radiation exposure as low as reasonable.

• Wear personnel radiation monitor(s) when provided.

• Survey hands, shoes and clothing for radioactivity after handling unsealed sources of radioactivity and reduce any contamination to an acceptable level prior to leaving the laboratory.

• Use appropriate protective devices and practices while working with radioactive materials.

• Do not eat, drink, smoke, chew gum, apply cosmetics or store similar items in areas where radioactive materials or radiation sources are used or stored. Such activities may be allowed in separate, designated “break rooms”, provided strict adherence to the institutional policy *Eating, Drinking and Related Activities in Laboratories, Revised April 30, 2010*. Refer to Chapter 9 for more information regarding “break room” requirements.

• Report significant radioactive spills, loss of radioactive materials or unsafe conditions to the Radiation Safety Office staff.

• Know the appropriate response to an emergency involving radioactive materials.

• Know the location of decontamination supplies stored in the laboratory.
6. OBTAINING AUTHORIZATION TO USE RAM

6.1 NON HUMAN USE

An individual planning to use radioactive material in their research activities at our institution should submit a completed Application for Possession and Use of Radioactive Materials, Excluding Human Use and the required supplementary information to Radiation Safety, Box 8053. (Note: links to all forms are given in Table 6-1.) A completed Statement Regarding Training and Experience Involving Radioactive Materials is required for the initial application to use radioactive material and supplementary information may be required in support of applications involving radioactive iodine (Radioiodine Questionnaire) and volatile tritiated material (Volatile Tritiated Material Questionnaire). Also, additional information must be provided using the Radioactive Materials in Animals Questionnaire if the proposed use includes the administration of radionuclides to animals. Finally supplementary information may be requested by Radiation Safety when applications specify the planned use of large annual activities of certain radionuclides, e.g., $^{32}\text{P}$ and $^{35}\text{S}$. Table 6-1 summarizes the use of the various forms. Questions regarding the forms should be directed to Radiation Safety Staff at 314−362−3476.

Submitted applications are reviewed by a special subcommittee of the Radiation Safety Committee when all preliminary requirements associated with the application have been fulfilled. Such requirements include:

- an interview with a member of the Radiation Safety Staff regarding the institutional radiation safety program for first time applicants,
- successful completion of the appropriate radiation safety exam(s) by all personnel designated to work with the radioactive material including the Authorized User. Arrangements for the safety exam are made by calling 314−362−3476.
- completion of baseline thyroid bioassays of the designated personnel if the proposed work involves single operations of unsealed radioiodine in amounts exceeding specified limits (see Chapter 10 for more information) and
- fume hood evaluation if the work involves amounts of radionuclides in single operations exceeding the quantities specified in Table 10-2 and Table 10-3).

The RSC approves users of radioactive material for specified amounts of each radionuclide with annual ordering and shipment limitations. Authorization is granted for periods ranging from two to five years based on a radiological safety evaluation. We recommend that an applicant request an initial amount for each radioisotope that is sufficient for one year. The authorization permits the individual to obtain and use an annual cumulative amount of each radioisotope up to the approved limit provided that the per-order limit is not exceeded. However, RSC reserves the right to modify, suspend or revoke the privilege of obtaining and using radioactive material.
Table 6–1. Forms Used to Request Approval to Use Radioactive Material

<table>
<thead>
<tr>
<th>Form Caption</th>
<th>Intended Use</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Application for Possession and Use of Radioactive Materials, Excluding Human Use</strong></td>
<td>Submitted as the (1) initial application to use radioactive material and (2) application for recertification, every two to five years after initial approval</td>
</tr>
<tr>
<td><strong>Application to Amend a Radioactive Materials Authorization</strong></td>
<td>To modify an existing condition at any time during a two year authorization</td>
</tr>
<tr>
<td><strong>Statement Regarding Training and Experience Involving Radioactive Material</strong></td>
<td>Supplementary information submitted only one time with ones initial application</td>
</tr>
<tr>
<td><strong>Radioiodine Questionnaire</strong></td>
<td>Supplementary information submitted only if the applicant requests labeled sodium iodide in excess of 1 mCi per shipment or 20 mCi per year</td>
</tr>
<tr>
<td><strong>Volatile Tritiated Material Questionnaire</strong></td>
<td>Supplementary information submitted only if the applicant requests a volatile tritiated compound in excess of 30 mCi per shipment or 100 mCi per year</td>
</tr>
<tr>
<td><strong>Radioactive Materials Use in Animals Questionnaire</strong></td>
<td>Supplementary information submitted only if the applicant plans to administer radioactivity to live animals</td>
</tr>
<tr>
<td><strong>Application for the Possession of Radioactive Materials for Investigational Human Use</strong></td>
<td>To receive authorization to purchase and possess radioactive material for investigational human use. Submitted in conjunction with Radioactive Drug Research Committee (RDRC) and Human Studies applications</td>
</tr>
</tbody>
</table>

Applications to authorize (1) the use of additional forms of radioactive materials, (2) an increase in the annual order limits or the limits per shipment, (3) the use of radioactive materials in animals or (4) a change of locations of use or storage require submission of a completed Application to Amend a Radioactive Materials Authorization.

### 6.2 HUMAN RESEARCH USE

An individual intending to administer radioactive material to humans as part of a research project must obtain the approval of the following Committees:
6.2.1 Radiation Safety Committee

The Committee evaluates the qualifications of the investigators and their staff to possess and use the proposed radionuclides and the radiation safety aspects of the proposal. To seek approval to obtain and possess the radioactive material, submit a completed Application for the Possession of Radioactive Material for Investigational Human Use. Information regarding the form may be obtained by calling 314–362–3476.

6.2.2 Human Studies Committee

The Committee evaluates the protocol design and the appropriateness of the proposed study. To apply for approval submit the required information specified in the Statement to Human Studies Committee form to the Human Studies Committee, Box 8089.

6.2.3 Radioactive Drug Research Committee

The Committee provides review of institutional research studies involving the administration of certain radioactive materials as required by the FDA (21 CFR Part 361.1). You should be aware that the US Nuclear Regulatory Commission has stringent training requirements for investigators planning to administer radioactive materials that are under the jurisdiction of the Commission to human research subjects. To apply for approval submit the required information to Barry Siegel, M.D., Box 8131. Information regarding application procedures may be obtained by telephone, 314–362–2810.
7. OBTAINING AND TRANSFERRING RAM

7.1 PROCEDURES FOR OBTAINING RADIOACTIVE MATERIALS

Radioactive materials intended for research or laboratory medicine are ordered by either Radiation Safety personnel or, under special circumstances, by designated individuals authorized by the Radiation Safety Officer. The restricted ordering is required by the US Nuclear Regulatory Commission to ensure that the requested materials and quantities are authorized by the licenses issued to our institution and that possession limits are not exceeded. Purchases of radioactive material are handled as follows:

7.1.1 Research Orders Using a WU Purchase Order Number

Orders for materials to be purchased using WU funds must be requested via the University's AISystems (AIS) Marketplace. Click here for guidelines on ordering RAM through Marketplace.

7.1.2 Orders Using a Barnes–Jewish Hospital (BJH), St. Louis Children's Hospital (SLCH), or Howard Hughes Medical Institute (HHMI) Purchase Order Number

Orders for radioactive materials using BJH, SLCH, or HHMI Purchase Order Numbers are placed directly with the supplier as authorized by special condition with the Radiation Safety Office specified as the shipping address. The individual placing the orders then notifies Radiation Safety of the RAM Order, specifying the following information: vendor name, authorized user (AU) name, radionuclide, activity, physical form (e.g., liquid, solid, sealed source, capsule, etc), chemical form, date RAM package will be delivered, location (building and room number) for delivery by Radiation Safety, name and phone number of individual who placed the order. Information on these RAM orders should be phoned (314–362–3476), faxed (314–362–1995) or emailed (radsafety@wustl.edu) to Radiation Safety prior to receipt of the RAM package, preferably at least the day before receipt.

7.1.3 Receipt of Radioactive Material Packages

Upon receipt of the package and completion of the initial package monitoring, Radiation Safety personnel deliver the package to the location specified at the time the material was requested. Certain Authorized Users may be approved by special condition to directly receive RAM packages.
7.2 PROCEDURE FOR TRANSFERRING RADIOACTIVE MATERIAL TO OTHER INSTITUTIONS

All transfers of radioactive material must be arranged by Radiation Safety in order to ensure

- verification of the institution's compliance with federal and/or state licensing requirements
- verification of recipient's authorized user status and proper radioactive materials receiving address
- WU compliance with DOT & NRC regulations governing correct packaging, labeling, documentation and transportation of radioactive material
- WU compliance with DOT training requirements for those who prepare RAM packages for shipment and
- internal documentation of the transfer and maintenance of that documentation for NRC or State review.

Individuals wanting to transfer radioactive material to another institution should call 314–362–3479 with the following information

- name of institution to which the RAM is being transferred
- name of intended recipient
- telephone number of Radiation Safety contact at institution
- identity of radionuclide, activity, physical and chemical form of material to be shipped and
- anticipated date of shipment.

Contact the Radiation Safety Office as far in advance of the transfer as possible. Radiation Safety personnel will contact the institution to verify licensing, authorized user status of recipient, proper RAM receiving address, etc., and also determine the type of packaging required for the shipment. The lab will be contacted and given the date and time to bring the material to the Radiation Safety Office for preparation. The lab will be responsible for providing dry ice if needed. The lab may also be asked to provide an appropriate shipping container if a special DOT approved container is not necessary. The departmental account number for the desired courier should be provided when the materials are presented for shipment. Radiation Safety personnel will package the material and prepare all necessary paper work. The material will be shipped from the Radiation Safety Office.
8. RECEIVING AND OPENING RAM PACKAGES

8.1 RECEIVING PACKAGES

All incoming packages of RAM used for research are delivered from vendors to the Radiation Safety Office, 4550 Scott Ave., Room 416 (314-362-3381). Each package is examined and surveyed by Radiation Safety personnel to insure that

- the order has been properly routed
- the material received is what was ordered
- the package appears to be undamaged and
- the levels of surface contamination and external exposure rate are within acceptable limits.

The results of each package inspection are recorded on a Radioactive Shipment Receipt Report. A sample copy of this form is included in this section. Radiation Safety personnel complete the upper portion of the report, attach it to the package and file a copy in the Radiation Safety Office. The laboratory group receiving the package is responsible for completing the remainder of the report and for maintaining a copy with the laboratory's radiation safety records indefinitely.

The package is delivered by Radiation Safety personnel to the location specified by the party placing the order (refer to Section 7). The signature of the individual accepting the package is required.

8.2 OPENING PACKAGES

Each package of RAM must be opened in the following manner:

a) Put on gloves to avoid contamination, remove the packing slip, open the package and remove and examine the final source container(s). Verify that the label on each container agrees with the description of the material specified in the packing slip and that the identity and activity of the material are consistent with what was ordered. Report any discrepancies to Radiation Safety personnel at 314–362–3476.

b) Quickly check the integrity of the final source container looking for a broken seal or a cracked vial or for evidence of loss of liquid, e.g., discoloration of the packaging material. Perform a wipe test survey in the final vial. If anything is other than expected, report the situation to Radiation Safety personnel at 314–362–3476 and ask for guidance.

c) Perform both wipe and meter surveys on the shipping carton and the packing material for contamination before discarding. If contaminated, treat as radioactive waste.
not contaminated, obliterate all radiation labels before discarding in the regular trash and

d) sign and date the middle section of the report to document that the proper steps concerning the opening of the package have been performed.

8.3 ACCOUNTABILITY FORM

Use the accountability form printed in the lower portion of the receipt report to document the use of the radioactive material. An entry must be recorded on the accountability form for each use of RAM. It must include the date of use, the amount of RAM removed, the amount of RAM remaining, and the initials of the user. The disposal portion at the bottom of the form requests the date and the remaining volume and activity at the time the original source vial is placed into the radioactive waste container.
9. GENERAL RULES FOR SAFE HANDLING OF RAM

9.1 LABORATORY RULES FOR THE SAFE USE OF RADIOACTIVE MATERIALS

Certain work habits are essential in minimizing personnel radiation doses and reducing the chance of accidental contamination. The following practices are required as a condition of our license to possess and use radioactive materials and they must be observed when working with unsealed radioactive materials:

- wear lab coats and disposable gloves at all times when handling unsealed RAM.
- wear personnel monitoring devices, if issued by Radiation Safety, while in areas where RAM is used or stored. Monitors should be stored in an area of normal background radiation during non-working hours.
- equipment used for RAM work such as seal–a–meals, gel dryers, glassware, etc., should be clearly labeled as radioactive.
- avoid contaminating objects such as telephones, light switches, water tap handles, doorknobs, etc.
- monitor work area, hands, shoes, and clothing for contamination after each procedure and before leaving area.
- dispose of radioactive waste only in specially designated and properly labeled containers. Dry waste must be disposed before it overflows. Promptly transfer waste containers with high levels of radioactivity to Radiation Safety.
- do not eat, drink, smoke, chew gum, apply cosmetics or store similar items in areas where radioactive materials or radiation sources are used or stored.
- Such activities may be allowed in separate, designated “break rooms”, provided strict adherence to the institutional policy *Eating, Drinking and Related Activities in Laboratories, Revised April 30, 2010*. This policy states that:
  - break rooms must be separated from the laboratory space and have floor to ceiling walls and a closed door,
  - only covered food or beverage items may be carried through the laboratory to a break room,
  - filling or rinsing of food or beverage containers in designated laboratory “wash sinks” is allowed only if no other sinks are available, if water in these sinks has been determined to be potable, and if the chosen sink area is not contaminated with hazardous materials and is not a designated radioactive materials disposal sink,
• food and beverage containers may not be stored in the laboratory and washed containers or utensils may not be dried on laboratory drying racks,

• refrigerators used for storing food or beverages should be dedicated to food only and should be located outside of the laboratory

• specific procedures must be developed by each laboratory director for the transport of covered food and beverage items through the lab and for use of a “wash sink”. These procedures must be maintained in the laboratory Environmental Health and Safety Manual (i.e. “Blue Book”), and be readily accessible for review and for inspection, and

• all individuals with access to the laboratory must be trained on this policy

• never pipette RAM by mouth.

• handle sources of RAM with tongs or tweezers if appropriate to the operation.

• hall freezers, freezers in common rooms, etc., must be kept locked at all times to ensure that RAM is secured against theft. Laboratories containing RAM stock and/or waste must also be kept locked when unattended to prevent RAM theft.

• significant activities of potential volatile RAM, e.g., sodium iodide, sodium borohydride, tritiated water, etc., must be used in a fume hood which has been tested and posted by Radiation Safety.

In addition, the following practices are strongly recommended in order to maintain personnel doses as low as reasonably achievable:

• all work involving unsealed RAM should be conducted on surfaces which have been covered with absorbent pads. Use easily discarded pads, absorbent on the top surface only, for containing and easily disposing of contamination.

• after each experiment involving unsealed RAM, monitor the area with a radiation survey instrument capable of detecting the radionuclide to identify areas of contamination. When using $^3$H, consider doing a wipe test for removable contamination in the area(s) of use.

• liquid RAM in glass or plastic containers other than those provided by Radiation Safety should have secondary plastic containers in case of breakage or leakage. Liquid waste containers should be capped when not in use.

• whenever possible, new procedures should first be performed with non–radioactive materials in order to discover and remedy potentially hazardous aspects of the procedure and to train personnel in the safe and efficient execution of the technique.
as a general practice, procedures involving RAM should be confined to as small an area of a laboratory as is realistic and as far from desks as practical, thus limiting the affected area in cases of accidental contamination.

all processes involving substantial activities should be conducted in a fume hood to provide an ample safety margin and to avoid the need of periodic bioassays (refer to bioassay Table 2 in Section 15).

use appropriate shielding, e.g., lead for gamma–emitters, Plexiglas™ for high energy beta–emitters, lead/Plexiglas™ combination for gamma–/high energy beta–emitters, etc.

decontamination supplies should be easily accessible to all personnel.

floors should be kept clean and waxed.

9.2 GENERAL PRINCIPLES

The instructional manual Training Manual for Users of Radioactive Material specifies work practices and procedures that help to ensure that personnel exposures are maintained ALARA. In addition, various textbooks and handbooks treat the subject of safe handling of radioisotopes in detail. Examples of such sources available at the WU Medical School Library include:


10. RADIATION MONITORING PROGRAM

It is important to know the radiation levels to which personnel are exposed. The US Nuclear Regulatory Commission (NRC) requires licensees to monitor and maintain records of personnel radiation doses and to annually report the doses to the individuals if the individuals are likely to receive more than 10 percent of the annual dose limits established by the NRC. The NRC employs several dose equivalent variations, including the following:

- **deep dose equivalent** — the dose due to external radiation computed for a tissue depth of 1.0 cm.

- **eye dose equivalent** — the dose to the lens of the eyes due to external radiation computed for a tissue depth 0.3 cm.

- **shallow dose equivalent** — the dose due to external radiation computed for a tissue depth of 0.007 cm (representative skin thickness).

- **committed organ dose equivalent** — the dose due to internal radioactivity to a specific organ during the 50–year period following the intake.

- **committed effective dose equivalent** — the computed effective dose equivalent (EDE) due to internal radioactivity during the 50–year period following intake. The EDE is obtained by adjusting (weighting) the dose equivalents to certain organs according to the organ's relative sensitivity to radiation harm and then summing the weighted doses.

- **total effective dose equivalent** — the sum of the deep dose due to external radiation and the committed EDE.

The NRC occupational dose limits are given in Table 10-1:

<table>
<thead>
<tr>
<th>Adults</th>
<th>Dose Category</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total effective dose equivalent (TEDE)</td>
<td>5 rem/yr</td>
</tr>
<tr>
<td></td>
<td>Total organ dose equivalent for maximally exposed organ</td>
<td>50 rem/yr</td>
</tr>
<tr>
<td></td>
<td>Lens dose equivalent</td>
<td>15 rem/yr</td>
</tr>
<tr>
<td></td>
<td>Shallow dose equivalent</td>
<td>50 rem/yr</td>
</tr>
</tbody>
</table>

**Embryo/fetus of a Declared Worker**

|               | Embryo/fetus dose equivalent | 0.5 rem for entire pregnancy |

Fortunately, it is very rare for any research or laboratory medicine personnel to ever have annual radiation doses greater than 10% of any of the NRC limits. Hence, the regulations of the
NRC generally do not require personnel radiation monitoring. However, we have adopted a policy to provide quarterly body monitors for individuals evaluated to "likely exceed a whole body deep dose equivalent of 100 mrem per year" (2% of the corresponding NRC limit). In addition, ring monitors are provided for individuals who are identified by the authorized user responsible for the radioactive material work as "likely to handle more than 100 mCi of $^{32}$P or other energetic beta emitter(s) per year" or more than 2mCi per experiment. Also, a monthly fetal monitor is provided to each radiation worker during the term of pregnancy after the worker has declared her pregnancy.

In addition, certain individuals who handle unsealed radioactivity in relatively large quantities are monitored by Radiation Safety personnel for internal contamination using methods that are referred to as bioassays. The bioassays are of two distinct types—measurement of radioiodine accumulation in the thyroid and measurement of the radioactivity in an urine specimen, so-called urinalysis.

### 10.1 BIOASSAY FOR $^{125}$I AND $^{131}$I

(Adapted from USNRC Regulatory Guide 8.20)

#### 10.1.1 Routine Assays

Thyroid bioassays are required of all personnel handling unsealed radioiodine quantities in single operations that exceed the amount shown in Table 10-2. Individuals who have been identified by an authorized user as currently working with radioiodine in amounts requiring bioassay have their thyroids monitored quarterly by Radiation Safety personnel, generally in the laboratory location where the individuals work. Individuals initiating work with radioiodine should have a baseline measurement prior to using the material. Call 314–362–3476 to make arrangements for non-scheduled thyroid bioassays.

**Table 10–2. Activity Levels Above Which Bioassay for $^{125}$I or $^{131}$I is Necessary**

<table>
<thead>
<tr>
<th>Type of Operation</th>
<th>Volatile or Dispersible, Including Sodium Iodide</th>
<th>Bound To Non–Volatile Agent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedures in open room with possible escape of iodine</td>
<td>0.1 mCi</td>
<td>1 mCi</td>
</tr>
<tr>
<td>Procedures with possible escape of iodine carried out within a fume hood of adequate design and face velocity</td>
<td>1.0 mCi</td>
<td>10 mCi</td>
</tr>
<tr>
<td>Procedures carried out within glove boxes, ordinarily closed, but with possible iodine release</td>
<td>10.0 mCi</td>
<td>100 mCi</td>
</tr>
</tbody>
</table>
10.1.2 **Action Levels**

Whenever the thyroid burden at the time of the measurement exceeds **120 nanocuries of $^{125}$I or 40 nanocuries of $^{131}$I**, the following actions are taken:

a) A Radiation Safety staff member conducts an investigation to determine the cause.

b) If the investigation indicates that further work in the area might result in significant additional thyroidal accumulation, the individual is restricted from further radioiodine work until the source of exposure is discovered and corrected.

c) Corrective actions that will eliminate or lower the potential for further exposure are considered and implemented, if practical.

d) A repeat bioassay is taken within two weeks of the previous measurement.

e) The USNRC is notified, if required.

If the thyroid burden at any time exceeds **500 nanocuries of $^{125}$I or 140 nanocuries of $^{131}$I**, the following actions are taken:

a) The steps described in the previous paragraph are carried out.

b) The individual is referred to an appropriate medical consultant for consideration of therapeutic procedures.

c) Repeated measurements at one week intervals are performed at least until the thyroid burden has decreased to less than 120 nanocuries of $^{125}$I or 40 nanocuries of $^{131}$I.

10.2 **ASSAY FOR RADIONUCLIDES OTHER THAN $^{125}$I AND $^{131}$I**

10.2.1 **Routine Assays**

A bioassay is required whenever an individual handles, **at any one time**, an **unsealed** quantity of a radionuclide that exceeds the amounts specified in Table 10-3. The type of bioassay is generally liquid scintillation counting of urine samples, i.e., urinalysis, and the urine samples should be obtained between 24 to 72 hours after handling the radioactivity. The urine samples should be taken to the Radiation Safety Office (4550 Scott Ave, Rooms 407-416) for assay. Personnel for whom bioassays are potentially required are reminded by a **Urine Bioassay Notification And Instructions** form that is attached to each package having single container activities in excess of the amounts specified in Table 10-3. In addition, a sticker indicating the bioassay "Control number" and a urine container are fastened to the package.
10.2.2 Action Levels

Whenever the calculated body burden at the time of the measurement exceeds the quantity specified in Table 10-3, the following actions are taken:

   d) A Radiation Safety staff member conducts an investigation to determine the cause.

   e) If the investigation indicates that further work of similar nature might result in significant additional internal contamination, the worker is restricted from using the radionuclide until the source of excessive exposure is discovered and corrected.

   f) Corrective actions that will eliminate or lower the potential for further exposure are considered and implemented, if practical.

   g) A repeat bioassay is performed within one week.

If the calculated body burden at any time exceeds 10 times the appropriate level specified in Table 10-3, the following actions are taken:

   h) The steps described in the previous paragraph are carried out.

   i) Bioassays are repeated at one week intervals until the body burden is less than that of the action level.

   j) The USNRC is notified, if required.
Bioassays are required if unsealed activities greater than those shown in this table are handled in single operations.

<table>
<thead>
<tr>
<th>Radionuclide&lt;sup&gt;(1)&lt;/sup&gt;</th>
<th>Non-Volatile Forms Used in an Open Area (millicurie)</th>
<th>With Protective Fume Hood or Glove Box (millicurie)</th>
<th>Body Burden Action Level&lt;sup&gt;(2)&lt;/sup&gt; (microcurie)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$^{14}$C</td>
<td>5</td>
<td>50</td>
<td>20</td>
</tr>
<tr>
<td>$^{45}$Ca</td>
<td>5</td>
<td>50</td>
<td>20</td>
</tr>
<tr>
<td>$^{36}$Cl</td>
<td>5</td>
<td>50</td>
<td>20</td>
</tr>
<tr>
<td>$^{57}$Co</td>
<td>10</td>
<td>100</td>
<td>40</td>
</tr>
<tr>
<td>$^{58}$Co</td>
<td>3</td>
<td>30</td>
<td>10</td>
</tr>
<tr>
<td>$^{60}$Co</td>
<td>0.6</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>$^{51}$Cr</td>
<td>20</td>
<td>100</td>
<td>400</td>
</tr>
<tr>
<td>$^{55}$Fe</td>
<td>10</td>
<td>100</td>
<td>90</td>
</tr>
<tr>
<td>$^{59}$Fe</td>
<td>2.5</td>
<td>25</td>
<td>8</td>
</tr>
<tr>
<td>$^{68}$Ge</td>
<td>10</td>
<td>100</td>
<td>50</td>
</tr>
<tr>
<td>$^{3}$H</td>
<td>20</td>
<td>200</td>
<td>800</td>
</tr>
<tr>
<td>$^{111}$In</td>
<td>10</td>
<td>100</td>
<td>40</td>
</tr>
<tr>
<td>$^{114m}$In</td>
<td>1</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>$^{54}$Mn</td>
<td>5</td>
<td>50</td>
<td>20</td>
</tr>
<tr>
<td>$^{22}$Na</td>
<td>1</td>
<td>12</td>
<td>4</td>
</tr>
<tr>
<td>$^{24}$Na</td>
<td>10</td>
<td>100</td>
<td>40</td>
</tr>
<tr>
<td>$^{32}$P</td>
<td>2</td>
<td>20</td>
<td>6</td>
</tr>
<tr>
<td>$^{33}$P</td>
<td>10</td>
<td>100</td>
<td>60</td>
</tr>
<tr>
<td>$^{86}$Rb</td>
<td>1.5</td>
<td>15</td>
<td>5</td>
</tr>
<tr>
<td>$^{35}$S</td>
<td>5</td>
<td>50</td>
<td>60</td>
</tr>
<tr>
<td>$^{85}$Sr</td>
<td>10</td>
<td>100</td>
<td>30</td>
</tr>
<tr>
<td>$^{90}$Sr</td>
<td>0.1</td>
<td>1</td>
<td>0.3</td>
</tr>
<tr>
<td>$^{99m}$Tc</td>
<td>10</td>
<td>100</td>
<td>800</td>
</tr>
</tbody>
</table>

<sup>(1)</sup> For other radionuclides contact Radiation Safety at 314–362–3479

<sup>(2)</sup> These levels represent 1.0% (0.01) of the annual limit of oral ingestion specified in regulations of the USNRC (Appendix B to 10CFR Part 20.1001)
11. ALARA PROGRAM

11.1 ALARA PHILOSOPHY

ALARA is the acronym for “As Low As Reasonably Achievable”. The Nuclear Regulatory Commission (NRC) regulations (10 CFR 20.1101) require every licensee to “develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities …” and to “use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are … ALARA.” Executive Management of Washington University in St. Louis and Washington University Medical Center (WU/WUMC) are committed to fulfilling the ALARA philosophy in all aspects of our radiation safety program. This commitment is required to be implemented by all individuals involved with the WU/WUMC radiation safety program.

Some examples of the WU/WUMC ALARA Program include:

- Radiation Safety Committee (RSC) annually reviews and audits the WU/WUMC radiation safety program.

- Radiation Safety Staff review each authorization request for use of radioactive material (RAM) to ensure the proposed use meets all safety and compliance requirements and will be done by properly trained and approved personnel.

- Authorized Users are required to establish authorization-specific procedures designed to meet the requirements of the WU/WUMC radiation safety program, including training of personnel, maintaining security for radioactive materials, performing radiation surveys and inventories, establishing action levels to respond to spills and contaminated areas, managing radwaste storage and disposal, providing required reports and documentation, and responding to emergencies and notifying Radiation Safety Staff.

- Radiation Safety Staff conduct periodic inspections and other surveillance to ensure proper documentation and procedures are in place, and that Authorized Users and Radiation Workers respond with effective corrective actions to correct identified deficiencies.

As you read this radiation safety manual, you will see other examples of the ALARA Program throughout.

11.2 ALARA REVIEWS AND INVESTIGATIONS

Authorized Users, Radiation Workers and other individuals who routinely work with radioactive materials or in radiation fields that may result in external radiation in excess of 10% of occupational dose limits are assigned personal dosimetry (whole body radiation badges or ring
badges). In addition, some individuals are periodically monitored for internal radiation dose. More information on these monitoring programs is found in Chapter 10.

Radiation Safety Staff compile quarterly ALARA reports of occupational doses which are reviewed by the RSC. As part of this review, Radiation Safety Staff identify individuals whose quarterly occupational dose has exceeded any ALARA Investigational Levels established by the RSC. Radiation Safety Staff investigate each time an ALARA Level is exceeded with the individual working with or near radioactive material and with that individual’s Authorized User and supervisor. This team evaluates whether the measured dose correctly represents the individual’s occupational dose. If the measured dose is correct, this team judges whether the individual’s dose was reasonable and whether additional ALARA measures should be put in place. For the situation where individuals in one group consistently exceed ALARA levels and doses are deemed reasonable, the team may recommend that the group be changed to a higher ALARA Category. If the measured dose is not correct, this team describes why the measured dose is not the correct occupational dose and provides justification and an estimated dose to change the individual’s permanent dose record. The ALARA Investigation is documented and reviewed by the RSC. Recommended changes to an individual’s permanent dose record or a group’s ALARA category are decided by the RSC.

The ALARA Investigational Levels for individuals working with radioactive materials are listed in Table 11-1. The Hospital X-Ray Safety Program has established its own ALARA Investigational Levels for individuals working with and around hospital x-ray units. Please contact the Radiation Safety office at 314−362−3476 or radsafety@wustl.edu for questions regarding which ALARA Category you are assigned.

11.3 ADDITIONAL CONTROLS TO PREVENT REGULATORY OVER-EXPOSURES

The ALARA Program works well at maintaining occupational radiation doses at acceptable and reasonable levels. The Radiation Safety Committee (RSC) has also adopted a two-step approach beyond the ALARA Investigational Levels aimed directly at preventing any individual from exceeding occupational dose limits. The RSC urges that Radiation Workers’ supervisors and Authorized Users, the RSO and Radiation Safety Staff, and Radiation Workers continue to manage occupational doses within the ALARA Program.

Whenever a Radiation Worker’s dose exceeds any of the levels established in Table 11-2, the RSC, or one of its subcommittees, sends a letter to the Radiation Worker, their supervisor and Authorized User. The letter includes the Radiation Worker’s dose, the corresponding level at which the Radiation Worker’s duties would require alteration, and suggestions to help reduce the dose. The Authorized User is required to respond in writing to the RSC or Subcommittee with a detailed plan describing the steps being taken to more aggressively control and reduce the Radiation Worker’s occupational exposure for the remainder of the dosimetry year. The Radiation Worker, their supervisor and the RSO are expected to endorse this written plan.

Whenever a Radiation Worker’s dose exceeds any of the levels established in Table 11-3, the Authorized User, supervisor and RSO are required to take action to alter the Radiation Worker’s duties and/or work environment to ensure that the individual’s annual radiation dose will not
exceed the occupational dose limits. In most cases the alteration is enforced until the end of the dosimetry year (January 14). The action to alter duty is reviewed and approved at the next RSC meeting.

**Table 11–1. Radioactive Materials Safety Program, ALARA Investigational Levels for Occupational External Doses**

<table>
<thead>
<tr>
<th>Dose Category</th>
<th>ALARA Category</th>
<th>Investigational Levels (mrem/quarter)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Level I ¹</td>
</tr>
<tr>
<td>Whole body (“deep” dose of chest body badge DDE)</td>
<td>A</td>
<td>125</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>250</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>400</td>
</tr>
<tr>
<td></td>
<td>D</td>
<td>600</td>
</tr>
<tr>
<td>Lens of Eyes (“lens” dose of body badge LDE)</td>
<td>A</td>
<td>500</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>1000</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>1600</td>
</tr>
<tr>
<td></td>
<td>D</td>
<td>2400</td>
</tr>
<tr>
<td>Skin of whole body (“shallow” dose of body badge, SDE)</td>
<td>A &amp; B</td>
<td>1250</td>
</tr>
<tr>
<td></td>
<td>C &amp; D</td>
<td>2400</td>
</tr>
<tr>
<td>Extremities (“shallow” dose of ring or other extremity badge)</td>
<td>A</td>
<td>1250</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>2500</td>
</tr>
<tr>
<td></td>
<td>C &amp; D</td>
<td>4000</td>
</tr>
</tbody>
</table>

¹ For ALARA Level I notifications, the Radiation Safety staff will review the dose with the badged individual and report results to the Radiation Safety Committee. No action is required unless deemed appropriate.

² For ALARA Level II notifications, the Radiation Safety staff will investigate in a timely manner the cause(s) the dose with the badged individual and, if warranted, take action. A report of the investigation and the individual's exposure record will be presented to the Radiation Safety Committee following completion of the investigation. The details of these reports will be recorded in the Committee minutes.

Effective 10/15/2006
Table 11–2.  Alert Letter Levels (40% of Federal Limit)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual deep dose equivalent (DDE)</td>
<td>2 rem</td>
</tr>
<tr>
<td>Annual lens (LDE)</td>
<td>6 rem</td>
</tr>
<tr>
<td>Annual shallow (SDE)</td>
<td>20 rem</td>
</tr>
<tr>
<td>Annual extremity (SDE, ME)</td>
<td>20 rem</td>
</tr>
</tbody>
</table>

Table 11–3.  Altered Duty Levels (70% of Federal Limit)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual deep dose equivalent (DDE)</td>
<td>3.5 rem</td>
</tr>
<tr>
<td>Annual lens (LDE)</td>
<td>10.5 rem</td>
</tr>
<tr>
<td>Annual shallow (SDE)</td>
<td>35 rem</td>
</tr>
<tr>
<td>Annual extremity (SDE, ME)</td>
<td>35 rem</td>
</tr>
</tbody>
</table>

**IMPORTANT NOTE:** Normal personnel dosimeter processing time is 4 to 6 weeks. Emergency processing (results received within a few days) can be obtained at additional cost.
12. LABORATORY SURVEYS

12.1 RADIATION SURVEYS

Radiation surveys of areas in which unsealed radioactive materials (RAM) are approved to be used or stored must be performed and documented on a regular basis. The results of the surveys must be recorded in an acceptable format and maintained as a laboratory record available for inspection by Radiation Safety Staff or by other inspectors, such as Nuclear Regulatory Commission (NRC) inspectors.

12.2 SURVEY METHODS

Surveys usually consist of a series of two types of measurements made at a number of locations within a laboratory area:

- a survey instrument reading of the radiation dose rate
- a test for removable contamination, the so-called "wipe test"

Survey results are documented on a form such as the sample Radiation Survey Sheet, available for customization.

Dose Rate Measurements

Dose rate surveys are conducted to document the radiation dose in and around areas where RAM is used or stored, for comparison to specific dose rate action levels and regulatory limits. The surveys also are valuable in identifying areas where radioactive contamination may be present. The measurements are made with a hand-held survey instrument in all areas of RAM use and storage. Dose rate measurements are required if gamma or x-ray emitting radionuclides are approved for use in the laboratory, and are also useful in open-window mode for identifying contamination from most beta-emitting radionuclides (tritium is the notable exception). Periodic dose rate measurements can also be useful to laboratories that possess only sealed sources of radioactive material, as a method to document that the source(s) remain in the expected location(s) and are not leaking or otherwise compromised, though documentation of this type of measurement is not required.

In the typical survey, a dose rate measurement is recorded at every location where a wipe test measurement is made. Dose rate surveys are documented using units of millirem per hour (mrem/hr). [Note: Many survey instruments display exposure rate in units of milliroentgens per hour (mR/hr), however the NRC considers the radiation exposure rate in mR/hr to be equivalent to the dose rate in millirem per hour (mrem/hr)].
Wipe Test Measurements

Wipe test measurements are made to quantify “removable” radioactive contamination, for comparison to specific regulatory removable contamination limits. The wipe test is accomplished by wiping the tested surface with a piece of absorbent paper, e.g., a filter disk, and then by assaying the removed activity. The assay is typically done with a liquid scintillation counter (LSC) although some laboratories use sensitive gamma counters. The required sensitivity almost always precludes the use of a portable survey instrument, e.g., a GM detector, for the assay. In certain cases, however, Radiation Safety Staff can allow wipe test assay by portable survey instrument. If you need this special consideration, contact us at 314–362–3476.

The removed activity is expressed in the units of disintegrations per minute (dpm) per 100 square centimeters of surface tested, i.e., units of dpm per 100 cm$^2$. Determination of the removed activity in dpm/100 cm$^2$ requires knowledge of the detection efficiency of the assay device in order to convert counts to disintegrations (or cpm to dpm) as well as the approximate area of the tested surface in increments of 100 cm$^2$. As an example, if an area of 200 cm$^2$ is wiped and a net count rate of 125 cpm is obtained from an instrument with an efficiency of 0.75 cpm/dpm (75%), the removable activity level is reported as 83 dpm/100 cm$^2$. Advice concerning how to determine the efficiency of an assay system may be obtained by calling Radiation Safety Staff at 314–362–3476.

A typical monthly or weekly wipe test survey of a laboratory consists of about 10 to 20 wipes of areas likely to be contaminated when unsealed radioactive materials are used, such as freezers, refrigerators, fume hoods, bench tops, floors, areas around radwaste containers, and sinks. All designated "break rooms" and “wash sinks” must be surveyed. Areas of the lab that would not be expected to become contaminated, such as desks, telephones, door knobs, light switches, etc, should also be randomly surveyed to assure that contamination has not occurred. It is a good practice to rotate the non-radioactive areas tested so the whole laboratory will be monitored over time and problem areas can be identified and decontaminated.

12.3 SURVEY FREQUENCY

Areas in which only small quantities of radioactive material are used in single operations (less than 200 microcuries at a time of any isotope) must be surveyed at least monthly. Any use of material above 200 microcuries (of any isotope) requires a survey within seven days of use.

Fume hoods shared by more than one Authorized User and used for iodinations must be surveyed immediately following each iodination.

During periods of non-use, when radioactive materials are in storage only, areas of RAM storage, radwaste storage, and approved “break rooms” or “wash sinks” must still be surveyed monthly. For extended periods of non-use, all radwaste must be transferred to Radiation Safety Staff for disposal.

During periods when there is no use or storage of radioactive materials of any kind within the lab, members of the lab staff must perform both meter and wipe surveys of all “break rooms”, “wash sinks”, RAM-approved sinks, and at least five other locations within the main lab,
regardless of the isotopes for which they are approved. This is to demonstrate the ongoing capability of the lab staff to perform these types of surveys, and is required as long as the Authorized User’s authorization remains “active”. Transferring the authorization to “inactive” status will alleviate the lab staff from this requirement.

12.4 SURVEY ACTION LEVELS

An area must be cleaned if the removable contamination level exceeds 200 dpm/100 cm$^2$, or if the exposure rate exceeds approximately two times the background reading. A repeat wipe test of the location must then be made and recorded to verify that the removable contamination level is less than 200 dpm/100 cm$^2$. All contamination should be reduced to a level as close to background as is reasonably achievable. Please contact Radiation Safety Staff at 314–362–3476 if you are unable to reduce your exposure rates or removable contamination to the levels listed here.

Locations in the vicinity of stored sources of radioactive material should be posted (using a sticker that may be obtained from Radiation Safety Staff) if the exposure rate to personnel present in the area regularly exceeds 0.2 mR/hr. Advice regarding shielding requirements for stored gamma-emitting radionuclides may be obtained by calling Radiation Safety Staff at 314–362–3476.

12.5 SURVEY RECORDS

The radiation survey records must include the following information for each survey:

- A drawing of the laboratory/room identifying the surveyed areas.
- Room location, radionuclides in use or storage, and equipment used for assay and monitoring.
- Wipe test results recorded in dpm/100 cm$^2$ and survey instrument results, if applicable, recorded in mrem/hr.
- Any corrective actions taken and the follow-up survey information.
- Signature of the person performing the survey and the full date of survey.

A sample Radiation Survey Sheet form is available and may be customized for recording the periodic radiation surveys.

Radiation survey records should be retained and be accessible in the lab at all times. Please consult your Radiation Safety Inspector for guidance on how and when to properly dispose of old survey records.
13. SURVEY INSTRUMENT CALIBRATION

13.1 CALIBRATION SERVICES

Survey instruments are routinely calibrated by the Radiation Safety staff, currently free of charge. Instruments needing calibration should be taken to the Radiation Safety Office, Rooms 407-416, 4550 Scott Ave., (314–362–3476). The turn-around time is typically a week. After an instrument is calibrated, it is returned by Radiation Safety personnel to the user group. Radiation Safety maintains a computer listing of our institution's inventory of survey instruments. Authorized users are notified by e-mail at one month and, again, at two weeks prior to the expiration of the annual calibration that the instrument should be submitted for re-calibration. The user-group should replace the batteries in each survey instrument before submitting it for calibration. In addition, personnel from Radiation Safety perform constancy–of–response tests of all the survey instruments at their locations of use. Descriptions of the calibration and reference check methods and records of the measurements are maintained at the Radiation Safety Office.

Survey instruments may be calibrated by an outside firm. The user group should then forward a copy of the calibration certificate along with the name of the authorized user to the Radiation Safety Office via either campus mail (WUSM Box 8053) or fax (314–362–1995).

13.2 CALIBRATION FREQUENCY

Survey instruments must be calibrated at least annually and subsequent to servicing.

13.3 CALIBRATION PROCEDURE

The calibration source must be an approximate point source and the source activity or the exposure rate at a specified distance must be traceable to a standard certified within 5 percent accuracy by the National Institute of Standards and Technology (NIST).

The source should be of sufficient strength to produce an exposure rate of approximately 30 mR/hr at 1 meter.

The inverse square law and the radioactive decay law must be used to correct for changes in exposure rate due to changes in distance and decay. In addition, attenuators whose attenuation factors are certified by the supplier may be used to modify the exposure rates for purposes of calibration.

Radiation Safety personnel check the status of the batteries of each survey unit and replace them prior to calibration unless the battery check mode clearly shows that they are adequate.

A particular calibration point on the instrument's scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 10 percent.
Readings within ± 20% will be considered acceptable for research low-level use if a correction chart or graph is prepared and attached to the unit.

Each linear scale of an instrument must be calibrated for at least two points such that the points are approximately 1/3 and 2/3 of full scale. Instruments with logarithmic scales must have two calibration points per decade at approximately 1/3 and 2/3 of the decade.

Exposure rates greater than 1 R/hr need not be calibrated. However, such scales should be checked for operation and approximately correct response.

13.4 REFERENCE CHECKS

The response of the instrument to a reference check source of long half-life positioned in a specific geometry is observed and recorded by Radiation Safety personnel subsequent to each calibration. Radiation Safety then conducts in-the-field constancy tests each time a laboratory is inspected, for our institution's entire inventory of survey instruments used in research and laboratory medicine (> 500 units). It is recommended that users also determine the response of each of their survey instruments immediately after calibration to a long-lived reference source and to use the source to verify constancy of response before and after subsequent use of the instruments for recorded surveys. A record of the user's constancy tests is not required.

13.5 CALIBRATION RECORDS

Radiation Safety prepares a report of each survey instrument calibration. The report includes the following:

- The name of the authorized user,
- identification of the unit that includes the manufacturer, model number, serial number and type of detector,
- the condition of the batteries and an indication of whether the batteries were replaced,
- for each calibration point, the calculated exposure rate and the measured exposure rate,
- the angle between the radiation field and the detector axis,
- the measured response of the check source, and
- the name of the person who performed the calibration and the date of the calibration.

In addition, Radiation Safety has on file a description of the calibration source and of the calibration procedure as well as certifications of exposure rate and attenuator factors.

The following information is provided on a sticker that is affixed to each instrument after calibration:
• the radionuclide used to calibrate the instrument,

• for each scale or decade, one of the following, as appropriate:
  • the average correction factor,
  • a graph from which the correction factor can be obtained
  • an indication that the scale was checked for function but not calibrated or
  • an indication that the scale or decade is inoperative.

• the angle between the radiation field and the axis of the detector during calibration, and

• the date of calibration.

The Radiation Safety Office maintains the records of calibration and constancy tests.

13.6 REPAIR SERVICES

Occasionally, survey instruments require repair. A list of companies that repair radiation survey instruments may be obtained from the Radiation Safety Office by calling 314–362–3476.
14. RADIOACTIVE WASTE STORAGE AND DISPOSAL

14.1 STORAGE OF RADIOACTIVE WASTE

All temporarily stored radioactive waste material must be kept in appropriate containers that are properly labeled. The required waste containers used for transfer are provided by Radiation Safety.

14.2 TRANSFER OF RADIOACTIVE WASTE

The disposal of all radioactive waste must be carried out with the approval and cooperation of the Radiation Safety Office. All radioactive waste material, except for specifically authorized drain discharges of low level liquid waste or other exceptions as specifically approved by Radiation Safety, must be transferred to Radiation Safety for proper disposal. In addition to other requirements listed below, all radioactive waste materials must be treated to reduce the hazard from any biological agents.

14.3 DRY WASTE

14.3.1 Short–lived waste

All dry waste containing radionuclides with half–lives of less than 120 days should be segregated from radionuclides with half–lives of >120 days. In addition, it is necessary to place all broken glass, syringe needles and other sharp objects in an unbreakable and puncture–proof container before placing it with other dry waste. Two sizes of dry waste containers (1.1 cubic feet and 0.6 cubic feet capacities) are provided by Radiation Safety. They are lined with yellow bags for easy identification by housekeeping and, in addition, each container is lined with a secondary clear plastic liner that allows inspection of the contents by Radiation Safety personnel. All short–lived dry waste must be delivered for transportation in one of the appropriately lined containers.

14.3.2 Long–lived waste

All dry waste containing radionuclides with half–lives greater than or equal to 120 days should be segregated from short–lived waste. It is absolutely necessary to separate long–lived incinerable materials from non–incinerable materials in order to avoid astronomical waste fees (Incinerable long–lived radioactive waste can be shipped out–of–state for incineration. The substantial volume reduction results in a significant savings versus shipping the initial waste volume for burial). The following materials, if contaminated with long–lived radionuclides, are not acceptable for incineration and therefore must be segregated: sharps, metal, glass, PVC (polyvinyl chloride), asbestos, listed RCRA hazardous wastes, explosives and pyrophorics. Due to activity concentration limits on incinerable materials, it is requested that unused portions of...
stock supplies of radionuclides be restricted from incinerable wastes. The incinerable long–lived materials must be maintained in waste containers that are appropriately labeled and plastic lined. The containers, labels and plastic liners are provided by Radiation Safety. Two sizes of dry waste containers (1.1 cubic feet and 0.6 cubic feet capacities) are provided by Radiation Safety. They are lined with yellow bags for easy identification by housekeeping and, in addition, each container is lined with a secondary clear plastic liner that allows inspection of the contents by Radiation Safety personnel. All dry waste must be delivered for transportation in one of the appropriately lined containers.

14.4 LIQUID WASTE

Aqueous based bulk liquid waste should be segregated from organic based bulk liquids. In addition, all liquid waste containing radionuclides with half–lives of less than 120 days should be segregated. Two sizes of liquid waste containers (5 gallon and gallon capacities) are available from Radiation Safety. All liquid waste must be delivered for transportation in one of these containers. All aqueous based liquid waste transferred to Radiation Safety must have a pH value between 4 and 10, inclusive.

A special category of liquid waste is so–called mixed hazardous waste, radioactive waste that also contains a material identified by the EPA as hazardous. You should be aware that it is very expensive to dispose of mixed hazardous waste, even if the radionuclide is relatively short–lived, e.g., $^{32}$P. The current waste broker fee for mixed hazardous waste is of the order of several hundred dollars per gallon, on the average. Researchers are advised not to generate mixed hazardous waste unless it is absolutely necessary.

Another special category of liquid waste is bulk scintillation fluid. Since the disposal fee for bulk scintillation fluid is substantially less than that for mixed hazardous waste, the two categories of liquid waste should not be combined.

Radiation Safety personnel (314–362–3476) should be contacted if you have any inquires about mixed hazardous waste or bulk scintillation fluid waste.

14.5 ANIMAL WASTE

Animal waste must be segregated into three categories:

- Deregulated — Animals containing only $^3$H and/or $^{14}$C in concentrations less than 0.05 µCi/gm when averaged over the whole carcass.

- Animals containing radionuclides with half–lives of less than 120 days.

- Animals containing radionuclides with half–lives of greater than or equal 120 days, excluding those containing only $^3$H and/or $^{14}$C in average concentrations less than 0.05 µCi/gm (see Deregulated above).
All animal waste must be delivered for transportation frozen and neatly packaged in double plastic bags in a strong, tight container.

14.6 SCINTILLATION VIALS

Scintillation vials should be segregated into several categories:

Scintillation Media

1. Segregate flammable liquid scintillation cocktails from non-flammable cocktails. We strongly encourage using non-flammable cocktails.

2. Segregate by half-life according to the following table:
   a) Deregulated-$^3$H and/or $^{14}$C with concentration less than 0.05 $\mu$Ci/ml
   b) Isotopes with half-life less than 30 days
   c) Isotopes with half-life greater than 30 days but less than 109 days
   d) Isotopes with half-life greater than 109 days

Liquid scintillation media is shipped out-of-state for incineration. The list of acceptable radionuclides for incineration changes from time to time. Call Radiation Safety personnel at 314–362–3476 for updates concerning radionuclides acceptable for incineration.

Scintillation vials with contents should be delivered in the original trays or in boxes lined with two plastic bags.

14.7 RADIOACTIVE WASTE TRANSFER DOCUMENTATION

Each container of radioactive waste that is delivered for transportation must be accompanied by a completed radioactive waste transfer form. Specific usage and packaging instructions are printed on the back of each transfer form.

Provide all the requested information. If the transfer forms are incomplete or if the waste is discovered to be packaged incorrectly the waste must be returned to the laboratory. Radiation Safety personnel at 314–362–3476 will provide guidance for safety questions concerning scintillation media and radioactive waste.

14.8 RADIOACTIVE WASTE TRANSFER SCHEDULE

Radiation Safety personnel are available at scheduled locations to accept properly packaged radioactive waste. In the event that Radiation Safety cannot make one of its scheduled pickups, the laboratory will be notified as early as possible by telephone and/or by signs posted near
elevators and at the loading dock. The radwaste pickup schedule is given on the Radiation Safety website.

14.9 LABORATORY DRAIN DISPOSAL OF LOW–LEVEL LIQUID WASTE

Drain disposal of significant amounts of radioactive material by a research group is prohibited by the Radiation Safety Committee. However, a laboratory may request approval for the disposal of aqueous-based liquid radioactive waste of low concentration via the drain. The activity released per quarter must not exceed the limits given in Table 14-1:

To request authorization, use the Drain Disposal Request form. (The form is also available on our forms webpage at https://radsafety.wustl.edu/An1Pages/An1-Forms.htm)

Upon approval, the specific sink to be used will be posted by Radiation Safety staff and you will begin keeping a record of all disposals, indicating the date and activity discharged for each radionuclide. At the end of each quarter, you will sum and report the total activity of each radionuclide disposed of. The disposals are logged using the Quarterly Drain Disposal Log Sheet and Summary form. The form is sent by Radiation Safety by email at the end of each calendar quarter to each group that has one or more approved drains. Quarterly totals must be promptly reported to Radiation Safety (within 15 days of the end of the quarter) through the Radiation Safety website so that reporting requirements of the Metropolitan St. Louis Sewer District can be fulfilled.

Table 14–1. Radionuclide Drain Discharge Limits

<table>
<thead>
<tr>
<th>Radionuclide</th>
<th>Maximum Activity to be Released per Quarter (microcuries)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$^{3}$H</td>
<td>750</td>
</tr>
<tr>
<td>$^{14}$C</td>
<td>150</td>
</tr>
<tr>
<td>$^{32}$P</td>
<td>150</td>
</tr>
<tr>
<td>$^{33}$P</td>
<td>150</td>
</tr>
<tr>
<td>$^{35}$S</td>
<td>150</td>
</tr>
<tr>
<td>$^{51}$Cr</td>
<td>150</td>
</tr>
<tr>
<td>$^{125}$I</td>
<td>150</td>
</tr>
<tr>
<td>$^{131}$I</td>
<td>150</td>
</tr>
<tr>
<td>Any other radionuclide, unless approved by the RSC</td>
<td>75</td>
</tr>
</tbody>
</table>
14.10 GASEOUS RELEASES TO THE ATMOSPHERE

Radioactive gases are released via fume hoods to the atmosphere. Federal agencies require that the radioactivity concentrations at the release sites do not exceed certain limits. The WU Radiation Safety Office has developed a program to evaluate and control the effluent concentrations released to the atmosphere. The Radiation Safety staff evaluates the prospective airborne concentration at the release point and limits the laboratory use of the potentially volatile radioactive material to an amount that will result in a calculated average release concentration that is 10% or less of the federal limit. In addition, retrospective computations of average concentrations are performed to insure that the average release concentrations are 10% or less of the limits, i.e., that we achieve ALARA.
15. ACCIDENTS INVOLVING RAM

15.1 POSTING OF EMERGENCY INSTRUCTIONS

Emergency instructions are posted in all areas where unsealed RAM is approved for use or storage. These instructions

- describe the immediate actions to be taken in order to prevent contamination of personnel and work areas,

- specify the telephone number to call in case of an emergency (for "off–hours" assistance, please call the Radiation Safety 24-hour Emergency Cell Phone at 314–299–1322), and

- provide basic guidance for personnel monitoring and decontamination.

To see a representative copy of the spill instructions provided by Radiation Safety, click this link: Emergency Instructions.

15.2 MAINTENANCE OF DECONTAMINATION SUPPLIES

Laboratories using unsealed RAM should have appropriate decontamination supplies available that are easily accessible to lab personnel. Supplies should include disposable gloves and booties, plastic–backed absorbent pads, and surface and skin decontaminating solutions (or foams).
16. BIOLOGICAL EFFECTS OF RADIATION EXPOSURE

16.1 RISKS FROM OCCUPATIONAL RADIATION EXPOSURE

The US Nuclear Regulatory Commission (NRC) requires that all persons working with radioactive material licensed by that agency be instructed in the health protection problems associated with the exposure to ionizing radiation. Similarly, the Occupational Safety and Health Administration (OSHA) requires instruction regarding the safety problems related to ionizing radiation exposure from x-ray devices, particle accelerators, naturally occurring radionuclides and accelerator-produced radioactivity. The US Environmental Protection Agency (EPA) in its radiation protection guidance for occupational exposure urges that workers be clearly informed of the biological implications of radiation exposure. It is intended that the following information will enable you to develop an attitude of healthy respect for the risk associated with radiation exposure rather than an unnecessary fear or lack of concern.

16.2 BACKGROUND INFORMATION

A measure of the biological damage sustained by tissue due to ionizing radiation is expressed by the tissue's dose equivalent (often referred to by just "dose"), the traditional unit of which is the rem. The dose equivalent is used to indicate the radiation dose due to internal radioactive contamination as well as external exposure. The dose pattern from organ to organ that results from internal radioactivity is normally very uneven. A computational method of handling non-uniform organ and tissue doses is the effective dose equivalent (EDE). A computed EDE, obtained by adjusting (weighting) designated organ doses according to the organ's relative sensitivity to harm by radiation, is a single quantity that indicates the potential harm or risk of the non-uniform dose pattern.

The total effective dose equivalent (TEDE) represents the sum of the deep dose due to external radiation and the EDE due to internal contamination.

To provide some perspective regarding the total effective dose equivalent, the natural "background radiation" level (due primarily to (a) radiation reaching earth from outer space, (b) the radioactive content of all terrestrial materials and (c) exposure to naturally occurring radon gas) results in a total EDE to all persons in the US that averages 0.3 rem (300 millirem) per year.

The biological effects of ionizing radiation can depend, among other factors, on: the type of radiation, the amount of the dose and the rate at which it is received, the type of tissues irradiated, and the age and sex of the exposed person. The biological damage is primarily due to the fact that the charged particles (ion pairs) that result from ionization, particularly in the water of body cells, yield highly reactive free radicals. The radicals then readily interact with molecules in the irradiated cells to break chemical bonds or produce other chemical changes. The resultant biological effects can be classified into three categories:
• **somatic** — effects occurring in the exposed person. The manifestation may be **prompt** or **delayed**. The period of time between exposure and demonstration of the delayed effect is referred to as the **latent** period.

• **genetic** — abnormalities occurring in the future children of exposed persons and in subsequent generations.

• **developmental or teratogenic** — effects observed in children who were exposed during the fetal or embryonic stages of development.

At the low levels of occupational exposure it is difficult to demonstrate the relationship between dose and effect. The changes induced by radiation often require many years or decades before being evident and, thus, a very long follow-up period is necessary to define risks. Studies of human populations exposed to low level radiation are the appropriate basis for defining risk. Yet the number of such investigations, from which the relationship between radiation dose and response can be determined, is limited, the best being those of the A–bomb survivors in Nagasaki and Hiroshima. Accordingly, there is considerable uncertainty and controversy regarding the best estimates of the radiation risk of low level doses.

### 16.3 SUMMARY OF CURRENT RADIATION RISK ESTIMATES

As used in this section, "risk" is the probability or chance of severe harm or death from radiation exposure.

#### 16.3.1 Somatic Effects

The somatic effects of interest are cataract and cancer induction.

**Cataract Induction** — The lens of the eye differs from other organs in that dead and injured cells are not removed. Single doses of several hundred rem have induced opacities that interfere with vision within a year. When the dose is fractionated over a period of a few years, larger doses are required and the cataract appears several years after the last exposure. The 1990 BEIR Report (ref. 1; a report prepared by a special committee of the National Research Council) concludes that **cataract induction should not be a concern** for the doses currently permitted radiation workers.

**Cancer Induction** — **Cancers** arising in a variety of organs and tissues **are thought to be the principal somatic effect of low and moderate radiation exposure**. Organs and tissues differ greatly in their susceptibility to cancer induction by radiation. Induction of leukemia by radiation stands out because of the natural rarity of the disease, the relative ease of its radiation induction and its short latent period (2–4 years).

However, the combined risk of induced solid tumors exceeds that of leukemia. It is currently thought that cancer induction is the only possible somatic effect due to exposure to low levels of ionizing radiation. According to the 1990 BEIR Report (ref. 1), the risk of radiation doses of the order of the natural background level (300 millirem average in the US) may be zero. However,
to be conservative, the risk factor derived from high dose data is often used to estimate the upper–limit risk of chronic radiation doses less than 10 rem. Accordingly, the International Commission on Radiological protection (ICRP; ref. 2) estimates that the total fatal risk is about $4 \times 10^{-4}$ per rem of effective dose equivalent (or 4 chances in 10000 per rem) when averaged over an adult population of radiation workers. This is also the somatic risk factor recommended by the US Nuclear Regulatory Commission for radiation workers (ref. 3).

The average effective dose equivalent for our research and laboratory medicine personnel is less than 10 millirem (0.010 rem) per year due to work related activities. This low dose value suggests an average upper limit fatal risk of about one chance in a quarter of a million due to each year's occupational exposure. This is an extremely low annual fatal risk which can be put into perspective by comparing it with other actions that suggest the same fatal risk level, e.g., smoking 14 cigarettes (in a year), driving an automobile 40 miles, drinking 30 cans of diet soda, etc., (ref. 4).

### 16.3.2 Genetic Effects

A mutation is an inheritable change in the genetic material within chromosomes. Generally speaking, mutations are of two types, dominant and recessive. The effects of dominant mutations usually appear in the first and subsequent generations while the effects of recessive mutations do not appear until a child receives a similarly changed gene for that trait from both parents. This may not occur for many generations or it may never occur. Mutations can cause harmful effects which range from undetectable to fatal. In this section **mutational effects** mean only those inheritable conditions which are usually severe enough to require medical care at some time in a person's lifetime.

The ICRP (ref. 2) estimates the probability of radiation–induced severe hereditary effects in all descendants of a population of radiation workers to be $6 \times 10^{-5}$ per rem (or about one chance in 17,000 per rem). An UNSCEAR report (ref. 5) estimates that about $\frac{1}{4}$ of the affected descendants would be children and grandchildren.

This information can be combined with the average annual dose of approximately 10 millirem to estimate the genetic risk of our research and laboratory medicine radiation workers. Assuming 11 years of exposure prior to conception (29 years is the average age of fathers at the time of birth in the US; the average age of the mother is less; 18 years is the minimum age for occupational exposure to ionizing radiation), the chance of a serious birth defect in all descendants of the worker due to prior occupational exposure is less than one chance in a hundred thousand due to prior occupational exposure ($11 \times 0.01 \times 6 \times 10^{-5} \sim 7 \times 10^{-6}$). This risk is very low. Many experts consider the risk to be nonexistent.

However, it should not be surprising for such a small dose. For perspective, the radiation dose due to single roundtrip air flight can be as high as 20 millirem (ref. 6), substantially higher than the average annual dose of our research and laboratory medicine personnel.
16.3.3 Developmental Effects

An exposed unborn child may be subjected to more risk from a given dose of radiation than is either of its parents. The developmental effects of radiation on the embryo and fetus are strongly related to the stage at which exposure occurs. The greatest concerns are of inducing malformations and functional impairments during early development and an increased incidence of cancer during childhood. The most frequent radiation-induced human malformations are small size at birth, stunted postnatal growth, microcephaly (small head size), microencephaly (small brain), certain eye defects, skeletal malformations and cataracts. Fortunately, these effects are observed only for radiation doses much larger than those permitted radiation workers.

The current knowledge regarding developmental effects, according to the ICRP, is as follows:

- exposure of the embryo during the first 3 weeks following conception may result in a failure to implant or an undetectable death of the conceptus. Otherwise, the pregnancy continues in normal fashion with no deleterious effects. This "all or nothing" response is thought to occur only for acute doses greater than several rem,

- after 3 weeks, malformations may occur which are radiation dose dependent but with a threshold dose estimated to be about 10 rem of acute exposure,

- from 3 weeks to the end of pregnancy it is possible that radiation exposure can result in an increased chance of childhood cancer with a risk factor of, at most, a few times (probably 2 to 3) that for the whole population, and

- irradiation during the development of the forebrain, in the period of 8–15 weeks after conception, may reduce the child's IQ by 0.3 point per rem, on the average, for relatively large doses.

These conclusions are reassuring for individuals who incur small work-related doses since the possible developmental effects are thought to occur only at much higher doses or to occur with very low probability, if at all.

The US Nuclear Regulatory Commission (NRC) has developed guidance for workers concerning the risks associated with occupational radiation exposure (ref. 3) that is more extensive than this summary. You may request a single copy of the USNRC document (Regulatory Guide 8.29 "Instruction Concerning Risks From Occupational Radiation Exposure") by calling Radiation Safety at 314–362–3476 and asking for a copy of Regulatory Guide 8.29.

References:


6. Radiation Answers – Answers to Questions about Radiation and You (http://www.radiationanswers.org)
17. PRENATAL RADIATION EXPOSURE

Protection of the unborn from ionizing radiation is an important and well established practice. The risk of harm following in utero exposure requires serious attention because of the severity of the possible effects, because they occur so early in life and because those who suffer the harm are involuntarily exposed. Accordingly, various advisory and regulatory groups have established limits for the radiation dose of a developing child due to the mother's work–related exposure. The US Nuclear Regulatory Commission (NRC) limits the effective dose to the embryo/fetus to 500 millirem if the pregnancy has been declared, in writing, by the mother. After the declaration of pregnancy, the NRC recommends that the embryo/fetus dose rate not exceed 50 millirem per month for the remainder of the pregnancy. Fortunately, the radiation doses incurred by research and laboratory medicine personnel are generally much less than the NRC dose limit for a developing child. Nevertheless, it is appropriate to review the possible adverse consequences of irradiating the unborn and to promote practices that are intended to maintain embryo/fetus doses as low as possible.

17.1 DEVELOPMENTAL EFFECTS

The developmental effects of radiation on the embryo and fetus are strongly related to the stage at which exposure occurs. The greatest concerns are of inducing malformations and functional impairments during early development and an increased incidence of cancer during childhood. The most frequent radiation–induced human malformations are small size at birth, stunted postnatal growth, microcephaly (small head size), microencephaly (small brain), certain eye defects, skeletal malformations and cataracts. Fortunately, most of these effects are observed only for radiation doses larger than those permitted radiation workers.

The current knowledge regarding developmental effects, according to the International Commission on Radiological Protection (ICRP) and the US Nuclear Regulatory Commission (NRC), is summarized as follows:

- Exposure of the embryo to high doses during the first 3 weeks following conception may result in a failure to implant or an undetectable death of the conceptus. Otherwise, the pregnancy continues in normal fashion with no deleterious effects. This "all or nothing" response if thought to occur only for acute doses greater than several rem.

- After 3 weeks, malformations may occur which are radiation dose dependent but with threshold doses generally estimated to be about 10 rem of acute exposure. An important exception may be the risk of small head size. According to the NRC the risk of small head size is a function of gestational age with approximate risks of 5 chances in a thousand per rem at 4 to 7 weeks after conception to a peak of about 9 chances in a thousand per rem at 8 to 11 weeks. For perspective, the NRC points out that the occurrence of small head size occurs in about 40 births out of 1,000 in the US due to causes other than radiation exposure.

- From 3 weeks to the end of pregnancy it is possible that radiation exposure of the embryo/fetus can result in an increased chance of childhood cancer with a risk factor of at
most, a few times that for the whole population. For example, the NCRP concludes that the lifetime risk resulting from exposure during gestation is two to three times that for an exposed adult. The NRC has reviewed the available scientific literature and has concluded that the 0.5 rem limit provides an adequate margin of protection for the embryo/fetus.

- The NRC states that the brain is most sensitive to induced developmental effects during the 8th to 15th weeks of gestation followed by a substantially less sensitive period for the 2 months after the 15th week. Although no brain developmental effects caused by radiation have been observed in humans at doses below the 5 rem occupational dose limit, scientists are uncertain whether they can occur at low doses. Because of this uncertainty, scientific advisory groups consider it prudent to limit the dose to the embryo/fetus to 0.5 rem due to the mother's work–related exposure. The ICRP, based on studies of children exposed in utero to much higher radiation doses than 5 rem, concludes that the irradiation during the development of the forebrain (in the period of 8–15 weeks after conception) may reduce the child's IQ by 0.3 point per rem, on the average.

It should be noted that the combined risk, i.e., the sum of the fatal cancer, small head size and mental retardation risks, for the embryo/fetus exposed to the limit of 500 millirem is 14 chances per 10,000, according to the NRC. This is in fair agreement with a 1987 report issued by the NCRP in which it is concluded that the total risk for the embryo/fetus is about 10 chances in 10,000 for a dose of 500 millirem. This is an unacceptably high risk for many. Hence, it is institutional policy to maintain the embryo/fetus radiation doses of pregnant personnel as low as is reasonably achievable.

In accord with this commitment, the following describes a policy to ensure that the exposure of every pregnant employee (and fetus) is substantially less than 0.5 rem (500 mrem) during the period of pregnancy:

- All radiation workers should be aware and understand the special precautions concerning exposure during pregnancy, especially that the dose equivalent to the embryo or fetus from occupational exposure of the expectant mother should not exceed 0.5 rem (500 mrem) and the reasons for this recommendation.

The US Nuclear Regulatory Commission (NRC) has developed guidance for workers concerning prenatal risks associated with occupational radiation exposure that is more extensive than this summary: Regulatory Guide 8.13, Revision 3, "Instruction Concerning Prenatal Radiation Exposure".

- Personnel exposed to ionizing radiation are encouraged to disclose their pregnancy, in confidence, and in writing, to the Radiation Safety Officer, Radiation Safety Division, WUSM Box 8053. The declaration must include your name, a statement that you are pregnant, the estimated date of conception, and the date you provide the letter to Radiation Safety.

You may use our sample Declaration of Pregnancy form (also on the Forms page of our website: https://radsafety.wustl.edu/documents/forms/pregnancy.pdf). You may use the form...
letter or compose your own. The employee's previous exposure history will be reviewed to determine whether the employee should consider requesting a modification in her work assignment.

- Radiation Safety personnel will review the employee's previous exposure history to determine if radiation monitoring is required during the remainder of the pregnancy.

- The reported deep doses for any subsequent monitoring of the worker will be reviewed each month by Radiation Safety.

- Radiation Safety will notify the individual if any reported deep dose exceeds 10 millirem in a month or if the cumulative reported deep dose exceeds 100 millirem.
18. CARE AND MANAGEMENT OF ANIMALS CONTAINING RAM

18.1 RADIOACTIVE MATERIALS

Many research projects include the administration of radioactive materials to animals. If the radioactive animals are not returned to an animal facility, e.g., a facility of the Division of Comparative Medicine (DCM), the care and management of the radioactive animals are the responsibility of the research group. However, there are additional precautions required of the research group when radioactive animals are returned to an animal facility.

18.2 ANIMAL QUESTIONNAIRE

A completed "Animal Questionnaire" must be included as supplementary information with applications submitted to the Radiation Safety Committee (RSC) if the proposed work includes the administration of radioactive materials to animals. A different questionnaire is required for each animal species and for each project or protocol. If the application is approved by the RSC, a copy of each animal questionnaire is forwarded to the Animal Studies Committee (ASC) and to the operations manager of the appropriate animal facility. In addition, Radiation Safety Staff review the proposed use of radioactive materials and send a completed copy of the "Radiation Safety Guidance for Animal Facility Personnel" form to the appropriate operation manager if the radioactive animals are returned to an animal facility after the research use.

The Animal Studies Committee and the Radiation Safety Committee work together to insure that protocols submitted to the ASC that involve the use of radioactive materials have had the radioactive research component approved by the RSC.

18.3 RESEARCH GROUP RESPONSIBILITY

When radioactive animals are returned to an animal facility, the research group is responsible for:

- posting the room where the animals are housed,
- providing information about the administered materials,
- performing the required periodic radiation surveys
- properly handing and disposing of radioactive material waste, e.g., contaminated bedding
- providing husbandry for the animal(s) until the exposure rate is less than 1 mrem/hr at 1 foot from the cage(s).

The required information about the administered radioactive materials is accomplished by completing a label, affixing it to an orange cage tag, and attaching the tag to the cage of the
returned animal(s). The red label, which can be obtained from either the animal facility operations manager or from Radiation Safety, is intended to provide the following information.

- animal name
- radionuclide
- half-life
- injection Date
- The exposure rate (mrem/hr) at 1 foot to be measured and recorded on the date of the transfer of husbandry responsibilities to DCM. This figure should not exceed 1 mrem/hour.
- Date anticipated for routine care by DCM
- Date anticipated to be not radioactive if applicable
- Research contact person and telephone number
- DCM contact person and telephone number

A sample copy of the label is shown at the end of this section.

If the measured exposure rate at a one foot distance from the animal cage is greater than 1 mrem/hr as determined with a survey instrument in current calibration (equivalently, the survey instrument will indicate more than 1 mR/hr), the research group must provide the animal husbandry until the exposure rate is less than the 1.0 mR/hr level. In addition, the room housing the animal(s) must be posted with a sign (similar to the one shown at the end of this section) in order to alert animal facility personnel of the elevated exposure level. Management of bagged waste, e.g., contaminated bedding, is the responsibility of the research group. The waste must be transferred to Radiation safety for disposal along with a completed waste transfer form (refer to section 14 of this manual).

In the case of very short–lived radionuclides (half–life less than 13 hours), some of the animal facilities provide a designated holding area for the bagged waste provided it is labeled with the information shown.

It is the responsibility of the research group to monitor the very short–lived waste after a holding period of ten half–lives or more. If the waste is at background level, a "Cold" label (also, a sample copy shown at the end of this section) is used to cover the previous radioactive label and the bagged waste is then transferred by research personnel to the non–radioactive biological or carcass waste stream, as appropriate. Records of the waste survey must be maintained by the research group.
18.4 RADIATION SAFETY OFFICE INSPECTIONS

Radiation Safety personnel conduct quarterly inspections of animal facility areas where radioactive animals are maintained to verify that the various safety requirements are being fulfilled. A copy of the results of each inspection is forwarded to the responsible authorized user (or designate) as well as to the operations manager of the animal facility. You can call Radiation Safety at 314–362–3476 for guidance about the requirements and recommended practices involving radioactive animals.
19. LABORATORY INSPECTIONS

Radiation Safety Staff periodically conduct inspections of locations where radioactive material (RAM) is produced, used or stored in order to verify that proper radiation safety practices are in effect. Radiation safety inspections vary according to the types of radioactive materials and uses. The major categories of inspections are described in the following paragraphs.

19.1 IRRADIATOR INSPECTIONS

Radiation Safety Staff conduct periodic inspections of the locations where gamma irradiators are utilized. The inspectors monitor compliance with the radiation safety aspects of each gamma irradiator. For more information, contact Radiation Safety Staff at 314–362–3476.

19.2 CYCLOTRON FACILITY INSPECTIONS

Inspections are periodically conducted by Radiation Safety Staff to examine radiation safety aspects of the cyclotron facilities used for the on-site production of radioactive materials and to review compliance with State and Federal requirements. For more information, contact Radiation Safety Staff at 314–362–3476.

19.3 MEDICAL AND HUMAN USE FACILITY INSPECTIONS

Inspections are periodically conducted by Radiation Safety Staff to examine radiation safety aspects of clinical medical use and human research use authorizations and compliance with 10 CFR 35 regulations. For more information, contact Radiation Safety Staff at 314–362–3476.

19.4 RESEARCH AND LABORATORY MEDICINE AREA INSPECTIONS

Inspections of all research and laboratory medicine areas in which radioactive materials are used or stored are conducted either quarterly, semi-annually, or annually, depending upon the types and amounts of radioactive materials for which the Authorized User (AU) is approved, and the method in which they are used. Radiation Safety Inspectors monitor the laboratory practices specified on the Radiation Safety Laboratory Inspection form, discussed in the following section. The findings of each inspection are provided to the laboratory staff. The AU is responsible to ensure all identified deficiencies are promptly and effectively corrected.

Authorized Users whose inspections indicate either an excessive number of deficiencies or repeat deficiencies are required to post a “Notice of Violation” in their lab and to provide the Radiation Safety Committee (RSC), through the Radiation Safety Officer (RSO), a written response identifying the cause of each deficiency and describing all corrective actions taken or planned. Any authorization that receives a Notice of Violation will have a follow-up Radiation Safety inspection performed by the end of the next month following the date of the original inspection. This follow up inspection will cover only the previously identified deficiencies, and will be documented as a “Follow-Up Inspection”. Failure to timely correct specified deficiencies or to respond in writing may result in a temporary suspension or permanent revocation of the AU's privilege to order, possess or use radioactive materials as determined by the RSO or the Radiation Safety Committee.
19.4.1 Explanation of Laboratory Inspection Form

The Radiation Safety Laboratory Inspection form identifies 62 specific deficiencies, in seven general deficiency groups, which the Radiation Safety Inspectors assess as they inspect each laboratory.

Each deficiency is assigned a number of penalty points, and the penalty points are totaled for all deficiencies identified in an inspection. If an excessive number of penalty points are assessed in an inspection, a Notice of Violation is issued to the AU, as described above.

The Radiation Safety Staff inspectors also have the option of applying a “multiplier” to any deficiency identified. This “multiplier” can be used to signify the repeat occurrence of that same deficiency during the period between inspections (e.g., two quarterly drain report summaries late for an authorization inspected every six months, two notices from Washington University Security that a lab was found unlocked after-hours, etc.).

The individual inspection form items are explained in the remainder of this section.

Posting & Records

1. NRC Form 3 not posted
   Federal regulation requires that the form be posted in a sufficient number of places to permit individuals engaged in licensed activities to observe it on their way to or from work.

2. Emergency Procedures not posted
   License condition requires posting in each area where unsealed radioactive material (RAM) is used or stored.

3. Authorized Personnel Only sign not posted
   This sign is conspicuously posted at the entrance of each laboratory in which RAM is used or stored.

4. Radioactive Materials sign not posted
   This sign is conspicuously posted at the entrance of each laboratory in which RAM is used or stored. It must also be posted on refrigerator/freezers used for RAM storage and on all radwaste containers, and in any location where RAM is present within a lab.

5. Radiation Area sign not posted
   Federal regulation requires posting to indicate radiation areas, i.e., areas, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 5 mrem in one hour at 30 cm from a radiation source or from any surface that the radiation penetrates.

6. Radiation Safety approved drain not posted
   Sinks which have been approved by Radiation Safety Staff via a written request for disposal of low–level RAM, must be posted with an appropriate sign and a daily log sheet, both provided by Radiation Safety Staff.
7. Airborne Radioactivity Area sign not posted

The Radiation Safety Program requires posting of this sign to indicate areas where the airborne activity concentrations are significant. Radiation Safety Staff must approve and post all fume hoods that will be used for significant amounts of volatile or potentially volatile radioactive materials, including $^3$H borohydride and $^{125}$I or $^{131}$I sodium iodide, and quantities of any other radionuclides that exceed specified amounts.

8. Exposure Levels exceeding 0.2 mR/hr not posted

The Radiation Safety Program requires posting of areas where an individual could be exposed to dose rates exceeding 0.2 mR/hr. Every effort should be made to effectively shield sources in any area such that the dose rate at 1 foot (30 cm) from the source or its shield does not exceed 0.2 mR/hr in excess of background. If the dose rate cannot be reduced, the sources should be located as far as practical from areas commonly frequented by personnel.

9. Notice of Violation not posted

Authorized Users with repeat deficiencies or an excessive number of penalty points are sent a "Notice of Violation" which must be posted in the lab until the following inspection. At that time Radiation Safety Staff will evaluate whether appropriate corrective actions have been taken and are effective, or whether deficiencies still exist. If all deficiencies have been corrected, Radiation Safety Staff will remove the Notice of Violation.

10. No written response to Radiation Safety Committee

When a Notice of Violation (NOV) is issued, the AU is required to provide, by a certain date, a written response explaining the cause of the deficiencies and describing corrective actions taken or planned.

11. Radiation Safety Manual and/or records inaccessible

The official Radiation Safety Manual is available on the Radiation Safety website at https://radsafety.wustl.edu. All Radiation Workers should have access to the Radiation Safety website, plus be trained to meet their responsibilities in the authorization-specific radiation safety procedures. All Radiation Workers must have access to the radiation safety records for the lab at all times. The lab records must be made accessible to any regulatory agency representatives upon request.

12. Lab members unaware of Manual/records location

All personnel, especially Radiation Workers, should know how to access the Radiation Safety Manual and pertinent radiation safety records at all times, and be able to direct regulatory representatives to them upon request.

13. Failure to accurately or timely provide RAM inventory

Each AU is requested to compile an inventory of radioactive materials in their possession as of June 30 of each year and to submit a completed, accurate inventory form within 15 days of the inventory date.
Training Requirements

14. Failure to timely conduct/document ALARA and/or Refresher training

An ALARA training session is required at least annually of all Authorized Users and their Radiation Workers. The session should include a review of NRC Form 3 and posted Emergency Procedures, Chapters 5, 9, & 11 of the Radiation Safety Manual, and information regarding the safe handling of RAM specific to your laboratory practices. A license condition requires that certain annual refresher training also be provided to individuals who handle RAM in their work. Radiation Safety Staff distributes general information concerning radioactivity and its safe use to research and laboratory medicine personnel every April with the ALARA training information. Both are usually completed together, and the documentation form must be returned to Radiation Safety by September 30. Several options are available for completion of these training sessions, including a Power Point slide presentation for use in lab meetings and the ability to log-on individually to an on-line version which is automatically reported to the Radiation Safety Staff via the University’s centralized training tracking system.

15. Radworker(s) not adequately trained in lab-specific or other procedures

As indicated in item 16, below, all Radiation Workers are expected to have successfully completed the required initial exams (or the current ALARA/Refresher annual training if they are a returning Radiation Worker), before being allowed to work with RAM without direct supervision by another Radiation Worker. In addition, each Radiation Worker must be trained in all authorization-specific and laboratory-specific procedures, and have performed these procedures under direct supervision of the Authorized User or the AU’s representative, before being allowed to handle RAM without this direct supervision.

16. Failure to pass applicable radiation safety exam(s) prior to working with RAM.

This would apply to any and all of the required examinations: Radiation Safety Exam (RSE), Exam for Handling Positron-Emitting RAM (PET), and Exam for Use of Self-Shielded Irradiators (IRR).

Internal & External Dosimetry

17. Personnel bioassay(s) delinquent

A urine bioassay is delinquent if the urine sample is not received at the Radiation Safety Office within three days of the initial RAM use and any subsequent uses of RAM in amounts requiring bioassay (refer to the bioassay levels specified in Table 10-3). Radiation Safety Staff (314−362−3476) must be notified when the anticipated initial RAM use is more than three days after receipt of the RAM package.

18. Personnel monitor(s)

a) delinquent — a monitor is delinquent if it is not received at the Radiation Safety Office within 15 days of the end of the wear period.

b) stored in a radiation work/storage area — as stated.

c) location of exposure records unknown — as stated.
d) not worn as intended — deficiencies include: not wearing a ring or other type badge while working with RAM (as appropriate), and wearing someone else's badge.

Radioactive Material Receipt & Transfer

19. RAM receipt records inadequate

Deficiencies include: (1) receipt documentation unavailable for inspection, (2) incomplete receipt documentation, e.g., the lower portion of the receipt document is not signed or dated (refer to Chapter 8).

20. RAM ordered/received directly from supplier

License condition requires that all research RAM including free samples, replacement shipments, etc., be shipped to the Radiation Safety Office (4550 Scott Ave, room 416), with a limited number of specifically approved exceptions.

21. RAM provided to unauthorized staff

License condition requires Authorized Users be approved by the RSC. Transfer between Authorized Users is permitted if each is authorized to use the transferred radionuclide and if they indicate the transfer in their accountability logs. It is recommended that Radiation Safety Staff immediately be notified of any substantial transfers, as information in the Radiation Safety database may need to be updated.

22. Unauthorized RAM removal from institution

Use of RAM is limited to locations specified in our NRC license, that is, only at WU/WUMC facilities listed for our license. Thus, RAM received under our NRC license can only be possessed and used at approved WU/WUMC facilities. Transfer of RAM to other locations approved under other licenses must comply with the requirements specified in 10 CFR 30.41. All transfers of RAM to other institutions, or from campus to campus, must be shipped by trained and approved Radiation Workers or by trained Radiation Safety Staff. Please contact Radiation Safety Staff (314-362-3476) for information on how to obtain training and approval to ship radioactive material.

Radioactive Material Use & Storage

23. Accountability records inadequate

Deficiencies include: (1) records incomplete or unavailable for inspection, (2) incomplete form, e.g., missing entries, initials, disposal date, etc.

24. RAM inadequately shielded; add lead/Plexiglas™

Gamma-emitter should be shielded with lead. Exposure levels should be less than 0.2 mR/hr at a distance of one foot from the shield. High energy beta-emitters should be shielded with Plexiglas™. Radwaste containers should be shielded on top as well as on the sides, as practical.

25. RAM improperly stored/transported

a) radwaste overflowing — overflowing radwaste can contaminate surrounding areas. A new radwaste container should be put into use before this occurs.
b) liquid radwaste needs secondary container — liquid RAM stored in containers other than those provided by Radiation Safety Staff should be kept in secondary plastic containers in case the original container leaks or breaks.

c) radwaste container(s) not capped — Lids must be secured on all radwaste containers at all times when the container is not in immediate use. The exception would be dry radwaste containers that are stored in covered outer containers. All liquid radwaste containers must be capped when not in use.

d) radwaste stored in improper container — All radwaste should be permanently stored in containers approved and provided by Radiation Safety Staff. RAM-labeled bench top plastic receptacles may be used while working with RAM, but must be emptied into an approved Radiation Safety container at the completion of the experiment.

26. Failure to request decommissioning prior to vacating/renovating RAM area, or before repair/disposal/transfer of equipment formerly used with RAM

Radiation Safety Staff must verify removal of all RAM and adequate decontamination of all surfaces before a RAM location can be renovated or closed out. Any labeled equipment used with RAM must also be inspected by Radiation Safety Staff prior to transfer, disposal or repair. Notify Radiation Safety Staff at 314−362−3476 to request assistance.

27. Use or storage of RAM in an unauthorized area

Deficiencies include the use or storage of RAM in an area not listed by the Authorized User in the currently valid application submitted to the Radiation Safety Committee.

28. RAM not secured against theft

a) unattended laboratory not locked — any laboratory where RAM is present must be kept locked when the lab is unattended if the RAM is not otherwise secured against unauthorized access. This includes rooms where radwaste is stored.

b) unlocked refrigerator/freezer or unattended RAM/radwaste in area of public access — refrigerators and freezers used for RAM storage must be kept locked if it is located in a hallway or in an unattended room. RAM and radwaste must never be left unsecured and unattended, especially in an area of public access – such as at the loading docks.

Safety Practices, Surveys & Supplies

29. Laboratory survey records inadequate

Deficiencies include but are not limited to: (1) no diagram of survey locations, (2) failure to specify room location, radionuclides in use or storage, equipment used for assay and monitoring, signature or initials of surveyor, and survey date, (3) failure to fulfill the weekly or monthly survey requirement, (4) failure to record wipe test results in dpm/100 cm², (5) failure to perform meter readings for gamma–emitters and record results in mrem/hr, and (6) failure to indicate corrective action and follow–up results when survey levels are greater than 200 dpm/100 cm² or 0.2 mrem/hr at 12 inches.
30. Failure to monitor personnel/area for contamination before leaving area

   After each experiment involving RAM, the work area should be monitored to identify any contamination. For most radionuclides the area should be scanned with the end window of a survey instrument. Hands, shoes, and clothing should be similarly monitored before leaving the area.

31. Personnel not wearing gloves and/or other proper PPE while working with RAM

   As stated, with PPE meaning “personal protective equipment”.

32. Failure to use approved fume hood as required

   Deficiencies include: (1) not using a fume hood for work involving significant activities of volatile RAM, (2) not using a fume hood or glove box when greater than the upper bioassay limits of RAM are used (refer to Table 10-3), and (3) use of a fume hood other than the one specified in the Authorized User's approved authorization.

33. Laboratory surfaces inadequately covered

   Laboratory surfaces must be covered with absorbent pads with the absorbent side up when liquid RAM is used.

34. Unmarked equipment/lab ware used for RAM

   Equipment used for RAM work such as seal–a–meals, gel dryers, glassware, etc., should be clearly labeled as radioactive. They must also then be a part of the required documented surveys.

35. Food/drink/smoking

   a) Door to break room not closed; or written procedure not in blue book – if a “break room” has been designated, the door separating it from any laboratory area must be closed while food or beverage is open or being consumed. Each laboratory director who wishes to have a “break room” must include in their Environmental Health and Safety Manual (i.e. “Blue Book”) a written procedure for the transport of covered food and beverage items through the lab.

   b) Evidence of eating/drinking/storing food or drink or smoking in laboratory — as stated.

36. Survey instrument inaccessible

   Deficiencies include: (1) failure to have an instrument in the lab or nearby and available for use when needed by lab personnel and (2) failure to have a survey instrument that reads exposure rates in mR/hr with a minimal capability of reading 0.1 mR/hr (or mrem/hr) or less for laboratories using gamma–emitters.

37. Survey meter not properly calibrated

   Must have a calibration certificate or sticker demonstrating that the meter has been calibrated within the past year by the vendor or by the Radiation Safety Office. Our calibration procedure is described in Chapter 13. Calibrations are due annually and after instrument repairs.
38. Lack of essential decontamination supplies

Laboratory personnel must have immediate access to essential decontamination supplies which include disposable gloves, absorbent pads, and surface and skin decontaminating solutions or foams.

Radioactive Material Waste Disposal

39. Radwaste disposal records inadequate

Deficiencies include: (1) not having an up-to-date record of approved drain disposal, (2) no record of amounts of activity kept in radwaste storage, (3) failure to label radwaste container as radioactive, (4) incomplete or incorrect information on radwaste transfer forms, and (5) failure to timely provide RAM drain disposal reports.

40. Improper packaging/segregation of radwaste

Deficiencies include failure to comply with the required procedure for radwaste preparation as specified in Chapter 14. Examples include: (1) no plastic liners in dry radwaste containers, (2) improper packaging of animal carcasses, (3) certain categories of radwaste packaged together, (4) radwaste transferred in glass containers or any containers other than those supplied or approved by Radiation Safety Staff, and (5) lead pigs in radwaste containers. Lead items should be monitored with a survey meter and, if not contaminated, given to Radiation Safety Staff in a sturdy box separate from any other radwaste.

41. Improper disposal of radwaste

Deficiencies include disposal of RAM in any way other than transfer to Radiation Safety Staff as described in Chapter 14, or as specifically approved by Radiation Safety Staff on a case-by-case basis, or as specified as a condition on the AU’s authorization. Under no circumstances is RAM allowed to be disposed via the regular trash. For assistance with radwaste related questions call Radiation Safety Staff at 314–362–3476.

42. OTHER

Any issue not otherwise specified on this inspection form.

19.4.2 Laboratory Self-Evaluation Form

Laboratory personnel/AUs are encouraged to use the Radiation Safety Laboratory Self-Evaluation form to assess their radiation safety compliance, and to identify and correct problems between routine Radiation Safety inspections. A quarterly frequency is suggested for such optional self-evaluations. If conducted, the self-evaluation should be retained in the lab notebook with other radiation safety records. Radiation Safety Inspectors will look at completed self-evaluation forms during their inspections, and will not issue deficiencies for self-identified compliance issues if they are not repetitive, corrective action was or is being taken, and the noncompliance is not significant from a risk perspective and does not, in the particular circumstances, pose an undue risk to public health and safety.
20. RADIATION SAFETY OFFICE CONTACTS

The Radiation Safety Office provides health physics support for all work involving radioactive materials (RAM) conducted at Washington University in St. Louis and the Washington University Medical Center (WU/WUMC). Our Directory of Services provides information on the primary individual(s) to contact for specific services or areas of the radiation safety program. Additional details on many areas of the radiation safety program are provided on our website: https://radsafety.wustl.edu.

The Radiation Safety Office 24-hour Emergency Cell Phone is 314-299-1322

For general information or questions, start with:

Office number: 314–362–3476
Email address: radsafety@wustl.edu

On-campus mailing address:

Campus Box 8053.

Off-campus mailing address:

Radiation Safety Office
Campus Box 8053
Washington University in St. Louis
660 S. Euclid Ave.
St. Louis, MO 63110

Physical location and non-RAM delivery address:

Radiation Safety Division
Washington University in St. Louis
4533 Clayton Ave.
St. Louis, MO 63110

RAM delivery address:

Radiation Safety Division
Washington University in St. Louis
4533 Clayton Ave.
St. Louis, MO 63110