Radiation Safety Standards for The Ohio State University

Radiation Safety Section of Environmental Health and Safety 2/11/2020

Table of Contents

	Section	Page
I.	Safety Culture and ALARA	2
II.	Administration of The OSU Radiation Safety Program	4
III.	Authorization For The Use of Radioactive Materials	10
IV.	Training Required For Approved Supervisors and Users	12
V.	Procurement of Radioactive Materials	13
VI.	Facilities For The Use and Storage of Radioactive Materials	14
VII.	Personnel Monitoring Programs	16
VIII.	Radiation Safety Inspections and Enforcement of State and Local Regulations	22
IX.	Procedures and Precautions For The Use of Radioactive Materials	34
Appen	dix A: Single Use Thresholds For Bioassay Participation	48
Appen	dix B: Glossary of Terms	49

- I. OSU Radiation Safety Culture and ALARA
 - A. OSU Radiation Safety Culture Policy Statement

Radioactive materials and radiation producing devices utilized in research and medicine at The Ohio State University are licensed by the Ohio Department of Health (ODH) and overseen by the University's Radiation Safety Committee and the Radiation Safety Section of Environmental Health and Safety. The ODH Bureau of Environmental Health and Radiation Protection (BEHRP) regulates the possession, use, handling, storage and disposal of radiation sources in order to maintain the radiation dose as low as reasonably achievable to the general population.

The following is the BEHRP's definition of Safety Culture:

"Safety Culture encompasses the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals (i.e., speed, profitability, staffing levels) to ensure protection of people and the environment."

Traits of a Positive Safety Culture

Experience has shown that certain personal and organizational traits are present in a positive safety culture. The following are traits of a positive safety culture:

Leadership Safety Values and Actions	Problem Identification and Resolution	Personal Accountability
Leaders demonstrate a commitment to safety in their decisions and behaviors.	Promptly and fully identify, evaluate, and correct safety issues commensurate with significance.	Take personal responsibility for safety.
Work Processes	Continuous Learning	Environment for Raising Concerns
Plan, implement, and control work activities so that safety is maintained.	Seek out opportunities to learn and implement ways to ensure safety.	Encourage raising safety concerns without fear of retaliation, intimidation, harassment, or discrimination.
Effective Safety Communications	Respectful Work Environment	Questioning Attitude
Maintain a focus on safety	Permeate trust and respect through the organization.	Avoid complacency and continually challenge exiting conditions to identify discrepancies that might result in inappropriate action.

OSU Radiation Safety Culture Policy Statement

The Ohio State University is committed to a positive safety culture and expects that individuals and organizations performing regulated activities involving radioactive material and radiation-generating devices will establish and maintain a positive safety culture environment.

Positive safety culture shall be an integral part of all regulated activities, including training and licensure of medical and research users; equipment operation and maintenance; and routine and emergency operating procedures. The intent of a positive safety culture, like all other aspects of our organization's radiation safety program, is to minimize radiation exposure to worker, patients and members of the public.

References:

Ohio Department of Health, Safety Culture Policy Statement - HEA 5506, 2012

U.S. Nuclear Regulatory Commission, Final safety culture statement, NRC-2010-0282. Federal Register 76:34773–34778; 2011.

B. As Low As Reasonably Achievable (ALARA)

ALARA is a general operating philosophy and a necessary basis for a program of maintaining occupational radiation exposures as low as reasonably achievable.

Even though current occupational exposure limits provide a very low risk of injury, it is prudent to avoid unnecessary exposure to radiation. The objective is to reduce occupational exposures as far below the specified limits as is reasonably achievable by means of good radiation protection planning and practice, as well as by management commitment to policies that foster vigilance against departures from good practice. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals should also be maintained at the lowest practicable level.

References:

U.S. NRC Regulatory Guide 8.10, Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable.

- II. Administration of The Ohio State University Radiation Safety Program
 - A. The University Radiation Safety Committee

The University Radiation Safety Committee (URSC) is mandated by the Ohio Department of Health (ODH), and is comprised of faculty and staff from The Ohio State University. The URSC oversees the Radiation Safety Program and acts as a liaison between faculty/staff/management and the Radiation Safety Section (RSS) of Environmental Health and Safety. The URSC is responsible for the control and direction of the Radiation Safety Program. The URSC reviews and approves all permits for the use of radioactive materials, makes policy decisions to be implemented by RSS and takes corrective actions when infractions of ODH rules are identified. The URSC has the authority to grant and revoke permission to use radiation-emitting sources at the facilities located at The Ohio State University, Columbus, Ohio; OSU Hospitals and James Cancer Center and affiliated facilities; at Stone Laboratory, Put-In-Bay, Ohio; Innovation Center; OARDC at Wooster, and at temporary job sites throughout the State of Ohio as authorized by various ODH-issued licenses.

1. The URSC's responsibilities are:

- a. Reviewing, approving, disapproving or tabling all applications for the use of radioactive materials at The Ohio State University.
- b. Maintaining awareness of regulations and license conditions pertaining to the Radiation Safety Program.
- c. Performing an annual review of routine operations of the Radiation Safety Section (RSS) of Environmental Health and Safety (EHS).
- d. Assisting the RSS with identification of problems, their causes and their solutions.
- e. Reporting all actions and recommendations to the President of the University through the Senior Vice President for Business and Finance.
- f. Developing, adopting and implementing policies and regulations specific to The Ohio State University for maintaining safety and compliance.
- g. Recommending actions requiring financial support. Following appropriate discussions with the URSC, it is the responsibility of the University to meet that support. Otherwise, the URSC must balance the resources provided for safety and compliance with the use of radiation emitting sources.
- 2. The URSC is comprised of three subcommittees: Medical Use Subcommittee, Crisis and Monitoring Subcommittee and the Audit Subcommittee.
 - a. Medical Use Subcommittee

The Medical Use Subcommittee (MUS) provides recommendations to the URSC regarding research and clinical applications to use radioactive materials with humans. The MUS has no independent authority; it recommends action to the URSC.

The MUS' responsibilities are:

i. Reviewing and recommending to the URSC actions on applications for medical use of radioactive materials in research with human subjects. Final approval by the URSC of these applications

requires final approval by the OSU Human Subjects Review Committee. Each radioactive investigational new drug must have an Investigational New Drug (IND) number.

- ii. Reviewing and recommending to the URSC approval of applications for medical use of radioactive materials in standard clinical procedures.
- Reviewing qualifications, training and experience of medical users and recommend approval to URSC for permission to participate in research and/or clinical procedures. Authorized User/Physicians must meet applicable requirements of OAC 3701:1-58.
- iv. Reviewing and recommending content of training programs for staff involved in conducting research with humans, and/or diagnosis and therapy of patients with radioactive materials.
- v. Reviewing routine departmental written directive reports and unusual incident reports such as medical events; identifying problems and recommending appropriate action to the URSC; following up on corrective actions.
- b. Crisis and Monitoring Subcommittee

The Crisis and Monitoring Subcommittee (CMS) provides recommendations to the URSC on resource needs and measures necessary to eliminate any perceived, or prevent any projected, non-compliance action by the ODH.

The CMS' responsibilities are:

- i. To recommend action deemed necessary and appropriate to remedy developing or actual issues of non-compliance involving committee-approved users.
- ii. To recommend measures necessary to eliminate any perceived, or prevent any projected, noncompliance action against the Radiation Safety Section of EHS by the Ohio Department of Health.
- iii. To identify resource needs and suggest possible solutions.
- iv. Act independently in an emergency situation of significant noncompliance or situations affecting the safety or welfare of the University or non-university communities. Actions taken by the CMS under emergency situations are temporary and require consideration within 30 days by the URSC. The URSC may approve, modify, extend or terminate any emergency action.
- c. The Audit Subcommittee (AS)

The Audit Subcommittee (AS) performs its own independent audit of the Radiation Safety program. The written annual report by the AS is provided to the URSC for review and final approval. The AS uses the Health Physicists/Radiation Safety Officer internal audit as a supplemental document

The program audit may consist of, but not necessarily be limited to, the following activities (different items may be selected each year):

i. Review of all radiation safety records with particular attention to those required by state regulations.

- ii. Review of selected portions of routine operations for compliance with regulations, rules and licenses.
- iii. Review of reports submitted by the URSO.
- iv. Review of the results of State of Ohio inspection reports.
- v. Review of adequacy of the University's management control system.
- vi. Review of Approved Supervisor's applications for one-year renewals.
- vii. Review of NRC-issued amendments of license for use of materials.
- viii. Review of procedures for controlling and maintaining radioactive materials inventories, procurement of radioactive material, individual possession limits, total license possession limits, transfer of radioactive materials within the University, and transfer of radioactive material to persons outside the University.
- B. Human Subjects Review Committee

Human Subject Review Committee is responsible for the review and approval of the research use of ionizing radiation in research involving human subjects. The active members of the Medical Use Subcommittee serve as the HSRC.

C. Radiation Safety Section of Environmental Health and Safety

Radiation Safety is responsible for insuring the safe use and the disposition of all sources of radiation in accordance with the laws, rules and regulations established by the Federal and State government and their agencies including, but not limited to, the Ohio Department of Health, the U.S. Nuclear Regulatory Commission, the Department of Health and Human Services (especially the Food and Drug Administration), the U.S. Department of Transportation and the U.S. and Ohio Environmental Protection Agencies.

1. University Radiation Safety Officer is responsible for the daily administration and operation of the Radiation Safety Program, drafting licenses and other regulatory documents, identifying program needs, advising administration of changes in regulation that will impact on the University, and providing administration with information concerning Radiation Safety Program activities. The URSO is a member of the URSC, may serve on subcommittees, and is the chief liaison between EHS and the URSC.

Revisions to the radiation safety program that do not require an amendment to our broad scope license can be implemented provided the change has been reviewed and approved by the Radiation Safety Officer and licensee management and the affected individuals are instructed on the revision before the changes are implemented. Revisions are in accordance with OAC 3701:1-58-13.

2. Radiation Safety Section Staff are assigned program responsibilities by the URSO consistent with license requirements and Ohio Department of Health (ODH) regulations. The section is responsible for insuring the safe use and disposition of all sources of ionizing radiation in accordance with the laws, rules and regulations established by Federal and State governments and their agencies. Health Physicists implement license requirements and ODH regulations. Staff responsibilities include:

- a. Maintaining a system of review and providing technical evaluations of all applications submitted by faculty of The Ohio State University and making recommendations to the URSC.
- b. Establishing and maintaining controls and records regarding the purchase, receipt, distribution and disposal of radioactive materials.
- c. Inspecting all laboratories that contain radioactive material or radiation-producing equipment to insure compliance with federal and state laws, rules, regulations, and University policy and procedures pertaining to the use of radioactive materials.
- d. Maintaining all Federal and State licenses associated with source, byproduct and special nuclear materials, and assuring that they are current.
- e. Providing advice and assistance to users of radioactive materials in obtaining radioactive materials for instruction, research and patient care.
- f. Calibrating, inspecting and certifying the portable instruments used by the section and by users.
- g. Establishing procedures for, and assuring the safety of, personnel who are involved in the care of patients being treated or diagnosed with radioactive substances.
- h. Providing training to users of radioactive materials and assuring that they are qualified to handle such materials.
- i. Maintaining a program to monitor the exposure of personnel engaged in the use of radioactive materials or radiation producing equipment to insure that permissible levels of exposure are as low as reasonably achievable.
- D. The Approved Supervisor
 - 1. Approved Supervisors are faculty or staff members with authorization from the University Radiation Safety Committee to use and possess radioactive materials. It is the Approved Supervisor's responsibility to assure compliance with regulations in his/her laboratories; this cannot be delegated. Primary responsibilities include:
 - a. Insuring a commitment to the philosophy to keep radiation exposures As Low As Reasonably Achievable (ALARA) in keeping with the University's commitment to the ALARA concept.
 - b. Insuring every user has been instructed in, or has read, the Ohio Administrative Code (OAC) 3701:1-38, OAC 3701:1-58 (if use of radionuclides will be in humans) and the Radiation Safety Standards for The Ohio State University. All personnel should be prepared to make such a declaration to any State of Ohio representatives.
 - c. Insuring all users have successfully completed the OSU Radiation Safety Course and required in-service training prior to beginning work under a permit.
 - d. Notifying Radiation Safety immediately of any new individuals who begin work after an application has been submitted so those individuals may receive approval for the use of radioactive materials.
 - e. Controlling contamination in areas of radioactive materials use.
 - f. Maintaining records of receipt and disposition of all radioactive materials.

- g. Insuring the procedures and precautions as outlined in an approved permit are followed.
- h. Insuring that radioactive materials are secured from unauthorized removal or access.
- i. Maintaining postings of form ODH Notice to Employees and other appropriate caution signs, labels and signals as may be required by the Ohio Administrative Code rule 3701-38-18.
- 2. An approved supervisor can either be an active or an inactive. An active approved supervisor maintains an inventory of radioactive material. An inactive approved supervisor has disposed of or transferred all radioactive material and has closed out all laboratory facilities for the use of radioactive materials. An inactive approved supervisor can easily return to active status by completing the following:
 - a. Contact Radiation Safety.
 - b. Review previous approval of radionuclides, procedures and training. Amend as necessary.
 - c. Participate in the supervisor evaluation conference, provide in-lab training to all users of radioactive materials and insure successful completion of the OSU Radiation Safety Course by all users.

A Laboratory Compliance Officer will inspect and post the laboratory facilities, and review all record keeping and safety requirements. Thirty days after the laboratory orders radioactive materials, Radiation Safety will perform a mock inspection of the approved supervisor. No points will be assessed during the mock inspection.

E. The User

A user is an individual who handles or uses radiation-emitting sources. Radioactive materials are to be used in accordance with The Ohio State University's Radioactive Materials License, the Ohio Department of Health regulations and guidance, and other applicable regulatory and/or oversight agencies. All users of radioactive material at The Ohio State University are responsible for competing required trainings and readings at the required frequency, to ensure his or her qualifications remain current. All users of radioactive material are responsible for using radioactive materials in a safe manner that is consistent with the provisions of this manual. Users must comply with all requirements of this program and those established by the permit of the Approved Supervisor or Authorized User. Each individual user is responsible for implementing appropriate ALARA practices, maintaining control of radioactive materials, reporting unusual events, reporting loss of theft of radioactive materials, and promoting a positive safety culture.

- III. Authorization For The Use of Radioactive Materials
- A. Permits for the Use of Radioactive Materials (non-human use)

To obtain authorization for the use of radioactive materials from the University Radiation Safety Committee (URSC), an RS-1 form, Permit for the Use of Radioactive Materials, must be completed. This form, and others that may be required, are available from the EHS web site, www.ehs.ohio-state.edu. The permit must undergo a pre-review by Radiation Safety prior to final submission to the URSC. The Approved Supervisor will receive a written notification of the permit's status after URSC review.

- 1. The URSC may take one of the following actions:
 - a. Final Approval The Approved Supervisor has approval for the purchase and use of radioactive materials as outlined in the RS-1 form.

- b. Conditional Approval The URSC has identified specific conditions which must be met through communication with Radiation Safety before final approval can be granted by Radiation Safety.
- c. Tabled Action on the permit has been deferred due to lack of sufficient information being supplied by the Approved Supervisor. Radiation Safety will inform the Approved Supervisor of the specific questions raised by the URSC. Response to the questions will be reviewed by the URSC at the next meeting.
- d. Disapproved The URSC has denied authorization for the purchase and use of radioactive materials. These permits may be resubmitted after consultation with Radiation Safety and/or URSC members. Disapproval on one permit will not influence committee action on subsequent permits.
- 2. It is possible for an individual to receive temporary authorization for the use of radioactive materials prior to the URSC review of the permit. Criteria for temporary approval of new approved supervisors are:
 - a. Final submission of the RS-1 Form and other RS forms as necessary (i.e. RS-2, RS-5, RS-6). This includes the pre-review process with the designated Laboratory Compliance Officer.
 - b. Documentation of the in-laboratory training provided to all users.
 - c. Completion of the Supervisor Evaluation Conference.
 - d. Successful completion of the OSU Radiation Safety Course by the individual applying for approved supervisor status and all lab personnel.
 - e. Once temporary approval has been granted, the designated Laboratory Compliance Officer will inspect and post the laboratory facilities. The Laboratory Compliance Officer will also review all record keeping and safety requirements. Thirty days after the laboratory orders radioactive materials, Radiation Safety will perform a mock inspection of the approved supervisor. No points will be assessed during the mock inspection.
 - f. Temporary approval will be in effect until the next scheduled URSC meeting.
- 3. Permits For The Use of Sealed Sources

Individuals using only sealed sources of radioactive material in research must complete an Application For the Use/Storage of Radioactive Sealed Sources. At the discretion of Radiation Safety, this request can be processed by RSS and does not need to be reviewed by the URSC.

B. Permit Renewals

Permits must be renewed annually. Radiation Safety will request a review of your permit summary (generated by RSS), update of users and documentation of the annual in-laboratory training sessions.

C. Applications for Amendment

Changes to current authorizations can be made by submitting a completed RS-7 form, Request for Amendment to Approved Permit. This form can be used for the addition of chemical groups, for activity increases, to add or delete locations of use, for procedural changes and for radionuclide additions. The form is available at the RS website, <u>www.ehs.ohio-state.edu/radsafety</u>.

IV. Training Required For Approved Supervisors and Users

A. The Ohio State University Radiation Safety Course

All Approved Supervisors and Users are required to successfully complete the OSU On-Line Radiation Safety Course prior to receiving authorization for the use of radioactive materials in research. In addition, all personnel who work within a posted laboratory shall take the on-line Radiation Safety Course. Individuals involved in the medical use of radioactive materials in humans must participate in the OSU Human-Use Radiation Safety Course.

B. Annual In-Laboratory Training Program

Approved Supervisors must provide for the initial and the annual training of users of radioactive materials. User's comprehension must be evaluated and documented by the Approved Supervisor. The training and evaluation must emphasize the particular techniques used in projects approved by the URSC, radiation safety practices appropriate to the approved projects, and responses to spills and personnel contamination. The training should emphasize performance-based methods of teaching and evaluation. The Approved Supervisor may designate the training to senior experienced laboratory personnel.

The content of the training program is reviewed by the University Radiation Safety Committee. Documentation of the annual in-laboratory training is required to be submitted to Radiation Safety for all new users and as part of the one-year renewal process.

C. Supervisor's Evaluation Conferences

Approved Supervisors must participate initially in an evaluation conference with the designated Laboratory Compliance Officer. The discussion will emphasize site-specific implementation and operation of the Radiation Safety Program, survey techniques, emergency plans, low-level radioactive waste, ALARA, maintenance activities specified in the permit and the safety instruction to be given to users by the Approved Supervisor.

V. Procurement of Radioactive Materials

A. Ordering Radioactive Materials

Radioactive materials are ordered through University Purchasing, Hospitals Purchasing and The Ohio State University Research Foundation (OSURF). All orders of radioactive material must use the on-line procurement system and must be approved by Radiation Safety. Free gifts must also be pre-approved by Radiation Safety. Procurement cards, standing orders and blanket orders cannot be used to acquire radioactive materials.

- 1. The following information must appear on each requisition:
 - a. Org, Fund and the radioactive materials account number, 61212
 - b. Radionuclide and chemical form (e.g. P-32 dATP)
 - c. Vendor and vendor catalogue number
 - d. Quantity of items to be ordered
 - e. Activity (microcuries or millicuries)
 - f. The Approved Supervisor' name
 - g. Contact person name and phone number
 - h. Name of person using the radioactive material
 - i. Proper "location" address (room and building)

Please note that all radioactive materials must be shipped to Radiation Safety. RSS staff will process the package and deliver it directly to the laboratory.

B. Transfer of Radioactive Materials between OSU-Approved Supervisors

Transfers to and from another Approved Supervisor are allowed provided both Approved Supervisors have URSC approval for the same radionuclide and chemical group. Documentation of the transfer is through the on-line inventory system, EHS Assist. EHS Assist will only allow transfers to authorized Approved Supervisors.

- C. Transfer of Radioactive Materials between Other NRC/Agreement State Licensees
 - 1. Transfers from another licensee are allowed provided the OSU recipient has approval for the radionuclide and chemical form. Prior approval from RSS is needed. The material must be delivered to Radiation Safety. Radiation Safety will deliver the material to the posted laboratory.
 - Transfers to another licensee are allowed provided OSU has a copy of the recipient's NRC or Agreement State-issued license. Radiation Safety must be contacted before preparing a shipment of any radioactive material to another licensee. Radiation Safety must provide shipping papers and verify the material is packaged according to the United States Department of Transportation regulations.

VI. Facilities For The Use and Storage of Radioactive Materials

A. Laboratory Facilities

The Approved Supervisor is responsible for providing adequate facilities and equipment for the proposed use of radioactive materials. The facilities and equipment must protect the health and safety of all users, ancillary personnel and the general public. The URSC recognizes three Facility Types: A, B and C. Determination of the Facility Type required is based on the proposed use, the radio-toxicity of the material and the activity requested. Other influencing factors the URSC considers when evaluating the adequacy of particular facilities include experience of the users, duration of the proposed work, chemical and physical forms of the materials involved.

- 1. Laboratory Classifications
 - a. Type C laboratories are basically a good chemistry laboratory. Specific requirements related to the use of radioactive materials are:
 - i. Operations limited to those with low potential for airborne contamination.
 - ii. Absorbent paper should be used over work surfaces.
 - iii. Normal room ventilation sufficient or may be complemented with fume hood.
 - iv. Waste must be properly controlled.
 - b. Type B laboratories are normal radioisotope laboratories. They must meet the requirements of a Type C facility in addition to the following:
 - i. Appropriate radiation detection instrumentation must be available.
 - ii. Walls should be smooth and floor surfaces should be nonporous.
 - iii. Working surfaces should be smooth and non-absorbent and should be covered with disposable materials when in use.
 - iv. A fume hood or glove box should be available and negative air pressure maintained.
 - v. If applicable, remote handling tools should be available.
 - vi. Shielding and appropriate support for shielding should be considered as required.

- c. Type A laboratories are designed to handle high hazard radioisotopes and must meet the requirements of a type B facility in addition to the following:
 - i. Processes involving risks of air contamination should be carried out in completely enclosed systems, glove boxes, or hot cells under negative pressure and provided with High Efficiency Particulate Air (HEPA) filters and transfer boxes.
 - ii. Emergency procedures specific to the work location must be posted.
 - iii. Radioactive substances should be stored only in a special area equipped with appropriate shielding and ventilation.
- 2. Status of Laboratory Facilities

Laboratories posted for the use of radioactive materials in non-sealed forms are either active laboratories or storage-only laboratories.

- a. Active laboratories are facilities posted for the open manipulation and handling of radioactive materials. Facilities designated for the storage of low-level radioactive waste are considered an active laboratory and must be surveyed by the Approved Supervisor at least monthly.
- b. Storage-Only laboratories are facilities posted for the storage of radioactive materials. Storageonly laboratories are required to maintain inventory records, security of radioactive materials and proper postings for radioactive materials. Open manipulation of radioactive materials is prohibited.

VII Personnel Monitoring Programs

There are various ways to measure an individual's exposure to radiation. These methods measure internal and external exposure.

The most common methods to measure for external exposure are whole body and ring dosimeters or badges. In order to detect and evaluate exposure to external radiation, dosimeters are issued to individuals who are likely to exceed 10% of the dose limits set for occupational workers.

The most common methods to measure for internal exposure are thyroid and urine bioassays.

- A. External Exposure
 - 1. Requirements for Individual Monitoring Devices (Badges)

In order to detect and evaluate exposure to external radiation, individual monitoring devices will be issued to individuals who are likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the applicable limits. The limits are:

	Dose Limit (rem/year)
Adult Worker	
Total Effective Dose Equivalent	5
Total Organ Dose Equivalent	50
Lens of Eye	15
Extremities/Skin	50
Embryo/Fetus	
Declared Pregnant Worker	Total Effective Dose Equivalent 0.5 rem per 9 months
Minor	
< 18 years of age	10% of Adult Limits

2. Pregnant Workers

A pregnant radiation worker may voluntarily declare her pregnancy in writing to the Radiation Safety Section of EHS (see Form and Instructions for RS-13, Declaration of Pregnancy). Radiation Safety will review the RS-13 form and recommend a personnel monitoring program based on the information supplied in the Declaration of Pregnancy form. Upon declaration of pregnancy, the radiation dose to the embryo/fetus during the entire pregnancy will not be allowed to exceed 0.5 rem Total Effective Dose Equivalent (TEDE).

3. Minors

If an individual under the age of 18 will be handling radioactive material or will be frequenting laboratories posted for the use of radioactive materials, an RS-14 form, Acknowledgment Of Radiation Exposure Limitations For A Minor, must be completed and submitted to the Radiation Safety Section of EHS. Radiation Safety will review the RS-14 form and recommend a personnel monitoring program based on the information supplied in the Acknowledgment Of Radiation Exposure Limitations For A Minor. The radiation dose to the minor will not be allowed to exceed 500 mrem TEDE per year.

4. Categories of Users for which Individual Monitoring Devices (whole body and ring badges) are required:

Radiation Emitter	Minimum Activity Used At Any One Time (mCi)	Example Radionuclides
I-125*	10	I-125
Other gamma emitters ⁽¹⁾ gamma constant ≥ 0.2	1	I-123, Mn-54, In-111, Rb-86
Gamma constant< 0.2	10	K-42, Cr-51, Rb-86, Tc-99m, Cd-109, I-129, Ce-141
B emitters ⁽²⁾ $E_{max} \ge 0.2$	10	P-32, Sr-90/Y-90, P-33, Ca-45
E _{max} < 0.2	Not applicable, no badge used	H-3, C-14, S-35
Beta-Gamma emitters	Lowest of above applicable activities	I-131, Na-22, Zn-65

* I-125 is listed separately from other gamma emitters because the gamma dose rate constant varies above and below 0.2 (mrem/hr)/mCi depending upon the source of reference.

5. Other Badge Requirements

Some individual monitoring devices are issued due to license conditions apart from the Ohio Administrative Code. Therefore, the following requirements are noted:

- a. Minors and declared pregnant workers when there is a reasonable possibility for measurable exposure. This includes working in a room where radioactive materials detectable with a dosimeter are being used
- b. Individuals operating irradiators or other facilities as may be required by the appropriate license
- c. Full time employees of the Nuclear Reactor Laboratory and other radiation workers visiting the NRL expected to exceed 10% of their occupational dose limit
- d. Division of Radiation Medicine personnel handling radioactive materials
- e. Division of Nuclear Medicine personnel handling radioactive materials
- f. Regular personnel of the Radiation Safety Section of Environmental Health and Safety expected to exceed 10% of their occupational dose limit
- g. Patient care coordinators (nurses) and patient care associates involved in the care of temporary brachytherapy implant patients or therapeutic radioiodine patients

- h. Users of x-ray generating devices or state-registered radioactive material likely to receive a dose in any calendar quarter in excess of 10% of applicable limits
- i. Individuals entering a high or very high radiation area
- j. Users operating under requirements from ODH-issued licenses, the University Radiation Safety Officer, and/or the University Radiation Safety Committee. Factors which may be considered typically include long handling times or lack of experience of handlers
- 6. Obtaining Dosimeters
 - a. If an individual is joining a laboratory group already supplied with dosimeters, a copy of a badge requisition (RS-10) can be obtained from the Badge Coordinator. The form must be completed, signed and returned to Radiation Safety. Upon receipt of the completed requisition, and completion of the online Radiation Safety Course, a temporary badge can be assigned until the permanent badge has been received.
 - b. If an individual or group needs to initiate dosimeter service, contact Radiation Safety for the appropriate forms. New badge groups, or "series", will not be started until Radiation Safety has received a completed RS-12: New Series Information and Billing Form, available from the Radiation Safety web site, <u>www.ehs.osu.edu</u>
- 7. More Information Relating to Dosimeters
 - a. Store dosimeters where they will not inadvertently be exposed to radiation, excessive heat or moisture. Badges should only be kept at work, never taken home. Badges are not to be stored on lead aprons.
 - b. Wear only the dosimeter(s) assigned to you.
 - c. Wear the whole body badge on the trunk of your body at the point where it is most likely to receive maximum exposure. Be consistent in wearing the badges on the same area of the body.
 - d. Wear ring badges under the glove on the hand that will receive the highest exposure with the dosimeter name label side toward the palm.
 - e. If wearing a lead apron, wear the badge on your collar outside of the apron. If you have two dosimeters, then the whole body badge is worn under the lead apron and the second dosimeter (designated as a collar badge) should be worn on your collar outside of the apron.
 - f. If appropriate, declared pregnant workers will be issued a fetal dosimeter along with their normal dosimeter for the duration of their pregnancy.
 - g. Dosimeters are exchanged the first day of each calendar quarter (i.e. January 1, April 1, July 1 and October 1). Upon receipt of the new dosimeters, immediately turn in the previous dosimeters to your designated badge coordinator. Dosimeters on a monthly exchange frequency are exchanged on the first day of each month.
 - h. If you leave the University, return your dosimeters to your designated badge coordinator. The badge coordinator must inform Radiation Safety to delete the dosimeters of all individuals who have left their series and return dosimeters immediately to Radiation Safety.

- i. Do not wear your dosimeter when you undergo medical exams or therapies which involve radiation exposure. This includes medical and dental x-rays.
- j. If you suspect that you or your dosimeter may have been overexposed or contaminated, contact Radiation Safety immediately.
- B. Internal Exposure
 - 1. Requirements for Bioassays

Urine and thyroid bioassays are required if an individual is expected to exceed 2% of an Annual Limit on Intake (ALI). An ALI is defined in OAC 3701:1-38-01 (A) (16) as the derived limit for the amount of radioactive materials taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 5 rems, or a committed dose equivalent of 50 rems to any individual organ or tissue.

- 2. Urine Bioassays
 - a. All radiation workers in a laboratory are required to submit monthly urine bioassays if the laboratory uses an unsealed or loose form on a yearly basis a quantity of radioactive material \geq 2000 ALI. For laboratories using multiple radionuclides the need for urine bioassays is determined by whether the sum of the laboratory's requested yearly activity for each radionuclide divided by 2000 ALI \geq 1. Urine bioassays are recommended for non-radiation workers in these labs.
 - b. A radiation worker is required to submit a urine sample within 72 hours for bioassay, if the individual's uses an unsealed or loose form at any one time a quantity of radioactive material \geq 100 ALI.
 - c. Urine bioassays will also be submitted in accordance with requirements from the University Radiation Safety Committee.
- 3. Thyroid Bioassays

a. All radioiodine workers are required to have a thyroid bioassay performed if the location uses an unsealed or loose form of radioiodine in accordance as listed below:

	Activity Handled in Unsealed Form Making Bioassay Necessary	
Type of Operation	Volatile or Dispersible	Bound to Nonvolatile Agent
Processes carried out in open room or bench, with possible escape of iodine from process vessels	1 mCi	10 mCi
Processes with possible escape of iodine carried out within a fume hood of adequate design, face velocity, and performance reliability	10 mCi	100 mCi
Processes carried out within glove boxes, ordinarily closed, but with possible release of iodine from process and occasional exposure to contaminated box and box leakage	100 mCi	1000 mCi

b. Thyroid Bioassays are required for individuals post iodination or post manipulation of unsealed radioiodine in accordance with the following schedule:

Isotope	Minimum	Maximum
¹²³ I	6 hours	24 hours
124 I	6 hours	7 days
125 I, 129 I, 131 I	6 hours	14 days

c. The term "manipulation" as used here includes transfers from stock containers. Thyroid bioassays are recommended for non-radiation workers in these areas as well. Individuals handling or administering sealed capsules will not be required to perform a bioassay.

d. Thyroid bioassays will be performed after any incident in which there exists the possibility of internalization of radioiodine. Bioassays may be required at any time at the discretion of the RSO or at the direction or the University Radiation Safety Committee.

C. Investigational Levels and Overexposures

1. Dosimeters

a. Investigational Level I Notification

If an individual whole body badge receives 125 mrem deep dose equivalent (DDE) or more, and if a ring badge receives 1250 mrem shallow dose equivalent (SDE) or more in a quarter, Radiation Safety will notify the individual in writing.

b. Investigational Level II Notification

If an individual whole body badge receives 375 mrem (DDE) or more, or if a ring badge receives 3750 mrem SDE or more in a quarter, Radiation Safety will notify the individual and his/her supervisor in writing. The Radiation Safety Section will investigate the exposure and implement reasonable corrective actions to avoid or reduce additional exposure.

c. When a protective apron is worn and collar and whole body badges (or collar only) are assigned to the individual, the effective dose equivalent (EDE) for external radiation shall be determined by the dosimetry vender and will be used for Investigational Level I and II reporting.

2. Bioassays

a. Investigational Level I Notification

If an individual has an intake of >1% but <10% of the smallest Annual Limit on Intake (ALI), the University Radiation Safety Officer and the URSC will be informed.

b. Investigational Level II Notification

If an individual has an intake of >10% of the smallest Annual Limit on Intake (ALI), the Radiation Safety Section will investigate the exposure and implement reasonable corrective actions to avoid or reduce additional exposure.

D. Planned Special Exposures

OSU may authorize in accordance with OAC 3701:1-38-12 (F) an adult worker to receive a Planned Special Exposure (PSE), which is an infrequent exposure to radiation, separate from and in addition to the annual dose limits.

E. Records

1. Records of Individual Monitoring Results

The Radiation Safety Section maintains the records of individual monitoring results for all individuals for whom monitoring is required, doses received during planned special exposures, accidents and emergency conditions. If an evaluation shows that the individual is not likely to exceed 10 % of any applicable limits, there are no record keeping or reporting requirements.

a. Quarterly summary reports for each badge are sent to Radiation Safety and to each series for all individuals issued dosimeters.

- b. "Occupational Exposure Record for a Monitoring Period" Forms (NRC Form 5 equivalent) are annual reports of an individual's occupational radiation exposure. Form 5s are sent to the wearers.
- 2. Determination of Prior Occupational Dose

For those individuals for whom monitoring is required, determination of current year exposure at other facilities is required. To document determination of current year exposure, the individual must provide a Lifetime Occupational History Form signed by the individual or a statement that includes the names of all facilities that provided monitoring for occupational exposure to radiation during the current year and an estimate of the dose received.

In addition, an attempt will be made to obtain the records of lifetime cumulative occupational radiation dose.

3. Records of Planned Special Exposures

Records of each PSE are kept in accordance with OAC Chapter 3701:1-38-20.

VIII. Radiation Safety Inspections and Enforcement of State and Local Regulations

A. Radiation Safety Laboratory Inspection Program

The Radiation Safety Section of Environmental Health and Safety performs semi-annual performance-based inspections of all Type B, C and storage-only laboratories posted for the use of radioactive materials. Type A laboratories are inspected monthly.

Items of Compliance

- 1. Performance-Based Assessment of Non-radioactive Material Worker
 - a. Completion of the on-line Radiation Safety course.
 - b. Aware of the OSU policy that requires radioactive material to be secured from unauthorized access or removal.
 - c. Aware of laboratory specific procedures for the receipt and storage of packages containing radioactive material.
 - d. Aware of the prohibition of eating, drinking, smoking, mouth pipetting, or applying cosmetics in laboratories posted for the use or storage of radioactive material.
 - e. Aware of where radioactive material is used and stored in the laboratory.
 - f. Aware of where the spill/personnel contamination emergency response procedure is posted.
- 2. Performance-Based Assessment of Radioactive Material User
 - a. Demonstrate appropriate survey meter use.
 - b. Demonstrate appropriate techniques for smear wipe surveys.
 - c. Implementation of ALARA.
 - d. Explain the lab-specific procedures for ordering radioactive material.
 - e. Explain lab-specific procedures for receipt, storage, and security of radioactive material packages.
 - f. Articulate and/or demonstrate proper procedures to follow if there is a spill of radioactive material or a personnel contamination incident.
 - g. Explain the lab-specific procedures for handling low-level radioactive waste.
 - h. Explain lab-specific personnel monitoring requirements.
 - i. Aware of proper postings and labeling requirements.
 - j. Proper use of EHS Assist
 - k. Explain the URSC-approved procedures for handling animals used with radioactive material.

3. Radiation Safety Inspection

a. All area surveys have been completed during periods of use and documentation is complete.

Frequency of laboratory surveys is based on the total activity used and must be performed at the frequency as specified by the committee-approved permit. If use is $< 100 \,\mu\text{Ci/month}$, surveys are required at least monthly. If use is $\geq 100 \,\mu\text{Ci/month}$ surveys are required at least weekly. Changes from weekly to monthly surveys must be by an approved RS-7 Form. Surveys do not need to be performed if there has been no use since the previous survey.

Results of smear wipe surveys and direct contamination surveys (survey meter surveys) must be maintained in units of disintegrations per minute (dpm). Areas with loose contamination is excess of $200 \text{ dpm}/100 \text{ cm}^2$ must be decontaminated and re-wipe results documented.

Radiation dose rate surveys shall be documented in units of mrem/hr. Dose rate surveys are normally performed with an ion chamber. Most laboratories using only beta emitting nuclides are not required to perform dose rate surveys.

Laboratory surveys must be documented on the RS-15 Form, Laboratory Survey Results (or equivalent).

b. All radioactive material is secured from unauthorized access or removal.

All laboratories or areas in which radioactive material is used or stored must be either under constant surveillance by laboratory works in the lab, or be locked when constant surveillance is not possible. Radioactive material must be secured from unauthorized access or removal.

c. Physical inventory accounted for all material on the inventory list.

Inventory records are required to be maintained by active and storage only laboratories. Inventory records are maintained on a web-based inventory system, EHS Assist. Radiation Safety will perform a physical inventory of all stock vials during an inspection.

d. Waste containers are labeled correctly and disposals are made in the appropriate manner.

Waste issues reviewed during a laboratory inspection include hot sink disposals, sharps in the solid waste, appropriate postings, storage of waste, and proper record keeping. Information on low-level radioactive waste can be found on our website. Radiation Safety will perform a physical inventory of all waste containers during an inspection.

e. Radiation survey instruments are within current calibration frequency and are appropriate for the radionuclides used.

Survey instruments are required to be calibrated at least annually and after any repair or other service performed by either the manufacturer or OSU. The Approved Supervisor is responsible for obtaining/borrowing an equivalent survey instrument when repair or calibration is being performed on the laboratory survey meter.

f. All personnel monitoring guidelines are followed as required.

Compliance of individuals required to wear dosimeters or participate in the OSU bioassay programs will be reviewed.

g. All laboratory radiation safety training is current.

Documentation of the in-laboratory training program on the RS-6 Form must be submitted with the one-year renewal of the permit and initially for new users to the laboratory. Documentation must also be maintained in the laboratory for review during an inspection. A 70% is needed to pass the written and performance-based evaluation.

All users and Approved Supervisors of radioactive material must successfully complete the on-line Radiation Safety course prior to using radioactive materials. In addition, all personnel who work within the posted laboratory must also take the on-line course.

All Approved Supervisors must participate in the initial Supervisor Evaluation Conference.

h. All laboratory postings and equipment labels are appropriate.

All laboratories are to be posted with appropriate caution signs, labels, and Notice To Employees as provided by RSS. All equipment used with radioactive material must be labeled with the trilobe symbol and/or "Caution, Radioactive Material" sign. All containers of radioactive material (e.g. stock vials, labeled proteins, or probes) must be labeled or marked with the radionuclide present, activity, date, and radiation level (if appropriate).

Radiation symbols or the wording "Caution, Radioactive Material" must be removed from shipping containers (after a smear wipe survey demonstrates no contamination) prior to disposal in the normal waste stream.

i. Personnel protective equipment is available and used as required.

All users must wear lab coats, gloves, and protective eyewear when manipulating radioactive material.

Appropriate shielding must be used.

Absorbent pads, trays, or bench covers must be used.

j. Evidence of eating, drinking, smoking, use of cosmetics, and mouth pipetting.

Eating, drinking, smoking, use of cosmetics, and mouth pipetting or evidence of these activities is prohibited in all posted areas, including storage only laboratories. Chewing gum and food preparation are also prohibited in posted laboratories as is the presence of food in refrigerators or freezers in active or storage only facilities.

k. Packaging of Radioactive Materials for Transportation (on-campus)

Radioactive material must be transported in closed containers. Containers with liquids must be surrounded with enough absorbent material to contain twice the volume of free liquid.

 Contamination discovered during a Radiation Safety audit in excess of 2,200 dpm/100 cm² may result in points assessed. Areas with contamination in excess of 200 dpm/100 cm² must be decontaminated and re-wipe results documented. m. Administrative items are in compliance.

Administrative items include following URSC-approved procedures; reporting spills; permit renewals; performance of maintenance surveys; documentation of corrective actions to deficiencies through EHS Assist; and completion of written corrective action plans. Deficiencies are closed once EHS personnel or the URSC have accepted the corrective actions.

n. Points Assessed

Items of Non-compliance	Points Assessed
Radiation worker is unable to articulate and/or demonstrate proper procedures to follow if there is a spill of radioactive material or a personnel contamination incident.	5
A laboratory under suspension used radioactive material.	5
Radiation worker is unable to demonstrate appropriate survey meter use. All radiation workers must be able to demonstrate which meter and detector is appropriate for the radionuclides in use; perform a battery check; and survey the work area.	4
Radiation worker is unable to demonstrate appropriate techniques for smear wipe surveys including locations to survey; avoiding cross-contamination of smear wipes; preparation of smear wipes for counting; interpretation of results; and documentation.	4
Removable contamination $>22,000 \text{ dpm}/100 \text{ cm}^2$.	4
All surveys were not performed during periods of use.	4
Radioactive material found unsecured (quantities > Appendix A of OAC 3701:1-38-18)	4
Transfers of radioactive material were not performed according to approved procedures (on or off campus).	4
Laboratory made an unauthorized acquisition of radioactive material.	4
Sharps were not segregated from other solid radioactive waste.	4
Radioactive waste was placed into the biohazard, chemical, or normal waste stream.	4
Personnel did not have the required dosimetry or did not wear it as required.	4
Bioassays were not performed as required.	4
Personnel did not perform or receive radiation safety training prior to using radioactive material (web- based Radiation Safety course and/or initial in-lab training).	4
Evidence of eating, drinking, smoking, application of cosmetics, or mouth pipetting.	4

Personnel did not wear lab coat, eye protection, or gloves as a minimum to handle radioactive material.	4
Appropriate shielding was not used.	4
A major spill or personnel contamination incident was not immediately reported to Radiation Safety.	4
Failure to submit a completed and signed written corrective action plan.	4
Non-radioactive material worker is unaware of the OSU policy that requires radioactive material to be secured from unauthorized access or removal.	3
Non-radioactive material worker is unaware of the regulation regarding the prohibition of eating, drinking, smoking, applying cosmetics, or mouth pipetting in laboratories posted for the use or storage of radioactive material.	3
Radiation worker is unable to explain the concept and site-specific implementation of an ALARA (As Low As Reasonably Achievable) program including time, distance, shielding, and containment.	3
Radiation worker is unable to explain lab specific procedures for receipt, storage, and security of radioactive material packages. Shipping materials must be smear wiped, free of contamination, and radiation symbols or the word "radioactive" removed or defaced prior to disposal.	3
Radiation worker is unaware of the lab specific procedures for handling low-level radioactive waste including appropriate waste segregation, decay-in-storage, long-lived waste, de minimus waste, mixed waste, and hot sink disposals.	3
Radiation worker is unaware of the lab specific personnel monitoring requirements which may include dosimeter types (whole body, ring) placement and storage, bioassay types (thyroid and urine), and that thyroid bioassays should occur 24-72 hours post use.	3
Radiation worker is unaware of proper posting and labeling requirements in a laboratory using radioactive material including door signs, hot sinks, spill response, and ODH "Notice To Employees" identifying their rights and responsibilities.	3
Radiation workers are not following the proper URSC-approved procedures for handling animals used with radioactive material.	3
Removable contamination >2,200 dpm/100 cm ² but <22,000 dpm/100 cm ² .	3
Radioactive material found unsecured (quantities < Appendix A values of OAC 3701:1-38-18 or radioactive material considered low specific activity i.e. radioactive waste).	3
Radioactive waste was not stored in an appropriate container.	3
Radioactive waste containers were not labeled with radionuclide and/or container number.	3
Long-lived radioactive waste was in a lab for a period of greater than 1 year after the container was sealed.	3

Survey meter was not operable or was not within the calibration frequency.	3
Survey meter or detector was not appropriate for the radionuclides used.	3
Annual in-lab training has not been provided and/or is not documented.	3
Equipment used with radioactive material was not labeled "radioactive".	3
Absorbent pads, bench covers, or trays were not used.	3
University Radiation Safety Committee-approved procedures were not followed.	3
Failure to provide an on-line corrective action response to deficiencies through EHS Assist and/or failure to provide a written record to correct deficiencies.	2
Non-radioactive material worker has not completed the on-line Radiation Safety course*	2
Non-radioactive material worker is unaware of laboratory specific procedures for the receipt and storage of packages containing radioactive material.	2
Non-radioactive material worker is unaware of where radioactive materials are used and stored in the laboratory.	2
Radiation worker is not entering data into EHS Assist at the appropriate frequency or is inaccurately entering disposal information. Radiation workers must be able to navigate EHS Assist or communicate disposal information to the data entry person.	2
Surveys are not documented correctly.	2
Inventory was not maintained on the web-based inventory system or was not entered in a timely manner.	2
Radioactive waste was not segregated according to approved procedures.	2
Decay-storage waste was stored in a lab for greater than 3 years after the container was sealed.	2
Survey meter was not used in the appropriate manner.	2
Dosimetry was not returned after the wear period.	2
Door postings were missing or incomplete.	2
All stock solutions > Appendix A quantities (OAC 3701:1-38-18) were not labeled with radionuclide, activity, and radiation level (as appropriate).	2
Radiation symbols or the wording "Caution, Radioactive Material" was not removed from shipping containers prior to disposal.	2
A minor spill was not reported to Radiation Safety within 24 hours.	2

One-year renewal of a radioactive material permit was not completed.	2
Failure to have a proper maintenance survey performed on labeled equipment prior to relocation or repair.	2
Non-radioactive material worker is unaware of where the spill/personnel contamination emergency response procedure is posted.	1
Radiation worker is unable to explain the laboratory's site-specific procedures for ordering radioactive materials and that all orders must be approved by Radiation Safety prior to OSURF or Purchasing placing the order with the vendor.	1
Web-based transactions were not entered correctly	1
Failure to label stock vials with EHS Assist inventory number	1

*If points are assessed for this item, additional deficiencies for non-radioactive material worker will not be issued points.

B. Enforcement Actions

Approved Supervisors are evaluated under the following Point System:

- 1. Accumulation of points is within a six-month rolling calendar. Failure to submit a written corrective action plan will result in the suspension of the rolling calendar. The points that are accumulated will remain until the written correction action plan is submitted and approved by the University Radiation Safety Committee.
- 2. Repeat items of non-compliance are double the original value assessed in the point system. Items of non-compliance are considered a repeat if it reoccurs within the 6 month rolling calendar.
- 3. Re-inspections will occur within 30 days if an Approved Supervisor has accumulated ≥8 points. If an Approved Supervisor is assessed ≥3 points during any single re-inspection, the lab will be inspected again within another 30 days.
- 4. When a written corrective action plan is required, it must address the following for each item of noncompliance:
 - a. Acknowledge and state the cause of the deficiency,
 - b. A statement of corrective actions implemented and actions taken to prevent future occurrences,
 - c. Date of full compliance,
 - d. Documentation that all users have signed a statement that describes the nature of the deficiency and corrective actions implemented.
- 5. For the four highest point total action levels, irrespective of the number of points accumulated, each attempt at reconciliation and punitive action must have already taken place before the next more severe punitive action is taken.
- 6. Offenses, situations, or circumstances endangering the immediate health and safety of employees, students, or visitors will be reported directly to the University Radiation Safety Officer who will implement whatever actions are appropriate to the circumstances.

7. Radiation Safety Enforcement Actions

Total Points	Enforcement Action
1-3	The Approved Supervisor of a laboratory that has accumulated 1-3 points shall receive documentation of the deficiencies through EHS Assist. The Approved Supervisor shall correct the deficiencies and document the corrective actions via EHS Assist within 14 calendar days from the date of notification.
	If a written record (e.g. RS-6) is required to correct the deficiencies, the Approved Supervisor has 14 calendar days from the date of notification to submit the required information.
	Failure to provide an on-line corrective action response to deficiencies through EHS Assist and/or failure to provide a written record to correct deficiencies will result in an additional 2 point violation.
4-7	The Approved Supervisor of a laboratory that has accumulated 4-7 points shall receive documentation of the deficiencies through EHS Assist. The Approved Supervisor shall correct the deficiencies and document the corrective actions via EHS Assist within 14 calendar days from the date of notification. In addition, a written corrective action plan must be submitted within 14 calendar days for review and approval by the University Radiation Safety Committee. If a corrective action plan is disapproved, the Approved Supervisor has 14 calendar days to resubmit a revised corrective action plan. The URSC may designate Radiation Safety to review and approve the revised corrective action plan.
	If a written record (e.g. RS-6) is required to correct the deficiencies, the Approved Supervisor has 14 calendar days from the date of notification to submit the required information.
	Failure to provide an on-line corrective action response to deficiencies through EHS Assist and/or failure to provide a written record to correct deficiencies will result in an additional 2 point violation.
	Failure to provide a written corrective action plan for URSC review will result in suspension of the use of radioactive materials until the written corrective action plan has been submitted and approved.
8-11	The Approved Supervisor of a laboratory that has accumulated 8-11 points shall receive documentation of the deficiencies through EHS Assist. In addition, written notification from the URSO will be issued with copies of the letter sent to the appropriate Dean and Department Chair.
	The URSO may impose a 2 week suspension of ordering privileges.
	The Approved Supervisor shall correct the deficiencies and document the corrective actions via EHS Assist within 14 calendar days from the date of notification. In addition, a written corrective action plan must be submitted within 14 calendar days for review and approval by the University Radiation Safety Committee. If a corrective action plan is disapproved, the Approved Supervisor has 14 calendar days to resubmit a revised corrective action plan. The URSC may designate Radiation Safety to review and approve/disapprove the revised corrective action plan.
	If a written record (e.g. RS-6) is required to correct the deficiencies, the Approved Supervisor has 14 calendar days from the date of notification to submit the required information.
	Failure to provide an on-line corrective action response to deficiencies through EHS Assist and/or failure to provide a written record to correct deficiencies will result in an additional 2 point violation.
	Failure to provide a written corrective action plan for URSC review will result in suspension of the use of radioactive materials until the written corrective action plan has been submitted and approved.

12-15	The Approved Supervisor of a laboratory that has accumulated 12-15 points shall receive documentation of the deficiencies through EHS Assist. In addition, written notification from the URSC Chair, Senior Director for Environmental Health and Safety, and the URSO will be issued with copies of the letter sent to the appropriate Dean and Department Chair.
	The URSC Chair will impose a 2 week suspension of the use of radioactive materials.
	The Approved Supervisor shall correct the deficiencies and document the corrective actions via EHS Assist within 14 calendar days from the date of notification. In addition, a written corrective action plan must be submitted within 14 calendar days for review and approval by the University Radiation Safety Committee. If a corrective action plan is disapproved, the Approved Supervisor has 14 calendar days to resubmit a revised corrective action plan. The URSC may designate Radiation Safety to review and approve/disapprove the revised corrective action plan.
	Failure to provide an on-line corrective action response to deficiencies through EHS Assist and/or failure to provide a written record to correct deficiencies will result in an additional 2 point violation.
	Failure to provide a written corrective action plan for URSC review will result in suspension of the use of radioactive materials until the written corrective action plan has been submitted and approved.
16-19	The Approved Supervisor of a laboratory that has accumulated 16-19 points shall receive documentation of the deficiencies through EHS Assist. In addition, written notification from the URSC Chair, Senior Director for Environmental Health and Safety, and the URSO will be issued with copies of the letter sent to the appropriate Dean and Department Chairperson. The Purchasing Agent will also be copied on the written notification.
	The URSO will impose suspension of the use of radioactive materials until the URSC rescinds the suspension.
	The Approved Supervisor shall correct the deficiencies and document the corrective actions via EHS Assist within 14 calendar days from the date of notification. In addition, a written corrective action plan must be submitted within 14 calendar days for review and approval by the University Radiation Safety Committee. The Approved Supervisor is required to attend the URSC meeting to show cause as to why the URSC should reinstate privileges to use radioactive materials. If a corrective action plan is disapproved, the Approved Supervisor has 14 calendar days to resubmit a revised corrective action plan. The URSC may designate Radiation Safety to review and approve/disapprove the revised corrective action plan.
	Failure to provide an on-line corrective action response to deficiencies through EHS Assist and/or failure to provide a written record to correct deficiencies will result in an additional 2 point violation.
<u>></u> 20	The Approved Supervisor of a laboratory that has accumulated 20 or more points shall receive written notification from the Sr. Vice President of Administration and Planning informing the Approved Supervisor that their Approved Supervisor status at The Ohio State University has been suspended for three years. The appropriate Dean, Department Chair, and Purchasing Agent are copied
	The Approved Supervisor must cease operations involving radioactive materials immediately and close out all areas posted for the use or storage of radioactive materials. No sanctions are imposed against the users. Users may seek user status under another Approved Supervisor.
	During the first year of the suspension, the individual may not use radioactive materials. During the second and third year of the suspension, the individual may use radioactive materials under the

- C. Radionuclide Risk Categories, Security and Required Training
 - 1. Radionuclide Risk Categories
 - a. Level 1: No Significant Risk
 - i. Areas where only generally licensed materials or naturally occurring radioactive materials (NORM) are used including small button check sources, Ni-63 electron capture detectors and compounds of uranium and thorium.
 - b. Level 2: Low Risk
 - i. Collections of unit dosages of nuclear medicine diagnostic radiopharmaceuticals.
 - ii. Unit dosages of most therapeutic radiopharmaceuticals used in nuclear medicine, including those containing P-32, Sr-90, Sm-153, and activities of I-131 not exceeding 100 mCi.
 - iii. Vials or groups of vials of typical tracers used in biomedical research labeled with radionuclides such as H-3, C-14, S-35, P-32, P-33 and I-125.
 - iv. Sealed Sources in activities less than 50 mCi
 - v. Total activity not exceeding 100 ALIs per laboratory.
 - c. Level 3: Intermediate Risk
 - i. Individual sealed sources or groups of sealed sources in a single location of Cs-137, Co-60, Sr-90, Ir-192, Pu-239 and Am-241 of total activity from 50 mCi up to a maximum of 1 Ci.
 - ii. Activity in a single location of I-131 exceeding 100 mCi.
 - iii. Mo-99/Tc-99m generators
 - d. Level 4: Higher Risk
 - Individual sources or groups of sources in a single location of Cs-137, Co-60, Sr-90, Ir-192, Pu-239 and Am-241 of total activity greater than 1 Ci.

- 2. Levels of Security and Training (Corresponding to Radionuclide Risk Categories)
 - a. Level 1: No Significant Risk
 - i. Security
 - An active police and security presence on campus
 - Laboratory entrances are locked during off-hours
 - ii. Training
 - Laboratory personnel should be trained with basic knowledge of chemical, biological and radiological hazards and procedures Lab Safety Training
 - b. Level 2: Low Risk
 - i. Security
 - An active police and security presence on campus
 - Laboratory entrances are locked during off-hours
 - Radioactive material must be secured or under constant surveillance
 - ii. Training
 - Laboratory personnel should be trained with basic knowledge of chemical, biological and radiological hazards and procedures Lab Safety Training
 - Personnel who work within the laboratory must take the On-Line Radiation Safety Course
 - Personnel who use radioactive material are required to take the Initial In-Lab training and Annual In-Lab training
 - c. Level 3: Intermediate Risk
 - i. Security
 - An active police and security presence on campus
 - Laboratory entrances are locked during off-hours
 - Radioactive material must be secured or under constant surveillance
 - Key access must be limited to authorized users
 - Ancillary personnel shall not be left unattended
 - ii. Training
 - Laboratory personnel should be trained with basic knowledge of chemical, biological and radiological hazards and procedures Lab Safety Training
 - All personnel who work within the laboratory must take the on-line Course (or equivalent for Nuclear Medicine and Radiation Medicine)
 - All personnel who use radioactive material are required to take the Initial In-Lab training and Annual In-Lab training
 - d. Level 4: Higher Risk
 - i. Security
 - An active police and security presence on campus
 - Laboratory entrances are locked during off-hours
 - Radioactive material must be secured or under constant surveillance
 - Key access must be limited to authorized users
 - Ancillary personnel must not be left unattended
 - Licensed materials must be separately locked

• Access to secondary keys must be by authorized users only

ii. Training

- Laboratory personnel should be trained with basic knowledge of chemical, biological and radiological hazards and procedures Lab Safety Training
- All personnel who work within the laboratory must take the on-line Course (or equivalent for Nuclear Medicine and Radiation Medicine)
- All personnel who use radioactive material are required to take the Initial In-Lab training and Annual In-Lab training.

IX. Procedures and Precautions For The Use of Radioactive Materials

A. Spill Response / Emergency Procedures

- 1. Minor Spill (< 100 microcuries)
 - a. Notify: Notify persons in the laboratory or affected area that a spill has occurred.
 - b. Shield The Source: Cover the spill with absorbent pads. If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing radiation exposure.
 - c. Prevent The Spread: Confine the movement of all potentially contaminated personnel and evaluate for contamination before allowing them to leave the location.
 - d. Clean Up: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Include all other contaminated materials such as disposable gloves.
 - e. Survey: With smear wipes, and if appropriate with a survey meter, check the area around the spill, hands and clothing for contamination.
 - f. Report: Report the incident to the Radiation Safety Section of Environmental Health and Safety within 24 hours. The Radiation Safety emergency response phone number is 614 561-7969.
- 2. Major Spills (≥ 100 microcuries)
 - a. Clear The Area: Notify all persons not involved in the spill to vacate the laboratory or affected area.
 - b. Call For Help: Report the incident to the Radiation Safety Section of Environmental Health and Safety immediately. The Radiation Safety emergency response phone number is 614 561-7969.
 - c. Shield The Source: Cover the spill with absorbent pads. If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing radiation exposure.
 - d. Prevent The Spread: Confine the movement of all potentially contaminated personnel and evaluate for contamination before allowing them to leave the location.
 - e. Close The Room: Leave the room and lock the door(s) to prevent entry. Placard the door so that no one inadvertently unlocks the door or enters the room.
 - f. Clean Up: Performed under the guidance of Radiation Safety personnel.
- 3. Personnel Contamination
 - a. Radiation Safety must be notified immediately of any incident involving personnel contamination, regardless of the radionuclide or activity. The Radiation Safety emergency response phone number is 614 561-7969.
 - b. Begin decontamination of skin surfaces immediately with soap and warm water. Contaminated clothing should be removed and stored for further evaluation by Radiation Safety. Decontamination should continue until no activity is detectable, but not to where effectiveness of the skin as a barrier is destroyed. Decontamination efforts should cease when the skin starts to become thin and reddened. The health of the skin is maintained to minimize absorption and internal deposition of radioactive material.

- B. General Rules for the Safe Use of Radioactive Materials
 - 1. Laboratory procedures, as outlined in the Permit for the Use of Radioactive Materials, will be adhered to. Changes in procedure will be approved by the URSC or Radiation Safety prior to implementation.
 - 2. All laboratories or areas in which radioactive material is used or stored must either be under constant surveillance by laboratory workers in the lab or be locked when constant surveillance is not possible. Radioactive material must be secured from unauthorized access or removal.

Authorized Users, Approved Supervisors and individuals authorized to use radioactive materials are responsible for reporting the loss or theft of radioactive materials to the Radiation Safety Section of Environmental Health and Safety (614 561-7969) immediately after it is determined that radioactive material is missing.

The RSO, or designee, will notify management and the appropriate authorities. The Radiation Safety Section will immediately report to the Ohio Department of Health if it is determined that the licensed radioactive material is an aggregate quantity equal to or greater than 100 times the quantity specified in Appendix A of OAC 3701:1-38-18. RSS will report to the Ohio Department of Health within 30 days if it is determined that the licensed radioactive material is an aggregate quantity greater than 10 times the quantity specified in Appendix A of OAC 3701:1-38-18. Written reports will conform to OAC 3701:1-38(A)(2).

- 3. Current and accurate records of receipt, transfer, use, decay and disposal of radioactive materials shall be maintained via EHS Assist web-based inventory system.
- 4. Frequency of laboratory surveys is based on the total activity used and must be performed at the frequency as specified by the committee-approved permit.
 - a. If use is $< 100 \mu$ Ci/month, surveys are required at least monthly.
 - b. If use is $\geq 100 \ \mu Ci/month$, surveys are required at least weekly.
 - c. Changes from weekly to monthly surveys must be by an approved RS-7 form.
 - d. Surveys do not need to be performed if there has been no use since the previous survey.
 - e. Results of smear wipe surveys and direct contamination surveys (survey meter surveys) must be maintained in units of disintegrations per minute (dpm).
 - f. The background reading of the survey meter must be recorded in counts per minute (cpm).
 - g. "No Use" may be documented, with the same frequency as normal surveys, in lieu of surveys.
 - h. Areas with loose contamination in excess of 200 dpm/100 cm2 must be decontaminated and re-wipe results documented.
 - i. Radiation dose rate results shall be documented in units of mrem/hr. Dose rate surveys are normally performed with an ion-chamber. Most laboratories using only beta emitting nuclides are not required to perform dose rate surveys.
 - j. Laboratory surveys must be documented on the RS-15 form, Laboratory Survey Results (or equivalent).
- 5. In the event of a spill, or whenever lab surveys show the presence of removable contamination, decontamination efforts will continue until smear wipes indicate removable contamination <200 dpm/100 cm2.
- 6. Eating, drinking, smoking, chewing gum, applying cosmetics, and/or storage of such effects are prohibited in all areas posted for the use of radioactive materials.
- 7. There will be no pipetting by mouth of any materials, radioactive or non-radioactive, in areas posted for the use of radioactive materials.
- 8. Laboratory coats, disposable gloves, and protective eyewear will be worn when handling radioactive material. Protective wear should not be worn outside the laboratory area.
- 9. Fume hoods will be used in all procedures involving the potential for release of airborne radioactivity in the form of dusts, gases, vapors, or aerosols. This includes vortexing and centrifugation or the opening of centrifuge tubes. Fume hoods must be certified at least annually.
- 10. Radioactive materials will be transported in closed containers. Containers with liquids will be surrounded with enough absorbent materials to contain twice the volume of free liquid.
- 11. Personnel monitoring devices and bioassay services will be utilized as required by the committee-approved permit and as provided by RS.
- 12. Appropriate shielding shall be used in all areas in which radioactive materials, including wastes, are stored.
- 13. Disposable items will be used for work with radioactive materials whenever possible.
- 14. Sharp and/or breakable solid waste items will be pre-packaged in puncture-resistant containers before addition to the solid waste container.
- 15. Small amounts of readily soluble or biologically dispersible radioactive liquid waste may be disposed of in a hot sink designated by RS. All disposals will be recorded and must meet the criteria for solubility and dispersibility as given in the RS-1 Instructions For Use. The total of all radionuclides released through a hot sink during any one month shall not exceed the limits established by Radiation Safety.
- 16. Only waste containers supplied or approved by Radiation Safety will be used for the disposal of solid and liquid wastes.
- 17. Disposal of radioactive wastes shall be accomplished through Radiation Safety or by decay-in-storage. EHS Assist is used to arrange for waste pickups and for verification of decay-in-storage waste.
- 18. If a posted fume hood is used for breathing zone safety, having proper hood flow is critical to ensure safety. Please note it is the responsibility of the Approved Supervisor to inform radiation safety if a posted hood fails an operation test.
- C. Area Survey Procedures

Laboratory area survey procedures include the following:

1. Frequency of Surveys

- a. Monthly If total laboratory radionuclide use rate is < 100 uCi/month
- b. Weekly If total laboratory radionuclide use rate is ≥ 100 uCi/month
- c. Surveys do not need to be performed if there has been no use since the previous survey. Refer to your laboratory's permit to ensure your compliance with survey procedures and frequency requirements.
- 2. Meter Surveys / Direct Frisking

Laboratories using only very low energy beta emitters may not be required to perform direct meter surveys. All other laboratories will need to perform meter surveys.

- a. Direct surveys are performed for two primary purposes:
 - i. To detect areas of contamination for analysis by smear wipe
 - ii. To determine whether contamination is loose or fixed

- b. Prior to using any survey instrument perform the following checks:
 - i. Battery Check Replace batteries as necessary
 ii. Physical Check Instrument, cable and probe in good physical condition
 iii. Calibration Check Instrument within calibration frequency
- c. When performing the survey, the probe should be held close to the surface (< $\frac{1}{2}$ inch) and moved slowly at a rate of approximately 1 2 inches per second.
- d. For "Survey Meter" results you are required to make a survey with a survey instrument appropriate for the nuclides used in your lab. Survey meter background is recorded in cpm on the top portion of the form. The results of the meter survey are recorded in dpm. Any survey meter results greater than 2000 dpm will be recorded on the survey map. If no contamination greater than 2000 dpm is detected with the survey meter, include a statement to that fact.

Example: No detectable activity >2000 dpm by survey meter survey.

- e. Survey equipment and all areas where radioactive material has been used or stored since the last survey (include floor, computer keyboards, light switches, etc.). Also survey personnel traffic routes, being sure to include entrances and exits from the area. If any meter readings exceed the instrument's operational range, contact Radiation Safety's emergency cell phone at 614 561-7969.
- 3. Smear Wipe Surveys
 - a. Smear wipe surveys have a much lower detection limit than direct frisking and may detect contamination that was not detected by meter survey. Smear wiping concentrates contamination from a larger area onto a very small smear wipe. Always consider a smear wipe to be contaminated until analysis is complete.
 - b. Protective gloves shall be worn while taking smear wipes. Avoid cross contaminating the samples by keeping them separated after performing the wipe test.
 - c. Be sure to smear wipe all suspect areas identified during the meter survey. Smear wipes shall be taken on representative equipment surfaces in the work area.
 - d. A dry cloth or paper disc should be used to wipe an area of 100 cm2. A four-inch square or an 18-inch "S" approximates 100 cm2. Cotton –tipped applicators may be used to smear small objects or hard to reach areas.

- e. Analyze the smear wipes on the appropriate counting equipment.
- f. Documentation of Smear Wipes and Meter Surveys
- g. A permanent record shall be kept of all survey results, including negative results (see RS-15 form, Laboratory Survey Results). The record will include:
 - i. Location, date and type of survey equipment used.
 - ii. Name of person conducting the survey.
 - iii. Drawing of the area surveyed, identifying relevant features such as storage areas, waste areas, benches, hot sinks and fume hoods.
 - iv. Loose surface (smear wipes) contamination levels documented in dpm/100 cm2, keyed to locations on the drawing.
 - v. Fixed contamination (meter survey) levels documented in dpm after all decontamination efforts are completed. Contamination surveys will not be documented in the units of mR/hr.
 - vi. Corrective action taken in the case of contamination, reduced contamination levels after corrective action, and any appropriate comments.
- 4. Action Levels for Contamination Surveys
 - a. Laboratory personnel shall decontaminate areas and/or equipment if loose surface contamination levels exceed 200 dpm/100 cm2.
 - b. If areas of fixed contamination > 2000 dpm exist after decontamination, perform the following:
 - i. Document fixed contamination on RS-15
 - ii. Label area as "Radioactive"
 - iii. Contact Radiation Safety for further actions
- 5. All radiopharmaceutical, elution, preparation and administration areas are surveyed at the end of each day of use with a low range, thin end window G.M. survey meter.

- D. Procedures for Servicing or Removing from Use Equipment Used with Radioactive Materials
 - 1. Maintenance Surveys

When equipment that has been used with radioactive materials requires service or is being sent to surplus for disposal, a survey for contamination must be performed prior to transport of the unit or performance of the work. Examples of such equipment include, but are not limited to: hot sinks, fume hoods, refrigerators, freezers and analytical instruments.

- a. Notification, Survey and Removal of Equipment from Use
 - i. Radiation Safety is notified by Facilities Operations and Development, Facilities Engineering, the Approved Supervisor or designee of an item that must be surveyed. The Approved Supervisor must ensure that all items in the unit (e.g. fume hood, refrigerator) have been removed and performed a preliminary survey. The survey consists of an instrument survey, if appropriate, and a smear wipes survey to determine the presence of contamination. The results of these surveys must be sent to Radiation Safety. Radiation Safety personnel will then perform a confirmatory survey.
 - ii. Radiation Safety personnel will tag the unit indicating a survey is being performed and that the unit may not be used, repaired or removed until results are obtained. The tag states, "Suspected Radioactive Contamination, Do Not Use This Unit, Do Not Remove This Tag, Removal of This Tag Must Be Done by Radiation Safety Personnel Only".
- b. Results of Survey for Removable Contamination
 - i. Contamination Not Present

If removable contamination is not found, Radiation Safety personnel will remove the original tag, replacing it with a tag that states "Do Not Use This Unit, Removal of This Tag Must Be Done by Physical Facilities Personnel Only." Radiation Safety will inform Physical Facilities that removable contamination was not found, and of any precautions to be taken. Please note that the laboratory must still complete a work order with Facilities Operations and Development. When the work is complete, Physical Facilities personnel should return the tag to Radiation Safety.

ii. Contamination Present

It is the responsibility of the laboratory supervisor to have the unit decontaminated to less than $200 \text{ dpm}/100 \text{ cm}^2$. Results of the decontamination survey must be submitted to Radiation Safety prior to service or work being performed on the unit. Radiation Safety personnel will perform a confirmatory survey. When decontamination is accomplished, Radiation Safety will institute the tagging system as described above.

E. Low-Level Radioactive Waste Disposal

- 1. Waste Classifications
 - a. Solid Waste this includes absorbent "diapers", gloves, disposable lab ware, pipettes and other similar items.

All Glass, sharps and/or breakable items should be boxed separately in puncture resistant containers before being placed in the waste box.

All waste containers must be appropriately labeled, clear poly liners shall be used for all solid waste containers and inventory records maintained. RSS will provide solid waste containers. Solid waste containers should be physically closed (e.g. cardboard box flaps shut or a lid on the container).

- b. Liquid Waste keep aqueous and organic wastes separate and collect the bulk liquids in RSS-provided plastic containers. Liquid waste cannot be stored in any glass containers.
- c. Mixed Waste is waste that is low-level radioactive waste and contains waste considered hazardous by the EPA because it either (1) is listed as a hazardous waste in Subpart D of 40 CFR 261 or (2) causes the low-level waste to exhibit any of the hazardous waste characteristics identified in Subpart C of 40 CFR 261.
- d. Biologicals are carcasses, tissue samples and/or body parts from animals euthanized after completion of experiments involving radioactive materials. All biologicals must be placed in clear poly bags. Do not use aluminum foil. Biological waste must be triple bagged, boxed and then frozen until pick up.
- e. Liquid Scintillation Vials vials should be returned to the same box in which they were received.
- 2. Waste Disposal Methods
 - a. Disposal Through RSS All classifications of waste must be disposed of through RSS. (Exceptions are hot sink disposals and decay-in-storage waste. See items b and c below.) Waste pick up requests are scheduled through the web-based inventory system or via an RS-24 Form if the web system is not an option.
 - b. Hot Sink Disposals Radiation Safety allows for the disposal of readily soluble aqueous liquids or readily dispersible biological material. Monthly limits are established for each approved supervisor based on possession limits and regulations regarding disposal into the sanitary sewer system.
 - c. Decay-in-Storage Materials held for decay-in-storage must have a half-life of less than 120 days and shall be held until a survey with an appropriate meter yields no counts above background (approximately ten half-lives) with storage not to exceed four years.
 - i. Place wastes into separate waste containers according to half-life.
 - ii. In preparation for disposal, solid waste must be directly monitored, using appropriate instrumentation (with the instrumentation set to the lowest scale) in a low background area and yield no counts above background.
 - iii. Liquid waste must be sampled and analyzed by liquid scintillation counting or other appropriate means for the isotope of concern. If the liquid waste is a readily soluble aqueous or readily dispersible biological material the best alternative may be to hot sink the material.

- iv. Decay-in-storage waste monitoring must be verified by Radiation Safety. This verification can be schedule through EHS Assist. All radiation labels/markings must be removed or obliterated before disposal. Radiation Safety maintains a record of each disposal for three years which includes the date of disposal, date placed in storage, radionuclide disposed, the survey instruments used, background dose rate, dose rate at the surface of each decay-in-storage container and the name of the individual who performed the disposal.
- d. De minimis is defined as C-14 or H-3 only, in animal tissue or liquid scintillation media only, and with a specific activity of <0.05 μ Ci/g. Each box of de minimis waste must be accompanied by a de minimis verification form.
- 3. Waste Storage
 - a. Closed containers of long-lived waste cannot be held in a laboratory for greater than 1 year.
 - b. Closed containers of decay-in-storage waste cannot be held in a laboratory for greater than 4 years.
- 4. Refusal to pick up waste

There are various reasons for refusal to pick up radioactive waste. These reasons include:

- a. Liquid in the solid waste
- b. Vials containing liquids mixed with solid waste
- c. Aqueous and organic liquids mixed in the same container
- d. No de miminis verification forms and/or failure to submit billing information
- e. Sharps in the solid waste

F. Procedures for Receiving, Surveying and Opening Packages Containing Radioactive Material

Radioactive materials packages must be placed in an area designated for the storage or handling of radioactive materials. This area must have absorbent padding covering the surface the radioactive material will be stored or used on, and have appropriate shielding to maintain the ALARA principle.

- 1. Before opening the package:
 - a. Observe the shipping container, if it appears to be leaking, crushed or damaged in any way, notify Radiation Safety immediately (292-1284).
 - b. Wear your personal monitoring devices, if required.
 - c. You must wear a lab coat, protective eyewear and disposable gloves when handling radioactive materials in addition to any other personal protective devices required in the approved permit.
- 2. While opening the package:
 - a. Visually inspect the inner container(s) for evidence of damage, loss of containment or leakage. If any of these conditions exist:
 - i. Notify Radiation Safety immediately (292-1284 or emergency pager 240-0705).
 - ii. Do not attempt to move, open or remove any contents of the package.
 - iii. Be sure to survey your hands and personal protective equipment for possible contamination with the appropriate survey method. If contamination is found, begin decontamination efforts.
 - b. Check the contents of the package for correctness.
 - i. If the radionuclides, chemical forms and the activities for each item ordered are not the same as received, notify Radiation Safety as soon as possible about the discrepancy.
 - c. If contents are undamaged and correct, move the radioactive material to its approved storage location.
- 3. To discard the empty packaging:
 - a. The inner package and *pig* must be considered "contaminated" until proved otherwise. Wear your personal monitoring devices, if required. You must wear a lab coat, protective eyewear and disposable gloves when handling radioactive materials in addition to any other personal protective devices as required in the approved application.

* *A* "pig" is the inner shipping container usually containing the actual radioactive material.

- b. If the pig does not contain lead:
 - i. Dispose of any dry ice contained in the package.
 - ii. Take a single smear wipe (covering at least 300 cm2) of the pig (inside and out), internal parts of the package (Styrofoam) and the exterior of the package.
 - iii. Run the smear wipe through a scintillation counter or gamma counter as appropriate. Make sure to convert your results to dpm (disintegrations per minute) if necessary.
 - iv. Divide the dpm results by 300cm2. This gives you dpm/cm2.
 - v. If your package contained any beta or gamma emitter; and the result is > 22 dpm/cm2, you must decontaminate the package to below this level, or you can place the package in a decay in storage environment if the half-life of the original radionuclide was less than 120 days.
 - vi. If your package contained any alpha emitter; and the result is > 2.2 dpm/cm2, you must decontaminate the package to below this level, or you can place the package in a decay in storage environment if the half-life of the original radionuclide was less than 120 days.
 - vii. If the results are less than the values in items v and vi above, then obliterate any radioactive markings present and dispose of the empty packaging in regular solid waste.
- c. If the pig contains lead:
 - i. Dispose of any dry ice contained in the package.
 - ii. Separate the pig from the rest of the packaging.
 - iii. Take a single smear wipe of the pig, inside and out. Estimate the area smear wiped in cm2.
 - iv. Take a single smear wipe (covering at least 300 cm2) of the internal parts of the package (Styrofoam) and the exterior of the package.
 - v. Run the smear wipes through a scintillation counter or gamma counter as appropriate. Make sure to convert your results to dpm (disintegrations per minute) if necessary.
 - vi. Using your estimate of the area wiped in item 3, divide the dpm results by the estimated area. This gives you dpm/cm2 for the pig.
 - vii. Divide the dpm results obtained by 300cm2. This gives you dpm/cm2 for the empty packaging.
 - viii. If your package and pig contained any beta or gamma emitter and the result is > 22 dpm/cm2, you must decontaminate the package to below this level, or you can place the package in a decay in storage environment if the half-life of the original radionuclide was less than 120 days.
 - ix. If your package and pig contained any alpha emitter; and the result is > 2.2 dpm/cm2, you must decontaminate the package to below this level, or you can place the package in a decay in storage environment if the half-life of the original radionuclide was less than 120 days.

- x. If the results are less than the above values in items viii and ix then obliterate any radioactive markings present, pack the pig into a box along with a copy of the survey results. Radiation Safety will then pick-up the pig(s) at your next waste pickup. Do not let large quantities of lead pigs accumulate before contacting RSS for pick-up. Dispose of the empty packaging in regular solid waste.
- G. Use of Radioactive Materials in Animals

Work that involves the use of radioactive materials in animals must have all experimental procedures, including handling, housing and waste disposal, included in the Permit For The Use Of Radioactive Materials and the RS-5 form (Radioactive Lab Animal Information). These will be reviewed and approved by the URSC. The applicant must also supply documentation of approval from the Institutional Animal Care and Use Committee (IACUC). Upon approval of the permit, the Approved Supervisor is responsible for all aspects of radiation safety involved with the care, handling and subsequent disposal of the animals and their waste.

No animal tissue can be disposed of in a manner that would permit its use either as food for humans or in animal feed. This includes tissue wastes held for decay-in-storage and de minimis tissue.

H. Use of Radioactive Materials in Humans

All uses of radioactive materials in humans must adhere to OAC 3701:1-58, "Medical Use of Radioactive Material" and applicable sections of OAC 3701:1-38. Applications for radioactive materials in humans must be approved by the Medical Use Subcommittee of the URSC and the URSC. The applicant must supply, where required, documentation of approval from the Institutional Review Board (IRB) and, where required, the Investigational New Drug (IND) number.

- Authorization of Users All individuals pursuing the use of specific types of radioactive materials at OSU
 must be approved prior being granted authorization to do so. OSU operates under a Type A Broad Scope
 ODH Radioactive Materials License. This type of license permits OSU to approve individuals for the use
 of radioactive materials in conjunction with humans following a thorough review by the OSU Medical Use
 Subcommittee and the University Radiation Safety Committee or the Human Subjects Review Committee.
 Human Subject Review Committee is responsible for the review and approval of the research use of
 ionizing radiation in research involving human subjects. The active members of the Medical Use
 Subcommittee serve as the HSRC.
 Functions include:
 - a. Review of Individual or Group Applications
 - b. Review of Preceptor Attestation for the following:
 - i. Authorized Medical Physicist
 - ii. Authorized Nuclear Pharmacist
 - iii. Authorized Medical Users (OAC Sections 32, 34, and 53)
 - iv. Authorized Medical Users (OAC Section 37)
 - v. Authorized Medical Users (OAC Sections 43 and 55)
 - vi. Authorized Medical Users (OAC Section 72)
 - c. Approval of Users pursuant to ODH Regulations/Guidance

- d. Credentialing review of board certifications in addition to preceptor attestations.
- 2. Quality Management Programs The Department of Radiation Medicine and the Division of Nuclear Medicine must adhere to the written quality management program to provide high confidence that byproduct materials or radiation from byproduct materials is administered as directed by the authorized physician/user.
- I. Use of Sealed Sources of Radioactive Material

A sealed source is any radioactive material that is permanently encapsulated to prevent leakage or escape of radioactive materials. Sealed sources are used for teaching and research as well as for medical procedures. Consult with Radiation Safety to determine if a sealed source is required to be approved by the URSC through the RS-1 Form, Permit For The Use Of Radioactive Materials. Users of sealed sources should ensure that:

- 1. Sealed sources are accounted for on inventories.
- 2. Sealed sources are made available to Radiation Safety personnel for routine leak testing and inventory.
- 3. Sealed sources are stored and used in a manner that is in keeping with the ALARA philosophy.
- J. Vehicle Transportation of Radioactive Materials within The Ohio State University Campus
 - 1. The preferred method of transport of radioactive material is through a courier service. All applicable Department of Transportation (DOT) regulations apply.
 - a. Individuals involved in preparing the shipment must have received appropriate DOT training available from the Radiation Safety Section of Environmental Health and Safety. This training must be completed every three years.
 - b. The Approved Supervisor's permit must include, or be amended to include, authorization to use a vehicle to transport radioactive material.
 - 2. Other Permitted Methods of Transport
 - a. The transportation of radioactive materials by Approved Supervisors or Users must follow all applicable DOT regulations and be performed in a state vehicle.
 - i. Individuals involved in preparing the shipment or transporting the package must have received appropriate DOT training available from the Radiation Safety Section of EHS. This training must be completed every three years.
 - ii. The Approved Supervisor's permit must include, or be amended to include, authorization to use a vehicle to transport radioactive material.
 - b. An Approved Supervisor or Authorized User may use their personal vehicle to transport radioactive materials on campus only under the following conditions:
 - i. The package to be transported is an excepted package for limited quantity (49 CFR 173.421) of radioactive material as defined by the Department of Transportation.
 - ii. Individuals involved in preparing the shipment or transporting the package must have received appropriate DOT training available from the Radiation Safety Section of EHS. This training must be completed every three years.

- iii. The Approved Supervisor's permit must include, or be amended to include, authorization to use a personal vehicle to transport radioactive material. Relevant criteria for justifying the personal transport of radioactive material include, but are not limited to:
 - It contains a very short-lived radionuclide with a half-life measured in hours.
 - It is a cell culture or a prepared compound that cannot survive for long at ambient temperatures.
 - It is a special product urgently required for a trial or other genuine reason at another site.
- iv. Transportation of a package labeled as a White I, Yellow II, Yellow III, or deceased or live radioactive animals in a personal vehicle is prohibited.
- v. Exempt quantities of radioactive materials are not subject to this policy.
- 3. Duties and Responsibilities of the Driver
 - a. Individuals involved in preparing the shipment or transporting the package must have received appropriate DOT training from the Radiation Safety Section of EHS. This training must be completed every three years.
 - b. Exercise reasonable care to ensure that none of the material is lost, escapes, or stolen from the vehicle or from any package.
 - c. Do not leave the vehicle unattended in a public place.
 - d. Transport documents must be readily available in accordance with DOT regulations.
 - e. Ensure that the material is delivered to a person authorized to receive it.
 - f. In the event of an incident, (i.e. loss, escape or theft of the material; or vehicle suffered serious damage following a collision, or involved in a fire) the driver is required to notify RSS, OSU police and the Consignor (Approved Supervisor) immediately.

APPENDIX A

SINGLE-USE THRESHOLDS FOR URINE BIOASSAY PARTICIPATION

The per radionuclide single-use threshold for urine bioassay participation	
Radionuclide	Activity (mCi)
Н-3	8,000
C-14	200
S-35	2,000
P-32	90
P-33	800
Ca-45	80
Cr-51	2,000
Tc-99m	20,000
In-111	600
Na-22	60
Co-57	70

APPENDIX B

Glossary of Terms

- Absorbed Dose means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the gray.
- Activity is the rate of disintegration (transformation) or decay of radioactive material. The units of activity are the curie (Ci) and the Becquerel (Bq). One Becquerel = 1 disintegration per second. One curie = 3.7×1010 Becquerel's = 2.22×1012 disintegrations per minute.
- Airborne radioactive material means radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.
- **ALARA** (As Low As Reasonably Achievable) means making every reasonable effort to maintain exposures to radiation as far below dose limits as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to state and socioeconomic considerations, and in relation to utilization of nuclear energy and license materials in the public interest.
- Annual Limit on Intake (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue.
- **Collective Dose** is the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.
- **Committed Dose Equivalent (CDE)** means the dose equivalent to organs or tissues of reference that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.
- **Committed Effective Dose Equivalent (CEDE)** is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues.
- **Contamination** means the deposition of radioactive material in any place it is not desired, particularly where its presence may be harmful. The harm may be actual exposure to individuals or release of the material to the environment or general public. Contamination may be due to the presence of alpha, beta particle or gamma ray emitting radionuclides. Common units for contamination are microcuries and dpm.

- **Declared Pregnant Worker (DPW)** means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.
- **Deep Dose Equivalent (DDE),** which applies to external whole-body exposure, is the dose equivalent at a tissue depth of 1 cm (1000 mg/cm2).
- **Derived Air Concentration (DAC)** means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work (inhalation rate 1.2 cubic meters of air per hour), results in an intake of one ALI.
- Direct Frisk means monitoring a surface with a survey instrument for radioactive contamination.
- **Dose Equivalent** means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).
- Effective Dose Equivalent (EDE) is the sum of the products of the dose equivalent to the organ or tissue and the weighting factors applicable to each of the body organs or tissues that are irradiated.
- External Dose means that portion of the dose equivalent received from radiation sources outside the body.
- Extremity means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.
- **Eye Dose Equivalent** applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 cm (300 mg/cm2).
- **Fixed Contamination** means radioactive contamination that is not readily removed from a surface by applying light to moderate pressure and wiping with a paper or cloth disk smear.
- **High Radiation Area** means an area accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour at 30 cm from the radiation source or from any surface that the radiation penetrates.
- **Individual Monitoring Devices** means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermo-luminescent dosimeters (TLDs), pocket ionization chambers, and personal air sampling devices.
- **Loose Surface Contamination** means radioactive contamination that is easily removed from a surface when wiped with a dry filter paper while applying moderate pressure.
- **Non-stochastic Effect** means health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a non-stochastic effect.

Quality Factor means the modifying factor that is used to derive dose equivalent from absorbed dose.

- **Rad** is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joule/kilogram (0.01 gray).
- **Radiation Area** means an area accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05mSv) in 1 hour at 30 cm from the radiation source or from any surface that radiation penetrates.
- **Radioactivity** is the spontaneous emission of radiation, generally alpha or beta particles, often accompanied by gamma rays, from the nucleus of an unstable isotope.
- **Rem** is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor.
- **Restricted Area** means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials.
- **Shallow Dose Equivalent (SDE)** which applies to the external exposure of the skin or extremity, is taken as the dose equivalent at a tissue depth of 0.007 cm (7 mg/cm2) averaged over an area of 1 square centimeter.
- **Stochastic Effects** means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.
- **Survey** means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive materials and measurements of calculations of levels of radiation, or concentrations or quantities of radioactive material present.
- **Total Effect Dose Equivalent (TEDE)** means the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).
- Unrestricted Area means an area, access to which is neither limited nor controlled by the licensee.
- Whole Body means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow and legs above the knee.