The Ohio State University
Wexner Medical Center

Radiation Safety Program

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Chapter 1: Radiation Safety Program

A. Purpose

The purpose of the Radiation Safety Program is to communicate administrative policy, operational procedures and standards of conduct regarding the use of radioactive material (RAM) and radiation generating equipment (RGE) at The Ohio State University Wexner Medical Center (OSUWMC). Policies regarding the OSUWMC RGE program are addressed in a separate RGE manual.

The Ohio State University (OSU) Medical Radiation Safety Program for RAM use is designed to:

1. Provide protection to individuals who administer and use RAM under OSU licenses.
2. Minimize the general public exposure to ionizing radiation from the use of RAM
3. Ensure that individuals comply with all applicable rules and regulations for the use of RAM
4. Meet the requirements of OSU's Ohio Department of Health (ODH) issued RAM licenses and other applicable licenses and registrations.

Every OSUWMC employee that uses RAM shall be familiar with and comply with the provisions of this manual.

B. Radiation Safety Culture Policy

1. RAM and RGE utilized in research, diagnosis and therapy at OSU are licensed by ODH and overseen by the University Radiation Safety Committee (URSC) and the Radiation Safety Section (RSS) of Environmental Health and Safety (EHS). The ODH Bureau of Environmental Health and Radiation Protection (ODH) regulates the possession, use, handling, storage and disposal of radiation sources to maintain the radiation dose as low as reasonably achievable to the general population.
2. The following is the ODH'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."
3. 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.

C. OSU Radiation Safety Culture Policy Statement

1. OSU is committed to a positive safety culture and expects that individuals and organizations performing regulated activities involving RAM and RGE will establish and maintain a positive safety culture environment.
2. 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.

D. As Low As Reasonably Achievable (ALARA)

1. ALARA is a general operating philosophy and a necessary basis for a program of maintaining occupational radiation exposures as low as reasonably achievable.
2. 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 comprehensive radiation protection planning and practices, 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.

Chapter 2: ALARA Program

A. Administrative Commitment

1. The administration of OSU is committed to the program described herein for keeping individual and collective radiation doses as low as reasonably achievable. In accord with this commitment, a description of the administrative organization for radiation safety is provided in this section, as well as the commitment to develop the necessary written policy, procedures, and instructions, fostering the ALARA concept at OSU. The organization includes the URSC, University Radiation Safety Officer (URSO), and the RSS.

2. Modifications to operating and maintenance procedures, and to equipment and facilities will be made if such measures are shown to reduce exposures. If modifications have been recommended, but not implemented, the reasons for not implementing such modifications shall be reviewed and approved by RSS.

3. In addition to maintaining radiation doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level.

B. University Radiation Safety Committee (URSC)

1. Review of proposed users and uses.
   a. The URSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials, and the methods of use for which an application has been made. This process is to ensure that the applicant will be able to take appropriate measures to maintain exposures ALARA.
   b. When considering a new use of RAM, the URSC will review the efforts of the applicant to maintain exposures ALARA.
   c. The URSC will ensure that users justify their procedures and that individual and collective doses will be ALARA.

C. Delegation of Authority

1. The judicious delegation of authority by the Senior Vice President for Administration and Planning is essential to the enforcement of the University ALARA Program.

2. The Senior Vice President for Administration and Planning will delegate authority to the URSC and RSS for the enforcement of the ALARA concept.

3. The URSC will support the RSS when it is necessary for the RSS to assert authority. If the URSC has overruled the RSS, it will record the basis for its action in the minutes of the Committee meeting.

D. Review of University ALARA Program

1. The URSC will review procedures of all protocols from individuals applying for Approved Supervisor status for adherence to the ALARA philosophy.

2. The RSS will perform a quarterly review of occupational radiation exposures with particular attention to instances in which the investigational levels in Table I are met or exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the University ALARA program's quality and to decide if action is warranted when investigational levels are met or exceeded.

3. Table 1. Investigational Levels (mrem per calendar quarter)

	Level I	Level II
Deep Dose Equivalent	125	375
Effective Dose Equivalent*	125	375
Lens Dose Equivalent	375	1,125
Shallow Dose Equivalent	1,250	3,750
Extremity Dose Equivalent	1,250	3,750

*If two dosimeters (collar and whole body) or a single collar badge are used to monitor radiation dose.

4. The URSC will evaluate the University's overall efforts for maintaining ALARA on an annual basis.

E. ALARA Reviews

1. Annual ALARA report.
   The RSS will submit an annual report to the URSC for adherence to the University ALARA program.

2. Quarterly review of occupational exposures.
   The RSS will review on a quarterly basis the external radiation dose of workers to determine that their doses are ALARA and will prepare a summary report for the URSC.

F. Education Responsibilities for ALARA Program

The RSS will ensure that Authorized Supervisors, Authorized Users (AUs), workers, and ancillary personnel who may be occupationally exposed to radiation will be instructed in the ALARA philosophy and informed that administration, the URSC, and the RSS are committed to implementing the ALARA concept.

G. Cooperative Efforts for Development of ALARA Procedures

1. The RSS ensures all new Approved Supervisors, AUs, and workers are familiar with ALARA procedures.

2. The RSS will evaluate the suggestions of individual workers for improving health physics practices and will encourage the use of these procedures.

3. Each AU should periodically review procedures to ensure good ALARA practices and will ensure that supervised individuals who are subject to occupational radiation exposures are trained and educated in comprehensive health physics practices and in maintaining exposures ALARA.

H. Individuals Who Receive Occupational Radiation Doses

1. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.

2. Workers will be instructed on their rights and responsibilities if they believe that safety practices are not being promoted on the job.

I. Establishment of Investigational Levels to Monitor Individual Occupational External Radiation Doses

1. The University has established investigational levels for occupational external radiation doses which, when equals or exceeds, will initiate review or investigation by the URSC and/or RSS. The investigational levels the University has adopted are listed in Table 1. These levels apply to the exposures of individual workers.

2. The RSS will review personnel monitoring records not less than once in any calendar quarter.

J. Personnel Dose Less Than Investigational Level I

Except when deemed appropriate by the RSS, no further action will be taken in those cases where an individual's radiation dose is less than Table 1 values for the Investigational Level I. Attention will be made to abnormally low radiation doses for individuals working in high radiation or output areas. Investigations of dosimetry values inconsistent with hours worked in a radiation area will be completed as deemed necessary.

K. Personnel Dose Equal to or Greater than Investigational Level I but less than Investigational Level II

The RSS will review the radiation dose of each individual whose quarterly radiation dose equals or exceeds Investigational Level I and will report the number of ALARA Level I notification at the next URSC meeting when the radiation dose is recorded. If the radiation dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the RSS.

L. Personnel Dose Equal to or Greater than Investigational Level II

The RSS will investigate in a timely manner the causes of all personnel radiation doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation and any actions taken will be presented to the URSC at the next meeting following the completion of the investigation. The details of these reports will be included in the URSC minutes.

M. Establishment of Investigational Levels Above Those Listed in Table 1

1. In cases where a worker's or group of workers' doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigational levels needs to be documented.

2. The URSC will review the justification for and must approve or disapprove all revisions of investigational levels.

Chapter 3: Administration of The Ohio State University Radiation Safety Program

A. The University Radiation Safety Committee (URSC)

1. The URSC is mandated by ODH and is comprised of faculty and staff from OSU. The URSC oversees the Radiation Safety Program and acts as a liaison between faculty/staff/management and RSS. 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 RAM, 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. .

2. The URSC's responsibilities are:
   - Reviewing, approving, disapproving or tabling all applications for the use of RAM at OSU.
   - Maintaining awareness of regulations and license conditions pertaining to the Radiation Safety Program.
   - Performing an annual review of routine operations of RSS.
   - Assisting the RSS with identification of problems, their causes and their solutions.
   - Reporting all actions and recommendations to the President of the University through the Senior Vice President for Business and Finance.
   - Developing, adopting and implementing policies and regulations specific to OSU for maintaining safety and compliance.
   - 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.

3. 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:
      - 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.
      - Reviewing and recommending to the URSC approval of applications for medical use of radioactive materials in routine 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/Authorized Medical Physicist/Authorized Nuclear Pharmacist must meet applicable requirements of the Ohio Administrative Code (OAC) rule 3701:1-58.
      - 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.

- 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:

- To recommend action deemed necessary and appropriate to remedy developing or actual issues of non-compliance involving committee-approved users.
- To recommend measures necessary to eliminate any perceived, or prevent any projected, non-compliance action against RSS by the ODH.
- To identify resource needs and suggest possible solutions.
- 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

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/URSO 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):

- Review of all radiation safety records with particular attention to those required by state regulations.
- Review of selected portions of routine operations for compliance with regulations, rules and licenses.
- Review of reports submitted by the URSO.
- Review of the results of State of Ohio inspection reports.
- Review of adequacy of the University's management control system.
- Review of Approved Supervisor's applications for one-year renewals.
- Review of NRC-issued amendments of license for use of materials.
- 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

1. Human Subject Review Committee (HSRC) is responsible for the review and approval of the use of ionizing radiation in research involving human subjects.

2. The active members of the Medical Use Subcommittee serve as the HSRC.

C. Radiation Safety Section of Environmental Health and Safety

1. RSS is responsible for ensuring 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 NRC, the Department of Health and Human Services (especially the Food and Drug Administration), the U.S. Department of Transportation (DOT) and the U.S. and Ohio Environmental Protection Agencies (EPA).

2. The URSO 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 URSO 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.

3. RSS Staff are assigned program responsibilities by the URSO consistent with license requirements and ODH regulations. The section is responsible for ensuring 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:

   - Maintaining a system of review and providing technical evaluations of all applications submitted by faculty of OSU and making recommendations to the URSC.
   - Establishing and maintaining controls and records regarding the purchase, receipt, distribution, and disposal of radioactive materials.
   - Inspecting all laboratories and auditing departments that contain or use radioactive material or radiation-generating equipment to ensure compliance with federal and state laws, rules, regulations, and University policy and procedures pertaining to the use of radioactive materials.
   - Maintaining all Federal and State licenses associated with source, byproduct, and special nuclear materials, and assuring that they are current.
   - Providing advice and assistance to users of radioactive materials in obtaining radioactive materials for instruction, research, and patient care.
   - Calibrating, inspecting, and certifying the portable survey instruments used by the section and by users.
   - Establishing procedures for, and assuring the safety of, personnel who are involved in the care of patients being treated or diagnosed with radioactive substances.
   - Providing training to users of radioactive materials and assuring that they are qualified to handle such materials.
   - Maintaining a program to monitor the exposure of personnel engaged in the use of radioactive materials or radiation producing equipment to ensure that permissible levels of exposure are as low as reasonably achievable.

D. The Approved Supervisor or Authorized User

1. Approved Supervisors and Authorized Users are physicians, faculty or staff members with authorization from the URSC to use and possess radioactive materials.
   Primary responsibilities may include:
   - Ensuring 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.
   - Ensuring every user has been instructed in, or has read, the OAC rules 3701:1-38 3701:1-58, the Radiation Safety Standards for The Ohio State University, the Quality Assurance and Radiation Protection Program and Manual, and The OSUWMC Radiation Safety Program manual, as applicable. All personnel should be prepared to make such a declaration to any State of Ohio representatives.
   - Ensuring all users have successfully completed the required training prior to beginning work and annually thereafter as applicable.
   - Notifying RSS 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.
   - Controlling contamination in areas of radioactive materials use.
   - Maintaining records of receipt and disposition of all radioactive materials.
   - Ensuring the procedures and precautions as outlined in an approved permit are followed.
   - Ensuring that radioactive materials are secured from unauthorized removal or access.
   - Maintaining postings of form ODH Notice to Employees and other appropriate caution signs, labels and signals as may be required by the OAC rule 3701-38-18.

E. The User or Radiation Worker

A user is an individual who handles or uses radiation-emitting sources. Users must be trained by and work under the supervision of an Approved Supervisor or Authorized User. They must also be instructed in, or have read, OAC 3701:1-38, OAC 3701:1-58, and the Radiation Safety Standards for The Ohio State University, the Quality Assurance and Radiation Protection Program and Manual, and The OSUWMC Radiation Safety Program manual, as applicable. Each user must successfully complete an applicable Radiation Safety Course and participate in initial and annual training, as applicable.

F. Authorization to Use RAM for Clinical and Human-Use Research

1. The use of licensed radioactive material in or on humans shall be by an AU as defined in OAC 3701:1-58-01.

2. AU/AMP/ANPs designated to use licensed material in or on humans shall meet the training criteria established in OAC 3701:1-58 and shall be designated by the URSC.

3. OSU will maintain records of individuals designated as AU/AMP/ANP for five (5) years after his or her last use of licensed material.

Chapter 4: Personnel Protection and Personnel Exposure Monitoring Program

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)
   a. 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 to the fetus not to exceed 0.5 rem during the gestation period
Minor	
< 18 years of age	10% of Adult Limits

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

Radiation Emitter	Minimum Activity Used At Any One Time (mCi)	Example Radionuclides
I-125 and Pd-103*	10	n/a
Gamma emitters[1] with gamma constant > 0.2	1	C-11, Co-60, F-18, Ga-68, I-123, I-124, I-131, In-111, Ir-192, N-13, Na-22, O-15
Gamma emitters[1] with gamma constant < 0.2	10	Cd-109, Co-57, Cr-51, I-129, Kr-85, Tc-99m
Beta emitters[2] with Emax > 0.2	10	Ca-45, P-32, P-33, Y-90
Beta emitters[2] with Emax < 0.2	Not applicable, no badge used	H-3, C-14, Ni-63, S-35
Beta-Gamma emitters	Lowest of above applicable activities	n/a

[1] Γ = specific gamma ray dose constant at 1 meter (rem/hr)/Ci.
[2] Emax = beta particle end point energy, MeV.
* I-125 and Pd-103 are 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.

c. Other Badge Requirements

Some individual monitoring devices are issued due to license conditions apart from the OAC. 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. Division of Radiation Oncology personnel handling radioactive materials.
d. Division of Nuclear Medicine personnel handling radioactive materials.
e. Regular personnel of RSS expected to exceed 10% of their occupational dose limit.
f. Users of radiation generating devices or state-registered radioactive material likely to receive a dose in any calendar quarter in excess of 10% of applicable limits.
g. Individuals entering a high or very high radiation area.
h. Users operating under requirements from ODH-issued licenses, the URSO, and/or the URSC. Factors which may be considered typically include long handling times or lack of experience of handlers.

2. Obtaining Dosimeters
   a. If an individual is joining a 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, 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, www.ehs.osu.edu

3. More Information Relating to Dosimeters
   a. Store dosimeters where they will not inadvertently be exposed to radiation, excessive heat or moisture.
   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. Upon leaving the University, dosimeters will be returned to your designated badge coordinator. The badge coordinator must inform RSS to delete the dosimeters of all individuals who have left their series and return dosimeters immediately to RSS.
   i. Dosimeters should not be worn when you undergo medical exams or therapies that involve radiation exposure. This includes medical and dental x-rays.

j. Any individual suspecting that they or their dosimeter may have been overexposed or contaminated, contact RSS immediately.

B. Internal Exposure

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.

1. Urine Bioassays
   a. All radiation workers are required to submit monthly urine bioassays if the location uses an unsealed or loose form on a yearly basis a quantity of radioactive material > 2000 ALI. For locations using multiple radionuclides the need for urine bioassays is determined by whether the sum of the locations requested yearly activity for each radionuclide divided by 2000 ALI > 1. Urine bioassays are recommended for non-radiation workers in these areas as well.
   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 > 100 ALI.
   c. Urine bioassays will also be submitted in accordance with requirements from the URSC.

2. Thyroid Bioassays
   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 URSO or at the direction or the URSC.

C. Investigational Levels and Overexposures

1. Dosimeters
   a. Investigational Level I Notification - If an individual receives the following per quarter, the RSS will notify the individual in writing:
      i. deep dose equivalent (DDE) ≥ 125 mrem but < 375 mrem
      ii. lens dose equivalent (LDE) ≥ 375 mrem but < 1125 mrem
      iii. shallow dose equivalent (SDE) ≥ 1250 mrem but < 3750 mrem
      iv. Extremity ring badge ≥ 1250 mrem but < 3750 mrem

   b. Investigational Level II Notification - If an individual receives the following per quarter, the RSS will notify the individual and badge coordinator in writing and request the individual complete the "Investigational Level II Radiation Exposure Report" questionnaire. Efforts to implement reasonable corrective actions to avoid or reduce additional exposure will also be considered by the RSS in conjunction with the individuals department or location.
      i. deep dose equivalent (DDE) ≥ 375 mrem
      ii. effective dose equivalent (EDE) ≥ 375 mrem
      iii. effective dose equivalent (EDE) = ≥ 375 mrem
      iv. lens dose equivalent (LDE) ≥ 1125 mrem
      v. shallow dose equivalent (SDE) ≥ 3750 mrem
      vi. Extremity ring badge ≥ 3750 mrem

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 URSO 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 RSS will investigate the exposure and implement reasonable corrective actions to avoid or reduce additional exposure.

3. Planned Special Exposures
   a. 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.

D. Records

1. Records of Individual Monitoring Results
   a. The RSS 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.
   b. Summary reports for each location are maintained by the RSS and provided to each location.

c. "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
   a. For those individuals for whom monitoring is required, determination of current year exposure at other facilities will be obtained in accordance with OAC rule 3701:1-38-12. 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.
   b. In addition, an attempt will be made to obtain the records of lifetime cumulative occupational radiation dose.

3. Records of Planned Special Exposures
   a. Records of each PSE are kept in accordance with OAC Chapter 3701:1-38-20.

Chapter 5: Fetal Dose Policy for Pregnant Employees and Minors

A. Pregnant Workers

OAC 3701:1-38-12(H) states that OSU shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem during the gestation period.

1. Declared pregnant individual by definition is an individual who has declared their pregnancy in writing to the RSS.

2. The OSU/OSUWMC fetal dose policy incorporated safety information and radiation dose guidelines for ensuring safe radiation limits for the embryo/fetus of occupationally exposed employee.

3. The declaration of pregnancy is voluntary, but it must be made known in writing. A pregnant radiation worker may voluntarily declare her pregnancy in writing to RSS by completing a RS-13 form.

4. RSS will review the RS-13 form and recommend a personnel monitoring program based on the information supplied in the Declaration of Pregnancy (RS-13) form.

5. Upon declaration of pregnancy, the radiation dose to the embryo/fetus during the gestation period will not be allowed to exceed 0.5 rem Total Effective Dose Equivalent (TEDE) unless the wearer has already received > 0.5 rem TEDE, in which an additional 0.05 rem will be permitted for the remainder of the pregnancy in accordance with OAC rule 3701:1-38-12.

6. Declared pregnant workers may request a meeting with a member of the RSS. During this meeting the RSS member will review the following, along with answering any questions the individual may have.
   a. The individual's exposure record. If the record indicates an exposure to the embryo/fetus greater than 0.5 rem may occur, an RSS member will initiate steps to move the individual to a position of lower radiation exposure and one that the exposure can be maintained less than 0.5 rem.
   b. Procedures to minimize exposure to the embryo/fetus.

7. Whether a pregnancy is declared or not, pregnant workers are expected to apply good radiation safety practices and keep their dose and the dose to their embryo/fetus as low as reasonably achievable, ALARA.

B. Minors (Individuals less than 18 years of age)

1. 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 Acknowledgment of Radiation Exposure Limitations for a Minor (RS-14) form, shall be completed and submitted to RSS.

2. 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.

3. The radiation dose to the minor will not be allowed to exceed 0.5 rem TEDE per year.

Chapter 6: Criteria for Evaluating Users Qualifications for the Use of Radioactive Materials and Establishing an Authorization to Use RAM

An Authorized User (AU) is an individual who by virtue of position, training and experience is designated by the URSC as a user of radioactive material under OSU broad scope radioactive material license. This authorization permits the procurement and use of radioactive material within a defined protocol or work activity under the supervision of the authorized user provided that the materials are used within the guidelines of safe practice, and within the rules, regulations and recommendations of the URSC and OSU policies. Two additional authorization categories exist, Authorized Medical Physicist (AMP) and Authorized Nuclear Pharmacist (ANP). Radiation Safety maintains a list of currently approved AU / AMP / ANPs on our departmental site at the OSUWMC SharePoint page.

To establish an authorization, the AU applicant must be qualified according to the criteria in the applicable part(s) of the ODH rules and through the completion of the OSU URSC application process. The applicant must complete the appropriate forms. An appointment to meet with RSS should be arranged prior to completing an application. By ODH definition:

A. Authorized Users (AU)

An "Authorized User" means a physician, dentist, or podiatrist who:

1. Meets the requirements in rule OAC 3701:1-58-22 of the Administrative Code and paragraph (A) of rule 3701:1-58-33, paragraph (A) of rule 3701:1-58- 36, paragraph (A) of rule 3701:1-58-40, paragraph (A) of rule 3701:1-58-41, paragraph (A) of rule 3701:1-58-42, paragraph (A) of rule 3701:1-58- 51, paragraph (A) of rule 3701:1-58-54, or paragraph (A) of rule 3701:1- 58-71 of the Administrative Code; or

2. Is identified as an authorized user on:
   a. A license issued by the Director, NRC, or an agreement state that authorizes the medical use of radioactive material;
   b. A permit issued by a NRC master material licensee that is authorized to permit the medical use of radioactive material;
   c. A permit issued by a NRC, or agreement state specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or
   d. A permit issued by a NRC master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

3. AUs are required to be trained and approved for the following modalities of use as described in the Ohio Administrative Code (OAC):
   a. 3701:1-58-32 – Use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required.
   b. 3701:1-58-34 – Use of unsealed radioactive material for imaging and localization studies for which a written directive is not required.
   c. 3701:1-58-37 – Use of unsealed radioactive material for which a written directive is required.
   d. 3701:1-58-37 – Oral administration of sodium iodide Iodine-131 requiring a written directive in quantities less than or equal to 33 millicuries.
   e. 3701:1-58-37 – Oral administration of sodium iodide Iodine-131 requiring a written directive in quantities greater than 33 millicuries.
   f. 3701:1-58-37 – Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required.

g. 3701:1-58-37 – Parenteral administration of any other radionuclide for which a written directive is required.
h. 3701:1-58-43 – Use of manual brachytherapy sources.
i. 3701:1-58-55 – Use of remote after-loader units (HDR).
j. 3701:1-58-72 – Use of new and emerging technologies (including at OSUWMC/The James/JOCC):
   - Gamma Knife Icon
   - Radioactive Seed Localizations (Iodine-125 RSL)
   - Yttrium-90 Microspheres therapy
   - Radium-224 Alpha Dart therapy

B. Authorized Medical Physicist (AMP)

An "Authorized Medical Physicist" means an individual who:

1. Meets the requirements in paragraph (A) of rule 3701:1-58-19 and rule 3701:1-58-22 of the Administrative Code; or

2. Is identified as an authorized medical physicist or teletherapy physicist on:
   a. A specific medical use license issued by the director, NRC, or an agreement state;
   b. A medical use permit issued by a NRC master material licensee;
   c. A permit issued by a NRC or agreement state broad scope medical use licensee; or
   d. A permit issued by a NRC master material license broad scope medical use permittee.

3. AMPs are required to be trained and approved for the following modalities of use as described in the Ohio Administrative Code (OAC):
   - 3701:1-58-43 – Use of manual brachytherapy sources.
   - 3701:1-58-55 – Use of remote after-loader units (HDR).
     3701:1-58-72 – Use of new and emerging technologies

C. Authorized Nuclear Pharmacist (ANP)

An "Authorized Nuclear Pharmacist" means a pharmacist who:

1. Meets the requirements in paragraph (A) of rule 3701:1-58-20 and rule 3701:1-58-22 of the Administrative Code; or

2. Is identified as an authorized nuclear pharmacist on:
   a. A specific license issued by the director, NRC, or an agreement state that authorizes medical use or the practice of nuclear pharmacy;
   b. A permit issued by a NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;
   c. A permit issued by a NRC or agreement state broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or
   d. A permit issued by a NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy;
   e. Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or
   f. Is designated as an authorized nuclear pharmacist in accordance with rule 3701:1-46-43 of the Administrative Code.

3. ANPs are required to be trained and approved for the preparation and administration of radiopharmaceuticals.

D. Individuals seeking AU/AMP/ANP status

Individuals seeking AU/AMP/ANP status must complete and submit the appropriate forms provided by RSS as they apply to the modality of use. Completed forms should be submitted to the RSS for review and submittal to the Medical Use Subcommittee.

Individuals seeking AU/AMP/ANP status must meet the training requirements outlined in OAC 3701:1-58. For new and emerging technologies, individuals must meet the training requirements listed in the applicable NRC guidance.

Individuals seeking AU/AMP/ANP status must complete 5 supervised cases under the direct supervision of an Authorized User. This includes individuals who have been granted AU/AMP/ANP status at other medical facilities.

Once all materials have been received and reviewed by the Medical Use Subcommittee, recommendations will be given to the URSC for final approval of the individual to act as an AU, AMP, or ANP based on the modality of radioactive material use.

Chapter 7: Emergency Procedures

A. Personnel Contamination

All personnel contamination must be reported to the RSS immediately.
Call (614) 561-7969 for all radiological emergencies.

Personnel Contamination

i. RSS must be notified immediately of any incident involving personnel contamination, regardless of the radionuclide or activity. The RSS emergency response phone number is (614) 561-7969.
ii. Begin decontamination of skin surfaces immediately with soap and warm water. Contaminated clothing should be removed and stored for further evaluation by RSS. 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.
iii. Document the incident and send to the RSS within 24 hours using the "Radioactive Material Spill Form" located on the RSS SharePoint page.

B. Radioactive Material Spill Procedures

OSU has developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with OAC rule 3701:1-38-11.

Minor Spill (< 100 microcuries)

i. Notify: Notify persons in the affected area that a spill has occurred.
ii. 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.
iii. Prevent the Spread: Confine the movement of all potentially contaminated personnel and evaluate for contamination before allowing them to leave the location.
iv. 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.
v. Survey: With smear wipes, and if appropriate with a survey meter, check the area around the spill, hands and clothing for contamination.
vi. Report: Report the incident to the RSS within 24 hours using the "Radioactive Material Spill Form" located on the RSS OneSource page. The RSS emergency response phone number is (614) 561-7969.

Major Spills (> 100 microcuries)

i. Clear the Area: Notify all persons not involved in the spill to vacate the affected area.
ii. Call for Help: Report the incident to RSS immediately. The RSS emergency response phone number is (614) 561-7969.
iii. 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.
iv. Prevent the Spread: Confine the movement of all potentially contaminated personnel and evaluate for contamination before allowing them to leave the location.
v. 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.

vi. Clean Up: Performed under the guidance of RSS personnel.
vii. Report: Report the incident to the RSS within 24 hours using the "Radioactive Material Spill Form" located on the Radiation Safety OneSource page. The Radiation Safety emergency response phone number is (614) 561-7969.

B. Stolen, Lost, or Missing Radioactive Materials

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

The URSO, or designee, will notify management and the appropriate authorities. RSS will immediately report to ODH 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 ODH 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).

C. HDR Remote After-loader

Emergency procedures for the HDR Remote After-loader are posted in the console area and all users are trained annually on these procedures.

D. Gamma Knife

Emergency procedures for the Gamma Knife are posted in the console area and all users are trained annually on these procedures.

Chapter 8: Personnel Training Program

A. Radiation Safety Program

The Radiation Safety Program of OSU provides for training in radiation safety for personnel likely to receive an occupational exposure in excess of 1 mSv (100 mrem) in one year.

B. Mandatory Training

Training is mandatory for all radiation workers and appropriate ancillary personnel and shall be completed prior to issuance of radiation dosimetry or permission to work in a radiation area or with radioactive materials.

C. Annual Training

Annual training will be provided for radiation workers likely to receive occupational exposure in excess of 1 mSv (100 mrem) in one year.

D. Radiation Workers

Radiation workers at OSU include, but are not limited to, the following:

1. Approved Supervisors (researchers, physicians, or other personnel specifically authorized by the URSC to use or supervise the use of radioactive materials),

2. AUs, AMPs, ANPs,

3. Users

4. Ancillary personnel – Personnel who may enter radiologically-posted rooms in the course of their duties but who do not routinely work with radioactive materials.

E. Elements of training program

1. At a minimum, initial training offered will include the elements specified in OAC 3701:1-38-10 (B) and will be provided electronically (e.g. on-line training program) or by the URSO and/or a qualified staff member.

2. Individuals involved in the medical use of radioactive materials in humans must participate in training commensurate with their job functions

F. Authorized User, Authorized Medical Physicists, and Authorized Nuclear Pharmacists

AUs, AMPs, and ANPs approved by the URSC must meet the criteria outlined in OAC 3701:1-58.

G. Training for Radiation Workers for routine patient care

a. Training for radiation workers will include further written or verbal instruction from the authorized users and/or Radiation Safety staff. Training should include, but not be limited to the following items:
   i. Demonstration of radioactive material handling and use techniques,
   ii. Demonstration of proper radiological controls practices such as performing contamination surveys, use of radiation detection instrumentation, and response to radiological emergencies,
   iii. Knowledge of site-specific safety instruction and license conditions for OSU,
   iv. Knowledge of applicable state regulations

H. Instructions for Nurses and Patient Caregivers for Inpatient I-131 and Brachytherapy

a. Instructions to nursing and patient care staff are given in accordance with:
   i. OAC 3701:1-58-38 “Safety Instructions for Unsealed Radioactive Material”
   ii. OAC 3701:1-58-39 “Safety Precautions for Unsealed Radioactive Material”
   iii. OAC 3701:1-58-46 “Safety Instructions for Manual Brachytherapy”
   iv. OAC 3701:1-58-47 “Safety Precautions for Manual Brachytherapy”

b. Training is given to new nursing and patient care staff initially and annually thereafter.

c. Additional instructions to nursing and patient care staff are reviewed with staff and/or posted in each patient or human research subject’s room. Instructions include but are not limited to:
   i. Misplaced or Dislodged Source(s)
   ii. Pictures detailing size and appearance of source(s)
   iii. Safe handling and shielding instructions
   iv. Patient Quarters and Visitation Restrictions
   v. Personal Protective Equipment Required (as necessary)
   vi. Housekeeping, Trash/Linen, and Meals – Waste Control
   vii. Lab Work and Additional Medical Procedures
   viii. Personnel Monitoring (as necessary
   ix. Radiation Safety Surveys and Patient Discharge
   x. Emergency Information in the event of:
      a. Patient requires emergency medical attention
      b. Patient must leave designated room
      c. Patient expires
      d. Unexpected leakage or spillage of body fluids

I. Training for Ancillary Personnel

a. Appropriate ancillary staff will be provided training appropriate to the level of their involvement with radiation and/or radioactive materials.

b. This training will meet the requirements of OAC 3701:1-38-10 (B) and may be incorporated into general orientation or general safety training.

J. Continuing Education

a. The RSS issues communications to radiation workers and authorized users on an as-needed basis. These communications may include information on policy changes, procedural changes, good radiation safety practices, and regulatory updates.

b. Authorized users are encouraged to share this information with all users under their supervision and to maintain copies of these communications in a central location.

   a. Departments are responsible for communicating any departmental policy changes with staff.

K. Records of Training

a. A copy of radiation safety training course contents will be retained by the RSS.

b. Records for each training session will be maintained and will include the date(s) training was provided and the names of attendees.

c. Records of the initial and annual training will be maintained by the RSS. Radiation Oncology will maintain all emergency procedure training records for the HDR and Gamma Knife Icon.

L. Radiation Safety Training Policy

Radiation Safety Training Policy for the OSUWMC has been adopted by the URSC and the Quality Assurance Committee. The policy delineates the required actions for the annual radiation safety training of all occupational radiation workers and ancillary workers/staff. See Appendix F.

Chapter 9: Sealed Sources

A. 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. Users of sealed sources should ensure that:

1. Sealed sources are accounted for on inventories.

2. Sealed sources are made available to RSS 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.

   i. A leak test is not required if the sealed radioactive source:
      - contains a radionuclide with a half-life of less than 30 days
      - contains only H-3
      - contains only gaseous nuclides
      - contains less than 100.0 µCi of beta or gamma-emitting material
      - contains less than 10.0 µCi of alpha-emitting material, or
      - is not designed to emit alpha particles and is in storage and not in use.

   ii. The leak test of a sealed source is also the physical inventory.

   iii. The leak test of a sealed source will be performed using the requirements stated in OSU Standard Operating Procedures “Use of Sealed Radioactive Sources”.

B. Leak Testing and Inventory

1. Sealed radioactive sources shall be leak tested on a semiannual basis.

2. Measurements shall be performed on an instrument capable of detecting 185 Bq (0.005 µCi) of radioactivity.

3. Gamma stereotactic radiosurgery sources are exempt from individual leak testing.

4. Sealed radioactive sources shall be inventoried on a semiannual basis.

5. Gamma stereotactic radiosurgery sources are exempt from individual inventory.

6. Record shall be maintained in accordance with OAC 3701:1-58-80 “Records of Leak Tests and Inventory of Sealed Sources and Brachytherapy Sources.”

C. Brachytherapy Source Accountability

1. Accountability of brachytherapy sources shall be kept in accordance with OAC 3701:1-58-45 “Brachytherapy Sources Accountability.”

2. For temporary implants records shall include:
   a. The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, the location of use; and

b. The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

3. For permanent implants the records shall include:
   a. The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;
   b. The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and
   c. The number and activity of sources permanently implanted in the patient or human research subject.

4. Records shall be maintained in accordance with OAC 3701:1-58-88 “Records of Brachytherapy Sources Accountability.”

Chapter 10: General Rules for the Safe Use of Radioactive Material and the Use of Personal Protective Equipment (PPE)

A. Safe Use of Unsealed Licensed Material

1. OSU has developed and will implement and maintain procedures for safe use of unsealed radioactive material that meet the requirements of OAC rule 3701:1-38-11 and OAC rule 3701:1-38-13."

    a. Wear laboratory coats or other personal protective equipment (PPE) when handling, manipulating, or administering licensed radioactive material.
    b. Wear disposable gloves at all times while handling radioactive materials.
    c. Regularly monitor your hands and feet for contamination in a low-background area using an appropriate survey instrument.
    d. Use syringe shields for reconstitution of radiopharmaceutical kits and administration of radiopharmaceuticals to patients, except when their use is contraindicated (e.g., recessed veins, infants). In these and other exceptional cases, use other protective methods such as remote delivery of the dose (e.g., use a butterfly needle.)
    e. Do not eat, store food/drink (unless for patient use), chew gum, smoke or apply cosmetics in any area where radioactive material is stored or used.
    f. Wear personnel monitoring devices, if required, at all times while in areas where radioactive materials are in use. These devices shall be worn as prescribed by the RSS. When not being worn to monitor occupational exposures, personnel monitoring devices shall be stored in the workplace in a designated low-background area.
    g. Appropriate shielding shall be used in all areas where radioactive materials, including wastes, are stored.
    h. Use tongs or other similar devices to handle high activity radionuclide dosages, elutions, and sealed sources.
    i. Wear extremity dosimeters, if required, when handling radioactive material.
    j. Fume hoods or equivalent shall be used during compounding or preparation of licensed radioactive material with the potential for release of airborne radioactivity in the form of dusts, gases, vapors, aerosols, etc.
    k. 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.
    l. Dispose of radioactive waste only in designated, labeled and properly shielded receptacles.
    m. Never pipette by mouth.
    n. Wipe-test unsealed byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate the area.
    o. Survey with a radiation detection survey meter all areas where unsealed radioactive material was prepared or administered in accordance with OAC 3701:1-58-29.
    p. Results of smear wipe surveys and area surveys must be maintained in units of disintegrations per minute and exposure rate maintained in units of mR/hr, respectively.
    q. Store radioactive solutions in shielded containers that are clearly labeled.
    r. Maintain a current and accurate record of receipt, transfer, use, decay and disposal of radioactive materials.
    s. Radiopharmaceutical multi-dose diagnostic and therapy vials must be labeled in accordance with OAC rules 3701:1-58-28 and 3701:1-38-18(C).
    t. Syringes and unit dosages must be labeled in accordance with OAC rules 3701:1-58-28 and 3701:1-38-18(C). Mark the label with the radionuclide, the activity, the date for which the activity is estimated and the kind of materials (i.e., radiopharmaceutical). If the container is

holding less than the quantities listed in Appendix A to OAC rule 3701:1-38-18(E), the syringe or vial need only be labeled to identify the radioactive drug (OAC rule 3701:1-58- 28). To avoid mistaking patient dosages, label the syringe with the type of study and the patient's name.

u. For prepared dosages, assay each patient dosage in the dose calibrator (or instrument) before administering it or measurement will be calculated by decay and volume (OAC rule 3701:1-58-25).
v. Do not use a dosage if it does not fall within the prescribed dosage range or if it varies more than ±20 percent from the prescribed dosage, except as approved by an authorized user.
w. When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle.
x. Check the patient's name and identification number and the prescribed radionuclide, chemical form and dosage before administering. If the prescribed dosage requires a written directive, the patient's identity must be verified and the administration must be in accordance with the WD (OAC rule 3701:1-58-16).
y. Always keep flood sources, syringes, waste and other radioactive material in shielded containers.
z. Secure all licensed material when not under the constant surveillance and immediate control of an authorized individual.

Chapter 11: Procedure for Ordering Radioactive Material

Therapeutic radionuclides used within Nuclear Medicine are ordered as needed by the Nuclear Pharmacy. Additionally, therapeutic radionuclides used within Radiation Oncology are ordered as needed by the Radiation Oncology Physics Department and/or Brachytherapy.

A. Nuclear Pharmacy

- Iodine-131 – Ordered as need per patient for diagnostic and therapeutic procedures
- Radium-223 – Ordered per patient therapy as needed.
- Lutetium-177 – Ordered per patient therapy as needed.
- Others as needed per patient / physician (AU) request.

B. Radiation Oncology

- Iodine-125 – I-125 brachytherapy seeds for eye plaque procedures are ordered as needed under patient specific treatment plans created by a physician and the Radiation Oncology Physics Department.
- Paladium-103 – Pd-103 brachytherapy seeds for prostate implant are ordered as needed under patient specific treatment plans created by a physician and the Radiation Oncology Physics Department.
- Yttrium-90 – Y-90 microspheres for liver implant are ordered as needed under patient specific treatment plans created by a physician and the Radiation Oncology Physics Department.
- Iridium-192 – Ir-192 HDR sources are ordered approximately every 2.5 months for source exchange.
- Cobalt-60 – Co-60 Gamma Knife sources will be replaced as needed, approximately every 5-6 years.
- Ra-224 Alpha Dart sources are ordered as needed under patient specific treatment plans created by a physician and the Radiation Oncology Physics Department.
- Others as needed per patient / physician (AU) request.

D. Procurement of radioactive materials may also be made by way of internal transfer(s).

Chapter 12: Records of Radioactive Material Use

A. Nuclear Medicine

All radioactivity dosages will be determined by measurement in a dose calibrator or calculated by decay and volume. Dosages given to human patients will be within a given range or with +/- 20% of the prescribed dosage. Therapeutic dosages that exceed +/- 10% of the prescribed dosage require AU approval and internal investigation.

1. For each unit dosage received from a supplier, a record will be made that includes:
    a. Radiopharmaceutical
    b. Date of receipt.
    c. Supplier.
    d. Lot number if one is assigned.
    e. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time.
    f. Date of administration or disposal.
    g. If administered:
        i. Prescribed dose
        ii. Measured activity in millicuries or microcuries and date and time of measurement if using a dose calibrator.
        iii. Patient name and identification number if one has been assigned.
    h. If discarded:
        i. The date
        ii. Initials of the individual who made the record.

2. Radiopharmaceuticals are received in multi-dose shipments in addition to the unit dose shipments mentioned above. For these materials, the hospital records the following:
    a. Radiopharmaceutical
    b. Date of receipt of preparation
    c. Date and time of initial assay and activity
    d. Supplier or kit manufacturer
    e. If administered, the prescribed dosage, date and time dosage was drawn/assay, the calculated volume needed for the dosage prescribed, the measured radioactivity and the patient's name.
    f. If discarded, the date discarded.
    g. The initials of the individual making the record.

B. Radiation Oncology

When manual brachytherapy sources are used, the following records of use must be kept

1. When temporary implant brachytherapy sources are removed from storage, a record will include
    a. The number and radioactivity of sources removed
    b. The time and date they were removed from storage
    c. The location of use and the name of the individual who removed them from storage

2. When temporary implant brachytherapy sources are returned to storage, a record will include
    a. The number and radioactivity of sources returned
    b. The time and date they were returned to storage

c. The name of the individual who returned them to storage

3. For permanent implants, a record will be made and will include

a. The number and radioactivity of sources removed from storage
b. The date they were removed from storage
c. The name of the individual who removed them from storage
d. The number and radioactivity of sources not implanted
e. The date they were returned to storage
f. The name of the individual who returned them to storage
g. The number and radioactivity of sources permanently implanted in the patient or human research subject

Chapter 13: Procedure for Safely Receiving Packages Containing Radioactive Material

A. Radioactive Materials Packages

Radioactive materials packages must be received in an area designated for the storage of radioactive materials.

B. Before opening the package

1. Observe the shipping container. If it appears to be leaking, crushed or damaged in any way, notify Radiation Safety immediately at (614) 561-7969.
2. Wear your personal monitoring device(s).
3. Wear PPE and disposable gloves when handling radioactive materials.

C. Incoming Package Monitoring

Incoming labeled packages will be monitored in accordance with OAC rule 3701:1-38-18 (F). OSUWMC only receives Type A labeled packages.

a. Monitor the external surfaces for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form.
b. Monitor packages for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as a package that is crushed, wet, or damaged.
c. Perform the monitoring as soon as practicable after receipt of the package, but not later than three hours after the package is received if it is received during normal working hours. If a package is received after working hours, the package will be monitored no later than three hours from the beginning of the next working day.

D. Opening the Package

1. Visually inspect the inner container(s) for evidence of damage, loss of containment or leakage. If any of these conditions exist:

    a. Notify Radiation Safety immediately at (614) 561-7969.
    b. Do not attempt to move, open or remove any contents of the package.
    c. 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.

2. Check the contents of the package for correctness.
3. If contents are undamaged and correct, move the radioactive material to its approved storage location.

E. Discard Empty Packaging

Once it has been determined no contamination exists on packaging materials and before the packaging materials may be disposed of as regular trash, any trefoil warning labels and/or “Radioactive” wording must be removed and obliterated or be completely defaced to prevent anyone from mistakenly identifying the material as being radioactive.

Chapter 14: Survey Procedures

A. Area Surveys – Frequency and Procedures

1. Area surveys shall be performed, and records maintained based on the following regulations:

   Nuclear Medicine and Nuclear Pharmacy areas will be surveyed in accordance with OAC 3701:1-58-29 "Surveys of Ambient Radiation Exposure Rate." Sealed-source and brachytherapy-source storage areas will be surveyed in accordance with OAC 3701:1-38-13(A)(2).

   a. Records will be maintained in accordance with OAC 3701:1-58-81 "Records of Surveys for Ambient Radiation Exposure Rate."

2. Survey Frequency and Procedures

   a. OSU has established and implemented the model procedures outline in Appendix R "Model Procedure for Area Surveys" of the U.S. NRC "Specific Guidance about Medical Use Licenses,NUREG-1556," Revision 3, Effective Date September 2019.

   b. Ambient Radiation Surveys

      i. Ambient radiation surveys of dose rates are performed in locations where workers may be exposed to radiation levels that could result in radiation doses in excess of 10% of the occupational dose limits where individuals work in an environment with dose rates of 2.5 mrem/hr or more.

      ii. Ambient radiation level surveys with a survey meter sufficiently sensitive to detect 0.1 milliroentgen (mR) per hour in the following areas, at the frequency specified:
      - Survey at the end of each day of use all radiopharmaceutical elution, preparation, assay and administration areas (except patient rooms, which will be surveyed at the end of the therapy instead of on the day of administration)
      - Survey weekly all radionuclide waste storage areas.
      - Survey quarterly all sealed-source and brachytherapy-source storage areas.

   c. If action levels are exceeded, follow internal procedures for responding and investigating what caused the action level to be exceeded. Action levels for restricted and unrestricted areas are presented in the table below.

Ambient Dose Rate Trigger Levels	
Area Surveyed	**Trigger Level**
Unrestricted	0.1 mR/hr
Restricted	2.0 mR/hr

3. Contamination Wipe Surveys

   a. Contamination surveys shall be performed with an instrument(s) suitable for detecting removable and fixed contamination. Removable contamination shall be detected and measured by conducting a wipe test of the surface(s) and counted in an appropriate counting instrument sufficiently sensitive to detect contamination for the radionuclides in use (e.g., 200 dpm/100 cm^2).

   b. Contamination surveys are performed in areas where unsealed forms of materials are used to evaluate the following:

      i. Radioactive contamination that could be present on surfaces of floors, walls, furniture, and equipment;
      ii. After any spill or contamination event;
      iii. When procedures or processes have changed;
      iv. To evaluate contamination of users and the immediate work area, at the end of the day, when licensed material is used.

   c. Removable contamination survey samples should be measured in a low-background area. The following areas and frequencies should be followed:

      i. Removable contamination surveys weekly for radiopharmaceutical hot labs.
      ii. Removable contamination surveys weekly for all preparation, assay, and administration areas for therapeutic doses of radiopharmaceuticals.
      iii. Removable contamination surveys weekly for radionuclide waste storage areas.

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

         - Action levels for restricted and unrestricted areas are presented in the table below.

Contamination Trigger Levels	
Area Surveyed	**Trigger Level**
Unrestricted	200 dpm/100cm2
Restricted	2,000 dpm/100cm2

         - Any areas found to be above the trigger levels listed below should be either decontaminated, shielded, or posted and restricted from use if it cannot be decontaminated.

         - If the trigger levels are exceeded, follow internal procedures for responding and investigating what caused the action level to be exceeded.

         - Contamination found in unrestricted areas and on personal clothing will be immediately decontaminated to background levels or contained as radioactive material.

B. High Dose Remote After-loader and Gamma Knife

1. Radiation surveys shall be completed in accordance with OAC 3701:1-58-68 “Radiation surveys for remote after-loader units, teletherapy units, and gamma stereotactic radiosurgery units.”

2. Surveys shall:
   a. Be completed to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the sealed source and device registry.

   b. Be completed at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

   c. Records shall be maintained in accordance with OAC 3701:1-58-99 “Records of surveys of therapeutic treatment units.

C. Surveys After Brachytherapy Source Implant, Removal and High Dose Remote After-loader

   a. Surveys will be completed for manual brachytherapy and HDR as required in OAC 3701:1-58-44 “Surveys after Source Implant and Removal,” and OAC 3701:1-58-56 “Surveys of Patients and Human Research Subjects Treated with Remote After-loader Unit,” respectively.

   b. Records shall be maintained in accordance with OAC 3701:1-58-87 “Records of surveys after source implant and removal.”

Chapter 15: Storage and Disposal of Radioactive Material

A. Waste Management

OSU has developed, implemented and maintains written waste disposal procedures for licensed material in accordance with OAC rule 3701:1-38-11(D) that also meet the requirements of the applicable OAC rule 3701:1-38-19."

B. 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 survey instrument until dose rates are indistinguishable from background. Storage must not to exceed four years.

1. Nuclear Medicine – Decay-in-storage is used at all Nuclear Medicine locations as well as within the Nuclear Pharmacy. OSU follows the guidance provided by Appendix W "Model Procedure for Waste Disposal by Decay-in-storage, Generator Return, and Licensed Material Return" of the U.S. NRC "Specific Guidance about Medical Use Licenses, NUREG-1556," Revision 3, Effective Date September 2019.

2. Radiation Oncology –Iodine-125 and Palladium-103 brachytherapy sources are held in temporary decay in storage pending return to the manufacturer. Ir-192 HDR sources and Co-60 Gamma Knife sources are returned to the manufacturer. Ra-224 Alpha Dart sources are disposed through a licensed broker. OSU follows the guidance provided by Appendix W "Model Procedure for Waste Disposal by Decay-in-storage, Generator Return, and Licensed Material Return" of the U.S. NRC "Specific Guidance about Medical Use Licenses, NUREG-1556," Revision 3, Effective Date September 2019.

3. Radioactive Seed Localizations (RSL) – Iodine-125 RSL sources are held in temporary decay in storage pending return to the manufacturer. OSU follows the guidance provided by Appendix W "Model Procedure for Waste Disposal by Decay-in-storage, Generator Return, and Licensed Material Return" of the U.S. NRC "Specific Guidance about Medical Use Licenses, NUREG-1556," Revision 3, Effective Date September 2019.

4. Records shall be maintained in accordance with OAC 3701:1-58-84 "Records for Decay-in-storage."

C. Waste Classifications

1. Solid Waste – Waste that includes absorbent pads, gloves, gowns, disposable food trays, pipettes and other similar items.
   a. All glass, sharps, and/or breakable items should be boxed separately in puncture resistant containers.
   b. All waste containers must be appropriately labeled and liners shall be used for all solid waste containers.
   c. Inventory records shall be maintained.

2. Liquid Waste
   a. Keep aqueous and organic wastes separate.
   b. Collect bulk liquids in RSS approved plastic containers.
   c. Liquid waste cannot be stored in any glass containers.
   d. Unused patient dosages will be disposed in a designated decay in storage container or transferred to the Radiation Safety, as applicable.

3. Mixed Waste
   Mixed waste consists of low-level radioactive waste and 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.

4. Biologicals
   Corpses, tissue samples, and/or body parts involving radioactive materials use or has radioactive material incorporated into it (i.e. seeds) shall be disposed of in accordance with approved medical center policies.

5. Liquid Scintillation Vials – Vials should be returned to the same box in which they were received.

D. Other Waste Disposal Methods

1. Disposal through the RSS – OSUWMC long-lived radioactive waste shall be disposed of through or under the direction of the RSS.

2. Disposals via Sanitary Sewer – RSS allows for the disposal of readily soluble aqueous liquids or readily dispersible biological material via the sanitary sewer (requires RSS approval). Patient excreta deemed radioactive should be disposed of via the sanitary sewer system.

E. Return of Sealed Radioactive Sources

Sealed radioactive sources can be returned to the manufacturer as follows:
a. Sealed radioactive sources used for instrument quality control.
b. Sealed radioactive sources used for low dose rate brachytherapy.
c. Sealed radioactive sources used for Radioactive Seed Localization procedures.
d. Sealed radioactive sources used in High Dose Remote After-loaders.
e. Sealed radioactive sources used in Gamma Knife Icon.

F. Waste Storage

1. Closed containers of long-lived waste cannot be held for greater than one (1) year in the laboratory and must be transferred to Radiation Safety for storage and proper disposal.
2. Closed containers of decay-in-storage waste cannot be held for greater than four (4) years.

   a. Record of each disposal shall be maintained for three years
      Records should include:
      i. Radionuclide
      ii. Date of disposal and corresponding survey
      iii. Survey instrument used
      iv. Background
      v. Individual who performed the disposal

Chapter 16: Written Directives

A. Written Directive

A written directive must be dated and signed by an authorized user before the administration of iodine-131 sodium iodide greater than 1.11 megabecquerels (thirty microcuries), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within forty-eight hours of the oral directive.

1. The written directive must contain the patient or human research subject's name and the following information:
   a) For any administration of quantities greater than 1.11 megabecquerels (thirty microcuries) of sodium iodide iodine-131: the dosage;
   b) For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide iodine-131: the radioactive drug, dosage, and route of administration;
   c) For gamma stereotactic radiosurgery (Gamma Knife Icon): the total dose, treatment site, the gamma angle, dose per fraction, number of fractions and values for the target coordinate settings and sector settings per treatment shot for each anatomically distinct treatment site;
   d) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose;
   e) For permanent implant brachytherapy:
      i. Before implantation: treatment site, the radionuclide, and the total source strength; and
      ii. After implantation but before the patient leaves the post-treatment recovery area: the treatment site, the number of sources implanted, the total source strength implanted, and the date when the licensee assessed the patient's implantation
   f) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:
      i. Before implantation: The treatment site, radionuclide, and dose; and
      ii. After implantation but before completion of the procedure: The radionuclide; treatment site; number of sources; total source strength and exposure time (or the total dose); and the date when the licensee assessed the patient's implantation.
2. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within forty-eight hours of the oral revision.
3. A copy of the written directive in accordance with rule 3701:1-58-75 of the Administrative Code.

4. Written directives will be completed and documented as stated in the following:
   a) OAC 3701:1-58-15 “Written Directives”
   b) OAC 3701:1-58-16 “Procedures for Administrations Requiring a Written Directive”
   c) OAC 3701:1-58-75 “Records of Written Directives”
   d) OAC 3701:1-58-76 “Records for Procedures for Administrations Requiring a Written Directive”
   e) Appendix S “Model Procedure for Developing, Maintaining, and Implementing Written Directives” of the U.S. NRC “Specific Guidance about Medical Use Licenses, NUREG-1556,” Volume 9, Revision 3, Effective Date September 2019.

B. Written Directive Procedures

1. Procedures for Written Directives will be maintained in accordance with OAC rule 3701:1-58-16. For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:
   a) The patient's or human research subject's identity is verified before each administration; and
   b) Each administration is in accordance with the written directive.

2. A copy of the procedures will be maintained in accordance with OAC rule 3701:1-58-76.

C. Quality Management Program (QMP) Review

1. Patient therapy cases are reviewed on a monthly or quarterly basis to ensure accuracy and compliance to stated Ohio Department of Health regulations. The results of this review are presented quarterly to the Medical Use Subcommittee for recommendation of approval by the URSC.

2. Nuclear Medicine

   Reviews are completed of Nuclear Medicine patient therapy documentation to determine whether the administered radiopharmaceutical dosage was in accordance with the written directive or plan of treatment. For each patient case reviewed, the reviewer(s) determine if there are any deviations from the written directive, the cause of each deviation, and action required to prevent recurrence. The review consists of the following areas:

   a. Criteria for Appropriateness:
      i. The radiopharmaceutical administered is consistent with the written directive and/or treatment plan.
      ii. The radiopharmaceutical dosage is +/- ten percent (10%) of the prescribed dose in the written directive and/or treatment plan. If the dosage is between 10% - 20%, Authorized User approval must be documented.
      iii. That prior to administration, a written directive is prepared, signed and dated before dosage.
      iv. Route of radiopharmaceutical administration is consistent with its approved use.
      v. Two-person sign-off by qualified individuals (AU, ANP, Nuclear Medicine Technologist, or Radiation Safety) prior to the administration of the radiopharmaceutical.
      vi. Post administration signature of an authorized user or designated individual who delivered the radiopharmaceutical dose.
      vii. Verify inclusion of basis for patient release.

3. Radiation Oncology – Brachytherapy

   Reviews are completed of brachytherapy procedures. For each patient care reviewed, the reviewer(s) determine whether the administered brachytherapy dose was in accordance with the written directive. For each patient case reviewed, the reviewer(s) look for deviations from the written directive, the cause of any deviation and action required to prevent recurrence.

   a. Criteria for Appropriateness:
      i. Prior to administration, the written directive was signed and dated by an authorized user
      ii. Prior to each administration the patient's identity is verified by more than one method as the individual named in the written directive.

iii. The final plan of treatment and calculations for the brachytherapy treatment are in accordance with the respective written directive.
iv. Each administration is recorded and signed in accordance with the written directive.
v. Patients with temporary application are surveyed after removal of sources.
vi. That any unintended deviation from the written directive is identified, evaluated, and appropriate action taken.

4. Radiation Oncology – Gamma Stereotactic Radiosurgery

Reviews are completed of gamma stereotactic radiosurgery procedures. For each patient care reviewed, the reviewer(s) determine whether the administered gamma stereotactic radiosurgery dose was in accordance with the written directive. For each patient case reviewed, the reviewer(s) looked for deviations from the written directive, the cause of any deviation and action required to prevent recurrence.

a. Criteria for Appropriateness:
   i. That prior to each administration the patient's identity is verified by more than one method.
   ii. Signed and dated Written Directive
   iii. The target site is recorded.
   iv. Verification of imported images.
   v. Prescription dose and prescription isodose are correctly entered into LGP (Leksell Gamma Plan).
   vi. Qualified person other than the LGP operator checks the printout.
   vii. Plan Transfer: patient info and plan ID verified.
   viii. Plan Transfer: all targets and shots verified.
   ix. The “Delivered Irradiation Form” was filled and signed properly.
   x. Any unintended deviation from the written prescription is identified.

Chapter 17: Procedures for the Use of Radioactive Material

A. Procedures for unsealed radiopharmaceutical therapies requiring a written directive

Use of unsealed radiopharmaceuticals for therapy shall be performed in accordance with OAC 3701:1-58-37 "Use of Unsealed Radioactive Material for which a Written Directive is Required"

- Iodine-131 (I-131) – Sodium Iodide
- Radium-223 (Ra-223) – Xofigo
- Lutetium-177 (Lu-177) Lutathera,
- Lutetium-177 (Lu-177) Pluvicto
- Others as applicable

B. Procedure for the Safe Use of Radiopharmaceutical Generators

Molybdenum-99 (Mo-99) and Germanium-68 (Ge-68) Breakthrough

- Measurements shall be made of the Mo-99 concentration as required in QAC 3701:1-58-35 "Permissible molybdenum-99, strontium-82, and strontium- 85 concentrations."
- Concentration of Mo-99 shall be less than 0.15 kilobecquerel per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m).
- Measurements of Ge-68 breakthrough shall be made in accordance with the current Eckert and Ziegler GalliaPharm™ Ge-68/Ga-68 Pharmacy Grade Generator Licensing Guidance released by the NRC.
- Breakthrough limits of Ge-68 shall be less than or equal 0.01 µCi Ge-68 per mCi Ga-68 (≤0.001 percent).
- Records shall be maintained in accordance with OAC 3701:1-58-85 "Records of molybdenum-99, strontium-82, and strontium-85 concentrations and the current NRC licensing guidance for the GalliaPharm™ Ge-68/Ga-68 generator.

C. Procedures for Therapies Requiring a Written Directive for Sealed Source Radioactive Material

1. Use of Sealed Radioactive Material

    a. The use of sealed radioactive material for therapy shall be performed in accordance with OAC 3701:1-58-43 "Use of Sources for Manual Brachytherapy" for:
        - Iodine-125 (I-125) – Eye Plaque
        - Palladium-103 (Pd-103) – Prostate Seed Implants
        - Others as applicable

    b. OAC 3701:1-58-55 "Use of Use of sealed source in a remote after-loader unit, teletherapy unit, or gamma stereotactic radiosurgery unit" for
        - Iridium-192 (Ir-192) – High Dose Rate Remote After-loader (HDR)
        - Others as applicable

    c. OAC 3701:1-58-72 "Other medical uses of radioactive material or radiation from radioactive material" for:
        - Cobalt-60 (Co-60) – Gamma Knife Icon
        - Yttrium-90 (Y-90) – Microspheres
        - Radium-224 (Ra-224) – Alpha Dart
        - Others as applicable

D. Reporting Medical Events and Other Reportable Occurrences

URSO or any RSS staff will be immediately notified in the event of a Medical Event or Reportable Occurrence. Notifications will be made in accordance with OAC 3701:1-58-101 “Report and Notification of a Medical Event.”

Chapter 18: Release Criteria of Patients or Human Research Subjects

A. Procedure for Release of Patients

All patients or human research subjects undergoing radionuclide therapy shall be released in accordance with OAC 3701:1-58-30 "Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material," and following the guidance provided by Appendix U "Release of Patients or Human Research Subjects Administered Radioactive Materials " of the U.S. NRC "Specific Guidance about Medical Use Licenses, NUREG-1556,"Volume 9, Revision 3, Effective Date September 2019.

B. Release instructions

Release instructions shall be provided to any patient or human research subject on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent (TEDE) to any other individual is likely to exceed 100 mrem.

1. Guidance shall be provided to patients or human research subjects undergoing radionuclide therapy who are breastfeeding.

2. Patients or human research subjects administered gamma emitting radiopharmaceuticals or permanent brachytherapy sources and are required to be furnished written instructions, will be provided a patient release card in accordance with OAC 3701 3701:1-58-30. The following information will be included on the card:
   a. Facility Name and Contact Information
   b. Patient Name
   c. Date of Administration
   d. Radionuclide Administered
   e. Radioactivity Administered
   f. Expiration date of the card

C. Records

Records shall be maintained in accordance with OAC 3701:1-58-82 "Records of the release of individuals containing unsealed radioactive material or implants containing radioactive material."

Chapter 19: Patient Housing

A. Iodine-131 (I-131)

1. The following patients receiving I-131 therapies will be treated as an inpatient:
    a. Patients exceeding the release criteria listed in OAC rule 3701:1-58-30.
    b. Patients with extenuating medical or living conditions.

2. Patients are admitted to a private, shielded room.

3. Preparations will be made for patients receiving I-131 and requiring an inpatient stay.
    a. A private room will be reserved and prepped for an inpatient stay;
    b. After administration of the I-131 radiopharmaceutical:
        i. an exposure rate survey will be taken with a portable ionization chamber at 0.3 meter and 1 meter from the patient's umbilicus;
        ii. the patient's body burden in (mCi) will be determined
    c. The patient will be housed as an inpatient until the maximum likely dose to a member of the public is < 500 mrem.

4. Room Preparation - Due to the potential for significant contamination of the patient room, special precautions include:
    a. Extra furniture and medical equipment are removed from room;
    b. Protective absorbent materials are used to cover the floor, furniture, tabletops, etc.,
    c. Plastic is used to cover handles, faucets, toilet, bed rails/controls, televisions, phone, etc.

5. Radiation Protection Practices – Physicians, nursing staff, and other staff members are required to follow certain radiation protection practices while attending to I-131 therapy patients undergoing treatment:
    a. Room and Visitation
        - Patient is not permitted visitors without prior approval by the RSS.
        - To minimize radiation exposures, the patient must have a private room.
        - Patient is not permitted to leave the room, unless medical care is needed, and the patient's room door should remain closed at all times.
    b. Shoe Covers and Personal Protective Equipment
        - All individuals entering patient room must wear shoe covers.
        - Gloves and a protective gown must be worn while inside the patient room
        - All protective clothing must be removed prior to exiting the patient room and disposed of in waste container designated by RSS.
    c. Medical Equipment
        - Use dedicated medical equipment (stethoscope, blood pressure cuff, etc.) for patient.
        - Equipment may become contaminated; this equipment should not be removed from the room or used on other patients until it has been cleared by RSS.
    d. Housekeeping, Trash / Linens, and Meals
        - Housekeeping shall not enter the patient's room.
        - Disposable meal trays, dishes, and utensils should be used.
        - All linen and trash must remain in the patient room in designated waste containers provided by RSS.
        - All biologicals and uneaten food should be flushed down toilet.
        - Male patients are instructed to sit when urinating.
    e. Lab Work and Addition Medical Procedures

- Blood draws etc., should be ordered and completed prior to patient dosing. Subsequent lab work should be delayed, if possible, until the patient is released from isolation and/or cleared by RSS.
- Lab work which cannot be delayed should be coordinated with the nursing staff and RSS.
- If patient needs additional medical procedures requiring the patient to leave room, contact RSS for instructions prior to patient leaving room (unless for emergency medical attention).

f. Personnel Monitoring
- Staff should implement ALARA principles when caring for patient.
- Patient care staff must wear a dosimeter if provided by RSS.
- Do not share or wear multiple dosimeters. Dosimeters are intended to monitor the radiation exposure of one individual for the duration of the patient stay. Each individual should document their information / badge ID information on the "Badge Request" form supplied by RSS.
- In emergency situations, patient care staff must contact RSS, but must not compromise patient care to do so. RSS will determine if bioassays are required for the staff involved.

g. Non-essential staff should not enter the patient's room.

h. RSS Surveys and Patient Discharge
- RSS will perform surveys and calculations as described in paragraph 4 of this section. All patients will be released in accordance with OAC 3701:1-58-30.
- I-131 patients must NOT be discharged until approved by RSS.
- RSS will notify the nursing staff that the patient has been cleared for discharge.
- After discharge, all equipment and articles must not leave the patient's room until surveyed by RSS. No one is permitted to enter the room until notified by RSS.
- RSS will survey all areas of the patient room including fixed and removable items; decontamination will be completed as necessary.
- Final authorization will be given to the nursing / floor staff once the room is ready to be used for another patient.

i. Emergency Information – Notify RSS Immediately if:
- Patient requires emergency procedures;
- Patient expires;
- There are any unexpected leakage or spillage of body fluids;
- Specimens are to be collected; or
- Patient required medical attention requiring them to leave room.

B. Brachytherapy

1. Patients undergoing I-125 eye plaque therapy procedures may be released in accordance with OAC 3701:1-58-30. However, patients may be treated as an inpatient at physician's discretion.

2. Inpatient Radiation Protection Practices – Physicians, nursing staff, and other staff members are required to follow certain radiation protection practices while attending to I-125 eye plaque therapy patients undergoing treatment:
   a. Lead Eye Shield
      - All I-125 eye plaque patients are fitted with a lead shield over the eye to reduce the radiation exposure rates.
      - The lead shield must be worn by the patient while visitors are present.
      - The lead shield may need periodic adjustment to ensure it is properly covering the eye.
   b. Patient and Patient Care Staff Restrictions and Guidance

- Nursing and patient care staff are not restricted from interacting with the patient. Due to the limited time spent with these patients as well as the lead shielding around the eye (radioactive source), no personal dosimetry badges for monitoring is required.

c. Visitor Restrictions and Guidance
    - There is no time limit on visitors.
d. Emergency Information
    - In the event of Medical Emergencies or Death
        i. Provide emergency medical care first if needed
        ii. Notify Radiation Safety and Radiation Oncology Immediately
e. Misplaced or Dislodged I-125 Source
    - Call Radiation Safety and Radiation Oncology Immediately
    - Never pick up source(s) with fingers
    - Stay at least 6 feet away from source(s)
    - Never attempt to reinsert the source(s)

Chapter 20: Radiation Detecting Equipment and Associated Quality Control

A. Health Physics Instrumentation

1. The instrumentation below is currently available to the RSS. Included are handheld survey meters, portable laboratory instruments and analytical instrumentation. The number and type of health physics instrumentation listed may be changed as required. Sufficient instrumentation will be maintained to provide adequate support of all licensed activities.

2. RSS Instrumentation:

Instrument Type	Detector	Radiation Detected	Type/Use
Ludlum 3 or equivalent	GM	β-γ	Count-Rate / Contamination Surveys
Ludlum 3-98 or equivalent	GM/NaI	β-γ Low Energy γ	Count-Rate / Contamination Surveys
Ludlum 12 or equivalent	Gas proportional	α-β	Final Status/Release Surveys
Ludlum 12 or equivalent	Large area GM	β-γ	Final Status/Release Surveys
Ludlum 18 or equivalent	Gas proportional	β-γ	Final Status/Release Surveys
Victoreen 450 Series or equivalent	Ion Chamber	γ	Dose-Rate / Radiation Surveys
Ludlum 15 or equivalent	BF3	η	Dose-Rate / Radiation Surveys
Beckman and/or Perkin Elmer	Liquid Scintillator	α, β-γ	Beta Spectroscopy / Activity Analysis Waste Stream Analysis

3. Calibration of Health Physics Instrumentation
   a. Instrument calibrations are performed annually, after maintenance (changing batteries or cord replacement are not considered maintenance) is performed, if instrument fails the performance test or if its proper operation is in question. All calibrations will be performed by the licensee or an NRC or Agreement State licensed calibration facility. For those instruments calibrated by the licensee, the following procedures will be used:
      i. Contamination survey instruments will be calibrated using a pulse generator. After calibration of instrument, the detector efficiency will be calculated using a reference source of the isotope or energy of concern, traceable to NIST.
      ii. Dose rate survey instruments will be calibrated using a NIST traceable sealed source. RSS currently uses a J. L. Shepherd Model 28-6A Calibrator with a 1.3 Ci (Assay date: 4/5/80) Cs-137 source.
      iii. Exposure rates for calibration of dose rate survey instruments will be calculated by assuming a point source of known activity and using the inverse square law and the radioactive decay law.
      iv. Each scale that is expected to be used for radiation protection purposes will be calibrated at points approximately 20% and 80% of scale. For digital or logarithmic scales, refer to the Instrument Instruction Manual for correct calibration points.
      v. Instruments will be calibrated to within + 10% of the expected reading. A correction factor will be calculated for any readings not within + 10% tolerance limit, but within + 20% tolerance limit.

vi. Instruments that cannot be calibrated to within + 20% of the expected reading will be considered not calibrated and taken out of service.

b. Each instrument which has been calibrated will be returned to the user with a Calibration Certificate containing the following information:
   i. Instrument model number and serial number. If the instrument has an attached probe, the probe model number and serial number shall also be included, if available.
   ii. Dose rate instruments shall include the attenuation used and the distance to source as well as the calibration source nuclide, activity and assay date.
   iii. Count rate instruments shall include the serial number and calibration date of the pulse generator used for calibration as well as the reference isotope nuclide, activity and assay date.
   iv. Prior to using any survey instrument perform the following checks:
      - Battery Check – Replace batteries as necessary
      - Physical Check – Instrument, cable and probe in good physical condition
      - Calibration Check – Instrument within calibration frequency

C. Dose Calibrators

1. Equipment used to measure radiopharmaceutical dosages will be calibrated in accordance with nationally recognized standards or manufacturer's recommendations.

2. Quality assurance tests results shall be +/- 10% of theoretical value.
   a. Constancy – Completed daily prior to measuring patient dosages
   b. Linearity – At installation and at least annually thereafter
   c. Accuracy – At installation and at least annually thereafter
   d. Geometry – At installation or geometric changes to equipment used

3. Records shall be maintained in accordance with OAC 3701:1-58-77 "Records of Calibrations of Instruments Used to Measure the Activity of Unsealed Radioactive Material."

D. Instruments Used for Diagnostic Purposes

Calibration, quality control, and maintenance of instruments used for diagnostic purposes will be performed routinely in accordance with the manufacturer's recommendations.

E. Therapy Unit – Calibration and Use

Calibration, quality control, and maintenance of instruments used for therapeutic purposes will be performed routinely in accordance with the manufacturer's recommendations and/or AAPM Task Group 40; Chapter V. Brachytherapy – Comprehensive QA for Radiation Oncology; Report of AAPM Radiation Therapy Committee Task Group 40.

F. Sealed Radionuclide – Calibration (NIST or AAPM)

1. Calibration shall be performed as required by OAC 3701:1-58-48 "Calibration Measurements of Brachytherapy Sources and/or OAC 3701:1-58-60 "Dosimetry Equipment" coupled with nationally recognized standards and/or manufacturer's instructions.

2. Records shall be maintained in accordance with OAC 3701:1-58-89 "Records of Calibration Measurements of Brachytherapy Sources."

Chapter 21: Inspections, Surveys, Audits

A. Audit Procedures

1. Senior Management

    a. The RSS keeps senior management aware of State of Ohio regulations, license provisions, and the compliance status of the radiation safety program through various written documents which may include quarterly activitis reports, internal audit reports, and the URSC annual audit.

2. University Radiation Safety Committee Audits

    a. The annual audit of the radiation safety program will be conducted by the Audit Subcommittee of the URSC. The Audit Subcommittee may utilize the services of an independent auditor. In an independent auditor reviews the program the results will be submitted via the Audit Subcommittee to the URSC for committee review and action; or
    b. The Audit Subcommittee (AS) will perform its own independent annual audit of the radiation safety program.
    c. The written annual report will be provided to the full membership of the URSC for review and final approval. The AS will use an RSS internal audit report 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 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 RSS.
        iv. Review the results of State of Ohio inspection reports.
        v. Review of written safety procedures.
        vi. Review of the adequacy of the University's management control system.
        vii. Review of AU/AMP/ANP applications.
        viii. Review of ODH-issued amendments of licenses for use of materials.
        ix. 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. RSS Audits

1. The RSS will perform audits and operational surveillances to ensure compliance with regulatory requirements, license conditions, and internal policies/procedures.

2. All audit reports will be distributed as follows:

    i. Area or Department Supervisor
    ii. URSO
    iii. URSC

4. Non-compliance issues and corrective actions shall be reported quarterly to the Radiation Safety Committee.

C. Circumstances Endangering the Immediate Health and Safety

Offenses, situations, or circumstances endangering the immediate health and safety of staff, patients, students, visitors, or member of the general public shall be reported directly to the URSO who will implement whatever actions are appropriate to the circumstances.

Chapter 22: Posting and Labeling

Area Postings and Labeling

- All areas using radioactive material shall be posted with appropriate caution signs and labels as applicable in accordance with OAC rule 3701:1-38-18. Departments utilizing radioactive material will have appropriate postings, including the ODH Notice to Employees.
- All equipment used with radioactive material must be labeled with a "Caution, Radioactive Material" label / sticker.
- All containers of radioactive material must be labeled or marked with the radionuclide present, activity, date, and radiation level (if appropriate).
- All containers for radioactive material waste must be labeled or marked with the radionuclide present, date opened, initials of individual opening radioactive waste container.
- Radiation symbols or wording must be removed from all materials prior to disposal in the normal waste stream.

Chapter 23: Transportation

A. Vehicle Transportation of Radioactive Materials within OSU Campus

1. The preferred method of transport of radioactive material is through a courier service or Radiation Safety. All applicable Department of Transportation (DOT) regulations apply.

    a. Individuals involved in preparing the shipment must have received appropriate DOT training available from RSS. This training must be completed every three years.

B. Other Permitted Methods of Transport

1. The transportation of radioactive materials must follow all applicable DOT regulations and be performed in a state vehicle.

    a. Individuals involved in preparing the shipment or transporting the package must have received appropriate DOT training available from RSS. 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. An Approved Supervisor or AU may use their personal vehicle to transport radioactive materials on campus only under the following conditions:

    a. The package to be transported is an excepted package for limited quantity (49 CFR 173.421) of radioactive material as defined by DOT.

    b. Individuals involved in preparing the shipment or transporting the package must have received appropriate DOT training available from RSS. This training must be completed every three years.

    c. 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
        - 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.

3. 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.
4. Exempt quantities of radioactive materials are not subject to this policy.

C. Duties and Responsibilities of the Driver

1. Individuals involved in preparing the shipment or transporting the package must have received appropriate DOT training from RSS. This training must be completed every three years.
2. Exercise reasonable care to ensure that none of the material is lost, escapes, or stolen from the vehicle or from any package.
3. Do not leave the vehicle unattended in a public place.
4. Transport documents must be readily available in accordance with DOT regulations.
5. Ensure that the material is delivered to a person authorized to receive it.

6. 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 immediately.

Chapter 24: Decommissioning

RSS must be notified of any renovation or remodeling prior to initiation of construction to evaluate the need for, and to perform, decommissioning surveys. Areas may only be released for unrestricted use where the residual radioactivity that is distinguishable from background radiation results in a total effective dose equivalent (TEDE) to an average member of the public does not exceed 0.25 millisievert (twenty-five millirem) per year.

APPENDIX A

Procedure for Safely Receiving and Shipping Packages Containing Radioactive Material

Procedure for Safely Receiving and Shipping Packages Containing Radioactive Material

A. Incoming Package Surveys

1. Receipt Surveys
   a. Inspect incoming package for any sign of damage.
   b. Package surface radiation level and TI will only be measured if there is evidence of degradation of package integrity, such as a package is crushed, wet, or damaged.
2. Contamination wipe test:
   a. Measure the background using an MCA or SCA (dpm).
   b. Wipe minimum of 300 cm^2 on the surface of the outer package.
   c. Measure the wipe sample with the MCA or SCA and determine disintegrations per minute (dpm). Document the results.
   d. Open the outer package and confirm that the inner container (vial shield) is free of damages.
   e. Notify RSS immediately if the shipment is:
      i. Leaking, crushed or damaged in any way
      ii. outer surface wipe exceeds 6,600 dpm

B. Outgoing Package Survey

Shipping packages containing radioactive material:

1. Contamination wipe test:
   a. Wipe at minimum 300 cm^2 on the surface of the outer container (i.e. shipping case).
   b. Measure the wipe sample with the MCA or SCA and determine disintegrations per minute (dpm).
   c. Measured activity must be ≤ 6,600 dpm/300 cm^2 prior to shipping the package.
   d. Note: if activity exceeds the set limit, the contaminated outer container must be decontaminated or replaced prior to shipment.
2. Measuring package surface radiation level:
   a. Using an appropriate survey instrument, determine the maximum exposure reading (mR/hr) at the surface of the package (shipping container).
   b. Determine the appropriate shipping category based on the surface exposure reading using the radioactive category label (Table 1 below)

3. Measuring package Transportation Index (TI) radiation level, at one meter away from package:
   a. Using an appropriate survey instrument, determine the maximum exposure reading (mR/hr) at 1 meter from the surface of the package (shipping container).
   b. Determine the appropriate shipping TI using the Radioactive Category Label (Table 1).

Table 1

Radioactive Category Label		
		
White-I	**Yellow-II**	**Yellow-III**
Radiation Surface Level (RSL):		
RSL ≤ 0.5 mR/hr	0.5 **< RSL ≤** 50 mR/hr	50 **< RSL ≤** 200 mR/hr
Transport Index (TI):		
TI = 0	0 < **TI** ≤ 1	1 < **TI** ≤10