

# The Ohio State University Wexner Medical Center

## Radiation Safety Program



THE OHIO STATE UNIVERSITY

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## Chapter 1: Radiation Safety Program

### A. Purpose

The purpose of this 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 The Ohio State University 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 broad scope license and other applicable licenses and registrations.

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

### B. Radiation Safety Culture Policy

1. Radioactive materials and radiation producing devices utilized in research, diagnosis and therapy at The Ohio State University are licensed by the Ohio Department of Health (ODH) and overseen by the University's Radiation Safety Committee and the Radiation Safety Section of Environmental Health and Safety. The ODH Bureau of Environmental Health and Radiation Protection (BEHRP) regulates the possession, use, handling, storage and disposal of radiation sources in order to maintain the radiation dose as low as reasonably achievable to the general population.
2. The following is the BEHRP's definition of Safety Culture:  
"Safety Culture encompasses the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals (i.e., speed, profitability, staffing levels) to ensure protection of people and the environment."

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 existing conditions to identify discrepancies that might result in inappropriate action.

**C. OSU Radiation Safety Culture Policy Statement**

1. The Ohio State University is committed to a positive safety culture and expects that individuals and organizations performing regulated activities involving radioactive material and radiation-generating devices will establish and maintain a positive safety culture environment.
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 is 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 The Ohio State University is committed to the program described herein for keeping individual and collective radiation doses as low as reasonably achievable (ALARA). 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 The Ohio State University. The organization includes the University Radiation Safety Committee, University Radiation Safety Officer, and the Radiation Safety Section.
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 Radiation Safety.
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

1. Review of proposed users and uses.
  - a. The University Radiation Safety Committee 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 radioactive material, the University Radiation Safety Committee will review the efforts of the applicant to maintain exposures ALARA.
  - c. The University Radiation Safety Committee 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 University Radiation Safety Committee and Radiation Safety Section for the enforcement of the ALARA concept.
3. The University Radiation Safety Committee will support the Radiation Safety Section when it is necessary for the Radiation Safety Section to assert authority. If the University Radiation Safety Committee has overruled the Radiation Safety Section, it will record the basis for its action in the minutes of the Committee meeting.

**D. Review of University ALARA Program**

1. The University Radiation Safety Committee will review procedures of all protocols from individuals applying for Approved Supervisor status for adherence to the ALARA philosophy.
2. The Radiation Safety Section will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table I are 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 exceeded.
3. Table 1. Investigational Levels (mrems per calendar quarter)

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

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

4. The University Radiation Safety Committee will evaluate the University’s overall efforts for maintaining ALARA on an annual basis.

**E. ALARA Reviews**

1. Annual ALARA report.  
The Radiation Safety Section will submit an annual report to the University Radiation Safety Committee for adherence to the University ALARA program.
2. Quarterly review of occupational exposures.  
The Radiation Safety Section will review on a quarterly basis the external radiation doses of workers to determine that their doses are ALARA and will prepare a summary report for the University Radiation Safety Committee.

**F. Education Responsibilities for ALARA Program**

The Radiation Safety Section will ensure that Authorized Supervisors, users, workers, and ancillary personnel who may be occupationally exposed to radiation will be instructed in the ALARA philosophy and informed that administration, the University Radiation Safety Committee, and the Radiation Safety Section are committed to implementing the ALARA concept.

**G. Cooperative Efforts for Development of ALARA Procedures**

1. The Radiation Safety ensures all new Approved Supervisors and Authorized Users are familiar with ALARA procedures.
2. The Radiation Safety Section 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 exceeded, will initiate review or investigation by the University Radiation Safety Committee and/or Radiation Safety Section. The investigational levels the University has adopted are listed in Table 1. These levels apply to the exposures of individual workers.
2. The Radiation Safety Section 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 Radiation Safety Section, 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 Radiation Safety Section 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 University Radiation Safety Committee 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 Radiation Safety Section.

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

The Radiation Safety Section 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 University Radiation Safety Committee at the next meeting following the completion of the investigation. The details of these reports will be included in the University Radiation Safety Committee minutes.

**M. Reestablishment of Investigational Levels to 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 University Radiation Safety Committee 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

1. The University Radiation Safety Committee (URSC) is mandated by the Ohio Department of Health (ODH), and is comprised of faculty and staff from The Ohio State University. The URSC oversees the Radiation Safety Program and acts as a liaison between faculty/staff/management and the Radiation Safety Section (RSS) of Environmental Health and Safety. The URSC is responsible for the control and direction of the Radiation Safety Program. The URSC reviews and approves all permits for the use of radioactive materials, makes policy decisions to be implemented by RSS and takes corrective actions when infractions of ODH rules are identified. The URSC has the authority to grant and revoke permission to use radiation-emitting sources at the facilities located at The Ohio State University, Columbus, Ohio; OSU Hospitals and James Cancer Center and affiliated facilities; at Stone Laboratory, Put-In-Bay, Ohio; Innovation Center; OARDC at Wooster, and at temporary job sites throughout the State of Ohio as authorized by various ODH-issued licenses.
2. The URSC's responsibilities are:
  - Reviewing, approving, disapproving or tabling all applications for the use of radioactive materials at The Ohio State University.
  - Maintaining awareness of regulations and license conditions pertaining to the Radiation Safety Program.
  - Performing an annual review of routine operations of the Radiation Safety Section (RSS) of Environmental Health and Safety (EHS).
  - 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 The Ohio State University 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 OAC 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 the Radiation Safety Section of EHS by the Ohio Department of Health.
- 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/Radiation Safety Officer internal audit as a supplemental document

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

- 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 is responsible for the review and approval of the research 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. Radiation Safety is responsible for insuring the safe use and the disposition of all sources of radiation in accordance with the laws, rules and regulations established by the Federal and State government and their agencies including, but not limited to, the Ohio Department of Health, the U.S. Nuclear Regulatory Commission, the Department of Health and Human Services (especially the Food and Drug Administration), the U.S. Department of Transportation and the U.S. and Ohio Environmental Protection Agencies.
2. University Radiation Safety Officer (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.
3. Radiation Safety Section Staff are assigned program responsibilities by the URSO consistent with license requirements and Ohio Department of Health (ODH) regulations. The section is responsible for insuring the safe use and disposition of all sources of ionizing radiation in accordance with the laws, rules and regulations established by Federal and State governments and their agencies. Health Physicists implement license requirements and ODH regulations. Staff responsibilities include:
  - Maintaining a system of review and providing technical evaluations of all applications submitted by faculty of The Ohio State University and making recommendations to the URSC.
  - Establishing and maintaining controls and records regarding the purchase, receipt, distribution and disposal of radioactive materials.
  - Inspecting all laboratories that contain radioactive material or radiation-producing equipment to insure compliance with federal and state laws, rules, regulations, and University policy and procedures pertaining to the use of radioactive materials.
  - 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 insure 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 University Radiation Safety Committee to use and possess radioactive materials. It is the Approved Supervisor's responsibility to assure compliance with regulations in his/her laboratories; this cannot be delegated. Primary responsibilities include:
  - Insuring a commitment to the philosophy to keep radiation exposures As Low As Reasonably Achievable (ALARA) in keeping with the University's commitment to the ALARA concept.
  - Insuring every user has been instructed in, or has read, the Ohio Administrative Code (OAC) 3701:1-38, OAC 3701:1-58 and the Radiation Safety Standards for The Ohio State University. All personnel should be prepared to make such a declaration to any State of Ohio representatives.
  - Insuring all users have successfully completed the required training prior to beginning work and annually thereafter as applicable.
  - Notifying Radiation Safety immediately of any new individuals who begin work after an application has been submitted so those individuals may receive approval for the use of radioactive materials.
  - Controlling contamination in areas of radioactive materials use.
  - Maintaining records of receipt and disposition of all radioactive materials.
  - Insuring the procedures and precautions as outlined in an approved permit are followed.
  - Insuring 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 Ohio Administrative Code 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. 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/ANP's 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 University Radiation Safety Committee.
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)
<b>Adult Worker</b>	
Total Effective Dose Equivalent	5
Total Organ Dose Equivalent	50
Lens of Eye	15
Extremities/Skin	50
<b>Embryo/Fetus</b>	
Declared Pregnant Worker	Total Effective Dose Equivalent = 0.5 rem per 9 months
<b>Minor</b>	
< 18 years of age	10% of Adult Limits

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

Radiation Emitter	Minimum Activity Used At Any One Time (mCi)	Example Radionuclides
I-125 and Pd-103*	10	n/a
Gamma emitters <sup>1</sup> 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 <sup>1</sup> with gamma constant < 0.2	10	Cd-109, Co-57, Cr-51, I-129, Kr-85, Tc-99m
Beta emitters <sup>2</sup> with E <sub>max</sub> > 0.2	10	Ca-45, P-32, P-33, Y-90
Beta emitters <sup>2</sup> with E <sub>max</sub> < 0.2	Not applicable, no badge used	H-3, C-14, Ni-63, S-35
Beta-Gamma emitters	Lowest of above	n/a

<sup>1</sup>  $\Gamma$  = specific gamma ray dose constant at 1 meter (rem/hr)/Ci.

<sup>2</sup> E<sub>max</sub> = 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 Ohio Administrative Code. Therefore, the following requirements are noted:

- a. Minors and declared pregnant workers when there is a reasonable possibility for measurable exposure. This includes working in a room where radioactive materials detectable with a dosimeter are being used.
- b. Individuals operating irradiators or other facilities as may be required by the appropriate license.
- c. Division of Radiation Oncology personnel handling radioactive materials.
- d. Division of Nuclear Medicine personnel handling radioactive materials.
- e. Regular personnel of the Radiation Safety Section of Environmental Health and Safety expected to exceed 10% of their occupational dose limit.
- f. Patient care coordinators (nurses) and patient care associates involved in the care of temporary brachytherapy implant patients or therapeutic radioiodine patients.
- g. Users of x-ray generating devices or state-registered radioactive material likely to receive a dose in any calendar quarter in excess of 10% of applicable limits.
- h. Individuals entering a high or very high radiation area.
- i. Users operating under requirements from ODH-issued licenses, the University Radiation Safety Officer, and/or the University Radiation Safety Committee. Factors which may be considered typically include long handling times or lack of experience of handlers.

### 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](http://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. Badges should only be kept at work, never taken home. Badges are not to be stored on lead aprons.
- b. Wear only the dosimeter(s) assigned to you.
- c. Wear the whole body badge on the trunk of your body at the point where it is most likely to receive maximum exposure. Be consistent in wearing the badges on the same area of the body.
- d. Wear ring badges under the glove on the hand that will receive the highest exposure with the dosimeter name label side toward the palm.
- e. If wearing a lead apron, wear the badge on your collar outside of the apron. If you have two dosimeters, then the whole body badge is worn under the lead apron and the second dosimeter (designated as a collar badge) should be worn on your collar outside of the apron.
- f. If appropriate, declared pregnant workers will be issued a fetal dosimeter along with their normal dosimeter for the duration of their pregnancy.
- g. Dosimeters are exchanged the first day of each calendar quarter (i.e. January 1, April 1, July 1 and October 1). Upon receipt of the new dosimeters, immediately turn in the previous dosimeters to your designated badge coordinator. Dosimeters on a monthly exchange frequency are exchanged on the first day of each month.

- h. Upon leaving the University, dosimeters will be returned to your designated badge coordinator. The badge coordinator must inform Radiation Safety to delete the dosimeters of all individuals who have left their series and return dosimeters immediately to Radiation Safety.
- i. Dosimeters should not be worn when you undergo medical exams or therapies which 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 Radiation Safety 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 University Radiation Safety Committee.

#### 2. Thyroid Bioassays

- a. All radioiodine radiation workers are required to have a thyroid bioassay performed if the location uses in unsealed or loose form on a yearly basis a quantity of radioiodine > 2000 ALI. For locations using multiple radionuclides, the need for thyroid bioassays is determined by whether the sum of the locations requested yearly activity for each radionuclide divided by 2000 ALI is greater or equal to 1. Bioassays must be performed 24 - 72 hours post iodination or post manipulation of > 1 mCi of radioiodine. The term "manipulation" as used here includes transfers from stock containers containing > 1 mCi. Thyroid bioassays are recommended for non-radiation workers in these areas as well.
- b. All radiation workers are required to have a thyroid bioassay within 24-72 hours if the individual uses in unsealed or loose form at any one time a quantity of radioactive material > 100 ALI.
- c. Thyroid bioassays will also be performed in accordance with requirements from the University Radiation Safety Committee.
- d. Bioassays for Nuclear Medicine and Nuclear Pharmacy – due to the use of the DRAXIMAGE SMART-FILL Dispensing System by the Nuclear Pharmacy for the preparation of I-131 patient dose capsules, the I-131 once placed into the capsule is no longer considered volatile. The following conditions apply:
  - i. Nuclear Medicine technologists shall perform thyroid bioassays following any contamination incident in which the technologist is involved in, was working in the general vicinity of at the time of the incident, and has assisted in the decontamination of personnel

- and/or area contamination, or any similar circumstance involving I-131 as required in the current Radiation Safety Standards.
- ii. Nuclear Medicine technologist shall perform thyroid bioassays following the administration of liquid form I-131 doses to patients as required in the current Radiation Safety Standards.
- e. Nuclear Pharmacy staff should perform thyroid bioassays between 24-72 hours following the manipulation and/or preparation of I-131 as required by the current Radiation Safety Standards.
  - i. Nuclear Pharmacy staff shall perform thyroid bioassays following any contamination incident in which they are involved, was working in the general vicinity of at the time of the incident, has assisted in the decontamination of personnel and/or area contamination, or any similar circumstance involving I-131 as required in the current Radiation Safety Standards.

### C. Investigational Levels and Overexposures

#### 1. Dosimeters

- a. Investigational Level I Notification - If an individual receives the following per quarter, the Radiation Safety Section will notify the individual in writing:
  - i. Whole body badge (no collar) deep dose equivalent (DDE)  $\geq 125$  mrem but  $< 375$  mrem
  - ii. Whole body with collar badge effective dose equivalent (EDE)  $\geq 125$  mrem but  $< 375$  mrem
  - iii. Collar badge only effective dose equivalent (EDE)  $\geq 125$  mrem but  $< 375$  mrem
  - iv. Whole body and/or collar badge lens dose equivalent (LDE)  $\geq 375$  mrem but  $< 1125$  mrem
  - v. Whole body badge shallow dose equivalent (SDE)  $\geq 1250$  mrem but  $< 3750$  mrem
  - vi. Extremity ring badge  $\geq 1250$  mrem but  $< 3750$  mrem
- b. Investigational Level II Notification - If an individual receives the following per quarter, the Radiation Safety Section 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 Radiation Safety Section in conjunction with the individuals department or location.
  - i. Whole body badge (no collar) deep dose equivalent (DDE)  $\geq 375$  mrem
  - ii. Whole body with collar badge effective dose equivalent (EDE)  $\geq 375$  mrem
  - iii. Collar badge only effective dose equivalent (EDE)  $\geq 375$  mrem
  - iv. Whole body and/or collar badge lens dose equivalent (LDE)  $\geq 1125$  mrem
  - v. Whole body badge shallow dose equivalent (SDE)  $\geq 3750$  mrem
  - vi. Extremity ring badge  $\geq 3750$  mrem
- c. When a protective apron is worn while working with medical fluoroscopic equipment and collar and whole body badges are assigned to the individual, the effective dose equivalent (EDE) for external radiation shall be determined by the dosimetry vendor and will be used for Investigational Level I and II reporting.

#### 2. Bioassays

- a. Investigational Level I Notification – If an individual has an intake of  $> 1\%$  but  $< 10\%$  of the smallest Annual Limit on Intake (ALI), the University Radiation Safety Officer and the URSC will be informed.
- b. Investigational Level II Notification – If an individual has an intake of  $> 10\%$  of the smallest Annual Limit on Intake (ALI), the Radiation Safety Section will investigate the exposure and implement reasonable corrective actions to avoid or reduce additional exposure.

### 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 Radiation Safety Section maintains the records of individual monitoring results for all individuals for whom monitoring is required, doses received during planned special exposures, accidents and emergency conditions. If an evaluation shows that the individual is not likely to exceed 10 % of any applicable limits, there are no record keeping or reporting requirements.
- b. Summary reports for each location are maintained by the Radiation Safety Section 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 is required. To document determination of current year exposure, the individual must provide a Lifetime Occupational History Form signed by the individual or a statement that includes the names of all facilities that provided monitoring for occupational exposure to radiation during the current year and an estimate of the dose received.
- 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 Radiation Safety Section.
2. The OSU/OSUWMC fetal dose policy incorporated safety information and radiation dose guidelines for ensuing 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 the Radiation Safety Section of EHS by filling out a RS-13 form.
4. Radiation Safety will review the RS-13 form and recommend a personnel monitoring program based on the information supplied in the Declaration of Pregnancy form.
5. Upon declaration of pregnancy, the radiation dose to the embryo/fetus during the entire pregnancy will not be allowed to exceed 0.5 rem Total Effective Dose Equivalent (TEDE).
6. Declared pregnant workers may request a meeting with a member of the Radiation Safety Section (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, a 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 RS-14 form, Acknowledgment of Radiation Exposure Limitations for a Minor, must be completed and submitted to the Radiation Safety Section of EHS.
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 500 mrem 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 University Radiation Safety Committee (URSC) as a user of radioactive material under the Ohio State University (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 OneSource website

To establish an authorization, the AU applicant must be qualified according to the criteria in the applicable part(s) of the Ohio Department of Health (ODH) rules and through the completion of the OSU URSC application process. The applicant must complete the appropriate forms. An appointment to meet with Radiation Safety 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 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, United States nuclear regulatory commission, or an agreement state that authorizes the medical use of radioactive material;
  - b. A permit issued by a United States nuclear regulatory commission master material licensee that is authorized to permit the medical use of radioactive material;
  - c. A permit issued by a United States nuclear regulatory commission, 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 United States nuclear regulatory commission 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 1.22 gigabecquerels (33 millicuries).
  - e. 3701:1-58-37 – Oral administration of sodium iodide Iodine-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (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. 3701:1-58-53 – Use of sealed sources for diagnosis.
- j. 3701:1-58-55 – Use of teletherapy units.
- k. 3701:1-58-55 – Use of remote after-loader units (HDR).
- l. 3701:1-58-55 – Use of gamma stereotactic radiosurgery units.
- m. 3701:1-58-72 – Use of new and emerging technologies (including at OSUWMC/The James):
  - Gamma Knife Perfexion
  - Radioactive Seed Localizations (Iodine-125 RSL)
  - Yttrium-90 Microsphere therapy (Y-90 TheraSphere)

## **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, United States nuclear regulatory commission, or an agreement state;
  - b. A medical use permit issued by a United States nuclear regulatory commission master material licensee;
  - c. A permit issued by a United States nuclear regulatory commission or agreement state broad scope medical use licensee; or
  - d. A permit issued by a United States nuclear regulatory commission 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 teletherapy units.
  - 3701:1-58-55 – Use of remote after-loader units (HDR).
  - 3701:1-58-55 – Use of gamma stereotactic radiosurgery units.
  - 3701:1-58-72 – Use of new and emerging technologies (including at OSUWMC/The James): Gamma Knife Perfexion

## **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, United States nuclear regulatory commission, or an agreement state that authorizes medical use or the practice of nuclear pharmacy;
  - b. A permit issued by a United States nuclear regulatory commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;
  - c. A permit issued by a United States nuclear regulatory commission 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 United States nuclear regulatory commission 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 following forms as they apply to the modality of use. Completed forms should be submitted to the Radiation Safety Section for review and submittal to the Medical Use Subcommittee. 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.

- RSM-1 – Medical Use of Radioactive Material Application
- RSM-2 – Medical Use Preceptor Statement
- RSM-3 – Authorized Medical Physicist Training, Experience, and Preceptor Attestation (3701 1-58-19)
- RSM-4 – Authorized Nuclear Pharmacist Training, Experience, and Preceptor Attestation (3701 1-58-20)
- RSM-5 – Authorized User Training, Experience, and Preceptor Attestation (3701 1-58-32, -34, -53, -72 RSL)
- RSM-6 – Authorized User Training, Experience, and Preceptor Attestation (3701 1-58-43, -55, -72 GKP, and -72 Y90)
- RSM-7 – Authorized User Training, Experience, and Preceptor Attestation (3701 1-58-37)
- Copy of Specialty Board Certification (as applicable)
- Specific Training Attendance Rosters / Certificates (as applicable)

#### **E. Training Requirements per ODH modality of Use**

1. OAC 3701:1-58-32 – “Use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required.” For authorization, an individual must meet the following criteria as outline in OAC 3701:1-58-33 – “Training for uptake, dilution, and excretion studies.”
2. Is certified by a medical specialty board whose certification process has been recognized by the director, United States nuclear regulatory commission, or an agreement state and who meets the requirements of this rule; or
3. Is an authorized user under this rule and rule 3701:1-58-36 or 3701:1-58-40 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state requirements; or
4. Has achieved the following requirements:
  - a. Has completed sixty hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the

medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

- i. Classroom and laboratory training in the following areas:
    - Radiation physics and instrumentation;
    - Radiation protection;
    - Mathematics pertaining to the use and measurement of radioactivity;
    - Chemistry of radioactive material for medical use; and
    - Radiation biology
  - ii. Work experience, under the supervision of an authorized user who meets the requirements in this rule, rule 3701:1-58-21, 3701:1-58-36, or 3701:1-58-40 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state requirements, involving:
    - Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
    - Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
    - Calculating, measuring, and safely preparing patient or human research subject dosages;
    - Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
    - Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
    - Administering dosages of radioactive drugs to patients or human research subjects; and
  - iii. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in this rule, rule 3701:1-58-21, 3701:1-58-36, or 3701:1-58-40 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements, that the individual has satisfactorily completed the requirements of this rule and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under rule 3701:1-58-32 of the Administrative Code.
- b. OAC 3701:1-58-34 – “Use of unsealed radioactive material for imaging and localization studies for which a written directive is not required.” For authorization, an individual must meet the following criteria as outline in 3701:1-58-36 – “Training for imaging and localization studies.”
- i. Is certified by a medical specialty board whose certification process has been recognized by the director, United States nuclear regulatory commission, or an agreement state and who meets the requirements this rule; or
  - ii. Is an authorized user under rule 3701:1-58-40 of the Administrative Code and meets the requirements of rule 3701:1-58-36 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements; or
  - iii. Has achieved the following requirements:
    - Has completed seven hundred hours of training and experience, including a minimum of eighty hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum:

- Classroom and laboratory training in the following areas:
    - Radiation physics and instrumentation;
    - Radiation protection;
    - Mathematics pertaining to the use and measurement of radioactivity;
    - Chemistry of radioactive material for medical use; and
    - Radiation biology; and
  - c. Work experience, under the supervision of an authorized user, who meets the requirements in this rule, rule 3701:1-58-21, or 3701:1-58-40 of the Administrative Code and this rule, or equivalent United States nuclear regulatory commission or agreement state requirements, involving:
    - i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
    - ii. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
    - iii. Calculating, measuring, and safely preparing patient or human research subject dosages;
    - iv. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
    - v. Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
    - vi. Administering dosages of radioactive drugs to patients or human research subjects; and
    - vii. Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclide purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and
  - d. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in this rule, rule 3701:1-58-21, or 3701:1-58-40 of the Administrative Code and of this rule, or equivalent United States nuclear regulatory commission or agreement state requirements, that the individual has satisfactorily completed the requirements of this rule and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under rules 3701:1-58-32 and 3701:1-58-34 of the Administrative Code.
5. OAC 3701:1-58-37 – “Use of unsealed radioactive material for which a written directive is required.” The training for this modality can be broken down into four sections based on a variety of factors including but not limited to the radionuclide, activity, and route of administration.
- a. 3701:1-58-40 – “Training for use of unsealed radioactive material for which a written directive is required.”
  - b. 3701:1-58-41 – “Training for the oral administration of sodium iodide iodine-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (thirty-three millicuries).”
  - c. 3701:1-58-42 – “Training for the oral administration of sodium iodide iodine-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (thirty-three millicuries).”
  - d. 3701:1-58-104 – “Training for the parenteral administration of unsealed radioactive material requiring a written directive.”
    - i. For full authorization of the use of unsealed radioactive material for which a written directive is required, an individual must meet the following criteria as outline in 3701:1-58-40 – “Training for use of unsealed radioactive material for which a written directive is required.”

- Is certified by a medical specialty board whose certification process has been recognized by the director, United States nuclear regulatory commission, or an agreement state and who meets the requirements of this rule; or
- Has achieved the following requirements:
  - Has completed seven hundred hours of training and experience, including a minimum of two hundred hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:
    - Classroom and laboratory training in the following areas:
      - \* Radiation physics and instrumentation;
      - \* Radiation protection;
      - \* Mathematics pertaining to the use and measurement of radioactivity;
      - \* Chemistry of radioactive material for medical use; and
      - \* Radiation biology; and
      - \* Work experience, under the supervision of an authorized user who meets the requirements in this rule or rule 3701:1-58-21 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements. A supervising authorized user, who meets the requirements of this rule, must also have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.
    - The work experience must involve:
      - \* Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
      - \* Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
      - \* Calculating, measuring, and safely preparing patient or human research subject dosages;
      - \* Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
      - \* Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
      - \* Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:
        - Oral administration of less than or equal to 1.22 gigabecquerels (thirty-three millicuries) of sodium iodide I-131, for which a written directive is required;
        - Oral administration of greater than 1.22 gigabecquerels, (thirty-three millicuries) of sodium iodide I-131. Experience with at least three cases in this paragraph also satisfies the requirement in this rule;
        - Parenteral administration of any beta emitter, or a photon- emitting radionuclide with a photon energy less than one hundred fifty keV, for which a written directive is required; and/or
        - Parenteral administration of any other radionuclide, for which a written directive is required; and

- Has obtained written attestation that the individual has satisfactorily completed the requirements in this rule, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under rule 3701:1-58-37 of the Administrative Code. The written attestation must be signed by a preceptor authorized user who meets the requirements in this rule or rule 3701:1-58-21 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements. The preceptor authorized user, who meets the requirements in paragraph (B) of this rule must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.
6. For authorization of the oral administration of sodium iodide iodine-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (thirty-three millicuries), an individual must meet the following criteria as outline in 3701:1-58-41 –“Training for the oral administration of sodium iodide iodine-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (thirty-three millicuries).”
- a. Is certified by a medical specialty board whose certification process has been recognized by the director, United States nuclear regulatory commission, or an agreement state and who meets the requirements of this rule.
  - b. Is an authorized user under rule 3701:1-58-40 of the Administrative Code for uses listed in rule 3701:1-58-40 of the Administrative Code, rule 3701:1-58-42 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements; or
    - i. Has achieved the following requirements:
      - Has completed eighty hours of classroom and laboratory training, applicable to the medical use of sodium iodide iodine-131 procedures requiring a written directive. The training must include:
        - Classroom and laboratory training in the following areas:
          - Radiation physics and instrumentation;
          - Radiation protection;
          - Mathematics pertaining to the use and measurement of radioactivity;
          - Chemistry of radioactive material for medical use; and
          - Radiation biology; and
        - Work experience, under the supervision of an authorized user who meets the requirements in this rule or rule 3701:1-58-21, 3701:1-58-40, this rule, or rule 3701:1-58-42 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements. A supervising authorized user, who meets the requirements of rule 3701:1-58-40 of the Administrative Code, must have experience in administering dosages rule 3701:1-58-40 of the Administrative Code. The work experience must involve:
          - Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
          - Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

- Calculating, measuring, and safely preparing patient or human research subject dosages;
  - Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
  - Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
  - Administering dosages of radioactive drugs to patients or human research subjects, that includes at least three cases involving the oral administration of less than or equal to 1.22 gigabecquerels (thirty-three millicuries) of sodium iodide I-131; and
- Has obtained written attestation that the individual has satisfactorily completed the requirements in this rule, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under rule 3701:1-58-37 of the Administrative Code. The written attestation must be signed by a preceptor authorized user who meets the requirements in this rule, rule 3701:1-58-21, 3701:1-58-40, or 3701:1-58-42 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements. The preceptor authorized user, who meets the requirements in rule 3701:1-58-40 of the Administrative Code, must also have experience in administering dosages as specified in rule 3701:1-58-40 of the Administrative Code.
7. For authorization of the oral administration of sodium iodide iodine-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (thirty-three millicuries), an individual must meet the following criteria as outline in 3701:1-58-42 – “Training for the oral administration of sodium iodide iodine-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (thirty-three millicuries).”
1. Is certified by a medical specialty board whose certification process has been recognized by the director, United States nuclear regulatory commission, or an agreement state and who meets the requirements of this rule.
  2. Is an authorized user under rule 3701:1-58-40 of the Administrative Code for uses listed in rule 3701:1-58-40 of the Administrative Code, rule 3701:1-58-42 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements; or
  3. Has achieved the following requirements:
    - a. Has completed eighty hours of classroom and laboratory training, applicable to the medical use of sodium iodide iodine-131 procedures requiring a written directive. The training must include:
      - Classroom and laboratory training in the following areas:
        - Radiation physics and instrumentation;
        - Radiation protection;
        - Mathematics pertaining to the use and measurement of radioactivity;
        - Chemistry of radioactive material for medical use; and
        - Radiation biology; and
      - Work experience, under the supervision of an authorized user who meets the requirements in rule 3701:1-58-21, 3701:1-58-40, or this rule of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state

requirements. A supervising authorized user, who meets the requirements of rule 3701:1-58-40 of the Administrative Code, must have experience in administering dosages rule 3701:1-58-40 of the Administrative Code. The work experience must involve:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
  - Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
  - Calculating, measuring, and safely preparing patient or human research subject dosages;
  - Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
  - Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
  - Administering dosages of radioactive drugs to patients or human research subjects, that includes at least three cases involving the oral administration of greater than 1.22 gigabecquerels (thirty-three millicuries) of sodium iodide I-131; and
- Has obtained written attestation that the individual has satisfactorily completed the requirements in this rule, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under rule 3701:1-58-37 of the Administrative Code. The written attestation must be signed by a preceptor authorized user who meets the requirements in this rule, rule 3701:1-58-21, 3701:1-58-40, or 3701:1-58-42 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements. The preceptor authorized user, who meets the requirements in rule 3701:1-58-40 of the Administrative Code, must also have experience in administering dosages as specified in rule 3701:1-58-40 of the Administrative Code.

8. For authorization of parenteral administration of unsealed radioactive material requiring a written directive, an individual must meet the following criteria as outline in 3701:1-58-104 – “Training for the parenteral administration of unsealed radioactive material requiring a written directive.”
- a. Is an authorized user under rule 3701:1-58-40 of the Administrative Code for uses listed in rule 3701:1-58-40 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state requirements;
  - b. Is an authorized user under rule 3701:1-58-51 or 3701:1-58-71 of the Administrative code, or equivalent United States nuclear regulatory commission or agreement state requirements and who meets the requirements in paragraph of this rule; or
  - c. Is certified by a medical specialty board whose certification process has been recognized by the director, United States nuclear regulatory commission, or an agreement state under rule 3701:1-58-51 or 3701:1-58-71 of the Administrative Code, and who meets the requirements in paragraph (B) of this rule.
  - d. Has completed eighty hours of classroom and laboratory training, applicable to the medical use of sodium iodide iodine-131 procedures requiring a written directive. The training must include:
    - Classroom and laboratory training in the following areas:
      - Radiation physics and instrumentation;
      - Radiation protection;
      - Mathematics pertaining to the use and measurement of radioactivity;

- Chemistry of radioactive material for medical use; and
  - Radiation biology; and
- Has work experience, under the supervision of an authorized user who meets the requirements in this rule, rule 3701:1-58-21, or 3701:1-58-40 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than one hundred fifty keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in rule 3701:1-58-40 of the Administrative Code must have experience in administering dosages as specified in paragraphs (B)(1)(b)(vi)(c) and/or (B)(1)(b)(vi)(d) of rule 3701:1-58-40 of the Administrative Code. The work experience must involve:
    - Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
    - Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
    - Calculating, measuring, and safely preparing patient or human research subject dosages;
    - Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
    - Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
    - Administering dosages of radioactive drugs to patients or human research subjects, that includes at least three cases involving the oral administration of greater than 1.22 gigabecquerels (thirty-three millicuries) of sodium iodide I-131; and
  - Has obtained written attestation that the individual has satisfactorily completed the requirements in this rule, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under rule 3701:1-58-37 of the Administrative Code. The written attestation must be signed by a preceptor authorized user who meets the requirements in this rule, rule 3701:1-58-21, 3701:1-58-40, or 3701:1-58-42 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements. The preceptor authorized user, who meets the requirements in rule 3701:1-58-40 of the Administrative Code, must also have experience in administering dosages as specified in rule 3701:1-58-40 of the Administrative Code.
9. OAC 3701:1-58-43 – “Use manual brachytherapy sources.” For authorization, an individual must meet the following criteria as outline in OAC 3701:1-58-51 – “Training for the use of manual brachytherapy sources.”
- a. Is certified by a medical specialty board whose certification process has been recognized by the director, United States nuclear regulatory commission, or an agreement state, and who meets the requirements in of this rule; or
  - b. Has achieved the following requirements:
    - i. Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:
      - Two hundred hours of classroom and laboratory training in the following areas:
        - Radiation physics and instrumentation;
        - Radiation protection;

- Mathematics pertaining to the use and measurement of radioactivity; and
      - Radiation biology; and
    - ii. Five hundred hours of work experience, under the supervision of an authorized user who meets the requirements in this rule or rule 3701:1-58-21 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements at a medical institution, involving:
      - Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
      - Checking survey meters for proper operation;
      - Preparing, implanting, and removing brachytherapy sources;
      - Maintaining running inventories of material on hand;
      - Using administrative controls to prevent a medical event involving the use of radioactive material; and
      - Using emergency procedures to control radioactive material; and
    - iii. Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in this rule or rule 3701:1-58-21 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements, as part of a formal training program approved by the "Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education" or the "Royal College of Physicians and Surgeons of Canada" or the "Committee on Postdoctoral Training of the American Osteopathic Association." This experience may be obtained concurrently with the supervised work experience required by paragraph (B)(1)(b) of this rule; and
    - iv. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in this rule or rule 3701:1-58-21 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements, that the individual has satisfactorily completed the requirements in paragraph (A)(1), or paragraphs (B)(1) and (B)(2) of this rule and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under rule 3701:1-58-43 of the Administrative Code.
10. OAC 3701:1-58-43 – “Use sealed source for diagnosis.” For authorization, an individual must meet the following criteria as outline in OAC 3701:1-58-54 – “Training for use of sealed sources for diagnosis.”
- a. Is certified by a specialty board whose certification process includes all of the requirements in paragraphs (B) and (C) of this rule and whose certification has been recognized by the director, United States nuclear regulatory commission, or an agreement state; or
  - b. Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device.
    - i. The training must include:
      - Radiation physics and instrumentation;
      - Radiation protection;
      - Mathematics pertaining to the use and measurement of radioactivity; and
      - Radiation biology; and

- c. Has completed training in the use of the device for the uses requested.
11. OAC 3701:1-58-55 – “Use of teletherapy units, remote after-loader units (HDR), and gamma stereotactic radiosurgery units.” For authorization, an individual must meet the following criteria as outline in 3701:1-58-71 – “Training for use of remote after-loader units, teletherapy units, and gamma stereotactic radiosurgery units.”
- a. Is certified by a medical specialty board whose certification process has been recognized by the director, United States nuclear regulatory commission, or an agreement state and who meets the requirements in of this rule; or
  - b. Has achieved the following requirements:
    - i. Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:
      - Two hundred hours of classroom and laboratory training in the following areas:
        - Radiation physics and instrumentation;
        - Radiation protection;
        - Mathematics pertaining to the use and measurement of radioactivity; and
        - Radiation biology; and
      - Five hundred hours of work experience, under the supervision of an authorized user who meets the requirements in this rule or rule 3701:1-58-21 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements at a medical institution, involving:
        - Reviewing full calibration measurements and periodic spot-checks;
        - Preparing treatment plans and calculating treatment doses and times;
        - Using administrative controls to prevent a medical event involving the use of radioactive material;
        - Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
        - Checking and using survey meters; and
        - Selecting the proper dose and how it is to be administered; and
      - Has completed three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in this rule or rule 3701:1-58-21 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements, as part of a formal training program approved by the "Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education" or the "Royal College of Physicians and Surgeons of Canada" or the "Committee on Postdoctoral Training of the American Osteopathic Association." This experience may be obtained concurrently with the supervised work experience required by this rule; and
      - Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (A)(1) or (B)(1) and (B)(2), and (C) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor

authorized user who meets the requirements in this rule or rule 3701:1-58-21 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

- Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

12. For authorization as an Authorized Medical Physicist, an individual must meet the following criteria as outline in 3701:1-58-19 "Training for an authorized medical physicist."

- a. Is certified by a specialty board whose certification process has been recognized by the director, United States nuclear regulatory commission, or an agreement state and who meets the requirements in this rule; or
- b. Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy with photons and electrons with energies greater than or equal to one million electron volts and brachytherapy services and must include:
  - i. Performing sealed source leak tests and inventories;
  - ii. Performing decay corrections;
  - iii. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote after-loading units as applicable; and
  - iv. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote after-loading units as applicable; and
- c. Has obtained written attestation that the individual has satisfactorily completed the requirements in of this rule, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in rule 3701:1-58-19 or 3701:1-58-21 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status and;
- d. Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

13. For authorization as an Authorized Nuclear Pharmacist, an individual must meet the following criteria as outline in 3701:1-58-20 – “Training for an authorized nuclear pharmacist.”

- a. Is certified by a specialty board whose certification process has been recognized by the director, United States nuclear regulatory commission, or an agreement state and who meets the requirements of this rule; or
- b. Has achieved the following requirements:
  - i. Has completed seven hundred hours in a structured educational program consisting of both:
    - Two hundred hours of classroom and laboratory training in the following areas:
      - Radiation physics and instrumentation;
      - Radiation protection;
      - Mathematics pertaining to the use and measurement of radioactivity;
      - Chemistry of radioactive material for medical use; and
      - Radiation biology; and
    - Supervised practical experience in a nuclear pharmacy involving:
      - Shipping, receiving, and performing related radiation surveys;
      - Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
      - Calculating, assaying, and safely preparing dosages for patients or human research subjects;
      - Using administrative controls to avoid medical events in the administration of radioactive material; and
      - Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and
    - Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, indicating the individual has satisfactorily completed the requirements of this rule and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

## Chapter 7: Emergency Procedures

### A. Personnel Contamination

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

### 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.

#### 1. Personnel Contamination

- i. Radiation Safety must be notified immediately of any incident involving personnel contamination, regardless of the radionuclide or activity. The Radiation Safety emergency response phone number is (614) 561-7969.
- ii. Begin decontamination of skin surfaces immediately with soap and warm water. Contaminated clothing should be removed and stored for further evaluation by Radiation Safety. Decontamination should continue until no activity is detectable, but not to where effectiveness of the skin as a barrier is destroyed. Decontamination efforts should cease when the skin starts to become thin and reddened. The health of the skin is maintained to minimize absorption and internal deposition of radioactive material.
- iii. Document the incident and send to the Radiation Safety Section within 24 hours using the "Radioactive Material Spill Form" located on the Radiation Safety OneSource page.

#### 2. 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 Radiation Safety Section 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.

#### 3. 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 the Radiation Safety Section of Environmental Health and Safety immediately. The Radiation Safety 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 Radiation Safety personnel.
- vii. Report: Report the incident to the Radiation Safety Section 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.

**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 The Ohio State University 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 The Ohio State University include, but are not limited to, the following:

1. Approved Supervisors (researchers, physicians, or other personnel specifically authorized by the Radiation Safety Committee to use or supervise the use of radioactive materials),
2. Authorized Users, Authorized Medical Physicists, Authorized Nuclear Pharmacists,
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 RSO 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

Authorized User, Authorized Medical Physicists, and Authorized Nuclear Pharmacists approved by the Radiation Safety Committee 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 Approved Supervisor 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 The Ohio State University,
- 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:
    - xi. Patient requires emergency medical attention
    - xii. Patient must leave designated room
    - xiii. Patient expires
    - xiv. 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 Radiation Safety Office issues communications to radiation workers and Approved Supervisors on an as-needed basis. These communications may include information on policy changes, procedural changes, good radiation safety practices, and regulatory updates.
- b. Approved Supervisors are encouraged to share this information with all users under their supervision and to maintain copies of these communications in a central location.

#### **K. Records of Training**

- a. A copy of radiation safety training course contents will be retained by the Radiation Safety Section.

- 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 Radiation Safety Section.

**L. Radiation Safety Training Policy**

Radiation Safety Training Policy for the OSUWMC has been adopted by the University Radiation Safety Committee 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 Radiation Safety personnel for routine leak testing and inventory.
3. Sealed sources are stored and used in a manner that is in keeping with the ALARA philosophy.
  - 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  $\mu\text{Ci}$  of beta or gamma-emitting material
    - contains less than 10.0  $\mu\text{Ci}$  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 The Ohio State University 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 following the guidance provided by Appendix P "Model Leak Test Program" of the ODH "Guidance about OAC Chapter 3701:1-58 Medical Use Licenses, NMS-LIC-09," Revision 0, Effective Date November 1, 2007.
2. Measurements shall be performed on an instrument capable of detecting 185 Bq (0.005  $\mu\text{Ci}$ ) 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 at all times 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(E) and OAC rule 3701:1-38-13.”
2. The OSU has established and implemented the model procedures outline in Appendix S “Model Procedure for Safe Use of Unsealed Licensed Material” of the ODH “Guidance about OAC Chapter 3701:1-58 Medical Use Licenses, NMS-LIC-09,” Revision 0, Effective Date November 1, 2007. Including but not limited to:
  - a. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
  - b. Wear disposable gloves at all times while handling radioactive materials.
  - c. Either after each procedure or before leaving the area: monitor your hands and feet for contamination in a low-background area using a hand and foot monitor.
  - 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, chew gum, smoke or apply cosmetics in any area where licensed material is stored or used.
  - f. Wear personnel monitoring devices, if required, at all times while in areas where radioactive materials are used or stored. These devices shall be worn as prescribed by the Radiation Safety Section. When not being worn to monitor occupational exposures, personnel monitoring devices shall be stored in the work place in a designated low-background area.
  - g. Appropriate shielding shall be used in all areas in which radioactive materials, including wastes, are stored.
  - h. Use tongs or other similar devices to handle high activity radionuclide dosages / elusions.
  - i. Wear extremity dosimeters, if required, when handling radioactive material.
  - j. Fume hoods or equivalent shall be used in all procedures involving the potential for release of airborne radioactivity in the form of dusts, gases, vapors, aerosols, etc.
  - k. Dispose of radioactive waste only in designated, labeled and properly shielded receptacles.
  - l. Never pipette by mouth.
  - m. Wipe-test unsealed byproduct material storage, preparation and administration areas weekly for contamination. If necessary, decontaminate the area.
  - n. Survey with a radiation detection survey meter all areas of licensed material use including the generator storage, kit preparation and injection areas daily for contamination. If necessary, decontaminate the area. Areas used to prepare and administer quantities of radiopharmaceuticals must be surveyed daily in accordance with OAC rule 3701:1-58-29 (except when administering therapy dosages in patients’ rooms when patients are confined).
  - o. Results of smear wipe surveys and are surveys must be maintained in units of disintegrations per minute and exposure (dose) rate, respectively.
  - p. Store radioactive solutions in shielded containers that are clearly labeled.
  - q. Maintain a current and accurate record of receipt, transfer, use, decay and disposal of radioactive materials.
  - r. 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).

- s. 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.
- t. For prepared dosages, assay each patient dosage in the dose calibrator (or instrument) before administering it (OAC rule 3701:1-58-25).
- u. Do not use a dosage if it does not fall within the prescribed dosage range or if it varies more than  $\pm 20$  percent from the prescribed dosage, except as approved by an authorized user.
- v. When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle.
- w. 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).
- x. Always keep flood sources, syringes, waste and other radioactive material in shielded containers.
- y. 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 – A standing order is used for delivery of I-131 to the Nuclear Pharmacy to be on-hand for diagnostic and therapeutic procedures ordered by Nuclear Medicine Authorized Users.
- Radium-223 – Ordered per patient therapy as needed.
- Samarium-153 – 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.
- Palladium-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.
- Others as needed per patient / physician (AU) request.

### C. Procurement of radioactive materials for research laboratories (non-human use)

Each permit for the use of radioactive materials must be reviewed and approved by the URSC (or received temporary authorization by the URSO) prior to the acquisition of radioactive materials. Requisitions to obtain radioactive material are presented to the RSS where the requisition is compared with the Approved Supervisor's permit. During this comparison, RSS personnel:

1. verify the radionuclide and chemical form,
2. assure that the activity of each radionuclide does not cause the Approved Supervisor's limit to be exceeded or cause The Ohio State University to exceed the state-issued license limit,
3. Forward the approved requisition to the appropriate purchasing department. Purchasing agents will not process requisitions for radioactive material without prior approval of the RSS,
4. Enter the information into a data base.

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

## Chapter 12: Records of Radioactive Material Use

### A. Nuclear Medicine

All doses will be either measured in a dose calibrator or measurement will be calculated by decay and volume. Doses given to human patients will be within a given dose range or with +/- 20% of the prescribed dose. Therapeutic doses that exceed +/- 10% of the prescribed dose 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 dose was drawn, the calculated volume needed for the dose prescribed, the measured activity 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 activity 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 activity 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 activity 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 activity 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 activity of sources permanently implanted in the patient or human research subject

## Chapter 13: Procedure for Safely Receiving & Shipping 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 a lab coat and disposable gloves when handling radioactive materials.

### C. Package Survey and Wipe Test

Perform package survey and wipe test in accordance with "Procedure for safely receiving and shipping packages containing radioactive material" in Appendix G.

### D. Opening the Package

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

1. Notify Radiation Safety immediately at (614) 561-7969.
2. Do not attempt to move, open or remove any contents of the package.
3. 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.
4. Check the contents of the package for correctness.
5. 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 must be removed and obliterated, or be completely defaced to prevent anyone from mistakenly identifying the material as being radioactive.

## Chapter 14: Survey Procedures

### B. 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. The OSU has established and implemented the model procedures outline in Appendix Q “Model Procedure for Area Surveys” of the ODH “Guidance about OAC Chapter 3701:1-58 Medical Use Licenses, NMS-LIC-09,” Revision 0, Effective Date November 1, 2007.

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.

<b>Ambient Dose Rate Trigger Levels</b>	
<b>Area Surveyed</b>	<b>Trigger Level</b>
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<sup>2</sup>).
- 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 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.

<b>Contamination Trigger Levels</b>	
<b>Area Surveyed</b>	<b>Trigger Level</b>
Unrestricted	200 dpm/100cm <sup>2</sup>
Restricted	2,000 dpm/100cm <sup>2</sup>

- 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.

### **C. 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 .

### **D. 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(E) 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 meter yields no counts above background (approximately ten half-lives) with storage 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 V “Model Procedure for Waste Disposal by Decay-in-storage, Generator Return, and Licensed Material Return” of the ODH “Guidance about OAC Chapter 3701:1-58 Medical Use Licenses, NMS-LIC-09,” Revision 0, Effective Date November 1, 2007.
2. Radiation Oncology – Decay-in-storage is used for all brachytherapy sources. OSU follows the guidance provided by Appendix V “Model Procedure for Waste Disposal by Decay-in-storage, Generator Return, and Licensed Material Return” of the ODH “Guidance about OAC Chapter 3701:1-58 Medical Use Licenses, NMS-LIC-09,” Revision 0, Effective Date November 1, 2007.
3. Radioactive Seed Localizations – Decay-in-storage is used for all brachytherapy sources. OSU follows the guidance provided by Appendix V “Model Procedure for Waste Disposal by Decay-in-storage, Generator Return, and Licensed Material Return” of the ODH “Guidance about OAC Chapter 3701:1-58 Medical Use Licenses, NMS-LIC-09,” Revision 0, Effective Date November 1, 2007.
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 “diapers,” 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 clear poly 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 Radiation Safety Section approved plastic containers.
  - c. Liquid waste cannot be stored in any glass containers.
3. Mixed Waste  
Low-level radioactive waste and contains waste considered hazardous by the EPA because it either (1) is listed as a hazardous waste in Subpart D of 40 CFR 261 or (2) causes the low-level waste to exhibit any of the hazardous waste characteristics identified in Subpart C of 40 CFR 261.
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. Radioactive seeds and / or injection shall be allowed to decay-in-storage or as directed by the Radiation Safety Section in accordance the ODH or similar guidance.
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 Radiation Safety Section – OSUWMC long lived radioactive wastes shall be disposed of through or under the direction of the Radiation Safety Section.
2. Disposals via Sanitary Sewer – Radiation Safety allows for the disposal of readily soluble aqueous liquids or readily dispersible biological material via the sanitary sewer. 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. High Dose Remote After-loader sources.
- d. Gamma Knifer Perfexion sources.

#### **F. Waste Storage**

1. Closed containers of long-lived waste cannot be held for greater than one (1) year.
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. Date placed into storage
    - ii. Radionuclide
    - iii. Date of disposal and corresponding survey
    - iv. Survey instruments used
    - v. Background
    - vi. Individual who performed the disposal

## Chapter 16: Written Directives

### A. Written Directive

Written directive is defined as an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject.

Written directives will be completed and documented as stated in the following:

- OAC 3701:1-58-15 "Written Directives"
- OAC 3701:1-58-16 "Procedures for Administrations Requiring a Written Directive"
- OAC 3701:1-58-75 "Records of Written Directives"
- OAC 3701:1-58-76 "Records for Procedures for Administrations Requiring a Written Directive"
- Appendix R "Model Procedure for Developing, Maintaining, and Implementing Written Directives" of the ODH "Guidance about OAC Chapter 3701:1-58 Medical Use Licenses, NMS-LIC-09," Revision 0, Effective Date November 1, 2007.

### B. Quality Management Program (QMP) Review

1. Patient therapy cases are reviewed on a monthly and 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 University Radiation Safety Committee.

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 audit looked for 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.
- 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 technologist sign-off (diagnostic I-131) or pharmacist/physician sign-off (all other radiopharmaceuticals) prior to the administration of the radiopharmaceutical.
- vi. Post administration signature of authorized user who delivered the radiopharmaceutical dose.
- vii. Verify inclusion of written patient education material, which instructs the patient on the steps to be taken to reduce exposures to family members and the general public.

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. That prior to administration a written directive is prepared for all brachytherapy treatments. The written directive must be signed and dated by the authorized user (treating physician).
  - ii. That 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 written directive is identified & evaluated & 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. The target site is recorded.
  - iii. Verification of imported images.
  - iv. Prescription dose and prescription isodose are correctly entered into LGP (Leksell Gamma Plan).
  - v. Qualified person other than the LGP operator checks the printout.
  - vi. Plan Transfer: patient info and plan ID verified.
  - vii. Plan Transfer: all targets and shots verified.
  - viii. The "Delivered Irradiation Form" was filled and signed properly.
  - ix. Any unintended deviation from the written prescription is identified.

## Chapter 17: Procedures for the Use of Radioactive Material

### A. Procedures for Therapies Requiring a Written Directive for Radiopharmaceutical Therapy Use of Radiopharmaceuticals

Use of 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
- Samarium-153 (Sm-153) – Quadramet
- Yttrium-90 (Y-90) – Zevalin
- Others as applicable

### B. Procedure for the Safe Use of Radiopharmaceutical Generators

Molybdenum-99 (Mo-99), Strontium-82 (Sr-82), Strontium-85 (Sr-85) 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 Germanium breakthrough shall be made in accordance to the Eckert and Ziegler GalliaPharm™ Ge-68/Ga-68 Pharmacy Grade Generator Licensing Guidance released by the NRC October 2016.
- Breakthrough limits of Ge-68 shall be less than or equal 0.01  $\mu\text{Ci}$  Ge-68 per mCi Ga-68 ( $\leq 0.001$  percent).
- Records shall be maintained in accordance with OAC 3701:1-58-85 "Records of molybdenum-99, strontium-82, and strontium-85 concentrations."

### 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 Perfexion
  - Yttrium-90 (Y-90) – Microsphere
  - Others as applicable

**D. Reporting Medical Events and Other Reportable Occurrences**

RSO 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 T "Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials" of the ODH "Guidance about OAC Chapter 3701:1-58 Medical Use Licenses, NMS-LIC-09," Revision 0, Effective Date November 1, 2007.

### 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 shall be provided a patient release card including:
  - a. Facility Name and Contact Information
  - b. Patient Name
  - c. Date of Administration
  - d. Radionuclide Administered
  - e. Activity Administered
  - f. Expiration Date of Card (Surgery Date for RSL)

### 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. Patients administered greater than 220 mCi of I-131, exceeding the release criteria, or with extenuating medical or living conditions shall be treated as an inpatient.
2. Patients are admitted to a private lead lined room.
3. Room Preparation:
  - a. Due to the potential for significant contamination of the patient room, special precautions are taken including but not limited to:
  - b. Patient's personal belongings are removed from room;
  - c. Extra furniture and medical equipment is removed from room;
  - d. Protective absorbent materials are used to cover the floor, furniture, table tops, etc.,
  - e. Plastic is used to cover handles, faucets, toilet, bed rails/controls, televisions, phone, etc.
  - f. 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:
  - g. Room and Visitation
    - Patient is not permitted visitors without prior approval by the Radiation Safety Section.
    - To minimize radiation exposures, the patient must have a private room.
    - Patient is not permitted to leave the room and the patient's room door must remain closed at all times.
  - h. 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 Radiation Safety.
  - i. 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 Radiation Safety.
  - j. Housekeeping, Trash / Linens, and Meals
    - Housekeeping shall not enter the patient's room.
    - Disposable meal trays, dishes, and utensils must be used.
    - All linen and trash must remain in the patient room in designated waste containers provided by Radiation Safety.
    - All biologicals and uneaten food should be flushed down toilet.
    - Male patients are instructed to sit when urinating.
  - k. Lab Work and Additional 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 Radiation Safety.
    - Lab work which cannot be delayed should be coordinated with the nursing staff and Radiation Safety.
    - If patient needs additional medical procedures requiring the patient to leave room, contact Radiation Safety for instructions prior to patient leaving room (unless for emergency medical attention).
  - l. Personnel Monitoring

- Staff should implement ALARA principles when caring for patient.
  - Physicians and patient care staff must wear a dosimeter provided by Radiation Safety.
  - 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 Radiation Safety.
  - Thyroid bioassays are only required for any staff member who may have close contact with very sick or critical patients for an extended time period and if any bodily fluid (vomit, urine, etc.) comes in contact with any staff member’s skin. Bioassays should be completed 24 to 72 hours post exposure.
- m. Residents, interns, students, and other non-essential staff should not enter the patient’s room. If entry is required they should spend no more than 10 minutes in room at a distance of 3 feet from patient.
- n. Radiation Safety Surveys and Patient Discharge
- Radiation Safety will perform a radiation survey at least daily of the radiation dose rate and estimate the activity remaining in the patient.
  - I-131 patients must NOT be discharged until approved by Radiation Safety.
  - Radiation Safety 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 Radiation Safety. No one is permitted to enter the room until notified by Radiation Safety.
  - Radiation Safety 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.
- o. Emergency Information – Notify Radiation Safety 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 shall be treated as an inpatient
2. 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 at all times except in cases where medical attention is necessary.
    - 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 is 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.
  - Housekeeping shall not enter room.
  - Patient may not leave room.
- c. Visitor Restrictions and Guidance
  - There is no time limit on visitors; however, visitors must leave patient room when lead shield over eye is removed for routine medical care.
  - Visitors are permitted to greet patient with an embrace or hand shake, but should remain at least 3-6 feet away for the remainder of their stay.
  - No pregnant visitors are permitted.
  - No visitors under the age of 18 are permitted.
- 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 Source
  - Call Radiation Safety and Radiation Oncology Immediately
  - Never pick up source(s) with fingers
  - Stay at least 6 feet away for 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 Radiation Safety Section. Included are hand held 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. Radiation Safety Section Instrumentation:

Instrument Type	Detector	Quantity	Radiation Detected	Type/Use
Ludlum 3 or equivalent	GM	8	$\beta$ - $\gamma$	Count-Rate / Contamination Surveys
Ludlum 3-98 or equivalent	GM/Nal	4	$\beta$ - $\gamma$ Low Energy $\gamma$	Count-Rate / Contamination Surveys
Ludlum 12 or equivalent	Gas proportional	2	$\alpha$ - $\beta$	Final Status/Release Surveys
Ludlum 12 or equivalent	Large area GM	1	$\beta$ - $\gamma$	Final Status/Release Surveys
Ludlum 18 or equivalent	Gas proportional	1	$\beta$ - $\gamma$	Final Status/Release Surveys
Victoreen 450 Series or equivalent	Ion Chamber	3	$\gamma$	Dose-Rate / Radiation Surveys
Ludlum 15 or equivalent	BF3	1	$\eta$	Dose-Rate / Radiation Surveys
Beckman and/or Perkin Elmer	Liquid Scintillator	2	$\alpha$ , $\beta$ - $\gamma$	Beta Spectroscopy / Activity Analysis Waste Stream Analysis

3. Calibration of Health Physics Instrumentation
  - a. Instrument calibrations are performed annually, after maintenance (changing batteries is 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:
  - b. 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.
  - c. Dose rate survey instruments will be calibrated using a NIST traceable sealed source. Radiation Safety currently uses a J. L. Shepherd Model 28-6A Calibrator with a 1.3 Ci (Assay date: 4/5/80) Cs-137 source.
  - d. 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.
  - e. 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.
  - f. 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.

- g. Instruments that cannot be calibrated to within + 20% of the expected reading will be considered not calibrated and taken out of service.
- h. 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 dosages will be calibrated in accordance with nationally recognized standards or manufacturer's institutions.
2. Quality assurance tests results shall be +/- 10% of theoretical value.
  - a. Constancy – Completed daily prior to measuring any dosages
  - b. Linearity – At installation and at least quarterly 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 Radiation Safety Section 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 activities 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 RURSC for committee review and action.
  - b. The Audit Subcommittee (AS) will perform its own independent annual audit of the radiation safety program. This written annual report will be provided to the full membership of the URSC for review and final approval. The AS will use a Radiation Safety Section 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):
  - c. Review of radiation safety records with particular attention to those required by state regulations.
  - d. Review of selected portions of routine operations for compliance with regulations, rules, and licenses.
  - e. Review of reports submitted by the RSS.
  - f. Review the results of State of Ohio inspection reports.
  - g. Review of written safety procedures.
  - h. Review of the adequacy of the University's management control system.
  - i. Review of Approved Supervisor's applications for one-year renewals
  - j. Review of ODH-issued amendments of licenses for use of materials.
  - k. 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. Radiation Safety Section Audits and Surveillances

1. The Radiation Safety Section will perform audits and operational surveillances to ensure compliance with regulatory requirements, license conditions, and internal policies / procedures.
2. All areas within The Ohio State University Wexner Medical Center that contain a hot lab will have an Audit/Surveillance performed on a routine basis.
3. Any non-compliance issues noted will be reported as follows:
  - i. Area or Department Supervisor
  - ii. University Radiation Safety Officer
4. Non-compliance issues and corrective actions shall be reported quarterly to the Radiation Safety Committee.

5. When a written corrective action plan is required, it must address the following for each item of non-compliance:
  - i. Acknowledge and state the cause of the deficiency,
  - ii. A statement of corrective actions implemented and actions taken to prevent future occurrences,
  - iii. Date of full compliance,
  - iv. Documentation that all users have signed a statement that describes the nature of the deficiency and corrective actions implemented.

**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 University Radiation Safety Officer who will implement whatever actions are appropriate to the circumstances.

## Chapter 22: Posting and Labeling

### Area Postings and Labeling

- All area using radioactive material are to be posted with appropriate caution signs, labels, and 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 The Ohio State University Campus

1. The preferred method of transport of radioactive material is through a courier service. All applicable Department of Transportation (DOT) regulations apply.
  - a. Individuals involved in preparing the shipment must have received appropriate DOT training available from the Radiation Safety Section of Environmental Health and Safety. This training must be completed every three years.
  - b. The Approved Supervisor's permit must include, or be amended to include, authorization to use a vehicle to transport radioactive material.

### B. Other Permitted Methods of Transport

1. The transportation of radioactive materials by Approved Supervisors or Users 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 the Radiation Safety Section of EHS. 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 Authorized User 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 the Department of Transportation.
  - b. Individuals involved in preparing the shipment or transporting the package must have received appropriate DOT training available from the Radiation Safety Section of EHS. This training must be completed every three years.
  - 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 isotope with a half-life measured in hours.
    - It is a cell culture or a prepared compound that cannot survive for long at ambient temperatures.
    - It is a special product urgently required for a trial or other genuine reason at another site.
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 the Radiation Safety Section of EHS. 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. Not, without reasonable cause, leave the vehicle unattended in a public place.

4. Keep on the vehicle the transport documents relating to the package.
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 Approved Supervisor immediately.

## Chapter 24: Decommissioning

Radiation Safety 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

Authorization Checklist - Authorized Medical Physicist

Review of HEA-0122 - Authorized Medical Physicist Training and Experience and Preceptor Attestation  
Specialty Board Certified Individuals

Review of HEA-0122 - Authorized Medical Physicist Training and Experience and Preceptor Attestation  
Current Authorized Medical Physicist Seeking Additional Authorization

Review of HEA-0122 - Authorized Medical Physicist Training and Experience and Preceptor Attestation Non-  
Board Certified Individuals

**Authorization Checklist - Authorized Medical Physicist**

Name of Proposed Authorized Medical Physicist: \_\_\_\_\_

**Requested Authorization(s): (check all that apply)**

- 3701:1-58-43 – Use of Manual Brachytherapy Sources

Radionuclides: \_\_\_\_\_

- 3701:1-58-55 – Use of Teletherapy Units
- 3701:1-58-55 – Use of Remote After-loader Units – HDR
- 3701:1-58-72 – Use of Gamma Knife Perfexion
- 3701:1-58-72 – Use of Yttrium-90 (Y-90) Microspheres

**Completed Forms**

- RSM-1 – Medical Use of Radioactive Material Application – User Information and Approved Supervisor Authorization
- ODH Form HEA-0122 (rev 6/13) - Authorized Medical Physicist Training and Experience and Preceptor Attestation

**Additional Forms for High Dose Rate Remote After-loader Unit Authorization:**

- HDR Radiation Safety and Emergency Training Attendance Record

**Additional Forms for Gamma Knife Perfexion Authorization:**

- Request for Authorized Medical Physicist Status Approval for Gamma Stereotactic Radiosurgery with Gamma Knife Perfexion
- Gamma Knife Perfexion Radiation Safety and Emergency Training Didactic Training Attendance Record
- Gamma Knife Perfexion Emergency and Security Training Attendance Record
- Gamma Knife Perfexion QA Process and Technical Overview Didactic Training Attendance Record

## Review of HEA-0122 - Authorized Medical Physicist Training and Experience and Preceptor Attestation Specialty Board Certified Individuals

- Yes     No    Name of Proposed Authorized Medical Physicist Completed
- Yes     No    Requested Authorizations Completed and Reviewed as Correct

### Completion of Part I – Training and Experience

Specialty Board Certification: \_\_\_\_\_

Date of Certification: \_\_\_\_\_

- Yes     No    Copy of Specialty Board Certification Attached
- Yes     No    Specialty Board Certification is on List of ODH Recognized Specialty Board Certifications\*

### AND – Table 3c

- Yes     No    Table 3c of Page 3 Completed for Each Type of Use for Which Authorization is Sought  
For "Use of Gamma Knife Perfexion," training must also include the differences in the device operation, safety procedures, and clinical use of the Perfexion. This training requirement may be satisfied by satisfactory completion of a training program provided by the Perfexion vendor and/or by receiving training supervised by an AU or AMP who is authorized for the Perfexion.
- Yes     No    Printed Name and Signature from Supervising Individual Present
- Yes     No    License Number of Supervising Individual Listed
- Yes     No    Medical Use(s) Indicated

### Completion of Part II – Preceptor Attestation

- Yes     No    Section I "Board Certification" Completed
- Yes     No    Section II Completed
- Yes     No    Section III Completed
- Yes     No    Section IV Completed
- Yes     No    Preceptor Name/Signature/Telephone Number/License Number/Facility Name and Date Present

**\* American Board of Radiology (ABR) certification process from June, 2007 to June 2010 for the Therapeutic Radiologic Physics specialty for diplomats who have been issued certificates before and after these dates with the words "AMP Eligible" appearing above the ABR seal; from May 2011 to May 2012 for Therapeutic Medical Physics specialty for diplomats who have been issued certificates with the words "AMP Eligible" appearing above the ABR seal; and from May 2012 to present for Therapeutic Medical Physics specialty for diplomats who have been issued certificates with the words "AMP Eligible" appearing above the ABR seal. Additionally, the certificates issued from May 2012 forward will initially be recognized for 4 years from the date of issuance. Canadian College of Physicists in Medicine (CCPM) certification process from January 2009 forward for the [Radiation Oncology Physics](#) specialty.**

**Review of HEA-0122 - Authorized Medical Physicist Training and Experience and Preceptor Attestation  
Current Authorized Medical Physicist Seeking Additional Authorization**

- Yes     No    Name of Current Authorized Medical Physicist Completed
- Yes     No    Requested Additional Authorizations Completed and Reviewed as Correct

**Completion of Part I – Training and Experience – Table 3c**

- Yes     No    Table 3c Completed for each Type of Use for Which Authorization is Sought  
For “Use of Gamma Knife Perfexion,” training must also include the differences in the device operation, safety procedures, and clinical use of the Perfexion. This training requirement may be satisfied by satisfactory completion of a training program provided by the Perfexion vendor and/or by receiving training supervised by an AU or AMP who is authorized for the Perfexion.
- Yes     No    Printed Name and Signature from Supervising Individual Present
- Yes     No    License Number of Supervising Individual Listed
- Yes     No    Medical Use(s) Indicated

**Completion of Part II – Preceptor Attestation**

- Yes     No    Section I Complete
- Yes     No    Section II Complete
- Yes     No    Section III Complete
- Yes     No    Section IV Complete
- Yes     No    Preceptor Name/Signature/Telephone Number/License Number/Facility Name and Date Present

**Review of HEA-0122 - Authorized Medical Physicist Training and Experience and Preceptor Attestation Non-Board Certified Individuals**

- Yes     No    Name of Proposed Authorized Medical Physicist Completed
- Yes     No    Requested Authorizations Completed and Reviewed as Correct

**Completion of Part I – Training and Experience – Table 3a, Page 1**

Master’s or Doctor’s Degree: \_\_\_\_\_ Major Field: \_\_\_\_\_  
 Date of Degree: \_\_\_\_\_  
 College or University \_\_\_\_\_

**AND Item 3b Table 3b, Page 2**

- Yes     No    Completed one (1) year of full time training in medical physics\*\*
- Yes     No    Completed one (1) year of full-time work experience under the supervision of an AMP\*\*
- Yes     No    Table 3b “Supervised Radiation Safety Experience” Complete\*\*\*
- Yes     No    Printed Name and Signature from Supervising Individual Present
- Yes     No    License Number Listing the Supervising Individual as an AMP Present
- Yes     No    Medical Use(s) Indicated

**AND Table 3c, Page 3**

- Yes     No    Table 3c Completed for each Type of Use for Which Authorization is Sought For “Use of Gamma Knife Perfexion,” training must also include the differences in the device operation, safety procedures, and clinical use of the Perfexion. This training requirement may be satisfied by satisfactory completion of a training program provided by the Perfexion vendor and/or by receiving training supervised by an AU or AMP who is authorized for the Perfexion.
- Yes     No    Printed Name and Signature from Supervising Individual Present
- Yes     No    License Number of Supervising Individual Listed
- Yes     No    Medical Use(s) Indicated

**Completion of Part II – Preceptor Attestation**

- Yes     No    Section I “Education, Training, and Experience” Complete
- Yes     No    Section II Complete
- Yes     No    Section III Complete
- Yes     No    Section IV Complete
- Yes     No    Preceptor Name/Signature/Telephone Number/License Number/Facility Name and Date Present

\*\* 1 year of full-time medical physics training and 1 year of full-time work experience cannot be concurrent.

\*\* Training and work experience must be conducted in clinical radiation facilities that provide high-energy external beam therapy (with photons and electrons ≥ 1 MeV) and brachytherapy sources.

## Appendix B

Authorization Checklist - Authorized Nuclear Pharmacist (ANP)

Review of HEA-0123 - Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation Specialty Board Certified Individuals

Review of HEA-0123 - Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation Structured Educational Program for Proposed Authorized Nuclear Pharmacist

## Authorization Checklist - Authorized Nuclear Pharmacist

Name of Proposed Authorized  
Nuclear Pharmacist:

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### Completed Forms

- RSM-1 – Medical Use of Radioactive Material Application – User Information and Approved Supervisor Authorization
- ODH Form HEA-0123 (rev 06/13) - Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation

**Review of HEA-0123 - Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation Specialty Board Certified Individuals**

- Yes     No    Name of Proposed Authorized Nuclear Pharmacist Completed
- Yes     No    Requested Authorization Completed and Reviewed as Correct

**Completion of Part I – Training and Experience**

Specialty Board Certification: \_\_\_\_\_

Date of Certification: \_\_\_\_\_

- Yes     No    Copy of Specialty Board Certification Attached
- Yes     No    Specialty Board Certification is on List of ODH Recognized Specialty Board Certifications\*

**Completion of Part II – Preceptor Attestation**

- Yes     No    Section I “Board Certification” Completed
- Yes     No    Nuclear Pharmacy or Medical Facility/License Number/Preceptor Name/Preceptor Signature/Telephone Number/Date Present

\*Board of Pharmaceutical Specialties certification process for Board Certified Nuclear Pharmacist from [March 6, 1996 to December 2009](#) and the Board of Pharmacy Specialties certification process for Board Certified Nuclear Pharmacist from [December 2010 to present](#).

**Review of HEA-0123 - Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation Structured Educational Program for Proposed Authorized Nuclear Pharmacist**

- Yes     No    Name of Proposed Authorized Nuclear Pharmacist Completed
- Yes     No    Requested Authorizations Completed and Reviewed as Correct

**Completion of Part I – Training and Experience – Table 2a, Page 1**

- Yes     No    Table 2a, Classroom and Laboratory Training Completed (200 hours minimum required)  
Must include classroom and laboratory training in basic radionuclide handling techniques of unsealed radioactive material, radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of radioactive material for medical use and radiation biology.

**AND Table 2b, Page 2**

- Yes     No    Table 2b, Supervised Practical Experience in a Nuclear Pharmacy Completed (500 hours minimum required)  
Must include ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys, performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters, calculating, measuring and safely preparing patient or human research subject dosages, using administrative controls to prevent a medical event involving the use of unsealed radioactive material and using procedures to contain spilled radioactive material safely and using proper decontamination procedures.
- Yes     No    Printed Name and Signature from Supervising Individual Involved in Experiential Training

**Completion of Part II – Preceptor Attestation**

- Yes     No    Section 2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist Completed
- Yes     No    Nuclear Pharmacy or Medical Facility/License Number/Preceptor Name/Preceptor Signature/Telephone Number/Date Present

## Appendix C

Authorization Checklist - Authorized User

3701:1-58-32; 3701:1-58-34, 3701:1-58-53 and 3701:1-58-72 RSL

Review of HEA-0124 - Authorized User Training and Experience and Preceptor Attestation  
Specialty Board Certified Individuals

Review of HEA-0124 - Authorized User Training and Experience and Preceptor Attestation  
Non-Board Certified Individuals

**Authorization Checklist – Authorized User 3701:1-58-32; 3701:1-58-34, 3701:1-58-53 and 3701:1-58-72 RSL**

Name of Proposed Authorized User: \_\_\_\_\_

**Requested Authorization(s): (check all that apply)**

- 3701:1-58-32 – Use of unsealed radioactive material for uptake, dilution and excretion studies for which a written directive is not required. (Training Section OAC 3701:1-58-33)  
 Radionuclides: \_\_\_\_\_  
 Radionuclides: \_\_\_\_\_
- 3701:1-58-34 – Use of unsealed radioactive material for imaging and localization studies for which a written directive is not required. (Training Section OAC 3701:1-58-36)  
 Radionuclides: \_\_\_\_\_  
 Radionuclides: \_\_\_\_\_
- 3701:1-58-53 – Use of sealed sources for diagnosis. (Training Section OAC 3701:1-58-54)  
 Radionuclides: \_\_\_\_\_  
 Radionuclides: \_\_\_\_\_
- 3701:1-58-72 – Use of Iodine-125 (I-125) Low Dose Rate Brachytherapy Seeds for Localization

**Completed Forms**

- RSM-1 – Medical Use of Radioactive Material Application – User Information and Approved Supervisor Authorization
- ODH Form HEA-0124 (rev 06/13) - Authorized User Training and Experience and Preceptor Attestation (for uses defined under OAC 3701:1-58-32, 3701:1-58-34 and 3701:1-58-53)
- RSM-2 – Medical Use Preceptor Statement (Documentation of Supervised Clinical Case Experience)

**Review of HEA-0124 - Authorized User Training and Experience and Preceptor Attestation  
Specialty Board Certified Individuals**

- Yes     No    Name of Proposed Authorized User Completed
- Yes     No    Requested Authorizations Completed and Reviewed as Correct
- Yes     No    For Use of I-125 Low Dose Rate Brachytherapy Seeds for Localization - 3701:1-58-72 Added

**Completion of Part I – Training and Experience**

Specialty Board Certification: \_\_\_\_\_

Date of Certification: \_\_\_\_\_

- Yes     No    Copy of Specialty Board Certification Attached
- Yes     No    Specialty Board Certification is on List of ODH Recognized Specialty Board Certifications\*

**STOP HERE For 3701:1-58-53 Authorization Only**

**Completion of Part II – Preceptor Attestation (Authorization of 3701:1-58-32, 3701:1-58-34, and 3701:1-58-72 (RSL))**

- Yes     No    Completion of RSM-2 Medical Use Preceptor Statement
- Yes     No    Section I “Board Certification” Completed for 3701:1-58-33 (For 3701:1-58-32)
- Yes     No    Section I “Board Certification” Completed for 3701:1-58-36 (For 3701:1-58-34)
- Yes     No    Section I Completed for 3701:1-58-72 (RSL) if authorization is sought
- Yes     No    Section II Completed
- Yes     No    Preceptor Name/Signature/Telephone Number/License Number/Facility Name and Date Present

**Completion of HEA-0124 Supplement for 3701:1-58-72 Use of I-125 Low Dose Rate Brachytherapy Seeds for Localization**

- Yes     No    For 3701:1-58-72 Use of I-125 Low Dose Rate Brachytherapy Seeds for Localization  
Work experience includes performing the related radiation surveys using the appropriate instrumentation; preparing, implanting, and removing RSL sources safely; use of remote handling tools to manipulate seeds and the proper use of shields; routine monitoring before, during, and after all uses of the seeds to ensure rapid identification and remediation of a broken or leaking source; using emergency procedures; reviewing and understanding the administrative controls in place to prevent a medical event; and inventories of radioactive material on hand.
- Yes     No    Printed Name and Signature from Supervising Individual Present
- Yes     No    License Number Listing Supervising Individual as an AU Present

## Completion of Preceptor Attestation for 3701:1-58-72 Use of I-125 Low Dose Rate Brachytherapy Seeds for Localization

- |                          |     |                          |    |  |
|--------------------------|-----|--------------------------|----|--|
| <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Completion of RSM-2 Medical Use Preceptor Statement  |
| <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Documentation of Supervised Clinical Cases For 3701:1-58-72 Use of I-125 Low Dose Rate Brachytherapy Seeds for Localization                  |
| <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Experience which includes at least 3 cases, wherein the proposed authorized user ordered, received and unpacked radioactive material safely. |

### \* For 3701:1-58-32

- American Board of Nuclear Medicine certification process from [October 20, 2005 to 2007](#) and from [2007 to present](#) for all physicians before and after these dates issued an ABNM certification with the word "United States" appearing under the certification number.
- Certification Board of Nuclear Endocrinology certification process from 2013 to present for all physicians issued a [CBNE Nuclear Endocrinology – Low Dose](#) or [CBNE Nuclear Endocrinology – High Dose](#) certificate. [Note, the NRC does not recognize the CBNE certification process that awards certificates that say "Hereby certifies with the designation of Grandfathered."]

### \* For 3701:1-58-34

- Certification Board of Nuclear Cardiology certification process from 2000 to [2006](#) with the wording "for Physicians Residing in the United States" appearing on the certificate; from [2006 to 2012](#) with the wording "for Physicians Trained in the United States" appearing in the certificate; and the Certification Board of Nuclear Cardiology, a Division of the Council for Certification in Cardiovascular Imaging, certification process from [2012](#) to present with the wording for "physicians trained in the United States" appearing in the certificate.
- American Board of Nuclear Medicine certification process from [October 20, 2005 to 2007](#) and from [2007 to present](#) for all physicians issued an ABNM certification before and after these at dates with the word "United States" appearing under the certification number.
- American Osteopathic Board of Radiology (AOBR) certification process from [July 1, 2000 to June 30, 2002](#) and from [July 1, 2002 to May 16, 2015](#) for the Diagnostic Radiology specialty; and from [May 17, 2015 forward](#) for Diagnostic Radiology certificates issued with the words "AU Eligible" appearing above the D.O. symbol. All certificates issued beginning in July 1, 2002 have a 10-year time limit. AOBR issues subsequent [10-year certificates](#) to document that an individual completed Osteopathic Continuous Certification requirements and is recertified. For individuals applying to become authorized users after expiration of the initial 10-year certificate, it is necessary to submit both the initial certificate and the current recertification certificate.
- American Osteopathic Board of Nuclear Medicine (AOBNM) certification process from May 18, 2006 forward for the [Nuclear Medicine](#) specialty.
- American Board of Radiology (ABR) certification process from June 2006 to July 2012 for the [Diagnostic Radiology](#) certificates with the words "AU eligible" appearing above the ABR seal; and from July 2012 forward for the [Diagnostic Radiology](#) certificates issued with the words "AU eligible" appearing above the ABR seal. Additionally, the certificates issued from July 2012 forward will initially be recognized for 4 years from the date of issuance.

## Review of HEA-0124 - Authorized User Training and Experience and Preceptor Attestation Non-Board Certified Individuals

- Yes     No    Name of Proposed Authorized User Completed
- Yes     No    Requested Authorizations Completed and Reviewed as Correct
- Yes     No    For Use of I-125 Low Dose Rate Brachytherapy Seeds for Localization -  
3701:1-58-72 Added

### Completion of Part I – Training and Experience – Table 3a, Page 2

- Yes     No    For 3701:1-58-32 and 3701:1-58-53 – Completion of 8 Hours (minimum) of Training  
Must include classroom and laboratory training in basic radionuclide handling techniques of radioactive material; radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; chemistry of radioactive material for medical use; and radiation biology.
- Yes     No    For 3701:1-58-34 – Completion of 80 Hours (minimum) of Training  
Must include classroom and laboratory training in basic radionuclide handling techniques of unsealed radioactive material; radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; chemistry of radioactive material for medical use; and radiation biology.

### AND Table 3b, Pages 2 and 3

- Yes     No    For 3701:1-58-32 – Completion of 52 Hours (minimum) of Work Experience  
Must include ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; calculating, measuring, and safely preparing patient or human research subject dosages; using administrative controls to prevent a medical event involving the use of unsealed radioactive material; using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and administering dosages of radioactive drugs to patients or human research subjects.
- Yes     No    For 3701:1-58-34 – Completion of 620 Hours (minimum) of Work Experience  
Must include ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; calculating, measuring, and safely preparing patient or human research subject dosages; using administrative controls to prevent a medical event involving the use of unsealed radioactive material; using procedures to contain spilled radioactive material safely and using proper decontamination procedures; administering dosages of radioactive drugs to patients or human research subjects; and eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for

radionuclide purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs.

- Yes     No    Printed Name and Signature from Supervising Individual Present
- Yes     No    License Number Listing Supervising Individual as an AU Present
- Yes     No    Medical Use(s) Indicated

**AND Table 3c, Page 3 (For 3701:1-58-53 Use ONLY)**

- Yes     No    Table 3c "Training of Use of Device(s)" Completed

**Completion of Part II – Preceptor Attestation**

- Yes     No    Completion of RSM-2 Medical Use Preceptor Statement
- Yes     No    Section I "Training and Experience" Completed for 3701:1-58-33 (For 3701:1-58-32)
- Yes     No    Section I "Training and Experience" Completed for 3701:1-58-36 (For 3701:1-58-34)
- Yes     No    Section I Completed for 3701:1-58-72 (RSL) if authorization is sought
- Yes     No    Section II Completed
- Yes     No    Preceptor Name/Signature/Telephone Number/License Number/Facility Name and Date Present

**Completion of HEA-0124 Supplement for 3701:1-58-72 Use of I-125 Low Dose Rate Brachytherapy Seeds for Localization**

- Yes     No    For 3701:1-58-72 Use of I-125 Low Dose Rate Brachytherapy Seeds for Localization  
Work experience includes performing the related radiation surveys using the appropriate instrumentation; preparing, implanting, and removing RSL sources safely; use of remote handling tools to manipulate seeds and the proper use of shields; routine monitoring before, during, and after all uses of the seeds to ensure rapid identification and remediation of a broken or leaking source; using emergency procedures; reviewing and understanding the administrative controls in place to prevent a medical event; and inventories of radioactive material on hand.
- Yes     No    Printed Name and Signature from Supervising Individual Present
- Yes     No    License Number Listing Supervising Individual as an AU Present

**Completion of Preceptor Attestation for 3701:1-58-72 Use of I-125 Low Dose Rate Brachytherapy Seeds for Localization**

- Yes     No    Completion of RSM-2 Medical Use Preceptor Statement
- Yes     No    Documentation of Supervised Clinical Cases For 3701:1-58-72 Use of I-125 Low Dose Rate Brachytherapy Seeds for Localization  
Experience which includes at least 3 cases, wherein the proposed authorized user ordered, received and unpacked radioactive material safely.

## Appendix D

Authorization Checklist – Authorized User  
OAC 3701:1-58-37

Review of HEA-0126 - Authorized User Training and Experience and Preceptor Attestation  
Specialty Board Certified Individuals – For Full 3701:1-58-37 Authorization

Review of HEA-0126 - Authorized User Training and Experience and Preceptor Attestation  
Non-Board Certified Individuals – For Full 3701:1-58-37 Authorization

Review of HEA-0126 - Authorized User Training and Experience and Preceptor Attestation  
Individual Authorization in Lieu of Full 3701:1-58-37 Authorization  
(Board Certified and Non-Board Certified Individuals)

**Authorization Checklist – Authorized User OAC 3701:1-58-37**

Name of Proposed Authorized User: \_\_\_\_\_

**Requested Authorization(s): (check all that apply)**

- 3701:1-58-37 – Use of unsealed radioactive material for which a written directive is required. (Training Sections 3701:1-58-40 and 3701:1-58-104)

Radionuclides: \_\_\_\_\_

Radionuclides: \_\_\_\_\_

**OR**

- 3701:1-58-37 – Oral administration of sodium iodide Iodine-131  $\leq 33$  mCi for which a written directive is required. (Training Section 3701:1-58-41)

- 3701:1-58-37 – Oral administration of sodium iodide Iodine-131  $> 33$  mCi for which a written directive is required. (Training Section 3701:1-58-42)

- 3701:1-58-37 – Parenteral administration of any beta emitter or photon-emitting radionuclide with a photon energy  $< 150$  keV for which a written directive is required. (Training Section 3701:1-58-104)

Radionuclides: \_\_\_\_\_

- 3701:1-58-37 – Parenteral administration of any other radionuclide for which a written directive is required. (Training Section 3701:1-58-104)

Radionuclides: \_\_\_\_\_

**Completed Forms**

- RSM-1 – Medical Use of Radioactive Material Application (User Information and Approved Supervisor Authorization)
- ODH Form HEA-0126 (rev 06/13) - Authorized User Training and Experience and Preceptor Attestation (for uses defined under OAC 3701:1-58-37)
- RSM-2 – Medical Use Preceptor Statement (Documentation of Supervised Clinical Case Experience)

**Review of HEA-0126 - Authorized User Training and Experience and Preceptor Attestation  
Specialty Board Certified Individuals – For Full 3701:1-58-37 Authorization**

- Yes     No    Name of Proposed Authorized User Completed
- Yes     No    Requested Authorizations Completed and Reviewed as Correct

**Completion of Part I – Training and Experience**

Specialty Board Certification: \_\_\_\_\_

Date of Certification: \_\_\_\_\_

- Yes     No    Copy of Specialty Board Certification Attached
- Yes     No    Specialty Board Certification is on List of ODH Recognized Specialty Board Certifications\*

**AND Table 3a, Page 2**

- Yes     No    OAC 3701:1-58-40 Selected for Full 3701:1-58-37 Authorization Selected
- Yes     No    Completion of 200 Hours (minimum) of Training  
Must include classroom and laboratory training in basic radionuclide handling techniques of unsealed radioactive material, radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of radioactive material for medical use and radiation biology.

**AND Table 3b, Page 3**

- Yes     No    OAC 3701:1-58-40 Selected for Full 3701:1-58-37 Authorization Selected
- Yes     No    Completion of 500 Hours (minimum) of Work Experience  
Must include ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys; performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; calculating, measuring, and safely preparing patient or human research subject dosages; using administrative controls to prevent a medical event involving the use of unsealed radioactive material; and using procedures to contain spilled radioactive material safely and using proper decontamination procedures.
- Yes     No    Printed Name and Signature from Supervising Individual Present
- Yes     No    License Number Listing Supervising Individual as an AU Present
- Yes     No    OAC 3701:1-58-40 Selected for Full 3701:1-58-37 Authorization Selected
- Yes     No    All Administrating Experience Options for Full 3701:1-58-37 Authorization Selected

**And Table 3c, Page 4**

- |                          |     |                          |    |   |
|--------------------------|-----|--------------------------|----|---|
| <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Completion of RSM-2 Medical Use Preceptor Statement   |
| <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Completion of Clinical Case Experience – 3 Cases in each of the following categories: <ul style="list-style-type: none"> <li>• Oral administration of sodium iodide Iodine-131 <math>\leq</math> 33 mCi for which a written directive is required.</li> <li>• Oral administration of sodium iodide Iodine-131 <math>&gt;</math> 33 mCi for which a written directive is required.</li> <li>• Parenteral administration of any beta emitter or photon-emitting radionuclide with a photon energy <math>&lt;</math> 150 keV for which a written directive is required.</li> <li>• Parenteral administration of any other radionuclide for which a written directive is required.</li> </ul> |
| <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Printed Name and Signature from Supervising Individual Present  |
| <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | License Number Listing Supervising Individual as an AU Present  |
| <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | OAC 3701:1-58-40 Selected for Full 3701:1-58-37 Authorization Selected  |
| <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | All Administrating Experience Options for Full 3701:1-58-37 Authorization Selected  |

**Completion of Part II – Preceptor Attestation**

- |                          |     |                          |    |  |
|--------------------------|-----|--------------------------|----|--|
| <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Section I 3701:1-58-40 “Board Certification” for Full 3701:1-58-37 Authorization Completed |
| <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Section II Completed   |
| <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | All Administration Options for Full 3701:1-58-37 Authorization Selected                    |
| <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Section III Completed  |
| <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | All Administration Options for Full 3701:1-58-37 Authorization Selected                    |
| <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Section V Completed  |
| <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | OAC 3701:1-58-40 Selected for Full 3701:1-58-37 Authorization Selected                     |
| <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | All Administrating Experience Options for Full 3701:1-58-37 Authorization Selected         |
| <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Preceptor Name/Signature/Telephone Number/License Number/Facility Name and Date Present    |

\* **For 3701:1-58-37** - Use of unsealed radioactive material for which a written directive is required.

- **American Board of Nuclear Medicine certification process from [October 20, 2005 to 2007](#) and from [2007 to present](#) for all physicians before and after these dates issued an ABNM certification with the word "United States" appearing under the certification number.**
- **American Board of Radiology (ABR) certification process from June 2007 to May 2012 for the [Radiation Oncology](#) specialty with the words "AU eligible" appearing above the ABR seal and from May 2012 to present for [Radiation Oncology](#) specialty with the words "AU eligible" appearing above the ABR seal. Additionally, the certificates issued from May 2012 forward will initially be recognized for 4 years from the date of issuance.**
- **American Osteopathic Board of Radiology (AOBR) certification process from [May 1, 2007 forward](#) for the Radiation Oncology specialty. All certificates issued since this date have a 10-year time limit.**

\* For 3701:1-58-37 - Administration of sodium iodide Iodine-131  $\leq$  33 mCi

- American Osteopathic Board of Radiology (AOBR) certification process from [July 1, 2000 to June 30, 2002](#) and from [July 1, 2002 to May 16, 2015](#) for the Diagnostic Radiology specialty; and from [May 17, 2015 forward](#) for Diagnostic Radiology certificates issued with the word "AU Eligible" appearing above the D.O. symbol. All certificates issued beginning in July 1, 2002 have a 10-year time limit. AOBR issues subsequent [10-year certificates](#) to document that an individual completed Osteopathic Continuous Certification requirements and is recertified. For individuals applying to be authorized users after expiration of the initial 10-year certificate, it is necessary to submit both the initial certificate and the current recertification certificate.
- American Board of Radiology (ABR) certification process from June 2006 to July 2012 for the [Diagnostic Radiology](#) specialty certificates issued before and between these dates issued with the words "AU eligible" appearing above the ABR seal; and from July 2012 forward for the [Diagnostic Radiology](#) certificates issued with the words "AU eligible" appearing above the ABR seal. Additionally, the certificates issued from July 2012 forward will initially be recognized for 4 years from the date of issuance.
- Certification Board of Nuclear Endocrinology certification process from 2013 to present for all physicians issued a [CBNE Nuclear Endocrinology – Low Dose](#) certificate. [Note, the NRC does not recognize the CBNE certification process that awards certificates that say "Hereby certifies with the designation of Grandfathered."]
- American Osteopathic Board of Nuclear Medicine (AOBNM) certification process from May 18, 2006 forward for the [Nuclear Medicine](#) specialty.
- American Board of Radiology (ABR) certification process from June 2006 to July 2012 for the [Diagnostic Radiology](#) certificates with the words "AU eligible" appearing above the ABR seal; and from July 2012 forward for the [Diagnostic Radiology](#) certificates issued with the words "AU eligible" appearing above the ABR seal. Additionally, the certificates issued from July 2012 forward will initially be recognized for 4 years from the date of issuance.

\* For 3701:1-58-37 – Administration of sodium iodide Iodine-131  $>$  33 mCi

- American Board of Radiology (ABR) certification process from June 2011 to July 2012 for the [Diagnostic Radiology](#) certificates issued with the words "AU eligible" appearing above the ABR seal; and from July 2012 forward for the [Diagnostic Radiology](#) certificates issued with the words "AU eligible" appearing above the ABR seal. Additionally, the certificates issued in July 2012 forward will initially be recognized for 4 years from the date of issuance.
- Certification Board of Nuclear Endocrinology certification process from 2013 to present for all physicians issued a [CBNE Nuclear Endocrinology – High Dose](#) certificate. [Note, the NRC does not recognize the CBNE certification process that awards certificates that say "Hereby certifies with the designation of Grandfathered."]
- American Osteopathic Board of Radiology (AOBR) certification process from [May 17, 2015 forward](#) for Diagnostic Radiology certificates issued with the words "AU Eligible" appearing above the D.O. symbol. All certificates have a 10-year time limit. AOBR issues subsequent 10-year certificates to document that an individual completed Osteopathic Continuous Certification requirements and is recertified. For individuals applying to become authorized users after expiration of the initial 10-year certificate, it is necessary to submit both the initial certificate and the current recertification certificate.

**Review of HEA-0126 - Authorized User Training and Experience and Preceptor Attestation  
Non-Board Certified Individuals – For Full 3701:1-58-37 Authorization**

- Yes     No    Name of Proposed Authorized User Completed
- Yes     No    Requested Authorizations Completed and Reviewed as Correct

**Completion of Part I – Training and Experience**

**Completion of Table 3a, Page 2**

- Yes     No    OAC 3701:1-58-40 Selected for Full 3701:1-58-37 Authorization Selected
- Yes     No    Completion of 200 Hours (minimum) of Training  
Must include classroom and laboratory training in basic radionuclide handling techniques of unsealed radioactive material, radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of radioactive material for medical use and radiation biology.

**AND Table 3b, Page 3**

- Yes     No    OAC 3701:1-58-40 Selected for Full 3701:1-58-37 Authorization Selected
- Yes     No    Completion of 500 Hours (minimum) of Supervised Work Experience  
Must include ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys; performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; calculating, measuring, and safely preparing patient or human research subject dosages; using administrative controls to prevent a medical event involving the use of unsealed radioactive material; and using procedures to contain spilled radioactive material safely and using proper decontamination procedures.
- Yes     No    Printed Name and Signature from Supervising Individual Present
- Yes     No    License Number Listing Supervising Individual as an AU Present
- Yes     No    OAC 3701:1-58-40 Selected for Full 3701:1-58-37 Authorization Selected
- Yes     No    All Administrating Experience Options Selected for Full 3701:1-58-37 Authorization

**And Table 3c, Page 4**

- Yes     No    Completion of RSM-2 Medical Use Preceptor Statement
- Yes     No    Completion of Clinical Case Experience – 3 Cases in each of the following categories:
- Oral administration of sodium iodide Iodine-131  $\leq$  33 mCi for which a written directive is required.
  - Oral administration of sodium iodide Iodine-131  $>$  33 mCi for which a written directive is required.
  - Parenteral administration of any beta emitter or photon-emitting radionuclide with a photon energy  $<$  150 keV for which a written directive is required.

- Parenteral administration of any other radionuclide for which a written directive is required.

- Yes     No    Printed Name and Signature from Supervising Individual Present
- Yes     No    License Number Listing Supervising Individual as an AU Present
- Yes     No    OAC 3701:1-58-40 Selected for Full 3701:1-58-37 Authorization Selected
- Yes     No    All Administrating Experience Options for Full 3701:1-58-37 Authorization Selected

**Completion of Part II – Preceptor Attestation**

- Yes     No    Section I 3701:1-58-40 “Training and Experience” for Full 3701:1-58-37 Authorization Completed
- Yes     No    Section II Completed
- Yes     No    All Administration Options for Full 3701:1-58-37 Authorization Selected
- Yes     No    Section III Completed
- Yes     No    All Administration Options for Full 3701:1-58-37 Authorization Selected
- Yes     No    Section V Completed
- Yes     No    OAC 3701:1-58-40 Selected for Full 3701:1-58-37 Authorization Selected
- Yes     No    All Administrating Experience Options for Full 3701:1-58-37 Authorization Selected
- Yes     No    Preceptor Name/Signature/Telephone Number/License Number/Facility Name and Date Present

**Review of HEA-0126 - Authorized User Training and Experience and Preceptor Attestation  
Individual Authorization in Lieu of Full 3701:1-58-37 Authorization (Board Certified and Non-  
Board Certified Individuals)**

- Yes     No    Name of Proposed Authorized User Completed
- Yes     No    Requested Authorizations Completed and Reviewed as Correct (Individual or Group Options):
- Specialty Board Certifications – See approved list of NRC Board Certifications listed above for individual authorization(s) requested.
- Complete Tables 3a, 3b, and 3c – Appropriate OAC section(s) and administration experience/route should be selected corresponding to the authorization(s) requested.

- 3701:1-58-41    Oral administration of sodium iodide Iodine-131  $\leq$  33 mCi for which a written directive is required.
- 3701:1-58-42    Oral administration of sodium iodide Iodine-131  $>$  33 mCi for which a written directive is required.
- 3701:1-58-104    Parenteral administration of any beta emitter or photon-emitting radionuclide with a photon energy  $<$ 150 keV for which a written directive is required.
- 3701:1-58-104    Parenteral administration of any other radionuclide for which a written directive is required.

- Training and Work Experience per authorization:

- 3701:1-58-41    Completion of 80 Hours (minimum) of Training
- Must include classroom and laboratory training applicable to the medical use of sodium iodide Iodine-131, basic radionuclide handling techniques; radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; chemistry of radioactive material for medical use; and radiation biology.
- Completion of Supervised Work Experience
- Must include ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; calculating, measuring, and safely preparing patient or human research subject dosages; using administrative controls to prevent a medical event involving the use of unsealed radioactive material; and using procedures to contain spilled radioactive material safely and using proper decontamination procedures.
- Documentation of Supervised Clinical Cases
- Experience in administering dosages to patients or human research subjects that includes at least three (3) cases involving the oral administration of  $\leq$  33 mCi of sodium iodide Iodine-131.

- 3701:1-58-42      Completion of 80 Hours (minimum) of Training
- Must include classroom and laboratory training applicable to the medical use of sodium iodide Iodine-131, basic radionuclide handling techniques; radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; chemistry of radioactive material for medical use; and radiation biology.
- Completion of Supervised Work Experience
- Must include ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; calculating, measuring, and safely preparing patient or human research subject dosages; using administrative controls to prevent a medical event involving the use of unsealed radioactive material; and using procedures to contain spilled radioactive material safely and using proper decontamination procedures.
- Documentation of Supervised Clinical Cases
- Experience in administering dosages to patients or human research subjects that includes at least three (3) cases involving the oral administration of > 33 mCi of sodium iodide Iodine-131.
- 3701:1-58-104      Completion of 80 Hours (minimum) of Training
- Must include classroom and laboratory training applicable to the medical use of sodium iodide Iodine-131, basic radionuclide handling techniques; radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; chemistry of radioactive material for medical use; and radiation biology.
- Completion of Supervised Work Experience
- Must include ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; calculating, measuring, and safely preparing patient or human research subject dosages; using administrative controls to prevent a medical event involving the use of unsealed radioactive material; and using procedures to contain spilled radioactive material safely and using proper decontamination procedures.
- Documentation of Supervised Clinical Cases
- Experience in administering dosages to patients or human research subjects that includes at least three (3) cases involving the parenteral administration of any beta-emitter or any photon-emitting radionuclide with a photon energy <150 keV for which a written directive is required.
- and/or
- Experience in administering dosages to patients or human research subjects that includes at least three (3) cases involving the parenteral administration of any other radionuclide for which a written directive is required.

- Part II Preceptor Sections I, II, III, and V – Appropriate OAC section(s) and administration experience/route should be selected corresponding to the authorization(s) requested.

## Appendix E

Authorization Checklist – Authorized User  
3701:1-58-43, 3701:1-58-55, 3701:1-58-72  
(Gamma Knife Perfexion) and 3701:1-58-72 (Y-90 Microsphere)

Review of HEA-0125 - Authorized User Training and Experience and Preceptor Attestation  
Specialty Board Certified Individuals

Review of HEA-0125 - Authorized User Training and Experience and Preceptor Attestation  
Current Authorized User Seeking Additional Authorization

Review of HEA-0125 - Authorized User Training and Experience and Preceptor Attestation  
Non-Board Certified Individuals

Review of HEA-0125 - Authorized User Training and Experience and Preceptor Attestation  
Additional Information for the Authorization of 3701:1-58-72 Use of Y-90 Microspheres

**Authorization Checklist – Authorized User 3701:1-58-43, 3701:1-58-55, 3701:1-58-72  
(Gamma Knife Perfexion) and 3701:1-58-72 (Y-90 Microsphere)**

Name of Proposed

Authorized User: \_\_\_\_\_

**Requested Authorization(s): (check all that apply)**

- 3701:1-58-43 – Use of Manual Brachytherapy Sources (Training Section OAC 3701:1-58-51)

Radionuclides: \_\_\_\_\_

- 3701:1-58-55 – Use of Teletherapy Units (Training Section OAC 3701:1-58-71)
- 3701:1-58-55 – Use of Remote After-loader Units – HDR (Training Section OAC 3701:1-58-71)
- 3701:1-58-72 – Use of Gamma Knife Perfexion
- 3701:1-58-72 – Use of Yttrium-90 (Y-90) Microspheres

**Completed Forms**

- RSM-1 – Medical Use of Radioactive Material Application (User Information and Approved Supervisor Authorization)
- RSM-2 – Medical Use Preceptor Statement (Documentation of Supervised Clinical Case Experience)
- ODH Form HEA-0125 (rev 06/13) - Authorized User Training and Experience and Preceptor Attestation (for uses defined under OAC 3701:1-58-43 and 3701:1-58-55)

**Additional Forms for High Dose Rate Remote After-loader Unit Authorization:**

- HDR Radiation Safety and Emergency Training Attendance Record

**Additional Forms for Gamma Knife Perfexion Authorization:**

- Gamma Knife Perfexion Radiation Safety and Emergency Training Didactic Training Attendance Record
- Gamma Knife Perfexion Emergency and Security Training Attendance Record
- Gamma Knife Perfexion QA Process and Technical Overview Didactic Training Attendance Record

**Review of HEA-0125 - Authorized User Training and Experience and Preceptor Attestation  
Specialty Board Certified Individuals**

- Yes     No    Name of Proposed Authorized User Completed
- Yes     No    Requested Authorizations Completed and Reviewed as Correct

**Completion of Part I – Training and Experience**

Specialty Board Certification: \_\_\_\_\_

- Yes     No    Copy of Specialty Board Certification Attached
- Yes     No    Specialty Board Certification is on List of ODH Recognized Specialty Board Certifications\*

**AND Table 3e, Page 4**

- Yes     No    Table 3e Completed for each Type of Use for Which Authorization is Sought  
For “Use of Gamma Knife Perfexion,” training must also include the differences in the device operation, safety procedures and clinical use of the Gamma Knife Perfexion. This training requirement may be satisfied by satisfactory completion of a training program provided by the Gamma Knife Perfexion vendor and/or by receiving training supervised by an AU or AMP who is authorized for the Gamma Knife Perfexion.
- Yes     No    Printed Name and Signature from Supervising Individual Present
- Yes     No    License Number Listing Supervising Individual as an AU Present
- Yes     No    Medical Use(s) Indicated

**Completion of Part II – Preceptor Attestation, Page 5**

- Yes     No    Completion of RSM-2 Medical Use Preceptor Statement (Documentation of Supervised Clinical Case Experience)
- Yes     No    Part II – First Section “Board Certification” Completed
- Yes     No    Part II – Second Section “Board Certification” Completed
- Yes     No    Part II – Third Section Completed
- Yes     No    Medical Use(s) Indicated
- Yes     No    Part II – Fourth Section Completed
- Yes     No    Medical Use(s) Indicated
- Yes     No    Part II – Fifth Section Completed
- Yes     No    Medical Use(s) Indicated
- Yes     No    Preceptor Name/Signature/Telephone Number/License Number/Facility Name and Date Present

**\* For 3701:1-58-43 - Use of manual brachytherapy sources.**

- **American Board of Radiology (ABR) certification process from June 2007 to May 2012 for the [Radiation Oncology](#) specialty with the words "AU eligible" appearing above the ABR seal; and from May 2012 to present [Radiation Oncology](#) specialty with the words "AU eligible" appearing above the ABR seal. Additionally, the certificates issued after May 2012 will initially be recognized for 4 years from the date of issuance.**
- **American Osteopathic Board of Radiology (AOBR) certification process from [May 1, 2007 forward](#) for the Radiation Oncology specialty. All certificates issued since this date have a 10-year time limit.**

**\* For 3701:1-58-55 – Use of remote after-loader units, teletherapy and gamma stereotactic radiosurgery units.**

- **American Board of Radiology (ABR) certification process from June 2007 to May 2012 for the [Radiation Oncology](#) specialty with the words "AU eligible" appearing above the ABR seal; and from May 2012 to present [Radiation Oncology](#) specialty with the words "AU eligible" appearing above the ABR seal. Additionally, the certificates issued after May 2012 will initially be recognized for 4 years from the date of issuance.**
- **American Osteopathic Board of Radiology (AOBR) certification process from [May 1, 2007 forward](#) for the Radiation Oncology specialty. All certificates issued since this date have a 10-year time limit.**

**Review of HEA-0125 - Authorized User Training and Experience and Preceptor Attestation  
Current Authorized User Seeking Additional Authorization**

- Yes     No    Name of Proposed Authorized User Completed
- Yes     No    Requested Authorizations Completed and Reviewed as Correct

**Completion of Part I – Training and Experience – Table 3e, Page 4**

- Yes     No    Table 3e Completed for each Type of Use for Which Authorization is Sought  
For “Use of Gamma Knife Perfexion,” training must also include the differences in the device operation, safety procedures and clinical use of the Gamma Knife Perfexion. This training requirement may be satisfied by satisfactory completion of a training program provided by the Gamma Knife Perfexion vendor and/or by receiving training supervised by an AU or AMP who is authorized for the Gamma Knife Perfexion.
- Yes     No    Printed Name and Signature from Supervising Individual Present
- Yes     No    License Number Listing Supervising Individual as an AU Present
- Yes     No    Medical Use(s) Indicated

**Completion of Part II – Preceptor Attestation, Page 5**

- Yes     No    Completion of RSM-2 Medical Use Preceptor Statement (Documentation of Supervised Clinical Case Experience)
- Yes     No    Part II – First Section Completed
- Yes     No    Part II – Second Section Completed
- Yes     No    Part II – Third Section Completed
- Yes     No    Medical Use(s) Indicated
- Yes     No    Part II – Fourth Section Completed
- Yes     No    Medical Use(s) Indicated
- Yes     No    Part II – Fifth Section Completed
- Yes     No    Medical Use(s) Indicated
- Yes     No    Preceptor Name/Signature/Telephone Number/License Number/Facility Name and Date Present

## Review of HEA-0125 - Authorized User Training and Experience and Preceptor Attestation Non-Board Certified Individuals

- Yes     No    Name of Proposed Authorized User Completed
- Yes     No    Requested Authorizations Completed and Reviewed as Correct

### Completion of Part I – Training and Experience – Completion of Table 3a, Page 1

- Yes     No    Medical Use(s) Indicated
- Yes     No    Completion of 200 Hours (minimum) of Training  
Must include classroom and laboratory training in basic radionuclide handling techniques of manual brachytherapy sources and sealed sources in therapeutic medical units, radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity and radiation biology.

### AND Table 3b for 3701:1-58-43 Use of Manual Brachytherapy Sources

- Yes     No    Completion of 500 Hours (minimum) of Supervised Work Experience\*  
Must include ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; checking survey meters for proper operation; preparing, implanting, and removing brachytherapy sources; maintaining running inventories of material on hand; using administrative controls to prevent a medical event involving the use of radioactive material; and using emergency procedures to control radioactive material.
- Yes     No    Completion of three (3) years of supervised clinical experience in radiation oncology in a formal training program approved by one of the following\*
- Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education
  - Royal College of Physicians and Surgeons of Canada
  - Committee on Postdoctoral Training of the American Osteopathic Association
- Yes     No    Printed Name and Signature from Supervising Individual Present
- Yes     No    License Number Listing Supervising Individual as an AU Present

### And Table 3d for 3701:1-58-71 Use of remote After-loader, Teletherapy, and 3701:1-58-72 Gamma Knife Perfexion.

- Yes     No    Medical Use(s) Indicated
- Yes     No    Completion of 500 Hours (minimum) of Supervised Work Experience\*  
Must include reviewing full calibration measurements and periodic spot checks; preparing treatment plans and calculating treatment doses and times; using administrative controls to prevent a medical event involving the use of radioactive material; implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or

- console; checking and using survey meters; and selecting the proper dose and how it is to be administered.
- Yes     No    Completion of three (3) years of supervised clinical experience in radiation oncology in a formal training program approved by one of the following\*
- Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education
  - Royal College of Physicians and Surgeons of Canada
  - Committee on Postdoctoral Training of the American Osteopathic Association
- Yes     No    Printed Name and Signature from Supervising Individual Present
- Yes     No    License Number Listing Supervising Individual as an AU Present

\* Training sections can be concurrently obtained.

#### AND Table 3e, Page 4

- Yes     No    Table 3e Completed for each Type of Use for Which Authorization is Sought For "Use of Gamma Knife Perfexion," training must also include the differences in the device operation, safety procedures and clinical use of the Gamma Knife Perfexion. This training requirement may be satisfied by satisfactory completion of a training program provided by the Gamma Knife Perfexion vendor and/or by receiving training supervised by an AU or AMP who is authorized for the Gamma Knife Perfexion.
- Yes     No    Printed Name and Signature from Supervising Individual Present
- Yes     No    License Number Listing Supervising Individual as an AU Present
- Yes     No    Medical Use(s) Indicated

#### Completion of Part II – Preceptor Attestation

- Yes     No    Completion of RSM-2 Medical Use Preceptor Statement
- Yes     No    Part II – First Section "Training and Experience" Completed
- Yes     No    Part II – Second Section "Training and Experience" Completed
- Yes     No    Part II – Third Section Completed
- Yes     No    Medical Use(s) Indicated
- Yes     No    Part II – Fourth Section Completed
- Yes     No    Medical Use(s) Indicated
- Yes     No    Part II – Fifth Section Completed
- Yes     No    Medical Use(s) Indicated
- Yes     No    Preceptor Name/Signature/Telephone Number/License Number/Facility Name and Date Present

## Review of HEA-0125 - Authorized User Training and Experience and Preceptor Attestation Additional Information for the Authorization of 3701:1-58-72 Use of Y-90 Microspheres

### Type of Y-90 Microsphere for which Authorization Sought

- TheraSpheres
- SIR-Spheres

### Completion of HEA-0125 Supplement – For 3701:1-58-72, Y-90 Microspheres

- Yes     No    Authorized for  
3701:1-58-43 “Use of Manual Brachytherapy Sources” or  
3701:1-58-37 “Use of unsealed radioactive material for which a written  
directive is required”

OR

- Yes     No    Meets the Training Requirements of  
3701:1-58-43 “Use of Manual Brachytherapy Sources” or  
3701:1-58-37 “Use of unsealed radioactive material for which a written  
directive is required”

OR

- Yes     No    Is an interventional radiologist who meets the training and experience  
guidelines as follows:
- American Board of Radiology certification in diagnostic radiology and subspecialty certification in interventional radiology; or
  - Three years supervised clinical experience in diagnostic radiology and one additional year of supervised clinical experience in interventional radiology.

AND

#### Completion of 80 Hours (minimum) of Training

Must include classroom and laboratory training including Y-90 microspheres, which may be concurrent with training received in accordance with Board Certification in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity and radiation biology.

AND

#### Completion of Supervised Work Experience

Must include ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; performing quality control procedures on instruments used to determine the activity of Y-90 microspheres and performing checks for proper operation of survey meters; evaluation of each patient or human research subject for the dose/activity of Y-90 microspheres to be administered to each treatment site; calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient or human research subject; using administrative controls to prevent a medical event involving the use of byproduct material; using procedures to control and to contain spilled byproduct material,

including Y-90 microspheres, safely and using proper decontamination procedures; and follow up and review of each patient's or human research subject's case history for Y-90 microspheres.

AND

- |                          |     |                          |    |   |
|--------------------------|-----|--------------------------|----|---|
| <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Successfully completed training in the operation of the delivery system, safety procedures and clinical use for each type of Y-90 microspheres for which authorization is sought by an authorized AU or vendor. |
| <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Completion of RSM-2 Medical Use Preceptor Statement   |
| <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Completion of 3 supervised hands-on cases for each type of Y-90 microsphere for which authorization is sought.  |

## I. Appendix F

### Radiation Safety Training Policy

## POLICY - Radiation Safety Training

This policy delineates the required actions for the annual Radiation Safety training of all Occupational Radiation Workers and Ancillary Workers/Staff.

The Radiation Safety Section provides Radiation Safety training for OSUWMC personnel likely to receive an occupational exposure in excess of 1 mSv (100 mrem) in one year. This training is mandatory for all radiation workers and appropriate ancillary personnel. Training shall be completed prior to issuance of personal radiation dosimetry or permission to work in a radiation area, with radiation generating equipment (RGE), or with radioactive materials.

This policy applies to all OSUWMC Occupational Radiation Workers, applicable Ancillary Workers and their supervisors.

### Definitions

Term	Definition
Occupational Radiation Workers	Workers whose responsibilities involve working with: <ul style="list-style-type: none"> <li>Sources of Radioactive Material (RAM) – referred to in this policy as a Materials Worker</li> <li>Radiation Generating Equipment (RGE) – referred to in this policy as an X-ray Worker</li> </ul>
Ancillary Workers	All personnel who may come in contact with or enter an area that contains radioactive material or radiation generating equipment.
Non-Radiation Worker	Personnel who in the course of their daily job function would not normally be expected to encounter radioactive material, radiation generating, equipment in the course of their employment.

## Policy Details

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### Categorization of Workers/Task List

All OSUWMC workers will be evaluated for their potential for radiation exposure based on the cost center(s) under which they are employed or have been granted clinical privileges, their job title and/or with the input of the appropriate supervisor. A job analysis was conducted to aide in the development of a detailed list of physicians, staff members, ancillary personnel and non-radiation workers by duty area. Required training course / topics were then assigned to each group. A Training Matrix was developed to capture this data and aid workers and their management in understanding the appropriate training that should be assigned/completed.

Based on this evaluation, workers are assigned to one of the following categories below. Note: some workers may be assigned to multiple groups as applicable to their job functions.

- Materials Workers
- X-ray Workers
- Ancillary Workers (e.g. Housekeeping)
- Non-Radiation Worker

### **Task-to-Training Matrix/Creation and Maintenance of Audiences and other Assignments**

Categories of workers and assignments (see Appendix 1 for Training Matrix)

#### **Initial and Continuing Education**

- Radioactive materials workers/staff will be assigned online eLearn modules(s) and hands-on/competency training upon hire; annually thereafter. Documentation of training will be retained in the BuckeyeLearn computer based training platform and/or the Radiation Safety Section files. Copies of department/division training records should be supplied to the Radiation Safety Section as necessary.
- X-ray workers and Ancillary workers/staff will be assigned online eLearn module(s) upon hire and annually thereafter if necessary. The assigned training shall reflect the details in the Training Matrix commensurate with their involvement in the use of Radiation Generating Equipment and/or Radioactive Materials.
- Non-radiation workers shall be assigned the eLearn module “Radiation Safety Awareness at the OSUWMC” upon hire.

#### **Training Assignment and Access**

- Radiation Safety training shall be assigned to workers by a member of the Radiation Safety Section, Human Resources, Credentialing, department/division managers, or similar. Employees and their immediate supervisor should receive a communication alerting a worker to their new Radiation Safety training assignment.
- Workers that do not have access to the online training platform (BuckeyeLearn) will be provided with alternative means of training as deemed appropriate by the Radiation Safety Section.
- The Radiation Safety Section may mandate additional special training at any time if deemed appropriate and necessary. This may include, but is not limited to:
  - Supplemental Training – Supplemental training may be initiated and assigned to a department/division as necessary by the Radiation Safety Section. Supplemental training will generally be delivered in person by the Radiation Safety Section. Training can cover a broad range of topics as deemed necessary for a particular department/division.
  - Competency Training (new or refresher) – Competency training will be used to demonstrate a worker’s knowledge of and use of various imaging technologies as well as other hands on tasks as deemed necessary and relevant to a particular department/division.

## Auditing of Continuing Education Compliance

- The Radiation Safety Section will audit the compliance of all Occupational Radiation Workers and Ancillary Workers on an annual basis.
  - Auditing will consist of reviewing:
    - Training/attendance records
    - Roster information generated by the computer based training platform (BuckeyeLearn)
- Levels of compliance will be shared with the following on an annual basis:
  - The University Radiation Safety Committee, Radiation Safety Quality Assurance (RSQA) Committee and/or Radiation Advisory Group
  - Supervisors/managers of cost centers with Occupational Radiation Workers and/or Ancillary Workers

## Enforcement of Compliance

It is the responsibility of the supervisor/manager of the worker to ensure compliance with any assigned Radiation Safety training deemed appropriate by the Radiation Safety Section.

Providers who have been granted clinical privileges are required to comply with all educational requirements, per the medical staff bylaws.

## Creation and Maintenance of Training Content

The Radiation Safety Section and the RSQA Committee are responsible for the creation and maintenance of the content of all Radiation Safety training provided to Occupational Radiation Workers and Ancillary Workers.

Training of Occupational Radiation and Ancillary Workers shall include at a minimum (see Appendix 2 for further information on training topics):

- Safety Culture in the Workplace
- Basic Fundamentals and Properties of Radioactive Materials
- Basic Fundamentals and Properties of Radiation Generating Equipment
- Proper use of Personal Dosimetry (where applicable)
- Policies and Procedures for Pregnant Workers
- Radioactive Material and Radiation Units of Measurement
- Sources of Radiation Exposure
- Methods of Radiation Protection (ALARA)
- Biological Effects of Radiation Exposure
- Radiation Protection Optimization Techniques (where applicable)

Updates to training content will be made at intervals deemed appropriate by the Radiation Safety Section.

As additional training requirements are identified by user groups, requests for the development of new training materials and/or modifications of existing materials will be coordinated between the Radiation Safety Section and the RSQA Committee

**Resources**

Radiation Safety Training Matrix

Appendix I “Model Training Program” – ODH NMS-LIC-09 “Guidance about OAC Chapter 3701:1-58 Medical Use

Licenses,” Rev.0, Effective Date: November 1, 2007.

Ohio Administrative Code 3701:1-38-10(B)

Ohio Administrative Code 3701:1-66-04(B)(6)

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## APPENDIX G

### Procedure for Safely Receiving and Shipping Packages Containing Radioactive Material

## Procedure for Safely Receiving and Shipping Packages Containing Radioactive Material

### A. Package Surveys

1. Receipt Surveys
  - a. Inspect incoming package for any sign of damage.
2. Measuring package surface radiation level:
  - a. Using an ion chamber survey meter, measure exposure reading (mR/h) at the surface of all sides of the package. Record the results of the highest reading on the packing slip.
3. Measure package Transportation Index (TI) radiation level, at one meter away from the package:
  - a. Using an ion chamber survey meter measure exposure reading (mR/h) at 1 meter from the surface of the package. Record the results on the packing slip.
4. Outer contamination wipe test:
  - a. Measure the background using a MCA or SCA (dpm).
  - b. With a Q-Tip smear wipe at minimum 300 cm<sup>2</sup> on the surface of the outer package.
  - c. Measure the Q-Tip smear with the MCA or SCA and determine disintegrations per minute (dpm). Record the results on the packing slip.
  - d. Open the outer package and confirm that the inner container (vial) is free of damages.
  - e. With a Q-Tip smear wipe at minimum 300 cm<sup>2</sup> on the surface of the inner container (i.e. vial, package, pig, etc.)
  - f. Measure the Q-Tip smear with the MCA or SCA and determine disintegrations per minute (dpm). Record the results on the packing slip.
  - g. Notify Radiation Safety immediately if the shipment is:
    - i. Leaking, crushed or damaged in any way
    - ii. outer surface wipe exceeds 6,600 dpm
    - iii. TI exceeds 10 mR/h
    - iv. surface reading exceeds 200 mR/h

### B. Outgoing Surveys

Shipping packages containing radioactive material:

1. Inner contamination wipe test:
  - a. Measure the background on the MCA or SCA (dpm).
  - b. With a Q-Tip smear wipe the surface of the inner containers (i.e. lead or tungsten pigs).
  - c. Measure the Q-Tip smear with the MCA or SCA and determine and record disintegrations per minute (dpm).
  - d. If the measured activity is  $\leq 6,600$  dpm seal the container with a zip tie.
  - e. Note: if activity exceeds the set limit, the contaminated inner container must be decontaminated or replaced prior to sealing the outer package.
2. Outer contamination wipe test:
  - a. With a Q-Tip smear wipe at minimum 300 cm<sup>2</sup> on the surface of the outer container (i.e. shipping case).
  - b. Measure the Q-Tip smear with the MCA or SCA and determine disintegrations per minute (dpm).
  - c. Measured activity must be  $\leq 6,600$  dpm 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.
3. Measuring package surface radiation level:
  - a. Using an ion chamber survey meter, determine the maximum exposure reading (mR/h) 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)

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

Radioactive Category Label		
		
<b>White-I</b>	<b>Yellow-II</b>	<b>Yellow-III</b>
Radiation Surface Level (RSL) :		
<b>RSL ≤ 0.5 mR/h</b>	<b>0.5 &lt; RSL ≤ 50 mR/h</b>	<b>50 &lt; RSL ≤ 200 mR/h</b>
Transport Index (TI):		
<b>TI = 0</b>	<b>0 &lt; TI ≤ 1</b>	<b>1 &lt; TI ≤ 10</b>