

RADIATION CONTROL
AND
SAFETY PROGRAM
MANUAL
(RCSP MANUAL)

University of Cincinnati

**RCSP MANUAL
RECORD OF REVISIONS PAGE**

UNIVERSITY OF CINCINNATI
RADIATION CONTROL AND SAFETY PROGRAM MANUAL

Revision No.	Date of Revision	Changes Entered
Original	04/01/98	None
1	03/29/00	Incorporates Ohio becoming Agreement State, revises IRB procedures, and adds miscellaneous administrative changes.
2	02/18/04	Adds GRI and Center Hill as locations of use under the RCSP; incorporates the revision of the human-use protocol review process approved by the RSC in 2002.
3	8/17/05	Adds Authorized Medical Physicist
4	11/16/05	Updates RCSP to remove TUH from the RGE portion of the RCSP as TUH transferred responsibility of TUH RGE from the RCSP to TUH effective 10/1/05; corrects some language to make it clear that the RCSP handling requirements are not limited to “employees” but to all individuals who possess or use ionizing radiation, including students, volunteers and visitors; corrects an oversight from the addition of AMP in revision 3.
5	5/17/06	Deleted all references to The University Hospital/TUH. TUH separated from the RCSP. The effective date of the revision is 6/17/06, the effective date of the separation.
6	11/13/13	Revised RSO and ARSO specifications. (Tasks that must be assigned to the RSO are no longer specified in regulation. Senior management desires more flexibility for specific job duties of the RSO and the ARSO.) Updated to current regulatory terminology and references. Updated to assure equivalence to other RCSP manuals. Removed requirements that no longer apply. Corrected typographical errors and inconsistencies with abbreviation usage, as noted.
7	8/04/21	Changed RSO of audit frequency requirement from twice a year to annually. Modified document to meet ADA compliance.

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1.0 JUSTIFICATION

1.1 Program Goals

1.1.1 The goals of this program are:

- 1.1.1.1 To provide protection to individuals who use radioactive material (RAM) and radiation generating equipment (RGE) under the University of Cincinnati's (UC) licenses and registrations and to minimize the general public exposure to ionizing radiation from the use of RAM and RGE;
- 1.1.1.2 To ensure the individuals comply with all applicable rules and regulations for the use of RAM and RGE; and
- 1.1.1.3 To meet the requirements of UC's Ohio Department of Health (ODH) issued broad scope license and other applicable licenses and registrations.

1.2 Rules and Regulations

1.2.1 Governmental rules and regulations that control the use of RAM and RGE under the program are:

- 1.2.1.1 U.S. Nuclear Regulatory Commission (NRC) regulations stated in Title 10 of the Code of Federal Regulations (10 CFR).
- 1.2.1.2 State of Ohio rules stated in Ohio Administrative Code. The primary chapters of which are:
 - 1.2.1.2.1 Chapter 3701:1-38 – General Radiation Protection Rules;
 - 1.2.1.2.2 Chapters 3701:1-40 to 58 – RAM rules; and
 - 1.2.1.2.3 Chapter 3701:1-66 to 68 – RGE use rules
- 1.2.1.3 U.S. Department of Transportation (DOT) regulations stated in Title 49 of the Code of Federal Regulations (49 CFR).
- 1.2.1.4 For the use of radiation in human patients or research subjects, additional regulations also apply (e.g., U.S. Food and Drug Administration, Ohio Board of Pharmacy, Ohio Board of Medicine).

1.3 UC Control

1.3.1 As required by the ODH, the administration of UC has established a Radiation Safety Committee (RSC) with the responsibility to define and implement proper safeguards for the use of ionizing radiation. To this end, the RSC developed this Radiation Control and Safety Program (RCSP), and UC assigns implementation to the Radiation Safety Officer (RSO).

1.4 ALARA

1.4.1 To ensure a safe and healthful working environment, the ALARA concept ("As Low As Reasonably Achievable") will be applied to the use of RAM and RGE. ALARA mandates that radiation exposure to individuals be kept as far below regulatory limits as practical, taking into account the state of technology, the economics of improvements in relation to the state of

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technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of licensed materials in the public interest.

1.5 Program Scope

1.5.1 This program is limited to the use of RAM and RGE at UC or affiliated institutions specified by the program.

1.5.1.1 The UC campuses covered by the program are the East Campus the West Campus, Blue Ash College, the Reading Campus, and the Center Hill Research Facility. The East Campus includes, but is not limited to, the College of Medicine, the College of Pharmacy, the College of Allied Health, the College of Nursing and Hoxworth Blood Center.

1.5.1.2 The affiliated institutions covered by the program are Cincinnati Children's Hospital Medical Center (CCHMC), and Cincinnati Shriners Burns Hospital for Children (SHC).

1.5.2 The program covers all RAM and RGE at UC campuses and affiliated institutions for uses, which include, but are not limited to: student instruction, research and development activities, irradiation of animals or materials, and human-use.

1.5.3 The program also covers all RAM and RGE exposure that may be received by a student during a professional practice, internship or other course work related experience from a program within UC. These programs include: the Advance Medical Imaging Program (e.g., Nuclear Medicine Technologist), the Dental Hygienist program, the Radiation Therapist program and the Radiologic Technologist program.

1.6 Program Distribution

1.6.1 Each Authorized User (AU) and/or each Authorized Medical Physicist (AMP) involved in RAM work and each Contact Person (CP) involved in RGE use is provided a copy of this document. Each RAM radiation worker will have access to the AU's and AMP's copy and RGE operators or radiation workers will have access to the CP's copy.

1.6.2 The RCSP will undergo periodic revisions. Revisions will be issued to each person required to maintain a copy of the RCSP manual.

1.6.3 It is the responsibility of each AU and CP to inform RAM radiation workers or RGE operators or radiation workers of RCSP manual revisions.

2.0 PROGRAM ORGANIZATION

2.1 Radiation Safety Committee (RSC)

2.1.1 Appointment

2.1.1.1 The RSC is a committee of the Office of the President of UC.

2.1.1.2 The Chairperson and the voting members are appointed either by the

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President or in the name of the President by the President's delegate.

2.1.2 Purpose

- 2.1.2.1 The RSC is created to assist the President and UC in generating, defining, implementing and monitoring an RCSP that complies with the requirements of the applicable regulatory agencies, licenses, permits and registrations.

2.1.3 Responsibilities

2.1.3.1 General

- 2.1.3.1.1 To carry out all responsibilities delineated by regulation and/or license condition.
 - 2.1.3.1.2 To acquire and maintain such licenses, permits and registrations which are required for UC to possess and use radiation sources (including both RAM and RGE).
 - 2.1.3.1.3 To review and approve safety evaluations of proposed uses of radiation sources before their use.
 - 2.1.3.1.4 To review and approve the following:
 - 2.1.3.1.4.1 Amendments and renewals of licenses; and
 - 2.1.3.1.4.2 All required responses to regulatory agencies.
 - 2.1.3.1.5 To define and implement an RCSP that complies with the requirements of licenses, permits and registrations. This includes developing necessary manuals and written policies to communicate requirements to effected individuals.
 - 2.1.3.1.6 To establish and maintain a UC Radiation Safety Office (RSOf) to carry out the day-to-day services for the RCSP.
 - 2.1.3.1.7 To oversee the operation of the RCSP.
 - 2.1.3.1.8 To review the operation of the RCSP, at least annually.
 - 2.1.3.1.9 To conduct periodic audits of records that are maintained to demonstrate compliance with applicable rules and regulations and specific license conditions.
 - 2.1.3.1.10 To assure compliance with the ALARA philosophy.
 - 2.1.3.1.11 To submit a report to the President of UC, at least annually, summarizing the functions, activities, and achievements of the RCSP.
 - 2.1.3.1.12 To hold meetings at least quarterly.
- 2.1.3.2 The RCSP delegates specific authority to the RSC for the following:
- 2.1.3.2.1 To grant and withdraw AU status;
 - 2.1.3.2.2 To require restrictions and/or limits on AU activities;

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- 2.1.3.2.3 To require AUs, CPs, and radiation workers to attend such training as may be specified by the RCSP and/or recommended by the RSO;
- 2.1.3.2.4 To monitor, inspect and/or audit the activities of the AUs as required under applicable licenses;
- 2.1.3.2.5 To amend the RCSP as necessary;
- 2.1.3.2.6 To establish a Medical Quality Management Program (QMP) to meet regulatory requirements for human use of RAM;
- 2.1.3.2.7 To establish a Quality Assurance Program to meet regulatory requirements for RGE;
- 2.1.3.2.8 To apply such enforcement actions as required by the RCSP and/or the RSC; and
- 2.1.3.2.9 To establish the qualifications of the RSO, RSO of technical staff, AUs, CPs and radiation workers.

2.2 Radiation Safety Officer (RSO)

2.2.1 Appointment

- 2.2.1.1 The RSO is designated by the Office of the President of UC as the person with the knowledge and responsibility for the overall RCSP.

2.2.2 Authority

- 2.2.2.1 The RSO has the authority to implement UC's RCSP and assure compliance to regulatory requirements.
- 2.2.2.2 The RSO shall be a radiation worker under the program.
- 2.2.2.3 In the absence of a designated ARSO, the RSO shall have the full authority and responsibilities assigned to the ARSO.

2.2.3 Responsibilities

- 2.2.3.1 Perform all duties delineated by regulation and/or license conditions.
- 2.2.3.2 Administer UC's RCSP and provide guidance to the day-to-day operation of the RSO regarding services that may be required by the program. Specific responsibilities follow:
 - 2.2.3.2.1 To regularly communicate with the RSC Chairperson and Administrative Representative concerning RCSP matters;
 - 2.2.3.2.2 To present reports of RCSP activities at meetings of the RSC;
 - 2.2.3.2.3 To assess the services provided by the RSO;
 - 2.2.3.2.4 To provide for a personnel radiation monitoring program;
 - 2.2.3.2.5 To establish a radiation safety training program;
 - 2.2.3.2.6 To ensure periodic surveys and audits are performed of all RAM

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use areas;

- 2.2.3.2.7 To exercise surveillance over the RCSP RAM inventory;
- 2.2.3.2.8 To ensure facilities and equipment to be used in conjunction with are appropriately inspected;
- 2.2.3.2.9 To provide consulting services to personnel at all levels of responsibility on all aspects of radiation protection;
- 2.2.3.2.10 To establish a RAM disposal program;
- 2.2.3.2.11 To ensure sealed RAM is tested for leakage, as applicable;
- 2.2.3.2.12 To maintain current copies of all applicable rules and regulations for control of RAM and RGE;
- 2.2.3.2.13 To stay abreast of developing issues at the state and national level concerning upcoming changes in rules and regulations affecting the use of RAM and RGE under the RCSP;
- 2.2.3.2.14 To inform AUs and CPs of changes in rules and regulations;
- 2.2.3.2.15 To ensure all appropriate records associated with the administration of the RCSP are maintained;
- 2.2.3.2.16 To review and approve, in conjunction with the RSC, all applications for RAM use;
- 2.2.3.2.17 To develop written procedures and ensure appropriate surveillance of the QMP;
- 2.2.3.2.18 To make notifications and reports to the ODH;
- 2.2.3.2.19 To implement a surveillance program approved by the RSC to identify non-compliance issues. The program should assign "points" or use other means to apply increasing disciplinary actions for AUs not in compliance with regulations;
- 2.2.3.2.20 To assure information is available to female radiation workers and their supervisors of the risks of prenatal exposure. (Reference Regulatory Guide 8.13); and
- 2.2.3.2.21 To foster the ALARA concept at all levels of RAM and/or RGE use.

2.2.4 Emergency Authority

- 2.2.4.1 The RSO is authorized to act independently to take prompt remedial action in emergency situations involving RAM and/or RGE. Such actions shall be taken only upon the determination by the RSO of conditions which present imminent danger or threat to personnel, property or the community at large. Actions taken in emergency situations by the RSO shall be considered a temporary expedient and include, but are not necessarily limited to the following:

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- 2.2.4.1.1 Suspension of work with RAM or RGE;
- 2.2.4.1.2 Establishment of exclusion and limited access areas;
- 2.2.4.1.3 Removal of personnel from the affected areas; and
- 2.2.4.1.4 Ordering of immediate bioassays for persons involved.

2.2.4.2 The RSO shall keep the RSC apprised of incidents that occur under the RCSP.

2.3 Assistant Radiation Safety Officer (ARSO)

2.3.1 Authority

2.3.1.1 The ARSO obtains programmatic direction from the RSO and assumes full authority to suspend activities when warranted in the absence of the RSO.

2.3.1.2 The ARSO provides through the RSO such services as may be required by the RCSP.

2.3.1.3 The ARSO shall be a radiation worker under the program.

2.3.2 Additional responsibilities:

2.3.2.1 The ARSO shall regularly communicate with the RSO concerning RSO services that may impact the RCSP; and

2.3.2.2 The ARSO provides day-to-day direct supervision of the technical RSO staff. Specific responsibilities follow:

2.3.2.2.1 To manage the daily technical operations of the RSO and assure appropriate records are generated and maintained;

2.3.2.2.2 To provide orientation, training, and performance reviews of the RSO staff;

2.3.2.2.3 To supervise surveys, leak tests and audits performed by the RSO staff;

2.3.2.2.4 To supervise the radiation safety training program;

2.3.2.2.5 To supervise the receipt, surveying and distribution of RAM packages and the associated record keeping;

2.3.2.2.6 To supervise and coordinate a RAM disposal program for users of RAM;

2.3.2.2.7 To supervise the preparation and inspection of radioactive wastes and outgoing RAM packages and the completion of all related documentation of these transfers;

2.3.2.2.8 To supervise the maintenance of inventories of RAM;

2.3.2.2.9 To supervise the calibration and maintenance of portable radiation detection instruments;

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- 2.3.2.2.10 To supervise the performance of personnel dosimetry services (e.g., “film badge” distribution and electronic dosimeter calibration);
- 2.3.2.2.11 To supervise the performance of surveys and audits of all uses and use areas of RAM;
- 2.3.2.2.12 To supervise the monitoring of therapy patient rooms;
- 2.3.2.2.13 To supervise University radiation safety training programs for authorized users (AU), radiation workers, ancillary personnel, and patient care personnel;
- 2.3.2.2.14 To supervise decontamination projects; and
- 2.3.2.2.15 To supervise the RAM purchase approval program.

2.4 Division/Department Chairperson

2.4.1 This person derives authority from UC administration or an affiliated institution's administration.

2.4.2 Responsibility

2.4.2.1 This individual has ultimate supervisory responsibility within the department for the following:

2.4.2.1.1 The conduct of all persons using radiation sources (RAM and RGE);

2.4.2.1.2 The use of all radiation sources (RAM and RGE); and

2.4.2.1.3 The payment of charges routinely passed to the AU and/or CP (e.g., dosimetry, waste disposal).

2.4.2.2 For human-use of RAM or RGE this individual has the responsibility for assuring day-to-day compliance with specified ODH regulations.

2.5 Authorized User (AU)

2.5.1 Authority

2.5.1.1 The AU is authorized by the RSC to possess and use RAM.

Authorization can be restricted or revoked by the RSC if the AU is found to be in non-compliance with the program or authorization requirements.

2.5.1.2 The AU shall be a radiation worker under the program.

2.5.2 Responsibility

2.5.2.1 Each AU shall comply with program requirements and is responsible for acts or omissions of persons using RAM under their authorization. The AU shall have the following specific responsibilities:

2.5.2.1.1 To maintain an up-to-date listing with the RSO of rooms or spaces in which RAM is stored or used;

2.5.2.1.2 To maintain an up-to-date listing with the RSO of the names of persons under his or her supervision who may use RAM;

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- 2.5.2.1.3 To allow only those listed persons, as specified above, to use RAM who are registered with the RSO of and who have been properly trained;
- 2.5.2.1.4 To maintain an inventory of the amount of RAM possessed and disposed;
- 2.5.2.1.5 To establish an adequate system to ensure that RAM possession limits are not exceeded;
- 2.5.2.1.6 To ensure unauthorized persons entering RAM use areas are escorted and lab workers are trained appropriately and are supervised;
- 2.5.2.1.7 To inform the RSO of any change in procedures; notification must be transmitted in writing to the RSO in a timely manner (i.e., prior to start, with sufficient time for review and approval);
- 2.5.2.1.8 To ensure personnel wear assigned radiation monitoring devices when handling RAM which requires the use of dosimetry, as specified by the RSC or program requirements;
- 2.5.2.1.9 To establish appropriate procedures to ensure compliance with posting, labeling and RAM security requirements;
- 2.5.2.1.10 To establish procedures to ensure work areas are in a safe and secured condition at the end of the work period;
- 2.5.2.1.11 To maintain occupational radiation exposure ALARA;
- 2.5.2.1.12 To conduct and document lab specific training for each radiation worker who will be using RAM under their authorization. At a minimum the training must include the radiation safety requirements for their work and their responsibilities as radiation workers;
- 2.5.2.1.13 To provide additional radiation safety training to radiation workers as necessary to ensure safe and proper work habits;
- 2.5.2.1.14 To provide supervision of radiation workers under his/her authorization;
- 2.5.2.1.15 To keep required records in active files that shall be made available for inspection by the RSO of or appropriate regulatory agencies;
- 2.5.2.1.16 To identify a source of funds (with approval of department head) for payment of routine charges associated with the use of RAM (e.g., dosimetry, and waste disposal); and
- 2.5.2.1.17 To provide a copy of this document, as amended, and a training manual to prospective radiation workers prior to site-specific (i.e., RSO of provided) radiation safety training.

2.6 Authorized Medical Physicist (AMP)

2.6.1 Authority

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2.6.1.1 The AMP is authorized by the RSC to supervise and perform medical physics duties as associated with specific therapeutic procedures. AMP status can be restricted or revoked by the RSC if the AMP is found to be in non-compliance with the program or authorization requirements.

2.6.1.2 The AMP shall be a radiation worker under the program and handle RAM under the supervision of an AU.

2.6.2 Responsibility

2.6.2.1 Each AMP shall comply with program requirements and is responsible for acts or omissions of persons performing medical physics duties under their authorization. The AMP shall have the following specific responsibilities for each therapeutic procedure approved under the AMP's authorization:

2.6.2.1.1 To protect patients and others from potentially harmful or excessive radiation;

2.6.2.1.2 To establish adequate protocols/procedures to ensure accurate patient dosimetry;

2.6.2.1.3 To measure and characterize radiation in patient therapy applications;

2.6.2.1.4 To implement the QMP;

2.6.2.1.5 To assist the AU physician in optimizing the balance between beneficial and deleterious effects of radiation;

2.6.2.1.6 To maintain an up-to-date list with the RSO of names of persons under his or her supervision who may perform medical physics duties under their authorization;

2.6.2.1.7 To allow only listed persons, as specified above, to perform medical physics duties who are also registered with the RSO and who have been properly trained;

2.6.2.1.8 To inform the RSO of any change in procedures; notification must be transmitted in writing to the RSO in a timely manner (i.e., prior to start, with sufficient time for review and approval);

2.6.2.1.9 To establish appropriate procedures to ensure compliance with posting, labeling and RAM security requirements for radiation sources;

2.6.2.1.10 To establish procedures to ensure work areas are in a safe and secured condition at the end of the work period;

2.6.2.1.11 To maintain occupational radiation exposure ALARA;

2.6.2.1.12 To conduct and document task specific training for each radiation worker who will perform medical physics tasks under their authorization. At a minimum the training must include policies and/or

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procedures applicable for the delegated medical physics tasks, the radiation safety requirements associated with the tasks and the individual's responsibilities as a radiation worker;

2.6.2.1.13 To provide additional radiation safety training to radiation workers as necessary to ensure safe and proper work habits;

2.6.2.1.14 To provide supervision of radiation workers under his/her authorization;

2.6.2.1.15 To keep required records in active files that shall be made available for inspection by the RSO or appropriate regulatory agencies; and

2.6.2.1.16 To provide a copy of this document, as amended, and a training manual to prospective radiation workers performing medical physicist duties prior to site-specific (i.e., RSO provided) radiation safety training.

2.7 RGE Contact person (CP)

2.7.1 Authority

2.7.1.1 The CP is designated by a department or division as the individual with the authority and responsible for the safe operation of specific RGE.

2.7.1.2 The CP shall be a radiation worker under the program.

2.7.2 Responsibility

2.7.2.1 The CP has the following specific responsibilities:

2.7.2.1.1 Be familiar with state of Ohio and other agency regulations regarding the use of RGE;

2.7.2.1.2 Train and qualify operators on the safe operation of RGE. Operators of human-use RGE require additional qualifications, including state licensure;

2.7.2.1.3 Maintain a list of current qualified operators for the RGE in use and ensure only qualified individuals operate RGE;

2.7.2.1.4 Conduct area-specific and/or unit-specific training for RGE radiation workers (e.g., individuals who frequent the RGE restricted area);

2.7.2.1.5 Ensure RGE operating procedures are current and readily available (e.g., in the room where the RGE(s) is housed) for operators to reference;

2.7.2.1.6 Ensure all required posting and labeling is maintained;

2.7.2.1.7 Ensure shielding and access controls, if required, are in place and/or operational;

2.7.2.1.8 Inform the RSO of any pending changes in machine status, e.g.,

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changing status from inoperable to operable, new acquisitions, disposals, relocations, and modifications and ensure changes in machine status meet program and regulatory requirements;

2.7.2.1.9 Ensure all mandated tests and inspections are performed;

2.7.2.1.10 Obtain dosimetry through the RSO for radiation workers who require monitoring, as specified by the RSC or program requirements, and ensure personnel wear assigned dosimetry;

2.7.2.1.11 Develop procedures and techniques to keep radiation exposures ALARA; and

2.7.2.1.12 Identify a source of funds (with approval of department head) for payment of routine charges associated with the use of RGE (e.g., dosimetry, state inspections).

2.8 Radiation Worker

2.8.1 Classes of radiation worker.

2.8.1.1 RAM radiation worker: Individuals who work with ionizing radiation from RAM shall be trained to meet regulatory and license requirements in a program. This training shall be approved by the RSC and administered by the RSO.

2.8.1.2 RGE radiation worker: Individuals who work with ionizing radiation produced by RGE shall be trained in the safe operation of RGE stressing radiation safety practices that reduce their exposure as well as others who must be near the RGE while it is in operation. This training shall be conducted by a knowledgeable individual.

2.8.2 Qualifications

2.8.2.1 Must be program RSO, ARSO, or an AU, AMP or CP, or must work under the supervision of one of these individuals who is responsible for the radiation worker's actions.

2.8.2.2 Must be able to demonstrate their understanding of regulations, safety notices and procedures concerning the safe handling of RAM or RGE by completing written and practical examinations and/or oral interviews.

2.8.2.3 May not volunteer as a subject to human research protocol that involves exposure to ionizing radiation (e.g., x-ray or nuclear medicine procedure) unless their physician referred them to the protocol.

2.8.3 Responsibilities

2.8.3.1 Comply with all requirements of this program and those established by the AU, AMP and/or CP.

2.8.3.2 Maintain occupational radiation exposure ALARA.

2.8.3.3 Maintain qualifications current by attending required retraining classes.

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2.8.3.4 Report to the AU, AMP or CP, and/or the RSO or RSO of any problems or concerns about the safe use of radiation sources (RAM or RGE) under this program.

2.8.4 Training

2.8.4.1 Before handling RAM an individual must complete the following required training:

2.8.4.1.1 Initial site-specific training approved by the RSC and conducted by the RSO of staff; and

2.8.4.1.2 Laboratory-specific training conducted by the AU for the following situations:

2.8.4.1.2.1 After an individual receives site-specific training;

2.8.4.1.2.2 A significant change in laboratory procedure(s); and

2.8.4.1.2.3 A radiation worker changes laboratories and/or AU.

2.8.4.2 To maintain radiation worker status for RAM after the first calendar year, in which the individual attended initial site-specific training, an individual must attend each calendar year thereafter a retraining session(s) presented by the RSO of staff.

2.8.4.3 Radiation workers who do not handle RAM will receive the following training before using RGE and anytime a procedure or piece of equipment changes:

2.8.4.3.1 Initial area-specific or unit-specific training conducted by the CP or other knowledgeable person; and

2.8.4.3.2 Any additional training required by the RSC or RSO.

3.0 CONTROL POLICIES

3.1 Radioactive Materials (RAM)

3.1.1 All uses of RAM must be approved by the RSO, in conjunction with the RSC.

3.1.2 Prior to use of RAM, safety procedures must be established to assure that radiation exposures will be maintained ALARA.

3.1.3 Application Requirements for AU (All)

3.1.3.1 All prospective AUs, must be in one of the following categories in order to apply for AU status and must remain in one of these categories to maintain AU status:

3.1.3.1.1 A full-time faculty member at UC;

3.1.3.1.2 A full-time faculty member at UC and paid by an institution under contract/affiliation with UC, e.g., CCHMC, SHC;

3.1.3.1.3 Emeritus professor or retired professor at UC with AU status at

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- the time of retirement or emeritus appointment;
- 3.1.3.1.4 A full-time paid employee at UC, CCHMC, SHC, or Hoxworth Blood Center holding the rank of UC Research Associate or Research Scientist, with or without parenthetical rank;
- 3.1.3.1.5 A full-time employee of UC having a pay grade of 16 or higher;
or
- 3.1.3.1.6 Be named RSO or ARSO for UC.
- 3.1.3.2 All prospective AUs must complete the following additional requirements:
 - 3.1.3.2.1 Meet the requirements for a radiation worker under the program;
 - 3.1.3.2.2 Complete any additional radiation safety training prescribed by the RSC;
 - 3.1.3.2.3 Possess the required minimum training and experience necessary to qualify as an AU;
 - 3.1.3.2.4 Possess the qualifications for an AU specified under the ODH "broad scope" license;
 - 3.1.3.2.5 Obtain applicable department chairperson approval;
 - 3.1.3.2.6 Submit all required documents to the RSO;
 - 3.1.3.2.7 Attend an orientation interview with the RSO; and
 - 3.1.3.2.8 Receive approval of the RSC.
- 3.1.4 Additional Application Requirements for AU (Human Use-Clinical)
 - 3.1.4.1 A prospective AU (Human Use-Clinical) must meet the following criteria:
 - 3.1.4.1.1 Be qualified according to the criteria in applicable sections of the regulation outlining qualification standards for the specific clinical use(s);
 - 3.1.4.1.2 Be board certified or eligible in Diagnostic Radiology, Radiation Therapy or Nuclear Medicine;
 - 3.1.4.1.3 Possess credentials approved by CCHMC or SHC, and by the Director of Radiology, Radiation Oncology or Nuclear Medicine; and
 - 3.1.4.1.4 Be licensed to practice medicine in the state of Ohio.
- 3.1.5 Additional Application Requirements for AU (Human Use-Investigational)
 - 3.1.5.1 A prospective AU (Human Use-Investigational) must meet the following criteria:
 - 3.1.5.1.1 Meet the qualifications for AU (Human Use-Clinical) in section 3.1.4 above;

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3.1.5.1.2 Have proper approval of the appropriate IRB(s) and, when applicable, the Radioactive Drug Research Committee (RDRC); and

3.1.5.1.3 Contact the RSO for additional instructions.

3.1.6 Application for Backup AU (Nonhuman-use)

3.1.6.1 When an AU is unavailable, e.g., out of town for a meeting, a Backup (secondary) AU may be designated to assist RWs during routine operations and emergencies.

3.1.6.1.1 The Backup AU must be an approved AU in accordance with the guidelines for AUs listed in section 3.1.3 above.

3.1.6.1.2 There shall be no more than two designated Backup AUs for any individual RAM authorization.

3.1.6.2 During extended absences an AU may designate an approved AU to oversee daily operations of the laboratory. This individual must be identified to the RSO in writing, e.g., listed as backup AU on authorization, and must be familiar with procedures used in the AU's laboratory.

3.1.7 Authorized Areas

3.1.7.1 Prior to use the RSO shall review all areas where RAM is to be stored or used.

3.1.7.2 All areas where RAM is used or stored shall be labeled and posted as required by the RSC or determined by the RSO.

3.1.7.3 All modifications to authorized areas of use shall be approved by the RSO, as delegated by the RSC, i.e., addition and removal of areas of use from an authorization does not require full RSC approval and is delegated to the RSO.

3.1.7.4 Departments planning to install or make changes in RAM irradiation units, e.g., irradiators containing RAM, shall obtain RSC approval of the plans prior to any procurement and/or modification.

NOTE

The term "changes" includes, but is not limited to, replacement of source slugs; structural alterations in the equipment or its housing; and alterations in shielding, including interlocks.

3.1.8 Purchase

3.1.8.1 All requests for the acquisition of RAM shall be approved by the RSO prior to order placement by the AU or designee.

3.1.8.1.1 Requests for the acquisition of RAM shall only be approved if the request does not exceed the AU's RSC approved per purchase limit.

3.1.8.1.2 The RSO will receive and survey all RAM packages except for

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packages containing RAM intended for human-use or other time-critical use where the RSC has approved direct shipment.

3.1.8.1.3 The RSO of shall notify the AU or designated AU staff upon receipt of RAM.

3.1.9 Inventory

3.1.9.1 A current inventory of all RAM will be maintained by each AU and a verified copy forwarded to the RSO of quarterly.

3.1.9.2 The RSO of will monitor and check AU inventories periodically.

3.1.10 Sealed Sources

3.1.10.1 A physical inventory of all sealed sources shall be conducted by the AU quarterly and a copy forwarded to the RSO of.

3.1.10.2 Leak-testing

3.1.10.2.1 Sealed sources requiring leak test by license requirement or regulations will be leak-tested by the RSO of on a periodic schedule established to meet regulatory requirements.

3.1.10.2.2 A copy of the leak test results will be forwarded to the AU, or designee, in a timely manner.

3.1.11 Storage

3.1.11.1 All RAM shall be stored in a manner approved by the RSO.

3.1.11.2 All storage containers shall display the following labels:

3.1.11.2.1 A visible RAM label;

3.1.11.2.2 AU name;

3.1.11.2.3 Type of RAM; and

3.1.11.2.4 Activity of the RAM with the date of assay/reference.

3.1.11.3 RAM in storage shall be identified on the AU's inventory.

3.1.11.4 All RAM shall be secured against unauthorized access or removal.

3.1.11.5 RAM storage areas shall be properly identified, labeled, and surveyed.

3.1.12 Transfer

3.1.12.1 An AU may transfer RAM to another AU under this program or to another institution provided the transfer has been approved in advance by the RSO of, and the transfer has been made in accordance with procedures developed under this program.

3.1.12.2 The RSO of must receive written confirmation that the recipients of transfers made outside the program have an approved license or license exemption for the RAM.

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3.1.13 Transportation

3.1.13.1 Transport of RAM outside the confines of areas included in UC's licenses or on public roads must conform to applicable rules and regulations e.g., ODH, DOT and the carriers.

3.1.13.2 Transport of RAM between identified work areas within areas included in UC's licenses shall proceed in a manner which will limit exposure and prevent the release of RAM. For example, RAM should be transported in closed, shielded containers to reduce radiation exposure to permissible levels.

3.1.14 Disposal

3.1.14.1 Disposal of RAM shall be in accordance with procedures established by the RSO.

3.1.14.2 All disposals will be recorded on appropriate inventory disposition records.

3.1.15 Theft or Loss

3.1.15.1 Theft or loss of RAM will be reported immediately to the RSO and Security.

3.1.16 Security

3.1.16.1 Unattended use areas containing RAM shall be secured against unauthorized access.

3.1.16.2 All RAM in unrestricted areas shall be attended by an approved worker or secured from unauthorized access or removal.

3.1.17 Possession Limits

3.1.17.1 The RSO will recommend and the RSC will set RAM order and possession limits for each AU. These limits shall be based on the health hazards associated with the RAM to be authorized; as well as the adequacy of proposed procedures and facilities to be used by the AU.

3.1.18 Audits

3.1.18.1 The RSO shall conduct audits of each active AU's operations at least annually. Audits may be unannounced and shall be conducted during RSO's normal working hours. Records of audits shall be maintained in permanent files in the RSO and shall be made available for inspection by regulatory agencies.

3.1.19 Radionuclide Use for Medical Research (Human-Use)

3.1.19.1 In order to use a radioactive agent on human patients or research subjects all of the following must be accomplished by the applicant.

3.1.19.1.1 Obtain approval of the RSC.

3.1.19.1.2 File with the FDA a "Notice of Claimed Exemption for a New

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Drug" (commonly known as an IND application) or reference a commercial manufacturer's IND or NDA, or obtain approval from a RDRC.

- 3.1.19.2 The AU is responsible for the actual prescribed human administration of radiopharmaceuticals or radiation sources and any medical events or misadministrations that may occur.
- 3.1.19.3 The Division/Department Director is ultimately responsible for assuring compliance with all other applicable regulations which apply to day-to-day operations of the Division/Department.
- 3.1.20 Radionuclide Use for Medical Clinical Service
 - 3.1.20.1 If a non-routine RAM protocol is to be conducted because, in the "best medical judgment" of the physician, it will be of direct, unique, and significant benefit in the medical care of a patient, then this will not be classified as a research application. The physician must, however, be an AU for the radiopharmaceutical or radiation source in question and must follow applicable rules for the practice of medicine of the College of Medicine, affiliated institutions and of the state of Ohio.
 - 3.1.20.2 The AU is responsible for the actual prescribed human administration of radiopharmaceuticals or radiation sources and any medical events or misadministrations that may occur.
 - 3.1.20.3 The Division/Department Director is ultimately responsible for assuring compliance with all other applicable regulations which apply to the day-to-day operations of the department regulations.
- 3.2 Machine-Generated Ionizing Radiation/Radiation Generating Equipment (RGE)
 - 3.2.1 Installation, modification and disposal
 - 3.2.1.1 All devices which generate ionizing radiation, including those for medical diagnostic or therapeutic purposes, must be registered with the state of Ohio.
 - 3.2.1.2 Departments planning to install modify, or dispose of RGE (e.g., x-ray machines, x-ray diffraction units, electron microscopes, and accelerators,) shall inform the RSO prior to procurement, modification, or disposal.

NOTE

The term "modification" includes, but is not limited to structural alterations in the equipment or its housing and alterations in shielding, including interlocks.
 - 3.2.1.3 Departments using RGE shall develop procedures to ensure the RSO is informed in a timely manner of impending acquisitions, modifications, or disposals of RGE.
 - 3.2.1.4 The RSO will coordinate RGE installation. A Certified Radiation Expert (CRE) shall monitor operations for regulatory compliance within

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program hospitals. The RSO shall monitor operations for regulatory compliance outside program hospitals (e.g., research, veterinary services, and health services).

3.2.1.5 All areas where RGE is used shall be labeled and posted as required by the RSC or determined by the RSO.

3.2.1.6 Use of RGE for medical research involving irradiation of human patients or research subjects requires review and approval by the IRB, as well as the RSC.

3.2.1.7 All uses of RGE must be approved by the RSO, who will establish safety procedures to assure that radiation exposure to personnel and the public will be maintained ALARA.

3.2.1.8 Disposal of RGE shall be in accordance with procedures established by the RSO.

3.2.1.9 All disposals will be recorded on appropriate inventory records and a copy of the record will be forwarded to the RSO.

3.2.2 Inventory

3.2.2.1 A current inventory of all RGE will be kept by each CP and a copy forwarded to the RSO on a frequency determined by the RSC. The RSO shall monitor and check CP inventories periodically.

3.2.2.2 A CP may transfer a RGE to another CP within the program or another institution provided arrangements are made through the RSO.

3.2.3 Theft or Loss

3.2.3.1 Theft or loss of RGE will be reported immediately to the RSO and Security.

3.2.4 Security

3.2.4.1 Unattended RGE shall be secured against unauthorized use (e.g., removing key from console).

3.3 Audits

3.3.1 The records, activities, and procedures associated with policies established in this program are subject to audit by the RSO, the RSC and/or the RSC.

3.3.1.1 Audits of any part of this program shall be documented and shall be made available for inspection as required.

4.0 PROGRAM SAFETY POLICIES

4.1 Personnel Radiation Monitoring

4.1.1 External Radiation Monitoring

4.1.1.1 Personnel monitoring is required whenever an individual enters an area with a radiation source (RAM or RGE) and it is likely the individual will receive a radiation dose requiring monitoring by regulation or license

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requirements.

4.1.1.2 The RSO shall provide personnel monitoring devices.

4.1.1.3 The monitor type and frequency of change shall be determined by the RSC.

4.1.1.4 Workers shall be instructed in procedures of care, use and timely replacement of personnel monitors.

4.1.1.5 Internal Radiation Monitoring

4.1.1.5.1 The RSO will determine the type and frequency of bioassays needed to monitor internalized RAM.

4.1.1.5.2 Bioassays may be requested for any worker.

4.1.1.5.3 All positive bioassay results will be reported to the RSO and the appropriate worker.

4.1.1.5.4 In the event that internal deposition of RAM is suspected, the RSO shall be contacted immediately.

4.1.2 Radiation Exposure Limits

4.1.2.1 Radiation exposure should always be maintained ALARA.

4.1.2.2 Radiation exposure will be controlled so that no individual will receive a radiation dose exceeding regulatory limits.

4.1.2.3 An ALARA investigational program will be developed which sets ALARA dose limits below regulatory dose limits. When an individual exceeds an ALARA dose limit an investigation appropriate for the ALARA level exceeded will be initiated.

4.2 Exposure Control

4.2.1 ALARA exposures will be achieved by an appropriate combination of worker training, engineered controls, procedures, and personal protective equipment (PPE).

4.2.2 The concepts of time, distance, and shielding will be used to limit the amount of exposure a worker will receive.

4.2.3 Appropriate PPE will be designated for wear when handling RAM.

4.3 Radiation Safety Training

4.3.1 Authorized Users (AU)

4.3.1.1 Each AU shall undergo initial training at UC and shall be retrained annually.

4.3.1.2 New procedures may require the AU to undergo additional training by the RSO.

4.3.2 Radiation Workers

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4.3.2.1 Each radiation worker shall undergo initial training at UC appropriate for the radiation usage. RAM radiation workers shall be retrained annually.

4.3.2.2 New procedures shall require the worker to undergo additional training with the RSO, and/or an AU, and/or a CP.

4.3.2.3 The AU shall provide specific training for direct use of RAM by RAM radiation workers.

4.3.3 Additional Training

4.3.3.1 The RSO shall review each AU's safety performance annually or as required.

4.3.3.1.1 The RSO may recommend additional training.

4.3.3.1.2 The RSC will consider RSO recommendations for additional training and take action as necessary.

4.3.4 Health Care Providers for Radiation Therapy Patients

4.3.4.1 Health care providers shall receive radiation safety training from the RSO prior to providing care to hospitalized patients containing unsealed or sealed RAM for which regulations require hospitalization because of the presence of the RAM.

4.3.4.2 Health care providers shall receive annual radiation safety training as prescribed by the RSC.

4.3.5 Ancillary Personnel

4.3.5.1 Ancillary personnel, i.e., housekeeping, maintenance, and security shall receive instruction in accordance with applicable regulations.

4.4 Surveys

4.4.1 AUs and CPs shall perform regular surveys of RAM or RGE as directed by the RSC.

4.4.2 The frequency and types of surveys shall be established by the RSC.

4.4.3 Records shall be kept of such surveys.

4.4.3.1 Records shall be maintained by the AU or CP.

4.4.3.2 Records shall be made available for inspection by the RSO, the RSO, the RSC and/or regulatory agencies.

4.4.3.3 Survey records are the property of UC and the affiliated institutions and shall be maintained by the AU or CP for a period of three years.

4.5 Security and Access Controls

4.5.1 The RSO shall evaluate the adequacy of security provisions and make recommendations as appropriate.

4.5.2 Unoccupied radiation source (RAM or RGE) areas shall be secured against

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unauthorized entry.

4.5.2.1 Entry into occupied radiation source (RAM or RGE) areas shall be controlled by the AU or CP and/or a radiation worker assigned to the area.

4.5.2.2 All untrained visitors shall be escorted by a qualified radiation worker while in a radiation source (RAM or RGE) area.

4.6 Instrumentation

4.6.1 Radiation monitoring instrumentation approved by the RSO shall be used.

4.6.1.1 The equipment should be kept in good working order.

4.6.1.2 The equipment shall be calibrated according to a schedule established by the RSC or RSO.

4.7 Incidents

4.7.1 In the event of any of the following incidents, procedures shall be established for prompt notification of the RSO by an AU, CP and/or a qualified radiation worker:

4.7.1.1 The unintentional exposure of persons;

4.7.1.2 The uncontrolled release of RAM;

4.7.1.3 A medical event, as defined in OAC 3701:1-58;

4.7.1.4 A misadministration, as defined in OAC 3701:1-67; or

4.7.1.5 Reportable "incidents" as required by ODH rules.

4.7.2 Radiation incidents requiring ODH notification shall only be reported to the ODH by the RSO or in the RSO's absence by a specifically designated individual.

4.8 Human-Use Research Protocols Involving Radiation

4.8.1 All Human-Use Research Protocols must be reviewed and approved by the appropriate IRB, and when applicable, the RDRC. Those involving the use of ionizing radiation in any form must also be reviewed and, when applicable, approved by the full RSC as designated in section 4.8.4 of this manual.

NOTE

Approval is given only for a specific protocol to be performed. The approval does not give investigators AU status or any other certification.

4.8.2 The RSC shall use a Human Research Subcommittee consisting of at least the following individuals. At least one member will be the primary RSC reviewer.

4.8.2.1 Physician with Radiation Oncology expertise;

4.8.2.2 Physician with Nuclear Medicine expertise;

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4.8.2.3 Physician with Radiology expertise; and

4.8.2.4 Medical Physicists.

4.8.3 Review and approval process

4.8.3.1 The RSC will develop forms to classify protocols, follow their review process, and record final decisions.

4.8.3.2 The principle investigator (PI) prepares the research protocol and submits it to the appropriate IRB for initial review.

4.8.3.2.1 Initial IRB review

4.8.3.2.1.1 The IRB issues each protocol a control number and screens each protocol for the use of ionizing radiation. If ionizing radiation is used the protocol is forwarded to the primary RSC reviewer.

4.8.3.2.1.2 The primary RSC reviewer reviews and classifies the protocol based on the radiation exposure involved and the extent of the review required.

4.8.3.2.1.3 The primary RSC reviewer distributes protocols for further subcommittee review, as applicable, and compiles replies.

4.8.3.3 The primary RSC reviewer forwards protocols for further processing and/or approval.

4.8.3.3.1 Protocols that do not require full RSC approval:

4.8.3.3.1.1 The protocol is considered approved by the RSC and is forwarded to the appropriate IRB and/or PI.

4.8.3.3.2 Protocols that require full RSC approval:

4.8.3.3.2.1 The protocol is forwarded to the RSO for review and tentative approval by the RSO and RSC chairperson;

4.8.3.3.2.2 A summary of the tentatively approved protocols is drafted;

4.8.3.3.2.3 The RSO distributes the summary to RSC members for review prior to the RSC meeting;

4.8.3.3.2.4 The full RSC approves a protocol after any questions or problems are addressed with the PI through the primary RSC reviewer;

4.8.3.3.2.5 The RSC notifies the applicable IRB in writing of any tentatively approved protocol which was not approved by the RSC; and

4.8.3.3.2.6 The RSC and/or primary RSC reviewer provides a copy of each approved human-use research protocol and its accompanying approval forms to the RSO and a file is maintained for the duration of the protocol.

4.8.4 Protocol classifications and minimum review requirements

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- 4.8.4.1 Class 1: No Radiation Exposure
 - 4.8.4.1.1 Full RSC approval is not required.
 - 4.8.4.1.2 Review limited to the primary RSC reviewer determining the classification.
- 4.8.4.2 Class IIA: Standard clinical procedure involving non-fluoroscopy/CINE use of x-ray and/or diagnostic nuclear medicine and patient is an adult.
 - 4.8.4.2.1 Full RSC approval is not required.
 - 4.8.4.2.2 Review limited to the primary RSC reviewer determining the classification.
- 4.8.4.3 Class IIB: Standard radiation therapy, where the investigational part of the protocol is not the radiation therapy, e.g., protocol investigating a new chemotherapy agent and the treatment includes a standard clinical radiation therapy technique.
 - 4.8.4.3.1 Full RSC approval is not required.
 - 4.8.4.3.2 Review limited to the primary IRB reviewer determining the classification.
- 4.8.4.4 Class IIC: Standard use of fluoroscopy and/or CINE and patient is an adult.
 - 4.8.4.4.1 Full RSC approval is not required.
 - 4.8.4.4.2 Review limited to that performed by the primary RSC reviewer. The review must include a determination of classification and must ensure the consent form includes a statement about risks associated with fluoroscopy/CINE, including the possibility of skin burns from longer fluoroscopy/CINE times.
- 4.8.4.5 Class IIIA: Radiation exposure to children from standard clinical procedures involving the use of x-rays and/or diagnostic nuclear medicine.
 - 4.8.4.5.1 Full RSC approval may be required.
 - 4.8.4.5.2 Review required by two physicians considered part of the Human Research Subcommittee with appropriate expertise of the radiation risks. One physician may be the primary RSC reviewer.
 - 4.8.4.5.3 For protocols where the radiation procedure is not part of the standard clinical care the review by the primary RSC reviewer must include ensuring the consent form includes a statement about the effective radiation dose and the risks associated with the dose. If the effective dose is not included on the consent form assistance from a medical physicist and/or the RSO must be obtained to determine the effective radiation dose and the consent form must be modified to include the effective dose and associated risks.

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- 4.8.4.5.4 If the effective dose is greater than 500-millirem full RSC approval, for personnel and public radiation safety issues, is required.
- 4.8.4.6 Class IIIB: Radiation exposure to normal subjects from standard clinical procedures involving the use of x-rays and/or diagnostic nuclear medicine.
 - 4.8.4.6.1 Full RSC approval is required.
 - 4.8.4.6.2 Pre-review by two physicians with appropriate expertise and considered part of the Human Research Subcommittee is required. The review must include ensuring that the consent form includes a statement about the effective radiation dose and the risks associated with the dose. If the effective dose is not included in the consent form assistance from a medical physicist and/or the RSO must be obtained to determine the effective dose and the consent form must be modified to include the effective dose and associated risks.
- 4.8.4.7 Class IV: Radiation exposure from experimental diagnostic radionuclides, experimental therapeutic use of radiopharmaceuticals, experimental brachytherapy or experimental external beam radiation therapy technique.
 - 4.8.4.7.1 Full RSC review is required.
 - 4.8.4.7.2 Pre-review by the RSO for health physics (personnel and the public) concerns is required.
 - 4.8.4.7.3 Pre-review by at least three other members of the RSC Human Research Subcommittee in regards to dosimetry and/or medical consideration is required. The subcommittee members must include either (a) one physician from each specialty and one medical physicist or (b) two medical physicists and one physician with knowledge in the associated use of radiation
- 4.8.5 Duties of the primary RSC reviewer:
 - 4.8.5.1 Reviews and classifies all protocols directed to them for review;
 - 4.8.5.2 Routes selected protocols to other physicians and/or medical physicists for review and comment; and
 - 4.8.5.3 Compiles responses and sends to the RSO of any protocol that requires full RSC approval for tentative approval by the RSO and RSC chairperson.
- 4.8.6 Duties of the RSO and RSC chairperson:
 - 4.8.6.1 Conducts a review of protocols forwarded by the primary RSC reviewer for radiation safety related matters;
 - 4.8.6.2 Indicates approval by signing the appropriate cover form or review sheet(s); and

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4.8.6.3 Forwards tentatively approved protocols to the primary RSC reviewer with a clear statement the approval is tentative until the next full RSC meeting.

NOTE

The IRB will not approve a protocol requiring full RSC approval without the approval sheet from the RSC and an approval signature from the IRB/RSC liaison.

4.9 New Human-Use Clinical Protocols Involving Radiation

4.9.1 Diagnostic and therapy protocols from the College of Medicine, CCHMC, and SHC will be reviewed and/or approved by the RSC in accordance with the following procedures.

4.9.1.1 New routine diagnostic protocols involving the use of a radionuclide and activity for which the AU is approved and involving a radiopharmaceutical that is approved by the FDA must be submitted to the RSC for review within 30 days of the first clinical use.

4.9.1.2 New routine diagnostic protocols that will require a change to the AU's authorization, e.g., new radionuclide or increase in activity limits, must be submitted to the RSC for review and approval prior to the first clinical use.

4.9.1.3 New or revised therapeutic protocols must be submitted to the RSC for review and approval prior to the first clinical use.

4.9.2 The RSC will review the new protocols for medical event and/or misadministration potential, exposure to personnel, and compliance with ODH rules, license requirements and the RCSP.

4.9.3 Review and approval process

4.9.3.1 A copy of each protocol must be submitted to the RSO.

4.9.3.2 The RSO will provide copies to the RSC for review.

4.9.3.3 Between meetings of the RSC an Executive Committee may tentatively review the new protocol.

4.9.3.3.1 The Human-use Executive Committee will consist of the RSC Chairperson, RSO, and any RSC member who is a physician and is not a member of the applicant's division or department.

4.9.4 Protocol Maintenance

4.9.4.1 All active protocols must be maintained within the division or department.

4.9.4.2 All protocols on file within the division or department, which required RSC review and became effective after 4/1/98, must include the date of RSC approval.

4.9.4.3 The RSO will maintain a file of all protocols submitted for RSC

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review.

5.0 MISCELLANEOUS

5.1 Records

5.1.1 All appropriate reports and/or forms associated with this program shall be maintained by the AU or CP and be made available for inspection by the RSO, the RSC, the RSCO and regulatory agencies. The following records as a minimum must be maintained.

5.1.1.1 Contamination and radiation survey results. (Maintained for at least three years.)

5.1.1.2 RW training conducted by the AU or CP. (Maintained for at least five years after person leaves.)

5.1.1.3 RAM inventory reports including RAM receipt, transfer, including transfer to RSO for disposal records. (Maintained for at least three years.)

5.1.1.4 Any records designated by the RSC and/or the RSO as required to meet regulatory and license requirements.

5.1.2 All records are the property of UC or the affiliated institutions and shall be held a minimum of three years. Some records will be held longer in accordance with RSC or regulatory agency requirements.

5.2 Emergency Planning

5.2.1 In the event of a radiological emergency, the UC emergency response plan shall be followed.

5.2.2 The radiological response procedures are outlined in the emergency response plan and will be applied to each AU's requirements.

5.2.3 The AU shall develop and implement emergency procedures that are appropriate to authorized work activities.

6.0 REVISIONS TO THE RADIATION CONTROL & SAFETY PROGRAM

6.1 Prior to issuing a revised version of this document, all proposed/required changes shall be approved by the RSC.

6.2 The approval action shall be recorded in the minutes of the applicable RSC meeting.

6.3 The changes shall be recorded in the revision log sheet included herein.