University of Cincinnati CCHMC Quality Assurance and Radiation Protection Manual for Human Use Radiation Generating Equipment (QA&RP MANUAL FOR HUMAN USE RGE)

QA&RP MANUAL FOR HUMAN USE RGE

RECORD OF REVISION PAGE

Revision	Date of	Change Entered
original	11/17/1998	
1	7/18/2000	
2	01/2001	Modified ALARA levels
3	11/2001	Modified section 7.2
4	05/2002	Modified section 9 and 13
5	8/2002	Modified "licensed practitioner"
6	8/2003	Modified section 7.1, 7.2, and 13
7	11/2004	Modified section 14
8	5/2005	Modified section 10 and 15.1 and section 8.5
9	11/2005	Updated manual to delete TUH and TUH only items from the QA Program as TUH transferred the TUH registration from the RCSP to TUH 10/1/05. (Note: the "TUH only" items deleted were those related to mammography and therapy). Updated manual to incorporate regulatory modification which allows designated delegates to attend QA meeting and to correct regulatory dose reporting requirements. Added ability of Nuclear Medicine Technologist to operate fusion imaging equipment per OAC 3701-72-04 and letter dated July 18, 2005. Corrected some inconsistencies noted within the manual. Replaced previous change log with this record of revisions page. Deleted Appendix A, which listed RGE testing requirements, and changed so requirements are
10	2/2006	Added statement University of Cincinnati issued dosimeters cannot be used outside the RCSP. Statement added to section 10.6.
11	6/17/06	Incorporated updated forms and ODH notice to employees. The documents are attachments to the manual and were approved by the RSC for The University Hospital leaving
12	2/21/07	Revised definition of "licensed practitioner" to meet updated definition approved by ODH May 2006. Revision added "physician assistant" to the list of individuals considered licensed practitioners.
13	5/16/07	Updated sections to cover regulatory change of "licensed dental assistant radiographer" to "certified dental assistant radiographer". Section changes included paragraphs 7.1.1.5, 7.1.1.5.1, 7.1.1.5.2 and 8.1.2.1.
14	1/1/08	Corrected typographical error in Appendix B. Corrected collar multiplication factor in footnote from 0.4 to 0.04.
15	8/20/08	Modified Appendix B, ALARA Investigational Levels, to delete special investigational level for the head.

QA&RP MANUAL FOR HUMAN USE RGE

Revision	Date of	Change Entered
16	11/19/08	Added follow-up and QA Committee oversight procedures to section 6.1 to assure the annual CRE audit is completed and submitted to the ODH in a timely manner, modified testing requirements in section 14.1 to add regulatory requirement to test CT and fluoroscopy units prior to use.
17	5/13/09	Modified manual to reflect re-organization of and new QA Program requirements enacted by the ODH in December 2008 and new fluoroscopy air-kerma testing and revised fluoroscopy log requirements enacted by the ODH in March 2009. Added specific safety requirements for CT-fluoroscopy. Revised QC test requirements to remove non- applicable references to mammography tests. Replaced requirement for CRE approval of blueprints with requirement for CRE acceptance of design documents. Added reference to QA materials being available on the Radiation Safety website (Radiation Safety Office).
18	02/16/11	Added allowance for IRRP/RSO to initiate QA Program changes, RSOf and TJC to list of abbreviations, QA responsibilities of the IRRP/RSO per OAC 3701:1-66-01 definition, reporting requirements to TJC, and requirements for inoperable RGE; removed MQSA from the list of abbreviations and other missed items associated with mammography only, corrected a few typographical errors
19	02/13/13	Updated the QC Tests to incorporate digital processes and eliminate processes no longer used. Modified "fluoroscopy log" requirements to be more flexible. Complete review by RSO - corrected/updated minor typographical errors and style inconsistencies noted.
20	05/15/13	For RCSP consistency reduced restricted area to 6 feet. Added definition for a radiation expert. Moved CRE designee notification to section 4.3. To put in line with general hospital policy the question about pregnancy age was increased to 12. Added lead drapes checks to QC checks. Added preventative maintenance requirements. Film was returned to imaging equipment requiring QC testing (outside hospitals film still used). Replaced "film" with alternate word as applicable to make clear film is not the only imaging receptor. Corrected typos noted.
21	11/3/14	Added definition for the word "Annual". Updated fluoroscopy unit dosimeter requirement. Updated CRE section to add therapeutic.
22	7/24/19	Removed references to Shriner's Hospital for Children (SHC). SHC had established a second standalone QA committee.

QA&RP MANUAL FOR HUMAN USE RGE

Revision	Date of	Change Entered
23	8/07/2024	Updated to be in compliance with revisions made to ODH Rules and Regulations. Significantly reorganized for improved program narrative. Removed minimum requirements for QA Committee Chair. Clarified CRE Annual Audit, equipment testing/PM/repair protocols, document distributions, Medical Events reporting, dosimeter exchange. Added Dose Review Committee content, references directly to department policies.

QA&RP MANUAL FOR HUMAN USE RGE

Table of Contents

QA&RP MANUAL FOR HUMAN USE RGE

1. Abbreviations

ARSO – Assistant Radiation Safety Officer
CP – Contact Person
CRE – Certified Radiation Expert
CCHMC – Cincinnati Children's Hospital Medical Center
ESE – Entrance Skin Exposure
IRRP – Individual Responsible for Radiation Protection
ME – Medical Event
OAC – Ohio Administrative Code
PM – Preventative Maintenance
QA – Quality Assurance
QC – Quality Control
RCSP – Radiation Control and Safety Program
RE – Radiation Expert
RGE – Radiation-Generating Equipment
RSC – Radiation Safety Committee
RSO – Radiation Safety Officer
RSOf – Radiation Safety Office
RW – RGE Radiation Worker
TJC – The Joint Commission

2. Purpose

2.1. The purpose of this manual is to satisfy the requirements of the Ohio Administrative Code (OAC) regarding the provisions of Quality Assurance (QA) as listed in OAC 3701:1-66-04, and radiation protection as listed in OAC 3701:1-38. QA procedures for proton therapy oversight by the CCHMC QA Committee are described in a separate manual.

2.2. Radiation generating equipment (RGE) usage on humans shall be conducted in accordance with policies, procedures and guidelines presented in this manual.

2.3. Each department using RGE and each contact person (CP) responsible for human-use under the University of Cincinnati Radiation Control and Safety Program (RCSP) shall maintain access to an electronic version or a copy of this manual. The manual must be readily available to personnel for consultation and information purposes.

2.4. This manual incorporates QA and radiation protection policies, procedures and guidelines. The Radiation Safety Committee (RSC) and the Cincinnati Children's Hospital Medical Center (CCHMC) QA Committee have reviewed and approved the initial version and each subsequent revision of this manual.

2.4.1. The manual shall be updated as necessary to reflect changes in policies, procedures, institutional equipment and/or regulatory changes. Order for changes:

2.4.1.1. First - changes suggested to and/or by the Certified Radiation Expert(s) (CRE) or the Individual Responsible for Radiation Protection/Radiation Safety Officer (IRRP)/RSO.

2.4.1.1.1. Any individual may suggest a change to the CRE and/or the IRRP/RSO.

2.4.1.2. Second - review and approval by CCHMC QA Committee.

2.4.1.3. Final - review and approval by RSC.

2.4.2. The IRRP/RSO is responsible for distributing copies of each revision to each CP and member of the CCHMC QA Committee within 30 days of RSC approval.

2.4.3. The CP and/or CCHMC QA Committee member is responsible for ensuring each RGE radiation

worker (RW) under their responsibility is informed regarding applicable changes incorporated in a revision within 60 days of RSC approval.

2.4.4. The IRRP/RSO is responsible for ensuring the current version of the manual is posted on the Radiation Safety website (Radiation Safety Office - Overview (uc.edu)).

2.4.5. All individuals operating RGE for human-use shall be made aware of this manual during their initial training.

3. Definitions

3.1. Ancillary Personnel

3.1.1. An individual who:

3.1.1.1. is not a RGE radiation worker;

3.1.1.2. is in the restricted area (e.g., room) when the x-ray is on; and

3.1.1.3. is performing a duty as part of their "job" (e.g., employee, student, volunteer).

3.2. Annual

3.2.1. Once per year at about the same time each year, plus or minus one month.

3.3. Certified Radiation Expert (CRE)

3.3.1. An individual who is certified by the state of Ohio in accordance with OAC 3701:1-66-03.

3.3.2. For the RCSP, a CRE must be appointed as designated in paragraph 4.4 of this manual.

3.3.3. CRE categories are:

3.3.3.1. Therapeutic;

3.3.3.2. diagnostic, other than mammography; and

3.3.3.3. mammography.

3.4. Contact Person (CP)

3.4.1. An individual designated by a department as responsible for ensuring departmental compliance with policies, procedures and guidelines covered in this manual.

3.5. Declared Pregnant Worker

3.5.1. A worker who has declared their pregnancy in writing to the University of Cincinnati Radiation Safety Office (RSOf).

3.6. Exposed Public

3.6.1. An individual who:

3.6.1.1. is not an RGE RW;

3.6.1.2. is not ancillary personnel; and

3.6.1.3. is not the patient.

3.7. Individual Responsible for Radiation Protection (IRRP)

3.7.1. Individual who meets the criteria in OAC 3701:1-66-02 and is designated by the registrant for registrations under the University of Cincinnati RSC, who has knowledge and responsibility for overall radiation safety and the quality assurance program at the facility to include daily radiation safety operations and compliance with the rules.

3.8. Licensed practitioner

3.8.1. An individual licensed by the State of Ohio to practice:

3.8.1.1. Dentistry;

3.8.1.2. medicine or surgery or osteopathic medicine or surgery;

3.8.1.3. podiatry;

3.8.1.4. chiropractic medicine;

3.8.1.5. as a clinical nurse specialist within the scope of practice of his or her collaborating physician;

3.8.1.6. as a physician assistant within the scope of practice of his or her supervising physician and in accordance with the utilization plan approved by the state medical board; or

3.8.1.7. An individual practicing within the scope of the license.

3.9. Medical Event (ME) to a patient

3.9.1. Unintended skin dose to the same area in a single procedure > 2 Sv (200 rem);

3.9.2. Unintended dose, other than skin dose, in a single procedure, or wrong patient or wrong site for entire procedure when the resultant dose is;

3.9.2.1. > 500 mSv (50 rem) to any organ; or

3.9.2.2. ≥ 50 mSv (5 rem) effective dose equivalent.

3.10. Minor

3.10.1. Any individual under the age of 18.

3.11. Radiation Expert (RE)

3.11.1. Any individual who meets the definition of a radiation expert outlined in OAC 3701:1-66-01

3.11.1.1. All RE at CCHMC will be approved in writing by the appropriate CRE.

3.12. Restricted Area

3.12.1. For human-use RGE, the restricted area is the room in which the RGE is present when energized or within 6 feet from the RGE when energized, whichever is smaller.

3.13. RGE Radiation Worker (RW)

3.13.1. For human-use, an individual performing any part of the radiologic procedure, i.e., operator or physician who controls or directs fluoroscopic exposure.

3.13.2. For human-use this individual must be licensed by the state of Ohio in accordance with state of Ohio requirements, which includes but may not be limited to, OAC 3701-72.

3.14. Radiation Safety Officer (RSO)

3.14.1. An individual who meets the criteria in OAC 3701:1-58-01, and who is designated by the licensee who has the knowledge and responsibility for the overall radiation safety program including but not limited to:

3.14.1.1. Under the authority of the RSC, the RSO implements radiation safety control outlined in the RCSP;

3.14.1.2. Responsibility for oversight of the QA program;

3.14.1.3. Oversight of the daily radiation safety operations and compliance with the rules;

3.14.1.4. Maintains the personnel radiation monitoring program;

3.14.1.5. Oversees the radiation safety training program;

3.14.1.6. Will liaise between CCHMC and the RCSP, and between CCHMC and the Ohio Department of Health Bureau of Environmental Health and Radiation Protection; and

3.14.1.7. Maintains an inventory of all RGE equipment with ODH.

3.15. University of Cincinnati Radiation Safety Committee (RSC)

3.15.1. The RSC of the University of Cincinnati administers the RCSP.

3.15.2. The RCSP maintains a manual on the University of Cincinnati website.

4. QA Program

4.1. In accordance with OAC 3701:1-66-04, the QA Program addresses the following:

4.1.1. Testing procedures and intervals of testing for all RGE equipment including responsible personnel for QC of each type of RGE.

4.1.1.1. Policies on training for personnel with QC responsibilities.

4.1.2. Maintaining occupational and public exposure limits

4.1.2.1. Policies on human patient protection, including pregnancy screening, pregnant patient exposure, patient shielding, patient education;

4.1.2.2. Including posting and signage and actions following an incident;

4.1.2.3. Notification of ODH of occupationally over-exposed individuals;

4.1.2.4. Instruction for individuals likely to receive annual occupational doses > 1 mSv (100 mrem);

4.1.2.5. Policies on personnel protection; and

4.1.2.6. Policies on occupational exposure of pregnant workers.

4.1.3. Training of operators of each type of RGE

4.1.3.1. Safe operating procedures for each type of RGE;

4.1.3.2. State licensure or certification of each operator of RGE; and

4.1.3.3. Policies on training of ancillary personnel.

4.1.4. Radiation workers role and responsibility for supporting QA Program

4.1.4.1. Dissemination of QA Program policies and education methods for affected workers.

4.1.5. Policies on verification of Patient identity and examination to be performed; appropriate body part

4.1.6. Policies so only licensed practitioners can order x-rays

4.1.7. Complete inventory of RGE

4.1.8. Description of QA Committee and CRE responsibilities

4.1.9. Criteria for Annual Audit

4.1.10. Notification of ODH of Medical Events

4.1.11. Dose Review Committee

4.1.12. Record Keeping Durations

4.1.13. RGE Room Construction

4.2. Responsibility of the QA Program

4.2.1. Overall assurance for radiation safety and compliance to rules within the QA Program is the responsibility of the RSC.

4.3. Implementation and Oversight of the QA Program

4.3.1. Implementation and oversight of the QA Program for all CCHMC registered human-use RGE locations e.g., hospitals, clinics etc. is the responsibility of:

4.3.1.1. the QA Committee; and

4.3.1.2. the IRRP/RSO;

4.4 Maintenance, guidance, and supervision of the QA Program

4.4.1. Maintenance, guidance, and supervision of the QA Program for hospital RGE is the responsibility of designated CRE(s) certified for the specialty by the ODH.

4.4.1.1. Diagnostic units: appointment of a qualified diagnostic CRE is by and responsibility of Radiology.

4.4.1.2. Therapeutic units: appointment of a qualified therapeutic CRE is by and responsibility of The Proton Center

4.4.1.3. The CRE may delegate tasks to a specified designee. The CRE shall provide the IRRP/RSO a list of names of approved designees and criteria used to select these individuals.

4.4.1.4. All referenced CCHMC policies will comply with current ODH requirements which may or may not be stricter than other guidelines.

5. RGE Safety and Usage Committees

5.1. General Requirements for the QA Committee:

5.1.1. The QA Committee is a subcommittee of the RSC. Under the RCSP, the QA Committee's official name is the *CCHMC QA committee for Radiation Generating Devices*

5.1.2. Referred to here as: CCHMC QA Committee.

5.1.2.1. The CCHMC QA Committee is responsible for implementation of the QA Program at CCHMC–Burnet and Liberty Campuses, out-patient imaging sites employing RGE, and the Cincinnati Proton Therapy Center (CPTC).

5.1.2.2. Changes to the CCHMC QA Program require approval of the CCHMC QA Committee prior to review and approval by the RSC.

5.2. Membership Requirements for the CCHMC QA Committee

5.2.1. The CCHMC QA Committee will consist, at a minimum, of the following members approved by an executive administrator of CCHMC:

5.2.1.1. A representative of the CCHMC executive administration;

5.2.1.2. The IRRP/RSO;

5.2.1.3. A radiologist or a radiation oncologist;

5.2.1.4. Designated diagnostic and therapeutic CRE(s);

5.2.1.5. A management representative of each department, i.e., the CP, of the hospital which has responsibilities involving the handling of RGE.

5.2.2. Committee meetings should be attended by the members. If a member is unable to attend, a guest from their department is welcome.

5.2.3. The chair of the committee will serve as the representative to the RSC.

5.2.4. Each member must attend at least one meeting each calendar year.

5.3. Meeting Requirements for the CCHMC QA Committee

5.3.1. The QA Committee shall meet at least quarterly.

5.3.2. At least one-half of the committee's membership must be present either in person or by telecommunication to establish a quorum and must include the following:

5.3.2.1. The committee chair;

5.3.2.2. the IRRP/RSO; (and)

5.3.2.3. The representative from the hospital executive administration.

5.3.2.4. To meet a quorum, the above individuals may be represented by their similarly qualified, designated alternates.

5.3.3. The CRE(s) shall submit to members of the QA Committee a written review of the QA Program, covering the previous quarter. The review shall include, but is not limited to:

5.3.3.1. Proposed radiation safety policy revisions for human-use RGE;

5.3.3.2. Occupational exposure record review, primarily consisting of any ALARA analysis, for individuals exposed to radiation from covered RGE;

5.3.3.3. Radiation safety incidents pertaining to covered RGE;

5.3.3.4. RGE equipment performance evaluation summaries, as applicable; and

5.3.3.5. Any recommended corrective action necessary to comply with requirements of rules and regulations pertaining to the human-use of RGE.

5.3.4. Minutes shall include:

5.3.4.1. The date of the meeting;

5.3.4.2. An indication of members present and absent;

5.3.4.3. A summary of the meeting, including any recommended actions and ALARA reviews;

5.3.4.4. A record of each meeting shall be maintained and distributed to each committee member;

5.3.4.5. A record of the minutes will be presented to the RSC.

5.3.4.6. Draft minutes shall include a water mark or other indication of the document being a "draft" version of the minutes.

5.3.4.7. Approved minutes shall include a water mark or other indication of the document being a final or approved version of the minutes.

5.4. QA Program Audits

5.4.1. The QA program shall be audited at least annually by a CRE. The scope of the audit report shall be defined by the following requirements:

5.4.1.1. Summary of annual RGE performance evaluations and any identified problems requiring corrective action including documentation of corrective action;

5.4.1.2. Radiation survey evaluations of shielding and surroundings conducted during this audit period;

5.4.1.3. Summary of new and revised policies and procedures instituted during this audit period;

5.4.1.4. Summary report of personnel monitoring showing individuals exceeding ALARA

or state limits;

5.4.1.5. Any recommendations of corrective action to comply with the OAC submitted to the QA committee members during this audit period.

5.4.2. The CRE(s) shall submit a copy of the final draft audit report to each member of the CCHMC QA Committee within 30 days of completion. After approval by CCHMC QA Committee, the audit report will be presented to the RSC at their next scheduled meeting.

5.4.3. The CRE(s) shall submit a copy of the final audit report and any associated documents such as the ODH report form, to the Director of the Ohio Department of Health within 90 days of completion.

5.4.3.1. The CRE shall provide the RSO/IRRP with any correspondence(s) received from the ODH regarding the submission of the annual audit report e.g., follow-up requests and review notification letters.

5.4.4. The CCHMC QA Committee shall implement any necessary corrective action.

5.5. Radiation dose review committees will be defined pursuant to [OAC 3701:1-66-04] as follows:

5.5.1. Fluoroscopically guided interventional examinations; and CT examinations excluding veterinary and cone beam CT examinations.

5.5.2. Committee membership, at a minimum, will consist of:

5.5.2.1. IRRP/RSO;

5.5.2.2. Diagnostic CRE;

5.5.2.3. Physician(s) that perform fluoroscopically-guided interventional and/or computed tomography procedures; and

5.5.2.4. Manager(s) of CT and interventional fluoroscopy.

5.5.3. Meetings will consist of the following:

5.5.3.1. A quorum of the committee members will meet at least annually in person or by telecommunication to carry out its duties;

5.5.3.2. A quorum is defined as at least one half of committee membership; and IRRP/RSO; and

5.5.3.3. Minutes must be recorded and documented including:

5.5.3.3.1. Date of meeting;

5.5.3.3.2. Members present; and

5.5.3.3.3. Summary of meeting including any recommended actions.

5.6. Specific committee requirements

5.6.1. Fluoroscopically – guided interventional examination written policies must include the following:

5.6.1.1. Identification of individuals authorized to conduct interventional procedures;

5.6.1.2. Chosen method to monitor patient radiation dose during procedures;

5.6.1.3. Establish dose notification levels and notify the operator during procedures;

5.6.1.4. Establish follow-up actions when these dose levels are exceeded; and

5.6.1.5. Review of any action items applicable to fluoroscopically guided interventional examinations from quarterly quality assurance program meetings.

5.6.2. Computed Tomography examinations

5.6.2.1. Determine and review written protocols to manage image quality and patient dose, at the minimum, for the following if performed:

5.6.2.1.1. Pediatric head and abdomen;

5.6.2.1.2. Adult head, chest, and abdomen; and

5.6.2.1.3. Brain perfusion

6. Patient Incident Action

6.1. Reportable patient RGE incidents

6.1.1. Upon discovery of a ME, the registrant shall:

6.1.1.1. Contact the Ohio department of Health within one business day;

6.1.1.2. Provide a written report, including the analysis of the ME, by a CRE to the IRRP within 13 days of the ME. The written report must include:

6.1.1.2.1. The handler or registrant's name;

6.1.1.2.2. The name of the prescribing physician;

6.1.1.2.3. A brief description of the event including the body site, dose delivered and any critical structures involved;

6.1.1.2.4. Why the event occurred;

6.1.1.2.5. The effect, if any, on the individual who received the medical event;

6.1.1.2.6. Actions, if any, that have been taken, or are planned, to prevent recurrence;

6.1.1.2.7. Certification that the handler notified the individual, or the individual's responsible relative or guardian, and if not, why not;

6.1.1.2.8. Provide a clinical summary to the prescribing physician and patient within fifteen business days; and

6.1.1.2.9. Maintain record of the medical event as part of the patient's permanent medical record.

6.1.1.3. The IRRP will provide a final written report within 15 days to ODH.

6.1.1.4. ME reports shall be maintained until the registration is terminated.

6.2. Recordable RGE Incidents

6.2.1. Recordable incidents include those that may or may not require reporting to the ODH.

6.2.2. Recordable incident categories:

6.2.2.1. Equipment related;

6.2.2.2. Employee related;

6.2.2.3. Employee exposures

6.2.3. Recordable incident action to be taken:

6.2.3.1. Problems with the operation of RGE shall be reported promptly to the section manager and the applicable engineering staff to evaluate the need for repairs.

6.2.4. Patient and RGE system recordable incidents shall be reported to:

6.2.4.1. The hospital's incident reporting process;

6.2.4.2. The section manager will notify the CRE;

6.2.4.3. If the CRE determines the incident is the result of a significant problem or concern, the CRE will notify the QA Committee Chair and IRRP; and

6.2.4.4. Otherwise, the incident will be reported to the QA Committee at the next regular meeting.

6.2.5. Any problems with the operation of RGE that may result in overexposure to personnel shall be reported promptly to the section manager and the CRE.

6.2.5.1. The CRE will investigate the problem and work with the applicable engineering staff implement corrective action.

6.2.5.2. The CRE will report corrective action to the CCHMC QA Committee.

6.2.6. Patient exposure exceeding machine-specific dose notification criteria:

6.2.6.1. For fluoroscopy: is defined in CCHMC policy POL-717-POL: *Fluoroscopic Patient Exposure Exceeding Machine- Specific Criteria*;

6.2.6.2. For CT: is defined in CCHMC Policy RAD-720-G: *CT Radiation Dose Management Plan*.

6.2.7. Employee & Affiliate Staff exposures

6.2.7.1. Contact 803-SAFE

6.2.7.2. Follow employee exposure policy: *RAD-722-PRO: Radiation Exposure Concerns reported by CCHMC Employees*

7. RGE Operator Requirements

7.1. License definitions for operators of human-use RGE

7.1.1. An operator of human-use RGE shall not be a minor and shall be licensed by the State of Ohio.

7.1.2. All operators must work under the direct or general supervision of a licensed practitioner, as applicable to their category.

7.1.2.1. A licensed practitioner is defined as a physician according to OAC 3701:72-01.

7.1.3. Individuals allowed to operate RGE equipment are as follows:

7.1.3.1. A general x-ray machine operator or limited scope operator as defined in OAC 3701:72-01:

7.1.3.1.1. Must work under direct supervision

7.1.3.1.2. Is an individual that may perform standard diagnostic radiologic procedures; whose performance of radiologic procedures is limited to specific body sites; and who does not, in any significant degree, determine the site or dosage of radiation to which a patient is exposed.

7.1.3.2. A licensed radiographer as defined in OAC 3701:72-01:

7.1.3.2.1. Is an individual who operates ionizing RGE, administers contrast, and determines procedure positioning and the dosage of ionizing radiation to perform a comprehensive scope of radiology procedures on human beings.

7.1.3.3. A licensed nuclear medicine technologist as defined in OAC 3701:72-01:

7.1.3.3.1. Is an individual, other than a licensed practitioner, who prepares and administers radio-pharmaceuticals to a patient and conducts in vivo or in vitro detection and measurement of radioactivity for medical purposes.

7.1.3.3.2. A nuclear medicine technologist may operate fusion imaging equipment as authorized under OAC 3701:72-04.

7.1.3.4. A radiation therapist or radiation therapy technologist as defined in OAC 3701:72-01:

7.1.3.4.1. Radiation therapist or radiation therapy technologist means an individual who utilizes ionizing RGE equipment, including therapy simulator RGE, for therapeutic purposes on humans.

7.1.3.5. A dental x-ray machine operator as defined in OAC 4715.51:

7.1.3.5.1. Is an individual who, under the direct supervision of a dentist, performs standard, diagnostic, radiologic procedures for the purpose of contributing to the provision of dental care to a dental patient.

7.1.3.5.2. This includes licensed dental hygienists as defined in OAC4715.52.

7.1.4. Individuals shall be licensed as defined in OAC 3701:72-02 and OAC 4715.52.

7.1.4.1. Each department that utilizes human-use RGE must maintain a record of current licensure for all personnel who operate RGE.

7.1.4.2. A copy of the license for an individual no longer working at the registrant facility must be maintained for 5 years post termination.

7.2. Radiologic examinations for human-use are performed only on the order of a licensed practitioner.

7.3. RGE operators shall ensure patient protection by:

7.3.1. When screening for pregnancy or managing pregnant patients, the operator shall follow CCHMC policy RAD-705-POL: *Pregnancy Inquiry – Adolescent Girls & Women*

7.3.2. When verifying patient identification including identification of the appropriate body part, the operator shall follow CCHMC policy RAD-400-POL: *Identification of Patients, Patient Allergies, and Exam Verification*

7.3.3. When considering shielding patients, the operator shall follow CCHMC policy RAD-707-POL: *Male/Female Gonadal Shielding*

7.3.4. Operators shall optimize radiation exposure to the patient during radiographic, fluoroscopic, and CT examinations by following CCHMC policy RAD-720-G: *Radiation Dose Management Plan.*

7.3.5. Instructing the patient about avoiding movement and if necessary, use of immobilization or positioning aids.

7.3.6. The Operator shall ensure the following when support for holding a patient or an image receptor is required:

7.3.6.1. No individual shall routinely hold patients or image receptors during radiologic procedures;

7.3.6.2. Using immobilization devices, and remote handling devices should be used whenever possible to avoid holding patients;

7.3.6.3. Instruct the holder about what protective equipment must be worn;

7.3.6.3.1. The protective equipment shall include a lead apron of at least 0.25-mm lead equivalent

7.3.6.4. Instruct the holder about where they should stand; and

7.3.6.4.1. This instruction shall include standing in a position that keeps the individual's body outside the primary beam.

7.3.6.5. All individuals holding a patient or image receptor during radiation exposures; unless they are the child's parent, shall be at least eighteen years of age.

8. RGE Operator Training Requirements

8.1. Prior to allowing an individual to operate a human-use RGE, the CP shall:

8.1.1. Ensure the individual is licensed in accordance with section 7 of this manual.

8.1.2. Ensure the individual has obtained radiation protection training. The minimum training shall include:

8.1.2.1. Health protection problems associated with exposure to radiation;

8.1.2.2. Procedures to minimize theirs and other individual's exposure by:

8.1.2.2.1. Operator is responsible for other individuals in the vicinity of the RGE;

8.1.2.2.2. Minimizing occupancy to the extent possible in the restricted area prior to exposure;

8.1.2.2.3. Increasing distance between individuals and source of scattered x-rays;

8.1.2.2.4. Using equipment shielding (e.g. table or image receptor drapes or shields) unless it interferes with a procedure or compromises a sterile field;

8.1.2.2.5. Closely following RGE operating procedures;

8.1.2.2.6. Not overriding interlocks or other safety features;

8.1.2.2.7. Following good practices such as ensuring examination room doors are closed during an examination/procedure;

8.1.2.2.8. Receiving appropriate instructions on how to wear the protective shielding:

8.1.2.2.8.1. Not less than 0.25 mm lead equivalent material when exposed to scatter radiation;

8.1.2.2.8.2. 0.5 mm lead equivalent material when exposed to primary (i.e., useful beam) radiation;

8.1.2.2.8.3. Wearing protective eye wear (i.e., lead eyeglasses) may be worn if desired by the operator when standing near a patient during a fluoroscopic procedure;

8.1.2.2.8.4. Collar shields (i.e., thyroid shields) of at least 0.25 mm lead equivalence may be worn by individuals operating a few feet from an energized fluoroscopic unit;

8.1.2.2.8.5. For fluoroscopic procedures, protective lead or lead equivalent gloves shall be used by individuals who are required to have their hands in or near the useful beam.

8.1.2.2.9. Remaining behind a mobile barrier of equivalent shielding for individuals not wearing protective shields in the examination or procedure room when x-ray units are energized;

8.1.2.2.10. When performing mobile radiography, the operator shall stand at least six feet from the x-ray tube, unless special patient care issues prevent this separation.

8.1.2.2.11. When performing mobile radiography in a location where non-radiation workers or visitors may be located, the operator shall announce they are taking the x-ray before they make an exposure to allow the remaining individuals to move as far away from the beam as practical.

8.1.3. Provide instruction with respect to area-specific information and departmental procedures for RGE and the operation of each type and model of RGE to be operated. Instruction shall include the area-specific:

8.1.3.1. Applicable warning signage;

8.1.3.2. The location of the restricted area;

8.1.3.3. A description of the RGE in use;

8.1.3.4. Proper storage and security procedures for the hand-held RGE; and

8.1.3.5. Ensure RGE-specific training is completed and documented for each type and model of the RGE to be operated by the individual. This training will meet or exceed the minimum training instructions specified in the relevant ODH requirements.

8.1.4. To schedule/use c-arms in the OR or ED, complete CRE approved fluoroscopy training and pass the machine specific hands-on training.

8.1.5. When new RGE is installed, all operators shall be trained in the operation by:

8.1.5.1. The manufacturer; or

8.1.5.2. An operator or supervisor who was trained by the manufacturer.

8.1.6. Instruction to report promptly any condition that may constitute or lead to or cause a violation of radiation protection or QA procedures, policies, rules, or regulations.

8.1.7. Changes to operating procedures and the QA Program shall be communicated to applicable operators in a timely manner, not to exceed 60 days:

8.1.7.1. Written, electronic and/or verbal communication of changes (e.g., memo to operators, discussion at departmental meeting, and

8.1.7.2. Addition of revised protocol in the departmental manual.

8.2. Ancillary Personnel Training

8.2.5. All employees who may receive an occupational dose under the RCSP in excess of 1 mSv (100 mrem) shall receive documented general radiation protection training. Generally, this training will be provided during new employee orientation but may also be obtained through the RSOf. The minimum training shall include:

8.2.5.1. Health protection problems associated with exposure to radiation and procedures to minimize the exposure;

8.2.5.2. Instruction to report promptly any condition that they know, or suspect may constitute or lead to or cause a violation of radiation protection or QA procedures, policies, rules or regulations;

8.2.5.3. Applicable warning signage; and

8.2.5.4. The location of the restricted area(s).

8.3. Training Records for RGE operators

8.3.5. Training records shall be maintained in readily accessible form(s).

8.3.6. Training records shall be current and made available upon request to the CRE, representatives of the RSOf, members of the QA Committee, members of the RSC or inspectors from the ODH.

8.3.7. Each department manager or CP is responsible for maintaining all required training records.

8.3.7.1. All training records associated with a RGE RW shall be maintained for five-years after deactivation of the individual as a RGE radiation worker.

8.3.7.2. All other training records shall be maintained for a minimum of three-years.

8.3.8. Records documenting completion of basic radiation training shall be provided to the RSOf upon application for dosimetry badge and shall be maintained by the RSOf with the individual's RGE radiation worker records.

8.3.9. Records documenting an individual has completed initial fluoroscopy training shall be recorded and documented in ELM.

8.3.10. Handlers of dental RGE shall conduct annual evaluations of x-ray operators to include the following:

8.3.10.1. Positioning of the x-ray tube;

8.3.10.2. Image processing;

8.3.10.3. Operator location during x-ray exposure;

8.3.10.4. Appropriate radiologic protocol; and

8.3.10.5. Applicable regulatory requirements.

9. Radiation Monitoring Requirements

9.1. Annual Exposure Limits

9.1.1. Whole body effective dose – 50 mSv (5 rem).

9.1.2. Any individual organ or tissue, other than the lens of the eye – 500 mSv (50 rem).

9.1.3. Lens of the eye – 150 mSv (15 rem).

9.1.4. Skin – 500 mSv (50 rem).

9.1.5. Extremity – 500 mSv (50 rem).

9.1.6. Minors – one tenth the above values.

9.1.7. Declared pregnant worker – 5 mSv (500 mrem) to the fetus during the pregnancy term.

9.1.7.1. Should it be determined that the embryo/fetus has exceeded the 5 mSv (500 mrem) before the declaration was made, any additional dose equivalent shall not exceed 0.5 mSv (50 mrem).

9.2. Dosimetry Requirements for RW

9.2.1. In accordance with regulations, at a minimum, a single dosimeter shall be worn by all personnel who may receive greater than 10% of the annual occupational dose limit.

9.2.2. The RSC may require exposure monitoring for any routinely exposed workers under the RCSP. This requirement may be more restrictive than the ODH requirements.

9.2.3. Exemptions from dosimetry requirements may be approved by the RSC.

9.2.3.1. Requests for exemptions shall be submitted, in writing, to either the CRE, RSO/IRRP, CCHMC QA Committee or directly to the RSC and shall include:

9.2.3.1.1. Reason for the request;

9.2.3.1.2. Documentation that the individual or individuals covered by the request are unlikely to receive in one year from all sources of radiation under the RCSP 10% of the regulatory annual occupational dose limit;

9.2.3.1.3. This documentation shall include potential doses from both routine operations and possible incident situations.

9.2.4. Dosimeters shall be provided by and applied for through the RSOf.

9.2.5. Single issued body dosimeter badge:

9.2.5.1. When wearing protective shielding, one dosimeter will be placed outside the apron, at the collar.

9.2.5.2. When not wearing protective shielding, one dosimeter shall be worn in the chest area of the individual.

9.2.6. Two issued body dosimeter badges:

9.2.6.1. When wearing protective shielding, two dosimeters will be worn, one outside the apron at the collar (labeled neck with a 'red' human graphic) and the second behind the apron at the abdomen (labeled waist with a 'yellow' human graphic).

9.2.6.2. Two dosimeters are required for those exposed to specialty fluoroscopy units (e.g., interventional radiology and cardiac catheterization).

9.2.7. If an individual's hands are likely to receive a dose that is 10% or more of the applicable limit, a ring dosimeter should be worn on each hand such that the dosimeter side of the ring faces the radiation source.

9.3. Dosimetry for Ancillary Personnel

9.3.1. Dosimeters are required if the ancillary personnel are likely to receive a dose that is 10% or more of the applicable limit.

9.3.2. Dosimeter requirements are equivalent to that for RW.

9.4. Declared Pregnant Workers

9.4.1. Pregnant individuals are not considered "declared pregnant workers" until they declare the pregnancy in writing to the RSOf. The declaration must include:

9.4.1.1. The name of the individual;

9.4.1.2. The date of declaration;

9.4.1.3. The type of radiation exposed to in the workplace; and

9.4.1.4. The estimated date of conception.

9.4.2. Declared pregnant workers shall be assigned an additional dosimeter labeled as "Fetal" and shall wear both dosimeters at the location indicated on the dosimeter.

9.4.2.1. The declared pregnant worker will wear their individual dosimeter in accordance to the requirements for RWs.

9.4.2.2. A second fetal dosimeter will be issued labeled "Fetal".

9.4.2.2.1. The badge will be worn at the level of the abdomen.

9.4.2.2.2. When wearing protective shielding, the fetal badge will be worn under the apron.

9.4.2.3. The radiation dose limit to the embryo/fetus of a declared pregnant worker is 5 mSv (500 mrem) total effective dose equivalent over the term of the pregnancy.

9.4.3. Pregnant workers may request a meeting with the IRRP/RSO or CRE. The IRRP/RSO or CRE will:

9.4.3.1. Review NRC regulatory guide 8.13. This guide covers the effects of radiation to the embryo or fetus;

9.4.3.2. Review the individual's exposure record; and

9.4.3.3. If the record indicates an exposure to the embryo/fetus is likely to be greater than 5 mSv (500 mrem), the IRRP/RSO or CRE will inform the department supervisor and collaboratively provide mitigation steps to help lower radiation exposure so the exposure can be maintained < 5 mSv (500 mrem) during the term of pregnancy.

9.4.4. Pregnant individuals may continue to operate and work around RGE unless deemed otherwise by the CRE or IRRP/RSO.

9.5. Area Dosimeter Option

9.5.1. A CP may request an area dosimeter for placement in a location of interest to monitor radiation exposure at the location.

9.5.2. Areas of interest may include the control panel or locations where members of the public may frequent.

9.6. Care of Dosimeters

9.6.1. Personal radiation dosimeters are for use by a single individual and shall not be shared, reassigned, or discarded.

9.6.2. Area dosimeters are for use at a single designated location.

9.6.2.1. Area dosimeters are directional i.e., the face of the dosimeter should face the source of radiation.

9.6.3. Personnel and area dosimeters issued by the RSOf are limited for use to monitor radiation exposure from radiation sources covered by the RCSP.

9.6.4. Personal radiation dosimeters shall be stored in low background areas (e.g., offices, non-RGE area) when not being worn or used to monitor a specific location.

9.6.5. Dosimeters should not leave CCHMC campuses unless they are being exchanged with the RSOf or the wearer is commuting to a secondary CCHMC work location.

9.6.6. Personnel radiation dosimeters shall not to be worn during personal medical or dental radiographic procedures.

9.7. Dosimetry Analysis and Reports

9.7.1. Dosimeter analysis reports are sent by the vendor to the RSOf. Copies are maintained in the RSOf. Copies are forwarded as follows:

9.7.1.1. CRE;

9.7.1.2. Individuals whose annual exposure exceeded 1 mSv (100 mrem) in the previous calendar year are provided copies of the previous year’s exposure totals; and

9.7.1.3. To individuals upon written request to the RSOf. Reports will be provided within 30 days after the request is made or within 30 days after receipt of the data for the last dosimeter, whichever is later.

9.8. Dosimetry Exchange Procedures

9.8.1. To prevent unmonitored exposure, before used dosimeters are returned, new dosimeters are delivered.

9.8.1.1. Monthly dosimeters are delivered by the third working day of the month. Quarterly dosimeters are delivered by the third working day of the quarter.

9.8.2. Personal dosimeters must be returned in a timely fashion to the RSOf for analysis.

9.8.2.1. Radiation badges are returned to department CP who is responsible for ensuring all issued radiation badges are returned timely to the RSOf.

9.8.2.2. RSOf will arrange delivery/pickup options of badges with the CP.

9.9. Lost, Late Return, or Damaged Dosimeters

9.9.1. Lost or damaged dosimeters shall be reported to the RSOf ASAP.

9.9.2. Temporary replacement dosimeters will be issued if dosimeters are reported as lost or damaged prior to the return exchange.

9.10. ALARA Investigations and Notifications

9.10.1. ALARA I (> 10% but < 30% of regulatory limit)

9.10.1.1. Investigational levels are 10% of the values listed in section 9.1 divided by 4 in each calendar quarter.

9.10.1.2. The IRRP/RSO will, in conjunction with the CRE, if necessary:

9.10.1.2.1. Provide a written report of the exposure to the individual and CCHMC Risk Management;

9.10.1.2.2. Request the individual submit an explanation of radiation exposure during the period in question; and

9.10.1.2.3. Review the exposure and the explanation, then further investigate if deemed necessary;

9.10.2. ALARA II (≥ 30% of regulatory limit)

9.10.2.1. Investigational levels are 30% of the values listed in section 9.1 divided by 4 in each calendar quarter.

9.10.2.2. The IRRP/RSO will in conjunction with the CRE, if necessary:

9.10.2.2.1. Provide a written report of the exposure to the individual and CCHMC Risk Management;

9.10.2.2.2. Request the individual submit an explanation of radiation exposure during the time period in question;

9.10.2.2.3. Investigate the cause(s) of the exposure; and

9.10.2.2.4. Personally, or assign a delegate to meet with the individual and discuss the results of the investigation and discuss corrective action as necessary.

9.10.3. When an exposure more than the annual limit is suspected the CRE and IRRP/RSO shall be

notified.

9.10.3.1. The CRE, in conjunction with the IRRP/RSO shall:

9.10.3.1.1. Investigate the possible overexposure.

9.10.3.1.2. Notify the Director of the ODH within 30 days of discovery. The notification shall include:

9.10.3.1.2.1. An estimation of the individual's dose;

9.10.3.1.2.2. The levels (dose or dose rate) of radiation involved;

9.10.3.1.2.3. The cause of the exposure;

9.10.3.1.2.4. Any corrective action taken or planned to assure against recurrence;

9.10.3.1.2.5. The name and date of birth of the exposed individual; and

9.10.3.1.2.6. In cases where the overexposed is an embryo/fetus, the information shall be provided to the declared pregnant worker.

9.10.3.1.3. Provide written notification to the individual. The written notification shall include:

9.10.3.1.3.1. Nature and extent of the exposure;

9.10.3.1.3.2. Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number;

9.10.3.1.3.3. Include the individual's exposure information; and

9.10.3.1.3.4. The following statement: "This report is furnished to you under the provisions of rule 3701:1-38-10 of the Ohio OAC. You should preserve this report for further reference."

10. Postings and Signs

10.1. Posting and signage is used to inform and protect registrant staff from radiation exposure from human-use RGE.

10.2. Each department where RGE is used shall post in conspicuous locations the ODH notice to employees materials found in OAC 3701:1-38-10, including (but not limited to):

10.2.1. Location(s) where this manual, applicable audit(s), and applicable inspection report(s) are maintained;

10.2.2. Method for contacting the CRE, IRRP, and RSO (if different than the IRRP).

10.3. Each human-use RGE shall have a label near any switch that energies the x-ray tube "Caution-this equipment produces radiation when energized" or equivalent.

10.4. Signs reminding patients to inform the radiographer/therapist prior to a study if there is a possibility of pregnancy shall be posted in accordance to hospital pregnancy policy.

10.5. Information for Exposed Public

10.5.1. Informational material shall be provided upon request or as considered necessary by the

11. Procedure for Evaluation of RGE

11.1. CCHMC Hospital RGE and CCHMC non-hospital human-use RGE shall be evaluated for compliance to applicable state regulations under the authorization of the applicable CRE in accordance with the following:

11.1.1. Computed Radiography (CR) and Digital Radiography (DR) systems

11.1.1.1. Image quality will be assessed at a minimum annually.

11.1.1.1.1. Image quality will be assessed by a CRE or CRE specified designee.

11.1.1.1.2. The process for acquiring the image quality assessment image will be defined by the CRE.

11.1.1.1.3. The image will be reviewed by a CRE.

11.1.1.2. Additional CR system QC procedures:

11.1.1.2.1. Inspection for damage and erasure of all CR plates weekly.

11.1.1.2.2. Testing will be performed by a CRE specified designee.

11.1.1.3. Additional DR system QC procedures

11.1.1.3.1. Assessment of system performance, and radiation output will adhere to minimum testing procedures and recommended tolerances as defined in OAC 3701:1-66-05.

11.1.1.3.2. Testing will be performed upon receipt and biennially thereafter.

11.1.1.3.3. Testing will be performed by the CRE or specified designee.

11.1.2. Fluoroscopic Systems

11.1.2.1. Assessment of system image quality, performance, and radiation output will adhere to minimum testing procedures and recommended tolerances as defined in OAC 3701:1-66-07.

11.1.2.2. Each system must be certified by a CRE prior to first patient use following initial installation; or following repair or replacement of any component which may alter radiation output or image quality.

11.1.2.3. Testing will be performed annually thereafter.

11.1.2.4. Testing will be performed by the CRE or specified designee.

11.1.3. CT systems

11.1.3.1. Assessment of system image quality, performance, and radiation output will adhere to a minimum testing procedures and recommended tolerances as defined in OAC 3701:1-66-10.

11.1.3.2. Each system must be certified by a CRE prior to first patient use following initial installation; or following repair or replacement of any component which may alter radiation output or image quality.

11.1.3.3. Testing will be performed annually thereafter.

11.1.3.4. Testing will be performed by the CRE or specified designee.

11.1.4. Bone densitometry systems (DEXA)

11.1.4.1. Assessment of system image quality, performance, and radiation output will adhere to a minimum testing procedure as defined in OAC 3701:1-66-11.

11.1.4.2. Testing will be performed upon receipt and biennially thereafter.

11.1.4.3. Testing will be performed by the CRE or specified designee.

11.1.5. On-board imaging RGE units integrated with the proton treatment gantry shall follow the procedures defined in the Proton Center QA manual.

11.1.6. Display Workstations

11.1.6.1. Primary viewing stations (i.e., reading room displays) shall be monitored regularly through manufacturer's software self-diagnosis.

11.1.6.2. Primary viewing station's grayscale output shall conform to GSDF standards and are annually reviewed under the supervision of the CRE.

11.1.6.3. Secondary viewing stations (i.e., viewing displays associated with each imaging system) shall be reviewed at the time each imaging system undergoes QC.

11.2. Resolution of Identified Deficiencies

11.2.1. Any deficiencies in performance or other non-compliance items identified during QC testing of RGE by the CRE, or specified designee, will be documented.

11.2.2. CRE will work with clinical engineering, or manufacturer affiliates, to ensure any identified deficiencies are appropriately resolved in a reasonable timeframe.

11.2.2.1. If the CRE deems the RGE is unsafe, the CRE shall have the authority to immediately remove the RGE from service/use.

11.2.3. QC Following repair or replacement

11.2.3.1. The following must be reviewed and deemed acceptable prior to patient use following repair or replacement of any component of fluoroscopic equipment which may alter the radiation output or image quality:

11.2.3.1.1. Perform and document measurements of air KERMA rates and or image quality performance; or

11.2.3.1.2. Document that the repairs or replacement will not cause a significant change in radiation output or significant degradation of image quality as specified in this manual.

11.2.3.2. The following must be reviewed and deemed acceptable prior to patient use following repair or replacement of any component of the CT equipment which may alter the radiation output or image quality:

11.2.3.2.1. Perform and document measurements of CTDIvol and or image quality performance, or

11.2.3.2.2. Document that the repairs or replacement will not cause a significant change in radiation output or significant degradation of image quality as specified in this manual.

11.2.3.3. For all other RGE systems following repair or replacement of any component which may alter the radiation output or image quality:

11.2.3.3.1. Document that the repairs or replacements meet required OAC 3701:1-66 testing criteria within 30 days; or

11.2.3.3.2. Document that the repairs or replacement will not cause a significant change in radiation output or significant degradation of image quality as

specified in this manual.

11.2.3.4. Documentation of all tests performed shall include the technique factors used in determining such results, include the name of the individual performing the measurements, include the date the measurements were performed, and copies shall be provided to the IRRP/RSO.

11.3. Technologist Performed QC

11.3.1. The CRE manages all aspects of technologist performed QC testing required by the manufacturer of the RGE, and as required by the ODH for the relevant RGE type and use.

11.3.1.1. Prior to performing any QC test, the operator shall receive training. This training shall include:

11.3.1.1.1. A protocol of how to perform the QC test; and

11.3.1.1.2. Hands on training and observation by an individual experienced in the QC test.

11.3.1.2. The technologist generates the prescribed QC images on each RGE unit using the QC test protocol and provided test equipment. Acquired images will be sent to the clinical PACS system, which will then send the QC images to the physics server for processing and archival.

11.3.1.3. CRE manages the computer analysis of the images received and generates summary reports in conjunction with any manual analyses performed by the technologist.

11.3.1.4. CRE periodically evaluates trends and other results of measured image quality over time in conjunction with radiographer analyses performed by hand.

11.4. QC for Personnel Protective Equipment

11.4.1. Checks of lead protective apparel.

11.4.2. Initial fluoroscopic or DR imaging check, tagging and documentation in Clinical Engineering data base:

11.4.2.1. Annual visual inspection for cracks, holes or penetrations through the lead. Fluoroscopy for any with questions; and

11.4.2.2. Annual color tagging of the apparel that has been checked.

11.5. Record Keeping Duration

11.5.1. Data and test results of periodic performance testing of RGE equipment: 5 years.

11.5.2. Maintenance logs for RGE equipment: 5 years.

11.5.3. Calibration certificates for all instruments used to perform area radiation surveys, calibrations, and evaluations: 5 years.

11.6. ODH inspections: All human-use RGE are evaluated by the ODH in accordance with the inspection schedule of the ODH.

11.6.1. Hospitals are generally inspected biennially.

11.6.2. Out-patient imaging sites are generally inspected every 3 years.

12. Preventative Maintenance (PM)

12.1. PM is performed according to manufacturer's recommendations by either:

12.1.1. Hospital Clinical Engineering staff members; or

12.1.2. Service representatives from the manufacturer of the RGE.

12.2. Each RGE will have a separate maintenance log, which shall include:

12.2.1. Identification of the piece of equipment;

12.2.2. Incidents and actions;

12.2.3. Maintenance performed;

12.2.4. Repair information; and

12.2.5. These Logs are maintained by Clinical Engineering and shall be available upon request.

12.3. Maintenance Manuals

12.3.1. Technical and service manuals for each RGE type and model shall be readily available for use by the operator and inspection by the CRE, IRRP/RSO, CP or state inspector.

13. RGE Acquisition, Inventory, Disposal or Transfer, and Inoperable Units

13.1. Acquisition (purchase or loaner) of New RGE

13.1.1. The acquisition of new RGE, or transferal of RGE equipment from one hospital registration to another, shall be reported to the IRRP/RSO (via the Gamma 2 web application) and the CRE by the CP or other designated responsible individual within the department within (30) days.

13.1.2. Information provided to the IRRP/RSO and CRE shall include, but is not limited to:

13.1.2.1. CP's name;

13.1.2.2. Department;

13.1.2.3. Machine's application (e.g., radiographic, fluoroscopic, CT, dental);

13.1.2.4. Description of machine (make, model);

13.1.2.5. Number of tubes with tube serial number(s);

13.1.2.6. Expected delivery date;

13.1.2.7. Planned location;

13.1.2.8. Examination room design where the RGE equipment will be permanently located (if applicable);

13.1.2.8.1. Room design will be used by the CRE for shielding evaluation and calculation.

13.1.3. The IRRP/RSO will ensure the state of Ohio registration allows for the acquisition. If the acquisition will result in the number of tubes exceeding the number listed on the registration, the IRRP/RSO shall amend the registration.

13.1.4. CRE shall acceptance test the unit and any required protective barriers in accordance with the Ohio OAC.

13.1.4.1. Acceptance testing of new or transferred systems shall adhere to testing procedures and tolerances outlined in section 11 of this manual.

13.1.5. Loaner RGE

13.1.5.1. CRE shall acceptance test prior to first use any loaner CT or fluoroscopy units prior to first patient use.

13.1.5.2. All testing will be performed as outlined in section 11 of this manual for the relevant RGE OAC requirements.

13.1.5.3. If a loaner RGE will be possessed by the registrant for more than 30 days it shall be reported to the IRRP/RSO and added to the registration.

13.2. RGE Inventory

13.2.1. RGE inventory will be maintained by the registrant and available for audit by the RSOf.

13.2.2. CP or their designee shall report RGE inventories quarterly to the RSOf via the Gamma 2 web application.

13.3. Disposal or Transfer of RGE

13.3.1. Disposal or transfer of RGE by their department, the CP or other designated responsible individual within the department shall inform the IRRP/RSO (via the Gamma 2 web application) and the CRE about the disposal or transfer.

13.3.2. The RSOf will amend the appropriate registration.

13.3.3. The RSC will be informed at the next quarterly meeting.

13.4. Inoperable RGE

13.4.1. The CP or other designated responsible individual within the department shall notify the IRRP/RSO (via the Gamma 2 web application) and Clinical Engineering whenever a previously operable RGE is determined to be inoperable.

13.4.1.1. Notification shall be within 5 business days of the CP becoming aware the RGE is inoperable.

13.4.1.2. All appropriate documentation will be submitted to the CCHMC QA committee and the RSC.

13.4.1.3. Clinical engineering will render the device fully inoperable using a "lockout" device.

13.4.1.4. The RSOf will amend the appropriate registration.

13.4.2. The CP or other designated responsible individual within the department shall notify the CRE and IRRP/RSO (via the Gamma 2 web application) when an inoperable RGE unit is ready to be returned to clinical service.

13.4.2.1. The CRE will arrange to survey the unit before patient use.

13.4.2.2. The IRRP/RSO will amend the hospital registration (if applicable).

14. RGE Room Construction - New or Remodeled

14.1. Prior to construction of a new RGE room or remodeling of an existing RGE room:

14.1.1. CRE shall calculate a shielding design to ensure the rooms meet the requirements for exposure to members of the public;

14.1.2. Shielding design document shall be submitted to the Facility Planning Department or architect prior to start of construction; and

14.1.3. The CRE will submit a final shielding design to the IRRP/RSOf for archiving.

14.2. During construction of a new RGE room or remodeling of an existing RGE room:

14.2.1. The project manager shall keep the CRE informed of the status of the project and obtain approval for any changes that may affect shielding; and

14.2.2. When possible, the CRE shall be notified by the project manager to visually inspect back side of installed shielding prior to installation of drywall on opposite side of studs to ensure shielding is being installed in accordance with the design specifications.

14.3. After construction of a new RGE room or remodeling of an existing RGE room:

14.3.1. The CRE shall perform all necessary surveys to ensure the room meets the requirements for

exposure to members of the public, and

14.3.2. The CRE will submit a shielding verification survey to the IRRP/RSOf for archiving.

14.4. Reinstallation of similar RGE equipment

14.4.1. Reinstallation of RGE of the same operating parameters, location, geometry, and patient volume does not require another area radiation survey if the previous documented area radiation survey is maintained and available for inspection.

14.5. The RSOf will maintain a list of all shielding designs and room surveys.

14.5.1. Data and test results of shielding evaluations will be maintained for five years after equipment disposal.