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

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.
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.

Revision	Date of	Change Entered
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	11/14/18	Major revision including the creation of two separate QA Committees, the first as UC and SHC and the second as UC and CCHMC. The UC/CCHMC QA Manual will stand alone outside of this manual.
23	7/24/19	Document formatting changes to comply with ADA requirements. Minor grammatical corrections. Correction to Rev 22 reference date to align with UC RSC approval.
24	08/13/25	Removal of references to Shriners, Hospital use, requirements of the QA committee, gonadal shielding, film, equipment not relevant to UC Human Use.

TABLE OF CONTENTS

1. General

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

1.2. 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.

1.3. This manual incorporates quality assurance (QA) and radiation protection policies, procedures and guidelines. The Radiation Safety Committee (RSC) has reviewed and approved the initial version and each subsequent revision of this manual.

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

1.3.1.1. First changes suggested to and/or by the Certified Radiation Expert(s) (CRE), the physician operator(s), CP or the Individual Responsible for Radiation Protection/Radiation Safety Officer (IRRP)/RSO. (Any individual may make a suggestion for change to the CRE and/or the IRRP/RSO.)

1.3.1.2. Second - review and approval by RSC.

1.3.2. The IRRP/RSO is responsible for distributing copies of each revision to each CP representing a department possessing human-use RGE within 30 days of RSC approval.

1.3.3. The CP 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.

1.3.4. The IRRP/RSO is responsible for ensuring the current version of the manual is posted on the Radiation Safety website (Radiation Safety Office).

1.4. All individuals operating RGE for human-use shall read and understand this manual prior to use of RGE on humans.

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.

3. Definitions and Abbreviations

3.1. Definitions

3.1.1. Ancillary Radiation Worker (AW)

3.1.1.1. An individual who:

3.1.1.1.1. Is not a RGE radiation worker (RW);

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

3.1.1.1.3. Is performing a duty as part of their "job" (e.g., employee, student,

volunteer)

3.1.2. Annual

3.1.2.1. At intervals not to exceed one year, or once per year at about the same time each year, plus or minus one month.

3.1.3. Certified Radiation Expert (CRE)

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

3.1.3.2. For the RCSP, a CRE must be appointed as designated in paragraph 4.3 of this manual.

3.1.3.3. CRE categories are:

3.1.3.3.1. Therapeutic;

3.1.3.3.2. Diagnostic, other than mammography; and

3.1.3.3.3. Mammography (not currently applicable to the RCSP).

3.1.4. Contact Person (CP)

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

3.1.5. Declared Pregnant Worker

3.1.5.1. A worker who has declared their pregnancy in writing to the University of Cincinnati Radiation Safety Office.

3.1.6. Exposed Public

3.1.6.1. An individual who:

3.1.6.1.1. Is not an RGE radiation worker;

3.1.6.1.2. Is not an ancillary radiation worker;

3.1.6.1.3. Is not the patient; and

3.1.6.1.4. Is in the restricted area (e.g., room) when the x-ray is energized.

3.1.7. Licensed practitioner

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

3.1.7.1.1. Dentistry;

3.1.7.1.2. Medicine or surgery or osteopathic medicine or surgery;

3.1.7.1.3. Podiatry;

3.1.7.1.4. Chiropractic medicine;

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

3.1.7.1.6. 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; and

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

3.1.8. Individual Responsible for Radiation Protection (IRRP)

3.1.8.1. Individual who is specified on the registration.

3.1.8.2. For registrations under the University of Cincinnati Radiation Control and Safety Program, the University of Cincinnati Radiation Safety Officer (RSO).

3.1.9. Minor

3.1.9.1. Any individual under the age of 18.

3.1.10. Radiation Expert

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

3.1.11. Restricted Area

3.1.11.1. 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.

3.1.12. RGE Radiation Worker (RW)

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

3.1.12.2. 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.

3.2. Abbreviations

3.2.1. ARSO – University of Cincinnati Assistant Radiation Safety Officer

3.2.2. AW – Ancillary Radiation Worker

3.2.3. CP – Contact Person

3.2.4. CRE - Certified Radiation Expert

3.2.5. IRRP - Individual Responsible for Radiation Protection

3.2.6. OAC - Ohio Administrative Code

3.2.7. QA - Quality Assurance

3.2.8. QC – Quality Control

3.2.9. RCSP - Radiation Control and Safety Program

3.2.10. RE - Radiation Expert

3.2.11. RGE - Radiation-Generating Equipment

3.2.12. RSC - Radiation Safety Committee

3.2.13. RSO - University of Cincinnati Radiation Safety Officer

3.2.14. RSOf – University of Cincinnati Radiation Safety Office

3.2.15. RW - RGE Radiation Worker

3.2.16. TJC – The Joint Commission

3.2.17. UC – The University of Cincinnati

4. QA Program

4.1. The QA Program addresses the following:

4.1.1. Intervals and procedures for evaluation of RGE (manual section 14);

4.1.2. Radiation monitoring requirements including audits and surveys (manual sections 6, 14, 17.1.4 & 18.3), occupational exposure limits (manual section 10.1), maintenance of records (manual section 10.8), and personnel and area monitoring (manual section 10);

4.1.3. ALARA and overexposure notification procedures (manual section 11);

4.1.4. Radiation safety specifics for each type of RGE (manual section 9);

4.1.5. RGE operator training (manual sections 7 & 8);

4.1.6. General training (manual section 8);

4.1.7. Quality control (QC) tests and frequencies (manual sections 14 & 15);

4.1.8. Licensure requirements (manual section 7);

4.1.9. Notification of QA Program changes (manual paragraphs 1.3 and 8.1.5);

4.1.10. RGE RW roles and responsibilities (RCSP Manual, manual paragraphs 1.2, and manual sections 14, 15 and 16);

4.1.11. Personnel protection (manual paragraph 7.5 and 9.2);

4.1.12. Prenatal exposure (manual paragraphs 7.7.1. 7.7.2 and 9.3);

4.1.13. AW training (manual section 8.2);

4.1.14. QC task training (manual section 15.1);

4.1.15. Patient protection (manual subsection 7.7);

4.1.16. Protection of the public (manual sections 7.6, 8.3 and 12);

4.1.17. Equipment logs (manual section 16);

4.1.18. Posting and signage (manual section 12); and

4.1.19. Incident action (manual section 13).

4.2. Overall 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 IRRP/RSO.

4.3. Oversight and Maintenance of the QA Program

4.3.1. Oversight and maintenance of the QA Program for non-hospital human- use RGE is the responsibility of the RSC.

4.3.2. A department may hire a qualified individual(s) to serve as the CRE or RE.

4.3.2.1. A contracted qualified physicist may perform maintenance, quality

control and equipment testing.

4.4. Implementation of the QA Program

4.4.1. Implementation of the QA Program for non-hospital human-use RGE is the responsibility of:

4.4.1.1. The RSC; and

4.4.1.2. The IRRP/RSO.

5. QA Committee(s)

5.1. General Requirements for the QA Committee

5.1.1. Only hospitals are required to have an official QA Committee.

5.1.2. The official QA Committee is a subcommittee of the RSC.

5.1.3. Under the RCSP there is one QA Committee.

5.1.3.1. The QA Committee's official name is the CCHMC QA Committee for Radiation Generating Devices.

5.1.3.1.1. The CCHMC QA Committee is responsible for implementation of the QA Program at Cincinnati Children's Hospital Medical Center (CCHMC) – Base and Liberty Campuses, and the Cincinnati Proton Therapy Center (CPTC).

5.1.3.2. The human use included in this manual does not pertain to the equipment at CCHMC and is not considered hospital use for RGE on UC properties.

5.1.3.2.1. The RSC is responsible for implementation of the QA Program throughout UC campuses.

5.1.4. Changes to the QA Program specific to the RGE throughout UC campuses require review and approval by the RSC.

6. Audits

6.1. QA Program Audits

6.1.1. The QA Program, as it applies to non-hospital human-use RGE, shall be audited at least annually as part of the Radiation Control and Safety Program (RCSP) audit.

6.2. Radiation Control and Safety Program (RCSP) Audits

6.2.1. The RCSP shall be audited annually.

6.2.2. The RCSP audit shall include a review of the QA Program audit and the status of the implementation of corrective action.

7. RGE Operator Requirements

7.1. All operators of human-use RGE shall be licensed by the State of Ohio.

7.1.1. Individuals shall be licensed appropriately as either:

7.1.1.1. A general x-ray machine operator;

7.1.1.2. A general x-ray machine operators 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.

7.1.1.3. A general x-ray machine operator must work under the direct supervision of a licensed practitioner. In order to provide the direct supervision, the supervising licensed practitioner must be onsite and must be able to immediately provide consultation and direction assistance.

7.1.1.4. A radiographer;

7.1.1.4.1. A radiographer may perform a comprehensive scope of radiologic procedure employing equipment that emits radiation, exposes radiographs and performs other procedures that contribute significantly to determining the site or dosage of ionizing radiation which a patient is exposed.

7.1.1.4.2. A radiographer must work under the general supervision of a licensed practitioner. In order to provide general supervision, the licensed practitioner must be readily available for consulting with and directing the procedures.

7.1.1.5. A licensed dental hygienist; (or)

7.1.1.5.1. A licensed dental hygienist may perform standard, diagnostic, radiographic procedures for the purpose of providing dental services.

7.1.1.5.2. A licensed dental hygienist must work under the general supervision of a licensed practitioner. In order to provide general supervision, the licensed dentist must be readily available for consulting with and directing the procedures.

7.1.1.6. A certified dental assistant radiographer;

7.1.1.6.1. A certified dental assistant radiographer may perform standard, diagnostic, radiologic procedures for providing dental services.

7.1.1.6.2. A certified dental assistant radiographer must work under the direct supervision of a licensed dentist. In order to provide the direct supervision, the supervising licensed dentist must be onsite and any radiographic procedures performed must be checked and approved by the licensed dentist prior to the patient leaving the dental facility.

7.2. Except as follows, radiologic examinations are performed only on the order of a licensed practitioner.

7.3. Before operating any RGE, the operator shall ensure they are familiar with the unit's operating characteristics, as well as the purpose and function of protective devices. Any operator who has questions concerning or doubts regarding the operation of a unit shall immediately seek guidance from their supervisor or other appropriate individual.

7.4. Operators shall report promptly to their supervisor or departmental CP any condition they know or suspect may constitute, lead to or cause a violation of regulations, or unnecessary exposure to radiation. If the condition goes uncorrected the operator shall report the condition to the Radiation

Safety Office.

7.5. Operators shall minimize their and other individuals in the restricted area radiation exposure by:

7.5.1. Reducing the time in the restricted area;

7.5.2. Staying as far away as possible from the radiation beam (e.g., increasing distance); and

7.5.3. Wearing required protective shielding (e.g., lead apron).

7.6. Operators shall minimize radiation exposure to members of the public by:

7.6.1. Closely following RGE operating procedures;

7.6.2. Not overriding interlocks or other safety features; and

7.6.3. Ensuring unauthorized and unprotected members of the public are not in the restricted area whenever an RGE is energized.

7.7. Operators shall ensure patient protection by:

7.7.1. Except for dental, questioning female patients of childbearing age (12 years old or older) regarding the possibility of pregnancy;

7.7.1.1. If the patient's response is anything but "no" or equivalent, the operator shall seek medical advice from a Radiologist, Cardiologist and/or the prescribing physician about whether the procedure should be performed.

7.7.1.2. If the patient is determined to be pregnant after the procedure, a Radiologist, Cardiologist and/or prescribing physician, and the CRE or qualified designee shall be informed.

7.7.1.2.1. The consulting physicist shall perform a fetal dose calculation.

7.7.1.2.2. If the fetal/embryo dose from an unintended exposure is less than or equal to an estimated dose of 50 mGy, deterministic health effects are not detectable, and the risk of stochastic effects is less than one percent. A record of the exposure and the doses involved will be maintained so procedures can be implemented to reduce the chance of further unintended exposures. No specific action regarding the embryo or fetus, other than assurance of the accuracy of the estimated dose, is warranted.

7.7.1.2.3. If the dose to the embryo/fetus from an unintended exposure exceeds an estimated dose of 50 mGy, expert medical evaluation and follow-up will be utilized on a case-by-case basis.

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

7.7.3. Verifying the identification of the patient prior to performing a procedure using one or more of the following methods:

7.7.3.1. Comparing the patient's name as listed on chart against the order;

7.7.3.2. Comparing the patient's name as listed on ID bracelet against the order;

7.7.3.3. Addressing the patient by name listed on the order;

7.7.3.4. Comparing the patient's demographics against those listed on the order; or

7.7.3.5. Comparing the patient's name as provided by a parent, guardian or significant other against the order.

7.7.4. Verification will include verbal confirmation with the patient and/or parent, guardian or significant other of the exam to be performed and the body part to be imaged.

7.8. Operators shall reduce radiation exposure to the patient by:

7.8.1. Applying good imaging techniques, including utilizing the automatic exposure control or having technique charts to assist in the selection of primary exposure factors, and collimating the x-ray beam to a size no larger than necessary to demonstrate the part examined;

7.8.2. Using correct patient positioning;

7.8.3. Minimizing fluoroscopy time;

7.8.4. Performing only those exams that are essential for proper diagnosis;

7.8.5. Minimizing "repeat" exposures; and

7.8.6. Having protocols in place:

7.8.6.1. Which indicate the number and/or series of images to be taken to prevent unnecessary exposure;

7.8.6.2. Collimating the areas of interest to avoid unnecessary exposure to breast tissue, gonads, thyroid and eye; and

7.8.6.3. Using compensation/protective filters when appropriate and/or possible.

7.9. Operators shall avoid holding patients by:

7.9.1. Ensuring that reasonable efforts are being taken to not hold a patient during a radiographic examination and that dental patients are not held; (Note: holding patients for dental is not allowed as it is against Ohio rules)

7.9.2. Using immobilization devices, restraint devices, and remote handling devices shall be used whenever possible to avoid holding patients; and

7.9.3. If someone must hold a patient, efforts shall be made to recruit a non-occupationally exposed individual for this purpose and the operator shall:

7.9.3.1. Question the individual, if applicable, of the possibility of pregnancy;

7.9.3.2. Instruct the individual about what protective equipment must be worn (The protective equipment shall include a lead apron of at least 0.5-mm lead equivalent and, if the individual's hands may be in the primary beam, lead gloves of at least 0.25-mm lead equivalent); and

7.9.3.3. Instruct the individual about where they should stand (This instruction shall include standing in a position that keeps the individual's body outside the primary beam).

7.10. Operators shall not be a minor.

8. Training Requirements

8.1. RGE Radiation Worker (RW) Training

8.1.1. Only individuals who meet the qualifications for an operator of human- use RGE may operate RGE.

8.1.2. Prior to allowing an individual to operate a human-use RGE, the contact person (CP) shall:

8.1.2.1. Ensure the individual either a licensed practitioner, is licensed in accordance with OAC 3701-72 or is certified or licensed in accordance with ORC 4715;

8.1.2.2. Ensure the individual has obtained radiation protection training. Generally, this training consists of viewing the general radiation protection training film. The minimum training shall include:

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

8.1.2.2.2. 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; and

8.1.2.2.3. Applicable warning signage.

8.1.2.3. Provide instruction with respect to area specific information and departmental procedures for RGE and the operation of each type of RGE to be operated.

8.1.2.3.1. Instruction shall include the area specific:

8.1.2.3.1.1. Applicable warning signage;

8.1.2.3.1.2. The location of the restricted area; and

8.1.2.3.1.3. A description of the RGE in use.

8.1.2.4. Ensure the individual has completed any necessary RGE specific training.

8.1.2.4.1. Fluoroscopy units, including C-arms and digital cine – RGE special training is required for individuals who operate fluoroscopy units. Prior to operating a fluoroscopy unit individuals shall:

8.1.2.4.1.1. Review the fluoroscopy training manuals;

8.1.2.4.1.2. Pass the fluoroscopy test; and

8.1.2.4.1.3. Receive equipment specific training.

8.1.3. Annually, competency shall be maintained by:

8.1.3.1. A competency review by the supervisor that can include, but is not

limited to, an assessment of the individual's operating ability for each pertinent RGE classification. The assessment may be performed:

8.1.3.1.1. By the individual reviewing their skills with the supervisor;

8.1.3.1.2. The supervisor observing the individual operating the piece of equipment; and/or

8.1.3.1.3. educational material review, e.g., newsletter or pamphlet.

8.1.4. New equipment - when new RGE is installed all operators shall be trained in the operation by:

8.1.4.1. the manufacturer;

8.1.4.2. An operator or supervisor who was trained by the manufacturer: (or)

8.1.4.3. An operator or supervisor who is skilled at using the RGE i.e., a competent resource/super user.

8.1.5. Changes to operating procedures and the QA Program shall be communicated to applicable operators in a timely manner but no later than 60 days after the change by:

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

8.1.5.2. Addition of revised protocol in the departmental manual.

8.1.6. Any special or non-routine procedures must be performed under the direct supervision of a physician.

8.2. Ancillary Radiation Worker (AW) Training

8.2.1. Ancillary Workers shall receive general radiation protection training. Generally, this training consists of viewing a radiation safety awareness training film during new employee orientation. The RCSP radiation safety awareness training film may also be viewed on the Radiation Safety website (Radiation Safety Office). The minimum training shall include:

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

8.2.1.2. 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;

8.2.1.3. Applicable warning signage; and

8.2.1.4. The location of the restricted area which may be provided by the area Contact Person (CP), equipment operator, department manager or other qualified individual.

8.3. Training for Exposed Public

8.3.1. Training for members of the public in the restricted area, e.g., family member holding patient, shall include instruction by the operator on procedures to minimize dose, which shall include:

8.3.1.1. Wearing a lead apron of at least 0.5 mm lead equivalent and, if the individual's hands may be in the primary beam, lead gloves of at least 0.25 mm lead equivalent; and

8.3.1.2. Where the individual should stand during the procedure.

8.4. Patient Training

8.4.1. Departments that perform procedures involving RGE shall maintain electronic access to digital informational material on procedures routinely performed.

8.4.2. Informational material shall be reviewed and explained upon request or as considered necessary by the prescribing physician.

8.5. Training Records

8.5.1. Training records shall be maintained in a readily accessible file(s).

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

8.5.3. Each Department, through the CP, is responsible for maintaining all required training records.

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

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

8.5.4. Copies of records documenting completion of initial training shall be provided to the Radiation Safety Office upon application for dosimetry and shall be maintained by the Radiation Safety Office with the individual’s RGE radiation worker records.

8.5.5. Copies of records documenting an individual has completed fluoroscopy initial training shall be maintained by the department operating the equipment.

9. Radiation Safety Procedures

9.1. General Radiation Safety Procedures for all RGE

9.1.1. All individuals shall wear their assigned dosimeters as required. (see radiation monitoring requirements, section 10).

9.1.2. Individuals whose presence during an exam is not required should not stay as an observer unless required as a part of the clinical learning process.

9.1.3. Reasonable efforts shall be made to avoid holding patients for radiologic examinations. Immobilization devices and restraint devices shall be used whenever possible to avoid holding patients. If someone must hold a patient, efforts should be made to recruit a non-occupationally exposed individual for

this purpose. If an individual must hold a patient, adequate protective clothing shall be worn to protect the exposed individual and they should stand in a position that keeps their body outside of the primary beam path.

9.1.4. Individuals in the restricted area shall minimize their radiation exposure by:

9.1.4.1. Minimizing the time spent in the restricted area;

9.1.4.2. Staying as far away as possible from the radiation beam (e.g., increasing distance); and

9.1.4.3. Wearing required protective shielding:

9.1.4.3.1. Aprons of at least 0.5 mm lead equivalence at the front of the shield shall be worn by all individuals in the restricted area;

9.1.4.3.2. Gloves of at least 0.25-mm lead equivalence shall be worn by all individuals whose hands are in or close to the "primary beam" because of the need to hold a patient; and

9.1.4.3.3. Collar shields (i.e., thyroid shields) of at least 0.5 mm lead equivalence shall be worn by individuals who risk significant exposure to the head and neck (e.g., within a few feet of an energized fluoroscopic unit or C-arm).

9.1.5. If a mobile shield is used as a primary barrier, the location for shield placement shall be clearly indicated (e.g., colored tape placed on floor marking location).

9.1.6. If a door is used as a primary barrier, the door must be closed during operation.

9.2. Additional Radiation Safety Procedures, by RGE Type

9.2.1. Safe operating procedures (SOPs) will be developed and posted for each RGE category on the current inventory. These may include additional specific procedures related to stationary, mobile, or hand-held radiographic, fluoroscopic, CT or dental RGE units, and shall comply with the applicable ODH standards for the RGE category.

9.2.1.1. RGE- specific SOPs shall be reviewed and updated during the annual RSOf audit.

9.2.2. Machine specific action levels for Entrance Skin Exposure (ESE), CTDI or a similar reference value (refer to Section 13.1.1.4) shall be established and followed for fluoroscopy and CT units.

9.2.3. Patients receiving an exposure greater than these levels will be evaluated at an approximately 3-week interval to assess the possibility of radiation induced skin changes and referred to the appropriate department personnel for follow-up, in accordance with hospital policy.

9.2.4. Operators shall follow departmental procedures for injection of contrast media and allergic reaction review and follow-up.

9.2.4.1. Operators shall be responsible to make every reasonable effort to minimize exposure to both the patient and personnel by:

9.2.4.1.1. Avoiding unnecessary exposures;

9.2.4.1.2. Utilizing dose-reduction techniques when available on the equipment; and;

9.2.4.1.3. Installing and using protective drapes or barriers unless it interferes with the procedure or compromises a sterile field.

9.2.5. If safety features ever malfunction, the unit shall not be used and the operator shall immediately report the problem to their supervisor and the appropriate CRE.

9.3. Additional Radiation Safety Requirements for Specific Workers

9.3.1. Pregnant Workers

9.3.1.1. Pregnant individuals are not considered declared pregnant workers until they declare the pregnancy in writing to the Radiation Safety Office. The declaration must include:

9.3.1.1.1. The name of the individual;

9.3.1.1.2. The date of declaration;

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

9.3.1.1.4. The estimated date of conception.

9.3.1.2. The radiation dose limit to the fetus/embryo of a declared pregnant worker is 500 millirem (0.500 rem) total effective dose equivalent over the term of the pregnancy.

9.3.1.3. Pregnant workers may request a meeting with the IRRP/RSO. The IRRP/RSO will:

9.3.1.3.1. Review the individual's exposure record. If the record indicates an exposure to the embryo/fetus greater than 500 millirem may occur, the IRRP/RSO will initiate steps to move the individual to a position of lower radiation exposure and one that the exposure can be maintained less than 500 millirem;

9.3.1.3.2. Review procedures to minimize exposure to the embryo/fetus; and

9.3.1.3.3. Answer any questions the individual may have.

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

9.3.1.5. Declared pregnant individuals shall not enter or be in a restricted area unless they are wearing a lead protective apron. Pregnant individuals should consider wearing the wrap-around type apron whenever possible as they provide the best protection.

9.3.1.6. Pregnant individuals will be provided either a physical or electronic copy of NRC regulatory guide 8.13 upon request or written declaration. This guide covers the effects of radiation to the embryo and fetus.

9.3.2. Minors

9.3.2.1. Minors shall have written authorization from their parents or guardians authorizing their potential exposure to radiation. Both the “Release of

Liability and Waiver Claim for Minors" form (RS Form 38) and the "Supervisor's Statement for Minors" form (RS Form 38A) shall be completed. Both forms are available on the Radiation Safety website (Radiation Safety Office).

9.3.2.2. Minors, who have obtained the appropriate written authorization, are limited to a radiation dose that is 10% of the limits for other workers.

10. Radiation Monitoring Requirements

10.1. Exposure Limits

10.1.1. The annual occupational radiation exposure limits are in accordance with OAC 3701:1-38-12.

10.2. General Personnel Dosimeter Requirements

10.2.1. In accordance with regulations, at a minimum a dosimeter shall be worn by all personnel who may receive greater than 10% of the annual occupational dose limit. However, under the RCSP additional (more restrictive) dosimetry is required as outlined in this manual or as deemed necessary by the RSC.

10.2.2. Dosimeters are also required as outlined in section 10.3 of this manual or as deemed necessary by the RSC.

10.2.3. Exemptions from dosimetry requirements outlined in section 10.3 of this manual may be approved by the RSC on a case-by-case basis.

10.2.3.1. Requests for exemptions shall be submitted, in writing, to either the IRRP/RSO or directly to the RSC and shall include:

10.2.3.1.1. The reason for the request; and

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

10.2.4. Dosimeters used for individuals exposed to RGE shall be able to detect photon radiation.

10.2.5. Dosimeters shall be provided by and applied for through the Radiation Safety Office.

10.3. Dosimetry for RGE Radiation Workers (RW)

10.3.1. Radiographic units

10.3.1.1. One dosimeter outside the apron, at the collar.

10.3.2. Dental radiographic units

10.3.2.1. One dosimeter worn at the collar.

10.3.2.2. If an apron is worn, the dosimeter is to be worn outside the apron.

10.3.2.3. Except for students and faculty in an academic program the dosimetry is optional.

10.3.3. Basic fluoroscopy units

10.3.3.1. One dosimeter outside the apron, at the collar.

10.3.4. If an individual's hands are likely to receive a dose that is 10% or more of the applicable limit, hand dosimetry is also required. A ring dosimeter shall be worn on each hand frequently in or near the x-ray beam.

10.4. Dosimetry for Ancillary Radiation Workers (AW)

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

10.4.2. Dosimeter requirements for frequently exposed AW are equivalent to that for RW.

10.5. Dosimetry for Declared Pregnant Workers

10.5.1. Declared pregnant workers who frequent the restricted area shall be assigned two dosimeters and shall wear the dosimeter at the location indicated on the label.

10.5.1.1. One dosimeter worn outside the apron, at the collar; and

10.5.1.2. Second dosimeter worn under the apron, at waist level (labeled as fetal).

10.6. Area Dosimeter Option

10.6.1. A CP may request an area dosimeter for placement in a location of interest to monitor radiation exposure at the location. Locations of interest may include the control panel or locations where members of the public may frequent.

10.7. Care of Dosimeters

10.7.1. Personal radiation dosimeters are for use by a single individual and shall not be shared, reassigned or discarded. Area dosimeters are for use at a single designated location.

10.7.2. Personnel and area dosimeters issued by the University of Cincinnati are limited for use to monitor radiation exposure from radiation sources covered by the RCSP.

10.7.3. Radiation dosimeters do not provide protection from radiation; it only provides an "after the fact" assessment of radiation to which it (and presumably the wearer) was exposed.

10.7.4. Radiation dosimeters shall be worn at the position appropriate for the work being performed (see dosimeters for RW, section 10.3).

10.7.5. Radiation dosimeters are very sensitive to environmental conditions such as heat, light and moisture. Dosimeters should be used properly, should not be

taken home or stored in cars or on windowsills.

10.7.6. 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.

10.7.7. Personnel radiation dosimeters are for occupational exposure only and are NOT to be worn during personal medical or dental procedures.

10.8. Dosimetry Analysis and Reports

10.8.1. Personal dosimeters must be returned in a timely fashion to the Radiation Safety Office for analysis.

10.8.2. Dosimeter analysis reports are sent by the vendor to the Radiation Safety Office. Copies are maintained in the Radiation Safety Office. Copies are forwarded as follows:

10.8.2.1. Monthly and quarterly series analysis reports are forwarded to:

10.8.2.1.1. The CP of departments that request in writing copies of the monthly/quarterly report and provide assurance the information will not be provided to individuals other than the specific monitored individual or supervisory personnel; and

10.8.2.1.2. The appropriate CRE or IRRP.

10.8.2.2. Individual analysis reports:

10.8.2.2.1. Monitored personnel shall be provided copies of the previous year's exposure as an individualized report in accordance with OAC 3701:1-38-10.

10.8.2.2.2. Monitored personnel are provided copies of individual dosimeter reports upon request. Requests must be made to the Radiation Safety Office. 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.

10.9. Dosimetry Exchange Procedures

10.9.1. To prevent unmonitored exposure, before used dosimeters are returned, new dosimeters are picked up from RSOf or delivered by RSOf.

10.9.2. Monthly dosimeters must be picked up by the third working day of the month. Quarterly dosimeters must be picked up by the third 3 working day of the quarter.

10.9.3. Monthly dosimeters from the previous month must be returned by the 10th day of the month after use. Quarterly dosimeters from the previous quarter must be returned by the 10th day of the quarter after use.

10.9.4. All late returned and non-returned dosimeters may result in inquiry or investigation by the Radiation Safety Office.

10.10. Lost, Late Return or Damaged Dosimeters

10.10.1. Lost or damaged dosimeters shall be reported immediately to the

Radiation Safety Office.

10.10.2. Temporary replacement dosimeters will be issued upon notification to RSOf if dosimeters are lost or damaged prior to the return exchange.

10.10.3. A radiation dosimeter follow-up may be required to be completed for all lost, late return and damaged dosimeters.

11. ALARA and Overexposure Investigations and Notifications Procedures

11.1. ALARA Investigations and Notifications

11.1.1. ALARA investigations shall be performed when individuals exceed 10% and 30% of the applicable regulatory limits for general radiation workers. However, because regulations for RGE include quarterly limits that are equal to the annual limit divided by 4, the 10% and 30% is applied to the quarterly fraction. The current ALARA investigation level doses are outlined in Appendix B.

11.1.2. ALARA I (greater than 10% but less than 30% of regulatory limit)

11.1.2.1. The IRRP/RSO or designee will:

11.1.2.1.1. Provide a written report of the exposure to the individual;

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

11.1.2.1.3. Report the results to the RSC at the next scheduled meeting.

11.1.2.2. The CRE will:

11.1.2.2.1. Review the exposure and the explanation, then investigate if deemed necessary.

11.1.3. ALARA II (greater than or equal to 30% of regulatory limit)

11.1.3.1. The IRRP/RSO or designee will:

11.1.3.1.1. Provide a written report of the exposure to the individual; and

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

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

11.1.3.2.1. Investigate the cause(s) of the exposure;

11.1.3.2.2. Implement corrective action as deemed necessary; and

11.1.3.2.3. Report the results to the RSC at the next scheduled meeting.

11.2. Worker Overexposure Investigations and Notifications

11.2.1. When an exposure in excess of regulatory limits is suspected the CRE and IRRP/RSO shall be notified.

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

11.2.2.1. Investigate the possible overexposure;

11.2.2.2. Notify the Director of the Ohio Department of Health within 30 days. The notification shall include:

11.2.2.2.1. An estimation of the individual's dose;

11.2.2.2.2. The levels of radiation involved;

11.2.2.2.3. The cause of the exposure; and

11.2.2.2.4. Any corrective action taken or planned to assure against recurrence.

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

11.2.2.3.1. The nature and extent of the exposure; and

11.2.2.3.2. The following statement:

11.2.2.3.2.1. "This report is furnished to you under provisions of rule 3701:1-38-10 of the Administrative Code. You should preserve this report for further reference."

12. Postings and Signs

12.1. Posting and signage is a primary mechanism used to inform and protect the public from radiation exposure from human-use RGE.

12.2. Each department where RGE is used shall post in conspicuous locations:

12.2.1. ODH notice to employees;

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

12.2.3. Location(s) where applicable rules and regulations are maintained;

12.2.4. Method for contacting the CRE, if applicable;

12.2.5. Method for contacting the IRRP/RSO; and

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

12.3. Signs reminding patients to inform the technologist/therapist prior to a study if there is a possibility

of pregnancy exist shall be posted in:

12.3.1. All human-use RGE exam rooms.

13. Patient Incident Action

13.1. QA Recordable Patient RGE Incidents ("recordable" incidents include those that may or may not be reportable to the ODH):

13.1.1. Patient recordable incidents description:

13.1.1.1. The wrong patient;

13.1.1.2. The wrong site (i.e., wrong body site);

13.1.1.3. A dose to an embryo or fetus that was unintended and/or unknown prior to the radiological procedure; and

13.1.1.4. Based on Entrance Skin Exposure (ESE) Threshold Value set by the CRE the CRE will determine a machine specific action level. If a clinical procedure exceeds that action level, the patient call- back and follow-up procedure will be initiated.

13.1.1.5. Reporting – patient recordable incidents shall be reported to:

13.1.1.5.1. The appropriate CRE;

13.1.1.5.1.1. If the CRE determines the incident is the result of a significant problem or concern, the CRE will convene a special meeting consisting of the IRRP/RSO and a select number of RSC voting members; otherwise, the incident will be reported to the RSC at the next regular meeting.

13.1.1.5.1.2. The appropriate Risk Management Office, if necessary and in accordance with the Universities incident reporting process.

13.1.2. Other recordable incidents and action to be taken:

13.1.2.1. Any problems with the operation of RGE shall be reported immediately to the supervisor and/or department CP.

13.1.2.2. Any problems reported to the supervisor and/or department CP that are not corrected in a reasonable amount of time shall be reported to the IRRP/RSO and/or the CRE.

13.1.2.3. Any problems with the operation of RGE that may result in an overexposure to personnel shall be reported immediately to the area supervisor, CRE and IRRP/RSO (i.e., exposure greater than allow limits located in sections 9.3.1.3.1, 9.3.2 and 10.1.1).

13.1.2.3.1. The CRE, in conjunction with the CP and IRRP/RSO shall investigate the problem and implement corrective action.

13.1.2.4. Any suspected personnel overexposure shall be immediately reported to the CRE and IRRP/RSO.

13.1.2.4.1. The CRE, in conjunction with the IRRP/RSO, shall investigate the overexposure and submit required reports to the Ohio Department of Health when required.

13.1.2.4.2. The CRE will provide a report on the overexposure to the IRRP/RSO and reported at the next scheduled RSC meeting.

13.1.2.5. Any radiation safety issues or concerns, submitted in writing, associated with radiation workers, hospital or support staff, and/or the general public shall be forwarded to the IRRP/RSO and/or the CRE.

13.1.2.5.1. The CRE will provide a report, including investigation action, to the IRRP/RSO to be reported at the next scheduled RSC meeting.

13.2. QA Reportable Patient RGE Incidents ("reportable" incidents are ones, by rule, which require a written report to the ODH or TJC):

13.2.1. "Overexposures" to personnel

13.2.1.1. "Overexposure" to personnel means greater than the limit(s) allowed by regulation.

13.2.1.2. “Overexposures” to personnel shall be reported by the IRRP/RSO to:

13.2.1.2.1. The Director of Health; and

13.2.1.2.2. The RSC.

13.2.1.3. “Overexposure” to personnel reports to the Director of Health shall be made by the IRRP/RSO:

13.2.1.3.1. Immediately by phone if personnel exposures of 25 rem or more to the whole body; 75 rem or more to the lens of the eye, and/or 250 rem or more to skin, an extremity or an organ. (Note: this must be followed by a written report as detailed in paragraph 13.2.1.4 of this manual.);

13.2.1.3.2. Within 24 hours by phone if personnel exposures of 5 rem or more to the whole body, 15 rem or more to the lens of the eye, 50 rem or more to the skin an extremity or an organ. (Note: this must be followed by the written report detailed in paragraph 13.2.1.4 of this manual.); and

13.2.1.3.3. Within 30 days, in writing if personnel exposure is greater than allowable limits.

13.2.1.4. Written reports of “overexposures” to personnel to the Director of

Health shall include:

13.2.1.4.1. The extent of the exposure;

13.2.1.4.2. The cause of the exposure; and

13.2.1.4.3. The corrective steps taken or planned to be taken to prevent recurrence.

13.2.1.5. Written reports regarding "overexposures" to personnel shall be sent by the IRRP/RSO to the individual receiving the overexposure. This report shall be in writing and shall:

13.2.1.5.1. Be made prior to a written report being submitted to the Director of Health; and

13.2.1.5.2. Include the wording identified in OAC 3701:1-38.

14. Intervals and Procedures for Evaluation of RGE

14.1. CRE/RE testing: Non-hospital human-use RGE evaluations shall include image quality, evaluations as appropriate for the equipment as established by a radiation expert or system manufacturer.

14.1.1. Non-hospital human-use RGE shall be valuated by a CRE, a RE or the ODH in accordance with the following schedule:

14.1.2. Evaluations shall include image quality evaluations as appropriate for the equipment as established by a radiation expert or system manufacturer.

14.1.3. Each radiography unit shall be evaluated upon receipt and biennially thereafter;

14.1.4. Each mobile unit shall be evaluated upon receipt and annually thereafter;

14.1.5. Each fluoroscopic unit shall be evaluated prior to first use and annually thereafter;

14.1.6. Each CT unit shall be evaluated prior to first use and annually thereafter; and

14.1.7. Each dental unit shall be evaluated upon receipt and biennially thereafter.

14.1.7.1. Dental hand-held units shall be evaluated prior to first use and annually thereafter.

14.2. RSOf audits and surveys: All human-use RGE on a University of Cincinnati campus shall be audited by the Radiation Safety Office annually for compliance with QA requirements.

14.3. Preventative maintenance (calibration) shall be documented in the RGE's maintenance log: Each human-use RGE shall have preventative maintenance and, if necessary, calibration preformed in accordance with the following schedule:

14.3.1. Each radiography unit shall be evaluated annually;

14.3.2. Each mobile unit shall be evaluated annually;

14.3.3. Each fluoroscopic unit shall be evaluated annually;

14.3.4. Each CT unit shall be evaluated annually; and

14.3.5. Each dental unit shall be evaluated biennially.

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

14.5. Evaluation follow-up:

14.5.1. Any RGE that fail an evaluation, i.e., evaluation results outside limiting criteria, within 60 days shall be removed from service or repaired.

14.5.2. Any RGE which is determined is unsafe or unacceptable shall be removed from service and must be evaluated prior to being placed back into service.

15. Quality Control (QC) Tests

15.1. General QC Requirements

15.1.1. QC tests and routine preventative maintenance of RGE-based diagnostic imaging devices (image acquisition, display, printing) shall be performed in accordance with the manufacturer's recommendations and approved by the CRE and/or IRRP/RSO.

15.1.2. Requests for less restrictive criteria than manufacturer's recommendations require justification that the difference will not negatively impact clinical care and image quality.

15.1.3. The CRE and/or IRRP/RSO may require more restrictive criteria than manufacturer recommendations.

15.2. QC Test Training

15.2.1. Prior to performing any QC test an individual shall receive appropriate training as deemed necessary by Departmental Supervisor and/or the CRE. At a minimum, this training shall include:

15.2.1.1. Demonstration of how to perform the QC test by a trained individual; (and)

15.2.1.2. Observation by a trained individual of the trainee performing the test.

15.3. QC for Imaging Equipment

15.3.1. General requirements:

15.3.1.1. Quarterly repeat/reject analysis.

15.3.2. Specific requirements for acquisition equipment:

15.3.2.1. CR systems:

15.3.2.1.1. Regular cleaning and primary erasure;

15.3.2.1.2. Monthly QC of CR reader; and

15.3.2.2.3. Semiannual check of CR cassettes.

15.3.2.2. DR systems:

15.3.2.2.1. Detector calibration shall follow manufacturer's recommendations.

15.3.3. Specific requirements for display equipment:

15.3.3.1. Regular self-diagnosis, including from manufacturer's software; and

15.3.3.2. Annual performance assessment that includes a visual evaluation of a test pattern.

15.4. QC for Personnel Protective Equipment

15.4.1. Annual apron checks of lead apparel for cracks, holes or penetrations through the lead; and

15.4.2. Annual check of lead drapes for cracks, holes or penetrations through the lead.

15.5. QC for RGE Testing Equipment

15.5.1. Annual calibration of radiation survey equipment; and

15.5.2. Biennial calibration of kVp and radiation exposure meters.

15.6. QC Corrective Action

15.6.1. Any equipment that does not meeting QC standards shall be removed from service, unless approved in writing by the CRE or IRRP/RSO.

15.6.2. Any equipment removed from service due to not meeting a QC standard must be rechecked prior to returning to service.

15.7. QC Record Maintenance

15.7.1. A listing of all equipment used for QC shall be maintained by the CP. The list of QC equipment shall be maintained in a readily auditable form.

15.7.2. A record of all calibration of instruments used for QC or on which QC is performed shall be maintained by the CP. The record shall be maintained in a readily auditable form.

16. RGE Logs and Operation Manuals

16.1. Maintenance Logs

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

16.1.1.1. Identification of the piece of equipment;

16.1.1.2. Incidents and actions;

16.1.1.3. Maintenance performed; and

16.1.1.4. Repair information.

16.2. Fluoroscopy Logs, or Equivalent

16.2.1. Each RGE that is classified as a fluoroscopy unit, including C-arms and CT's operated in the fluoroscopy mode shall have a record maintained of patient radiation exposure.

16.2.2. The record must include:

16.2.2.1. The patient's name and medical record number;

16.2.2.2. The date of exam;

16.2.2.3. The procedure(s) performed;

16.2.2.4. The physician operator's name; and

16.2.2.5. The procedure's total air kerma or dose area product, or alternately the mode of operation (e.g., high or pulsed mode), the cumulative fluoroscopy time and/or the number of spot images.

16.2.3. The record must be readily available for audit/inspection and maybe maintained:

16.2.3.1. As an individual log by fluoroscopy unit;

16.2.3.2. In the patient's record; or

16.2.3.3. In a patient radiation management system.

16.3. Operations Manuals

16.3.1. Each RGE shall have an operation manual, which is readily available as a reference to operators.

16.3.2. For each RGE type there shall be a safe operating manual, which is readily available as a reference to operators.

16.4. Maintenance of Logs and Manuals

16.4.1. RGE logs and manuals shall be maintained in or accessible from (e.g., computer terminal) the area (e.g., room) where the RGE is housed.

16.4.2. RGE logs and manuals shall be readily available for use by the operator and inspection by the CRE, IRRP/RSO, CP or state inspector.

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

17.1. Acquisition (purchase or loaner) of New RGE

17.1.1. The acquisition of all RGE shall be reported to the IRRP/RSO and the CRE.

17.1.1.1. For purchase orders, reporting shall be within (30) days of order

placement, but prior to receipt of new RGE.

17.1.1.2. For loaners, reporting shall be as soon as possible, within (5) days prior to receipt of the loaner RGE and prior to use.

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

17.1.2.1. Individual responsible name;

17.1.2.2. Department;

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

17.1.2.4. Description of machine (make, model);

17.1.2.5. Number of tubes with tube serial numbers;

17.1.2.6. Expected delivery date; and

17.1.2.7. Planned location.

17.1.3. 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.

17.1.4. The CRE and CP shall arrange a time for initial acceptance testing.

17.1.4.1. Initial acceptance testing shall be performed:

17.1.4.1.1. Within 30 days of installation for all other units and prior to use.

17.1.4.2. Initial acceptance testing shall include:

17.1.4.2.1. Evaluation testing in accordance with state regulations and/or manufacturer's recommendations.

17.1.4.2.2. For fluoroscopy and CT units, room evaluation testing for compliance with rules pertaining to exposure to members of the public and/or radiation workers, with copies of the room evaluation shall be forwarded to the IRRP/RSO; and

17.1.4.2.3. If applicable, room safety feature evaluation testing (e.g., interlocks, remote visual).

17.2. RGE Inventories

17.2.1. The Radiation Safety Office shall maintain an inventory of RGE.

17.2.2. The inventory will be reviewed by the applicable department CP quarterly.

17.2.2.1. By the 15th day of the second month of each calendar quarter (i.e., February, May, August, November), the Radiation Safety Office shall have available the current inventory to appropriate CP via the Gamma 2 Web application.

17.2.2.2. Each CP shall review the inventory, indicate changes, then sign and digitally submit the inventory record to the Radiation Safety Office

via the Gamma 2 Web application by the end of the second month of each calendar quarter.

17.2.2.3. The IRRP/RSO will review the results and ensure the inventory is in accordance with the applicable registration. If necessary, the IRRP/RSO shall amend the registration.

17.3. Disposal or Transfer of RGE

17.3.1. Prior to disposal or transfer of RGE by their department, the CP shall inform the IRRP/RSO and the CRE about the disposal or transfer.

17.3.2. Information provided to the IRRP/RSO shall include:

17.3.2.1. Name and location (e.g., address of the facility) where the material will be disposed or transferred;

17.3.2.2. The make, model and serial number of the RGE being transferred or disposed;

17.3.2.3. The company or individual responsible for removal of equipment;

17.3.2.4. The "ship to destination" phone number; and

17.3.2.5. The anticipated date of disposal or transfer.

17.3.3. The Gamma 2 Web application should be used to document disposal or transfer of RGE. The RGE transfer and disposal options are found under the "Inventory" header and the "RGE Inventory Verification" sub-header.

17.4. Inoperable RGE

17.4.1. The CP shall notify the IRRP/RSO whenever a previously operable RGE is determined to be inoperable.

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

17.4.1.2. Notification shall be completed via the Gamma 2 Web application; and

17.4.1.3. The CRE or IRRP/RSO shall promptly confirm the RGE is inoperable, determine an approximate time period for repair, and assure the CP is aware that the IRRP/RSO must be promptly informed once the unit is repaired.

17.4.2. The CP shall notify the IRRP/RSO whenever a previously operable RGE unit is repaired.

17.4.2.1. Notification shall be within 5 business days of the CP becoming aware the RGE is operable;

17.4.2.2. Notification shall be via the Gamma 2 Web application, which may include electronic mail; and

17.4.2.3. The CRE or IRRP/RSO shall promptly make arrangements to survey the unit.

17.4.3. If during an audit an RGE is determined to be inoperable, the auditor (e.g., CRE or IRRP/RSO delegate) shall ensure a University of Cincinnati Radiation Control and Safety Program Inoperable/X-ray/Radiation Generating Equipment Form (RS Form 39) is completed or is on file in the RSOf and the CP is aware of the requirements for promptly informing the IRRP/RSO when the unit is repaired.

17.5. From the information provided, the IRRP/RSO shall submit any necessary quarterly reports to the Ohio Department of Health covering the installation, disposal, transfer, or change in operability status of RGE.

18. RGE Room Construction - New or Remodeled

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

18.1.1. The appropriate CRE, or qualified designee, shall perform shielding analysis of the design to ensure the rooms meet the requirements for exposure to members of the public; and

18.1.2. Any design document for shielding shall require acceptable approval by the appropriate CRE or qualified designee prior to start of construction.

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

18.2.1. 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

18.2.2. The CRE, or qualified designee, shall review, as necessary, the construction to ensure shielding is being installed in accordance with the design specifications.

18.3. After construction, but prior to use of a new RGE room or remodeling of an existing RGE room:

18.3.1. The CRE or qualified designee shall perform all necessary surveys to ensure the room meets the requirements for exposure to members of the public; and

18.3.2. If applicable, room safety feature evaluation testing (e.g., interlocks, remote visuals).

Appendix A
Forms

Associated Radiation Safety Forms

RS FORM 38	RELEASE OF LIABILITY AND WAIVER CLAIM FOR MINORS
RS FORM 33	DECLARATION OF PREGNANCY
RS FORM 38A	SUPERVISOR'S STATEMENT FOR MINORS

Forms Available on Radiation Safety Website
Radiation Safety Office

Appendix B

ALARA Investigational Levels

ALARA Investigational Levels

AREA/DOSE	ALARA I (10%) LEVEL	ALARA II (30%) LEVEL
Effective Dose*	125 mrem	375 mrem
Any organ, other than eye	1250 mrem	3750 mrem
Eye	375 mrem	1125 mrem
Skin	1250 mrem	3750 mrem
Extremity	1250 mrem	3750 mrem

Effective dose based on "Webster Formulas" if a lead apron is worn. If two dosimeters are worn the effective dose = 0.04 (collar-outside apron dosimeter reading) + 1.5 (waist-under apron dosimeter reading). If one dosimeter is worn the effective dose = 0.3 (collar-outside dosimeter reading)