THE OHIO STATE UNIVERSITY

Wexner Medical Center

Quality Assurance and Radiation Protection Program and Manual

Human-Use Radiation Generating Equipment

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1. General

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

B. This manual is for each department using RGE and each contact person (CP) responsible for human-use. The manual must be readily available to personnel for consultation and information purposes.

C. This manual incorporates quality assurance (QA) and radiation protection policies, procedures and guidelines. The University Radiation Safety Committee (URSC) and the Quality Assurance Committee (QA Committee) have reviewed and approved the initial version and each subsequent revision of this manual.

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

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)/URSO. (Any individual may make a suggestion for change to the CRE and/orIRRP/URSO.)

2) Second - review and approval by the QA Committee.

E. The IRRP/URSO is responsible for distributing copies of each revision to each CP andmember of the QA Committee within 30 days of approval.

F. The Departmental 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 approval.

G. The IRRP/URSO is responsible for ensuring the current version of the manual is posted on the Radiation Safety website.

H. All individuals operating RGE for human-use shall read and understand the pertinent sections of this manual.

2. Scope and Purpose

A. The scope of this program manual is intended to include human use RGE for facilities of the OSU Wexner Medical Center, including off-campus facilities staffed by Medical Center employees. Other OSU facilities may adopt policies from this manual, as applicable.

B. This manual defines those aspects of the OSUWMC quality assurance program required by the Ohio Administrative Code (OAC) including the provisions of quality assurance (QA) as listed in OAC 3701:1-66, OAC 3701:1-67 and radiation protection as listed in OAC 3701:1-38.

3. Definitions and Abbreviations

A. Definitions

1) Ancillary Radiation Worker (AW)

a) An individual who:

- is not a RGE radiation worker (RW)
- is in the restricted area (e.g., room) when the x-ray is on
- is performing a duty as part of their "job" (e.g., employee, student, volunteer)

2) Certified Radiation Expert (CRE)

a) an individual who is certified by the state of Ohio in accordance with OAC 3701:1-66-03

b) CRE must be appointed as designated in paragraph 4.3 of this manual

c) CRE categories are:

- therapeutic
- diagnostic, other than mammography
- mammography

3) Contact Person (CP)

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

4) Declared Pregnant Worker

a) A worker who has declared their pregnancy in writing to the Ohio State University Radiation Safety Office.

5) Exposed Public

a) An individual who:

- is not an RGE radiation worker
- is not an ancillary radiation worker
- is not the patient

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

b) Includes, but are not limited to:

- family, e.g., parent, guardian, spouse, significant other
- security/police officer
- patient attendant employed by another facility

6) “Fluoroscopically-guided interventional (FGI) procedures" means an interventional diagnostic or therapeutic procedure performed via percutaneous or other access routes, usually with local anesthesia or intravenous sedation, which uses external ionizing radiation in the form of fluoroscopy to localize or characterize a lesion, diagnostic site, or treatment site, to monitor the procedure, and to control and document therapy. This statement is focused on the FGI subset of potentially high-dose procedures.

7) Licensed practitioner

a) An individual licensed by the State of Ohio to practice

- dentistry
- medicine or surgery or osteopathic medicine or surgery
- podiatry
- chiropractic medicine
- clinical nurse specialist within the scope of practice of his or her collaborating physician and in accordance with the standard care arrangement
- as a physician assistant within the scope of practice of his or her supervisingphysician and in accordance with the utilization plan approved by the state medical board, and

b) An individual practicing within the scope of their license.

8) Individual Responsible for Radiation Protection (IRRP)

a) Individual Responsible for registrations under the Ohio State University Radiation Program who has the 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.

9) Minor

a) Any individual under the age of 18.

10) Radiation Expert

a) Any individual who meets the definition of a radiation expert outlined in OAC

3701:1-66-01.

11) Restricted Area

a) 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 larger

12) RGE Radiation Worker (RW)

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

b) 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.

B. Abbreviations

1) ALARA – As Low As Reasonably Achievable
2) AW - Ancillary Radiation Worker
3) CP - Contact Person
4) CRE - Certified Radiation Expert
5) IRRP - Individual Responsible for Radiation Protection
6) OAC - Ohio Administrative Code
7) ODH – Ohio Department of Health
8) QA - Quality Assurance
9) RE - Radiation Expert
10) RGE - Radiation-Generating Equipment
11) URSC – University Radiation Safety Committee
12) URSO - The Ohio State University Radiation Safety Officer
13) RSS – The Ohio State University Radiation Safety Section of EHS
14) RW - RGE Radiation Worker
15) TJC – The Joint Commission

4. QA Program

A. Scope of the QA Program: The QA Program addresses the following.

1) Intervals and procedures for evaluation of RGE
2) Radiation monitoring requirements including audits and surveys, occupational exposure limits, maintenance of records, and personnel and area monitoring
3) ALARA and overexposure notification procedures
4) Radiation safety specifics for each type of RGE
5) RGE operator training
6) General training

7) Quality control (QC) tests and frequencies
8) State licensure and certification requirements for operators
9) Notification of QA Program changes
10) RGE RW roles and responsibilities
11) Personnel protection
12) Prenatal exposure
13) AW training
14) QC task training
15) Patient protection
16) Protection of the public
17) Equipment logs
18) Posting and signage
19) Incident action

B. Overall Responsibility of the QA Program

1) Overall assurance for radiation safety and compliance to rules within the QA Program is the responsibility of the IRRP/URSO.

C. Oversight and Maintenance of the QA Program

1) Oversight and maintenance of the QA Program for hospital RGE is the responsibility of designated CRE(s) certified for the specialty by the Ohio Department of Health.

a) Radiation Therapy

- Appointment of a Therapeutic CRE is by and the responsibility of the Department of Radiation Oncology

b) Diagnostic units including mammography

- Appointment of a Diagnostic other than Mammography CRE, and a Mammography CRE, is appropriate to the applicable RGE is by and the responsibility of departments.

c) CRE's may delegate tasks to specified designees. CRE(s) shall provide the IRRP/URSO a list of names of approved designees.

2) Oversight and maintenance of the QA Program for non-hospital human-use RGE is the responsibility of the URSC.

D. Implementation of the QA Program

1) Implementation of the QA Program for hospital RGE is the responsibility of:

a) the QA Committee (and)

b) the CRE(s) and the IRRP/URSO

2) Implementation of the QA Program for non-hospital human-use RGE is theresponsibility of:
   a) The URSC
   b) The IRRP/URSO

5. QA Committee

A. General Requirements for the QA Committee
   1) Hospitals are required to have an official QA Committee.
   2) Changes to the QA Program require approval of the QA Committee prior to implementation.

B. Membership Requirements for the QA Committee
   1) Committee members will be approved by an executive administrator.
   2) Committee meetings may be attended by the members or similarly qualified, designated alternates.
   3) The QA Committee membership will include at least the following members:
      a) A member of executive administration
      b) The IRRP/URSO
      c) A radiologist or radiation oncologist
      d) A certified radiation expert representing each of the following, as applicable in each hospital:
         - Radiation Therapy Services
         - Mammography
         - Diagnostic radiography other than mammography
      e) A management representative of each department of the hospital which has responsibilities involving the handling of radiation-generating equipment

   4) The chair shall be either:

      a) a medical representative of Radiology (or)

      b) the administrative Director of Radiology (or)

      c) a representative of hospital executive administration

C. Meeting Requirements for the QA Committee
   1) The QA Committee shall meet at least biannually.
   2) The QA Committee meeting(s) may be held in person or virtually.
   3) To establish a quorum, at least one-half of the QA Committee members will be present, either in person or by telecommunication, and will include the IRRP/URSO and the member of the executive administration.
   4) A record of each meeting will be maintained and distributed to each member which will include

the following:

a) The date of the meeting;
b) An indication of members present; and
c) A summary of the meeting including any recommended actions and ALARA reviews;

D. Quality Assurance Program Reviews
   1) Each quarter, the CRE(s) will submit a review of the quality assurance program to each member of the QA Committee. The review of the quality assurance program which will contain the following, as applicable:
      a) Radiation safety policy revisions proposed by the CRE(s);
      b) A review of occupational exposure records by the CRE(s);
      c) Radiation safety incidents;
      d) Performance evaluation summaries for radiation-generating equipment including a description of any issues found; and
      e) Any corrective actions recommended by the CRE(s) that are necessary to comply with OAC Chapter 3701:1-66.

6. Dose Review Committee

A. General Requirements for the Dose Review Committee
   1) Facilities performing Computed Tomography (CT) or Fluoroscopically Guided Intervention (FGI) studies are required to have an official Dose Review Committee.
   2) Changes to the Dose Review Committee Program require approval of the QA Committee prior to implementation

B. Membership requirements for the Dose Review Committee
   1) The IRRP/URSO
   2) The Diagnostic CRE
   3) As applicable, a physician that performs FGI and/or CT procedures
   4) As applicable, a technologist that performs FGI and/or CT procedures

C. Meeting Requirements
   1) Each Dose Review Committee must meet at least annually
   2) A quorum will consist of at least half of the committee membership present either in person or by telecommunication and must include the IRRP/URSO
   3) Minutes shall include:
      a) The date of the meeting
      b) An indication of members present; and
      c) A summary of meeting including any recommended actions

D. Committee purpose
   1) FGI Committee shall establish at a minimum the following:
      a) Identification of individuals who are authorized to use fluoroscopic equipment for interventional procedures

b) A method used to monitor patient radiation dose during fluoroscopically guided interventional procedures

c) Maintain policies for dose notification levels at which the physician will be notified, and appropriate actions are taken for patient safety

d) Substantial radiation dose level values following national standards

e) Actions to be taken for cases when these levels are exceeded, which may include patient follow up; and

f) Annually reviewing policies mentioned in a) through e) of this paragraph

2) CT Committee shall establish at a minimum the following:

a) Determine and review written protocols to improve image quality and minimize dose

b) Annually reviewing the following clinical protocols:

- Pediatric Head
- Pediatric Abdomen
- Adult Head
- Adult Abdomen
- Adult Chest
- Brain Perfusion (if performed)

7. Audits

A. QA Program Audits

1) The QA Program, as applicable to the OSUWMC hospitals, shall be audited at least every 12 months. The audit is called the CRE annual report.

2) The audit shall be performed by the CRE(s).

a) the CRE(s) shall:

- review and approve the QA Program
- prepare an audit report that shall include:

i. a synopsis of the findings listed on an ODH report form, as prescribed by the Director of the Ohio Department of Health. At a minimum the synopsis shall include:

- a determination of whether the written QA Program properly addresses the requirements of the regulations (and)
- a determination of whether the QA Program is being carried out in accordance with the written QA Program (and)
- any necessary corrective action

ii. a summary of evaluations performed on RGE that:

- tabulates the evaluation results (and)
- lists corrective action required and/or taken (and)

iii. verification that an individualized detailed evaluation report per RGE is on file

- submit a copy of the final draft audit report to each member of the QA Committee within 30 days of completion and, after approval by QA Committeeto the URSC at their next scheduled meeting
- 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

3) To ensure timely submission and review of the report, the QA Committee and CRE(s) shall work together.

a) By the first of April of each calendar year, the QA Committee shall provide a reminder to the CRE(s) that it is time to begin performing the CRE annual audit and request a status report by mid-April

b) By mid-April of each calendar year, the CRE(s) shall provide a status report of the CRE annual audit to selected members of the QA Committee. The member shall include, but do not have to be limited to:

- the QA Committee chair
- the IRRP/URSO
- each departmental representative of the departments with responsibility for the RGE inventory included in the audit.

c) By May 15 of each calendar year, the CRE(s) shall provide an initial draft audit report to selected members of the QA Committee. These members shall include, but do not have to be limited to:

- the QA Committee chair
- the IRRP/RSO
- each departmental representative of the department(s) with responsibility forthe RGE inventory included in the audit

d) By June 1 of each calendar year, the CRE(s) shall provide a final draft report to the entire QA Committee for formal review

e) The QA Committee shall review the audit findings no later than the first routine meeting after receipt of the audit report

- the QA Committee shall implement any necessary corrective action

f) Copies of the audit report shall be maintained in:

- the CRE(s) office (and)
- Radiology Administration (and)
- the Radiation Safety Office

8. RGE Operator Requirements

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

1) Individuals shall be licensed appropriately as either:

a) a general x-ray machine operator (or)

- a general x-ray machine operators may perform standard diagnostic radiologic procedures; whose performance of radiologic procedures is limited to specificbody sites; and who does not, in any significant degree, determine the site or dosage of radiation to which a patient is exposed
- 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.

b) a radiographer (or)

- 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
- 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

c) a nuclear medicine technologist (or)

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

d) a radiation therapist, or a radiation therapy technologist (or)

- a radiation therapist or radiation therapy technologist may utilize ionizing

radiation-generating equipment including therapy simulator radiation-generating equipment for therapeutic purposes on any patient.

- a radiation therapist or radiation therapy technologist must work under the direct supervision of a licensed practitioner. In order to provide the direct supervision, the supervising licensed practitioner must be on site and must be able to immediately provide consultation and direction assistance.

e) a dental hygienist or dental assistant, as defined by ORC 4715-9 and 4715-12

- a dental hygienist or dental assistant may utilize ionizing radiation-generating equipment intended only for dental use 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.

f) a licensed practitioner

2) State licensure maintenance

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

b) Licensure maintenance must be in an easily auditable form.

c) If a license is found to be expired, the individual shall not use any RGE.

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

1) Standing Order Policy provisions approved for use in an emergency room where the policy has been approved by

a) the chief attending physician of the emergency room,

b) the IRRP/URSO and

c) the applicable executive administrative representative from the QA Committee

C. Except as follows, all radiotherapy treatments require a written directive that must be dated and signed by a physician authorizing its use prior to the administration of radiation treatments by any RGE as required by OAC 3701:1-67-04, and as outlined in the Radiation Oncology Quality Management program policies.

1) If, because of the patient's condition, a delay in the order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in the patient's record and a revised written directive is signed by an authorized user within forty-eight hours of the oral revision

D. 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 concerningor doubts regarding the operation of a unit shall immediately seek guidance from their supervisor or other appropriate individual.

E. 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 appropriate CRE or IRRP/URSO.

F. Operators shall minimize their, and other individuals in the restricted area, radiation exposure by following the procedures identified in Section 9, Radiation Safety Procedures.

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

1) closely following RGE operating procedures
2) not overriding interlocks or other safety features
3) ensuring unauthorized and unprotected members of the public are not in the restricted area whenever an RGE is energized

H. Operators shall ensure patient protection by:

1) Performing a pregnancy assessment for all females of child-bearing age in accordance with department policy
2) Instructing the patient to avoid movement and, if necessary, use immobilization or positioning aids.
3) Verify the identification of the patient prior to performing a procedure in accordance with departmental procedures.
4) Utilizing the automatic exposure control, as appropriate, or using 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.
5) Using correct patient positioning
6) Minimizing fluoroscopy time
7) Performing only those exams that are essential for proper diagnosis
8) Minimizing "repeat" exposures

I. Operators shall avoid holding patients by:

1) using immobilization devices, restraint devices, and remote handling devices shall be used whenever possible to avoid holding patients
2) if someone must hold a patient, efforts shall be made to recruit a non-occupationally exposed individual for this purpose and the operator shall:

a) question the individual, if applicable, of the possibility of pregnancy

b) instruct the individual about what protective equipment must be worn (The protective

equipment shall include a lead apron of at least 0.25-mm lead equivalent and, if the individual's hands may be in the primary beam, lead glovesof at least 0.5-mm lead equivalent)

c) instruct the individual regarding where they should stand (this instruction shall include standing in a position that keeps the individual's body outside the primarybeam)

d) For radiation therapy no individuals other than the patient will be allowed to remain inside the treatment rooms at any time for any reason when the treatment beam is turned on.

J. Operators who are minors shall:

1) obtain written approval from their parents or guardians.

2) be limited to an occupational dose of 10% of the annual occupational limits

9. Training Requirements

A. RGE Radiation Worker (RW) Training

1) RGE Operator Training

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

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

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

- health protection problems associated with exposure to radiation andprocedures to minimize the exposure (and)
- instruction to report promptly any condition that may constitute or lead to orcause a violation of radiation protection or QA procedures, policies, rules or regulations (and)
- applicable warning signage

d) Provide instruction with respect to area specific information and departmentalprocedures for RGE and the operation of each type of RGE to be operated

- instruction shall include the area specific:
  i. applicable warning signage (and)
  ii. the location of the restricted area (and)

iii. a description of the RGE in use

- and ensure the individual has completed any necessary RGE specific training

i. 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 complete the CRE approved fluoroscopy training program.

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

a) the manufacturer (or)

b) an operator or supervisor who was trained by the manufacturer (or)

c) an operator or supervisor who is skilled at using the RGE (e.g., individual trained by an individual who was trained by the manufacturer)

d) training is not required if the operator has previously been trained on similar equipment.

3) Changes to operating procedures and the QA Program shall be communicated to applicable operators by each department in a timely manner after the change by:

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

b) addition of revised protocol in the departmental manual

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

5) Hand-held x-ray devices - Operator training will include documented specific instruction to the x-ray operator regarding:

a) Not placing any part of their body into the useful beam unless protected by not less than 0.5 millimeter lead equivalent material;

b) The proper use of source-to-image distance for the examination to assure the size of the radiation beam is no larger than necessary;

c) Ensuring that all individuals obligated for the examination are wearing the appropriate lead equivalent aprons and no bystanders are in the vicinity;

d) The areas of use, proper storage and security procedures for the hand-held radiation-generating equipment; and

e) The use of the dead-man switch and software safety devices such as locks and sensors.

B. Ancillary Radiation Worker (AW) Training

1) All employees who are likely to receive an occupational dose in excess of 100 millirem (0.1 rem) shall receive general radiation protection training. The minimum training shall include:

   a) health protection problems associated with exposure to radiation and procedures to minimize the exposure

   b) 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

   c) applicable warning signage

   d) the location of the restricted area

   e) RGE special training is required for individuals who participate in procedures utilizing fluoroscopy units, including C-arms and digital cine. These individualsshall complete the CRE approved fluoroscopy training program prior to participating in procedures utilizing fluoroscopy units.

C. Training for Exposed Public

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:

   a) wearing a lead apron of at least 0.25 mm lead equivalent and, if the individual's hands may be in the primary beam, lead gloves of at least 0.5 mm lead equivalent(and)

   b) where the individual should stand during the procedure

D. Patient Education

1) Departments that perform procedures involving RGE shall maintain informational material on procedures routinely performed.

2) Informational material shall be provided upon request or as considered necessary by the prescribing physician.

E. Training Records

1) Training records shall be maintained in a readily accessible file(s). Training records shall be current and made available upon request to the associated CRE, representatives of the RSS, and members of the associated QA Committee members of the URSC or inspectors from the ODH.

2) Each department, through the CP, is responsible for maintaining all required training records.

   a) 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

b) all other training records shall be maintained for a minimum of three-years

3) 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.

4) Copies of records documenting an individual has completed fluoroscopy initial training shall be maintained by the administering department.

10. Radiation Safety Procedures

A. General Radiation Safety Procedures for RGE

1) All individuals shall wear their assigned dosimeters as required. (see radiation monitoring requirements, section 11)

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

3) Individuals in the restricted area shall minimize their radiation exposure by:

a) minimizing the time spent in the restricted area

b) staying as far away as possible from the radiation beam (e.g., increasing distance)

c) wearing required protective shielding

- aprons of at least 0.25 mm lead equivalence at the front of the shield shall be worn by all individuals in the restricted area

- gloves of at least 0.5-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 apatient.

- collar shields (i.e., thyroid shields) of at least 0.5 mm lead equivalence shall beworn 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)

4) The holding of image receptors shall be minimized. If an image receptor must be held then lead-lined gloves shall be worn.

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).

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

B. Additional Radiation Safety Procedures, by RGE

1) Mobile radiography

a) Any individual performing any part of the radiologic procedure shall:

- be a licensed practitioner or a licensed Radiologic Technologist

b) Mobile radiography should be performed only when it is not practical to bring the patient into a fixed radiographic room.

c) When performing mobile radiography in a location where non-radiation workers or visitors may be located, the operator shall be responsible to clear the area of individuals who are not required for patient care. The operator shall announce they are taking an x-ray before they make an exposure to allow the remaining individuals to move as far away from the beam as practical.

d) When performing mobile radiography, the operator shall stand at least six feet from the patient and outside the primary beam, unless it is necessary forthe operator to stand closer due to patient care issues.

e) When performing mobile radiography, the operator shall wear a lead apron.

f) The prevention of unauthorized use of mobile radiography systems will be controlled through a key/badge operational controls.

2) Fluoroscopic procedures, including digital cine

a) Individuals who must be in the room during a procedure shall stand as far away from the tube as practical.

b) Individuals who must work in the radiographic room or within 12 feet of the area of the patient being examined in the O.R. or on the floor during any C-arm (including mini C-arms) fluoroscopic procedures shall wear protective apparel as appropriate. Under no circumstances shall less than a lead apron be worn. Lead gloves shall be worn when the hands must be placed in or near the x-ray beam. Lead thyroid shields, lead eyeglasses and protective barriers should also be available and used, as appropriate.

c) Portable protective shielding should be used when possible.

d) The table apron shall be installed and used unless it interferes with the procedure or compromises a sterile field.

e) Avoid unnecessary fluoroscopic exposure. Use image freeze capabilities when possible. Utilize pulsed fluoroscopy techniques if the machine is so equipped. Conduct examinations with as little fluoroscopy time as possible.

f) Some fluoroscopy units have an under the table tube for fluoroscopy and an overhead tube for radiographic work. When the fluoroscopy mode is engaged, the operator can only fluoro and cannot utilize the overhead tube. If this safety feature ever malfunctions, the unit shall not be used and the operator shall immediately report the problem to their supervisor and the appropriate CRE.

g) Any patients receiving an exposure exceeding the thresholds for patient follow-up be evaluated.

3) C-arm fluoroscopy, including digital cine

a) The mobile C-arm should be used only when it is not practical to perform the examination in a fluoroscopic room.

b) The operator of the C-arm shall be responsible to make every reasonable effort to minimize exposure to both the patient and personnel by:

- avoiding unnecessary fluoroscopic exposure
- using image freeze capabilities when possible.
- using pulsed fluoroscopy techniques if the machine is so equipped
- conducting examinations with as little fluoroscopy time as possible

c) Any patients receiving an exposure exceeding the threshold for patient follow-up will be evaluated.

4) Diagnostic Computed Tomography (CT)

a) Any individual performing any part of the radiologic procedure shall be a licensed practitioner or licensed Radiologic Technologist only.

b) Operators shall follow the general radiation safety procedures (section 10.1).

c) Operators shall follow departmental and/or hospital procedures for injection of contrast media and allergic reaction review and follow-up.

d) Operators shall follow departmental procedures to verify correct patient and body part are selected for each examination.

5) Computed tomography with fluoroscopy (CT-fluoro)

a) Any individual performing any part of the radiologic procedure shall be a licensed practitioner or licensed Radiologic Technologist only.

b) Operators who operate a CT-fluoro in fluoroscopy mode must complete fluoroscopy training (refer to Section 10.2.1.1.2)

c) Individuals in a CT-fluoro room when the fluoroscopy mode is activated must follow fluoroscopy safety procedures (refer to Section 10.2.1).

d) Any patients receiving an exposure exceeding the threshold for patient follow-up as described in Policy: Monitoring and Tracking Fluoroscopic Radiation Skin Doses) shall be evaluated.

6) Megavoltage radiation generating equipment (for Radiation Therapy)

a) The Safe Operating Procedures for Megavoltage RGE used in Radiation Therapy applications are outlined in Radiation Oncology RGE Policy #6 (SOP Linear Accelerator)

b) The Emergency shutoff procedures for RGE used in Radiation Oncology are outlined in Radiation Oncology RGE Policy #13

7) Dental equipment

a) Any individual performing any part of the radiologic procedure shall be a licensed practitioner, licensed Radiologic Technologist, or licensed dental assistant or hygienist only.

b) Maintain six feet distance from the useful beam, unless a hand-held device is used, in which case the operator must be wearing a lead apron.

8) Hand-held x-ray devices

a) Hand-held radiation-generating equipment will be used for intraoral, extremity, or small animals purposes only;

b) Examination specific source-to-image distances will be developed and implemented to assure the useful beam is limited to the area of clinical interest or no larger than the image receptor;

c) Operators of the hand-held radiation-generating equipment and individuals participating in the x-ray procedure will be protected from direct scatter radiation by protective aprons of not less than 0.25-millimeter lead equivalent material;

d) If the hand-held radiation-generating equipment is designed with a back scatter shield, the backscatter shield will be in place during all radiographic exposures;

e) Storage and security procedures will be developed and implemented to assure hand-held radiation-generating equipment is secured against unauthorized use or removal when not under the control and constant surveillance of the handler;

f) Hand-held radiation generating equipment will not be used in hallways or waiting rooms;

C. Additional Radiation Safety Requirements for Specific Workers

l) Pregnant Workers

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

- the name of the individual (and)
- the signed and dated declaration (and)
- the type of radiation exposed to in the workplace (and)

- the estimated date of conception

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

c) Pregnant workers may request a meeting with the IRRP/URSO. The IRRP/URSO will:

- review the individual's exposure record. If the record indicates an exposure tothe embryo/fetus greater than 500 millirem may occur, the IRRP/URSO 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
- review procedures to minimize exposure to the embryo/fetus
- answer any questions the individual may have

d) Pregnant workers may continue to operate and work around RGE unless deemed otherwise by the CRE or IRRP/URSO.

e) Pregnant individuals should review NRC regulatory guide 8.13. This guide covers the effects of radiation to the embryo and fetus.

2) Minors

a) Minors shall have written authorization from their parents or guardians authorizing their potential exposure to radiation.

b) Minors, who are RWs or AWs, are limited to a radiation dose that is 10% of the annual occupational radiation exposure limits.

11. Radiation Monitoring Requirements

A. Exposure Limits

1) The annual occupational radiation exposure limits are:

a) Whole body effective dose - 5 rem (50 mSv)

b) Any individual organ or tissue, other than the lens of the eye - 50 rem (500 mSv)

c) Lens of the eye - 15 rem (150 mSv)

d) Skin - 50 rem (500 mSv)

e) Extremity - 50 rem (500 mSv)

f) Minors – 10% of the annual occupational exposure limits.

g) Declared pregnant worker – 0.5 rem (5 mSv) to the fetus during the pregnancy

B. General Personnel Dosimeter Requirements

1) In accordance with regulations, a dosimeter shall be worn by all personnel who are likely to receive greater than 10% of the annual occupational dose limit.
2) Dosimeters are also required as outlined in section 10.3 of this manual or as deemed necessary by the QA Committee or the URSC
3) Exemptions from dosimetry requirements outlined in section 10.3 of this manual may be approved by the IRRP/URSO on a case-by-case basis

   a) requests for exemptions shall be submitted in writing, and shall include:

      - the reason for the request
      - documentation that the individual or individuals covered by the request are unlikely to receive in one year from all sources of radiation under 10% of the regulatory annual occupational dose limit. This documentation shall include potential doses from both routine operations and possible incident situations

4) Dosimeters used for individuals exposed to RGE shall be able to detect photon radiation.
5) Dosimeters shall be applied for and provided by through the Radiation Safety Office.

C. Dosimetry for RGE Radiation Workers (RW)

1) radiographic units

   a) one dosimeter outside the apron, worn at the collar

2) fluoroscopy units

   a) one dosimeter outside the apron, worn at the collar (labeled whole body)

      - one dosimeter outside the apron, worn at the collar (labeled whole body)

   b) if an individual's extremities are likely to receive a dose that is 10% or more of the applicable limit, extremity dosimetry is also required. A ring dosimeter should be worn on the extremity frequently in or near the x-ray beam

D. Dosimetry for Ancillary Radiation Workers (AW):

1) Dosimeters are required if the AW is likely to receive a dose that is 10% or more of the applicable limit.
2) Dosimeter requirements for frequently exposed AW are equivalent to that for RW.

E. Dosimetry for Declared Pregnant Workers

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.

   a) one dosimeter worn outside the apron, at the collar (labeled whole body)

   b) second dosimeter worn under the apron, at waist level (labeled fetal)

F. Area Dosimeter Option

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.

G. Care of Dosimeters

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.

2) Personnel and area dosimeters issued by the Ohio State University are limited for use to monitor radiation exposure from radiation sources.

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.

4) Radiation dosimeters shall be worn at the position appropriate for the work being performed (see dosimeters for RW, section 11.C).

5) Radiation dosimeters are very sensitive to environmental conditions such as heat, light and moisture. Dosimeters should be used properly.

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.

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

H. Dosimetry Analysis and Reports

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

12. ALARA and Overexposure Investigations and Notifications Procedures

A. ALARA Investigations and Notifications

1) ALARA investigations shall be performed when individuals exceed 10% and 30% of the applicable regulatory limits for general radiation workers. The current ALARA investigation level doses are outlined in Appendix B.

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

a) The IRRP/URSO will:

- provide a written report of the exposure to the individual
- no further action is needed unless deemed necessary
- report to the results to the QA Committee at the next meeting

b) The IRRP/URSO and/or the CRE will:

- review the exposure and the explanation, then investigate if deemed necessary
- report the results to the QA Committee at the next meeting

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

a) The IRRP/URSO will:

- provide a written report of the exposure to the individual
- request the individual submit an explanation of radiation exposure during thetime period in question

b) The IRRP/URSO, in conjunction with the CRE, if necessary, will:

- investigate the cause(s) of the exposure
- implement corrective action as deemed necessary

c) The CRE, in conjunction with the IRRP/URSO, will:

- report the results to the QA Committee at the next meeting

B. Overexposure Investigations and Notifications

1) An "Overexposure" to personnel means greater than the limit(s) allowed by regulation

2) When an exposure in excess of regulatory limits is suspected the CRE and IRRP/URSO shall be notified.

3) "Overexposures" to personnel shall be reported by the IRRP/URSO to:

a) the Director of Health

b) the QA Committee, and

c) the URSC

4) "Overexposure" to personnel reports to the Director of Health shall be made by the IRRP/RSO:

a) 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.

b) Within 24 hours by phone if personnel exposures of 5 rem or more to the wholebody, 15 rem or more to the lens of the eye, 50 rem or more to the skin an extremity or an organ.

c) For a) or b), within 30 days, in writing if personnel exposure is greater than allowable limits

d) Written reports of "overexposures" to personnel to the Director of Health shallinclude:

- extent of the exposure
- the cause of the exposure
- corrective steps taken or planned to be taken to prevent recurrence

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

- be made prior to a written report being submitted to the Director of Health

13. Patient Incident Action

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

1) Patient recordable incidents

a) Description:

- the wrong patient
- the wrong site (i.e., wrong body site)
- the wrong treatment
- a dose to an embryo or fetus that was unintended
- fluoroscopic exposures exceeding the threshold values defined in Policy:Monitoring and Tracking Fluoroscopic Radiation Skin Doses
- occurrences not consistent with the routine care of a patient as described by theRadiation Oncology Event Reporting Policy.

b) Reporting - patient recordable incidents shall be reported to:

- the appropriate CRE

i. If a medical event, as defined by OAC 3701:1-66-01, has, or has possibly

occurred the event shall be reported to the Diagnostic CRE and the IRRP/URSO.

ii. If a medical event has, or has possibly occurred, the reporting actions described in the Radiation Oncology Event Reporting Policy will be taken.

iii. If the CRE determines the incident is the result of a significant problem or concern, the CRE will convene a special meeting of the QA Committee; otherwise the incident will be reported to the QA Committee at the next regular meeting.

iv. Reports will be entered into the hospital Patient Safety Reporting system

2) Other recordable incidents and action to be taken:

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

b) 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 CRE.

c) 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/URSO.

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

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

C. “Overexposures” to patients

1) “Overexposures” to patients means a TJC sentinel event of prolonged fluoroscopy with permanent tissue injury resulting from improperly performed procedures. “Overexposures” to patients shall include a self-investigation and root cause analysis, and be reported by the IRRP/URSO to:

a) the hospital CEO

b) the QA Committee

14. Postings and Signs

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

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

1) ODH notice to employees

2) location(s) where this manual, applicable audit(s) and applicable inspection report(s) are maintained

3) location(s) where applicable rules and regulations are maintained

4) method for contacting the CRE, if applicable

5) method for contacting the IRRP/URSO

6) A sample posting is included in Appendix C.

7) Each human-use RGE shall have a warning label near any switch that energizes thex-ray tube that cautions that radiation is produced when energized.

C. Signs reminding patients to inform the technologist/therapist prior to a study if there is a possibility of pregnancy shall be posted in locations visible to patients.

15. Intervals and Procedures for Evaluation of RGE

A. CRE/RE testing: RGE shall be evaluated for compliance to applicable state and federal regulations by an appropriately credentialed CRE on an annual basis, not to exceed 13 months.

B. Imaging RGE shall be evaluated at intervals and using the procedures described in the Radiology Policy - Medical Physics Quality Control Testing. RGE used in Radiation Therapy applications shall be evaluated at intervals and using the procedures described in Radiation Oncology RGE Policy #2 (Evaluation of the Therapeutic Radiation Generating Equipment), Radiation Oncology RGE Policy #9 (Evaluation of the OBI Fixed Systems) and Radiation Oncology RGE Policy #11 (Evaluation of CT Simulators).

C. Following evaluations of individual RGE, the CP and clinical engineering will be notified of any issues of non-compliance.

1) Issues of non-compliance shall be addressed within 60 days, or a time frame determined by the CRE, or the unit shall be removed from service.

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

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

E. Post-Maintenance Evaluation

1) Fluoroscopic and CT Systems undergoing major maintenance require an assessment of image quality and radiation output approved by a CRE (medical physicist) prior to being returned to clinical use in accordance with Radiology Policy "Quality Assurance of Radiation Generating Equipment after Repair"

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

1) Hospitals are generally inspected biennially.
2) Medical clinics are generally inspected every three years.
3) University campuses are generally inspected every three years.

16. Quality Control (QC) Tests

A. QC Requirements

1) QC tests and routine preventative maintenance of RGE diagnostic imaging devices (image acquisition, display, and printing) shall be performed in accordance with applicable departmental policies.

2) QC tests and routine preventative maintenance of RGE radiation therapy devices shall be performed in accordance with departmental policies.

B. QC Training

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:

a) demonstration of how to perform the QC test by a trained individual (and)

b) observation by a trained individual of the trainee performing the test

C. QC for Personnel Protective Equipment

1) Annual checks of the integrity of radiation protection apparel will be performed in accordance with Radiology Policy: Radiation Protective Apparel Quality Assurance).
2) Lead drapes should be checked at the time of use for cracks, holes or penetrations through the lead.

D. QC for RGE Testing Equipment

1) annual calibration of radiation survey equipment
2) biennial calibration of kVp and radiation exposure meters

E. QC Corrective Action

1) Any equipment that does not meeting QC standards shall be removed from service, unless approved in writing by the CRE or IRRP.
2) Any equipment removed from service due to not meeting a QC standard must be rechecked prior to returning to service.

F. QC Record Maintenance

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.
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.

17. RGE Logs and Operation Manuals

A. Maintenance Logs

1) Each RGE will have a separate maintenance log, maintained by Clinical Engineering, which shall include:

a) identification of the piece of equipment

b) incidents and actions

c) maintenance performed

d) repair information

B. Fluoroscopy Logs, or Equivalent

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.
2) The record must include:

a) the patient's name and medical record number

b) the date of exam

c) the procedure(s) performed

d) the physician operator's name

e) 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 thenumber of spot images.

f) The record must be readily available for audit/inspection and may be maintained:

- the patient's record
- In a patient radiation management system.

C. Operations Manuals

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

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

D. Maintenance of Logs and Manuals

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.

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.

3) RGE logs and manuals shall be kept for five years.

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

A. Acquisition (purchase or loaner) of New RGE

1) The acquisition of all RGE shall be reported first to Clinical engineering, then to the IRRP/URSO and appropriate CRE.

2) Information may be provided to the IRRP/URSO and CRE utilizing the form "Notice of Transfer or Disposal of Radiation-Generating Equipment (RGE)". Otherwise, the following minimal information shall be provided:

a) CP's name

b) Department

c) machine's application (e.g., radiographic, fluoroscopic, CT, dental)

d) description of machine (make, model)

e) number of tubes

f) expected delivery/transfer date

g) planned location

B. Registration

1) The IRRP/URSO 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/URSO shall amend the registration.

C. Acceptance Testing

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

2) Initial acceptance testing shall be completed:

a) prior to patient use

b) Initial acceptance testing shall include:

- evaluation testing in accordance with that list in hospital policy (and)
- for angiography, 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 theIRRP/URSO (and)
- if applicable, room safety feature evaluation testing (e.g., interlocks, remotevisual)

D. RGE Inventories

1) The Radiation Safety Office shall maintain registrations of RGE.
2) Inventories of RGE will be maintained and reviewed by the applicable departments.
3) The IRRP/URSO will review the results and ensure the inventory is in accordancewith the applicable registration. If necessary, the IRRP/URSO shall amend the registration.

E. Disposal or Transfer of RGE

1) Prior to disposal or transfer of RGE by their department, the CP shall inform the IRRP/URSO and the CRE about the disposal or transfer.
2) Information may be provided to the IRRP/URSO and CRE utilizing the form "Notice of Transfer or Disposal of Radiation-Generating Equipment (RGE)".
3) Alternately, information provided to the IRRP/URSO and CRE shall include:

a) name and location (e.g., address of the facility) from which the equipment will bedisposed or transferred

b) the make, model and serial number of the RGE being transferred or disposed

c) the anticipated date of disposal or transfer

F. Inoperable RGE

1) The CP shall notify the IRRP/URSO and CRE whenever a previously operable RGE is determined to be inoperable
2) Notification shall be within 5 business days of the CP becoming aware the RGE is inoperable.
3) The CRE or IRRP/URSO shall promptly confirm the RGE is inoperable, and assure the CP is aware that the IRRP/URSOmust be promptly informed once the unit is repaired.
4) The CP shall notify the IRRP/URSO whenever a previously operable RGE unit is repaired.

a) notification shall be within 5 business days of the CP becoming aware the RGEis operable

5) notification shall be by written correspondence, which may include electronic mail,

letter or memorandum

6) the CRE or IRRP/URSO shall promptly make arrangements to appropriately surveythe unit in accordance with applicable regulations.

7) From the information provided, the IRRP/URSO shall submit any necessary reports tothe Ohio Department of Health covering the installation, disposal, transfer, or change in operability status of RGE

19. RGE Room Construction - New or Remodeled

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

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

2) any design document for shielding shall require acceptable approval by the appropriate CRE or qualified designee prior to start of construction

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

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)

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

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

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)

2) if applicable, room safety feature evaluation testing (e.g., interlocks, remote visuals)

Appendix A
Forms

Associated Radiation Safety Forms

Notice of Transfer or Disposal of Radiation-Generating Equipment (RGE)

Badge Request form

Declaration of Pregnancy Form

Unreturned or Lost Badge

Appendix B
ALARA Investigational Levels

ALARA Investigational Levels per calendar quarter

DOSE	ALARA I (10%) LEVEL	ALARA II (30%) LEVEL
Deep Dose Equivalent	125 mrem (1.25 mSv)	375 mrem (3.75 mSv)
Effective Dose Equivalent*	125 mrem (1.25 mSv)	375 mrem (3.75 mSv)
Lens Dose Equivalent	375 mrem (3.75 mSv)	1125 mrem (11.25 mSv)
Shallow Dose Equivalent	1250 mrem (12.5 mSv)	3750 mrem (37.5 mSv)

- **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)**