University of Cincinnati

Quality Assurance
and
Radiation Protection
Manual
For
Human-Use
Radiation Generating Equipment
(QA&RP MANUAL FOR HUMAN-USE RGE)
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<th>Revision #</th>
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<tr>
<td>original</td>
<td>11/17/1998</td>
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<tr>
<td>1</td>
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<td>Modified ALARA levels</td>
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<td>2</td>
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<td>Modified section 7.2</td>
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<td>3</td>
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<td>4</td>
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<td>Modified “licensed practitioner”</td>
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<td>Modified section 7.1, 7.2, and 13</td>
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<td>6</td>
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<tr>
<td>8</td>
<td>5/2005</td>
<td>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 listed in a hospital policy.</td>
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<tr>
<td>9</td>
<td>11/2005</td>
<td>Added statement University of Cincinnati issued dosimeters cannot be used outside the RCSP. Statement added to section 10.6.</td>
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<tr>
<td>10</td>
<td>2/2006</td>
<td>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 the RCSP.</td>
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<tr>
<td>11</td>
<td>6/17/06</td>
<td>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.</td>
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<td>12</td>
<td>2/21/07</td>
<td>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.</td>
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<tr>
<td>13</td>
<td>5/16/07</td>
<td>Corrected typographical error in Appendix B. Corrected collar multiplication factor in footnote from 0.4 to 0.04.</td>
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<td>14</td>
<td>1/1/08</td>
<td>Modified Appendix B, ALARA Investigational Levels, to delete special investigational level for the head.</td>
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<td>Date of Revision</td>
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<tr>
<td>16</td>
<td>11/19/08</td>
<td>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.</td>
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<tr>
<td>17</td>
<td>5/13/09</td>
<td>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 (<a href="http://www.uc.edu/radsafety">www.uc.edu/radsafety</a>). Corrected minor typographical errors and style inconsistencies.</td>
</tr>
</tbody>
</table>
# QA&RP MANUAL FOR HUMAN-USE RGE

## TABLE OF CONTENTS

1. **General** 1
2. **Purpose** 1
3. **Definitions and Abbreviations** 1
   3.1 Definitions 1
   3.2 Abbreviations 3
4. **QA Program** 3
   4.1 The QA Program addresses 4
   4.2 Oversight and maintenance of the QA Program 4
   4.3 Implementation of the QA Program 5
5. **QA Committee(s)** 5
   5.1 General requirements 5
   5.2 Membership requirements 5
   5.3 Meeting requirements 6
6. **Audits** 7
   6.1 QA Audits 7
   6.2 Radiation Control and Safety Program Audits 8
7. **RGE Operator Requirements** 8
8. **Training Requirements** 12
   8.1 RGE Radiation Worker 12
   8.2 Ancillary Radiation Worker 13
   8.3 Exposed Public 14
   8.4 Patient 14
   8.5 Records 14
9. **Radiation Safety Procedures** 15
   9.1 General for RGE 15
   9.2 Additional safety procedures, by RGE 15
      9.2.1 fluoroscopic procedures, including digital cine 15
      9.2.2 mobile radiography 16
      9.2.3 C-arm fluoroscopy, including digital cine 17
      9.2.4 computer tomography (CT) 17
      9.2.5 computer tomography with fluoroscopy (CT-fluoro) 17
   9.3 Additional requirements for specific worker 18
      9.3.1 pregnant workers 18
      9.3.2 minors 18
10. **Radiation Monitoring Requirements** 18
    10.1 Exposure limits 18
    10.2 General personnel dosimetry requirements 19
    10.3 Dosimetry for RGE radiation workers (RW) 19
    10.4 Dosimetry for ancillary radiation workers (AW) 20
    10.5 Dosimetry for declared pregnant workers 20
    10.6 Area dosimeter option 20
    10.7 Care of dosimeters 20
    10.8 Dosimetry analysis and reports 21
    10.9 Dosimetry exchange procedures 21
    10.10 Lost, late return or damaged dosimeters 21
11. **ALARA and Overexposure Investigations and Notifications** 22

(Revision 17)
# QA&RP MANUAL FOR HUMAN-USE RGE

## TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.1 ALARA investigation and notifications</td>
<td>22</td>
</tr>
<tr>
<td>11.2 Overexposure investigation and notifications</td>
<td>22</td>
</tr>
<tr>
<td>12. Posting and Signs</td>
<td>23</td>
</tr>
<tr>
<td>13. Incident Action</td>
<td>23</td>
</tr>
<tr>
<td>13.1 QA recordable RGE incidents</td>
<td>23</td>
</tr>
<tr>
<td>13.2 QA reportable RGE incidents</td>
<td>25</td>
</tr>
<tr>
<td>15. Quality Control (QC) Tests</td>
<td>26</td>
</tr>
<tr>
<td>15.1 QC test training</td>
<td>26</td>
</tr>
<tr>
<td>15.2 Film developing equipment</td>
<td>26</td>
</tr>
<tr>
<td>15.3 Personnel protective equipment</td>
<td>27</td>
</tr>
<tr>
<td>15.4 RGE testing equipment</td>
<td>27</td>
</tr>
<tr>
<td>15.5 Corrective action</td>
<td>28</td>
</tr>
<tr>
<td>15.6 Record maintenance</td>
<td>28</td>
</tr>
<tr>
<td>16. RGE Logs and Operations Manuals</td>
<td>28</td>
</tr>
<tr>
<td>16.1 Maintenance logs</td>
<td>28</td>
</tr>
<tr>
<td>16.2 Fluoroscopy logs, or equivalent</td>
<td>28</td>
</tr>
<tr>
<td>16.3 Operations manuals</td>
<td>28</td>
</tr>
<tr>
<td>16.4 Maintenance of logs and manuals</td>
<td>29</td>
</tr>
<tr>
<td>17. RGE Acquisition, Inventory, and Disposal or Transfer</td>
<td>29</td>
</tr>
<tr>
<td>17.1 Acquisition (purchase or loaner) of new RGE</td>
<td>29</td>
</tr>
<tr>
<td>17.2 Inventory</td>
<td>29</td>
</tr>
<tr>
<td>17.3 Disposal or transfer</td>
<td>30</td>
</tr>
<tr>
<td>18. RGE Room Construction – new or remodeled</td>
<td>30</td>
</tr>
<tr>
<td>18.1 Prior to construction or remodeling</td>
<td>30</td>
</tr>
<tr>
<td>18.2 During construction</td>
<td>30</td>
</tr>
<tr>
<td>18.3 After construction, but prior to use</td>
<td>31</td>
</tr>
</tbody>
</table>

Appendix A - Forms
Appendix B - ALARA Investigational Levels
Appendix C - Sample Posting
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 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) and the CCHMC/SHC Quality Assurance Committee (QA Committee) have 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)

1.3.1.2. second - review and approval by CCHMC/SHC QA Committee(s)

1.3.1.3. final - review and approval by RSC.

1.3.2. The Radiation Safety Officer (RSO) is responsible for distributing copies of each revision to each CP and member of the CCHMC/SHC QA Committee within 30 days of RSC approval.

1.3.3. The CP and/or CCHMC/SHC QA Committee member is responsible for ensuring each RGE radiation worker (RW) under their responsibility is informed regarding applicable changes incorporated in a revision within 60 days of RSC approval.

1.3.4. The RSO is responsible for ensuring the current version of the manual is posted on the Radiation Safety website (www.uc.edu/radsafety).

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

3.1.2. Certified Radiation Expert (CRE)

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

3.1.2.2. for the RCSP, a CRE must be appointed as designated in paragraph 4.2 of this manual

3.1.2.3. CRE categories are:

3.1.2.3.1. therapeutic (not currently applicable to the RCSP)

3.1.2.3.2. diagnostic, other than mammography

3.1.2.3.3. mammography (not currently applicable to the RCSP)

3.1.3. Contact Person (CP)

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

3.1.4. Declared Pregnant Worker

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

3.1.5. Exposed Public

3.1.5.1. An individual who:

3.1.5.1.1. is not an RGE radiation worker

3.1.5.1.2. is not an ancillary radiation worker

3.1.5.1.3. is not the patient

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

3.1.5.2. Includes, but are not limited to:

3.1.5.2.1. family, e.g., parent, guardian, spouse, significant other

3.1.5.2.2. police officer

3.1.5.2.3. patient attendant employed by another facility

3.1.6. Licensed practitioner

3.1.6.1. An individual licensed by the State of Ohio to practice

3.1.6.1.1. dentistry

3.1.6.1.2. medicine or surgery or osteopathic medicine or surgery

3.1.6.1.3. podiatry

3.1.6.1.4. chiropractic medicine
3.1.6.1.5. as a clinical nurse specialist within the scope of practice of his or her collaborating physician, or

3.1.6.1.6. 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

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

3.1.7. Individual Responsible for Radiation Protection (IRRP)

3.1.7.1. Individual who is specified on the registration.

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

3.1.8. Minor

3.1.8.1. Any individual under the age of 18.

3.1.9. Restricted Area

3.1.9.1. For human-use RGE, the restricted area is the room in which the RGE is present when energized or within 12 feet from the RGE when energized, whichever is smaller.

3.1.10. RGE Radiation Worker (RW)

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

3.1.10.2. 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. AW - Ancillary Radiation Worker

3.2.2. CP - Contact Person

3.2.3. CRE - Certified Radiation Expert

3.2.4. IRRP - Individual Responsible for Radiation Protection

3.2.5. MQSA - Mammography Quality Standards Act

3.2.6. QA - Quality Assurance

3.2.7. RCSP - Radiation Control and Safety Program

3.2.8. RGE - Radiation-Generating Equipment

3.2.9. RSC - Radiation Safety Committee

3.2.10. RSO - University of Cincinnati Radiation Safety Officer

3.2.11. RW - RGE Radiation Worker

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, 3.1.2 and 3.1.10, 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)

4.1.19. Incident action (manual section 13)

4.2. **Oversight and maintenance of the QA Program**

4.2.1. 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.

4.2.1.1. Therapy

4.2.1.1.1. Appointment of a therapeutic CRE is by and the responsibility of Radiation Oncology

4.2.1.2. Diagnostic units, other than mammography

4.2.1.2.1. Appointment of a diagnostic CRE is by and responsibility of Radiology

4.2.1.3. Mammography

4.2.1.3.1. Appointment of a mammography CRE is by and the responsibility of
Radiology

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

4.3. Implementation of the QA Program

4.3.1. Implementation of the QA Program for hospital RGE is the responsibility of:

4.3.1.1. the QA Committee (and)
4.3.1.2. the University of Cincinnati Radiation Safety Officer

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

4.3.2.1. the University of Cincinnati Radiation Safety Officer

5. QA Committee(s)

5.1. General requirements

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

5.1.2. The official QA Committee(s) 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/SHC QA Committee and is responsible for implementation of the QA Program at Cincinnati Children's Hospital Medical Center (CCHMC) and the Cincinnati Shriners Hospital for Children (SHC).

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

5.2. Membership requirements

5.2.1. The QA Committee will consist of:

5.2.1.1. a medical representative of Radiology (and)
5.2.1.2. the administrative Director of Radiology (and)
5.2.1.3. each hospital’s CRE (who may or may not be the same individual) (and)
5.2.1.4. a representative of the applicable hospital(s) executive administration. (and)
5.2.1.5. the University of Cincinnati Radiation Safety Officer (and)
5.2.1.6. a representative from each department that handle RGE for human-use within each hospital.

5.2.2. the chair shall be either:

5.2.2.1. the medical representative of Radiology (or)
5.2.2.2. the administrative Director of Radiology (or)
5.2.2.3. the representative of hospital executive administration
5.3. Meeting requirements

5.3.1. Each QA Committee shall meet at least quarterly.

5.3.1.1. Quarterly meeting are considered "routine" meetings.

5.3.1.2. Additional meeting are considered "special" meetings.

5.3.2. A quorum will consist of:

5.3.2.1. one half of the committee membership who shall include:

5.3.2.1.1. the chair, or the chair's delegate (and)

5.3.2.1.1.1. The chair's delegate will act for the chair in the chair's absence at QA Committee meetings and may be any member of the QA Committee.

5.3.2.1.2. one CRE or the CRE’s designated delegate (and)

5.3.2.1.3. the IRRP/RSO or the University of Cincinnati Assistant Radiation Safety Officer who is the designated delegate (and)

5.3.2.1.4. the representative from each hospital executive administration or their designated delegate

5.3.2.2. The CRE(s) shall provide each member of the QA Committee one (1) week prior to each quarterly meeting a review of the QA Program. The review shall include, but is not limited to:

5.3.2.2.1. proposed radiation safety policy revisions for human-use RGE

5.3.2.2.2. occupational exposure record review, primarily consisting of any ALARA analysis, for individuals exposed to radiation from covered RGE

5.3.2.2.3. radiation safety incidents pertaining to covered RGE

5.3.2.2.4. RGE equipment performance evaluation summaries, as applicable.

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

5.3.3. minutes shall include:

5.3.3.1. the date of the meeting (and)

5.3.3.2. an indication of members present and absent (and)

5.3.3.3. a summary of the meeting, including any recommended actions and ALARA reviews (and)

5.3.3.4. a copy of the CRE QA Program review (and)

5.3.3.5. when applicable, a copy of the CRE annual audit

5.3.4. copies of the minutes, once approved by the QA Committee, shall be forwarded to:

5.3.4.1. the Chair of the RSC (and)

5.3.4.2. the Chief Executive Officer of the hospital (and)
5.3.4.3. the Director of each department that uses RGE

5.3.5. copies of the minutes shall be maintained by:

5.3.5.1. the Chair of the QA Committee

5.3.5.2. the CRE(s).

6. Audits

6.1. QA Audits

6.1.1. The QA Program, as it applies to hospitals, shall be audited at least every 12 months. The audit is called the CRE annual report.

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

6.1.2.1. the CRE shall:

6.1.2.1.1. review and approve the QA Program

6.1.2.1.2. prepare an audit report that shall include:

6.1.2.1.2.1. 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:

6.1.2.1.2.1.1. a determination of whether the written QA Program properly addresses the requirements of the regulations (and)

6.1.2.1.2.1.2. a determination of whether the QA Program is being carried out in accordance with the written QA Program (and)

6.1.2.1.2.1.3. any necessary corrective action

6.1.2.1.2.2. a summary of evaluations performed on RGE that:

6.1.2.1.2.2.1. tabulates the evaluation results (and)

6.1.2.1.2.2.2. lists corrective action required and/or taken (and)

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

6.1.2.1.3. 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 Committee to the RSC at their next scheduled meeting

6.1.2.1.4. 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

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

6.1.3.1. 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
6.1.3.2. 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:

6.1.3.2.1. the QA Committee chair
6.1.3.2.2. the IRRP/RSO
6.1.3.2.3. each departmental representative of the department(s) with responsibility for the RGE inventory included in the audit

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

6.1.3.3.1. the QA Committee chair
6.1.3.3.2. the IRRP/RSO
6.1.3.3.3. each departmental representative of the department(s) with responsibility for the RGE inventory included in the audit

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

6.1.3.5. the QA Committee shall review the audit findings no later than the first routine meeting after receipt of the audit report

6.1.3.5.1. the QA Committee shall implement any necessary corrective action

6.1.3.6. copies of the audit report shall be maintained in:

6.1.3.6.1. the CRE(s) office (and)
6.1.3.6.2. Radiology Administration (and)
6.1.3.6.3. the Radiation Safety Office

6.1.4. The QA Program, as it applies to non-hospital human-use RGE, shall be audited at least biannually 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 be performed by the RSC.

6.2.3. 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 (or)

7.1.1.1.1. 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.

7.1.1.1.2. 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.

7.1.1.2. a radiographer (or)

7.1.1.2.1. 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

7.1.1.2.2. 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

7.1.1.3. a nuclear medicine technologist (or)

7.1.1.3.1. a nuclear medicine technologist may operate fusion imaging equipment as authorized under OAC 3701:1-72-04, after completion of training and verification of competency as outlined in the letter to the ODH dated July 18, 2005

7.1.1.3.2. 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

7.1.1.4. a licensed dental hygienist (or)

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

7.1.1.4.2. 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

7.1.1.5. a certified dental assistant radiographer (or)

7.1.1.5.1. a certified dental assistant radiographer may perform standard, diagnostic, radiologic procedures for providing dental services

7.1.1.5.2. 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.
7.1.1.6. a licensed practitioner

7.1.2. State licensure maintenance

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

7.1.2.2. Licensure maintenance must be in an easily auditable form.

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

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

7.2.1.1. the chief attending physician of the emergency room,

7.2.1.2. the individual responsible for radiation protection (i.e., UC’s Radiation Safety Office), and

7.2.1.3. the applicable executive administrative representative from the QA Committee

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 appropriate CRE.

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)

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

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 (10 years old or older) regarding the possibility of pregnancy if the procedure involves direct exposure to the abdomen/pelvis.
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 in accordance with hospital procedures.

7.7.2. Utilizing gonadal shielding whenever it does not directly interfere with diagnosis, compromise a sterile field or interfere with the operation of the equipment.

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

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

7.7.4.1. comparing the patient's name as listed on chart against the order
7.7.4.2. comparing the patient's name as listed on ID bracelet against the order
7.7.4.3. addressing the patient by name listed on the order
7.7.4.4. comparing the patient's demographics against those listed on the order
7.7.4.5. comparing the patient's name as provided by a parent, guardian or significant other against the order

7.7.5. Reducing radiation exposure to the patient by:

7.7.5.1. 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:

7.7.5.2. using correct patient positioning
7.7.5.3. minimizing fluoroscopy time
7.7.5.4. performing only those exams that are essential for proper diagnosis
7.7.5.5. minimizing "repeat" exposures
7.7.5.6. and in the case of scoliosis examinations:

7.7.5.6.1. having the physician evaluate the number and/or series of films to be taken to prevent unnecessary exposure
7.7.5.6.2. collimating the areas of interest to avoid unnecessary exposure to breast tissue, gonads, thyroid and eye
7.7.5.6.3. using gonadal shielding when appropriate and/or possible
7.7.5.6.4. using compensation/protective filters when appropriate and/or possible

7.8. Operators shall ensure that reasonable efforts to avoid holding patients are being taken (note: holding patients for dental is not allowed as it is against Ohio rules).
Immobilization devices, restraint devices, and remote film handling devices shall be used whenever possible to avoid holding patients. If someone must hold a patient, efforts shall be made to recruit a non-occupationally exposed individual for this purpose. If an individual must hold a patient the operator shall:

7.8.1. question the individual, if applicable, of the possibility of pregnancy

7.8.2. 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.)

7.8.3. 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.)

7.9. Operators who are minors shall:

7.9.1. obtain written approval from their parents or guardians (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 (www.uc.edu/radsafety).)

7.9.2. be limited to an occupational dose of 0.5 rem total effective dose equivalent per year

8. Training Requirements

8.1. RGE Radiation Worker (RW)

8.1.1. Only individuals who meet the qualifications for an operator of human-use RGE may operate RGE in a clinical (human-use) setting.

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 (and)

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 (and)
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

8.1.2.3.2. and ensure the individual has completed any necessary RGE specific training

8.1.2.3.2.1. 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:

8.1.2.3.2.1.1. review the fluoroscopy training manual
8.1.2.3.2.1.2. pass the fluoroscopy test

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 (or)
8.1.3.1.2. the supervisor observing the individual operating the piece of equipment and/or

8.1.3.2. 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 (or)
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 (e.g., individual trained by an individual who was trained by the manufacturer)

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)

8.2.1. All employees who may receive an occupational dose under the RCSP in excess of 100 millirem (0.1 rem) 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 at or signed out from the Radiation Safety Office, or be viewed on the Radiation Safety website (www.uc.edu/radsafety). 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

8.2.1.4. the location of the restricted area

8.3. 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

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

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

8.5. 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 associated QA Committee, 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 hospital’s Radiology department.

9. **Radiation Safety Procedures**

9.1. **General for 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)

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.

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. The holding of image receptor cassettes (film or CR) shall be minimized. If a cassette must be held then lead-lined gloves shall be worn.

9.1.6. 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).

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

9.2. **Additional safety procedures, by RGE**

9.2.1. fluoroscopic procedures, including digital cine

9.2.1.1. Any individual performing any part of the radiologic procedure shall:
9.2.1.1. be a licensed practitioner or licensed Radiologic Technologist only
9.2.1.2. have completed the fluoroscopy training requirements

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

9.2.1.3. 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 C-arm fluoroscopic 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.

9.2.1.4. Portable protective shielding should be used when possible.

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

9.2.1.6. 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.

9.2.1.7. Any patients receiving an exposure greater than the Entrance Skin Exposure (ESE) Threshold Level as determined by the machine specific action levels (refer to Section 13.1.1.1.4) shall be recalled at a 3-week interval to evaluate the possibility of radiation induced skin changes and referred to the appropriate department personnel for evaluation, in accordance with hospital policy.

9.2.1.8. Some fluoroscopy units have an under the table tube for fluoroscopy and an overhead tube for radiographic work. When the fluoroscopy button 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.

9.2.2. mobile radiography

9.2.2.1. Any individual performing any part of the radiologic procedure shall:
9.2.2.1.1. be a licensed practitioner or licensed Radiologic Technologist only
9.2.2.2. Mobile radiography should be performed only when it is not practical to bring the patient into a fixed radiographic room.
9.2.2.3. 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 a film before they make an exposure to allow the remaining individuals to move as far away from the beam as practical.
9.2.2.4. When performing mobile radiography the operator shall stand at least six
feet from the patient and outside the primary beam, unless it is necessary for the operator to stand closer due to patient care issues.

9.2.2.5. When performing mobile radiography the operator shall wear a lead apron.

9.2.3. **C-arm fluoroscopy, including digital cine**

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

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

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

9.2.3.3. Any patients receiving an exposure greater than the Entrance Skin Exposure (ESE) Threshold Level as determined by the machine specific action levels (refer to Section 13.1.1.1.4) shall be recalled at a 3-week interval to evaluate the possibility of radiation induced skin changes and referred to the appropriate department personnel for evaluation, in accordance with hospital policy.

9.2.4. **computer tomography (CT)**

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

9.2.4.2. Operators shall follow the general radiation safety procedures (section 9.1).

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

9.2.5. **computer tomography with fluoroscopy (CT-fluoro)**

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

9.2.5.2. Operators who operate a CT-fluoro in fluoroscopy mode must complete fluoroscopy training (refer to Section 9.2.1.1.2)

9.2.5.3. Individuals in a CT-fluoro room when the fluoroscopy mode is activated must follow fluoroscopy safety procedures (refer to Section 9.2.1).

9.2.5.4. Any patients receiving an exposure greater than the Entrance Skin Exposure (ESE) Threshold Level as determined by the machine specific action levels (refer to Section 13.1.1.1.4) shall be recalled at a 3-week interval to evaluate the possibility of radiation induced skin changes and referred to the appropriate department personnel for evaluation, in accordance with hospital policy.
9.3. Additional requirements for specific workers

9.3.1. pregnant worker

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 (and)

9.3.1.1.2. the date of declaration (and)

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 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 RSO. The 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 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

9.3.1.3.3. answer any questions the individual may have

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

9.3.1.5. 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 should review NRC regulatory guide 8.13. 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 (www.uc.edu/radsafety).

9.3.2.2. Minors, who are RWs or AWs, 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:
10.1.1.1. Whole body effective dose - 5 rem
10.1.1.2. Any individual organ or tissue, other than the lens of the eye - 50 rem
10.1.1.3. Lens of the eye - 15 rem
10.1.1.4. Skin - 50 rem
10.1.1.5. Extremity - 50 rem
10.1.1.6. Minors – one tenth the above values
10.1.1.7. Declared pregnant worker – 0.5 rem to the fetus during the pregnancy

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 CCHMC/SHC QA Committee or 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 CCHMC/SHC QA Committee or directly to the RSC and shall include:

10.2.3.1.1. the reason for the request

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. Dosimeters 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. fluoroscopy units

10.3.3.1. two dosimeters, as labeled.

10.3.3.1.1. one dosimeter outside the apron, at the collar (labeled neck or collar)

10.3.3.1.2. second dosimeter under the apron, at waist level (labeled waist or chest)

10.3.3.2. 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. Dosimeters 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. Dosimeter 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 (labeled neck or collar)

10.5.1.2. second dosimeter worn under the apron, at waist level (labeled waist or chest)

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 series analysis reports are forwarded to:

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

10.8.2.1.2. the appropriate CRE

10.8.2.2. individual analysis reports:

10.8.2.2.1. Monitored personnel are provided copies of the previous year's exposure as an individualized report during the second quarter of the year (generally with the April or May dosimeters).

10.8.2.2.1.2. 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. **Dosimeter exchange procedure**

10.9.1. To prevent unmonitored exposure, before used dosimeters are returned, new dosimeters are picked up.

10.9.2. All dosimeters shall be picked up in the Radiation Safety Office during the first 3 working days of the month.

10.9.3. All dosimeters shall be returned to the Radiation Safety Office during the first 10 days of the month.

10.9.4. All late returned and non-returned dosimeters require completion of a radiation dosimetry follow-up form. The Radiation Safety Office shall issue the form upon receipt of a report indicating a dosimeter was not returned as required.

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 if dosimeters are lost or
damaged prior to the return exchange.

10.10.3. A radiation dosimeter follow-up is 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 RSO 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

11.1.2.2. The CRE will:

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

11.1.2.2.2. report the results to the QA Committee at the next meeting

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

11.1.3.1. The RSO will:

11.1.3.1.1. provide a written report of the exposure to the individual

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 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

11.1.3.3. The CRE will:

11.1.3.3.1. report the results to the QA Committee at the next meeting

11.2. **Overexposure investigation and notifications**

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

11.2.2. The CRE, in conjunction with the 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
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. nature and extent of the exposure
11.2.2.3.2. the following statement

"This report is furnished to you under provisions of the Ohio Public Health Council's rules entitled 'General Radiation Protection Standards.' (Chapter HE-38 of the Ohio Sanitary Code) You should preserve this report for future 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:
   12.2.1.1. ODH notice to employees
   12.2.1.2. location(s) where this manual, applicable audit(s) and applicable inspection report(s) are maintained
   12.2.1.3. location(s) where applicable rules and regulations are maintained
   12.2.1.4. method for contacting the CRE, if applicable
   12.2.1.5. method for contacting the RSO

12.2.2. A sample posting is included in Appendix C.

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

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 radiology department waiting rooms
   12.3.2. radiology patient dressing rooms
   12.3.3. radiology patient bathrooms
   12.3.4. all human-use RGE exam rooms

13. Incident Action

13.1. QA recordable RGE incidents are: ("recordable" incidents include those that may or may not be reportable to the ODH)
   13.1.1. Patient recordable incidents
13.1.1. Description:
13.1.1.1. the wrong patient
13.1.1.1.2. the wrong site (i.e., wrong body site)
13.1.1.1.3. a dose to an embryo or fetus that was unintended and/or unknown prior to the radiological procedure
13.1.1.1.4. based on an Entrance Skin Exposure (ESE) Threshold Value set by the individual hospital QA Committee, the CRE will determine a machine specific action level. The action level will be posted on the machine. If a clinical procedure exceeds that action level, the Additional Safety Procedures, by RGE (Section 9.2) will be initiated (see Sections: 9.2.1.7 (fluoro and digital cine), 9.2.3.3 (C-arm fluoro and digital cine), 9.2.4.5 (CT-fluoroscopy).

13.1.1.2. Reporting - patient recordable incidents shall be reported to:
13.1.1.2.1. the appropriate CRE
13.1.1.2.1.1. 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.
13.1.1.2.2. the appropriate Risk Management Office, if necessary and in accordance with the hospital's 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 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 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 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 RSO.
13.1.2.4.1. The CRE, in conjunction with the RSO, shall investigate the overexposure and submit required reports to the Ohio Department of Health.
13.1.2.4.2. The CRE will provide a report on the overexposure to the QA Committee at the next scheduled 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 RSO and CRE.

13.1.2.5.1. The CRE will provide a report, including investigation action, to the QA Committee at the next scheduled meeting.

13.2. QA reportable RGE incidents ("reportable" incidents are ones, by rule, which require a written report to the ODH)

13.2.1. "Overexposures" to personnel - ("overexposure" means greater than the limit(s) allowed by regulatory requirements for personnel) shall be reported by the RSO to:

13.2.1.1. the Director of Health
13.2.1.2. the QA Committee, and
13.2.1.3. the RSC

13.2.2. Reports to the Director of Health shall be made by the RSO:

13.2.2.1. Immediately by phone if personnel exposures of 25 rems or more to the whole body; 75 rems or more to the lens of the eye, and/or 250 rems or more to skin, an extremity or an organ. (note: this must be followed by a written report as detailed in paragraph 13.2.3 of this manual.)

13.2.2.2. Within 24 hours by phone if personnel exposures of 5 rems or more to the whole body, 15 rems or more to the lens of the eye, 50 rems or more to the skin an extremity or an organ. (note: this must be followed by the written report detailed in paragraph 13.2.3 of this manual.)

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

13.2.2.4. Written reports to the Director of Health shall include:

13.2.2.4.1. extent of the exposure
13.2.2.4.2. the cause of the exposure
13.2.2.4.3. corrective steps taken or planned to be taken to prevent recurrence

13.2.3. Written reports shall be sent by the RSO to the individual receiving the overexposure. This report shall be in writing and shall:

13.2.3.1. be made prior to a written report being submitted to the Director of Health
13.2.3.2. include the wording - "This report is furnished to you under the provisions of the Ohio Public Health Council's rules entitled "General Radiation Protection Standards" (Chapter HE-38 of the Ohio Sanitary Code). You should preserve this report for future reference."


14.1. Hospital RGE shall routinely be evaluated for compliance to applicable state and federal regulations by the CRE.

14.1.1. Each radiography unit shall be evaluated upon receipt and annually thereafter.

(Revision 17)
14.1.2. Each mobile unit shall be evaluated upon receipt and annually thereafter.

14.1.3. Each fluoroscopic unit shall be evaluated upon receipt prior to first use and annually thereafter.

14.1.4. Each CT unit shall be evaluated upon receipt prior to first use and annually thereafter.

14.1.5. Each dental unit shall be evaluated upon receipt and annually thereafter.

14.2. Minimum evaluation requirements for hospital RGE, by unit type above, are listed in hospital policy.

14.3. All non-hospital human-use RGE shall be evaluated by a medical physicist, a CRE or the ODH in accordance with the inspection schedule listed in paragraph 14.1 of this manual.

14.4. 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. 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.

14.5.1. For hospital RGE the re-evaluation shall be performed by a CRE or CRE approved designee. The CRE shall provide the RSO/IRRP and the CP with a list of names of approved designees.

14.5.2. For all other human-use RGE, the re-evaluation shall be performed by a medical physicist, CRE, CRE-approved designee or the ODH.

15. Quality Control (QC) Tests

15.1. QC test training

15.1.1. 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:

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

15.1.1.2. observation by a trained individual of the trainee performing the test

15.2. Film developing equipment

15.2.1. The following QC tests may be performed by any individual so assigned by Departmental Supervisors or their designate.

15.2.1.1. Monthly preventative maintenance

15.2.1.1.1. cleaning of racks

15.2.1.1.2. cleaning of crossovers

15.2.1.1.3. chemical exchange

15.2.1.2. Semiannual check of film/CR cassettes and intensifying screens

15.2.1.2.1. cleaned and inspected
15.2.1.2.2. limiting criteria: visual scratches, cracks or damage that may affect interpretation or quality of image.

15.2.2. The following QC test shall be performed by an image technician, radiologic technologist or individual trained in the testing procedure(s) by one of the individuals specified in this paragraph.

15.2.2.1. film processor sensitometry test: measure and chart mid-density, density difference, and base plus fog.  

15.2.2.1.1. weekly for diagnostic units  

15.2.2.1.1.1. limiting criteria:  

15.2.2.1.1.1.1. the base plus fog density shall be within + 0.05 of the established operating level.  

15.2.2.1.1.1.2. the mid-density shall be within +/- 0.20 from the established operating level.  

15.2.2.1.1.1.3. the density difference shall be within +/- 0.20 from the established operating level.  

15.2.2.1.1.1.4. the developer temperature shall be in the range recommended by the manufacturer and posted as required by ODH.  

15.2.2.1.1.1.5.

15.2.2.2. repeat/reject analysis annually,

15.2.2.2.1. divide rejected images by number of images produced

15.2.2.2.2. limiting criteria: less than 10% reject rate, except for teaching areas

15.3. Personnel protective equipment

15.3.1. The following QC test shall be performed by an image technician, radiologic technologist or individual trained in the testing procedure(s).

15.3.1.1. apron checks, annually

15.3.1.1.1. fluoroscope aprons looking for cracks, holes or penetrations through the lead

15.3.1.1.2. limiting factor: any penetrations greater than listed in hospital policy

15.4. RGE testing equipment

15.4.1. All RGE testing equipment, e.g., "cutie pie", ion chambers, shall be calibrated at least every two years.

15.4.2. All RGE testing equipment shall be calibrated by the Radiation Safety Office, or an individual/company approved by the NRC, an agreement state or a licensing state.

15.4.3. Copies of the calibration shall be maintained by the CRE and provided to the CP upon request.
15.4.4. Limiting criteria: ± 20% of expected value. If greater than ± 10% a chart must be attached to the meter.

15.5. Corrective action

15.5.1. Equipment outside limiting criteria must be removed from service until repaired, unless exempted by the applicable CRE. Equipment must be rechecked prior to returning to service.

15.5.2. Repeat analysis outside limiting criteria must be brought to the immediate attention of the CRE and shall be monitored by the QA Committee.

15.6. Record maintenance

15.6.1. 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.

15.6.2. 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
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 an individual log, or documentation shall be recorded in the patient record that lists:

16.2.1.1. the patient's name and medical record number
16.2.1.2. the date of exam
16.2.1.3. the procedure(s) performed
16.2.1.4. the physician operator's name
16.2.1.5. 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 films.

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
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, RSO, CP or state inspector.

17. RGE Acquisition, Inventory, and Disposal or Transfer

17.1. Acquisition (purchase or loaner) of new RGE

17.1.1. The acquisition of all RGE shall be reported to the 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 RSO and CRE shall include, but is not limited to:

17.1.2.1. CP's 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
17.1.2.6. expected delivery date
17.1.2.7. planned location

17.1.3. The 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 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 that list in hospital policy (and)
17.1.4.2.2. 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 the RSO (and)
17.1.4.2.3. if applicable, room safety feature evaluation testing (e.g., interlocks, remote visual)

17.2. Inventory
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 distribute copies of the current inventory to appropriate CP.

17.2.2.2. Each CP shall review the inventory, indicate changes, then sign and return the inventory to the Radiation Safety Office by the end of the second month of each calendar quarter.

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

17.3. Disposal or transfer

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

17.3.2. Information provided to the 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 anticipated date of disposal or transfer

17.3.3. The RSC approved form “Notice of Transfer or Disposal of Radiation Generating Equipment (x-ray)” should be used to document disposal or transfer of RGE. The form is available on the Radiation Safety website (www.uc.edu/radsafety).

17.4. From the information provided, the RSO shall provide any necessary quarterly reports to the Ohio Department of Health covering the installation, disposal or transfer 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

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:

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:**

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

<table>
<thead>
<tr>
<th>Form Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>RS FORM 2.0</td>
<td>RADIATION WORKER/DOSIMETER APPLICATION</td>
</tr>
<tr>
<td>RS FORM 37A</td>
<td>RELEASE OF LIABILITY AND WAIVER CLAIM FOR MINORS</td>
</tr>
<tr>
<td>RS FORM 37B</td>
<td>SUPERVISOR’S STATEMENT FOR MINORS</td>
</tr>
<tr>
<td>RGE Deposition</td>
<td>NOTICE OF TRANSFER OR DISPOSAL OF RADIATION PRODUCING EQUIPMENT (X-RAY)</td>
</tr>
</tbody>
</table>

Forms Available on Radiation Safety Website

[www.uc.edu/radsafety](http://www.uc.edu/radsafety)
Appendix B
ALARA Investigational Levels
# ALARA Investigational Levels

<table>
<thead>
<tr>
<th>AREA/DOSE</th>
<th>ALARA I (10%) LEVEL</th>
<th>ALARA II (30%) LEVEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective Dose*</td>
<td>125 mrem</td>
<td>375 mrem</td>
</tr>
<tr>
<td>Any organ, other than eye</td>
<td>1250 mrem</td>
<td>3750 mrem</td>
</tr>
<tr>
<td>Eye</td>
<td>375 mrem</td>
<td>1125 mrem</td>
</tr>
<tr>
<td>Skin</td>
<td>1250 mrem</td>
<td>3750 mrem</td>
</tr>
<tr>
<td>Extremity</td>
<td>1250 mrem</td>
<td>3750 mrem</td>
</tr>
</tbody>
</table>

- 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)
Appendix C
Sample Posting
The University of Cincinnati

Radiation Control and Safety Program (RCSP)

The RCSP covers licensed sources of radioactive material used and possessed at University of Cincinnati campuses (East, West, RWC, OCAS, GRI and Center Hill), The University Hospital, Cincinnati Children’s Hospital Medical Center and associated Ohio outpatient clinics, and Cincinnati Shriners Hospital for Children. The RSCP also covers registered radiation generating equipment (RGE) used and possessed at University of Cincinnati campuses (East, West and RWC), Cincinnati Children’s Hospital Medical Center and associated Ohio outpatient clinics, and Cincinnati Shriners Hospital for Children. The broad scope license (license# 02110310010), the source material license (license# 01129310010), the RGE registrations and the license/registration inspection reports may be examined at the Radiation Safety Office (RSOf). Copies of policies and procedures are available at the RSOf and are posted on the RSOf website www.uc.edu/radsafety. Current applicable rules are posted on the Ohio Department of Health (ODH) website www.odh.state.oh.us.

University of Cincinnati Radiation Safety Office
(513) 558-4110, ML 0591
Office-hours 8:00 am – 5:00 pm standard university business days

OHIO DEPARTMENT OF HEALTH
NOTICE TO EMPLOYEES

In radiation protection rules adopted under Chapter 3748 of the Ohio Revised Code, the Ohio Department of Health has established standards for your protection from radiation sources which are required to be licensed/registered with the Ohio Department of Health

YOUR EMPLOYER'S RESPONSIBILITY

Your employer is required to:
1) Inform you of the occurrence of radiation or radiation sources and the presence of a restricted area;
2) Instruct you in the safety problems associated with exposure to radiation and in precautions or procedures to minimize exposure to radiation; instruct you in the applicable laws for the protection of personnel from exposure to radiation;
3) Post or otherwise make available to you a copy of the operating procedures applicable to work under the license/registration;
4) Apply the radiation protection rules to all work involving licensed/registered sources of radiation; and
5) Post notices of violation involving radiological working conditions.

YOUR RESPONSIBILITY AS A WORKER

You should familiarize yourself with those provisions of the radiation protection rules and operating procedures that apply to the work you are engaged in. You should observe their provisions for your own protection, the protection of your co-workers and others. If you should observe violations of the law, or have a safety concern, you should report them to your supervisor. You may also report them to ODH.

WHAT IS COVERED BY THESE RULES

1) Limits on exposure to radiation and radioactive materials in restricted and unrestricted areas;
2) Measures to be taken after accidental exposures;
3) Personnel monitoring; surveys and equipment;
4) Caution signs, labels and safety interlock equipment;
5) Exposure records and reports; and
6) Related matters.

REPORTS ON YOUR RADIATION EXPOSURE HISTORY

Your employer is required to advise you of your dose annually if you are exposed to radiation for which monitoring was required by ODH or upon request. In addition, you may request a written report of your exposure when you leave your job.

INSPECTIONS

All activities covered by the ORC 3748 and other radiation protection laws are subject to inspection by representatives of the Ohio Department of Health.

POSTING REQUIREMENTS

Copies of this notice must be posted in a sufficient number of places in every facility where employees are engaged in activities subject to the radiological working conditions, you may request an inspection. Your request should be addressed to the Ohio Department of Health, Bureau of Radiation Protection, and must describe the alleged violation in detail. It must be signed by you, or your representative.

DISCRIMINATION

Your employer is prohibited from firing or otherwise discriminating against you for bringing safety concerns to the attention of your employer or ODH. You may not be fired or discriminated against because you:
- ask ODH to enforce the law against your employer;
- refuse to engage in activities that violate the law;
- provide information or are about to provide information to the ODH or your employer about violations of laws or safety concerns;
- are about to ask for, or testify, help, or take part in an ODH or other state proceeding.

The ODH will investigate each allegation of harassment, intimidation, or discrimination.

CONTACT INFORMATION

Bureau of Radiation Protection
Ohio Department of Health
246 North High Street
Columbus, Ohio 43215
BRadiation@odh.ohio.gov

Radioactive Materials
Phone 614-644-2727
Fax 614-466-0381

Radiologic Technology Section (X-ray)
Phone 614-644-2727
Fax 614-466-0381

If you have questions or concerns contact the Radiation Safety Officer or the certified radiation expert (CRE).
Radiation Safety Officer – Victoria Morris, CHP (513) 558-4110

ODH 4786.32 (Rev. 8/06)