

	North Carolina Department of Environment and Natural Resources Division of Environmental Health RADIATION PROTECTION SECTION Radiology Compliance Branch	Page(s)		
		1	of	6

MEDICAL SAFETY PROGRAM GUIDE

This guide may be used to help construct a Radiation Protection Program specific for each facility, but cannot be used to substitute the registrants Radiation Protection Program.

Facilities shall review the safety program and keep these records for inspection review.

Each registrant must develop procedures for each modality used and should be included in the program (Diagnostic, Fluoroscopy, C-Arm, Special Procedures, CT, Bone Density, Dental).

The following sections of the regulations, if applicable, need to be addressed, reference **15A NCAC 11 .0100 .0200, .0600, .1000, .1100 and .1600**:

ITEMS TO INCLUDE IN A RADIATION SAFETY PROGRAM

❖ **General Information [.1603(a)]**

- Name and duties of the Radiation Safety Officer [.0203(b)(2) & (3)]
- Describe retention for all records, to include but not limited: to current registration, plan reviews, letter of acknowledgements, post installation room surveys, and FDA forms (2579) [.0603(a)(2)]
- Updating the Notice of Registration (NOR) when any changes occur [.0209]
- Location in the facility of the following items: **(where can the employees see these documents)**
 - Notice to Employee [.1002(c)] **(keep all documents for inspection review)**
 - NC Regulation Book [.1002(a)(1)]
 - Plan Review [.0603(a)(2)(A)] **See - [Records Reviewed During Inspections](#)**
 - Acknowledgement Letters [.0603(a)(2)(A)]
 - Report of Assembly (FDA 2579) [.0603(a)(2)(A)]
 - Post-Installation Survey [.0603(a)(2)(B)]
 - Notice of Registration [.0603(a)(2)(A)]
 - Written Safety Program [.0603(a)(1)(D)]
 - Review of Written Safety Program **(annually and/or when changes are made)** [.1603(c)] [.1636(a)(2)]

❖ **Facility Policies & Procedures to include but not limited to:**

Personnel Training Policy [.1603(a)] [.0603(a)(1)(B)]

- Describe the training for operators of the x-ray equipment:
 - If in house trained: name of trainer, name of trainee and topics covered; or
 - Certification: if all x-ray operators are required to be licensed/certified a statement to this fact is sufficient.
- Describe the location of the operator during exposures
- Technique Chart contents [.0603(a)(1)(C)]
 - Describe the procedures for selecting exposure techniques for the different body size and each exam performed
- Persons allowed in the x-ray room during exposures [.0603(a)(1)(E)]
 - Requirements for professional staff (if in room during exposure)[.0603(a)(1)(E)(ii)] [.0603(a)(1)(J)] [.1614]
 - Requirements for non professional and ancillary individuals in room during exposure other than patient [.0603(a)(1)(E)(iv)]

Continue Facility Policies & Procedures

- Use of Lead shielding [.0603(a)(1)(F) & .0603(a)(1)(E)(ii) **(patients and personnel)**]
- Ordering of examinations and “re-takes” [.0603(a)(1)(G)]
- Auxiliary support of patient or film during a radiograph [.0603(a)(1)(H)]
 - Describe the training for using mechanical restraining devices for humans.
 - Describe the requirements for selecting a human holder.
 - Describe the training for a human holding patients during a radiograph
- Principals of ALARA [.0603(a)(1)(I)] [.1603(b)] [Pregnancy Policy](#)
 - Define personnel voluntary declared pregnancy policy [.1610] [.1640(f)]
 - Patient pregnancy policy
 - Speed of screen film combinations to minimize patient exposure
 - Describe measures taken to keep exposure to a minimum
- Mobile/Portable exams [.0603(a)(1)(I)(iii)] [.0603(a)(1)(E)(iii) & (iv)] **(if applicable)**
 - Use of mobile or portable machine
 - Shielding of patients not being examined when possible
- Closing doors during exposures to prevent unnecessary exposure to staff or public [.0604(b)]
- Visual contact with the patient [.0604(b)(1)(C)]
- Visual and audible indication for control panel during exposure [Medical-.0606(b)(2)(B)(ii)] [Dental-.0607(e)(3)]
- Describe any additional radiation safety activities being preformed in the facility [.0603(a)] [.1603(a)]

Radiation Exposure Limits

❖ **Personnel**

- Describe the personnel exposure policy [.1603(a)] [.1614]
 - If monitoring not provided, document how the choice to not monitor was determined.
 - Time frame for exchanging badges
 - Describe how the control and personnel monitoring devices are stored
 - Retention of exposure records **(keep all dosimetry reports)** [.1640]
- Occupational dose limits for adults [.1604] [Dose Limits](#)
- Occupation dose limits for minors [.1609]
- Acquiring prior occupational dose for new workers [.1638(a)(1)&(2)]
- Retention of exposure records **(keep all dosimetry reports)** [.1640]

❖ **General Public**

- Dose Limits For Individual Members Of The Public [.1611] [Dose Limits](#) (Bottom of front page)
- Describe compliance method to ensure dose limits to general public is below limits.[.1612]

❖ **Exceeding Exposure Limits [.1647] [Dose Limits](#) (Middle of front page)**

- Describe reporting of exceeding limits [.1647(a)]
- Information to be reported [.1647(a)(3)(b) &(c)]
 - Name of person, social security number, date of birth and dose amount
 - What caused the exposure
 - What steps have been taken to prevent this from happening in the future
- Notify appropriate individuals and/or agencies [.1647(d)&(e)] [.0111]

❖ **Quality Assurance Activities (Recommendation Only)**

A sound Quality Assurance (QA) program is recommended to consistently produce high quality imaging and optimized processing conditions. QA helps to minimize the need for unnecessary retakes while reducing exposure to patients.

Many Facilities perform some activities for which they have no procedures or forms. The links below will assist you in adopting forms and/or procedures for these activities.

- **Digital Image Acquisitions Systems – Describe each of the following policies**
 - Follow quality assurance/quality control protocol for image processing established by the manufacturer if no manufacturer's protocols are available, by the registrant.
- **Radiographic Machines (to include veterinary) [.0606]**
 - X-ray tube warm up procedures
 - Processor QC (Sensitometry)
 - Repeat Analysis
 - Film and Chemical Storage
 - Chemicals, (developer-time & temperature)
 - Darkroom fog test
 - Lead Apron, Glove, Gonadal, and Thyroid Shield Integrity
 - Screen-Film Contact Test
 - Cleaning screens
 - Compatibility of film/screens (blue or green)
 - Speed system of film/screen combination (100-200-400)
 - Viewboxes
 - Visual Checklist
- **Fluoroscopic Machines (also include the applicable parts of the radiographic unit) [.0605]**
 - Fluoroscopy Image Quality Check
 - High Contrast Resolution and Patient Exposure Test
 - Fluoroscopy System Visual Checklist
 - Fluoroscopic High-Level Control Test

Some QA activities regarding service to x-ray machines and processors can be performed by service providers or the facility can develop their own QA activities. Describe any QA activities in the facility.

If service providers are performing the QA tasks in the facility:

- name of service provider
- type of service provided
- frequency of service
- location of service records

AND/OR

The facility develops their own activities or procedures using the links below:

- include the facilities procedures ****See links below****

QA & QC Links:

The information contained in the sites below are for guidance to help develop and follow a Quality Assurance/Quality Control program for your facility. It is recommended that an adequate QA/QC program be developed to ensure the highest quality radiographs with the lowest dose to the patient as possible.

RADIOGRAPHY QA/QC

American Association of Physicists in Medicine (AAPM) Report No. 74

Quality Control in Diagnostic Radiology, July 2002.

http://www.aapm.org/pubs/reports/rpt_74.PDF

Conference of Radiation Control Program Directors, Inc. (CRCPD)

Quality Control Recommendations for Diagnostic Radiology, Radiographic or Fluoroscopic Machines (Volume 3), Publication 01-6

<http://www.crcpd.org/Pubs/QC-Docs/QC-Vol3-Web.pdf>

Conference of Radiation Control Program Directors, Inc. (CRCPD)

Quality Control Recommendations for Diagnostic Radiology, Dental Facilities (Volume 1), Publication 01-4

<http://www.crcpd.org/Pubs/QC-Docs/QC-Vol1-Web.pdf>

U.S Food and Drug Administration

21CFR1000.55

Recommendation for quality assurance programs in diagnostic radiology facilities

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm>

Conference of Radiation Control Program Directors, Inc. (CRCPD)

QA Collectible- Methods to Reduce Patient Dose, July 1988

http://www.crcpd.org/PDF/7-88_QA.pdf

Conference of Radiation Control Program Directors, Inc. (CRCPD)

QA Collectible- Processor Sensitometric Control, December 1992

<http://www.crcpd.org/PDF/12-92qac.pdf>

Conference of Radiation Control Program Directors, Inc. (CRCPD)

QA Collectible-Processor QC for Low Volume Facilities, April 1991

<http://www.crcpd.org/PDF/4-91qac.pdf>

Center for Devices and Radiological Health, Food and Drug Administration

Screen-Film Speed Combinations, May 2004

http://www.crcpd.org/Docs/Screen-filmSpeedCombos_040506.pdf

Glossary

“ALARA”: (acronym for “as low as reasonably achievable”) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in the rules as is practical.

“Declared Pregnant Woman” means a woman who has voluntarily informed the licensee or registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the woman declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

Exposure: Means being exposed to ionizing radiation or to radioactive materials.

Personnel Monitoring Equipment: Devices such as film badges, pocket dosimeters, and thermoluminescent dosimeters, designed to be worn or carried by an individual for the purpose of estimation the dose received by the individual.

Quality assurance: The planned and systematic actions that provide adequate confidence that a diagnostic x-ray facility will produce consistently high quality images with minimum exposure of the patients and healing arts personnel.

Quality control: Monitoring or testing and maintenance of the components of an x-ray system.

Radiation Safety Officer (RSO): An individual named by the licensee or registrant who has knowledge of, responsibility for, and authority to ensure compliance with appropriate radiation protection rules, standards, and practices on behalf of the licensee or registrant and who meets the requirements of 15A NCAC 11 .0510(h) of this the North Carolina Regulations for Protection Against Radiation.

QC Manual: Should be created and reviewed at least annually. The manual should include the facility’s objectives, QC instructions, QC results, and personnel responsibility. Items that should be included in a **QC Manual** are:

- A list of the tests to be performed and the frequency for each test, including acceptable test limits, test procedures, maintenance, and service records
- A list of equipment to be used for testing
- Policy and procedures for QC tests as well as for the facility
- Sample forms

Other Links: **NC Radiation dictionary:** <http://ncradiation.net/xray/dictionary.htm>

The NC Radiation website: http://ncradiation.net has the following information:	
Inspection Check List	information the inspectors ask to see during an inspection
Tips For Answering Violations	how to reply to violations
Reference Guides For Facilities	information to help the facilities write their own safety program
Plan Reviews & Surveys	registered service providers that are qualified to provide this service
Writing Safety Program Outline	an outline to help the facilities develop a safety program
Postings	documents that need to be posted in the facility
Registration Forms	form to complete to register a facility and x-ray machines or if changes have occurred

