

North Carolina Department of Environment and Natural Resources
 Division of Environmental Health
RADIATION PROTECTION SECTION
Radiology Compliance Branch

MEDICAL RADIATION PROTECTION & SAFETY PROGRAM GUIDE

This is a guide to help construct a Radiation Protection Program specific for each facility, but not used as a substitute for the registrants Radiation Protection Program. The purpose of a written Radiation Protection Program is to inform operators of the required safety procedures to follow during the use of x-ray equipment to protect operators, personnel, patients and the public from unnecessary exposure to radiation. All operators shall be familiar with these procedures.

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

Each registrant must develop and document procedures for each modality used at the facility. Modalities include Diagnostic, Fluoroscopy, C-Arm, Special Procedures, CT, Bone Density, and Dental.

Address the following sections of the regulations, if applicable, **15A NCAC 11 .0100, .0200, .0600, .1000, .1100 and .1600:**

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

ITEMS TO INCLUDE IN A WRITTEN RADIATION PROTECTION & SAFETY PROGRAM

❖ **General Information**

- Name of facility to which the written safety procedures apply [.1603(a)]
- Name and duties of the Radiation Safety Officer [.0203(b)(2)]
- Location and retention of the following required documents: **See - [Records Reviewed During Inspections](#) (Where can the employees see these documents? Keep all documents for inspection.)**
 - Plan Review and Letter of Acknowledgement [.0603(a)(2)(A)] [.0603(b)]
 - Current Notice of Registration [.0603(a)(2)(A)] [.0209]
 - Post Installation Survey (not required for intra-oral units) [.0603(a)(2)(B)] [.0603(c)]
 - FDA 2579 form [.0115]
 - NC Regulation Book [.1002(a)(1)]
 - Notice to Employees [.1002(c)]
 - Written Safety Procedures [.0603(a)(1)(D)]
 - Review of Written Procedures **(annually and when changes to activities or procedures are made)** [.1603(c)][.1636(a)(2)]

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

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

- Describe the education or training requirements for operators to operate x-ray equipment:
 - If it is required for operators to be registered or certified, a statement to this fact is sufficient.
 - If it is not required for operators to be registered or certified, describe name of trainer, name of trainee and topics covered during training.
- Technique Chart contents [.0603(a)(1)(C)]
 - Describe exposure techniques for the different body sizes and exams performed. *If more than one method is used, describe each.* (Example: technique chart, pre-programmed units, or AEC units)
- Describe how written safety procedures are available to all individuals operating x-ray equipment. [.0603(a)(1)(D)]
- What is required for a person, other than the patient, to be in the x-ray room during exposures [.0603(a)(1)(E)]
 - Professional staff [.0603(a)(1)(E)(i)&(ii)] [.0603(a)(1)(J)] [.1614]
 - Non-occupationally exposed professional staff and/or ancillary personnel [.0603(a)(1)(E)(i),(ii)&(iv)]

Facility Policies & Procedures *Continued*

- How and when is gonad and/or lead shielding used on patients? [.0603(a)(1)(F)]
- Who can order x-rays and re-takes in the facility? [.0603(a)(1)(G)]
- Auxiliary support of patient and/or image receptor during an exposure: [.0603(a)(1)(H)]
 - When is mechanical holding devices used? [.0603(a)(1)(H)(i)]
 - Outline instructions provided to the human holding a patient during an exposure. [.0603(a)(1)(H)(ii)&(iii)]
 - What is the criteria for a selecting a human holder? [.0603(a)(1)(H)(iv)]
- What procedures are performed and auxiliary equipment used in the facility to minimize patient and personnel exposure? This includes, but is not limited to, the following requirements: [.0603(a)(1)(I)]
 - Is the speed of film or screen and film combinations the fastest speed consistent with the diagnostic objective of the exams performed? [.0603(a)(1)(I)(i)]
 - How are radiation exposures to the patient minimized to produce images of good diagnostic quality? *One example of this for a digital unit is to monitor the exposure index, after making an exposure, to ensure it is within the range for the particular body part x-rayed established by the manufacture of the equipment.* [.0603(a)(1)(I)(ii)]
 - Patient pregnancy policy: How is it determined if a patient may be pregnant? Are precaution taken if patient pregnant?
 - Are there any additional procedures or equipment used to meet the objective of minimizing exposure that is specific to the facility not described in the safety program? If so, include the information in the safety program.
- Mobile/Portable exams (**if applicable**)
 - Describe when mobile or portable machines are used. [.0603(a)(1)(I)(iii)]
 - Describe shielding or moving patients unable to be removed from the room during an exposures. [.0603(a)(1)(E)(iii)]
- Describe how the operator is to maintain visual contact of the patient during an exposure. (*Dental- Describe visual contact with patient during Pan, CT, Tomography or Cephalometric procedures*) [.0604(b)(1)(C)]
- What is the location of the operator during an exposure? [Medical-.0606(b)(2)(B)(i)][Dental-.0607(e)(2)(A)]
- Describe visual indicator & audible signal observable at or from the operators protected area during an exposure. [Medical-.0606(b)(2)(B)(ii)][Dental-.0607(e)(3)]

❖ Radiation Exposure Limits

ALARA (As Low As Reasonably Achievable)

- What procedures and engineering controls are used based upon sound radiation principles to achieve occupational doses and doses to members of the public ALARA. [.1603(b)]
 - Identify when closure of doors or controlling hallways are required to prevent unnecessary exposure to staff or public
 - Identify any additional procedures or controls used that are specific to the facility to achieve ALARA.

Personnel

- What are the annual occupational dose limits? [.1604(a)(1)] [Dose Limits](#)
- What is the facilities personnel voluntary declared pregnancy policy? [.1610] [.1614(1)(c)] [.1640(f)] [Pregnancy Policy](#)
- What is the personnel exposure policy? [.1614]
 - *If personnel monitoring not provided to operators, explain how facility met compliance to the regulations.*
 - What is the frequency of exchanging personnel monitoring badges?
 - How are the control and personnel monitoring badges stored?
- How is prior occupational dose for new workers acquired? [.1638(a)(1)&(2)]
- What is the retention period for exposure records? (**keep all dosimetry reports**) [.1640(a)(1)&(g)]

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

- When are exceeding dose limits reported? [.1647(a)(2)]
- What data of the affected person needs reported? [.1647(b)&(c)]
 - Estimated dose
 - Cause of elevated exposure
 - Corrective Action
 - Name
 - Social security number
 - Date of birth
- What individuals and/or agencies need notification? [.1647(d)&(e)] [.0111]

REVIEW OF SAFETY PROGRAM

The development of these safety procedures is to facilitate safe radiological working conditions. Everyone must adhere to these procedures. For ANY deviation from these procedures, prior approval is required.

In accordance with Rule .1603 (c) , the registrant shall annually review the radiation protection program content and implementation. These procedures are available to each individual who operates the x-ray equipment.

(Signature of Radiation Safety Officer)

Date

OPERATOR STATEMENT:

I have read the procedures and agree to abide by them.

Signatures

Date

_____	_____
_____	_____
_____	_____
_____	_____

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

A good Quality Assurance (QA) program helps to consistently produce high quality imaging and optimize processing conditions. QA helps minimize the need for unnecessary retakes that contribute to unnecessary patient exposure to radiation.

Digital Image Acquisitions Systems: Follow the quality assurance & quality control protocol established by the manufacturer.

Radiographic Machines (to include veterinary): [.0606]

-X-ray tube warm up procedures	-Cleaning screens
-Processor QC (Sensitometry)	-Screen-Film Contact Test
-Chemicals, (developer-time & temperature)	- Compatibility of film/screens (blue or green)
-Film and Chemical Storage	- Speed of film/screen combination (100-200-400)
-Darkroom fog test	-View boxes
-Repeat Analysis	-Visual Checklist
- Lead Apron, Glove, Gonad, and Thyroid Shield Integrity	

Fluoroscopic Machines: (also include the applicable parts of the radiographic unit) [.0605]

- Fluoroscopy Image Quality Check	- Fluoroscopy System Visual Checklist
- High Contrast Resolution and Patient Exposure Test	- Fluoroscopic High-Level Control Test

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

If service providers are performing the QA tasks in the facility, information to document:

-Name of service provider	- Frequency of service
-Type of service provided	- Location of service records

Many Facilities perform activities for which they have no procedures or forms. The links below will assist you in adopting forms and/or procedures for these activities. Include the facilities procedures ****See the following links****

QA & QC Links:

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

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/cfcfr/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

PODIATRY QA/QC**Conference of Radiation Control Program Directors, Inc. (CRCPD)**

Quality Control Recommendations for Diagnostic Radiology, Podiatric Facilities (Volume 2), Publication 01-5

<http://www.crcpd.org/Pubs/QC-Docs/QC-Vol2-Web.pdf>

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 register a facility and x-ray machines or if changes have occurred