Radiology Compliance Branch
RADIATION PROTECTION SECTION

Division of Health Service Regulation ● N.C. Department of Health and Human Services

RADIATION PROTECTION PROGRAM GUIDE - MEDICAL WRITTEN SAFETY PROCEDURES

Each registrant shall develop, document, and implement a Radiation Protection Program commensurate with the scope and extent of registered activities to ensure compliance with the provisions of **10A NCAC 15 [.1600**]. In accordance with Rule **[.1603 (c)]**, the registrant shall annually review the radiation protection program content and implementation.
NC Radiation Dictionary
NC Radiation Regulations

ITEMS TO INCLUDE IN RADIATION PROTECTION PROGRAM AND SAFETY PROCEDURES

Radiation Protection Program: [.1603(a)]

ALARA (As Low As Reasonably Achievable) Radiation Protection Principles
- Describe procedures and engineering controls that are used based upon sound radiation principles to achieve occupational doses and doses to members of the public ALARA. **[.1603(b)]**
  - Identify closure of doors or controlling hallways 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
- Describe how individuals are notified if occupational doses exceed 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue **[.1004]** ***(effective 1/1/14)***
- State the facility's annual occupational dose limits. **[.1604(a)]** Dose Limits
- Explain how doses an individual may receive in the current year are reduced by the occupational exposures received while employed by another person. **[.1604(f)]**
- State the dose limits to an Embryo/Fetus. **[.1610] [.1614(1)(c)]**
- Explain the facility's personnel voluntary declared pregnancy policy. **[.1640(f)]** Pregnancy Policy
- Describe the facility's personnel monitoring exposure policy. **[.1614]**
  - Frequency of exchanging badges
  - Storage of control and personnel badges
  - *If personnel monitoring not provided to operators, explain how facility met compliance to regulations.*
- Describe the facility's process to obtain prior occupational dose for new workers. **[.1638(a)(1)&(2)]**
- Explain the facility's retention period for exposure records. *(keep all dosimetry reports)* **[.1640(a)(1)&(g)]**

Unit Security [.1622]
- Equipment control measures in place to prevent unauthorized use or device removal.

Exceeding Exposure Limits [.1647)] Dose Limits
- Identify the facility's reporting process for when a dose limit is exceeded? **[.1646] [.1647]**
- Describe how data of the affected person is reported to both the individual and to Radiation Protection. **[.1647(b)(c)(d)(e)] [.0111]**
  - Estimated dose
  - Cause of elevated exposure
  - Corrective Action
  - Name & Date of Birth
  - The last 4 of the Social security number and/or employee identifier

Written Safety Procedures: [.0603(a)(1)(D)]

- Describe how written safety procedures are made available to all individuals operating X-ray equipment. **[.0603(a)(1)(D)]**
- Explain types of auxiliary support of patient and/or image receptor that may be used during an exposure: **[.0603(a)(1)(H)]**
  - State the facility requirements for selecting a mechanical holding device. **[.0603(a)(1)(H)(i)]**
  - State the instructions provided to a human holder during an exposure. **[.0603(a)(1)(H)(ii)&(iii)]**
  - Identify the facility's criteria for selecting a human holder **[.0603(a)(1)(H)(iv)]**

RECOMMENDATIONS TO INCLUDE IN SAFETY PROCEDURES

Registrants should consider including the following recommended items that apply to their facility. Providing operator's specific instructions in safe work practices and in safe operating procedures, for use of the equipment will help the operators identify potential safety issues so they can notify the correct entity for evaluation and prompt attention as necessary.

Procedures should include each modality used at the facility. Some examples of modalities; but not limited to include: Diagnostic, Fluoroscopy, CT, C-Arm, Special Procedures, Bone Density, and Dental.

Applicable sections of regulations for Medical X-ray**: 10A NCAC 15 [.0100]; [.0200]; [.0600]; [.1000]; [.1100] and [.1600]**

Medical & Dental Facilities:

- Operator Training Policy **[.0603(a)(1)(B)]**
  - Describe the education or training requirements for operators of equipment:
    - If it is required for operators to be registered or certified, a statement to this fact is sufficient.
    - If operator is not registered or certified, document trainer, trainee and topics covered during training.
- Technique Chart **[.0603(a)(1)(C)]**
  - Describe exposure techniques for the different body sizes and exams performed.
  - If more than one method used, describe each. *(Example: technique chart, pre-programmed units, or AEC units)*
- Define your requirements 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)]**
- State how and when gonad and/or lead shielding used on patients **[.0603(a)(1)(F)][.0603(a)(1)(I)]**
- Define who can order X-rays and re-takes in the facility. **[.0603(a)(1)(G)]**
- Outline the procedures performed & auxiliary equipment used at the facility to minimize patient & personnel exposure. This includes, but is not limited to the following requirements: **[.0603(a)(1)(I)]**
  - State how patients' radiation exposures are minimized to produce images of good diagnostic quality? **CR (Computed Radiography) or DR (Digital Radiography)** *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)]**
  - Explain the facility's patient pregnancy policy: How is it determined if a patient may be pregnant?
  - Precautions taken if the patient is pregnant.
- Define any additional procedures or equipment used specific to the facility to meet the objective of minimizing exposure.
- Mobile/Portable exams **(if applicable)**
  - Describe when mobile or portable machines are used. **[.0603(a)(1)(I)(iii)]**
  - Describe your policy shielding or moving patients unable to be removed from the room during 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)]**
- State 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. Both the audible and visible indicators must work properly to help ensure unnecessary repeat exposures to the patient. *Explanation to the operator of what steps to take in the event either the audible or the visual indicator is not working.* **[Medical-.0606(b)(2)(B)(ii)][Dental-.0607(e)(3)]**

Veterinary Facilites (if applicable)

- Describe operator location in relation to the useful beam & animal during radiographic exposures **[.0610(c)(1)]**
- Detail when individuals are allowed in room during exposures **[.0610(c)(2)]**
- Describe mechanical supporting devices used **[.0610(c)(3)]**
- Describe shielding devices and location of individuals during exposures **[.0610(c)(3)]**

REVIEW OF RADIATION PROTECTION PROGRAM

In accordance with Rule .1603 (c) , the registrant shall annually review the radiation protection program content and implementation.

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(Signature of Radiation Safety Officer) ***Date***

The NC Radiation website 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 facility's write their own safety program
Plan Reviews & Surveys	Registered service providers that are qualified to provide this service
Registration Requirements	Requirements for new and existing facilities
Steps To Install X-Ray Equipment or Register	Guide for installing equipment
Registration Forms	Form to register a facility / X-ray machines or amend a registration
Registration: Owning or Possessing X-Ray Equipment	Guide for Owning or Possessing X-Ray Equipment in NC
Postings	Documents that need to be posted in the facility

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 QA & QC protocols established by the manufacturer.

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

Visual Checklist	Cleaning screens	Processor QC (Sensitometry)
X-ray tube warm up procedures	Compatibility of film/screens *(blue or green)*	Chemicals (developer-time & temperature)
Repeat Analysis	Speed of Film/Screen Combination *(100-200-400)*	Film and Chemical Storage
Viewing Conditions	Screen-Film Contact Test	Darkroom fog test
Lead Apron Integrity (Gloves, Gonad, Thyroid Shield, ½ and whole body)		

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

Fluoroscopy Image Quality Check	Fluoroscopy System Visual Checklist
High Contrast Resolution and **Entrance Skin Air Kerma Rate** measurements with appropriate phantoms.	Fluoroscopic High-Level Control Test

Service providers can perform QA activities regarding service to X-ray machines and processors or the facility can develop their own QA activities. If service providers perform QA tasks in the facility, document the following: name of service provider, type of service provided, frequency of service, and location of records.

QA & QC Links:
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 facility's procedures. ***See the following 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
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
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
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
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
www.crcpd.org/PDF/7-88_QA.pdf

Conference of Radiation Control Program Directors, Inc. (CRCPD)
QA Collectible- Processor Sensitometric Control, December 1992
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
www.crcpd.org/PDF/4-91qac.pdf

Center for Devices and Radiological Health, Food and Drug Administration
Screen-Film Speed Combinations, May 2004
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
www.crcpd.org/Pubs/QC-Docs/QC-Vol2-Web.pdf