Radiology Compliance Branch

RADIATION PROTECTION SECTION



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

CABINET X-RAY RADIATION PROTECTION PROGRAM GUIDE

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

FDA Cabinet Regulations 21CFR 1020.40

ITEMS TO INCLUDE IN RADIATION PROTECTION PROGRAM AND OPERATING PROCEDURES

Radiation Protection Program: [.1603(a)]

ALARA (As Low As Reasonably Achievable) Radiation Protection Principles

- Describe the 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 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 facilities annual occupational dose limits. [.1604(a)] Dose Limits
- Explain how doses that 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 facilities personnel voluntary declared pregnancy policy. [.1640(f)] Pregnancy Policy
- Describe the facilities personnel monitoring exposure policy. [.1614]
 - Frequency of exchanging badges
 - Storage of control and personnel badges
- Explain the facilities 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 from facility's registered physical location
- Key actuated control required. (Password protected is acceptable for some units)

Exceeding Exposure Limits [.1647)]Dose Limits

- Identify the facilities reporting process for when a dose limit is exceeded? [.1646][.1647]
- Describe how the data of the affected person is to be 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

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Operating Requirements [.0805][.0806]

- Written operating procedures shall be written and available for operators and support staff.
- Operators must receive instruction in the operating and emergency procedures
- The process to bypass a safety device must be included in the radiation protection program. THE WRITTEN APPROVAL (from the RSO) MUST INCLUDE AN EXPIRATION DATE.

Instructions to Worker [.1003]

All individuals who during employment are likely to receive in a year an occupational dose in excess of 100 millirem (mR) shall be:

- Informed about storage, transfer, or use of radiation in the restricted areas
- Instructed in health protection problems associated with exposure to radiation.
- **Instructed** in precautions or procedures to minimize exposure.
- **Instructed** in purposes and functions of all protective devices employed. <u>(Lead drapes, safety interlocks etc.)</u>
- **Instructed** to report promptly to the registrant any condition which may lead to or cause a violation of rules in this Chapter (Regulations).
- **Instructed** in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation.

Additional Controls and Indicators for cabinet systems designed to admit humans. [.0117]; [21CFR1020.40(c)(7)]

- Describe the control within the cabinet for preventing and terminating X-ray generation, which cannot be reset, overridden or bypassed from the outside of the cabinet.
- Describe the **audible** and **visible** warning signals within the cabinet. These warning signals must be actuated for at least 10 seconds immediately prior to the first initiation of X-ray generation after closing any door designed to admit humans.
- Describe the required signs, which indicate the meaning of the warning signals visible within the cabinet. The signs must be legible, accessible to view, and illuminate when the main power control is in the "on" position.

REVIEW OF RADIATION PROTECTION PROGRAM

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

(Signature of Radiation Safety Officer)	

The NC Radiation link https://radiation.ncdhhs.gov/Xray/reference.htm 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 qualified to provide this service
Registration Requirements	Requirements for new and existing facilities
Steps To Install X-Ray Equipment or	Guide for installing equipment
Register	
Registration Forms	Form to register a facility / X-ray machines or amend a registration
Registration: Owning or Possessing X-	Guide for Owning or Possessing X-Ray Equipment in NC
Ray Equipment	
<u>Postings</u>	Documents that need to be posted in the facility

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