

Radiology Compliance Branch

RADIATION PROTECTION SECTION



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

CABINET X-RAY INSPECTION CHECKLIST

Security Screening Units (mail, baggage), Industrial QC Cabinets and Medical Specimen Cabinets

North Carolina Regulations For Protection Against Radiation [10A NCAC 15](#) rule references shown in brackets

General Documents:

- Waivers on file (if applicable) [.0108(a)]
- Report of Sale / Installation Report [.0115]
- Current Notice of Registration [.0209] [.1002(a)(2)]
- Current State Regulations [.1002(a)(1)]
- Notice to Employees [.1002(c)] (posted in restricted area)

Operating Requirements / Radiation Protection Program

- Manufacturer's manual and instructions (technical, safety and maintenance schedule) [.0117]; [21CFR1020.40(c)(9)(i)]
- Operating requirements [.0805]; [.1002(a)(3)]
- Current copy of the radiation protection program [.1603(a)]

Labels

- Identification Label (Manufacturer/date) [.0117]; [21CFR1010.3]
- The insertion of any part of the human body through any port into the primary beam shall not be possible (*Examples: guards / drapes / sensors*) [.0117]; [21CFR1020.40(c)(3)(i)]
- "Caution: X-Rays Produced When Energized" (located on control) [.0117]; [21 CFR 1020.40(c)(8)(i)]
- "Caution: Do Not Insert Any Part of the Body When System is Energized-X-ray Hazard" (located on each port) [.0117]; [21CFR 1020.40(c)(8)(ii)]

Warning Lights [.0803(k)(I)] [.0117]; [21CFR1020.40(c)(6)(iii)]

- Labeled: "X-Ray On"
- Located: Near any switch, that energizes tube **or** conspicuously located near source / beam(s)
- Visible: From all instrument access areas
- Activates: When energized

Area Requirements [.0804(c)]

- "CAUTION- X-RAY EQUIPMENT" posted at each area of use or room

Safety Interlocks and Security:

- Safety interlocks on each door (2 req.) [.0117]; [21CFR1020.40(c)(4)(i)]
- Access Panel interlock functioning (1 req.) [.0117]; [21 CFR 1020.40(c)(4)(ii)]
- Key-actuated control [.0117]; [21 CFR 1020.40(c)(6)(i)]
- Unit security [.1622]

Records:

- Training documentation of person responsible for radiation protection [.0203(b)(3)]
- Survey reports: [.0804(b)]; [.1613]; [.1637]
 - Within 30 days of initial operation
 - Prior to use following any change in initial arrangement
 - Prior to use following maintenance
- Annual testing for proper operation of safety devices (interlocks/shutters/warning lights) [.0805] (*effective 10/1/15*)
- Operating and emergency procedures training documentation records [.0806 (a)(2)]
- Annual radiation protection program review by registrant [.1603(c)]; [.1636]
- Personnel monitoring and exposure records [.1614]; [.1640]

****See specific requirements in 21CFR 1020.40 for cabinets that admit humans****

