CERTIFIED CABINET X-RAY RADIATION PROTECTION PROGRAM GUIDE

This is a guide to help construct a written Radiation Protection Program specific for each facility. A registrant may not use this document as a substitute for the written 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, and the public from unnecessary exposure to radiation. All operators shall be familiar with these procedures. [.0207(a)(3)]; [.1603(a)]

Facilities shall review the Radiation Protection Program and keep these records for inspection review.

NC Radiation Protection Rules Effective February 2015
FDA Cabinet Regulations 21CFR 1020.40

ITEMS TO INCLUDE IN A WRITTEN RADIATION PROTECTION PROGRAM

● General Information
  ● Name and address of facility to which the written radiation protection procedures apply [.0203(b)(1)]
  ● Name and experience of the Radiation Safety Officer [.0203(b)(3)], [.0207(1)]
  Small Facility RSO Requirements, Large Facility RSO Requirements
  ● Duties and responsibility of the Radiation Safety Officer outlined [.0104(123)]; [.0207(2),(3)]
  ● Post or Identify Location and Retention of the following required documents: (Where can the employees see these documents? Keep all documents for inspection.)
    - Operating Procedures [.0518(1)(a)]; [.1002(a)(3)]; [.1003]
    - Operator training records [.0518(1)(b)]
    - NC Regulation Book [.1002(a)(1)]
    - Waivers on file (if applicable) [.0108(a)]
    - Current Notice of Registration [.1002(a)(2)]; [.0203(a)(1)]; [.0209]
    - Notice to Employees [.1002(c)]
    - Radiation Protection Program [.1603(a)] [.1636]
    - Radiation Safety Officer review of the Written Radiation Protection Program [.1603(c)]; [.1636(a)(b)] (Annually and when changes to activities or procedures are made)
    - Initial Survey [.1613(a)] [.1637 (a);(b)(1)]
    - Records/Reports of individual monitoring [.1640(a)(b)]; [.1649]
    - Manufacturer’s Manual (operating instructions and maintenance schedule) [.0117(a)(4)]; [21CFR1020.40(c)(9)(i)]
  ● Recommended
    - Previous inspection reports and letters of correspondence
    - “Caution X-Ray Equipment” sign posted on each door or area containing x-ray machines

● Personnel Training Policy (Instructions to Worker) [.0518(1)(a)]; [.1003]
  Describe the education or training requirements for operators to operate cabinet units. The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area. At a minimum the following topics should be taught. Operators should be given a written test on training material.
  ● Specific x-ray machine operating procedures provided to the operator.
  ● Instruction in operation of equipment prior to initial operation.
• Worker understanding of operating procedures and competence demonstrated prior to operation.
• Health protection problems associated with exposure to radiation.
• Precautions or procedures to minimize exposure.
• Purposes and functions of all protective devices employed. (Lead drapes, safety interlocks etc.)
• Instructed in, within the worker's control, the applicable provisions of this Chapter (Regulations).
• Instructed to report promptly to the licensee or 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.

• Unit Security: [.1622]; [.0117(a)(4)]; [21 CFR 1020.40(c)(6)(i)]
  • If the unit is located in a controlled or unrestricted area, describe how the unit is secure from unauthorized removal or access when not in use or unattended.
  • Describe how the room door or area is secured where unit is located.
  • Describe how the unit key is controlled. Passwords can be configured as an acceptable alternative to a physical key if necessary for the intended purpose of the system. Describe all conditions that apply.
  • If the unit is powered on by a key, can the key be removed when x-rays are generated?
    Controlled area: means an area outside of the restricted area but inside the site boundary, access to which can be limited by the registrant for any reason.
    Unrestricted area: means an area in which access is neither limited nor controlled by the registrant.

• Warning Labels & Lights:
  • Describe the visual indicator that must be visible from each door, access panel, and port. The indicator is to indicate when and only when x-rays are generated and must be legibly labeled “X-RAY ON. [.0117(a)(4)]; [21CFR1020.40(c )(6)(iii)]
  • At least one indicator must be visible from each door, access panel, and port. These indicators must be legibly labeled “X-RAY ON”. These additional indicators cannot be milliammeters. The additional indicators must indicate when and only when x-rays are being generated. If the x-ray generation period is less than one-half second, the indicators must be activated for one-half second. [.0117(a)(4)]; [21CFR1020.40(c )(6)(iv)]
  • Describe the warning label required at the location of any control which can be used to initiate x-ray generation. The label must be clearly legible and visible stating “Caution: X-Rays Produced When Energized” [.0117(a)(4)] [21 CFR 1020.40(c)(8)(i)]
  • Describe the warning label required at the location adjacent to each port if applicable. The label must be clearly legible and visible stating “Caution: Do Not Insert Any Part of the Body When System is Energized –X-Ray Hazard”. [.0117(a)(4)]; [21CFR 1020.40(c)(8)(ii)]
    Port: means any opening in the outside surface of the cabinet which is designed to remain open, during generation of x-rays, for the purpose of conveying material to be irradiated into and out of the cabinet, or for partial insertion for irradiation of an object whose dimensions do not permit complete insertion into the cabinet.

• Ports and/or apertures safety measures [.0117(a)(4)];[21 CFR 1020.40(c)(3)(i)]; [21 CFR 1020.40(c)(3)(ii)] (if applicable)
  • Describe the mechanisms in place to prevent accidental and routine operator exposure to the primary x-ray beam. Under this provision, insertion of any body part into a port must not be a standard operating procedure.
  • This requirement is not intended to prevent people from intentionally attempting to defeat system safety features to reach the primary beam. Contorting to reach into, crawling into, or riding through the port into the system are examples of intentional defeat of safety systems.
    • Things to consider: Is there a reason to reach into a port during normal operation and
    • Is it possible to inadvertently reach the primary beam?
  • If cabinet length is not sufficient to prevent access to the primary beam, what other ergonomic and engineered controls are present? Examples include:
    • A system with a straight tunnel that is at least 36 inches from any port to the primary beam
    • Integrating the system into a production line where the products being examined move fast enough to limit access to the port itself

- Describe the interlock requirements for cabinet units that contain doors. Doors are used for loading and unloading items from the cabinet and not intended for maintenance activities.
- Describe the minimum number safety interlock required per door (2 per door).
- One of the door interlocks must:
  - Physically disconnect the energy supply circuit and
  - Not be dependent on any moving part other than the door.
- Describe any Access panels that are used for maintenance if applicable. This does not include doors that are used for loading and unloading items from the cabinet.
  - Example: clearing baggage jams is maintenance.
  - Describe the interlock requirements for one of the safety interlock.
  - Describe the requirement for a tool to open access panel. Tools can be keys or common tools such as screwdrivers and wrenches. No tool required implies it is a door.
- Additional Items to Include:
  - Does the opening of each door or access panel stop x-ray generation?
  - Does closing a door or access panel cause x-ray generation to immediately resume?
  - Does resumption of x-ray generation require operator action? After the triggering of any interlock, it must be necessary to use a control that is in compliance with the control regulations to resume x-ray generation. This requirement prevents the use of an interlock as a switch to turn x-ray production on.
  - Describe the requirement for interlocks to be independent of the possibility of failure of any single component shall not cause the failure of more than one safety interlock.

Access panel - means any barrier or panel which is designed to be removed or opened for maintenance or service purposes, requires tools to open, and permits access to the interior of the cabinet.

Door - means any barrier which is designed to be movable or opened for routine operation purposes, does not generally require tools to open, and permits access to the interior of the cabinet.

Additional Controls and Indicators for cabinet systems designed to admit humans. [.0117(a)(4)];[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 indicating the meaning of the warning signals containing instructions for the use of the control. These signs must be located within the cabinet. They must be legible, accessible to view, and illuminated when the main power control is in the "on" position.

Additional requirements for baggage inspection systems. [.0117(a)(4)]; [21CFR 1020.40(c)(10)]

- X-ray baggage systems must have a means to ensure that the operator is present at the controls so that the operator can clearly view the ports and doors at all times during x-ray generation. Describe the measures in place to ensure operator at control area for port and door surveillance. Surveillance can be accomplished by direct view, mirrors, or video camera.
- Mandatory operator presence for security systems when:
  - Located in a public area and
  - Loaded by owner of item to be screened
- Examples include initiating the control button on control panel and stepping on a floor mat to initiate the x-ray.
Additional Note: This requirement includes any place where members of the public walk up to an x-ray system for the purpose of security screening of their carried belongings. Therefore, cabinet x-ray security screening systems used in office buildings, court houses, and schools are also subject to requirement. Cabinet x-ray systems that are in controlled access areas and are always loaded and unloaded by trained operators are not subject to this section.

- **Surveys**
  - Describe the following conditions requiring a survey for cabinet x-ray units. [.1613(a)(1)]; [.1613(a)(2)(A),(C)]; [.1637(a)]; [.1637(b)(1)]
    - Initial survey
    - Survey following change in initial arrangement of equipment.
    - Survey following maintenance requiring assembly or removal of a major component.

- **Occupational Dose Limits** [.1604(a)(1)]; [.1604(a)(2)]
  - What are the annual occupational dose limits? [.1604(a)(1)] Dose Limits

- **Voluntary Declared Pregnancy Policy** [.1610]; [.1614(1)(c)]; [.1640(f)]
  - What is the facility's personnel voluntary declared pregnancy policy? Describe the employee's and employer’s responsibilities upon declaration of pregnancy. (A woman can voluntarily inform her employer, in writing, of her pregnancy and the estimated date of conception. Declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant. Fetal dosimeter is required) Pregnancy Policy

- **Monitoring of Occupational Dose** [.1614]
  - What is the personnel exposure monitoring policy?
  - If personnel monitoring is not provided to operators, explain how facility met compliance to the regulations.
  - What is the frequency of exchanging dosimeters (personnel monitoring badges)?
  - How are the control and personnel monitoring badges stored?
  - Describe the registrant's responsibility to inform workers of radiation dose. Include details of how individuals are notified if occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue (effective 1/1/14) [.1004(b)]
  - How is prior occupational dose for new workers acquired? [.1638(a)(1)&(2)]
  - What is the length of time that the facility is required to maintain exposure records? *(Keep all Dosimetry Reports)* [.1640(a)(1)&(g)]

- **Notification of Incidents / Exceeding Exposure Limits** [.1646(a)]; [.1647(a)(2)]
  - When are exceeding dose limits or any incident in which threatens to cause dose limits to be exceeded reported? *(Within 30 days of incident)*
  - Describe the required actions that must be taken in the event of the Loss of control of any source of radiation. [.1646(b)]
  - What data of the affected person needs to be reported? [.1646 (c )]; [.1647(b)&(c)]
    - Name
    - Date of birth
    - Last 4 digits of social security number and/or employee identifier
    - Estimated dose
    - Cause of elevated exposure
    - Corrective Action
  - What individuals need notification? [.1004(d)]; [.1647(e)]
    - Employee must be provided a copy of the report.
  - What Agency needs notification? [.1646(d)]; [.1647(d)]; [.0111]
    - Radiation Protection Section
    - Division of Health Service Regulation
    - Department of Health and Human Services
    - 1645 Mail Service Center
    - Raleigh, NC 27699
    - Phone 919-814-2250
REVIEW OF RADIATION PROTECTION 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’s 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

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