

# CPG Sec. 398.100 Definition of General Purpose Radiographic X-Ray System - 21 CFR 1020.30(b)

## BACKGROUND:

21 CFR 1020.30(b) \*\* states that a “general purpose radiographic \*x-ray\* system means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions”.

Questions continue to arise concerning the meanings of “general purpose” and “other than general purpose” as they appear in Subsections 1020.31(d), (e) and (f) of the performance standard and the applicability of these sections to a manufacturer's product.

This policy summarizes and restates FDA's criteria for determining when a system is “general purpose ” and when it is “other than general purpose ”for the purposes of Section 1020.31.

## POLICY:

- A. An x-ray system designed for and limited by its design for diagnostic purposes to only one of the following body regions is classified as "other than general purpose" for the purposes of Section 1020.31.
  1. extremities
  2. head or head and neck
  3. thoracic
  4. abdominal
- B. An x-ray system, designed for and limited by its design for diagnostic purposes to only one of the following specialized applications, is classified as “other than general purpose” for the purposes of Section 1020.31.
  1. System designed for cystographic, urologic or other specialized exams of the kidney, bladder and/or urinary tract.
  2. Dental x-ray system designed for use with intraoral and/or extraoral image receptors.
  3. Cephalometric x-ray system or dental x-ray system designed for use with extraoral image

receptors whenever special cephalometric devices are attached.

4. X-ray system designed specifically for chest or spinal radiography, when installed with fixed SID, a non-tilting vertically mounted wall bucky stand or cassette holder, and no x-ray table. For the purposes of this paragraph, any table with its tabletop interposed between the patient and the image receptor during normal use is an x-ray table. This includes but is not limited to any table equipped with a cassette tray (or bucky) or cassette tunnel beneath the tabletop.
  5. Mammography x-ray system.
  6. Therapy simulation x-ray system.
  7. System designed for and installed in operating rooms.
  8. Pantomographic x-ray system.
  9. Tomographic x-ray system (when used in the tomography mode of operation).
- C. Any x-ray system, which by its design is not limited to radiographic examination of a specific anatomical region and does not meet the requirements of paragraphs A or B preceding is considered to be “general purpose” for the purposes of Section 1020.31.

\*Material between asterisks is new or revised\*

Issued: 10/1/80

Revised: 3/2005

### **More in Compliance Policy Guides**

**(/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm)**

### **Foreword: Compliance Policy Guides (CPGs)**

**(/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116271.htm)**

### **Chapter 1 - General**

**(/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116280.htm)**

### **Chapter 2 - Biologics**

**(/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116336.htm)**

### **Chapter 3 - Devices**

**(/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116801.htm)**

### **Chapter 4 - Human Drugs**

**(/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm119572.htm)**

**Chapter 5 - Food, Colors, and Cosmetics**

**(/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm119194.htm)**

**Chapter 6 - Veterinary Medicine**

**(/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm117042.htm)**