

# CPG Sec. 398.400 Automatic Adjustment of the X-ray Field Size to the Selected Spot-Film Size - 21 CFR 1020.31(g)(1)

## BACKGROUND:

Section 1020.31(g)(1) of the Diagnostic X-Ray Standard addresses field limitation and alignment for spot-film devices. It requires that the manufacturer provide means for the adjustment of the x-ray field size to the size of that portion of the film which the user selects on the spot-film selector. It is further required that the x-ray equipment perform this adjustment automatically, except when the x-ray field size is smaller than that of the selected portion of the film.

This policy guide has been prepared to clarify the requirements of the standard for this latter condition, that is, when the x-ray field size being used during fluoroscopy is smaller than the selected size of the spot film.

## POLICY:

If the size of the x-ray field at the film is smaller than the selected spot film size, it is the intent of the standard to require that fluoroscopic/-spot-film systems be designed to permit the fluoroscopist to maintain this smaller x-ray field size when taking a spot film. Such designs will minimize exposure to the patient because the automatic enlargement of the x-ray field size to cover the size of the film portion selected would result in a field size larger than desired by the fluoroscopist and unnecessary radiation exposure to the patient. For this reason, manufacturers should interpret Section 1020.31(g)(1) as prohibiting the manufacture of a fluoroscopic/spot-film system which does not permit the fluoroscopist to maintain the x-ray field size when taking a spot film if the size of the x-ray field at the film is smaller than the selected spot-film size.

There may be occasions, however, when the fluoroscopist may desire to increase the x-ray field size from a size smaller than the selected format to the selected format size. The following systems are examples that would allow such flexibility but would not conflict with the intent of Section 1020.31(g)(1).

1. A system that provides the fluoroscopist a manual adjustment to the selected spot film size, or

2. A system that provides a switch, button, or similar device, which must be activated prior to each spot-film exposure whenever the full selected spot film size is desired, or
3. A system that provides the fluoroscopist a choice of two modes of operation. In one mode, the beam limiting device would adjust automatically to the selected spot-film size while in the other mode the beam limiting device would not automatically adjust to the selected spot-film size when the size of the x-ray field at the film is smaller than the selected spot-film size. This mode selection should be changeable at any time by the fluoroscopist, but should remain in the selected mode until changed. (This is the only acceptable design for those x-ray systems using the same x-ray tube for spot film and other radiographic procedures. For those systems, the requirements applicable to PBL systems (21 CFR 1020.31(e)) should be met when automatic spot film sizing is selected. When the other mode is selected, the requirements applicable to spot-film devices (21 CFR 1020.31(g)) should be met).

Issued: 10/1/80

**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)**