CPG Sec. 398.450 Applicability of Positive Beam Limitation (PBL) Requirements When PBL is Provided on "Other than Stationary General Purpose" Radiographic System

BACKGROUND:

According to the FDA Compliance Policy Guide No. 7133.11 (dated October 1, 1980) 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 purpose of Section 1020.31.

1. Extremities
2. Head and Neck
3. Thoracic
4. Abdominal

Some x-ray system manufacturers market other than general purpose systems with PBL even though it is not required. The question has been raised as to whether the PBL requirements of 1020.31(e)(2) would apply when PBL itself is not required.

POLICY:

A system in which the user depends on PBL rather than manual collimation creates an additional hazard if the PBL system does not function properly (especially if it oversizes the x-ray field). Therefore, when a radiographic system provides PBL operation, it must meet all requirements applicable to PBL systems, e.g., 1020.31(d)(1) and (2), and 1020.31(e)(1) and (2) even if PBL is not required. A system complying with the PBL requirements will be considered as complying with the requirements of 1020.31(f)(4).

Issued: 8/1/83

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)