CPG Sec. 398.300 Registration of Assemblers of Diagnostic X-Ray Systems as Device Manufacturers

BACKGROUND:

Questions have been raised as to whether an assembler of diagnostic X-ray systems must register as a device manufacturer.

POLICY:

Assemblers of diagnostic X-ray systems are subject to the assembler certification (reports of assembly) requirements in 21 CFR 1020.30(d) and the Federal Food, Drug, and Cosmetic Act, Chapter V, Subchapter C - Electronic Product Radiation Control.* Such assemblers are exempt from registration.

Material between asterisks is new or revised

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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)