

CPG Sec. 390.400 Examples of Electronic Products Subject to the Reporting Requirements Under 21 CFR 1000.15(a)

BACKGROUND:

A company manufactures a shutter system for mounting externally on x-ray diffraction generators. However, the company does not manufacture equipment as defined under Subpart B, paragraph 1000.15. The shutter system does not produce radiation; is this equipment exempted from reporting requirements?

POLICY:

It is true that such products do not produce x-radiation, but they do affect the quantity and/or quality and/or direction of the x-radiation being utilized and are subject to regulation under the Federal Food, Drug, and Cosmetic Act, Subchapter C-Electronic Product Radiation Control. However, at this time under *21 CFR 1002.1*, shutter systems are not a "listed electronic product" and the manufacturer is not required to submit initial reports, annual reports, or model change reports. He is, however, responsible for reporting accidental radiation occurrences associated with his product as specified in 21 CFR 1002.20.

Material between asterisks is new or revised

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