

CPG Sec. 390.225 Early Defects or Noncompliance - 21 CFR 1004.6

BACKGROUND:

If a product defect or noncompliance with the Federal standard is discovered by a manufacturer (or x-ray equipment assembler), he may wish to initiate repair simultaneously with notification to FDA so that down time is minimized. Part 1003 requires that FDA (and others) be notified of radiation safety defects or failure to comply with a performance standard, and Part 1004 requires that the manufacturer must repair, replace, or refund the purchase price of a defective or noncompliant product. The correction of the product must be performed pursuant to a plan approved by FDA (21 CFR 1004.6)

POLICY

The *Federal Food, Drug, and Cosmetic Act, Subchapter C-Electronic Product Radiation Control,* and the regulations, do not preclude purchaser notification and correction of a defect or noncompliance prior to the approval of a plan; however, such corrective action would still be subject to a plan approved by FDA. To avoid the possibility of having to prepare and implement a second corrective action plan, a manufacturer or assembler should communicate with the Food and Drug Administration as early as possible after discovery of a defect or failure to comply.

Material between asterisks is new or revised

Issued: 10/1/80

Revised: 3/95

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

[\(/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm117042.htm\)](#)