

CPG Sec. 398.375 Obligations of Factory-based Manufacturers and Assemblers of Diagnostic X-ray Equipment Under the Performance Standard for Diagnostic X-ray Equipment

BACKGROUND:

The Food and Drug Administration has information which indicates that some assemblers and manufacturers of diagnostic x-ray equipment are failing to notify FDA of radiation safety defects and noncompliances with performance standards discovered during the repair or installation of diagnostic x-ray systems. In addition, some owners of x-ray systems are being charged for correction of such defects or noncompliances where the law requires that these corrections be made at no cost to the owner.

An x-ray system or component may have a defect as defined by 21 CFR 1003.2 or fail to comply with the performance standard because of improper assembly, installation, or repair by the assembler; poor design or construction by the factory-based manufacturer; or abuse, improper maintenance, or repair by the owner.

The *Federal Food, Drug, and Cosmetic Act, Chapter V, Subchapter C - Electronic Product Radiation Control* obligates the manufacturer to correct defective or noncompliant diagnostic x-ray equipment at no cost to the owner and places specific reporting requirements on the manufacturer of diagnostic x-ray components or systems when defects or noncompliances are caused by the manufacturer. (A manufacturer is defined as a person who manufactures, assembles, or imports diagnostic x-ray equipment.) FDA considers non-compliance or defects to be violations of the law when caused by (1) improper assembly or installation by the assembler (manufacturer), or (2) improper design or manufacture by the factory-based manufacturer.

POLICY:

When an assembler (manufacturer) discovers a defect or noncompliance with the performance standard, the assembler must determine the cause of the noncompliance or defect, perform the appropriate corrective action, and notify the FDA in accordance with 21 CFR 1003 and 1004 as follows:

1. If the assembler determines that the noncompliance or defect was caused by improper assembly or installation, the assembler must correct the noncompliance or defect at no charge to the user by either repairing the system, replacing it, or refunding the cost of the x-ray system. The assembler must submit written notification to the nearest FDA office.
2. If the assembler determines that noncompliance or defect was in any way caused by the factory-based manufacturer, the assembler must provide written notification to the nearest FDA office and the factory-based manufacturer. The assembler should arrange for the factory-based manufacturer to correct the defect or noncompliance at no cost to the owner. The factory-based manufacturer must report all manufacturer caused noncompliances and defects to FDA Headquarters *(CDRH).*
3. If the assembler determines that the noncompliance/or defect was caused by the owner, because of unwarranted user abuse, improper maintenance by the user, or attempted repairs by the user or another party, the assembler should report the noncompliance to the owner and make appropriate corrections with the owner's agreement for payment after corrections. The assembler may charge for services to correct a noncompliance or defect only where the assembler has obtained documented evidence of user abuse, lack of proper maintenance, or improper repair.

Failure to correct or notify the FDA of any defect or noncompliance with the performance standard is a violation of the *Federal Food, Drug, and Cosmetic Act, Chapter V, Subchapter C - Electronic Product Radiation Control,* and the person failing to correct or notify is subject to a civil penalty of up to \$1000 per offense. Immediate correction of defects or noncompliances by the factory-based manufacturer or assembler, at the time they are discovered, does not exempt the manufacturer or assembler from 21 CFR 1003 reporting requirements.

Material between asterisks is new or revised

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