

CPG Sec. 398.200 Hazardous Diagnostic X-ray Systems

BACKGROUND:

A Class A defect or noncompliance with the standard is a violative condition which presents a serious radiation hazard to the public health and warrants immediate correction. FDA's review of corrective actions has determined that immediate correction is not always attainable and that under certain conditions users may return the x-ray system to service before the radiation hazard is rectified.

Since *Chapter V, Subchapter C - Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (FD&C Act)* does not provide for the detention or seizure of violative electronic products, the only effective means of removing a violative product from service, and protecting the user and patient from hazardous radiation emissions, is State intervention or the detention/seizure of the violative article under the authority provided by Section *304 of* the FD&C Act.

However, it is the Agency's position that often the continued delivery of health care services to the patient outweighs the risk of excess radiation exposure from Class A noncompliances or defects. Most x-ray systems may be operated safely by a user who, after being informed of the problem, uses alternate procedures and precautions. The only exception is where the radiation hazard is the result of a condition which is not predictable and for which there are *no* alternative procedures and precautions (e.g., radiographic timer nontermination).

POLICY:

When x-ray nontermination is demonstrated, detention/seizure under *Section 304 of* the FD&C Act is indicated if the radiographic portion of the x-ray system is returned to use before the timer has been corrected. Detention/seizure should be considered only when all administrative and voluntary options, including intervention by State and local authorities, have been exhausted. A diagnostic x-ray system exhibiting timer nontermination in the radiographic mode is considered to be a misbranded device within the meaning of 502(f) and (j) of the FD&C Act.

Material between asterisks is new or revised

Issued: 7/1/83

Revised:3/95

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