CPG Sec. 398.700 Reloaders of X-ray Tube Housing Assemblies; Applicability of Medical Device Establishment Registration, Device Listing and Biennial Inspection

BACKGROUND:

X-ray tube housing assemblies are finished medical devices consisting of an x-ray tube insert encased in a radiation shielded shock proof housing. Periodically, the x-ray tube insert will deteriorate to the point that it must be replaced. The replacement of a new tube insert into an old housing is called reloading. While all original equipment x-ray tube manufacturers also perform tube reloading, many of them have established regional reloading stations throughout the United States. Most of these reloading stations are a part of local x-ray assembler facilities. The reloading operations at these regional stations involve either:

1. Repair services for the existing owner of the tube housing, usually with a very fast turnaround time (i.e., 24 hours), or
2. One-for-one exchange for an identical reloaded tube housing assembly with the same mechanical, electrical, and radiation leakage characteristics.

Some facilities also reload and stock a very small inventory of the most popular models for sale to any willing purchaser.

Many of these reloading stations have registered with the Center for Devices and Radiological Health (CDRH) and have listed the product.

A review of the regulatory history of x-ray tube housing reloaders and an assessment of testing of x-ray tube housing assemblies reveals no identified significant problems associated with the reloading process. Therefore, the FDA concludes that under Chapter V, Subchapter C - Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act, the Diagnostic X-ray Standard, and through Good Manufacturing Practices requirements for devices, adequate enforcement can be effectively accomplished by considering reloaders of x-ray tube housing

assemblies as x-ray assemblers, if a reloaded x-ray tube housing assembly is the only finished medical device produced for sale or exchange by the firm. Therefore, the following policy is established:

POLICY:

For purposes of compliance with medical device regulations, firms whose primary activity is the assembly of x-ray components are exempt from establishment registration, device listing, and biennial inspection requirements, even if a portion of their activities include reloading of x-ray tube housing assemblies. Manufacturers of original equipment tube housing assemblies continue to be subject to establishment registration, device listing, and biennial inspections.

X-ray tube housing reloaders must retain complaint files, injury reports, and failure analysis records. These records must be available for agency inspection. Inspections will be on a for cause basis as described in Compliance Program *7386.003.*

Material between asterisks is new or revised

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