digital format. Examples include systems employing video frame grabbers, and scanners which use lasers or charge-coupled devices.

(b) **Classification.** Class II (special controls; voluntary standards—Digital Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std.).

[63 FR 23387, Apr. 29, 1998]

§ 892.2040 Medical image hardcopy device.

(a) **Identification.** A medical image hardcopy device is a device that produces a visible printed record of a medical image and associated identification information. Examples include multifORMAT cameras and laser printers.

(b) **Classification.** Class II (special controls; voluntary standards—Digital Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std., Society of Motion Picture and Television Engineers (SMPTE) Test Pattern).

[63 FR 23387, Apr. 29, 1998]

§ 892.2050 Picture archiving and communications system.

(a) **Identification.** A picture archiving and communications system is a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. Its hardware components may include workstations, digitizers, communications devices, computers, video monitors, magnetic, optical disk, or other digital data storage devices, and hardcopy devices. The software components may provide functions for performing operations related to image manipulation, enhancement, compression or quantification.

(b) **Classification.** Class II (special controls; voluntary standards—Digital Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std., Society of Motion Picture and Television Engineers (SMPTE) Test Pattern).

[63 FR 23387, Apr. 29, 1998]

Subparts C–E [Reserved]
§ 892.5700 Remote controlled radionuclide applicator system.

(a) Identification. A remote controlled radionuclide applicator system is an electromechanical or pneumatic device intended to enable an operator to apply, by remote control, a radionuclide source into the body or to the surface of the body for radiation therapy. This generic type of device may include patient and equipment supports, component parts, treatment planning computer programs, and accessories.

(b) Classification. Class II.

§ 892.5710 Radiation therapy beam-shaping block.

(a) Identification. A radiation therapy beam-shaping block is a device made of a highly attenuating material (such as lead) intended for medical purposes to modify the shape of a beam from a radiation therapy source.

(b) Classification. Class II.

§ 892.5730 Radionuclide brachytherapy source.

(a) Identification. A radionuclide brachytherapy source is a device that consists of a radionuclide which may be enclosed in a sealed container made of gold, titanium, stainless steel, or platinum and intended for medical purposes to be placed onto a body surface or into a body cavity or tissue as a source of nuclear radiation for therapy.

(b) Classification. Class II.

§ 892.5740 Radionuclide teletherapy source.

(a) Identification. A radionuclide teletherapy source is a device consisting of a radionuclide enclosed in a sealed container. The device is intended for radiation therapy, with the radiation source located at a distance from the patient’s body.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §892.9.

§ 892.5840 Radiation therapy simulation system.

(a) Identification. A radiation therapy simulation system is a fluoroscopic or radiographic x-ray system intended for...