US Food and Drug Administration's Regulation of Software and Picture Archiving and Communication Systems

Mary P. Anderson, Loren A. Zaremba, and David G. Brown

THERE ARE two main aspects to the US Food and Drug Administration's software activities: a premarket review function for software in devices, and the policy itself; ie, given that software meets the definition of a device, how should it be regulated. This tutorial will give an update on these efforts and will concentrate on the current status of the regulation of picture archiving and communication systems.

The Medical Device Amendments of 1976 (the Act) (Public Law 94-295) and the Safe Medical Device Amendments of 1990 (Public law 101-629) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the Act established three classes of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval). The premarket notification procedure (510(k)) provides the mechanism by which devices brought to market after May 28, 1976, may be found substantially equivalent to devices classified under this scheme.

Historically, picture archiving communication systems (PACS) devices have been treated as accessories to the classified radiologic imaging modality with which they were used. It is now recognized that the devices are intended for use

with multiple modalities. In addition, the lack of classification regulations has prevented the Agency from establishing exemptions from premarket notification for some of these devices when it would be appropriate. To remedy this situation, a classification proposal for five medical image management devices has been developed and was published in the Federal Register (Vol. 61, No. 232/Monday, December 2, 1996). Under the proposal, medical image storage devices and medical image communications devices would be classified into class I (general controls), and products of these types that do not use irreversible compression would be exempted from the requirement of premarket notification. Medical image digitizers, medical image hardcopy devices, and PACS would be classified into class II (special controls).

Comments on the proposal are being received and will be analyzed, and the proposed classifications will be modified as needed. Until the proposed rule is finalized, we expect to continue to receive premarket notifications on all these products.

From the Center for Devices and Radiological Health, US Food and Drug Administration, Rockville, MD.

Address reprint requests to Mary P. Anderson, ScD, FDA/CDRH HFZ-142, 12720 Twinbrook Pkwy, Rockville, MD 20857.

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