



FDA Report to C63[®] SC8

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FDA EMC Activities

- IEC 60601-1-2 Edition 4 (see IEC SC62A MT23 report)
- SC7 C63.27 WG on wireless interference and coexistence
- EMC reviews
- Guidance: RF wireless technology in medical devices
 - Final should be posted in 2013
 - Working on communication/messaging (web)

FDA EMC Activities

- Asking medical device manufacturers to explicitly specify the intended use environments and asking for higher test levels for environments where they are warranted, as specified in IEC 60601-1-2 SC 6.2.1.1.

FDA EMC Activities (cont'd)

■ RFID

- ❑ Worked with Association for Automatic Identification and Mobility (AIM Global) RFID Experts Group (REG) to draft protocol for testing immunity of medical devices to RFID systems
- ❑ Protocol being validated at MET Labs
<http://www.prweb.com/releases/medical-device/rfid-susceptibility/prweb8900624.htm>
- ❑ More medical device EUTs needed
- ❑ IEEE Standards Association is interested