



FDA Report to C63[®] SC8

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FDA EMC Activities

- EMC and wireless reviews
- Research
- C63[®] standards
- IEC standards
- AAMI standards
- ISO standards
- AIM/REG (RFID)
- FCC liaison
- Presentations

FDA EMC Activities

- EMC and wireless reviews
 - Increasing workload
 - Especially when one or more EMC reviewers is out
 - Developing triage protocol
 - Preparing periodic training for ODE reviewers
 - June 17 and 18

FDA EMC Activities

- Research
 - Susceptibility of patient cables of automatic external defibrillators below 80 MHz and comparison of results of conducted and radiated immunity testing
 - Round robin evaluation of C63.27 conducted and radiated test methods

FDA EMC Activities (cont'd)

- C63[®] standards
 - C63.12
 - C63.16
 - C63.27
- IEC standards
 - IEC 60601-4-2 – medical performance TR (see SC62A MT23 liaison report)
 - IEC 60601-1-2 Ed 5

FDA EMC Activities (cont'd)

- AAMI
 - Co-chair of wireless coexistence TIR working group and document development in progress
 - Co-chair of working group – EMC test protocols for cardiac rhythm management
 - Working on EMC section of a standard for cochlear implants

FDA EMC Activities (cont'd)

- AAMI (cont'd)
 - Humidity in the operating room
 - American Society of Heating, Refrigeration and Air Conditioning (ASHRAE) changed national minimum recommendation from 30% to 20%
 - AAMI communication issued 12 January 2015 – recommendations for healthcare facilities

FDA EMC Activities (cont'd)

- ISO standards
 - Working on the second edition of ISO/TS 10974, Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device
- Wireless coexistence
 - SC7 C63.27 WG
 - AAMI WG on wireless interference and coexistence
 - Ongoing work with OU Tulsa

FDA EMC Activities (cont'd)

- Meetings/working with FCC
 - (And also with SAE) on wireless charging of electric vehicles
 - FCC/FDA Joint Workshop on Wireless Medical Test Beds
 - March 31, 2015

FDA EMC Activities (cont'd)

- RFID
 - Working with Association for Automatic Identification and Mobility (AIM Global) RFID Experts Group (REG) on protocol for testing immunity of medical devices to RFID systems
 - Protocol completed
 - Circulated to the REG for comment 4 May 2015
 - Comments due 22 May 2015

FDA EMC Activities (cont'd)

- Presentations
 - J. Silberberg, An FDA Perspective on EMC of Medical Devices
 - Workshop – Introduction to Medical EMC, March 20, 2015, at EMC Santa Clara 2015
 - Workshop - Living Together - Wireless Electronics and Electrical Medical Devices, sponsored by the EMC Chapter of the Twin Cities Section of the IEEE, May 8, 2015
 - J. Silberberg, Introduction to Risk Management of EMC, in workshop - Risk-Managing EMC, March 20, 2015, at EMC Santa Clara 2015