FDA Report to C63® SC8
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FDA EMC Activities

- EMC and wireless reviews
  - More wireless medical devices
- IEC 60601-1-2 Edition 4 (see IEC SC62A MT23 report)
- SC7 C63.27 WG on wireless interference and coexistence
- Quarterly meeting with FCC, Nov 6, 2013
- Recognition of IEC 80001 series, *Application of risk management for IT Networks incorporating medical devices*

FDA EMC Activities (cont'd)

- Guidance: RF Wireless Technology in Medical Devices
  - Final posted August 13, 2013
  - http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm077210.htm
  - In-house reviewer training September 17, 2013
    - Faculty: Rashmi Doshi (FCC), Rick Hampton (Partners Healthcare), Seth Seidman, Don Witters, Jeff Silberberg (FDA)

RF Wireless Guidance Table of Contents

- Introduction
- Scope
- Considerations for Design, Testing, and Use of Wireless Medical Devices
  - Selection and performance of wireless technology
  - Wireless Quality of Service
  - Wireless coexistence
  - Security of wireless signals and data
  - EMC of the wireless technology
  - Information for proper set-up and operation
  - Considerations for maintenance

RF Wireless Guidance Table of Contents (cont'd)

- Recommendations for Premarket Submissions for Devices that Incorporate RF Wireless Technology
  - Description of device
  - Risk-based approach to verification and validation
  - Test data summaries
  - Labeling related to wireless medical devices
- Appendix A: Glossary for Wireless Medical Devices and Device Systems
- Appendix B: Reference Standards and Information

FDA EMC Activities (cont'd)

- Guidance: RF Wireless Technology in Medical Devices
  - Final posted September 25, 2013
  - http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm263366.pdf
  - In-house reviewer training September 17, 2013
    - Faculty: Rashmi Doshi (FCC), Rick Hampton (Partners Healthcare), Seth Seidman, Don Witters, Jeff Silberberg (FDA)

FDA EMC Activities (cont'd)

- Guidance: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
  - Draft posted June 14, 2013
  - http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm356186.htm
- Guidance: Design Considerations for Devices Intended for Home Use
  - Harmonized with IEC 60601-1-11
  - Final under development

FDA EMC Activities (cont'd)

- Guidance: Mobile Medical Applications
  - Final posted August 13, 2013
  - http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm077210.htm

FDA EMC Activities (cont'd)

- AAMI/FDA Summit on Healthcare Technology in Nonclinical Settings, October 2013
  - FDA representatives prepared presentations, including:
    - IEC 60601-1-2 draft Edition 4 immunity test levels for the Home Healthcare Environment
  - FDA could not attend due to the Government shutdown
    - Presentations are posted (anyway) at http://www.aami.org/summit2013/papers/

FDA EMC Activities (cont'd)

- AAMI Wireless Strategy Task Force (WSTF)
  - Hot Topics web site http://www.aami.org/hottopics/wireless/index.html
  - AAMI Wireless Standards group formed
    - D. Witters and S. Berger co-conveners
    - Coordinating with C63 SC7
- AAMI TIR 18 up for reaffirmation

FDA EMC Activities (cont'd)

- RFID
  - Working 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 was validated
    - at MET Labs using medical devices submitted for testing
    - at FDA using in-house medical devices
  - Currently undergoing working group review

FDA EMC Activities (cont'd)

- Working on Ed. 2 of ISO/TS 10974, *Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device*
  - Among MRI issues
    - active implant functionality (EMC)
    - test and modeling uncertainty

FDA EMC Activities (cont'd)

- IEC 1906 award received by FDA employee
  - In recognition of his role as a leading member of SC 62A/MT 23 and as a well-recognized expert on the electromagnetic compatibility aspects of medical electrical equipment. For many years, Mr. Silberberg served as the unofficial Secretary of the MT. In that role, he provided invaluable support to the current and past Convenors of MT 23 and assisted SC 62A Secretariat by preparing the many documents associated with several editions of IEC 60601-1-2. Mr. Silberberg is being recognized for his dedication to the work of MT 23 and for his many contributions to improving the safety of medical electrical equipment in the electromagnetic environment.