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FDA Report to C63<sup>®</sup> SC8  
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# FDA EMC Activities

- EMC and wireless reviews
- C63<sup>®</sup> standards
- IEC standards
- AAMI standards
- ISO standards
- AIM/REG (RFID)
- FCC liaison
- Other
- Publications and presentations

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# FDA EMC Activities (cont'd)

- C63<sup>®</sup> standards

- C63.12

- C63.16

- C63.27

- IEC standards

- IEC 60601-1-2:2014

- Medical performance TR

- IEC 61000-4-39: Radiated fields in close proximity immunity test (77B/717/CD)

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## FDA EMC Activities (cont'd)

- IEC 60601-1-2:2014 (Edition 4)
  - FDA recognized IEC and ANSI/AAMI/IEC versions of Ed 4 mid-2014
    - One allowance is excluded from recognition:  
Table 8, 61000-4-6 row, exemption of SIP/SOPS (I/O) cables < 3 m long
  - 60601-1-2:2007 (Ed 3) will no longer be recognized after April 1, 2017
- Performance TR – See IEC SC62A MT23 report

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# FDA EMC Activities (cont'd)

## ■ AAMI

- Co-chair of wireless coexistence TIR working group
- Co-chair of working group – EMC test protocols for cardiac rhythm management
- Working on EMC section of a standard for cochlear implants
- Humidity in the operating room

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# 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

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# 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 was validated
  - at MET Labs using medical devices submitted for testing
  - at FDA using in-house medical devices
- Currently undergoing WG and AIM review

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## FDA EMC Activities (cont'd)

- Guidance: Design Considerations for Devices Intended for Home Use
  - Harmonized with IEC 60601-1-11
  - Final announced August 5, 2014
  - References ANSI/AAMI/IEC 60601-1-2:2014 for EMC
  - Will be revised with immunity test levels that are recommended for use with 60601-1-2:2007



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## FDA EMC Activities (cont'd)

- Wireless coexistence
  - SC7 C63.27 WG
  - AAMI WG on wireless interference and coexistence
  - Ongoing work with OU Tulsa
- Meetings with FCC
  - Recent meetings also with SAE on wireless charging of electric vehicles

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# FDA EMC Activities (cont'd)

- Publications

- S. Seidman and N. LaSorte, An Experimental Method for Evaluating Wireless Coexistence of a Bluetooth Medical Device, IEEE Electromagnetic Compatibility Magazine, Vol. 3 No. 3, 3<sup>rd</sup> Quarter 2014.

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# FDA EMC Activities (cont'd)

- Presentations

- J. Silberberg, An FDA Perspective on EMC of Medical Devices, in workshop Introduction to Medical EMC, August 4, 2014, at EMC 2014.
- J. Silberberg, Introduction to Risk Management of EMC, in workshop Risk-Managing EMC, August 8, 2014, at EMC 2014.