

In the Matter of

**FDA Draft Guidance
on Wireless in Medical Devices**

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Docket No. 2006D-0504

COMMENTS
FROM
IEEE 11073 TECHNICAL COMMITTEE,
RF WIRELESS SUBCOMMITTEE

On January 3, 2007 the FDA announced their draft guidance document and requested input in the form of written or electronically submitted comments. The IEEE 11073 technical committee, subcommittee on RF wireless (11073 RF wireless), is pleased to provide the following comments to the FDA. IEEE 11073 RF wireless is composed of participants with a broad range of expertise and representing a wide range of industry, academic, and government interests relevant to the topic of wireless transport of medical data. The scope of IEEE 11073 RF wireless is to profile available and standardized wireless technology for use in medical data communication. This includes both short-range (wPAN) and networked (wLAN, wWAN) systems.

General Comments:

- Existing requirements (e.g., Section 8 / 21 CFR 820.30(g)) should be referenced and separated from new recommendations associated with this guidance document
- The document needs to provide consistent content and flow between sections (e.g., Sections 2, 4, 6 all speak to wireless coexistence, performance, data integrity, security EMC)
- Many of the co-existence issues are being addressed in relevant industry consortium / standard groups (e.g., WFA, BT SIG, IEEE 802) and these efforts should be referenced. Cognitive radios (which may become more prevalent in the future) address co-existence

- by scanning and transmitting on the most available spectrum. With that said, however, it should also be mentioned that in practice many medical devices still use proprietary protocols, or to add more confusion build upon a standard protocol and tweak it to perform a specific application (which may impact co-existence). Therefore, true conformance to standards with regard to co-existence is also important to verify
- There are several stakeholders, although the most important with respect to the instant guidance are medical device manufacturers and FDA review staff. However, additional stakeholders may have different focused areas where they need guidance and information, and perhaps the document could be structured to address or summarize the specific interests of each of the different stakeholder groups

Specific Comments:

- In section 4 (first paragraph) - Concerns Related to RF Wireless Technology Use in an Around Medical Devices:
 - In the section title “Use” should probably be “Used”.
 - In the first set of bullet points, an additional bullet might be added: Multiple RF devices supported by the same network that either degrade other coexisting signals by contributing elevated in-band background noise or compete for limited channel space and resources within the network (although not everyone in the 11073 wireless group thought this change was essential)
- In section 4, subsection: Integrity of data transmitted wirelessly
 - The fact that data transport can be slow on certain systems may be more problematic for certain types of medical data than others. The hard to predict variability of data rate can be influenced by multiple factors, including traffic. In some cases, the rate of data transfer (not the signaling rate or the variability) determines whether a delayed packet is dropped and thus (if enough packets are dropped) whether the system “fails.”

- In section 4, subsection: Brief summary of examples of potentially problematic situations:
 - Second to last bullet – it is often the case that data packets on cellular / PCS systems can be significantly delayed due to prioritization of voice traffic. It can also be the case that the link on a cellular network is dropped prior to the data packet being successfully launched. In these cases, if the data packet arrives too late for the information to be processed and used, the end effect is that the medical information is lost to the medical device.
- In Section 6 (Design and Development), subsection on EMC and Telecommunications
 - IEC 60601-1-2 (2001) is correctly referenced with regard to evaluating baseline electromagnetic immunity of medical devices. AAMI TIR 18 (1997) is correctly referenced with regard to assuring electromagnetic compatibility of medical devices operating in environments with various RF sources. However, guidelines specifically designed to guide the deployment of specific RF systems for communication (e.g., mobile phones, WiFi systems) to avoid medical device electromagnetic interference is addressed by ISO Technical Report #21730, and should be referenced. ANSI ASC C63.24 is analogous to ANSI ASC C63.18, although for non-medical devices. However, due to the close synergy of the two ad hoc testing protocols, it might be mentioned and referenced as such.
- In Section 6, subsection on Emergency Vehicles
 - Cellular (mobile) phones can also be included, as the Sprint/Nextel push-to-talk system have been employed by several EMT groups
- In section 7:
 - ETSI standards are not applicable in the US. However, if they are to be referenced, they should include EN 301.328 (2.4GHz WLAN) and EN 301.893 (5GHz WLAN)
- In section 11 (Corrective and Preventive Action):

- Consideration might be given to mentioning the MDR reporting structure and how to specify issues that specifically pertain to a problem with wireless data transport (which is currently not specified on MDR reporting forms)
- In the References
 - The complete reference for the IEEE 11073-00101 Technical Report is: P11073-00101™/D01J - Guide for Health informatics–Point-of-Care Medical Device Communication–Guidelines for the Use of RF Wireless Technology. The TR is not yet published, but has completed the initial ballot phase; comments are addressed, and are currently out for ballot approval.
 - The more relevant RTCA SC202 reference may be DO-294, although I am not sure this needs to be referenced at all in this document.
 - RTCA DO-160D may not be the most recent revision of the referenced document, we believe it to be DO-160E
 - The relevant FCC references for cellular (part 22, part 24) PCS (part 27) and SMR (part 90) should be added

Respectfully submitted,

**IEEE 11073 Technical Committee,
RF Wireless Subcommittee**

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