



Medical Products Group

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Division of Dockets Management (HFA -305)
Food and Drug Administration
5630 Fishers Lane - Room 1061
Rockville, MD 20852

RE: *Radio-Frequency Wireless Technology in Medical Devices; Draft Guidance for Industry and FDA Staff [Docket 2006D-0504]*

Dear Sir or Madam:

Abbott Laboratories submits the following comments regarding FDA draft guidance document "Radio-Frequency Wireless Technology," published in the Federal Register on January 3, 2007 at 72 FR 137.

Abbott Laboratories is a global, broad-based health care company devoted to discovering new medicines, new technologies and new ways to manage health. Our products span the continuum of care, from nutritional products and laboratory diagnostics through medical devices and pharmaceutical therapies.

Comments

Section 6 Design and Development

Fifth bullet point

The guidance states, "Integrity of data transmitted wirelessly, including latency and throughput." This bullet point should emphasize not only speed issues (latency, throughput), but also the ability to detect, correct, and/or prevent data communication corruption.

Sixth bullet point

The guidance recommends factors to address in the device design and development, including "security of data transmitted wirelessly, including protection against unauthorized wireless access to device control or data (e.g., encryption, data access control)."

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Additional guidance in regards to security is recommend. There are various types of encryption and data access. In addition to the intended use and anticipated environments of the device, we recommend the guidance include communication method or technology employed as a consideration in determining data security.

Section 10 Purchasing Controls and Acceptance Activities

The guidance states, "FDA recommends you *provide* procedures and controls..." and "FDA also recommends you *provide* written acceptance procedures..."

Use of the word "provide" in this section is unclear, as the section describes manufacturers activities under the Quality System regulations. We recommend replacing the word "provide" with "maintain" for additional clarity.

Section 12 Servicing

The guidance states, "FDA recommends you investigate EMI as a possible explanation for device malfunction when no problem is found in a device received for service" and "you identify if RF wireless transmitters or sources of EMD that were in the vicinity of the malfunctioning device."

Additional guidance in terms of the investigation is recommended, such as that contained in FDA's "Guide to the Inspections of Electromagnetic Compatibility Aspects of Medical Device Quality Systems." For example, inclusion of the following in the firm's complaint handling process:

- Additional events, which may have contributed to the EMI; additional diagnostic procedures that necessitated use of other devices, which may have contributed to the EMI
- Additional equipment used in conjunction with the device
- Environmental conditions which may have contributed to the event
- Repeatability of the event and comparison to similar events at the same facility or other geographic areas

Thank you for the opportunity to provide these comments. Should you have any questions, please contact me at (847) 937-8197 or by e-mail at april.veoukas@abbot.com.

Sincerely,

April Veoukas, J.D.
Director, Regulatory Affairs
Medical Products Group
Abbott Laboratories