Before the
Food and Drug Administration

Comments on FDA Docket No 2006D-0504 Draft Guidance for Industry and FDA Staff: Radio Frequency Wireless Technology in Medical Devices

COMMENTS OF Wi-Fi Alliance

Wi-Fi Alliance (WFA) hereby respectively submits comments on the Food and Drug Administrations FDA Docket No 2006D-0504 Draft Guidance for Industry and FDA Staff: Radio Frequency Wireless Technology in Medical Devices. WFA is encouraged by the initiative of the FDA in developing and releasing this document to address an extremely important issue.

Medical facilities are increasingly dependent on mobile communications to perform day to day routine functions. Though the medical facilities can install these wireless systems based on industry guidelines and available best practice, the issue has been the lack of clear engineering guidelines for installing wireless transmitters into actual medical devices themselves. This may have delayed the introduction of new wireless technologies and beneficial services in cases when a manufacturer or end user concerns about the FDA's view of these systems is not sufficiently clear.

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Since 1999, the Wi-Fi Alliance (WFA), an international non-profit organization has been promoting and certifying the interoperability of IEEE 802.11-based wireless products. The WFA has grown from its original five member companies to more than 300 in 2006. Over 3,300 products have been Wi-Fi CertifiedTM and over 200 million chipsets have been shipped. The WFA promotes the use of interoperable advanced wireless devices and fosters their continued development and deployment – all of which benefit governments, industry, and consumers around the world. With 802.11 having emerged as the leading standard for broadband wireless access (BWA) in client devices globally, and with Wi-Fi technology rapidly evolving to meet changing customer needs, the WFA supports opportunities to make additional spectrum available for 802.11 and other innovative technologies.

Draft Guidance Document – Radio-Frequency Wireless Technology in Medical Devices

WFA encourages the agency to continue with the development and release of the Guidance Document which clarifies RF enablement for the medical provider, manufacturer or system integrator wishing to develop, install or operate a wireless system or device for medical applications.

The FDA draft document clearly outlines possible issues on enabling medical devices with RF Wireless Technology. Those that have been actively involved with the characterization of these issues will find a common forum here to work with the regulatory agency that is in part responsible for consideration of addressing wireless in this specific environment.

When considering the integration of wireless into medical devices it is important to consider the operational parameters, interference characteristics, coexistence impacts, Electromagnetic compatibility and security. This Draft Guidance document provides a background and definition framework on the subject.

The adoption of the outcome of this process will influence the further enablement of medical devices with RF as well as place into relevance the work being done by the IEEE 11073 working groups and other industry organizations developing standards for wireless products to be deployed into medical environments.

Discussion on Interference

In reviewing the topics addressed in the guidance document, interference concerns are the first and foremost issue that manufacturers and installers are faced with.

There are several aspects to this that revolve around interference both to the medical device the RF wireless capability is being integrated into as well as to other devices that will be used with or in proximity to the medical device. Aspects include Electromagnetic Compatibility (EMC), coexistence, and Interference issues in general. Coexistence problems and EMC problems will result in increased risk of interference which could impact the operation of the system the RF wireless is being installed in.

The responsibility of EMC compliance, interference and in part the coexistent issue officially falls to the Federal Communications Commission. They are responsible for product

approvals of wireless and non wireless communications systems and addressing interference issues in the field. However in the case of these medical installations their role is limited to the verification of compliance to the regulatory rules. The FCC rules are primarily designed to protect the airwaves and reduce interference to licensed wireless systems. The general limits for spurious emissions help reduce interference to non wireless systems but the FCC rarely gets involved with solving interference issues to non wireless Part 15 systems.

Licensed wireless systems such as Cell phones and some Wireless Medical Telemetry systems operate under Part 22, 24 or 90 of the FCC rules. These systems are protected from interference from other services and devices including intentional and unintentional radiators that operate under Part 15 of the rules and Part 18 devices that operate under the ISM[1] rules.

Other wireless systems and all of the non wireless electronic systems being operated in a medical environment typically operate under Part 15[2] regulations. This means they operate under two specific Part 15 rules, 1) they cannot cause harmful interference and 2) they must accept interference.

Beyond addressing the actual product compliance issues and providing the basic guidance notes to reduce interference to receivers, this issue of interference to other systems is assumed to be covered by EMC regulations and industry practice.

[1] Code of Federal Regulations, Title 47, Part 18 Industrial Scientific and Medical Devices

[2] Reference Code of Federal Regulations Title 47, Part 15.

Therefore the discussion in this document is relevant to addressing the issues of interference not specifically already addressed by the 47 CFR FCC Rules.

As stated under Part 15 of the FCC rules, the device must accept interference including interference that could effect operation. However unlike in the European Union[3], there is no mandatory testing for EMC compliance of a device for RF generated fields to determine if the product could work with an RF emitter in close proximity.

Though one can assume that most manufacturers would perform a complete EMC test suite to determine compliance, it would be helpful for the FDA to define more exactly what requirements are recommended, which will help provide clearer guidance.

For example, devices that are being sold for use in the medical environment in the EU, compliance to the EU Medical Directive is required. As part of this, the product must demonstrate compliance with IEC 60601.1.2[4], which addresses specific EMC requirements for systems operating in this type of environment?

Currently this EMC requirement is only mandatory for systems that require FDA 510(k) listing to demonstrate compliance and not required as part of the basic US EMC approvals to get wireless devices on the market. Some medical facilities in the US have asked for manufacturers to demonstrate compliance to IEC 60601.1.2 but it has been on a case by case

[3] Per the EU EMC Directive, EMC immunity for RF fields and other phenomenon's is required.

[4] IEC 60601.1.2 Medical electrical equipment General requirements for safety Collateral standard EMC requirements and tests.

basis and this has required wireless manufacturers to test their radios, but generally unless the products are being developed specifically for the medical market, the products are not evaluated to it.

WFA supports the FDA recommendations on requiring this IEC standard as part of systems being deployed in the medical environment in general in accordance with the recommendations and exemptions as stated in the standard for certain types of operation and or equipment. This requirement along with the FCC radiated and conducted emission requirements will help mitigate possible interference issues. However the FDA needs to make it clear that this is only applicable for devices being sold into the medical market for direct patient care, and not mandatory for general networking devices.

The FDA also discusses the issue of co existence; this issue in part is being addressed by the FCC as well as organizations such as CTIA, Wi-Fi alliance as well as the manufacturers.

The Commission crafts its rules as such to avoid possible interference issues from competing services in the same or adjacent bands, the industry groups are addressing the coexisting issues between various service transmitters being installed in the same device.

WFA agrees that even demonstrating compliance with the referenced EMC standard or recommendations with regard to co existence, will not resolve all interference issues. In part this is because the referenced standards themselves are often limited in scope to frequencies of measurement with specific bands and more often importantly limited to measurements at the

far field (i.e. plane wave) and not designed to address the near field / close proximity coupling models.

Therefore addressing potential interference requires a multi prong approach. First the vendor installing the wireless radio in the medical device needs to work with the medical device manufacturer to understand and address potential interference issues that could arise with the installation. This already requires close communication between the radio and medical device manufacturers for interoperability reasons and thus the WFA believes is not an area that is in need of additional regulatory guidance.

Second, as part of the EMC review of the product, verifying that the system overall meets the radiated and conducted emissions limits will help reduce the probability of interference both internal to the system and external. Therefore the guidelines should recommend that as part of the EMC validation that the manufacturer verify his system is operating as fully intended.

However beyond the integration of the radio, there are other issues that must be considered as well. In addition, since most of the RF susceptibility standards are based on far field coupling models, the WFA supports the suggestion to recommend some near field RF immunity scan or test such as the ad-hoc testing procedure as referenced in ANSI C63.18[5] to determine if any near field RF sources could disrupt the device or impact the radio operation as well. In most cases of interference it is the near field coupling that disrupts the systems and not the far field. Therefore we believe this issue needs to be raised and addressed as part of the design cycle.

[5] ANSI C63.18-1997 American National Standard Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to Specific Radio-Frequency Transmitters

Though near field testing will not eliminate all problems it will help reduce or in some cases point out where possible problems may occur and where either additional EMI hardening is needed or recommended exclusion zones needed to prevent some interference problems.

One issue raised by the FDA is the exclusion bands for the actual transmitter and receiver bands as well as a discussion on how to address this. In fact as part of the recommendations, the FDA suggests some possible solutions such as additional testing. Interference to the radio receiver or the transmitters is very much part of the concern when wireless products are being developed and interference or coexistence testing is generally part of the design process and product review.

From the industry view this issue is best addressed by the manufacturers then by a regulatory agency. In fact radios such as Wi-Fi are designed for spectrum sharing – which avoids a lot of interference issues that plague systems not designed for spectrum sharing.

The FCC entertained a discussion on the possible development of a receiver specification as one way of mitigating interference. The wireless industry raised concerns on a one size fits all approach to design receivers to avoid interference. Currently the FCC has not issued a final opinion and WFA believes that the FDA proposal in the light of FCC inaction on the subject is premature at the best. Further WFA believes the FDA should not specify technical parameters for receiver or transmitter design beyond the FCC rules.

We do agree that from a radio integration aspect that the issue of interference to the radio from the host device needs to be addressed. Therefore we believe that the system integrator or medical device maker needs to consider this as part their system evaluation and address it in the engineering phase to avoid problems in the field.

Devices Interfering with External Systems

The FDA Guideline notes, on page 8, that there are several aspects to RF interference issues surrounding wireless medical devices, including emissions from one device can affect another device or external system, and that medical devices will be exposed to significant sources of RF energy.

Therefore in addition to the potential for the transmitter to interfere with the medical device it is installed into, there could be interference with other medical devices in the RF-sensitive environment such as hospitals. Therefore we recommended that the healthcare facility develop best practices guidelines based on recommendations in this guidance document. The development of these is a better alternative to regulatory guidelines with restrictions that prohibit intentional transmitters[6] .

To resolve such issues medical facilities will need to ensure that their system installers, bio medical people, and other relevant staff are familiar with the intricacies of wireless interference issues to avoid such problems.

[6] . Example: Federal law prohibits operation of intentional transmitters on board aircraft during specific parts of the flight

Therefore additional information on addressing interference on site should be referenced in this document. This should include more emphasis on EMC site surveys and ad-hoc testing since this is generally beyond the scope of the actual equipment manufacturer responsibilities.

Further emphasis should be added to use factory trained and or a certified technical specialist[7] to perform such surveys and installations.

Data Integrity, Performance and Security

The FDA discussion on both data integrity and performance is useful since it raises some issues that manufacturers may not have considered. However other then raising the subject the FDA does not provide any guidelines and it is not clear by the discussion if the FDA believes the standards are adequate to address their concerns.

Therefore it is suggested that the FDA consider addressing their concerns to the standards committees developing the various wireless standards.

The same applies for the security discussion. Other than the mandatory compliance to HIPAA as required by law, the FDA did not provide any further guidance on exactly what level of security is adequate or what additional features they are concerned with. Again we urge the FDA to address this with the groups developing the various wireless security standards.

[7] Example: such as a NARTE certified telecom engineer or wireless installer, NARTE is a non profit 3rd party organization that certifies engineers and technicians.

Conclusion

The WFA applauds the FDA's initiative to address the issue of wireless devices and medical devices. These guidelines will provide the basic engineering requirements that medical device manufacturers need to consider before integrating wireless into medical equipment or installing such systems into facilities.

Further WFA suggest that the guide be developed in 2 distinct parts one for the system integrator and one for the system installer or operator since in some case's the requirements are somewhat different.

The increasing use of wireless in general requires more emphasis on EMC compliance to mitigate the potential for interference from radio devices as well as other electronic devices. This draft document is a good step in the right direction to meet this requirement.

Sincerely,

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