0409 7 APR -5 P3:13

April 2, 2007

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

Re: Docket No. 2006D-0504
*Draft Guidance for Industry and Food and Drug Administration Staff*
*Radio-Frequency Wireless Technology in Medical Devices*
Comments of GE Healthcare

To Whom It May Concern:

GE Healthcare submits the attached comments to FDA's Draft Guidance on Radio-Frequency Wireless Technology in Medical Devices, which was announced in the *Federal Register* on January 3, 2007 (72 Fed. Reg. 137).

If there are any questions regarding these comments, please contact me at 414-721-3945 or Neal Seidl, Wireless System Architect, 414-362-3413.

Sincerely Yours,

Gerry Buss/NEG.

Gerald Buss
Regulatory Affairs Manager, Clinical Systems
GE Healthcare

2006D-0504

C 8

**GE Healthcare Comments on**
**Draft Guidance for Industry and Food and Drug Administration Staff**
**Radio-Frequency Wireless Technology in Medical Devices**
**Docket No. 2006D-0504**

GE Healthcare (GEHC) appreciates the opportunity to comment on the FDA's recent *Draft Guidance for Industry and FDA Staff; Radio-Frequency Wireless Technology in Medical Devices* (Draft Guidance).[1] GEHC commends the FDA for its efforts, as reflected in this Draft Guidance, to assist medical device manufacturers in the development of products that incorporate radio-frequency (RF) wireless technologies. The Draft Guidance highlights a number of key considerations and good design practices for wireless medical devices. GEHC believes, however, that certain modifications would help improve the effectiveness of the Draft Guidance. These suggestions are detailed below.

## I. FACTORS THAT DETERMINE WIRELESS QUALITY OF SERVICE

The draft guidance contains a sub-section entitled, *Wireless quality of service.*[2] Although this sub-section addresses only cellular technology, quality of service (QOS) considerations, such as packet error rate, throughput, latency and jitter, are a key concern in the design of any wireless system – regardless of the underlying technology. Among the universal factors that influence wireless QOS are the nature of the RF spectrum utilized (e.g., unlicensed/shared vs. licensed/exclusive), link budget factors (e.g., transmitter ERP, path loss, receiver sensitivity, multi-path fading, design margin), modulation and demodulation schemes, media access control schemes (e.g., CSMA, TDMA, CDMA, frequency hopping.), and error detection and correction provisions (e.g., CRC, FEC, ARQ).

The fickle performance of many "macro" cellular telephone networks that is alluded to in the Draft Guidance is not inherent to the underlying cellular *technologies.* To the contrary, because of their deterministic capacity and bandwidth allocation mechanisms, and their operation on a primary basis in exclusive-use licensed spectrum, contemporary cellular standards such as GPRS, EDGE, cdma2000, and UMTS in principle offer superior reliability and robustness compared to alternatives, such as WiFi LANs, that lack deterministic MAC and QOS mechanisms and that operate on an unlicensed basis in increasingly congested shared spectrum.

No wireless technology, protocol or standard can by itself, however, guarantee good QOS. Proper signal coverage and capacity provisioning are absolutely crucial. The familiar reliability shortcomings of "macro" cellular networks are generally due to best-effort signal coverage designed for usual consumer and commercial applications. Yet when employed for safety-of-life or mission-critical applications within a building, much more comprehensive coverage, which would be unwarranted and cost prohibitive in the macro network, may be provided by means of a dedicated distributed antenna system and base station in order to achieve excellent QOS.

---

[1] *Draft Guidance for Industry and Food and Drug Administration Staff; Radio-Frequency Wireless Technology in Medical Devices; Availability,* 72 Fed. Reg. 137 (Jan. 3, 2007) (Draft Guidance).
[2] *Id.* at 8, 9.

Therefore, GEHC proposes that the Draft Guidance be revised to address the general design factors affecting wireless QOS for all systems and to avoid the implication that ensuring adequate QOS is a consideration applicable only to devices employing cellular technology.

## II. SPECIFICATION OF RF ENVIRONMENTS

The Draft Guidance repeatedly emphasizes the importance in design, risk management, verification, validation and labeling of accounting for the RF environment in which a wireless medical device will be used. For example:

> *"FDA recommends you address the following issues regarding expected characteristics of the electromagnetic environment where your device will be used:*
> *• performance of wireless functions*
> *• wireless coexistence*
> *• wireless quality of service*
> *• integrity of data transmitted wirelessly*
> *• security of data transmitted wirelessly and wireless network access*
> *• EMC."*[3]
>
> *"FDA recommends you describe in your premarket submission and labeling the wireless technology and RF specifications (e.g., RF frequency and modulation), the testing performed, and your results demonstrating the wireless functions will operate safely and effectively in the intended use environment."*[4]
>
> *"Therefore, FDA recommends you indicate in your premarket submission and as part of your QS records... testing you performed to demonstrate the wireless function will operate as intended in the expected environment of use."*[5]
>
> *"Based on intended use and anticipated environments for your medical device, FDA recommends you address the following factors in the device design and development ..."*[6]
>
> *"FDA recommends you address your device's environmental requirements, including...associated sources of EMD expected in specific use environments."*[7]
>
> *We recommend device EMC immunity test levels be representative of the intended electromagnetic environment of use."*[8]
>
> *"FDA recommends you verify your RF wireless technology will function properly in its expected use environment..."*[9]

---

[3] *Id.* at 7.
[4] *Id.*
[5] *Id.* at 9.
[6] *Id.* at 12.
[7] *Id.* at 13.
[8] *Id.* at 16.
[9] *Id.*

*"FDA recommends the device design and development verification process include...expected use environments."*[10]

GEHC agrees that consideration of the specifically intended RF environments as well as the potential but unintended RF environments is crucial to good product design. However, due to variation in factors such as use-scenarios, physical environments, and RF propagation characteristics, and because of the nearly limitless combinations of devices and signals that may be present – especially in unlicensed spectrum – the RF environment is highly complex and amorphous. Therefore, providing an adequate yet practicable treatment is a very challenging task for which a well-defined scope and framework is a necessity.

For this reason, GEHC suggests that terms such as *expected environment*, *anticipated environment* and *intended environment* be precisely defined and deliberately used throughout the guidance, including the excerpts quoted above. In particular, the guidance should distinguish clearly between the intended and the expected electromagnetic environments as follows. The *intended* RF environment should be defined as the RF environment in which the device is specifically intended to operate – i.e., the environment consistent with the *intended use* under 21 C.F.R. § 801.4. The *expected* RF environment should be defined as the RF environment resulting from any reasonably foreseeable scenario, including the unintended (e.g., the scenario where co-channel interference is present due to a second transmitter having been incorrectly programmed to the same frequency channel).

Using these distinctions, the risk management, design, verification and validation efforts can be more precisely formulated not only to ensure safe and effective operation in the in the intended environment but also to ensure safe operation in any expected environment – even when fully effective performance is not be possible due to non-intended but foreseeable scenarios. When describing the intended environment as recommended in the guidance,[11] the device labeling (e.g., the operator's manual) can then explicitly enumerate those expected potential factors that are not intended and therefore excluded from the intended environment and therefore the intended use.

## III. CONSIDERATIONS RELATED TO COMPLEX WIRELESS SYSTEMS

Wireless devices that are medical devices under the Federal Food, Drug and Cosmetic Act often are actually complex *systems* such as a distributed antenna system or an access point infrastructure that include many "building block" sub-systems and may be assembled and configured uniquely for each individual deployment. The Draft Guidance does not specifically distinguish such systems from mass-produced, self-contained devices. Such complex systems, however, warrant more focused consideration that addresses their unique considerations. Control of the standard deployment and commissioning processes, for example, are as important as the design and manufacture of the individual components from which the system is built.

---

[10] *Id.* at 17.
[11] *Id.* at 19, 20.

## IV. RELIANCE ON AD-HOC SYSTEM-LEVEL TESTING FOR VERIFICATION AND VALIDATION INCLUDING COEXISTENCE TESTING

The Draft Guidance recommends that device validation be performed "in the presence of the number and type of in-band [RF] sources at the expected proximity specified for the device."[12] Due to the nature of most RF wireless environments as having essentially limitless combinations of expected concurrent users, applications, traffic and signals and due also to the nature of many complex wireless systems that have virtually unlimited possible configurations from deployment to deployment, GEHC believes that such ad-hoc system-level testing alone is impractical and ineffective to validate proper device performance.

Although ad-hoc system-level tests such as those described by ANSI C63.18 can be useful for detecting specific problems and incompatibilities, successful completion of such tests cannot generally ensure that a device will function acceptably across the entire continuum of intended and expected scenarios. In addition, this type of testing is relatively inefficient to perform and tends to suffer from poor repeatability.

GEHC suggests that design verification processes are a more suitable and effective means than validation to evaluate many of the effects of wireless environmental variables. Specifically, as an alternative to such validation testing, GEHC proposes the following approach.

A wireless device or system should first be partitioned into physical or logical subsystems, for example:

- data acquisition unit,
- client RF transceiver,
- wireless links (including important RF environmental factors),
- access point transceiver,
- wired-network (e.g., Ethernet) infrastructure, and
- physiological data processing, alarming and display subsystems

For each subsystem, critical performance and behavioral specifications should be captured as design requirements. These design requirements for each subsystem then should be verified in accordance with 21 C.F.R. § 820.30(f). This lower-level subsystem verification has the advantage of typically being able to be more sophisticated and well controlled and is able to better isolate and more completely exercise each subsystem. With the performance of each subsystem well characterized by detailed design requirements and the associated low-level verification, the verification and validation of system-level design and user requirements can then be carefully devised to address overall system-level behavior and performance under all critical scenarios (e.g., data lost or delayed on wireless link) regardless of the actual root cause (e.g., failure of client, failure of access point, co-channel interference by various sources, etc.). Within such a framework, it is possible to apply analysis, modeling and simulation in addition to testing to accomplish more comprehensive system-level verification and validation in a more efficient manner compared to testing alone. This approach also facilitates more rigorous risk management procedures.

---

[12] *Id.* at 18, 19.

## V. RF TRANSMIT POWER RECOMMENDATIONS

The Draft Guidance recommends that wireless medical devices "limit their RF output to the lowest power necessary to reliably accomplish their intended functions."[13] With regard to this recommendation, GEHC would like to emphasize that a design tradeoff often exits between transmit power and overall system cost because transmit power can typically be lowered if infrastructure density is increased. However, this will usually have a significant adverse impact to infrastructure invasiveness and cost. Similarly, implementation of dynamic power control mechanisms, which attempt to maintain the lowest necessary transmit power required at any instant in time, are possible but may also result in increased system complexity and cost to the user.

Although the Draft's Guidance's recommendation may be appropriate for medical devices incorporating simple limited range point-to-point or point-to-multipoint wireless links for which the maximum signal attenuation can be determined with certainty to allow substantially less power than otherwise feasible and permitted by FCC regulations(e.g., short "cable replacement" applications), it is less practical for other medical devices. Specifically, for systems that must provide seamless wireless coverage over large areas (e.g., telemetry systems), a simple point-to-point or point-to-multipoint architecture is not suitable, so an infrastructure of distributed antennas or access points must be employed. In such systems, transmit power may in principle be reduced while still maintaining both the same scale of coverage and level of reliability provided that antenna or access point density is increased sufficiently to compensate. But generally increasing infrastructure density is undesirable to users because it adversely affects the cost and invasiveness of the installation (e.g., antennas need to be placed in each hospital room vs. a few in the hallways). Therefore, compelling reasons exist to not strictly and absolutely minimize transmit power in such systems. Accordingly, GEHC suggests that the Draft Guidance be modified to acknowledge this inherent tradeoff and the appropriateness of balancing transmit power minimization against other key system requirements including cost and invasiveness to users.

[13] *Id.* at 7.