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March 30, 2007

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BY ELECTRONIC MAIL

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

Re: Comments Concerning Radio-Frequency Wireless Technology in Medical Devices
Draft Guidance Document (Docket No. 2006D-0504)

Dear Sir or Madam:

On behalf of Welch Allyn, Inc. (Welch Allyn), the undersigned submits these comments in response to the Food and Drug Administration's (FDA) request for comments regarding its draft guidance document concerning Radio-Frequency (RF) Wireless Technology in Medical Devices.

Welch Allyn was founded in 1915 and is today a leading manufacturer of innovative medical diagnostic and therapeutic devices, cardiac defibrillators, patient monitoring systems, and miniature precision lamps. Welch Allyn manufactures a large number of devices that incorporate RF technology and focuses its efforts entirely on helping frontline practitioners in acute care and primary care by providing the tools required in family practice (including pediatrics, and OB/GYN), emergency medicine, internal medicine, and inpatient care medical disciplines. Headquartered in Skaneateles Falls, New York, USA, Welch Allyn employs more than 2,300 people and has numerous manufacturing, sales, and distribution facilities located throughout the world.

The comments provided below represent our thinking on specific elements that should be considered by FDA in drafting the final guidance document.

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General Comments

Welch Allyn recognizes that this guidance document will concern how FDA will interpret and apply its own regulations as they pertain to wireless technology in medical devices. However, for clarity's sake, Welch Allyn suggests limiting the instances where such regulations and other standards are restated in the guidance document to the absolute minimum and, instead, provide references to the appropriate regulations/standards.

Welch Allyn also suggests that the guidance document be thoroughly reviewed and edited to eliminate potentially confusing recitations of the same standards in various sections of the document. For example, in Section 6 (Design and Development) the first bulleted list is a superset of those presented in Sections 2 (Scope) and 4 (Concerns Related to RF Technology Use in and Around Medical Devices). As a result, some readers may mistakenly believe that certain standards are inapplicable. In addition, there are numerous instances of inconsistent capitalization and punctuation relating to the acronyms (e.g., LANS and LANs) used in the document. Thorough review and editing for consistency will make the final document more readable and easier to understand.

a. Scope of Guidance

It appears that the scope of this draft guidance document is not sufficiently broad. There are many products that emit RF energy. Only a portion of the devices that emit RF energy are actually intended to emit such energy in performing their intended use. Examples of devices that incidentally produce RF energy include computers, monitors, electric motors, and power supplies. Products that incidentally emit RF energy can adversely affect the RF environment in which an RF transmitting device may be expected to operate. For example, a common microwave oven operating at 2.45 GHz generates significant disturbance levels for 802.11b/g products operating in the 2.4 GHz frequency range. Further, FDA does not make recommendations for non-RF devices that are expected to operate proximally to intentional transmitters. As an example, 802.11 WLANs are becoming pervasive in hospitals and therefore, RF immunity to these devices should be considered for inclusion in this document. Insofar as this draft guidance document does not address issues related to devices that incidentally emit RF energy in the presence of intentional RF emitters, its scope is too narrow because it leaves open the possibility of device failures caused by such devices even when the RF transmitting device manufacturer has fully complied with the agency's guidance. Because it is not possible to design a medical device that uses RF energy that is immune to all potential sources of RF interference, Welch Allyn suggests that the scope of the guidance be either expanded to include devices that incidentally emit RF energy and devices that operate in the presence of devices that intentionally emit RF energy to reduce this potential risk. In the alternative, FDA could recognize that the planned changes to EN 60601-1-2 to include immunity up to 5 GHz cover the concerns raised by these impending changes herein.

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Likewise, manufacturers of non-medical RF devices are omitted from the scope of this document. The guidance contained in this document will do little to help assure the safe and effective use of RF wireless technology in medical devices if it does not also address all elements of the shared wireless networks that are found in device user facilities. These networks can include products manufactured for non-medical device applications such as wireless computer network products (e.g., client devices, routers, access points, and building-to-building bridges) as well as actual medical devices (e.g., vital signs patient monitors, Radio Frequency Identification (RFID) scanners, and point-of-care records management systems). The standards and conventions used by these non-medical devices are subject to frequent and unpredictable revision as market forces dictate and technology evolves. Welch Allyn encourages FDA to properly consider this fact when finalizing this guidance document and citing to any specific wireless technology standard.

b. Issues Related to User Facilities

Moreover, Welch Allyn notes that device user facilities also appear to be excluded from the scope of this draft guidance document. Shared networks are designed, created, and maintained by device user facilities and are tailored to fit a particular facility's specific needs. Because these needs can vary widely, it is impossible for each wireless medical device manufacturer to guarantee network performance on a network where the hospital controls the number and types of loads. For example, a device manufacturer can add an application to a user facility's network, verify that it performs as intended, but if the user facility subsequently alters its shared network, it may compromise the performance of the previously installed RF medical device in a manner that is out of the control of the device's manufacturer. As another example, Welch Allyn understands that in some locales, the WMTS frequency coordinator has subscribed multiple, proximal hospitals to the same operating band. This creates the potential for device malfunctions created by separate networks operating on the same band. In addition, Welch Allyn also understands that some manufacturers of broadband WMTS devices are recalcitrant in allowing room in the RF spectrum for other co-existing devices to operate properly despite applicable Federal Communications Commission (FCC) requirements. Welch Allyn also encourages FDA to consider these circumstances when considering the scope and content of the final guidance and, where necessary, coordinate its efforts with the FCC.

c. Listed Wireless Technologies

In several places, the draft guidance's discussion of RF technologies appears to omit a number of current important RF technologies to include Medical Implant Communications Service (MICS), Private Land Mobile Radio Service (PLMRS), and Family Radio Service (FRS). Welch Allyn suggests that FDA attempt to provide a comprehensive listing of technologies that will be affected by the guidance document.

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d. References to Wireless Devices

The draft guidance's discussion of the various RF technologies appears to confuse communications technologies with the various types of products that make use of these technologies. For example, the list identifies "personal digital assistants"¹ and "wireless modems for laptop computers"² as examples of "current RF technologies." In fact, a personal digital assistant (PDA) may use a number of technologies to include cellular telephone networks, Broadband Personal Communications Service (PCS), 802.15.1, and/or 802.11a/b/g. As a result, the term "PDA" cannot be used interchangeably with any one of these terms. Likewise, wireless modems for laptop computers generally use cellular telephone networks or PCS radio communications and cannot be used interchangeably with either of these terms. As another example, the draft guidance document appears to use the term "WMTS" to identify a type of device. "WMTS" does not refer to one particular device. Rather, the term encompasses multiple types of devices that use different RF technologies to include narrow-band FM, PCM, as well as spread-spectrum.

Likewise, there may be confusion in interpreting references to "Part 15" devices which incorporate an enormous range of technologies, including auditory assistance devices, biomedical telemetry devices, cordless telephone systems, and others. For example, wireless computers and wireless PDAs are examples of Part 15 devices if they transmit in the ISM band(s). Also, digital devices that generate pulses at a rate in excess of 9000 pulses per second are Part 15 devices that are not necessarily RF wireless technologies. Welch Allyn suggests that the draft guidance document should be revised accordingly to avoid any potential confusion regarding specific RF technologies and devices that would fall under the scope of the guidance.

Concerns Related to RF Wireless Technology Use in and Around Medical Devices (Section 4)

a. Data Integrity

The draft guidance document contains a number of apparently inaccurate statements regarding data integrity. Foremost, statements in Section 4 appear to indicate that the data integrity issues are limited to the ISM frequency bands. Using a commonly accepted definition for data integrity³ which reads "the condition of the data is identically maintained," data integrity issues are virtually non-existent for 802.11 with a 32-bit cyclic redundancy code (CRC). 802.11i adds an additional check of a Message Integrity Code. What usually occurs is that data are identified as

¹ A personal digital assistant is a product that may use Cellular, PCS, 802.15.1, and/or 802.11a/b/g technologies.

² Wireless modems for laptop computers generally use of cellular telephone networks or PCS radio communications.

³ See http://en.wikipedia.org/wiki/Data_integrity

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corrupt at the receiver when the CRC check is made and the 802.11 Media Access Control layer causes a re-transmission. In contrast, industry experience (as evidenced by multiple listings in FDA's MedWatch database regarding conventional telemetry devices) has shown that data integrity issues are not limited to just the ISM bands nor is it limited to shared networks.

Welch Allyn believes the guidance document mistakenly considers latency and data integrity as the same issue. Latency indicates how long after transmission the data arrives and Quality of Service is the appropriate term to describe if data arrives in a timely manner (or at all). Latency is typically related to how busy the network is and the amount of RF interference in the communication channel. In the former case, a busy network can cause a client device to have to wait for "free" air time in which to transmit, leading to longer latencies. In the latter case, RF interference may cause a bit error, which is detected by the CRC check. A system such as 802.11 then causes the data to be re-transmitted, but of course this re-transmitted data arrives with additional latency. For 802.11 with the 32-bit CRC, data integrity issues are mitigated by re-transmission, at a cost of additional latency.

Likewise, the draft guidance document appears to indicate that data latency is a factor that is under the exclusive control of the device manufacturer. However, data latency can be affected by the infrastructure created by the device user facility. To this extent, data latency issues at the device user facility are largely out of the control of the device manufacturer. The ideal way to address data integrity issues is for the medical device manufacturer to define the latency and throughput requirements for an application so that the device user facility, working with the manufacturer, can ensure that the facility's infrastructure meets these requirements. Welch Allyn suggests amending the guidance document accordingly.

b. Data Security

Many of the security concerns addressed in the draft guidance have already been addressed in HIPAA. Therefore, it may be appropriate for FDA to cross-reference the relevant provisions in this document after ensuring that they are consistent with FDA's goals. If, after such review, FDA believes it is necessary to include additional data security guidance, Welch Allyn suggests such guidance should include the following concepts related to authentication and encryption:

1. Ensuring that only intended users/devices are on the network;
2. Ensuring that users/devices are on the intended network; and
3. Prevention of data "sniffing" and data modification.

The draft guidance document indicates that wired access systems are generally more secure than wireless access systems. However, this is not always the case. Typically, wireless access systems require some form of authentication as a basic security measure. On the other hand, many wired access systems do not. In this case, these wired systems are not as secure as authenticated

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wireless systems. This is because the wired access system is open to anyone who can plug into an open Ethernet jack. While security is a concern for wireless networks, it is no less a concern for wired networks. FDA should not use this guidance to impose security standards on wireless systems that are not also applicable to wired systems.

c. Listed Technologies

Welch Allyn notes that there are several typographical errors that could cause potential confusion in interpreting FDA's intent. In the first place, the reference to "WLAN 802.11.a/b/g/" should be corrected to read, "WLAN 802.11a/b/g/." In addition, the reference to "802.153a" should be corrected to read, "802.15.3a."

Design and Development (Section 6)

a. EMC and Telecommunications

Welch Allyn notes that the requirement for a device manufacturer to provide EMI protection exists whether or not the device includes an RF transmitter. Nevertheless, Section 6 of the draft guidance appears to mandate a description of EMC shielding in the premarket submissions for devices containing an RF transmitter. There is no like requirement for devices which do not contain an RF transmitter. Historically, it has been sufficient for manufacturers to conduct, identify, and mitigate EMC and telecommunications hazards as part of the design process, including FMEA and testing, and document the results in the Design History File (DHF), including for devices such as those that use the WMTS service. The draft guidance document appears to be changing this standard, but only as it applies to devices which contain RF transmitters. In addition, this requirement would have the practical effect of requiring the completion of EMC testing prior to submitting a premarket notification. This would significantly increase the amount of time it would take for a manufacturer to bring such a device to the market. Therefore, it appears that this requirement will unfairly burden manufacturers of devices containing RF transmitters. Welch Allyn suggests that this requirement should be eliminated altogether.

b. Environmental Requirements

The multiple listings of sample RF sources and devices in medical device use areas are helpful. However, actual hospital configurations may vary and the listed examples may not be representative of actual hospital practices and uses of RF devices and sources. Therefore, Welch Allyn suggests that FDA provide a single inclusive list of example RF devices and sources. This list should also include other known RF sources that have been omitted from the current list including: WTMS devices; electrosurgical/electrocautery units; paging systems; Bluetooth devices

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(including cellular handsets); PLMRS radios; FRS radios; microwave ovens; battery powered food carts; floor polishers; and faulty fluorescent light ballasts.

Design and Development Verification (Section 7)

Welch Allyn believes that this section contains information that is redundant and possibly inconsistent with information previously stated in Section 6 of the draft guidance. For example, with regard to the design and testing of RF devices, Section 6 states, "We recommend you design and test RF wireless medical devices for EMC performance using appropriate standards (e.g., IEC 60601-1-2:2001...)." Whereas, Section 7 states, "We recommend EMC be demonstrated by the device's conformance to one or both of the following standards...IEC 60601-1-2:2001...IEC 61326." As a consequence, it is difficult to determine which testing standard FDA is actually recommending for this purpose. Please ensure FDA's guidance is consistent throughout the final guidance document.

The agency's suggestions regarding elements to be considered for inclusion in the design and development verification process are not completely clear. Welch Allyn believes that the verification process should include *testing* against all claims of device use. However, the draft document does not indicate why the agency believes that the verification process must include "all claims for device use and RF wireless functions." In Welch Allyn's opinion, FDA's suggestions for calling out a "summary of all limitations, warnings, and contraindications..." "Brief summary of all RF wireless..." and a "Brief explanation of any device EMC or other modifications..." are all appropriate for inclusion in the DHF. However, they do not constitute a part of the actual verification process as one might conclude from the draft document.

In addition, Welch Allyn feels that specifically prescribing such requirements in this guidance document would unfairly burden RF device manufacturers. As Welch Allyn understands it, virtually all class II and III medical devices require EMC modifications to meet immunity and emissions standards. It does not follow that FDA would require manufacturers of RF medical devices to explain any device modifications that were required in order for an RF device to be able to pass testing when it does not impose a like requirement on the manufacturers of non-RF devices that must also make modifications to their devices to pass the same testing. Welch Allyn firmly believes that the Quality System Regulation (QSR) sufficiently defines the scope of verification and validation activities to cover all functions (including wireless RF functions) and that the additional recommendations in this document are not necessary.

In addition, the statement regarding information to be summarized in a premarket submission (pp. 17-18) is phrased in a confusing manner. It is possible to interpret this statement as a requirement to include the listed information in either the premarket submission or the device's labeling. It is also possible to interpret this statement as a requirement to include the listed information in both the premarket submission and the device's labeling. Welch Allen does not feel

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that it is always appropriate to provide the listed information as part of a device's labeling. Nor does Welch Allyn believe this was the agency's intent. Therefore, Welch Allyn requests that the agency rephrase the statement so that it may not be misinterpreted as a requirement to provide the entirety of listed information in a device's labeling.

Design and Development Validation (Section 8)

The fourth bulleted item on page 18 recommends that device manufacturers test the "security of production units." It is not clear in what sense FDA is using the word "security." One can reasonably presume that, when used in this sense, the word security means an assurance that any other device will not break in over the wireless network and alter the device's function. If this is the case, Welch Allyn again notes that onboard device security mechanisms work in concert with network security systems in order to provide device security. Welch Allyn believes that as long as an individual device's security mechanisms can be verified pursuant to QSR requirements, they need not be validated. Similarly, data transmission rate, latency, and bit error rate are criteria that can typically be verified. When verification of specific performance criteria is possible, validation of the specific criteria is not required. Welch Allyn understands that validation that a device conforms with the user needs and intended uses is still required, but the examples called out for validation in the draft document are specifications that can typically be verified. Accordingly, Welch Allyn recommends that FDA clarify its intent in making this recommendation and if our presumption about FDA's intent is correct, that FDA replace the word "validation" with either the word "verification" or the phrase "validation and/or verification," as appropriate.

In addition, the phrase "For example, if other in-band RF sources are expected to be used in proximity to the RF wireless medical device, we recommend you test: ..." should be rephrased for clarity to read, "For example, if other in-band RF sources are expected to be used in proximity to the RF wireless medical device, we recommend you verify any critical wireless performance parameters remain within limits when these other in-band RF sources are transmitting."

Labeling (Section 9)

Welch Allyn does not believe it is necessary to include "how testing was conducted" and "susceptibilities discovered" in product labeling. Although this information may be called out in IEC 60601-1-2; 2001, and to the best of Welch Allyn's knowledge, its inclusion in product labeling is not a regulatory requirement under United States law. Moreover, Welch Allen believes that these issues are adequately addressed by the Quality System Regulation through the FMEA and risk analysis processes. Welch Allyn also sees no reason to single out wireless medical devices for this additional labeling requirement. The inclusion of these additional labeling requirements could have the effect of significantly delaying a device's availability to healthcare practitioners. Welch Allyn suggests removing these requirements from the final guidance document.

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This section also appears to contain requirements that are redundant of current FCC and IEC requirements in that it contains labeling recommendations regarding radiated power and frequency characteristics are already covered by FCC and IEC requirements. Welch Allyn suggests providing appropriate references to these standards in this section in lieu of re-stating these requirements multiple times.

Additional Information About RF Wireless Communications (Appendix A)

This section omits the concept that certain communications equipment operate on unlicensed frequencies, as well as on exclusive licensed frequencies. For example, two-way radios exist in unlicensed frequencies including citizens' band and FRS frequencies. In addition, mobile wireless equipment can also operate in vacant TV bands, WTMS, MICS, and PLMRS. In addition, the "three broad categories" listed in this section do not address conventional WMTS equipment that are not 802.11 standards based, transmit only a limited amount of power, and do not support dynamic transmit power control.

There are also a number of technical errors in this section that should be corrected. The reference to the 802.11 standard should be rephrased to state that the standard provides transmission rates "...between 6 and 54 Mbps in the 5GHz..." Also, the description of the 802.11g standard would be more accurate if it were rephrased as follows:

802.11g - An extension to 802.11 that applies to wireless LANs and provides transmission rates between 6 and 54 Mbps in the 2.4 GHz ISM band. The 802.11g standard specifies an orthogonal frequency division multiplexing modulation scheme.

Finally, please note that the phrase "Wi-Fi" is a trademark of the Wi-Fi Alliance which may object to its use in this document.

Reference Standards and Telecommunications Information (Appendix B)

The following relevant standards appear to have been omitted from the recitation of European Telecommunications Standards Institute standards:

ETS/EN 300 328 – Radio equipment and systems; wideband transmission systems; technical characteristics and test conditions for data transmission equipment operating in the 2.4 GHz ISM band using spread spectrum modulation techniques.

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ETS/EN 301 893 – Broadband radio access networks; 5 GHz high performance RLAN.

Welch Allyn believes that it is appropriate for this section to reference the additional applicable following standards:

47 C.F.R. §§ 2.1091 and 2.1093 regarding FCC Specific Absorption Rate (SAR) and Maximum Permissible Exposure (MPE) requirements.

ANSI/IEEE C95.3 and C95.1 regarding SAR and MPE limits.

This section also uses incorrect nomenclatures to refer to some standards, i.e., references to ETS 300339 and ETS 300683 should be ETS/EN 300 339 and ETS 300 683. In order to avoid potential confusion, only officially published conventions should be adopted when referring to standards within this document.

Another source of potential confusion in this section is the reference to ‘802.x standards’ which can easily be confused with the 802.1x standard. A better way to accomplish the agency’s intent may be to use the phrase “802.11 standard and extensions” in place of ‘802.x standards.’”

Conclusion

We hope that FDA finds these comments on the draft guidance document concerning Radio-Frequency (RF) Wireless Technology in Medical Devices useful. Welch Allyn urges the agency to provide an additional opportunity to review and comment upon a revised draft guidance document in light of the nature and amount of changes that are required prior to implementation of final guidance document.

Sincerely,



Evan P. Phelps

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