American Hospital Association

Regulatory Advisory

ASHE

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FDA Public Health Notification: Risk of Electromagnetic Interference with Wireless Medical Telemetry Systems Operating in the 460-470 MHz Frequency Bands

November 23, 2005

A Message to AHA and ASHE Members:

On November 16, 2005, the Food and Drug Administration (FDA) issued a Public Health Notification to health care facilities, warning them that after **December 31, 2005**, any medical telemetry system operating in the 460-470 MHz frequency band is at increased risk for interference, which could compromise patient safety. On June 15, 2005 and July 23, 2004, the American Hospital Association (AHA) and the American Society for Healthcare Engineering (ASHE) issued Regulatory Advisories urging hospitals to assess their risks of interference to medical telemetry systems operating in the 460-470 MHz band and to migrate out of the band by December 31, 2005. This FDA notification reinforces those advisories.

The attached advisory is a follow-up to our June 15, 2005 advisory, which addressed several issues and concerns associated with the expiration of the freeze, including the requirement that hospitals must register their wireless medical telemetry equipment with ASHE, the FCC-designated medical telemetry coordinator.

After reviewing this advisory, check off the following items from your to-do list:

- ✓ Share this advisory with your clinical and biomedical engineering professionals, critical care physicians, nursing staff and risk managers.
- ✓ Register your telemetry equipment.

The AHA and ASHE will continue to work closely with the FDA and FCC to ensure that interference does not compromise patient care and safety.

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FDA Public Health Notification: Risk of Electromagnetic Interference with Wireless Medical Telemetry Systems Operating in the 460-470 MHz Frequency Bands

November 23, 2005

The Food and Drug Administration's (FDA) November 16 Public Health Notification reminds hospitals operating wireless medical telemetry equipment in the 460-470 MHz frequency that they need to migrate out of that band by December 31, 2005 and into one of three bandwidths dedicated to wireless medical telemetry equipment, or risk interference which could compromise patient safety.

Background

The American Hospital Association (AHA) and the American Society for Healthcare Engineering (ASHE) expressed concern that electromagnetic interference with wireless medical telemetry equipment could affect patient safety[1]. In response, the Federal Communications Commission (FCC) in 2000 dedicated a portion of the radio spectrum for use by wireless medical telemetry devices such as wireless heart, blood pressure and respiratory monitors. The Wireless Medical Telemetry System (WMTS) was created as a result.

The private land mobile radio service (PLMRS) has had "primary status" in the 460-470 MHz band for several years. When the FCC allocated the WMTS bands (608-614 MHz, 1395-1400 MHz, and 1427-1432 MHz), it ceased issuing licenses to high-powered users in the 460-470 MHz band for three years to allow hospitals time to migrate to the WMTS. Recognizing hospitals' difficulty in transitioning to WMTS due to limited resources and the lack of wireless medical telemetry equipment on the market, ASHE and the AHA worked with the FCC and leaders of the PLMRS community to extend the licensing freeze until December 31, 2005. The FCC announced this final extension of the freeze in its July 8, 2004 Public Notice. In addition to extending the 460-470 MHz freeze, the FCC public notice reminded all users that **hospitals are required to register their wireless medical telemetry equipment and frequencies through ASHE,** the FCC-designated medical telemetry frequency coordinator.

Interference for Secondary Medical Telemetry Users

In addition to the WMTS where hospitals enjoy primary user status, wireless medical telemetry operates as secondary users in several other bands, including the PLMRS, digital television (DTV), and industrial scientific and medical bands. Even if wireless medical telemetry equipment is currently

[1] In March of 1998, Dallas TV station WFFA tested its new digital television (DTV) transmitter on a previously vacant TV channel. The powerful signal from this testing overwhelmed low-power heart monitors at Baylor University Medical Center and Methodist Hospital, both of which were tuned to operate in the same vacant TV channel as WFFA.

operating outside the WMTS with minimal observed interference, the likelihood of interference will increase dramatically after December 31, 2005, when the FCC freeze on high-powered PLMRS devices in the 460-470 MHz band expires. At that time, the FCC expects to grant a considerable number of licenses for high-powered devices, defined as operating at two watts or higher, or the equivalent of operating at over 100 times their currently allowed power levels in the 460-470 MHz band. Even at the currently required lower power levels, ASHE has received several reports of hospitals' wireless medical telemetry systems receiving interference from a variety of licensed primary users, including mobile radios and walkie-talkies used by policemen, firemen, taxis and delivery trucks. Conservative estimates indicate that PLMRS devices outnumber wireless medical telemetry devices 10 to one.

Actions to Take for Secondary Telemetry

To avoid harmful interference, hospitals should migrate their wireless medical telemetry equipment out of the 460-470 MHz band by December 31, 2005 or obtain a license from the FCC to operate their equipment as a primary user under Part 90 of the FCC rules. However, a license may not be granted or may be difficult to enforce because a license already may have been granted to a high-powered user, pending the lifting of the freeze on December 31, 2005.

Registration of Equipment Operating in Primary WMTS Bands

Equipment operating in the WMTS bands (608-614 MHz, 1395-1400 MHz, and 1427-1432 MHz) has primary, licensed status and is protected by FCC rules from interference by other devices. **WMTS is the only frequency spectrum designated exclusively for wireless medical telemetry systems.** Hospitals deploying telemetry systems in the WMTS bands must ensure that **device registration has been completed before the equipment is operational.** In accordance with FCC rules, Section 95.1111, all WMTS users must register specific information about their WMTS equipment including frequency, power output and other details. **Failure to do so means that your system is not protected from interference, and you are operating illegally.**

Steps to register your equipment in the WMTS:

- Use the online registration form at www.ashe.org or call ASHE at (312) 422-3805 to establish an account. You must provide information on the hospital or facility where wireless medical telemetry equipment will be installed and pay a one-time administrative fee per hospital (not per health system). Each hospital needs a separate account.

- Look for the appropriate account information from ASHE, including a login identification and password, to enter your WMTS deployment into the WMTS Frequency Coordination Database, found through ASHE's Web site or at www.wmtssearch.com.

- Once in the WMTS database, enter information as prompted, perform a frequency search and select frequencies. There is no charge to perform a frequency search. However, once you do so, your deployment will be entered into the database and you will be charged a registration fee. For more information about WMTS, including pricing information, download the WMTS User Information Guide at http://www.ashe.org/ashe/wmts/pdfs/wmts_userguide.pdf.

Once you've finished registering, download a coordination certificate which will include a summary of your registered deployment, i.e., at what frequency along the spectrum your equipment is operating.

Frequency Coordinators

As the FCC-designated medical telemetry frequency coordinator, ASHE will maintain a database of WMTS transmitters and notify users of potential frequency conflicts. For more information about ASHE's role as frequency coordinator, please visit www.ashe.org or contact John Collins, director of engineering compliance, at (312) 422-3805 or jcollins@aha.org. To check if your hospital's WMTS equipment is registered with ASHE go to http://www.ashe.org/ashe/wmts/registeredhospitals.html.

Please contact the AHA's Mary Beth Savary Taylor at msavary@aha.org or (202) 626-2270, or ASHE's Dale Woodin at dwoodin@aha.org or (312) 422-3812 if you have questions about hospitals' use of wireless medical telemetry equipment and patient safety.