Performing a risk assessment to identify factors that could disrupt the effective, safe, and reliable operation of medical equipment is nothing new. Clinical engineers and biomedical technicians have complied for many years with the Joint Commission’s “Management of the Environment of Care” standard EC.6.10, which calls for a risk assessment of medical equipment and systems. It requires that medical equipment be assessed for potential physical risks associated with use, equipment function, and equipment incident history. The intensified use of wireless devices* brings to the fore a factor implicit in this standard: assessment for electromagnetic compatibility (EMC). The lack of EMC is a particularly urgent problem with medical telemetry systems. Rapid increase in use of telemetry, coupled with increasingly crowded bandwidth, makes initial assessment and coordination critical to assure safe and reliable medical equipment operation.

The Critical Nature of Reliable Operation

Telemetry monitoring of patients’ vital signs is no longer simply a function of cardiac care or cardiac rehab. Often, patients are monitored upon first arriving at the emergency department and throughout their hospital stay. The steady rise in patient acuity has intensified the need to monitor the patients’ vital signs. Telemetry allows for the real-time monitoring of critical patient data, but the level of surveillance and care is only as reliable as the telemetry monitoring system. Interference can lead to unreliable monitoring, including potentially missed alarms and even missed life-threatening events. For example, if a patient is being monitored for cardiac arrhythmia and an event occurs, this event may be captured at the patient-worn transmitter, but because of interference, it may not actually be transmitted to the central monitoring system. In addition, a life-threatening event like low heart rate may be masked by interference or not be transmitted to the central monitors. Telemetry monitoring capabilities have expanded so vastly—larger antenna systems over multiple patients and in numerous locations throughout the building and campus—that the potential to receive interference and unintended signals has ballooned.

Explosive Growth in Wireless Devices Leads to Competition for Bandwidth

In the past the Federal Communications Commission (FCC) did not commonly license medical telemetry transmitters because their low-power operation did not represent an interference threat to other

Sidebar 1: Steps to Effectively Assess the Risk and Reduce Vulnerabilities to Interference

1. Develop a complete inventory of all medical telemetry equipment, including manufacturer, model, operating frequency, output power, and locations where the equipment will be used.
2. Depending on the operating frequencies, assess the risk for potential future interference (for example, if existing equipment is operating on TV [UHF/VHF], contact local TV stations to determine future plans for that channel; if 460–470 MHz, contact local businesses that utilize mobile communications [such as taxis and delivery companies] to determine future plans).
3. Discuss the findings of the risk assessment with the safety committee. If the risk assessment indicates the potential for increased future interference, consider migration to Wireless Medical Telemetry Service (WMTS).
4. Check the intended WMTS site for local interference. See the list of potential interferers on pages 5 and 11.
5. Perform a prepurchase evaluation of other WMTS and adjacent channel users. Perform a site survey of the intended locations for the WMTS equipment by using a frequency analyzer or similar RF evaluation equipment.
6. Register your equipment with ASHE.

* Wireless devices, for this discussion, are devices that receive and transmit information using radio frequencies. Common wireless devices include cell phones, walkie-talkies, mobile e-mail devices, and wireless local area networks. In a health care setting, these devices are common as point-of-care tools for patient charting, results reporting, and caregiver communication.
radio frequency (RF) communication systems. Likewise, telemetry systems were chosen to fill in “gaps” in unused RF spectrum such as vacant TV channels or spaces between Private Land Mobile Radio (PLMR) channels. FCC realignment and compression of PLMR channels (termed “refarming”) and the filling of previously vacant TV channels with digital (DTV) broadcasts and local Low Power (LPTV) broadcasts has eliminated the spectrum that medical telemetry once called home.

**Risk Assessment of Current Medical Telemetry Operations**

Because of this rapidly changing environment, past reliable operation of telemetry should not be taken as assurance of future reliability. Two significant events will change the environment overnight:

1. **Expiration of the 460–470 MHz freeze.** The FCC has set December 31, 2005, as the expiration date for the freeze on granting new licenses to high-power PLMR users. Literally millions of new licenses for equipment operating up to 100 watts have been held up, pending expiration of the freeze. The American Hospital Association (AHA) and the American Society for Healthcare Engineering (ASHE) have twice successfully petitioned the FCC to extend the freeze, giving hospitals more time to migrate out of the 460–470 MHz band. However, the FCC granted the last extension with the warning that there would be no further extension or delays. After December 31, hospitals still using 460–470 MHz are likely to experience unreliable operation, ranging from random interference from mobile sources as they pass by the hospital to continuous interference and loss of signal from high-powered fixed transmitters.

2. **Increased activation of DTV broadcasts.** The FCC has required that network affiliates in the 100 largest media markets broadcast ABC, NBC, CBS, and FOX in DTV by July 1, 2005. For markets outside the top 100, these same requirements exist for broadcasts by July 1, 2006. If a hospital is still operating on a vacant TV channel designated for reassignment to DTV, that broadcast may completely overwhelm the telemetry system (depending on the hospital’s distance from the TV antenna).

Hospitals that continue to operate on these older bands will need to assess their potential risks for interference and take immediate steps... (continued on page 11)
Risk Assessment for Medical Telemetry Interference
(continued from page 5)

to mitigate their effects, up to and including moving to another band.

WMTS—FCC’s Designated Home for Medical Telemetry

Foreseeing the impending “train wreck” of unreliable telemetry operation, the AHA convened a task force of medical equipment manufacturers and hospitals in the late 1990s to study the problem and make recommendations† to the FCC. Based on these recommendations, the FCC created the Wireless Medical Telemetry Service (WMTS)‡ and prohibited further manufacturing of telemetry equipment operating in the PLMR and TV bands. Because no single band was open and available for assignment to WMTS, the FCC designated the following three distinct frequency ranges as making up the total 16 MHz of the WMTS:

- 608–614 MHz
- 1395–1400 MHz
- 1427–1429.5 MHz

Prepurchase Assessment and Frequency Coordination Necessary

Because each WMTS frequency range was previously assigned to another usage, selecting which frequency range is appropriate depends on other users in the area. A hospital must choose a bandwidth and coordinate with local users to prevent interference. Potential sources of interference include the following:

- 608–614 MHz is TV channel 37. If there are existing or potentially new transmitters (DTV and/or LPTV), the potential for using an adjacent channel should be explored. In addition, this range is also the home for Radio Astronomy. There are 13 Radio Astronomy sites, which will require that hospitals perform additional coordination to prevent interference.
- 1385–1400 MHz was previously assigned to 17 government radar sites. Although these sites will eventually discontinue operation, additional coordination is needed to prevent interference.
- 1427–1432 MHz is home to approximately 40 Utility Telemetry operators. Because these are mobile transmitters, additional coordination is needed in seven specific areas throughout the United States, including Pittsburgh, Pennsylvania, Washington, DC, Richmond–Norfolk, Virginia, Austin–Georgetown, Texas, Battle Creek, Michigan, Detroit, Michigan, and Spokane, Washington.

In addition to coordination with incumbent holders of the spectrum in certain geographic locations, each new WMTS installation is required by the FCC to register its deployment before the equipment is used. This required coordination is in lieu of holding an FCC license for operations and allows WMTS users to “license by rule.” ASHE has been designated by the FCC as the exclusive WMTS coordinator and has partnered with Comsearch, a provider of spectrum management services, to provide WMTS coordination services. Equipment manufacturers and vendors may assist hospitals with the registration of their equipment, but it is each hospital’s responsibility to assure that all coordination activity has been completed prior to placing telemetry equipment into service. See Sidebar 1 on page 4 for the specific steps hospitals should take.

Conclusion

Assessment and management of risks in the use of medical equipment has long been a core requirement of the environment of care. But as technology and clinical application continue to advance, so must the factors considered in assessing the risk and identifying potential vulnerabilities. The risk of compromised function and diminished reliability from interference is a real and evolving concern, particularly in equipment such as telemetry monitoring that relies on EMC to perform its vital patient care function. The risks of interference are well known, as are the solutions to decrease vulnerability and ensure reliable operations.

—The American Society for Healthcare Engineering (ASHE) is an association of diverse professionals dedicated to continued improvement in the health care environment through advocacy, education, information, and collaboration. For more information, go to http://www.ashe.org.

Resources and Links

Environment of Care® News Articles
- “Preventing Equipment Interference,” April 2003

Web Sites
- WMTS User Information Guide
  http://www.ashe.org/ashe/wmts/pdfs/wmtsyguide.pdf
- ASHE WMTS Home page
  http://www.ashe.org/ashe/wmts/index.html
- FCC WMTS Home page
  http://wireless.fcc.gov/services/personal/medtelemetry
- FDA WMTS Home page
  http://www.fda.gov/cdrh/emc/wmt2.html
- WMTS Registration
  http://www.ashe.org/ashe/wmts/onlineregistration.html

‡ See http://wireless.fcc.gov/services/personal/medtelemetry/.