Time to upgrade

New telemetry standards call for a new generation of wireless equipment

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On June 8 the Federal Communications Commission ruled on providing a dedicated frequency spectrum for medical telemetry systems. This means hospitals must move quickly and plan to replace their Wireless Medical Telemetry Systems (WMTS) with equipment that will operate in the new spectrum or, if possible, have their equipment modified to operate in the new spectrums.

The primary allocation of spectrum for the WMTS is 608-614 MHz, 1395-1400 MHz, and 1429-1432 MHz. It also means that medical personnel can now monitor their patients more efficiently with a minimum of risk that electromagnetic interference will block or alter patient monitoring signals.

Telemetric monitoring systems transmit patients electrocardiograms (EKGs) and, in some cases, other physiologic parameters, such as hemoglobin oxygen saturation and blood pressure, to a central station display and/or to a bedside monitor. Analyzing EKGs and other physiologic parameters can reveal changes in the patient’s condition and help medical and nursing staff determine appropriate treatment.
Secondary status

In the past, health care institutions utilized WMTS as non-licensed, secondary users in mostly VHF and UHF frequencies that are normally used for television and private land mobile radio signals.

The FCC accommodated their use of the system on an unlicensed basis under Part 15. Part 15 permits operation of biomedical telemetry devices in the 174-216 MHz (VHF TV channels 7-13) and 470-668 MHz (TV Channels 14-46) bands with field strengths of 200 mV/m, measured at three meters.

As with all other Part 15 unlicensed devices, operation of a biomedical telemetry device in these bands was, and still is subject to the condition that no interference may be caused to any other user, and all interference from any other use of the band must be tolerated.

Biomedical telemetry devices may also be operated at higher power levels in the 450-470 MHz bands, on a licensed basis. However, all such operations were on a secondary basis to the primary land-mobile radio uses, and must accept interference from, and avoid creating interference to primary users.

Scoping the problem

In March of 1998, Dallas TV station WFFA turned on its new digital television (DTV) transmitter to test it 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 also tuned to operate in the same vacant TV channel as WFFA.

The DTV signal caused electromagnetic interference, which disrupted the operation of critical medical telemetry monitors. Nurses were unable to monitor
heart patients using the wireless medical telemetry equipment. Fortunately no patient was harmed, however, this disruption of monitoring services placed the patients at both facilities at risk with the potential to cause serious injury or death.

On April 27, 1998, a meeting was called to investigate this serious problem at the Center for Devices and Radiological Health of the Food & Drug Administration. Discussions focused on the impact of DTV signals on medical telemetry equipment, methods to prevent the degradation, the DTV signal and the impact of PLMRS (Private Land Mobile Radio Systems).

Representatives from manufacturers, government and hospitals took part in the meeting. I was there representing Walter Reed Army Medical Center, the U.S. Army Medical Command, the American Society for Healthcare Engineering and the American Hospital Association. As a result of the meeting I agreed to contact medical facilities to attain a statistical sample of the density of telemetry equipment throughout the United States, develop a statistical analysis and a plan to minimize the risk by attaining a dedicated frequency spectrum. This information would then be presented to the FCC.

**Crunching numbers**

I developed the statistical analysis and ASHE sent out the survey via fax and mail on May 1, 1998. Information from over 500 hospitals and almost 22,000 telemetry units was received within two weeks and the staff of the Clinical Engineering Division at Walter Reed Army Medical Center, Washington, DC processed the data into a spreadsheet.

Sixty-one of the facilities surveyed owned telemetry equipment that operates in the frequency spectrum of 450 to 470 megahertz. The majority of the other thirty nine percent were in the DTV–VHF range, meaning that all of medical telemetry equipment was in harms way.
As it happens, the survey also indicated that the majority of the equipment had an average age of three to five years with a life expectancy of 10 years. Thus, the FCC’s June 2000 ruling on the dedicated frequency spectrum is very timely for the majority of the hospitals since their equipment will need to be replaced in the next three years or so.

On July 17, 2000 in the Federal Register, Volume 65, (Rule and Regulations) the FCC published the Wireless Medical Telemetry Service Summary of ET Docket 99-255 Final Rule adopted on June 8, 2000 and published on June 12, 2000 for comment with October 16, 2000 as the effective date of the ruling. The document covers several areas important to healthcare engineering professionals.

In its report the FCC stated that the 608–614 MHz band is constrained as a result of radio astronomy quiet zones, including some sites in large markets, and interference from adjacent TV channels. The remaining 8 MHz that FCC has allocated is constrained by adjacent band interference from high power radar located below 1390 MHz and grandfather protected Federal sites. However, this allocation ensures that at least 6 MHz is available for WMTS in all locations, consistent with the AHA needs assessment, with at least some additional spectrum available to accommodate long-term needs.

The FCC noted that this is in fact significantly less than the amount of spectrum that is currently available to medical telemetry on an unprotected basis. However, the benefits of a primary allocation dedicated to this service compensates for the reduced availability of spectrum. The FCC does not anticipate any further allocations for medical telemetry devices and expects manufacturers and the health care community to ensure that this spectrum is used efficiently to meet long-term needs.

The FCC will coordinate the frequency allocations with Canadian and Mexican governments as appropriate. Given the low-power nature of this equipment, they do not anticipate any interference issues in border areas.
Licensing requirements

The licensing of WMTS equipment is proposed to be “Licensed by Rule” rather than requiring individual operator’s license. Additionally the FCC has proposed that only authorized health care providers can be eligible to operate transmitters in the WMTS. For the purpose of this service, an “authorized health care provider” would be defined as:

· A physician or other individual authorized under state or federal law to provide health care services.

· A health care facility operated by or employing individuals authorized under state or federal law to provide health care services.

· Any trained technician under the supervision and control of an individual or health care facility authorized under state or federal law to provide health care services.

The FCC also defined a “health care provider facility” as a hospital or other establishment that offers services, facilities and beds for use beyond a 24 hour period in rendering medical treatment, and organizations regularly engaged in providing medical services through clinics, public health facilities and similar establishments, including government entities and agencies such as Veterans Administration Hospitals.

Health care facilities on tribal lands would also be included under their proposed definition. A health care facility would not include an ambulance or other moving vehicle, and this definition would also not allow home use of WMTS equipment.

A frequency coordinator will be utilized but will not have decision-making authority as to which frequency should be used. The coordinator will notify users of potential frequency conflicts, and users should be able to resolve any conflicts.
among themselves. The FCC expects that there will be few conflicts between users of WMTS equipment due to its low operating power, but the Commission will make the final decision on a case-by-case basis in disputes between users, if necessary.

The coordinator must be familiar with the medical telemetry user community, and must make its services available to all parties on a first-come, first-served, non-discriminatory basis. The frequency coordinator must be willing to serve a five-year term, which could be renewed by the Commission. In the event that a frequency coordinator does not wish to continue at the end of the five-year term, the user database will go to another designated entity.

The following information is to be submitted to the frequency coordinator for inclusion in the database:

- Frequency range(s) used
- Modulation scheme used
- Effective radiated power
- Number of transmitters in use at the health care facility at the time of registration
- Legal name of the authorized health care provider
- Location of transmitter (coordinates, street address, building)
- Point of contact for the authorized health care provider.
- Equipment manufacturer and model number for determining the interference potential of WMTS equipment and locating certain devices in the event there is a question of compliance with the rules.
Equipment registrations will remain valid until the healthcare provider requests cancellation. ASHE is interested in providing the frequency coordinator service to the medical community.

**WMTS deadlines**

The FCC has proposed that all new medical telemetry equipment that receives an equipment authorization starting two years after the adoption of final rules must operate in the newly authorized frequency bands. Based on the comments received, the FCC is confident that manufacturers will be able to meet this deadline. The FCC declined to allow equipment approved after that deadline to have the capability of operating in the current part 15 and part 90 bands. Therefore, medical telemetry users are encouraged to migrate out of the current frequency bands and into the new frequency bands.

However, the FCC will permit medical telemetry equipment that has received an equipment authorization to operate in current part 15 and part 90 bands prior to the two year transition date to be manufactured, imported, marketed and operated without a cutoff date. This action will ensure that manufacturers will be able to make replacement parts for systems operating in the old bands, and that hospitals will be permitted to operate their existing systems as long as possible until replacement is necessary due to age or interference concerns.

Of significant importance is the FCC decision to lift the freeze on 460 - 470 MHz PLMRS three years from the effective date of this proposal. This means that if hospitals do not replace their equipment by October 16, 2003, the equipment operating in these frequency ranges will be more subject to interference from commercial vehicles. Being that our survey indicated that 61 percent of the telemetry equipment in use fell in this range, hospitals would be subjecting their patient to additional risk of equipment degradation from EMI.
Lastly the FCC has stated that new equipment for the WMTS will not have to operate in the newly allocated frequency bands until two years after the effective date of the new rules. If the effective date is October 16, 2000, this requirement will take place on October 16, 2002.

The FCC is comfortable that this will allow sufficient time for manufacturers to develop equipment for the new bands, thus reducing the development costs for small businesses.

**Now is the time**

Healthcare engineering professionals, physicians, administrators, nursing staff and hospital CEOs need to be planning now to replace existing Wireless Medical Telemetry System equipment by October 16, 2002. Close communication with the manufacturers will be imperative to make the equipment transition smooth as possible.

Also decision will need to be made on whether to wait for the design and manufacture of new equipment in the 1395-1400 MHz and 1429-1432 MHz range or to start replacing your equipment now in the 608-614 MHz range.

Thought should be given to phasing in the equipment replacement possibly over the two-year period and budgeting for this equipment replacement to allow minimum displacement to patients. Also hospitals need to be looking at the future regarding the type of patients to be treated five years from now and whether the WMTS bought today can be expanded to future patient requirements.

Over the past two-and-a-half years I am proud to say that I was part of a team that has truly made medical history. I look forward to the new technology that will come to health care in the future now that there is a safer spectrum available to provide patient care in our nation’s hospitals.
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