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March 8, 2001

Magalie Roman Salas
Secretary
Federal Communications Commission
445 Twelfth St. S.W.
TW-A325
Washington, D.C. 20554

Re: *ET Docket No. 00-221*

Dear Ms. Salas:

I enclose on behalf of the American Hospital Association Task Force On Medical Telemetry an electronic copy of its comments and associated attachments in the above-referenced proceeding. Please contact the undersigned if you have any questions.

Sincerely,

Timothy J. Cooney

Lawrence J. Movshin
Timothy J. Cooney

cc: Chairman Michael K. Powell
Commissioner Gloria Tristani
Commissioner Susan Ness
Commissioner Harold W. Furchtgott-Roth
Thomas J. Sugrue, Wireless Telecommunications Bureau
William Kunze, Wireless Telecommunications Bureau
Donald Abelson, International Bureau
Thomas S. Tycz, International Bureau
Bruce Franca, Office of Engineering and Technology
Julius P. Knapp, Office of Engineering and Technology
Hugh Van Tuyl, Office of Engineering and Technology
Thomas Mooring, Office of Engineering and Technology

Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

In the Matter of	)	
	)	
Reallocation of the 216-220 MHz,	)	**ET Docket No. 00-221**
1390-1395 MHz, 1427-1429 MHz,	)	**RM-9267**
1429-1432 MHz, 1432-1435 MHz,	)	**RM-9692**
1670-1675 MHz and 2385-2390 MHz	)	**RM-9797**
Government Transfer Bands	)	**RM-9854**

COMMENTS OF THE AMERICAN HOSPITAL ASSOCIATION TASK FORCE ON WIRELESS MEDICAL TELEMETRY

AMERICAN HOSPITAL ASSOCIATION
TASK FORCE ON MEDICAL TELEMETRY

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March 8, 2001

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SUMMARY

The American Hospital Association Task Force on Wireless Medical Telemetry ("the Task Force") is the lead proponent of the newly established Wireless Medical Telemetry Service ("WMTS"), and, as such, its interests are directly affected by the Notice of Proposed Rulemaking in ET Docket No. 00-221. The Task Force vigorously opposes any action by which the Commission does not protect the full 8 MHz allocation for WMTS in the 1.4 GHz spectrum or otherwise does not preclude co-channel operations by other services that could create harmful interference to WMTS licensees.

In the recently concluded WMTS proceeding in ET Docket No. 99-255, the Commission properly concluded that a 14 MHz allocation to WMTS was needed to assure not only the immediate needs of the industry, but the industry's ability to expand the availability of medical telemetry equipment to new populations of patients. As the Task Force explains in these comments, the Commission's bases for reaching that conclusion have not changed.

The Task Force cannot support any of the three options proposed by the Commission. WMTS cannot share a co-primary allocation with utility telemetry services ("UTS") in only three megahertz of spectrum. The Commission apparently misinterpreted a joint letter by the AHA and Itron (a provider of utility telemetry systems) submitted in Docket No. 99-255 in which the signatories expressed optimism that WMTS and UTS could utilize the *entire* 1427-1432 MHz band on a co-primary basis.

Consistent with its commitment in Docket No. 99-255, the Task Force has continued to pursue proposals that would promote efficient use of the available 1.4 GHz band, holding technical discussions with representatives of the UTS (Itron), Little LEO, and RFID industries. Although the Task Force and Itron have concluded as a general matter that UTS and WMTS cannot operate on a co-primary, co-channel basis in the same geographic area, they have developed a band sharing plan to allow use of the available spectrum without harmful interference to each other. Under "modified Option 2" described in the comments, WMTS and UTS will effectively be accorded primary user status in 2.5 MHz each within the 1427 - 1432 MHz band and will have secondary access to the other 2.5 MHz. The Task Force and Itron each submit a copy of the proposed band sharing plan for codification into the Commission's rules. The Task Force believes that the "modified Option 2" proposed herein provides the most efficient opportunity for medical telemetry devices to transition out of the bands where they currently are secondary users prone to interference and for the growth of WMTS, as contemplated in the WMTS order.

Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

In the Matter of	)	
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Reallocation of the 216-220 MHz,	)	**ET Docket No. 00-221**
1390-1395 MHz, 1427-1429 MHz,	)	**RM-9267**
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1670-1675 MHz and 2385-2390 MHz	)	**RM-9797**
Government Transfer Bands	)	**RM-9854**

COMMENTS OF THE AMERICAN HOSPITAL ASSOCIATION TASK FORCE ON WIRELESS MEDICAL TELEMETRY

The American Hospital Association Task Force on Medical Telemetry ("the AHA Task Force" or "Task Force"), by its attorneys and pursuant to Section 1.415 of the Commission's Rules, hereby comments on the Notice of Proposed Rulemaking released November 20, 2000, FCC 00-395 ("Notice") in the above-captioned proceeding.[1] While the Notice asks for comment on the appropriate allocation of several spectrum bands being transferred from Government Use, the Task Force has limited its comments to the proposals affecting the current allocation to the Wireless Medical Telemetry Service (the "WMTS") in the 1429-1432 MHz band, in the middle area of the spectrum that the Commission terms the "1.4 GHz spectrum."[2]

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[1] Members of the AHA Task Force include representatives of hospitals, clinics and other users of medical telemetry systems, manufacturers of medical telemetry devices, and representatives of trade associations involved in the development of medical devices and the delivery of health care. While these comments and the Joint Statement of Position with Itron reflect a consensus of the members of the Task Force, individual members may differ with particular recommendations.

[2] The 1.4 GHz spectrum "consists of the 13 megahertz of spectrum in, four segments at 1390-1395 MHz, 1427-1429 MHz, 1429-1432 MHz, and 1432-1435 MHz." *Notice* at para. 19.

Noting the number of potential claimants for the 1.4 GHz spectrum, as well as the recent allocation of a portion of this band for primary use by the WMTS, the Commission has solicited comment in the Notice on three options ostensibly affecting the "dedicated" spectrum for WMTS at 1429 - 1432 MHz. Each of these three options contemplates that WMTS would share co-primary status for this 3 megahertz allocation with licensees providing utility telemetry services (hereafter "UTS"). For the reasons discussed below, which echo the record just recently compiled and discussed by the Commission in Gen Docket No. 99-255,[3] the Task Force vigorously opposes any action in this proceeding by which the Commission does not protect the full 8 MHz allocation for WMTS in the 1.4 GHz spectrum or otherwise does not preclude co-channel operations by other services that could create harmful interference to WMTS licensees.

However, consistent with the commitment made during the proceedings in Docket No. 99-255, the Task Force has continued discussions with parties representing other parties requesting allocations in the 1.4 GHz spectrum, including Itron, Inc., representing licensees for UTS, and Final Analysis, representing licensees of satellite services, so-called "Little LEOs." These discussions have focused on alternative options that could maximize the use of this band without creating adverse consequences for the primary WMTS uses. The Task Force is pleased to join Itron in urging the Commission to adopt a modification of Option 2 that would allow UTS and WMTS licensees to satisfy their urgent and reasonably foreseeable needs for spectrum by jointly using the 1427-1432 MHz band. For the reasons discussed below, the modified Option 2

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3 *Amendment of Parts 2 and 95 of the Commission's Rules to Create a Wireless Medical Telemetry Service*, 15 FCC Rcd 11206, FCC 00-211, 65 FR 43995, 65 FR 53190, (released June 12, 2000) (the "WMTS Order")

that accords co-primary status in the entire 1427 - 1432 MHz band to WMTS and UTS, subject to a frequency management plan developed jointly by the Task Force and Itron, Inc., should be codified into the Commission's rules.

I. THE PUBLIC INTEREST REASONS FOR THE COMMISSION'S ALLOCATION LESS THAN ONE YEAR AGO OF 8 MHZ IN THE 1.4 GHZ BAND REMAIN IN PLACE; WMTS USERS STILL HAVE SUBSTANTIAL NEEDS FOR EXCLUSIVE USE OF SPECTRUM AT 1.4 GHZ.

In Docket 99-255, the Commission compiled a substantial record regarding the uses and needs for wireless medical telemetry in meeting the advanced health care requirements of our nation's hospital patients. In the June, 2000 *WMTS Order*, the Commission determined to establish a new Wireless Medical Telemetry Service "which will enhance the ability of health care providers to offer high quality and cost-effective care to patients with acute and chronic health care needs."[4] The Commission noted that "this action addresses consumer concerns that medical telemetry devices are increasingly at risk of harmful interference due to more extensive use of spectrum resources by other applications."[5] The Commission further determined to "allocate 14 Megahertz (MHz) to WMTS on a primary basis, which will allow potentially life-critical medical telemetry equipment to operate on an interference-protected basis."[6]

On the basis of that record, the Commission properly concluded that a 14 MHz allocation – 6 MHz in the 608-614 MHz band already being used for medical telemetry systems (but previously without a primary allocation), 5 MHz in the 1395-1400 MHz band, and 3 MHz in the

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4 *Id* at 11206.

5 *Id.*

6 *Id.*

1429-1432 MHz band[7] was needed to assure not only the immediate needs of the industry, but also the industry's ability to expand the availability of medical telemetry equipment to new populations of patients. As the Commission summarized its findings,

> [I]t is likely that the use of medical telemetry will become more widespread, driven by the need to reduce medical care costs and by increasing advances in medical technology. Medical telemetry devices can reduce health care costs by helping to speed the patient recovery time and reduce the duration of hospital stays. Advances in medical technology will allow monitoring of an increasing number of patient parameters, which will increase spectrum requirements. We also note that demand is likely to be influenced by the growing population of elderly people in the United States.[8]

The Commission also recognized the need to provide adequate spectrum to accommodate the migration of users with equipment currently operating in the 450-470 MHz band, already allocated for long-term use by the land mobile community.[9]

Because medical telemetry had no protection from interference from the primary users of the available bands,[10] the Commission, as well as the Food and Drug Administration ("FDA"), recognized that the absence of a primary allocation for medical telemetry was increasingly threatening the efficacy of medical telemetry devices. As noted in the *WMTS Order*, not only were more incidents of interference from high power land mobile devices being reported, but the potential interference threat from digital television (DTV) use of vacant channels had become an

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7 The Task Force had requested that the frequency allocation above 1.3 GHz be allocated in "split" bands to facilitate the potential use of those bands for two-way data and waveform communications.

8 *WMTS Order*, 15 FCC Rcd at 11210.

9 Indeed, the Commission expressly noted in the WMTS Order that it intended to open the 460-470 MHz band within two-three years, urging the medical industry to expedite its use of the new 2 allocated WMTS bands. *Id.* at 11226-11228

10 *Id.* at 11207.

alarming reality.[11] The establishment of a new Wireless Medical Telemetry Service under Part 95 of the Commission rules represented the culmination of government and industry efforts to resolve these immediate problems. Indeed, the urgent need for this exclusive allocation of spectrum mandated a departure from the Commission's normal allocation philosophy:

> We also wish to note that this medical telemetry allocation is an exception to the approach we have been taking toward more flexible allocations that are not service specific. A specific allocation is necessary in this case to protect the public safety by providing spectrum where medical telemetry equipment can operate without interference.[12]

It should also be emphasized that the Commission recognized that the bands of spectrum allocated on a primary basis for WMTS were not without encumbrances, and would not be available in all areas where spectrum might be necessary.[13] In fact, the Commission recognized that this allocation:

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11 *Id.* at 11208.

12 *Id.* at 11210-11211.

13 As the Commission recognized in the *WMTS Order*, the 608 - 614 MHz lower band is constrained as a result of its use in some areas for radio astronomy, so that health care facilities in approximately ten mid-sized cities, including Cedar Rapids and Iowa City, Iowa, would be precluded from using the 608-614 MHz band. WMTS use of this band also might not be available in other geographic areas due to potential interference from high power transmissions on adjacent TV channels 36 or 38. Use of the middle band for WMTS is constrained by the potential for interference from high power radars located below 1390 MHz. And protected Federal sites, including those in major metropolitan areas such as the Washington, D.C. - Baltimore, Maryland corridor, which are currently operating in the 1429 - 1432 MHz band, are grandfathered for primary status until 2004. WMTS use of the 1429 - 1432 MHz band is further constrained by adjacent band interference above 1432 MHz by military airborne operations. And as noted, the FCC has already strongly encouraged the migration of existing medical telemetry devices out of the 450 - 470 MHz band, a process that cannot be completed successfully unless useable spectrum is available elsewhere.

> 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. *We note that this is in fact significantly less than the amount of spectrum that is currently available to medical telemetry on an unprotected basis. However, we find that the benefits of a primary allocation dedicated to this service compensates for the reduced availability of spectrum.*[14]

Simply stated, the Commission was fully justified in June, 2000, in creating the WMTS and allocating for WMTS licensees a total of 14 MHz on a primary basis. Most significantly to the Commission's consideration in this proceeding, ***the Commission's bases for reaching that conclusion have not changed.***[15]

II. WMTS AND UTS CANNOT BE SATISFIED IN ONLY THREE MEGAHERTZ OF SPECTRUM AS PROPOSED IN THE COMMISSION'S THREE OPTIONS.

Notwithstanding the conclusions it reached in establishing the WMTS, less than six months after the release of the *WMTS Order*, the Commission solicited in the *Notice* comment on the appropriate allocation of 27 MHz of spectrum transferred from Government to non-Government use pursuant to the provisions of two federal statutes, one enacted in 1993 (abbreviated by the Commission as OBRA-93) and the other enacted in 1997 (abbreviated by the

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14 *WMTS Order*, at 15 FCC Rcd at 11210 (footnote omitted, emphasis supplied).

15 Indeed, although two petitions for reconsideration of the WMTS Order were filed (one by the Satellite Industry Association and one jointly field by three Little LEO applicants), the focus of both petitions was the same – the claimed impact of the specific allocation of 1429-1432 MHz on the Little LEOs' ability to obtain an international allocation for satellites in that band. Rather than duplicate the record that was developed in Docket No. 99-255, and considering its obvious relevance to the proceedings undertaken in this docket, the Task Force requests that the Commission incorporate the record in that docket into this proceeding. For ease of reference of any parties who did not participate in that proceeding, however, the Task Force is attaching to these Comments as Attachment A the Task Force Report that was filed in Docket No. 99-255, which provides ample justification for the allocation requested and made in that proceeding.

Commission as BBA-97),[16] including the 1429-1432 MHz band.[17] The Commission noted that insufficient spectrum was available to accommodate all the requests for allocations of the 1.4 GHz spectrum and explained that its objective is to ensure that the available spectrum is put to the best use.[18]

To facilitate meaningful comment on the possible allocation schemes for the 1.4 GHz spectrum, the Commission has developed three options; in each of these options, WMTS would lose its exclusive primary allocation and would instead share a three megahertz block with UTS (in Options 1 and 2, the 1429 - 1432 MHz band would be shared; in Option 3 the 1427 - 1430 MHz band would be shared).[19] The Commission's proposal for WMTS and utility telemetry to

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16 *Notice* at para. 1. The 27 MHz of spectrum is spread across seven relatively narrow bands: 216 - 220 MHz, 1390 - 1395 MHz, 1427 - 1429 MHz, 1429 - 1432 MHz, 1432 - 1435 MHz, 1670 - 1675 MHz and 2385 - 2390 MHz.

17 The Commission explained that a number of potential claimants have sought allocation to their services of one or more of the 13 MHz available in the four segments in the 1.4 GHz spectrum. The potential claimants include representatives of the private land mobile radio service ("PLMRS"); Itron, a representative of the utility telemetry automated meter reading industry; representatives of licensees in the non-voice, non-geostationary Mobile-Satellite Service (NVNG MSS or "Little LEOs"); MicroTrax, Inc., a provider of proposed Personal Location and Monitoring Service ("PLMS"); and ArrayCom, Inc. which has developed "smart antenna" systems using spatial diversity multiple access.

18 *Notice* at para. 30.

19 The three options, as they affect the WMTS allocation, are as follows:

Option 1: Under FCC Option 1, utility telemetry would be elevated to co-primary status with WMTS in the 1429 - 432 MHz band.

Option 2: Under this option, the 1427 - 1429 MHz band would be allocated on a primary basis exclusively for telemetry operations, and utility telemetry operations would also be allowed to share the 1429 - 1432 MHz band on a co-primary basis with WMTS.

Option 3: Under FCC Option 3, the Commission would elevate the secondary allocation

share spectrum is apparently based on the May 31, 2000, joint letter that the AHA and Itron submitted in ET Docket No. 99-255.[20] The Commission, however, has clearly misinterpreted the substance of the parties' position in presenting this joint letter.

Specifically, in the letter written while the WMTS rulemaking was still pending, the parties noted that Itron had recently filed a Petition for Rulemaking requesting that the Commission allocate the 1427 - 1432 MHz band for automatic meter reading and utility telemetry operations, a band which was then under consideration for the WMTS. The parties explained that they had held technical discussions "to develop a framework by which WMTS and [utility telemetry] could utilize the *entire* 1427 - 1432 MHz band on a co-primary basis" (emphasis supplied). The parties recommended that the Commission adopt rules "implementing the co-primary status of both types of users in the *entire* 1427 - 1432 MHz band with an appropriate sharing arrangement between WMTS and [utility telemetry] users" (emphasis supplied).

Key to the agreement to seek a technical solution for sharing at that time was the recognition by experts in both the WMTS and UTS communities, based on preliminary analysis of information presented by both parties, that co-channel, higher power utility telemetry operations are *not* compatible with low power WMTS operations in the same geographic area; it could reasonably be expected that harmful interference to WMTS would be caused by co-channel

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for utility telemetry in the 1427 - 1430 MHz band to primary status, while shifting the allocation for WMTS from 1429 - 1432 MHz to 1427 - 1430 MHz on a co-primary basis with utility telemetry.

[20] *Notice* at para. 34 n. 72. A copy of the May 31, 2000, joint letter is attached as Appendix B.

utility telemetry operations. Although the parties believed in good faith that an arrangement could be developed to share the five megahertz band from 1427 - 1432 MHz so that both WMTS and UTS could operate in the same geographic area, the May 31, 2000, letter simply cannot be read as endorsing any arrangement that would limit these two uses to sharing only a three megahertz block, either at 1429 - 1432 MHz (FCC Options 1 and 2) or at 1427 - 1430 MHz (FCC Option 3). Three megahertz simply is not sufficient spectrum to meet the needs of both WMTS and utility telemetry operating in the same geographic area.

III. BECAUSE WMTS LICENSEES ARE WILLING TO SHARE SPECTRUM BANDS WITH COMPATIBLE USERS, THE TASK FORCE AND ITRON HAVE DEVELOPED A MODIFIED OPTION 2 COVERING THE FIVE MHZ BAND FROM 1427-1432 MHZ.

Consistent with the Task Force's commitment in Docket No. 99-255, members of the Task Force have continued to pursue proposals that would promote efficient use of the available 1.4 GHz spectrum bands. To that end, the Task Force has had numerous discussions about sharing of frequency bands with representatives of the utility telemetry industry, the Little LEOs, and the RFID industries.

These discussions have been premised on exploring other uses of the spectrum already allocated on a primary basis to the WMTS that would not create harmful interference to WMTS operations that are critical to patient safety and recovery. WMTS systems generally operate at very low powers, and may be found in a variety of environments within a medical facility – from the innermost areas of a hospital where shielding from outside interference is substantial, to the virtually free-space environment on patient floors where a monitored patient could be within feet of a solarium window or outdoors on the hospital campus where patients will be encouraged to

walk. It is therefore critical that any other co-channel user be able to operate efficiently at relatively low power.

With that key element as a threshold, the Task Force has conducted discussions with representatives of the Little LEOs. While it appears that the Little LEOs will propose reductions in their maximum power flux density to levels that theoretically might not interfere with WMTS, any upward deviation at all from those levels due to the real-world demands (for example, rain fade) of providing a commercially viable Little LEO service would cause significant interference to other users in the band. Under these circumstances, the Little LEOs remain a less attractive co-primary user of WMTS spectrum.[21]

The Task Force has also engaged in substantial discussions with Itron, representing the interests of UTS. From these discussions, both the Task Force and Itron have concluded that, as a general matter, UTS and WMTS cannot operate on a co-primary, co-channel basis in the same geographic areas. As a practical matter, in any area in which a UTS system was operating at or near its full power requirements, it would almost certainly and regularly interfere with WMTS systems throughout that area, making the "co-primary" status entirely illusory for WMTS. But in contrast to Little LEO systems, which would have nationwide coverage, UTS systems have certain uses which are geographically limited so that they can provide interference protection for both WMTS and utility telemetry using the same channel.[22] Recognizing this geographic and

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21 Moreover, because Little LEO downlinks will have ubiquitous, nationwide coverage, the potential for interference to a number of WMTS facilities would be great, while the ability to defect and isolate the source of the interference would be extremely difficult.

22 Because utility telemetry utilizes higher power than WMTS, WMTS is more likely to be the victim of interference rather than the cause of harmful interference.

channel separation, WMTS and UTS are able to share spectrum on a geographically defined basis and allow efficient use of the available spectrum without causing harmful interference to each other. But even in this case, the amount of spectrum that each of these licensee groups will need has not diminished below the five megahertz that, in total, each group has requested or been allocated.

Building on its May 31, 2000, joint letter to the Commission, the Task Force and Itron have developed a band sharing plan for the entire 1427 - 1432 MHz band. The band sharing plan is the culmination of many months of technical discussions and is embodied as a joint position paper that is attached as Appendix C to these comments. The highlights of the band sharing plan are as follows:

A. The entire 1427 - 1432 MHz band will be allocated to WMTS and Utility Telemetry on a co-primary basis, and this band will not be allocated for any other uses.

B. The FCC will codify into its rules the Frequency Management plan setting forth the primary and secondary status of each such use throughout the United States, and the technical characteristics that will govern such use, as follows:

1. UTS will have primary status in the 1429.5 - 1432 MHz ("Utility Band"). Licensees for WMTS may operate in this band only on a secondary, non-interference basis to Utility Telemetry.

2. Licensees for WMTS will have primary status in the 1427 - 1429.5 MHz. ("WMTS Band"). Licensees for Utility Telemetry may operate in this band only on a secondary, non-interference basis to WMTS.

3. Notwithstanding the frequency designations set out above, in certain specified geographic areas ("Utility Defined Areas"), in each of which Utility Telemetry have operating systems on or before February 1, 2001, the Utility Band will be the bands 1427 - 1429 MHz and 1431.5 - 1432 MHz, the WMTS band will be the band 1429 - 1431.5 MHz. In addition, the Utility Telemetry Systems operating in certain other specified areas will be grandfathered to continue using the WMTS Band on a primary

basis until February 1, 2006. Such systems may not expand outside of the designated areas or add channels or frequencies, and, after February 1, 2006, shall be treated as secondary users, subject to the provisions described in subsection B.5 below.

4. Co-channel use of the Utility Band by WMTS Licensees and co-channel use of the WMTS Band by Utility Telemetry Licenses will be permitted on a secondary, non-interference basis to an existing or future primary licensee of that band, as follows:

   a. The co-channel users must be located at a sufficient distance apart to maintain a field strength of < 150uV/m, H and V, measured over any 1 MHz with an averaging detector as measured at the interfered site.

   b. In the event of any dispute between the primary and secondary users, such dispute shall be resolved by reference to an industry-standard propagation study conducted at the expense of the secondary user and approved by the frequency coordinator/manager specified for each of the services.

5. The maximum transmitter output power for UTS Telemetry shall be no greater than 1 watt EIRP in the 1429.5 - 1430.5 MHz band, no greater than 10 watts EIRP in the 1430.5 - 1431.5 MHz band, and no greater than 100 watts EIRP in the 1431.5 - 1432 MHz band. The maximum transmitter output power (expressed in field strength) for WMTS shall be not greater than those limits specified in Part 95 of the FCC rules 740m V/m at 3 meters over 1 MHz (160mW EIRP). The maximum level of "out-of-band" emissions between Utility Telemetry use and WMTS use and between WMTS use and Utility Telemetry use shall be no greater than 150u V/m, H and V, measured over any 1 MHz with an averaging detector as measured at the interference site.

C. Specific assignments in the Utility Telemetry Band will be subject to prior frequency coordination by the designated Utility Telemetry frequency coordinator. Registration of licensed WMTS users in the WMTS Band into the frequency coordination database for the WMTS will be implemented through the American Society of Health Care Engineers. Secondary uses of the bands must be coordinated/registered with the appropriate frequency coordinator/manager prior to installation and operation.

As a result of the FCC's adoption of this Frequency Management Plan, the WMTS and UTS radio services will effectively be accorded primary user status in 2.5 MHz each within the 1427 - 1432 MHz band. Moreover, assuming that their systems can be designed to operate within lower power levels, each of these radio services will have access on a secondary basis to the other 2.5 MHz in the band. Even though WMTS will have secondary status on certain frequencies, because of the shielding effect of the hospital building structure, total reuse of the frequencies between WMTS and UTS likely will be practical. Possible locations for such use include wireless operating rooms or cardiac rehabilitation centers. This will ensure efficient use of the band throughout the country, while allowing both the WMTS and UTS industries to meet critical needs for the safety of life and property.

Moreover, while modified Option 2 provides the WMTS with less dedicated, primary spectrum, i.e., 2.5 MHz rather than the 3 MHz at 1429 - 1432 MHz, the AHA Task Force considers the spectrum available under this option to be more beneficial in quality than the current WMTS upper band allocation. For example, except in the areas that have grandfathered utility telemetry systems, WMTS will be able to utilize the 1427 - 1429.5 MHz band, a band that will be more conducive to low power WMTS operations than the 1429 - 1432 MHz band. The neighbor for WMTS at the lower end of the 1427 - 1429.5 MHz band is the relatively quiet Radio Astronomy service; and the AHA Task Force believes that WMTS and these relatively quiet operations will not cause adjacent channel interference with each other. The neighbor on the upper end of the 1427 - 1429.5 MHz band would be utility telemetry whose adjacent channel operations at the power levels prescribed under the proposed Frequency Management Plan would be compatible with WMTS.

Even in the grandfathered areas where WMTS will be the primary user of the 1429 - 1431.5 MHz band, WMTS will benefit by being surrounded by the more compatible utility telemetry operations below 1429 MHz and at 1431.5 to 1432 MHz. Indeed, in light of the several other claimants for the 1432-1435 MHz band, it is far more likely that the 1432 - 1435 MHz band will be populated by higher powered devices (which would effectively require the use of expensive filtering or a modest guard band as part of the 3 MHz allocation). Using the lower portion of the band will actually allow the WMTS industry to make more efficient use of the overall spectrum allocated to it.

IV. CONCLUSION

For the foregoing reasons, the AHA Task Force recommends the confirmation of the WMTS requirements for a significant, dedicated band of spectrum in the 1.4 GHz band. To that end, the Task Force believes that the modified Option 2 proposed herein provides the most efficient opportunity for medical telemetry devices to transition out of the 450-470 MHz band and for the growth of WMTS, as contemplated in the WMTS Order.

Respectfully submitted,

AMERICAN HOSPITAL ASSOCIATION
TASK FORCE ON MEDICAL TELEMETRY

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March 8, 2001

APPENDIX A

EX PARTE OR LATE FILED

ORIGINAL
Docket #
99-255

April 16, 1999

The Honorable William E. Kennard
Chairman
Federal Communications Commission
445 12th Street, S.W.
Room 8-B201
Washington, D.C. 20554

RECEIVED
JUL 19 1999
FEDERAL COMMUNICATIONS COMMISSION
OFFICE OF THE SECRETARY

Dear Chairman Kennard:

Nearly 14 months ago, the initiation of Digital Television Service in Dallas created unanticipated interference with wireless biomedical telemetry devices operating at the Baylor University Medical Center in Dallas, Texas. In response to that incident and a growing number of problems of interference to wireless medical telemetry devices from land mobile systems, the American Hospital Association (AHA) -- working with the staffs of the Federal Communications Commission (FCC) and the Food and Drug Administration -- created a Task Force to study this problem and determine solutions. On January 21, 1999, I submitted to you the preliminary reports of a number of work groups that were created with representatives of health care facilities, manufacturers, and health care practitioners, and with liaisons from trade associations representing users in the licensed services and the FCC.

I am pleased to submit to you the AHA Task Force's Report, a consolidated and comprehensive consensus recommendation of the Task Force, which addresses the potential critical safety risks to patients from interference with wireless medical telemetry. The Task Force recommends the allocation of dedicated spectrum that can reasonably satisfy the nation's current and anticipated requirements for wireless biomedical telemetering capabilities in a relatively interference-free environment. The report also contains proposals for a process that should ensure that the dedicated spectrum is utilized efficiently and without creating interference between or among authorized users of the designated bands.

In light of the substantial efforts already undertaken by the Commission's staff in conjunction with the Task Force's efforts, we are hopeful that the submitted recommendations can form the basis for the FCC to issue a Notice of Proposed Rulemaking to initiate the proposed allocation.

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We believe that there is broad-based support in the health care field, and among the broadcasting and land mobile communities, for resolving the growing interference problem with such an allocation. We urge the Commission to act quickly on these recommendations in order to implement a new, interference-free allocation of spectrum for a Wireless Medical Telemetry service, so that the nation's health care providers can continue to efficiently provide this critical element of patient care.

We look forward to working with you and your staff to reach a favorable conclusion on this patient safety issue.

Sincerely,

Rick Pollack

Rick Pollack
Executive Vice President

Enclosure

REPORT OF THE
AMERICAN HOSPITAL ASSOCIATION
TASK FORCE ON MEDICAL TELEMETRY

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REPORT OF THE AMERICAN HOSPITAL ASSOCIATION TASK FORCE ON MEDICAL TELEMETRY

The American Hospital Association ("AHA") created a Task Force on Medical Telemetry in 1998, in order to study, and make recommendations, concerning the growing problem of interference to biomedical telemetry devices from licensed radio services. Various workgroups were created to study specific elements of the problem, including future spectrum requirements for the industry, possible frequency bands in which to operate with less interference, and a regulatory regime by which this critical element of the health care industry could meet patient needs in a less congested radiofrequency ("RF") spectrum environment. It is with great pleasure that the AHA presents the Commission with a consolidated recommendation[1] for the allocation of dedicated spectrum that can reasonably satisfy the nation's current and anticipated requirements for wireless biomedical telemetering capabilities in a relatively interference-free environment. We believe that this recommendation can, and should, expeditiously form the basis for a *Notice of Proposed Rulemaking* from which the Commission can implement a new, interference-free allocation of spectrum for a Wireless Medical Telemetry service.

INTRODUCTION

Wireless biomedical telemetry devices are used in hospitals to transmit waveforms and other physiological data from patient measurement devices to a nearby receiver's antenna. One of the main purposes of patient monitoring is early detection of life-threatening physiologic developments so that appropriate intervention can be rendered in a timely manner in support of recovery. Typical devices may monitor ECG, oxygen saturation, blood pressure or respiration. The use of these devices offers patients mobility earlier in their recovery, as well as improved comfort while still being monitored for adverse symptoms. Early mobility is particularly important for the recovery of cardiac and certain other patients, but could be dangerous in the absence of telemetry monitoring. In addition, such devices allow more patients to be monitored by each health care worker, thus decreasing health care costs.

The profile of telemetry patient monitoring is expanding. While recovering cardiac patients continue to represent the largest segment of patients being monitored by wireless telemetry, more acute patients are also being monitored, as are the supplemental devices, *e.g.*, ventilators, infusion pumps, *etc.*, that support them. Indeed, reference to "wireless medical telemetry" must now include all measurement and recording of physiological parameters and

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[1] This consolidated recommendation presents the efforts of four different workgroups; the reports of these workgroups were submitted to Chairman Kennard, by letter from Rick Pollack, Executive Vice President, Government and Public Affairs, of the American Hospital Association, dated January 21, 1999. Each of whose reports, containing substantially more detailed analysis, is also separately attached in Appendix II.

other patient-related information via radiated bi-directional and uni-directional electromagnetic signals in order to accommodate future developments within the industry. In addition, consideration must be given to the use of such devices in a broad array of environments constituting health care facilities, including not merely hospitals, but also in other establishments that offer services, facilities, and beds for use beyond 24 hours in rendering medical treatment, and in institutions and organizations regularly engaged in providing medical services through clinics, public health facilities, and similar establishments, including governmental entities and agencies for their own medical activities.

The FCC currently accommodates the use of biomedical telemetry devices on an unlicensed basis in the 174-216 MHz (VHF TV channels 7-13) and 470-668 MHz (TV Channels 14-46) bands under Part 15 of its rules and at higher power levels in the 450-470 MHz band on a licensed basis under Part 90.[2] Part 15 permits operation of biomedical telemetry devices with field strengths of 200 mV/m, measured at three meters,[3] while hospitals or health care institutions that already hold Part 90 licenses are permitted to operate medical radio telemetry devices in the 450-470 MHz band without additional specific authorization with output powers up to 20 mW (330 mV/m at three meters).[4] Operation of biomedical telemetry devices in these bands is generally 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.[5]

The spectrum needs of the medical community for biomedical telemetry operations were considered as recently as 1997, when the Commission concluded a study of the industry's growth in ET Docket No. 95-177. As a result of the information submitted in that proceeding, the FCC modified its Part 15 rules (a) to expand the frequency bands in which such devices could operate

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2 *See* 47 C.F.R. §§ 90.20(d)(27), 90.35(c)(30), 90.238(e), and 90.267.

3 *See* 47 C.F.R. § 15.242.

4 *See* 47 C.F.R.§ 90.267(a)(5). Moreover, under Section 90.238(e), health care facilities may be licensed to operate individual medical telemetry devices at output powers up to 2 watts.

5 *See, e.g.*, 47 C.F.R. § 15.5. Under the Refarming Order [see n. 13, infra], it is possible that some low-powered medical telemetry devices would be allowed co-primary status, but the number of "low powered" channels has not yet been determined, and low-power devices will not be able to effectively co-exist on a co-primary basis with higher powered devices operating under the Refarming Order.

and (b) to allow for increased power by such devices within those new bands.[6] At the time, the Commission recognized the possibility that biomedical telemetry devices might create interference to the use of the television bands by recently-authorized advanced digital television ("DTV") and low power television services ("LPTV"). However, the agency believed that the number of channels available for use by wireless medical telemetry devices and the technical parameters adopted for such devices in that rulemaking, would be adequate to protect such licensed services from interference. As the Commission then concluded, "these changes support spectrum efficiency by facilitating the sharing of scarce radio spectrum and facilitating use of radio spectrum to provide cost-efficient and needed medical technologies to health care communities."[7]

At the time these new allocations were considered under Part 15, a number of commenters asked the Commission also to consider allocating dedicated spectrum for the use of biomedical telemetry devices, especially in light of the then forthcoming introduction of DTV in the VHF and UHF bands. However, the Commission deferred consideration of a dedicated spectrum allocation,[8] finding that the record before it was not sufficiently complete to determine which, if any, additional channels should be employed. Nonetheless, the Commission did recognize that "sufficient TV channels may not be available for biomedical use in all major cities [and] [w]ith regard to the forthcoming introduction of DTV, for some period of time coordination may prove more challenging for biomedical telemetry device users."[9]

In the eighteen months that have followed the adoption of those new rules, the use of wireless biomedical telemetry in health care has continued to expand, even as the profile of the telemetry patient has changed to include more categories of acute patients and associated supplemental devices that support them. Contrary to the Commission's hopes, the introduction of DTV in the major markets and the anticipated increase in the number of applicants for LPTV stations has already created a real potential for interference to the existing and future uses of the allocated television bands for wireless medical telemetry.[10] At the same time, the Commission's

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6 *Amendment of Part 15 of the Commission's Rules to Permit Operation of Biomedical Telemetry Devices on VHF TV Channels 7-13 and UHF TV Channels 14-46, Report and Order*, 12 FCC Rcd 17828 (1997) (the "1997 R&O").

7 1997 R&O at 17828.

8 *Id.* at 17832.

9 *Id.*

10 *See, e.g.*, Office of Engineering and Technology Fact Sheet, "Sharing of Analog and

(continued...)

decisions on "refarming" the land mobile bands has similarly introduced a greater threat of interference to the use of the available UHF bands for wireless medical telemetry. The decisions in that proceeding authorize higher powered devices operating on the offset frequencies that have been used for lower powered medical telemetry; as a result, the available spectrum is shrinking as the need for wireless medical telemetry is increasing.

In light of these developments, the Task Force was created to determine a realistic projection of the uses of wireless medical telemetry for the coming decades, and to study and recommend means of satisfying those requirements. After much debate, the Task Force has determined that a real and present need exists for deployment of interference-free wireless medical telemetry. The Task Force further concluded that such need requires access to new spectrum on a primary basis to meet the immediate and foreseeable needs of the health care industry and to protect future advanced DTV and Private Land Mobile Radio ("PLMR") Services from creating, or being the object of, potential interference.

DISCUSSION

I. There is a clear need for additional, dedicated spectrum to satisfy the reasonably foreseeable needs of the health care industry for reliable, efficient, wireless medical telemetering capabilities.

The biomedical telemetry industry has developed devices for low-power, unlicensed, secondary or shared (which we will refer to as "secondary" as well) uses of the spectrum under Parts 90 and 15. However, the greater need for wireless medical telemetry by health care providers and the increased use of these bands for non-medical purposes makes this status no longer a feasible, long-term alternative. Ironically, in the 1997 debate over whether to expand the frequencies that could be available for biomedical telemetry under Part 15, both the broadcast and the health care industries agreed that biomedical telemetering devices should not be subject to a substantive risk of interference from licensed devices any more than they should be in a position to create interference to licensed devices.[11]

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[10] (...continued)
Digital Television Spectrum by Medical Telemetry Devices," March, 1998; *see also* "Joint Statement of the Federal Communications Commission and the Food and Drug Administration Regarding Avoidance of Interference Between Digital Television and Medical Telemetry Devices," March 25, 1998.

[11] The Commission noted, for example, the comments of the Society of Broadcast Engineers that "potentially life-critical biomedical telemetry has no place as a 'bottom-of-the-food-chain" Part 15 device, while it noted the similar comments of the FDA's Center
(continued...)

As secondary users of the frequencies on which they operate under Parts 90 and 15 of the Commission's rules, medical facilities must proactively manage the patient risks associated with the potential for interference from other primary users, by avoiding utilization of any frequencies known to be occupied by such users in their geographic area.[12] Furthermore, hospital personnel also need to react to transient interference, often from unknown sources, which is also expected to increase as usage by other primary licensees expands. The Task Force determined that this transient interference currently may be encountered several times per week (6-12 times depending on the reporting institution), potentially affecting the well being of a significant number of patients.

The Commission hoped that its decision to expand the available spectrum on which these Part 15 devices could operate would provide sufficient leeway from the primary licensees. Unfortunately, the advent of DTV services in the VHF spectrum (174-216 MHz) has resulted in increased potential for interference to biomedical telemetering devices in this spectrum. An incident of interference occurred at the Baylor University Medical Center in Dallas, Texas upon the initiation of one of the nation's first DTV stations; as noted above, the Commission has already issued public advisories urging broadcasters and health care facilities to work even more closely together to avoid additional incidents. In several cities where the VHF bands are already heavily utilized for analog television signals, the availability of any channels in this band is questionable once all of the broadcast stations introduce DTV on the few vacant channels remaining. Moreover, the upper UHF band (470-668 MHz) is still subject to interference from broadcast and low power television service use, which could increase significantly over time. There are virtually no biomedical telemetry products currently available on the market which utilize that portion of the spectrum, and the market for such products is likely to be limited in light of this potential interference risk. Simply stated, the current allocation of frequencies available under Part 15 will not satisfy the need for biomedical telemetry over the near, medium

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11 (...continued)
for Devices and Radiological Health, which expressed concern about "the potential for injury to patients that might occur if there is interference between the medical device and the primary licensees." 1997 R&O at 17830, 17831.

12 As the FCC has recognized, television broadcasters have been asked to notify health care facilities in their broadcast region of their intent to begin use of a previously unoccupied television channel for their DTV expansion. However, these notifications are not necessarily addressed to the hospital personnel who understand and can react appropriately, so that the interference often is identified only after the problem is created. Moreover, as the Commission has noted, in major markets where the television bands are already heavily utilized, the older biomedical telemetry devices may not have enough tuning range to move to the rare frequencies that remain unoccupied as all television stations begin their introduction of DTV on previously unauthorized channels.

or long terms, notwithstanding the FCC's decision to make new UHF bands available to the biomedical telemetry industry on a secondary use basis.

The situation in the 450-470 MHz band available under Part 90 is no less problematic. In the Commission's 1995 Refarming Order,[13] frequencies offset 12.5 kHz from the regularly assignable frequencies ("offset channels") that are heavily used for medical telemetry were made available for high power operations on a primary basis. The Commission left to the industry the task of developing a consensus plan for dedicating channels for low-power use in order to address the need for biomedical telemetry and other low-power services in this band, in conjunction with the formulation of a consolidation plan under the "Refarming" approach. However, as the Commission recognized in the Second Report in the same proceeding,[14] coordinators have been reluctant to designate any channels specifically for low power use due to the uncertainty surrounding consolidation of the PLMR Services; the effort to reach a consensus plan with users has therefore failed, reflecting in large measure the incompatibility of co-channel high powered mobiles and low-powered medical telemetry operations.

To protect existing low-powered uses of these channels, and until such new designations are completed, the Commission has frozen applications for higher powered stations on these offset channels.[15] Were that freeze on licensing co-channel, higher powered operation to be lifted without designating new, low-powered only channels,[16] and providing a transition plan, existing

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13 Replacement of Part 90 by Part 88 to Revise the Private Land Mobile Radio Services (Report and Order and Further Notice of Proposed Rule Making), 10 FCC Rcd 10076 (1995).

14 Replacement of Part 90 by Part 88 to Revise the Private Land Mobile Radio Services (Second Report and Order), 12 FCC Rcd 14307, 62 FR 18833 (1997).

15 *See* Public Notice, "Freeze on the Filing of High Power Applications for 12.5 kHz Offset Channels in the 450-470 MHz Band" (PR Docket 92-235, FCC 95-255), DA 95-1771, (released Aug. 11, 1995).

16 In the Second Report, the Commission delegated to the frequency coordinators the authority to designate low power frequencies, and to add or subtract from the designated list as may be warranted by local requirements. The agency expected low power operation on the designated channels to be protected through coordination and the Commission's licensing process. However, the frequency coordinators for the PLMR Service channels have not been able to develop a consensus on such a plan, largely because of the extreme difficulty of developing a coordination procedure that can reasonably protect lower powered operations such as biomedical telemetry from

(continued...)

biomedical telemetering devices could not continue to operate in these bands because of disabling interference from the new higher powered users.[17] Indeed, even with the freeze, operation of biomedical telemetry devices pursuant to Part 90 is becoming more difficult, as adjacent-channel interference from licensed mobile operations continues to make some of the "frozen" offset channels unusable in certain locations. Moreover, increased congestion from low powered biomedical telemetry and other lower powered uses in the band is making it difficult for health care administrators to find any other frequencies to which to switch their operations when disabling interference makes a currently used channel unusable, or even to add more telemetry units when needed to provide care to patients.

The problems associated with a shrinking pool of quiet channels on which to operate in a relatively interference-free environment is exacerbated by the significant growth in the use of biomedical telemetry as a staple element in the provision of health care in the future. According to surveys taken of hospitals by the Task Force, many hospitals already have in excess of 300 patient-connected transmitting devices in use at one time. Those surveys also show that within 10 years, medium to large hospitals will use an *average* of 1,000 patient-connected transmitting devices. These devices will serve more types of acute patients and will monitor additional vital signs measurements. In sum, there is, in the Task Force's view, a clear and present need to develop a new approach for meeting the nation's need for wireless biomedical telemetry services. In this case, the need can best be satisfied by identifying specific frequency bands in which biomedical telemetry devices will have primary status.

Allocating frequencies for use by low powered devices and granting such devices regulatory parity with other higher powered licensed transmitters is no longer a novel idea within the Commission's spectrum allocation tools. This approach has been utilized in allocating spectrum for use on a primary basis for the Unlicensed Personal Communications Service,[18] to which specific frequencies were allocated for use under Part 15, Subpart D; it has also been used more recently in authorizing the use of spectrum under Part 15, Subpart E for the fixed,

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16 (...continued)
interference from higher powered mobile operations within the same geographic area. As discussed in Section V below, the Task Force does not believe that such coordination will be effective.

17 This concern has been confirmed through testing conducted by the Commission's Technical Research Branch in Columbia Maryland, which demonstrated that low powered biomedical telemetry devices could not co-exist with higher powered mobile devices operating on the same or adjacent channels.

18 Amendment of the Commission's Rules to Establish New Personal Communications Services, 8 FCC Rcd 7700 (1993).

point-to-point Unlicensed National Information Infrastructure ("U-NII") devices in the 5.725-5.825 GHz band.[19] In promoting the expansion of the 902-928 MHz bands for Location and Monitoring Services, the Commission has also recently created "safe harbor" technical criteria in which Part 15 unlicensed devices are able to operate with a presumption that they are not causing interference to any licensed services operating in the band.[20] A similar approach has also been utilized in creating licensed services: the Family Radio Service, for example, was created under Part 25, and through technical and operating rules, has been licensed to individuals "by rule"[21]; the Commission has also taken the same approach recently when it proposed the creation of a new Medical Implant Communications Service.[22]

In sum, as demonstrated in the Task Force Report, the public safety, health and welfare clearly justify the initiation of proceedings by the Commission to find adequate spectrum for use on a primary basis by wireless biomedical telemetry devices, to which such devices can readily migrate in order to operate without the threat of interference from other licensed and unlicensed devices.

II. The new allocation must have adequate bandwidth to accommodate existing and reasonably foreseeable demands for the use of wireless biomedical telemetering devices in the nation's health care system.

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19 Amendment of the Commission's Rules to Provide for Operation of Unlicensed NII Devices in the 5 GHz Frequency Range, 12 FCC Rcd 1576 (1997). The Commission did not believe that any public interest considerations warranted unique protection for U-NII devices beyond that created by the technical characteristics available to the bands' users, which are designed to avoid virtually all interference. However, the Task Force demonstrates below that health and public safety concerns will warrant a higher level of protection for wireless biomedical telemetry devices operating in any newly allocated bands, more akin to the primary allocation approach taken with Unlicensed PCS spectrum.

20 *See,.e.g., Amendment of Part 90 of the Commission's Rules to Adopt Regulations for Automatic Vehicle Monitoring Systems, Report and Order*, PR Docket No. 93-61, 10 FCC Rcd 4695 (1995).

21 Amendment of Part 95 of the Commission's Rules to Establish a Very Short Distance Two-way Voice Radio Service, 11 FCC Rcd 12977, 61 FR 28768 (1996).

22 Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band, WT Docket No. 99-66, RM No. 9157, FCC 99-23 (released February 24, 1999).

It is clear to the Task Force that the demand for wireless biomedical telemetering is growing; therefore, any allocation of spectrum for such uses must therefore provide sufficient bandwidth so that any single health care facility's needs can be satisfied without creating internal or external interference to and among patients. As the Task Force found, there are a number of causes for this concern, including:

- Patient acuity is rising, *e.g.*, the typical hospitalized patient entering the hospital is sicker. This means that patients who in the past were housed in an intensive care unit are now, and in the future will in greater numbers be, housed on general nursing units where they still require the monitoring and treatment capabilities that were previously deliverable only in the intensive care setting. Moreover, patient outcomes are optimized by moving them from the intensive care unit to a general nursing unit as quickly as possible. All of these factors contribute to the increase in the number of telemetering units in use in any given facility.

- As a cost containment and quality improvement effort, hospitals desire to house patients in a specialty ward that is most capable of addressing that patient's acute health care needs; as a result, there is an emerging population of patients that require physiologic monitoring outside of the traditional hard-wired monitoring wards. There is also a growing need to include data acquisition from stand-alone equipment, monitoring devices, and therapeutic devices via telemetry.

- As consolidation of health care providers continues to escalate, the need for wireless telemetry will become more important as patient monitoring expands outside of the campus of the monitoring hospital to, for example, community based hospitals, ambulatory surgery centers, long-term facilities, and even home health care.

In light of all of these factors, the Task Force undertook a study to determine the industry's likely reasonable bandwidth requirements. This study included a survey of geographically dispersed hospital administrators, biomedical engineering directors, principal clinicians responsible for medical telemetry, and clinical professional organizations.[23] Based on the results of this survey, a model was developed based on the number of concurrently operating telemetry transmitters, and a 0.8 bit per second per Hertz spectral efficiency metric currently recommended by section 90.203 (which is better utilization than medical telemetry technology currently affords).

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[23] These professional groups included the American Association of Critical Care Nurses, the American College of Cardiology, the Society of Critical Care Medicine, the American Medical Association, the American Association of Respiratory Care, the American Academy of Neurology, and the American Association of Cardiovascular & Pulmonary Rehab.

With this study in hand, the Task Force now estimates that based on the number of wireless telemetry units that may currently be simultaneously operating within a health care facility or campus, and assuming the use of sophisticated communications technology a minimum spectrum bandwidth of 6.125 MHz is needed to satisfy reasonably anticipated requirements of most health care facilities today.[24] With reasonably anticipated growth, the Task Force believes that a minimum allocation of 6 MHz of bandwidth must be made available for immediate use today, with an additional allocation of 6 MHz to be made available for use over the next ten years, in order to assure biomedical telemetry operations in an interference-free environment. An allocation of *at least* 12 MHz of interference-free spectrum, available on a primary basis throughout the country, is essential to assure that the nation's needs for safe and reliable wireless biomedical telemetry capabilities will be satisfied.

III. Dedicated, interference-free bands must be identified to accommodate a multiplicity of different applications for wireless medical telemetry well into the next century.

Having identified the anticipated amount of spectrum which would be reasonably necessary to satisfy the needs for wireless biomedical telemetry, the Task Force's next major objective was to identify one or more spectrum bands in which such devices could operate in a relatively interference-free environment. In considering such bands, the Task Force was also sensitive to the need to accommodate a variety of potential applications -- some known, some not yet even considered -- for this technology in the burgeoning health care industry. The Task Force recognized that until new spectrum is identified and allocated, telemetry equipment manufacturers cannot feasibly begin the development of new products which will allow for the migration of users to the new bands.[25]

As a predicate to selecting suitable spectrum, the Task Force focused on real-time communications between the patient, his/her instrumentation, and a centralized monitoring/ processing site. In order to provide focus to its efforts, a workgroup developed a specific definition of wireless medical telemetry as "the measurement and recording of physiological

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24 It must be noted, however, that this requirement was calculated based on a spectral efficiency of 0.8 bits per second per Hertz (the FCC's current recommendation), which is better utilization than medical telemetry technology currently affords. The Task Force also recognized that even this bandwidth might not satisfy the requirements of the largest facilities, and that it certainly would not satisfy any reasonable estimation of future requirements.

25 As discussed in Section V below, the Task Force estimates that telemetry equipment manufacturers will require at least a 3-year period to bring products operating in these new bands to market, which is consistent with the likely budgeting cycles that will be faced by most health care facilities hoping to introduce the newer devices.

parameters and other patient-related information via radiated bi or unidirectional electromagnetic signals." Other communications devices (*e.g.*, pagers, *etc.*) used within a health care facility not directly meeting the Task Force's definitional parameters for wireless medical telemetry were not considered as part of this spectrum selection process.

The Task Force obtained input from liaison organizations including the FCC, FDA, NTIA and NAB; from informal discussions with members of wireless local area network and radio astronomy communities interested in the selection of frequency bands; and from a wide variety of interests in the medical telemetry field. The proposed bands for primary medical telemetry operations were chosen with several basic criteria in mind:

- Communications Reliability — medical telemetry monitoring is performed 24 hours per day; it was therefore essential to find bands in which co-channel and adjacent channel interference to medical telemetry operations would not generally exist.

- Spectrum Attributes — the selected spectrum had to have sufficient bandwidth, and it had to be suitable in supporting multiple modulation and transmission schemes for spectral efficiency and frequency re-use. Other spectral factors associated with a particular band were also considered (*e.g.*, path loss, level of noise floor, and susceptibility to multi-path fading). Finally, given the international marketplace for telemetering devices, consideration was given to whether the allocated use of the spectrum internationally was compatible.

- Operating Characteristics — the Task Force sought to minimize the recurring costs of ownership (*e.g.*, battery costs) and initial installation, equipment, and upgrade costs, including the ability to economically migrate any current users.

- Product Implementation Considerations — the current and anticipated availability of commercial RF components and low-cost field support instrumentation was considered, in order to provide some assurance that manufacturers and field technicians would be incented to bring new products to market in a timely fashion, and to facilitate the site survey/installation process; given the need to find spectrum to replace any channels that may be affected once they are utilized by higher powered land mobile transmitters after the "Refarming Order" applications freeze is lifted, it is essential that the bands chosen for the dedicated spectrum be among those in which cost-effective and expeditious manufacturing of product is clearly possible.

- Safety Considerations — the Task Force considered the susceptibility to RF radiated power to which other sensitive medical instrumentation would be exposed at particular frequency bands; the spectrum selected had to be efficient at field strengths not exceeding 3 V/m.

The Task Force was also concerned with finding channels in which the biomedical effects of radiofrequency exposure would not be problematic. In this regard, biomedical telemetry technology is carefully regulated by the Food and Drug Administration to assure that patient safety is not compromised in obtaining telemetry information. Nevertheless, in determining acceptable frequencies for dedication to wireless medical telemetry, the Task Force was cognizant of the amount of radiated power that the patient, as well as other sensitive medical instrumentation, would likely be exposed to in particular frequency ranges. In general, the higher operating frequencies would suffer additional path loss, mandating more radiated power to overcome, thereby introducing concerns for patient and device exposure. To reconcile these concerns, the Task Force reviewed ANSI/IEEE C95.1-1992 and assured that in each proposed spectrum solution, the energy that a transmitter would need to radiate to work effectively would be lower than the maximum permissible partial body exposure allowed for an uncontrolled environment.

Taking all of the above factors into consideration, the Task Force recommends the allocation of three distinct bands: 608-614 MHz ; 1385-1390 MHz ; and 1432-1435 MHz bands; for a total allocation of 14 MHz .[26]

In deciding to recommend the allocation of these bands, the Task Force found the following:

1. 608-614 MHz :

   - the band is currently authorized for medical telemetry use under Part 15, and thus multiple component vendors are available with off-the-shelf parts; it provides a strong opportunity for early development of newer devices, with a clear opportunity for quick migration of devices in particularly problematic interference situations.

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[26] The 1385-1390 and 1432-1435 MHz bands were recently identified by NTIA for reallocation to non-government use, in accordance with Title III, Section 3002(e) of the Balance Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251 (1997). *See* Spectrum Allocation Report, U.S. Department of Commerce, NTIA Special Publication 98-36 (Feb. 1998) (the "1998 NTIA Report").

- medical telemetry operations can be compatible with radio astronomy,[27] which is the predominant use of the band on a primary basis today; this will require frequency management for devices operating around such facilities.

- spectrum surveys revealed favorably low noise floors.

- although estimated path losses are higher than losses in the 470 MHz band, the differences are tolerable.

2. 1385-1390 and 1432-1435 MHz :

- there are already multiple component vendors available with off-the-shelf parts, facilitating the early introduction of devices operating in these bands.

- although the bands are currently in use by the federal government for radar operations, most of these operations must cease after 2008; thereafter, the use of the 1432-1435 MHz spectrum must be managed in expressly identified geographic exclusion zones affecting no more than 14 states; these bands would provide a strong area for future growth of the technology, as federal users migrate out of the band.

- estimated path loss is higher than at 470 MHz .

- spectrum surveys revealed low noise floors.

While not all of the characteristics of any of these bands are favorable, the Task Force believes that these bands hold the greatest promise for establishing an interference-free environment in which biomedical telemetering devices can operate effectively, efficiently and safely, on a primary or co-primary basis, with the least amount of disruption to other existing licensed services.

In this regard, perhaps the most difficult issues involve the use of these allocations in areas where these bands are currently authorized for use by radio astronomy service licensees (the 608-614 MHz band), and/or government radars (the 1385-1390 MHz band). Medical telemetry operations are currently authorized to operate in the 608-614 MHz band on a secondary basis; as the Commission noted in the 1997 R&O, "with regard to operation on TV channel 37, the Commission recognizes that most radio astronomy operations generally are

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[27] The Commission has already reached this conclusion in authorizing the operation of wireless medical telemetry devices operating in this band under Part 15. *See, e.g.*, 1997 R & O at ¶31.

located in rural areas where demand for biomedical telemetry devices is least. . . .[T]here may also be circumstances where there is a need for biomedical telemetry devices to be operated on TV channel 37 near such observatories [and] [t]his is a matter that must be addressed on a case-by-case basis."[28] As discussed below, the Task Force assumes that use near radio astronomy observatories would be managed by the designated frequency coordinator, in order to assure reasonable co-existence of these co-primary users. Similarly, as NTIA noted in the 1998 NTIA Report, the 1385-1390 MHz band is used primarily by military radar facilities, and will continue to be so used at several sites through the year 2008. The band 1432-1435 MHz is also used by the military for tactical radio relay communications, and essential federal government operations will have to be protected at certain designated sites indefinitely. The Task Force concluded that even as a co-primary user, medical telemetry devices would be able to coordinate with such federal government licensees sharing the band on a primary basis (at least through 2008), in those rare instances when medical facilities are sufficiently proximate to the other primary licensee as to have the potential for creating (or suffering) harmful interference. The Task Force concluded that, even with these limited geographical restrictions on the use of medical telemetry operations in these bands, interference to or from others can be avoided, and the bands can provide substantial value for wireless medical telemetering uses.

As to the licensing of spectrum allocated for wireless medical telemetry uses, the Task Force believes that the Commission can and should include this allocation within the definition of "public safety radio services" under Section 309(j)(2) of the Communications Act, as amended by the Balanced Budget Act of 1997,[29] thereby exempting it from auction.

The Balanced Budget Act of 1997 revised the Commission's auction authority by amending Section 309(j)(1) of the Communications Act so to require the Commission to award mutually exclusive applications for initial licenses or permits using competitive bidding procedures, except as provided in Section 309(j)(2). Sections 309(j)(1) and (2) now state:

> (1) General Authority. — If, consistent with the obligations described in paragraph (6)(E), mutually exclusive applications are accepted for any initial license or construction permit, then, except as provided in paragraph (2), the Commission shall grant the license or permit to a qualified applicant through a system of competitive bidding that meets the requirements of this subsection.
>
> (2) Exemptions. — The competitive bidding authority granted by this subsection shall not apply to licenses or construction permits issued by the Commission —

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[28] 1997 R&O at 17840.

[29] P.L. 105-33, § 3002, 111 Stat. 251 (1997).

> (A) for public safety radio services, including private internal radio services used by State and local governments and non-government entities and including emergency road services provided by not-for-profit organizations, that--
>
> (i) are used to protect the safety of life, health, or property; and
>
> (ii) are not made commercially available to the public;
>
> (B) for initial licenses or construction permits for digital television service given to existing terrestrial broadcast licensees to replace their analog television service licenses; or
>
> (C) for stations described in section 397(6) of this title [applicable to "noncommercial educational" and "public" broadcast stations].[30]

There can be little doubt that health care facilities operating wireless medical telemetry devices are entitled to the exemption from competitive bidding applicable to "public safety radio services" under Section 309(j)(2)(A).[31] Medical telemetry devices are used by hospitals solely to save lives and preserve the health of patients, and they are not made commercially available to the public. The Commission recognized this fact recently when it stated that "it appears that frequencies used by medical telemetry equipment may fall within [the Section 309(j)(2)] exemption."[32]

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[30] 47 U.S.C. § 309(j)(1), (2) (as amended by Balanced Budget Act, § 3002).

[31] It is significant to note that Congress made clear that the Section 309(j)(2) exemption for "public safety radio services" is "much broader than the explicit definition for 'public safety services'" included in Section 337(f)(1) of the Communications Act. *See* H.R. Conf. Rep. No. 105-217, 105th Cong., 1st Sess., at 572 (1997). For purposes of comparison, Section 337(f)(1) defines "public safety services" as follows:

> The term "public safety services" means services —
>
> (A) the sole or principal purpose of which is to protect the safety of life, health, or property;
>
> (B) that are provided (i) by State or local government entities or (ii) by nongovernmental organizations that are authorized by a governmental entity whose primary mission is the provision of such services; and
>
> (C) that are not made commercially available to the public by the provider.

47 U.S.C. § 337(f)(1).

[32] *Implementation of Sections 309(j) and 337 of the Communications Act*, WT Docket No. 99-87, *Notice of Proposed Rule Making*, FCC 99-52 at ¶ 30 (released March 25, 1999).

The Task Force recognizes that the 1385-1390 MHz and 1432-1435 MHz bands were recently identified by NTIA for reallocation to non-Government use, in accordance with Title III, Section 3002(e) of the Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251 (1997).[33] However, though this legislation requires that a certain amount of spectrum be reallocated, it does not mandate that competitive bidding be used to assign licenses to use the reallocated frequencies. Thus, the Commission has the authority to determine that these bands should be used for "public safety radio services" and therefore are exempt from competitive bidding under Section 309(j)(2).

Congress clearly did not intend that all spectrum reallocated pursuant to the Balanced Budget Act of 1997 would be auctioned.[34] Inclusion in this legislation of the public safety radio services exemption now found in Section 309(j)(2) indicates that reallocated spectrum need not be subjected to competitive bidding. Allocation of the 608-614 MHz, 1385-1390 MHz and 1432-1435 MHz bands for wireless medical telemetry uses thus would be consistent with the statutory scheme.[35]

IV. Maximum technical flexibility should be afforded within the allocated bands to encourage innovation, while also ensuring the maximum potential use of the band without creating co-band or out-of-band interference to other primary users.

As the Commission has consistently recognized in analogous circumstances, the least intrusive technical regulations are often the best technical regulations, and the Task Force has determined that this approach should hold true for any new spectrum allocation into which wireless medical telemetry uses may migrate. To that end, and following the approaches recently adopted, for example, in allocating spectrum for the use of U-NII,[36] the Task Force recommends

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33 These provisions are codified at 47 U.S.C. § 923(a) and (b). *See* 1998 NTIA Report.

34 Indeed, Section 3004 of the Balanced Budget Act of 1997 mandates reallocation to public safety use of certain frequencies currently used in UHF channels 60-69. *See* 47 U.S.C. § 337.

35 If the Commission feels it necessary to consider the potential revenue impact of exempting the 14 MHz from competitive bidding, it is worth noting that allowing medical telemetry use of these frequencies will clear other UHF spectrum, thereby increasing its potential value when auctioned.

36 "We continue to believe that the best regulatory framework to facilitate the introduction of U-NII devices is one that provides the maximum technical flexibility in their design and operation by imposing only the minimum technical rules necessary to prevent

(continued...)

that technical restrictions imposed on the use of these new bands should be limited to the following: (1) specifying the maximum allowable effective radiated power ("ERP"), (2) imposing a limitation on out-of-band emissions, and (3) requiring that all devices operating within these new bands should be subject to a "declaration of conformity" equipment authorization program. Moreover, and in order to maximize the sharing of the bands by both wideband and narrowband technologies, the Task Force recommends a limited channelization of the 608-614 MHz band only when used by devices employing wideband technologies. In addition, and as further assurance that the use of the new spectrum will be maximized, all users of the new bands would be required to register prior to use with a designated frequency coordinator as to the physical location at which the device will be installed; the modulation scheme utilized by the device; the ERP at which the device will operate; and the frequency range in which the device will operate, in order that an accurate database of device locations can be maintained, from which any incidents of interference can be resolved.[37]

In the view of the Task Force, it is critical that the industry be able to develop new and innovative products without the yoke of inflexible technical standards. Indeed, the Task Force hopes to encourage manufacturers to utilize different modulation types or schemes and any desirable channelization scheme within each band, without imposing any particular modulation efficiency standard and without being subject to particular frequency stability standards. Moreover, the Task Force believes that all types of information flows should be permissible in these bands on both a unidirectional and bi-directional basis. Only with such flexibility will

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36 (...continued)
harmful interference to primary operations and to provide for basic spectrum sharing among unlicensed devices. . . . We believe that adoption of minimum technical rules would not only permit unlicensed devices to operate successfully on a shared basis, but would also encourage maximum flexibility in the types and designs of unlicensed digital devices that could use this band. . . . These rules specify power limits (in terms of peak power and power spectral density), emission limits, radio frequency hazard requirements, and other basic technical rules appropriate for unlicensed Part 15 operations. Further, . . . we are not adopting a channeling plan, spectrum modulation efficiency requirement or a spectrum etiquette as we believe such technical standards are unnecessary at this time, could preclude certain technologies, and could unnecessarily delay implementation of U-NII devices." *Amendment of the Commission's Rules to Provide for Operation of Unlicensed NII Devices in the 5 GHz Frequency Range, Report and Order*, ET Docket No. 96-102, 12 FCC Rcd 1576, 1592 (1997) ("U-NII Order").

37 A more detailed description of the unique role anticipated for the designated frequency coordinating committee for the Wireless Medical Telemetry Service is attached as Appendix IV.

clinical users be able to drive manufacturers to develop different applications for medical telemetry.

In light of the highly competitive nature of the manufacturing industry for wireless biomedical telemetering devices, the Task Force does not believe that the lack of standards will lead to inefficient uses of these bands. To the contrary, by allowing the industry to move forward without government imposed standards, Task Force members believe that a high degree of innovation will result. Such innovation will be critical to meeting health care providers' desire to use technology to reduce risk to patients through more applicable and efficient monitoring; to the containment of costs of health care delivery; and to improvements in the quality of patient care through better diagnostic and monitoring data. And as potential uses of these bands increase, competitive manufacturers will be encouraged to use even more efficient technologies to develop new capabilities such as bi-directional telecommand, as dictated by future medical trends. In the view of the Task Force, limitations on the amount of maximum permissible power and limitations on out-of-band emissions, accompanied by a viable equipment authorization and user registration program, will be effective to accomplish these goals.

The only exception to this overall flexibility that the Task Force has considered is a modest limitation on the use of wideband technologies. The Task Force is aware of the substantial efficiencies that wideband technologies, for example some of the spread spectrum techniques, may bring to the industry in assuring that these new bands can accommodate the large number of devices anticipated for the future. On the other hand, there was some concern that the use of a wideband technology in a particular geographic area on a particular band could effectively inhibit the ability of other health care facilities (or even different health care practitioners within the same health care facility) within that area to also utilize narrowband techniques. To mitigate this concern, the Task Force recommends that the regulations provide that in the 608-614 MHz band, wireless medical telemetry devices utilizing broadband technologies such as spread spectrum shall be capable of operating within one or more channels of 1.5 MHz each,[38] up to a maximum of 6 MHz, and shall operate on the minimum number of such channels necessary to avoid harmful interference to any other wireless medical telemetry devices. Any wireless medical telemetry device operating in this band that utilizes wide band technology system should have the capability of being "throttled back" so that it will occupy as little as one of these 1.5 MHz channels, to the extent that narrowband systems operating in the area need to operate in one or more of the other channels to avoid interfering with, or being subject to interference from, such a wideband device. No similar restrictions are necessary in the other two allocated bands.

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[38] Specifically, this band would be divided for wideband systems, only, into the following four channels: 608-609.5 MHz, 609.5-611 MHz; 611-612.5 MHz; and 612.5-614 MHz.

In a similar circumstance, the Commission recently recognized that flexible technical regulations could be quite effective in allowing multiple users and multiple uses to co-exist without creating a substantial threat of interference to or among other users.[39] There is no reason to believe that the same considerations will not hold true for the burgeoning wireless medical telemetry industry, which should be able to coexist quite effectively with other remaining users of these reallocated bands without detailed technical restrictions or requirements.

Indeed, as an adjunct to the flexibility afforded under the technical rules, the Task Force strongly recommends that individual licenses would not be issued to users of devices operating in either the existing allocations or the newly allocated bands. Instead, the new service would be licensed "by rule," just as the Commission has done for the Family Radio Service (see, e.g., Section 95.401).[40] To maintain a reasonable basis for interference avoidance, however, any device operating in the new bands would require registration with a newly designated frequency coordinator prior to operation. Moreover, all such devices would continue to be subject to equipment authorization procedures under Part 2 of the rules, preferably to a manufacturers' "declaration of conformity" program.

While existing biomedical telemetry devices are operating primarily under the strictures of Parts 15 and 90, those sections may no longer be appropriate to allow for the regulatory parity which the Task Force believes is essential to the future growth and development of these critical health care capabilities in the newly allocated bands. To avoid any confusion in this regard, the Task Force recommends that a new rule part of the FCC's regulations should be created to accommodate use of the bands for biomedical telemetering. Suggested rules are included in Appendix III.

There are a number of alternatives for achieving this objective. First, the Commission could use the approach taken with Unlicensed PCS and U-NII devices, creating a separate section of Part 15, and requiring the database registration through a designated entity (much like UTAM is designated for certain spectrum management responsibilities under Part 15, Subpart D).

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39 As the Commission noted there, "we continue to believe that U-NII devices can share these bands with existing and future operations. . . .[T]he power limits, power spectral density requirements and emission limits that we are adopting herein will permit the robust development of U-NII devices without a significant impact on other spectrum users." U-NII Order at 1609.

40 Some accommodation must also be made in the FCC's rules to allow the operation of devices in this "licensed" service by health care facilities operated by federal government agencies, for example, the Veterans' Administration, so that the change from Part 15 regulation to a licensed service does not inadvertently impact such facilities ability to utilize wireless medical telemetry devices otherwise available to the rest of this sector.

Alternatively, and in the Task Force's view, the better approach, the new "Wireless Medical Telemetry Service" could be created under Part 90 or even under Part 95 -- or, if the Commission believes it to be appropriate, under a new Part 16 created for this and other "medical industry" devices -- allowing these devices to have the imprimatur of a "licensed" service.[41] In such case, however, the Commission should clearly license individual users and stations "by rule," much as it has done in creating the Family Radio Service.[42] Given the nature and number of devices that are anticipated to be operated in this new service, and the number of separate licensees that could co-exist in any given area, there is simply no basis for imposing the administrative burden of individual licensing. Moreover, these devices will be under the supervision and control of health care providers, who are, as a class, extremely sensitive to the need to avoid any radiofrequency interference. And the Task Force believes that the proposed device registration can be effective to anticipate and control inter-device interference. Medical telemetering devices and associated operations simply do not need to be licensed in order to provide regulatory parity with other licensed services.

A very important part of such "licensing" by rule is the ability of users, manufacturers and other licensees with whom this new service will, over time, continue to co-habitate in the spectrum, to access an accurate database of locations of low power devices operating in the new spectrum. The Task Force therefore recommends the appointment of a frequency coordinator who will maintain the requisite database, subject to the general restrictions imposed on designated frequency coordinators in accordance with the provisions of Section 332(b) of the Communications Act to provide database management services on a non-discriminatory basis for any user of a wireless biomedical telemetry device, maintaining a database of the following information:

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41 This approach (or a new rules section under Part 90) would have the additional advantage of allowing the Commission to designate all new radio services under the new Part 16 as "public safety services," thereby avoiding any doubt as to the ability of the Commission to issue licenses for these services without utilizing competitive bidding.

42 Amendment of Part 95 of the Commission's Rules to Establish a Very Short Distance Two-Way Voice Radio Service, FCC 98-293, WT Docket No. 95-102; RM-8499 (November 9, 1998). The Task Force is aware, however, of the need to expand eligibility for such a licensed service to recognize the rights of health care facilities operated by agencies of the Federal government to utilize devices operating in these new bands. Such health care facilities, *e.g.* hospitals operated by the Veteran's Administration, currently utilize biomedical telemetry devices operating under Part 15, and will therefore face the same problems as non-government facilities. The change to a licensed service should not prejudice these health care facilities' operations, so the rules adopted for the Wireless Medical Telemetry Service must accommodate their operations or allow for co-primary operations under the government allocation in these bands.

- legal name of end user
- location of transmitter (coordinates, street address, building)
- number of transmitters
- end user point of contact — name, office, position
- *frequency range(s) used (for wideband systems)
- *center frequency of operation (for narrowband systems)
- *modulation scheme used
- *effective radiated power
- *vendor legal name

As part of the manufacturer's declaration of conformity, each manufacturer would be required to provide each purchaser of a device with the items identified by an asterisk (*); moreover, and to further assure compliance with the registration requirements, the Commission should consider requiring each manufacturer of a wireless medical telemetry device operating in these new bands to provide with all new products sold to end user a standard registration form pre-printed with the asterisked information (thereby increasing the likelihood that the end user will have the requisite registration form and complete it for filing with the Coordinator).[43] Each user would be required to complete the registration form and submit it to the frequency coordinator, and further to re-submit a form at any time that the equipment is moved or changed, in order to assure that the database reflects current information. A registration would remain valid for a period of five years, at which time it could be renewed by a new registration if the device was still in use.[44]

A strong, centralized coordination system like that used in most of the other PLMR Services is not necessary for coordinating a Wireless Medical Telemetry Service. First, and foremost, health care providers will not expect or be granted any "protected service area" for the use of their devices, so it is less important to coordinate those licensees to obtain the desired protected area. Rather, the "license" associated with wireless medical telemetry devices will entitle the user to interference-free use of the devices, subject to the rights of other, similarly situated users of medical telemetry devices (and in some areas, other licensed services) to operate in the same general area, with similar protection. As with other low-powered services, it is anticipated that the technical regulations will provide the primary basis of protection for all users, without the need for frequency "coordination" oversight for each installation.

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43 The Task Force believes that the modest expense associated with the printing of such forms will be more than offset by the substantial benefits that manufacturers will receive in assuring that an accurate database is available for planning the sale and installation of new products into a target health care facility/end user.

44 The AHA is prepared to act as the initial frequency coordinator for these devices.

Second, the number and nature of licensees is quite different than in the PLMR Services, generally. Users of Wireless Medical Telemetry devices will be health care professionals, highly trained and dedicated to the patient care and safety; these licensed devices will not be used to advance their economic interests, per se, but rather as a key element of patient care. While there may be a multitude of user groups within a single health care environment, they will typically be under the management of the health care facility in which they are operating and, in light of the potentially devastating impact of interference, all users will be highly motivated to cooperate in advance of making any new installation, and also while operating any telemetry devices, to avoid being the creators of or being susceptible to such problems.

Third, and in the same vein, there is a relatively small manufacturing community for Wireless Medical Telemetry devices, and this community depends upon maintaining the satisfaction of those highly motivated health care practitioners in assuring that neither the technologies nor the designs of medical telemetry systems create internal or external interference to other similarly situated users. This community is also heavily regulated by the Food and Drug Administration in assuring that health and safety standards are maintained. Indeed, the competitive marketplace in which this manufacturing community is operating provides strong incentives for managing the use of the spectrum without the interposition of a central coordinating body.

In light of these factors the Task Force envisions a much less centralized functionality for the Wireless Medical Telemetry Coordinator; rather, the Coordinator's role will be as a database manager, centralized informational source and point of contact for anticipating the possibility of, and thus avoiding, potential interference among and between health care facilities and providers and any other authorized users of the allocated spectrum. The goal of this unique coordination system would be to accommodate all reasonable uses of the available spectrum in a variety of closely-spaced health care facilities, while avoiding unacceptable interference to neighboring health care providers and/or other licensed services.[45]

Nevertheless, to be effective, the registration process must have some potency. To that end, the Task Force envisions regulations under the Wireless Medical Telemetry Service that assure that the Coordinator is able to maintain an accurate engineering database of "licensed" wireless medical telemetry transmitters. Specifically, the rules must assure that no user of a

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[45] The Task Force also envisions that the Coordinator's database would be a helpful source of information in facilitating the transition of existing users to the newer frequencies, as the introduction of DTV and/or the use of higher powered devices by land mobile licensees in the offset channels in the 450-470 MHz band increases the potential for interference to grandfathered wireless medical telemetry devices operating under other sections of Parts 15 and 90.

medical telemetry device would be authorized to operate that device in this service unless, and until, it had filed a registration with the Coordinator.

With an accurate database assured by requiring registration in advance of installation, it would be the responsibility of each user (assisted by information supplied by the manufacturer from which the user is purchasing new products) to determine, in advance of installation, whether its new devices were likely to cause or be susceptible to interference from devices already registered in the Coordination database. The Task Force is convinced that health care practitioners will be highly motivated to use the registration system in order to avoid interference; the risks of doing otherwise are simply too great.

If, on review of the information in the database, interference was likely to occur from or to other registered devices, the proponent of the newly registered device would bear the responsibility of coordinating with existing users to avoid the interference. In the unlikely event that the users (with the assistance of their manufacturers) were unable to develop an engineering solution to the problem, then the Commission would be available to arbitrate such matters.

However, if interference occurred to any device that was not registered in advance with the Coordinator database, the operator of that device would have no protection from newly installed transmitters, and in fact would be required to resolve any interference problem at its own expense. The Task Force believes that this penalty will act as a significant deterrent to non-registration, as the failure to register would, in effect, lower the licensee's status to a "secondary" nature as to any subsequent installations within its area.

V. A reasonable transition is required to accommodate the manufacturing and budgeting cycles. All existing equipment should be grandfathered indefinitely.

As noted above, and in light of the increasing use of the existing bands by other, primary licensed services, it is critical to the health care industry that the FCC act quickly to identify and allocate new spectrum for wireless biomedical telemetering uses. Only when such bands have been allocated can manufacturers invest the capital and resources necessary to bring new and innovative uses of this technology to these new bands. Nevertheless, once the Commission has acted, time will be needed before the equipment capable of operating in these new bands is commercially available, and additional time will then be needed before health care facilities can budget the required funds to upgrade to these new devices.

The Task Force believes that a period of three years *after* the allocation of frequencies is completed will be needed before devices operating in these new bands are developed and being

competitively marketed.[46] Therefore, the Task Force has recommended that manufacturers should *not* be *required* to manufacture and market devices capable of operating in the newly allocated "primary" bands until at least four years after the adoption of an order allocating new spectrum for this service. In order to encourage development of products in these new bands, the Task Force therefore urges that all *newly designed* devices (*i.e.*, not those devices operating under Parts 15 or 90 that are merely being re-authorized to reflect minor modifications) that are first subject to an equipment authorization after the fourth year anniversary of a Report and Order allocating the new channels must be capable of operating in the newly allocated spectrum.

However, because health care facilities may desire to maintain the use of the existing Part 15 and Part 90 devices as long as they are not experiencing interference, manufacturers should be able to continue manufacturing and marketing devices operating in the existing allocations for as long as market demands warrant such activity.[47] **In addition, the use of any device lawfully manufactured and in operation should be grandfathered until it is replaced by the user.** The health care industry simply cannot afford to replace all of the myriad of existing wireless telemetry devices until they have outlived their usefulness, either because they are no longer in acceptable working order *or* because they are being operated in an area where they are subject to objectionable interference from other primary licensees.

In order to accommodate an orderly migration to the newly allocated spectrum, the health care industry will continue to need the use of the existing Part 15 and Part 90 spectrum allocations. To that end, therefore, the Commission must also maintain some part of the current Part 90 spectrum allocation available for low-powered uses. Lifting the licensing freeze across the *entire* 450–470 MHz band prior to a transition period of *at least* five years *starting with the*

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[46] It must be remembered that all such devices will be subject to additional review and authorization by the Federal Food and Drug Administration as well as the Commission.

[47] The Commission will need to distinguish between devices that are being redesigned and/or to which modest changes are being made (requiring, nevertheless, a new declaration of conformity) and those truly "new" product lines first introduced after the deadline. It is not the Task Force's intent to require all manufacturers to abandon their existing product lines, even after the new frequencies are allocated, until the marketplace demand for such products naturally creates such a result. To the contrary, there may continue to be some market for existing product to satisfy the demands of those hospitals in less urban areas where the spectrum congestion and/or introduction of DTV is not a problem, and where existing products will continue to satisfy patient health care requirements without creating any adversarial relationships with other primary licensees.

Report and Order allocating the new spectrum for Wireless Medical Telemetry, would create disastrous consequences to the wireless biomedical telemetry community.[48]

In any area where the freeze is lifted -- even rural areas where there is really no shortage of PLMR spectrum otherwise available to the land mobile community and where there are otherwise channels available today for medical telemetry -- health care facilities will have to assume that these channels will be assigned for high powered operations. Even in areas where there is no problem today, the situation could quite quickly deteriorate to become an area where there are few, or no, channels available in this band, since there simply will not be any way to readily regulate or identify any particular areas in which the unfrozen channels will be assigned,[49] particularly when mobile technology is involved, and even a lower powered mobile station has the ability to interfere with a truly low powered medical telemetry device. All health care facilities will accordingly have to plan to replace existing equipment with devices that will operate in the new band whenever the freeze is lifted from this 450-470 MHz band.

In this light, any transition must provide enough time (and potentially enough incentive) for the manufacturing community to develop and produce sufficient quantities of devices operating in the new bands to satisfy the potential demand that will develop once the freeze is lifted,[50] and for the medical community to purchase and install such devices. The transition must be sensitive to the design cycle needed by manufacturers once that new spectrum is allocated in order to bring devices to market on a wide scale basis; the transition must also account for the time element associated with the introduction by a typical health care facility of new biomedical telemetry devices which are replacing existing products to mitigate a potentially debilitating interference problem. Time is also needed to develop and react to the "registration" process that

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[48] A determination by the Commission to lift the freeze from the 450-460 MHz band prior to the end of this five year transition may further exacerbate the shortage of channels in the upper 10 MHz portion of the band, as devices operating in the lower 10 MHz will be forced to migrate to the higher channels or to the newly allocated spectrum.

[49] The Task Force has assumed that land mobile coordinators will not be able to develop and/or implement a method for coordinating high powered uses with lower powered telemetry systems.

[50] Obviously the mere lifting of the freeze will not create an immediate flood of interference since land mobile users will need to obtain licenses and construct systems operating in these new channels. However, since there will be no way of knowing where the problems will exist in the near or mid-term environment, health care providers who have been relying on this band will have to be prepared to react (or assume the worst case scenario) to avoid being subject to devastating interference when the first licensees do begin operating on these offset channels in their areas.

will be introduced to assure that the new dedicated frequencies are most effectively utilized. Simply stated, a freeze must be retained to some degree for at least five years after new spectrum is allocated for wireless medical telemetry.

CONCLUSION

The Task Force is aware, and appreciative, of the efforts of the Commission's Office of Engineering and Technology and its Wireless Telecommunications Bureau, to develop solutions to the current potential for conflict between and among licensed uses of the VHF and UHF bands available for biomedical telemetering, and the low power biomedical telemetry devices which are currently operating in these bands. The efforts of the Task Force have been focused on assisting the Commission in those efforts. We believe that the attached workgroup reports, which in total represent the work product of the Task Force, can provide a strong basis on which the Commission can expeditiously issue a *Notice of Proposed Rule Making* and initiate the administrative processes necessary to create a "co-primary" allocation of spectrum for biomedical telemetering users. The Commission's urgent attention to this task is therefore requested.

APPENDIX I

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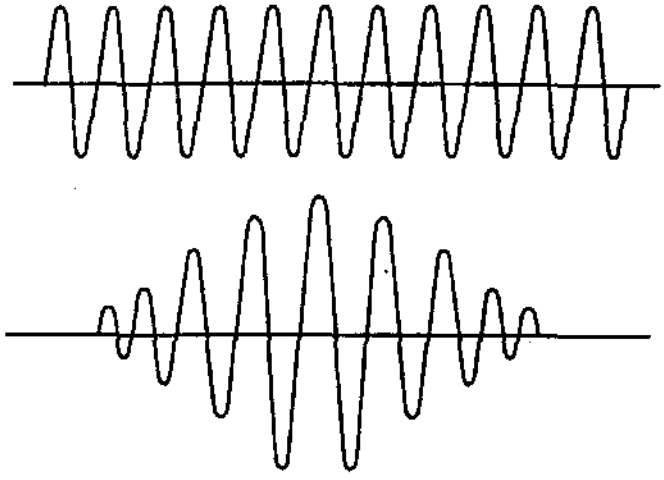
APPENDIX II

WORKGROUP REPORTS

FINAL REPORT OF THE WORKGROUP DEFINING WIRELESS MEDICAL TELEMETRY

December 17, 1998

YADIN DAVID, CHAIR



FINAL REPORT OF THE WORKGROUP DEFINING MEDICAL TELEMETRY

The working group recently completed its task of formulating a definition for present and future applications of medical telemetry systems. The process for arriving at the definition included a series of information exchanges between representatives from the user community, manufacturers of wireless medical telemetry equipment, members of the task force, the regulatory group, and information from professional societies. All input received was reviewed and considered before action was taken. Information received from other working groups, such as the data collected by the working group on parameters driving the spectrum allocation was considered as well. Via the internet, colleagues in other hospitals and professional organizations were able, in a fairly short time frame, to respond to various versions of the definition's draft presented to them. It is the intent of this working group to facilitate the safe, interference-free, and robust use of medical technology in general, and of medical telemetry in particular, at present and for the foreseeable future. This major effort should focus, as it does, on patient's needs and the capacity of medical telemetry to meet those needs.

Wireless Medical Telemetry is defined as follows:

Medical telemetry is defined as a measurement of something at a distance. Wireless medical telemetry is therefore defined as the measurement and recording of physiological parameters and other patient-related information via radiated bi or unidirectional electromagnetic signals. This technology may be contained within a healthcare facility or extend beyond to other buildings and locations.

FINAL REPORT TO THE AMERICAN HOSPITAL ASSOCIATION TASKFORCE ON MEDICAL TELEMETRY

December 17, 1998

PREPARED BY THE PHYSIOLOGIC PARAMETERS WORKGROUP

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David Pettijohn	VitalCom, Inc.
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FINAL REPORT TO THE AMERICAN HOSPITAL ASSOCIATION
TASKFORCE ON MEDICAL TELEMETRY
December 17, 1998

EXECUTIVE SUMMARY

The Physiologic Parameters Workgroup was created to determine the spectrum bandwidth required to accommodate the needs of medical telemetry. These needs were determined through surveying fourteen hospitals of various sizes in both metropolitan and suburban/rural areas and various professional groups (Attachment A). Based on these survey results, the Workgroup determined what the spectrum needs would be today if appropriate patient care and communication technology were available to the medical community. The physiologic monitoring needs were defined as follows:

CURRENT TELEMETRY MONITORING NEEDS	
Physiologic Parameter	**Number of Concurrent Patients**
adult electrocardiogram	200 - 600
pulse oximetry	16 - 210
obstetrical (fetal/maternal) parameters	0 - 150
invasive pressures	17 - 420
respirations	4 - 210
12 sets of episodic data, e.g. noninvasive blood pressure, temperature.	up to 500 patients

The telemetry manufacturers represented in the Workgroup have determined that with the use of sophisticated communications technology, these physiologic parameters can be accommodated utilizing the following bandwidth:

Physiologic Parameter	Concurrent Patient Use Model	Required Bandwidth
electrocardiogram	500	4.000 MHz
pulse oximetry	250	0.150 MHz
obstetrical parameters	100	1.300 MHz
invasive pressures	300	0.400 MHz
respirations	100	0.025 MHz
12 sets of parametric data	500	0.250 MHz
TOTAL		6.125 MHz

These bandwidth calculations were based on a spectral efficiency of 0.8 bits per second per Hertz (the current FCC spectral efficiency recommendation).

This bandwidth will accommodate only today's patient care needs. There are several factors which will result in significant growth in spectrum needs over the next ten years. The main factor influencing this growth is that the patient acuity is rising, e.g. patients entering the hospital are sicker. This means that

patients that were formally housed in the intensive care unit are now housed on the general nursing units where they still require the monitoring and treatment capabilities that were formally deliverable only in the intensive care unit setting. Secondly, patient outcomes are optimized by moving them from the intensive care unit to a general nursing unit setting as quickly as possible. The general nursing unit environment is less stressful and more conducive to returning the patient to a more normal lifestyle which in turns accelerates the healing process. Thirdly, more chronic medical ailments are inherent to the increasingly elderly patient population. Therefore, the monitoring needs outside of the intensive care setting is rapidly escalating. **These critical monitoring needs are fulfilled utilizing telemetry. Based on these factors and the firm data used to determine today's telemetry needs, future needs were extrapolated and the spectrum needs for the next ten years were calculated to be 12 MHz.**

The telemetry manufacturers cannot feasibly begin development of technology utilizing a dedicated spectrum allocation until that allocation is determined. The manufacturers representatives in the Workgroup estimate that a 3 year period will be required following the allocation to bring products to market. This product development will include the necessary regulatory processes applicable to medical devices. The hospital representatives estimate that a 3 year period will be required to prepare the hospitals to acquire that technology. That preparation will accommodate the budgeting cycle and installation activities related to the telemetry monitoring. These two 3 year periods are not necessarily concurrent. **Therefore, a minimum transition period of three to five years is recommended.**

FINAL REPORT TO THE AMERICAN HOSPITAL ASSOCIATION
TASKFORCE ON MEDICAL TELEMETRY
December 17, 1998

1. WORKGROUP OBJECTIVE

The objective of the Physiologic Parameters Workgroup was to determine the spectrum bandwidth required to accommodate the needs of medical telemetry.

2. PATIENT SAFETY CONCERNS TODAY

In the current secondary user status, medical facilities proactively manage the patient risks associated with interference by avoiding utilization of frequencies occupied by licensed users in their geographic area and by reacting to transient interference from often unknown sources. This transient interference is encountered several times per week (6-12 times depending on the reporting institution), potentially affecting a significant number of patients.

The Physiologic Parameters Workgroup appreciates the need to reallocate spectrum related to digital television and the need to reallocate and redistribute spectrum related to land mobile communications. However, the Workgroup is concerned that the transitional situation lends itself to loss of monitoring capabilities because of the following reasons.

- As broadcasters receive digital television frequency allocations and as frequencies utilized by land mobile radio services expand, the remaining frequencies available for use by medical telemetry is diminished in both the UHF and the VHF bands. In certain geographic locations, this issue is very critical.
- Although the FCC granted use of the upper UHF band (470-668 MHz), these bands are still subject to interference from broadcast and low power television services use. There are currently no products available on the market which utilize that band and given the risk of interference from broadcast and low power television in that band, introduction of these products will be slow at best. Therefore, this grant of spectrum has no practical impact on the shrinking availability of frequencies for use by medical telemetry.
- Although television broadcasters have voluntarily been notifying healthcare facilities in their broadcast region of their intent to begin use of different frequencies, these notifications are not necessarily addressed to the hospital personnel which understand and can react appropriately to that notification.

Given these factors, the Physiologic Parameters Workgroup is concerned that the potential for interference still threatens the safety of the patient population. One of the primary purposes of patient monitoring is early detection of life-threatening physiologic developments so that appropriate intervention can be rendered in a timely manner in support of recovery. Unavailability of spectrum severely restricts the clinicians' ability to provide that intervention. The Workgroup firmly believes that the inherent risks to patient safety caused by the potential for interference and subsequent loss of monitoring capability can

only be addressed through allocation of dedicated spectrum to medical telemetry. The Physiologic Parameters Workgroup very strongly supports sole use of a portion of the spectrum and has implemented a systematic methodology for quantifying the medical telemetry spectrum needs.

3. METHODOLOGY FOR DETERMINING BANDWIDTH

In order to derive the bandwidth required to support the medical community, the Workgroup aggressively gathered input from various clinical groups. Fourteen hospitals of various sizes in both metropolitan and suburban/rural areas were surveyed and these hospitals were geographically distributed across the country in hopes of obtaining broad representation of various care delivery models. Additionally, various professional groups including the American Association for Critical Care Nurses, American College of Cardiology, Society of Critical Care Medicine, American Medical Association, American Association for Respiratory Care, and the American Association of Cardiovascular & Pulmonary Rehab were asked to participate in the survey. The list of parameters contained in the survey was developed in response to previous customer requests to manufacturers and from initial phone interviews with representatives of the professional organizations. Sample questionnaires for both the hospital and professional groups are attached.

4. TELEMETRY NEEDS TODAY

The results of the hospital questionnaires are summarized below.

CURRENT TELEMETRY MONITORING NEEDS	
Physiologic Parameter	**Number of Concurrent Patients**
adult electrocardiogram	200 - 600
pulse oximetry	16 - 210
obstetrical (fetal/maternal) parameters	0 - 150
invasive pressures	17 - 420
respirations	4 - 210
12 sets of episodic data, e.g. noninvasive blood pressure, temperature.	up to 500 patients

5. TRENDS IMPACTING FUTURE GROWTH

Although the survey data presents a **current** snapshot of the telemetry monitoring needs, there were several very immediate market forces that will increase those needs very dramatically in the future. The Workgroup believes that the unpredictable impact of those market forces has led to a very broad range of anticipated growth rates (from 3% to over 400% in 10 years) to be reported through the survey process.

The relevant market forces are as follows.

- As decreasing reimbursement encourages further cost containment, hospitals are pressured to use innovative approaches to monitoring needs. Toward that end, the respondents were excited about growing capabilities to utilize wireless technologies in support of patient care because of its inherent flexibility.
- As a cost containment and quality improvement effort, hospitals desire to house patients in the specialty ward that is most capable of addressing that patient's acute healthcare needs. While it is not financially feasible to equip every bed in the hospital with a hardwired patient monitor, it is financially feasible to provide for the patient's monitoring needs via telemetry at virtually any location in the hospital. Hence, there is an emerging population of patients that require physiologic monitoring outside of the traditionally hard-wired monitoring wards. Frequently, the monitoring needs of those patients exceed that of the electrocardiogram that has traditionally been provided via telemetry. Therefore, there is also a growing need to include data acquisition from stand-alone equipment, monitoring devices, and therapeutic devices via telemetry.
- Healthcare institutions aggressively pursue reduction in patient lengths of stay as a means of achieving cost containment. One of the methods used to achieve a reduced length of stay is encouraging earlier ambulation while continuing to monitor the patient. This cannot practically be achieved through use of hard-wired technology.
- Consolidation of health care providers continues to escalate. As these healthcare enterprises are developing, it is difficult to predict the monitoring models which will emerge within the enterprise and consequently it is difficult to predict the volume of telemetry services that will be needed. It is certain that the needs will increase as the telemetry services are consolidated and begin to monitor patient populations that do not reside on the campus of the monitoring hospital. These external patient locations may include community based hospitals, ambulatory surgery centers, and long term facilities, and may even support home health care.
- There is a new demand for telemetry in the obstetrical environment. Currently, some expectant mothers need to ambulate during labor in order to promote progression of their labor. Without telemetry, there is no practical means for monitoring, which places this population at risk for negative outcomes.
- It is difficult for clinicians to forecast their monitoring needs prior to the emergence of new technologic capabilities. In other words, prior to the development of a new monitoring capability, it is difficult for the clinician to anticipate its volume of usage.

6. BANDWIDTH REQUIREMENT TO SUPPORT TELEMETRY NEEDS

Based on these market trends, the Workgroup realized that the growth of telemetry needs is likely to increase very rapidly in the near future. In recognition of the need to support this future growth, the Workgroup attempted to interpret the survey data which represents today's needs with some measure of reason. For example, the survey data revealed that there is a very broad interest in voice and also an interest in real-time 12 lead ECG monitoring. In recognition of other potential modalities for supporting this need, the Workgroup excluded them from the near-term analysis. The Workgroup also recognized that the respondent hospitals probably would not implement all of the requested parameters immediately even if sufficient spectrum were provided because of the required capital investment. Additionally, hospitals that responded with uniquely large volumes for certain parameters were excluded from the analysis. Using this methodology, the spectrum needs were defined as follows.

Physiologic Parameter	Concurrent Patient Use Model	Required Bandwidth
Electrocardiogram	500	4.000 MHz
pulse oximetry	250	0.150 MHz
obstetrical parameters	100	1.300 MHz
invasive pressures	300	0.400 MHz
respirations	100	0.025 MHz
12 sets of parametric data	500	0.250 MHz
TOTAL		**6.125 MHz**

These bandwidth calculations were based on a spectral efficiency of 0.8 bits per second per Hertz (the current FCC spectral efficiency recommendation) which is better utilization than medical technology currently affords. As previously mentioned, this bandwidth will not necessarily meet the needs of the largest of users and certainly will not meet future needs. Based on projected growth rates obtained during the hospital survey process and the influence of the aforementioned market forces, it is anticipated that telemetry needs will likely double within ten years. Therefore, to meet the healthcare community's needs, medical telemetry manufacturers will need to develop mechanisms for more efficient use of the spectrum in their technologies. Given that most of these manufacturers primarily market monitoring product lines and secondarily market telemetry product lines, this certainly presents a challenge to the manufacturers.

7. RECOMMENDATIONS

In conclusion, the healthcare industry is certainly not unique in its growing appetite for spectrum or its need for interference-free communications. Given the inherent risk for patient injury when interference causes an interruption in monitoring capabilities, the healthcare industry places a very high priority on the ability to avoid interference. Therefore, the Workgroup is appreciative of this opportunity to poll representative healthcare institutions in an attempt to quantify the dedicated spectrum needs and has determined those **current** needs to be at least 6.125 MHz. The Workgroup believes that this amount of bandwidth will meet the needs of most of the institutions in the short term. Because of the projected growth related to market trends, even this 6.125 MHz will not be sufficient to meet longer term needs. **In ten years, the spectrum need is projected to grow to greater than 12 MHz.** Certainly these projections will motivate the medical telemetry manufacturers to design technology for more efficient use of the

spectrum. In addition, the Workgroup recommends that the Federal Communications Commission give careful consideration to these future spectrum needs in making a dedicated spectrum allocation for medical telemetry. Furthermore, given that the results of the ASHE survey regarding medical telemetry equipment suggests that hospitals will continue to utilize their existing telemetry equipment well into the future, an extended transition period is recommended.

ATTACHMENT A

Hospitals Surveyed

BJC Health System
One Barnes Hospital Plaza
St. Louis, MI 63110

Texas Children's Hospital
6621 Fannin Street
Houston, TX 77030-2303

Baylor University Medical Center
3500 Gaston Ave.
Dallas, TX 75246

Huntsville Hospital
101 Sivley Road
Huntsville, AL 35801

Yuma Regional Medical Center
2400 Avenue A
Yuma, AZ 85365

Sutter Health
52nd & F Streets
Sacramento, CA 95819

Mayo Foundation
200 First Street, SW
Rochester, MN 55905

Washington Hospital Center
110 Irving Street, N.W.
Washington, D.C. 20010

Walter Reed Army Medical Center
6825 16th Street, N.W.
Washington D.C. 20307-5001

New England Baptist Hospital
125 Parker Hill Ave.
Boston, MA 02120

Memorial Heart Institute
Long Beach Memorial Hospital
2801 Atlantic Ave.
P.O. Box 1428
Long Beach, CA 90806

Montefiore/Einstein
111 E. 210th Street
Bronx, NY 10467

Professional Organizations Surveyed

Society of Critical Care Medicine

American Association of Critical Care Nurses

American Medical Association

American Association of Cardiovascular & Pulmonary Rehab

American Association of Respiratory Care

American College of Cardiology

American Academy of Neurology

Professional Group Questionnaire

A letter was faxed to you on October 21 explaining the objectives & intent of the Medical Telemetry Task Force assembled by the AHA at the request of the FCC to advise the FCC on future telemetry use.

Confirm Receipt: yes no
If no, obtain fax number for sending copy of letter:

As explained in that letter, one of the objectives of that Task Force is to define the physiologic parameters to be monitored via telemetry in 5, 10, & 15 years based on the input of various clinical groups. You have been identified as the respondent for (input professional organization). This information is being gathered via a phone survey of professional groups and hospitals.

If you could monitor any physiologic parameter via telemetry, what would you monitor? Be careful not to limit your response to those parameters which are technologically possible today. For example, 12 leads of ECG are not technically possible via telemetry today, but if it were, would that be a physiologic parameter that you would have a need to monitor using telemetry? What other parameters do you envision monitoring?

Physiologic Parameters

_____
_____
_____
_____
_____
_____

Just to stimulate your thinking further, here are some other parameters that that the Task Force has suggested might be monitored via telemetry. **If the requisite technology and airspace were available, would you see a need to monitor these parameters via telemetry?**

Physiologic Parameters	Use	
12 lead ECG	Yes	no
Arterial Pressure	Yes	no
Pulmonary Artery Pressure	Yes	no
Central Venous Pressure	Yes	no
Non-invasive Pressure	Yes	no
Intracranial Pressure	Yes	no
Respiration	Yes	no
Pulse Oximetry	Yes	no
Continuous Cardiac Output	Yes	no
Temperature	Yes	no
Ventilator Data	Yes	no
Continuous Gas Monitoring	Yes	no
End Tidal CO_2	Yes	no
Gastric tonometry	Yes	no
Urimetry	Yes	no
Balloon pump parameters	Yes	no
External uterine contractions	Yes	no
Intra-Uterine Pressure	Yes	no
Fetal Heart Rate	Yes	no
Patient Location	Yes	no
Anesthesia Drip Line	Yes	no
Intercom/Voice	Yes	no

Hospital Questionnaire

A letter was faxed to you on October 21 explaining the objectives & intent of the Medical Telemetry Task Force assembled by the AHA at the request of the FCC to advise the FCC on future telemetry use.

Confirm Receipt: yes no
If no, obtain fax number for sending copy of letter:

As explained in that letter, one of the objectives of that Task Force is to define the physiologic parameters to be monitored via telemetry in 5, 10, & 15 years based on the input of various clinical groups. You have been suggested as a respondent for your organization on that issue. The information is being gathered via a phone survey of professional groups and hospitals.

If you could monitor any physiologic parameter via telemetry, what would you monitor? Be careful not to limit your response to those parameters which are technologically possible today. For example, 12 leads of ECG are not technically possible today, but if it were, would that be a physiologic parameter that you would have a need to monitor using telemetry? What other parameters do you envision monitoring? **If those parameters were available to you today via telemetry, how much would you use. Please respond in terms of patient-days per year.**

Physiologic Parameters	Number of Patient-Days/Year

Just to stimulate your thinking further, here are some other parameters that that the Task Force has suggested be monitored via telemetry. **If the requisite technology and airspace were available, would you see a need to monitor these parameters via telemetry?**

Physiologic Parameter	Use		Number of Waveforms, if any	Data	Peak Number of pts. @ once	Projected Pt-Days/Year
ECG	yes	No				
Arterial Pressure	yes	No				
Pulmonary Artery Pressure	yes	No				
Central Venous Pressure	yes	No				
Non-invasive Pressure	yes	No				
Intracranial Pressure	yes	No				
Respiration	yes	No				
Pulse Oximetry	yes	No				
Continuous Cardiac Output	yes	No				
Temperature	yes	No				
Ventilator Data	yes	No				

Continuous Gas Monitoring	yes	No				
End Tidal CO_2	yes	No				
Gastric tonometry	yes	No				
Urimetry	yes	No				
Balloon pump parameters	yes	No				
External uterine contractions	yes	No				
Intra-uterine pressure	yes	No				
Fetal heart rate	yes	No				
Patient Location	yes	No				
Anesthesia Drip Line	yes	No				
Intercom/Voice	yes	No				

Are there peak periods in the year when you see an increase in patient volume? If so, define those peak periods & the % increase in patient volume that you experience.	

Please project your growth in 5, 10, & 15 years as a percentage.

Growth Period	Projected Growth (%)
5 years	
10 years	
15 years	

Will you have need to monitor patients that do not reside on your campus? If so, what parameters?

Physiologic Parameters

_____

_____

_____

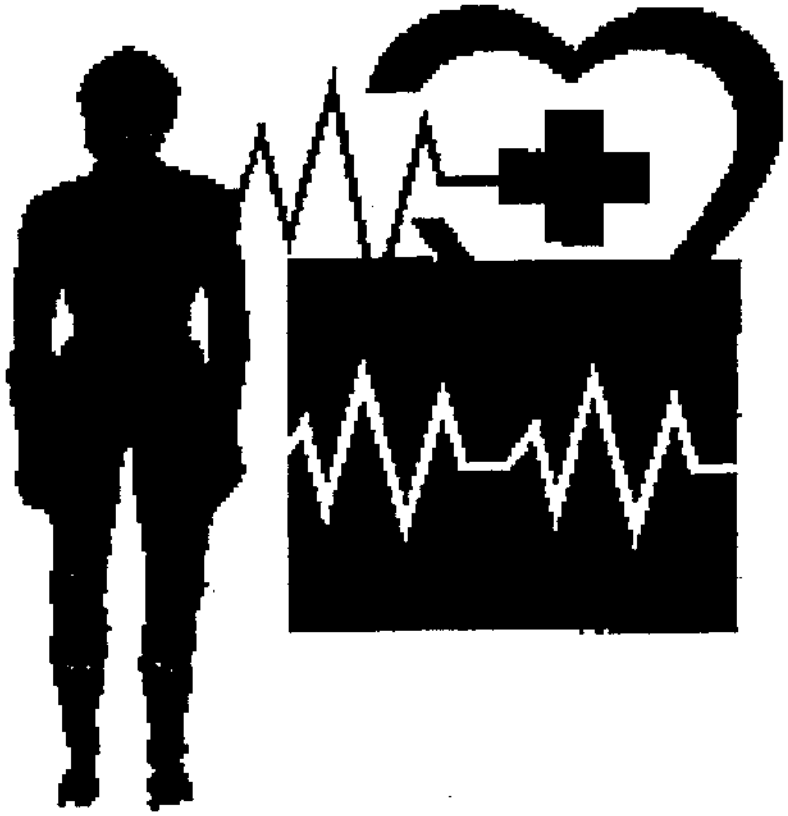
_____

_____

_____

FINAL REPORT TO THE AMERICAN HOSPITAL ASSOCIATION TASKFORCE ON MEDICAL TELEMETRY

December 17, 1998



PREPARED BY THE SPECTRUM SELECTION WORKGROUP

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Julius Knapp	FCC (Liaison)

FINAL REPORT TO THE AMERICAN HOSPITAL ASSOCIATION TASKFORCE ON MEDICAL TELEMETRY
December 4, 1998

EXECUTIVE SUMMARY

The Spectrum Selection Workgroup was created in response to the potential for interference from digital television transmissions and private land mobile radio operations to patient-connected wireless monitoring. Changes in spectrum use for these two services have created uncertainty and concern to medical telemetry users. To address this concern, this Workgroup's mission was to:

- identify spectrum candidates for future medical telemetry use
- evaluate these candidates against objective criteria
- develop specific recommendations for the American Hospital Association (AHA), that will lead to the implementation of dedicated, exclusive spectrum for medical telemetry needs

Three frequency bands are being recommended for dedicated spectrum allocation for medical telemetry operations. These bands include:

- 608 MHz to 614 MHz (TV channel 37)
- 1385 MHz to 1390 MHz
- 1432 MHz to 1435 MHz

Medical telemetry operation should be considered as "primary" status on these bands, preventing incompatible transmissions from causing unacceptable interference to wireless patient monitoring systems.

These three frequency bands are in addition to present medical telemetry spectrum allocations under 47CFR Part 15 and Part 90 of the Federal Communications Commission (FCC) Rules. Within this frequency spectrum (174 MHz to 216 MHz - TV channels 7 through 13; 460 MHz to 470 MHz; 470 MHz to 668 MHz - TV channels 14 through 46), medical telemetry must still operate, but do so as a "secondary" status user, having to accept potential interference from, and to avoid creating interference to, "primary" status users.

The additional recommendations of this Workgroup are:

- New spectrum allocations for medical telemetry should permit the use of flexible communications technologies (e.g. spectrally efficient modulation schemes, telecommand, non-vital signs data, etc.).

- AHA should serve as a frequency administrator for the medical telemetry industry, and interface with the FCC to alert Hospitals and telemetry equipment manufacturers in advance of new "primary" status spectrum assigned medical telemetry frequencies.

- The AHA Taskforce on Medical Telemetry should file petitions before the FCC to implement these spectrum allocation recommendations.

The use models and technical assumptions documented within this report have attempted to respond to the clinical community's need for expanded deployment of interference-free medical telemetry, while also acknowledging the need to promulgate more spectrally efficient technologies to take advantage of the limited available spectrum. It is acknowledged there may be current or future products that indirectly may be considered "medical telemetry". Efforts have been made to consider the requirements of these communications technologies where possible. However, within the narrow view of addressing the current issue of potential interference from deployment of new broadcast television services and from other consumer and business-related communications devices, emphasis has been placed on patient-connected monitoring applications (real-time communications between the patient, his/her instrumentation, and a centralized monitoring/processing site) within the hospital or a dedicated healthcare facility.

Petitions to implement these recommendations must be promptly filed. To this extent, this Workgroup stands ready and committed to support the efforts of this process to its full completion. The uncertainty regarding the FCC regulatory status of medical telemetry has end-users and manufacturers alike greatly concerned. This uncertainty can be reduced by the submission of well crafted petitions to the FCC and its expedited review in the rulemaking process.

This Workgroup is very grateful to the AHA, FCC, Food and Drug Administration (FDA), National Telecommunications and Information Administration (NTIA), and the many other clinicians, professional societies, and other Workgroups which have contributed to our better understanding of telemetry monitoring and the challenges we all face within the next few years in this important delivery of healthcare information.

Finally, an expression of gratitude must be given to the organizations that employ the members of this Workgroup, without whose support this industry collaboration would not have been possible. The gravity of this issue has transcended corporate boundaries and speaks directly to the issue of public health and safety. In this regard, the spirit of cooperation has been exemplary.

FINAL REPORT TO THE AMERICAN HOSPITAL ASSOCIATION TASKFORCE ON MEDICAL TELEMETRY
December 4, 1998

1. GOALS FOR MEDICAL TELEMETRY SPECTRUM SELECTION

In attempting to consider spectrum candidates for medical telemetry use, this Workgroup assumed the following goals for guiding its deliberations:

- **Dedicated, interference-free, spectrum**

  Digital television (DTV) services in the VHF spectrum (174 MHz to 216 MHz), and the desired deployment of more spectrally efficient communications devices in the Private Land Mobile Radio portion of the UHF spectrum (450 MHz to 470 MHz) have created two threats to medical telemetry operations. The first threat is the demonstrated potential for disruption of medical telemetry patient monitoring in both frequency bands. The second threat is the limitation of telemetry monitoring growth due to medical telemetry's FCC regulatory status ("secondary") in these bands. There is insufficient spectrum for increases in telemetry channel growth as "primary" users extend their usage of a shared band.

- **Spectrum bandwidth to accommodate 1000 telemetry transmitters**

  The profile of telemetry patient monitoring is changing. While cardiac patients are still the largest segment of monitored patients in telemetry, more acute patients are being monitored, as are the supplemental devices (e.g. ventilators, infusion pumps, etc.) that support them. It has been observed that many hospitals currently have in excess of 300 patient-connected transmitting devices in use at one time. Initial surveys have indicated that within 10 years, medium to large hospitals will use 1000 patient-connected transmitting devices. With this increase in acute patient monitoring, other vital signs measurements, in addition to ECG, will be added to medical telemetry. Accordingly, this additional telemetered patient data will require suitable spectrum bandwidth for present and future patient populations. The mission critical nature of this increased patient data underscores the requirement that a spectrum candidate be dedicated, exclusive, and free of potential interference.

- **Flexible spectrum allocation to accommodate different applications**

  Clinical users will drive different applications for medical telemetry.

Hospitals will use technology to reduce risk to patients through more applicable and efficient monitoring, and to contain costs of healthcare delivery, while improving the quality of patient outcomes through better diagnostic and monitoring data. Any spectrum candidate for medical telemetry must therefore be flexible enough in its technical and FCC regulatory attributes to support, rather than limit, the different types of communications applications that can meet the end-user's goals.

- **Ease of transition to new spectrum for existing telemetry users**

  Some consulting firms have estimated the value of medical telemetry equipment installed in U. S. Hospitals to be in excess of $100 million. The ASHE survey of some 500 hospitals shows the median age of this equipment to be approximately 3.5 years; the mode is 1 year. Given a depreciation period of 10 years for this type of equipment, it is clear that transition to another frequency could be very costly to hospitals. The only way to avoid this cost is to extend the transition period of these new bands and choose the new bands in such a way as to allow some salvage of the hospital's basic investment.

2. TECHNICAL REQUIREMENTS FOR MEDICAL TELEMETRY SPECTRUM SELECTION

Five major technical requirements were established for use in selecting appropriate spectrum candidates. These requirements reflected the themes outlined in the goals above and provided a framework for comparing spectrum candidates.

- **Communications Reliability**

  The proposed spectrum must not have in-band or adjacent band users that create interference to medical telemetry operations. Medical telemetry monitoring is performed 24 hours a day, and cannot tolerate interference. Decisions, ranging from patient treatment choices to immediate care interventions, can be compromised by an unreliable communications link. The desired spectrum candidate must offer the expectation that the possibility of interference will be remote.

- **Spectrum Attributes**

  Spectrum attributes considered include the amount of available bandwidth, its contiguity, and the suitability to support multiple modulation and transmission schemes for spectral efficiency and frequency re-use. Further consideration was given to domestic and international allocation status.

- **Propagation Characteristics**

  The physical transmission path loss (the attenuation of the radiated telemetry signal through the air and the physical structures within the hospital) of the proposed spectrum candidate was evaluated relative to the current predicate medical telemetry bands. The noise floors (the level of other undesired signals from atmospheric, space, or man-made sources, from which the desired telemetry radio signal must be extracted by the telemetry receiver) and susceptibility to multi-path fading (the propagation properties of two or more electromagnetic waves from the same telemetry transmitter that interfere with each other to attenuate the desired signal at the telemetry receiver) were also reviewed. These characteristics have direct impact on recurring cost of ownership (e.g. battery costs) and initial installation and equipment costs (e.g. upgrade/migration feasibility, antenna system deployment, receiver complexity).

- **Safety Considerations**

  This requirement took into account the amount of RF radiated power that the patient, as well as other sensitive medical instrumentation would be exposed to. In general, the higher the operating frequency, the more radiated power is required to overcome additional path loss.

  Specifically, the Workgroup reviewed ANSI/IEEE C95.1-1992 for the maximum permissible partial body exposure allowed for an uncontrolled environment. In order for the proposed spectrum solution to meet this requirement, the energy that, in the transmitter in the proposed spectrum solution would need to radiate, must be lower than the C95.1 limit.

  The Workgroup also examined the potential for each of the proposed spectrum candidates to require telemetry products to generate field strengths in excess of 3 volts per meter (refer to the international electromagnetic susceptibility standard of EN60601-1-2). These fields could create possible electromagnetic interference to other medical devices.

- **Product Implementation Considerations**

  The final requirement is the availability of commercial RF components and low cost field support instrumentation. This is required to bring new product to market in a timely fashion, and to facilitate the site survey/installation process.

3. WORKGROUP INPUTS

The Spectrum Selection Workgroup obtained input from the liaison organizations (FCC, FDA, NTIA); informal discussions with members of the wireless local area network (LAN) and radio astronomy communities, and other Workgroups chartered by the AHA Taskforce.

- **Definition of Medical Telemetry**

Using the definition that "...wireless medical telemetry is the measurement and recording of physiological parameters and other patient-related information via radiated bi or unidirectional electromagnetic signals contained within a healthcare facility or extending beyond to other buildings and locations...", this workgroup focused the spectrum selection process on real-time communications between the patient, his/her instrumentation, and a centralized monitoring/processing site. Other communications devices (e.g. pagers, etc.) used within a healthcare facility not directly meeting this definition were not considered as part of this spectrum selection process.

- **Parameter Use Models**

The Clinical Parameters Workgroup developed a model for monitored parameter usage and duration by conducting a survey. The survey was administered to geographically dispersed hospital administrators, biomedical engineering directors, principal clinicians responsible for medical telemetry, and clinical professional organizations. Repeated below is a summary of the results from this survey.

CURRENT TELEMETRY MONITORING NEEDS	
Physiologic Parameter	**Concurrent Patients**
adult electrocardiogram	200 - 600
pulse oximetry	16 - 210
obstetrical (fetal/maternal) parameters	0 - 150
invasive pressures	17 - 420
respirations	4 - 210
12 sets of parametric data	up to 500 patients

Physiologic Parameter	Concurrent Use Model	Number of Concurrent Waveforms	Required Bandwidth
Electrocardiogram	500	3	4.000 MHz
Pulse oximetry	250	1	0.150 MHz
Obstetrical parameters	100	3	1.300 MHz
Invasive pressures	300	2	0.400 MHz

Respirations	100	1	0.025 MHz
12 sets of parametric data	500	0	0.250 MHz
TOTAL			**6.125 MHz**

This use model is based on the assumption of 500 concurrently operating telemetry transmitters today, and a 0.8 bit per second per Hertz spectral efficiency metric currently recommended by FCC (see 47CFR 90.203, Section 3). This results in a spectrum bandwith requirement of 6.1 MHz (note that nearly 10 MHz is in use today for 25 kHz channelized telemetry units in the UHF band, and approximately 12 MHz in use for 100 kHz channelized telemetry units in the VHF band). This amount of spectrum is expected to double to more than 12 MHz if one considers a growth in 5 to 10 years to 1000 telemetry transmitters. Thus, a potential spectrum band candidate must have at least 6 MHz in available bandwidth.

- **Spectrum Candidates**

  The following frequency bands (MHz) were considered for use for medical telemetry operations:

  - 174 - 216
  - 216 - 220
  - 328 - 335
  - 402 - 406
  - 450 - 470
  - 470 - 668
  - 608 - 614
  - 746 - 806
  - 902 - 908
  - 1385 - 1390
  - 1432 -1435
  - 2385 - 2390
  - 2390 - 2400
  - 3650 - 3700

4. EVALUATION OF SPECTRUM CANDIDATES

The attached spreadsheet below summarizes the evaluation on the final spectrum candidates. Earlier candidates were dismissed due to their potential for in-band/adjacent band interference; inadequate bandwidth; their current FCC regulatory status; undesirable path loss and power requirements; or limited merchant market support for off-the-shelf RF components.

Consideration	Issue Weight	Band in Question			
		608-614	608-614+	1385-1390	2385-2400
Cost					
Initial Cost	3	5.00	5.00	2.60	2.00
Equipment					
Installation					
Upgrade costs					
Cost of Ownership	5	5.00	5.00	3.40	1.00
Disposable cost (batteries, etc.)					
Licensing					
Cost of migration of any current users	3	4.20	3.67	2.20	1.50
Data Reliability					
Vulnerability to interference	5	4.60	3.67	4.20	3.50
Intentional					
Co-channel interference					
Unintentional Interference					
Level of noise floor					
Adjacent band					
Susceptibility to multi-path fading	5	3.80	4.33	3.00	2.00
Use Model Issues					
Size of transmitting device	3	4.20	3.67	4.60	3.50
Impact of transmitting frequency on human tissue/cells	5	4.60	4.33	4.00	1.67
Heat generation	5	5.00	7.50	3.00	3.50
Technical Considerations					
Bandwidth availability	5	2.60	4.33	1.80	4.50
How contiguous is the bandwidth?	3	4.20	3.67	3.80	5.00
Power consumption of transmitting device	5	5.00	5.00	3.40	1.00
Radio network topology (cellular or distributed) (less important)	1	4.60	4.33	3.80	3.00
Suitability of various modulation/transmission schemes (spread spectrum, GMSK, etc.) (less important)	3	4.20	3.67	3.80	4.00
Ease of site survey/infrastructure installation (less important)	1	4.20	3.67	3.00	2.50
Radiation efficiency	5	3.00	3.00	3.80	3.00
Applicability of "off-the-shelf" components (ease of implementation)	3	5.00	5.00	3.80	2.50
In-building transmission efficiency	3	5.00	5.00	4.20	2.00
Applicability of two-way communications	3	4.60	4.33	4.20	4.50
Ability to support latency requirements	5	4.60	4.33	4.60	4.00
Ability to support spectral reuse	5	3.40	2.33	3.80	5.00
Allowable ERP	3	4.33	4.33	3.00	1.67
Time to market	5	4.60	4.33	2.20	1.50
Regulatory Considerations					
Likely availability of band (strength of competition)	5	4.60	1.67	3.80	3.50
Current incompatible users of band	5	4.60	1.67	3.00	3.50

Extent of changes needed to FCC rules	3	4.60	3.00	3.00	2.50
Weighted Ranking		408.00	376.50	319.80	267.83
SMI Ranking		420	394	306	254
HP Ranking		344	322	234	252
MQ Ranking		422	376	316	266
VC Ranking		419	0	335	251
TCH Ranking		409	0	405	0

Comments on 608 - 614 MHz (TV 37):

- ◊ multiple component vendors available with off-the-shelf parts
- ◊ requires frequency coordination around radio astronomy facilities as defined in 47CFR 2.106 (US 311)
- ◊ telemetry can be compatible with radio astronomy
- ◊ currently authorized for medical telemetry by FCC 97-379
- ◊ band is not internationally harmonized
- ◊ estimated path loss is 6 dB greater than that at 470 MHz
- ◊ measured indoor path loss was 3 dB greater than that at 470 MHz
- ◊ spectrum surveys revealed low noise floors in Workgroup member locations

Comments on 608 - 614 + MHz (TV 14 to TV 46):

- ◊ similar characteristics to 608 MHz to 614 MHz
- ◊ medical telemetry already granted "secondary" status
- ◊ unused television channel spectrum near TV 37 may be available on a "secondary" status basis in regional areas where use of TV 37 bandwidth is exceeded or areas of the country where "radio quiet" zones exist and coordination for "primary" status may not be available
- ◊ unused TV channels in this band may be used by LPTV without notification

Comments on 1385 - 1390/1432-1435 MHz:

- ◊ multiple component vendors available with off-the-shelf parts
- ◊ band has geographic exclusion zones affecting AK, AL, AZ, CA, FL, ID, MD, NC, NM, NV, OH, UT, VA, WA (See NTIA web-site for Final Spectrum Reallocation Report, Appendix F of NTIA Special Publication 95-32)
- ◊ grandfathered radars shut off after 2008

- ◊ band is not allocated in Regions 1 (Europe, Africa) and 3 (Australia, East Asia)
- ◊ estimated path loss is 17 dB greater than that at 470 MHz
- ◊ spectrum surveys revealed low noise floors in Workgroup member locations

5. RECOMMENDATIONS

Given existing exclusion zones and frequency administration requirements around the two proposed dedicated candidate bands, and the prospect that growth for medical telemetry will need more than 12 MHz of spectrum once 1000 telemetry devices are required, the Spectrum Selection Workgroup makes the following recommendations:

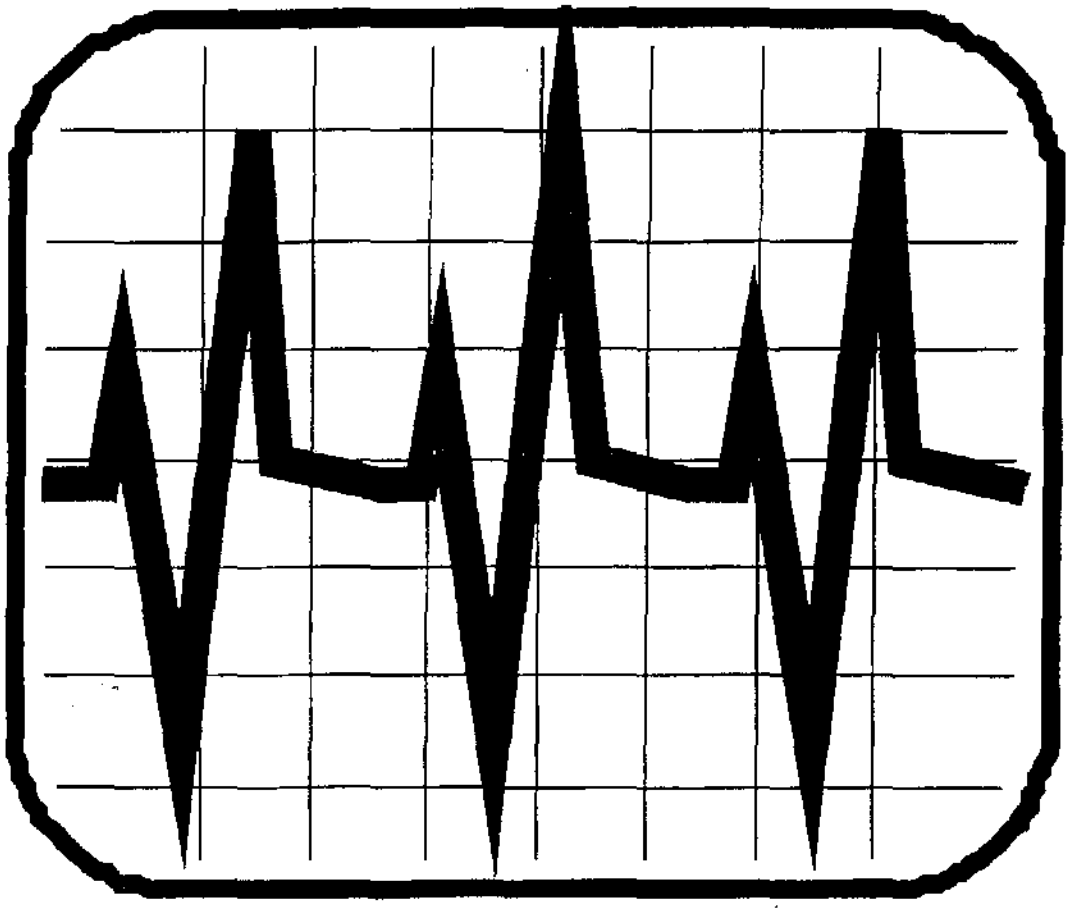
- Medical telemetry should seek "co-primary" status for the 608 - 614 MHz band (TV37), and "primary status" for 1385 - 1390 MHz/1432 - 1435 MHz band.

- Current Medical telemetry spectrum allocations (174 - 216 MHz/460 - 470 MHz/470 MHz - 668 MHz) should continue. Existing users of this equipment who are not at risk of interference from "primary" status users may still use these bands under existing rules.

- The American Hospital Association (AHA) should serve as the frequency administrator for the medical telemetry industry. In this capacity, AHA can speak for the Hospital users and their spectrum needs. Further, for those Hospital users whose spectrum needs exceed the bandwidth capacities of the above dedicated primary status bands, AHA can advise manufacturers and end-users on clear, "secondary" spectrum status, and alert end-users when these bands may be licensed by primary status users (such alerts will be necessary to permit these medical telemetry "secondary" users to gracefully relocate to other acceptable spectrum). This role is needed to give medical telemetry single point representation in spectrum allocation discussions and facilitate industry migration to the dedicated frequency bands.

- All new spectrum allocations for medical telemetry shall permit the use of flexible communications technologies, including, but not limited to, bi-directional transmissions (telecommand), spectrally efficient modulation schemes, and non-vital signs data (e.g. voice).

- The Spectrum Selection Workgroup strongly urges the AHA to retain legal counsel for purposes of promptly preparing and submitting petitions embodying the intent of these recommendations.



FINAL REPORT OF THE EDUCATION WORKGROUP

December 17, 1998

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The Education Workgroup's Mission: To educate the medical and/or health care community about EMI and how to minimize the risk to patients.

The education workgroup believes that the following initiatives could be implemented to educate the health care community about EMI:

- Health care Societies need to establish partnerships to share specialty information on areas that impact across the societies. In other words, although it is needed for health care engineers to present current information at society meetings, (ASHE, IEEE, AAMI, ACCE, etc.), it is necessary to present this information to the direct patient care and administration societies that would include physicians, nurses, hospital administrators, etc.

- AHA, ASHE, and ACC will establish lesson plans for health care institutions to assist them in the training of their employees on electromagnetic interference. This same information will be forwarded and nursing schools in an attempt to assist them in establishing the

appropriate curriculum for these learning institutions.

- AHA, ASHE, and ACC will establish an executive level Power Point Presentation on electromagnetic interference in order to further assist their members to manage the risk.

- The possibility of establishing video as well as interactive computer education on electromagnetic interference is also under consideration.

The education workgroup believes that the following suggestions could be implemented by hospitals and other health care facilities to increase the educational awareness of the health care institutional staff on Electromagnetic Interference:

- All new employees should receive an EMI briefing within the first 30 days of their employment to ensure awareness of the risks involved in this phenomenon.

- Briefings for users to include clinicians and the nursing staff should be conducted annually by the area supervisor to maintain awareness -- Documentation should be maintained by the supervisor to validate the employee's competency relating to EMI issues.

- Repair personnel should be trained on the proper equipment servicing to ensure EMC equipment integrity is maintained. Only subject matter experts should conduct training.

- Other ways to learn more about EMI is by using the following:

  Libraries
  Publications
  Professional Societies
  Internet

- The FDA has a World Wide Web page on EMI located at "http://www.fda.gov/cdrh/emc/" which is an outstanding educational tool.

- Even small libraries can be a wealth of information, many publications (e.g. Test & Measurement World, Evaluation Engineering, Wireless Systems Design, NASA Tech Briefs, etc.) can be used as sources. However, for more authoritative sources, professional Engineering Societies can be utilized (e.g. ASHE, ASME, IEEE, ACCE, AAMI, SPIE, etc.).

Education on Preventive Measures

The following is a list of possible preventive measures that can be taken:

- The use of cellular telephones, two way radios and all other portable radio frequency (RF) generating devices should be prohibited in patient equipment dependent locations (PEDL's). PEDL's are areas where interference induced equipment malfunctions (cardiac and apnea monitors, ventilators, infusion pumps, defibrillators and alarm systems) have the potential to cause serious injury or death to the patient.

- The use of RF transmitting devices should restricted from within 3 feet of any electronic medical devices. This is based on the eleven month risk assessment performed at Walter Reed Army Medical Center, which clearly indicated that interference from equipment within this range had the potential to sufficiently interfere with equipment operation.

- As outlined in a proposed Ad Hoc test procedure from the FDA's C-63 document, "Whether or not a medical device meets minimum electromagnetic immunity standards, assuring that the medical device is not exposed to ambient RF fields that exceed its radiated immunity, can help prevent interference problems. This can often be accomplished by maintaining physical separation between the medical device and RF transmitters. While the field strength to which a medical device is exposed can only be determined accurately by precise RF measurements, if the radiated immunity of a medical device and the peak effective radiated power of a transmitter are known, the distance to be maintained between them to help prevent interference, referred to as the "protection distance," can be estimated within approximately an order of magnitude".

- Other areas of possible restrictions are loading docks, emergency room driveways and any areas where the use of possible vehicular radios and phones could cause equipment degradation. Vehicles that may cause problems are delivery trucks, taxies, etc. that use high-powered radios or cellular devices for mobile communication. Consideration may be given to have pay phones available on loading docks to allow delivery personnel to contact their dispatcher without utilizing their wireless devices.

- All radio frequency producing electronic equipment ordered for use in the medical treatment facility should be approved by the medical equipment service and repair manager/supervisor to ensure that the equipment conforms to EMC standards and maintain the projected area of use for electromagnetic compatibility prior to the purchase order going to the contract office. The medical equipment service and repair manager/supervisor should be given the authority to restrict the type of equipment purchased in order to minimize the risk. Equipment purchased should conform to appropriate EMC standards. International Electromechanical Commission (IEC) standard 601-1-2 specifies a general immunity test level of 3 V/m. More specific EMC requirements may be specified in product-specific standards. Equipment that meets these standards can have a higher or lower immunity. Therefore, the medical equipment service and repair manager/supervisor should examine the EMC test report to determine the pass/fail criteria used and how the medical device performed during the test. Specifications and/or the SOW (Statement of Work) involving the procurement of new equipment should require manufacturers conformance to IEC 601-1-2.

- The medical equipment service and repair manager/supervisor should establish a methodology, possibly by the use of a data base program, to track NPF (No Problems Found) to determine the possibility of a an EMI causation. Equipment service personnel should report incidents of NPF to the medical equipment service and repair manager/supervisor.

- All equipment users and service personnel should follow the manufacturer's recommendations for avoiding electromagnetic interference as outlined in the appropriate literature.

- Equipment servicing personnel and contractors should ensure that shielding is not defeated or compromised during servicing. The use of manufacturers specified replacement parts; cover-plates, screws and hardware must be adhered. Short cuts such as leaving out part of cover plate-mounting screws and shielding off to allow rapid re-entry to the device internal components must be avoided.

- The biomedical equipment service and repair manager/supervisor for the medical treatment facility (hospital, medical center, etc.) should be responsible for the installation and servicing of all medical or non-medical equipment, communication systems, computers, LANS or any other potential RF emitting device that can be co-located near and around medical equipment.

- Rooftop RF transmitters found to disrupt the performance of medical devices within the facility should be removed.. If it is impossible or impractical to remove these sources, then shielding to windows and the facility should be considered if excessive equipment degradation is encountered.

- Users who may have witnessed EMI problems, incidents or anomalies that may have electromagnetic interference implications and should report them to the proper authorities. (i.e. Chief, Clinical Engineering, Biomedical Engineering, BMET, Risk Management or whomever is the appropriate biomedical equipment manager.)

- Health care employees who have a need for wireless communication should give consideration to using low powered cellular phones in lieu of walkie-talkies.

- Proper precautions should be taken for equipment on emergency power specifically during emergency power generator testing due to the fact that power surges and interruption can cause conductive EMI.

- Large hospitals of HMO might consider establishing an EMI Overwatch Committee reporting through the clinical staff to the Board of Governors or Medical Treatment Facility CEO.

- Preventative measures can range from the simple to the complex. Since many of the EMI problems are associated with the commercial electrical power distribution systems and since most electronic equipment is connected to commercial power systems the concern for power quality has increased by both providers and users of electric power. This problem has been aggravated as modern electronic systems incorporate embedded computers, microprocessors

and other complex solid state components. These devices operate at low energy levels and high speeds making the very susceptible to electrical power noise. However, at the same time they often contribute to the power noise levels in the system as well. The term power quality is commonly used within power utilities in regard to power related EMI problems. High quality indicates a lack of power line disturbances. Therefore, a power quality audit is important to know and understand as a baseline measurement.

- The primary purpose of a grounding system is the control of undesirable electrical currents, fault currents, electrostatic discharge currents, high frequency noise currents, etc. To improve the performance and reliability of the required electronic load equipment to acceptable levels, it is often sufficient to follow the National Electrical Code (NEC) safety requirements and nationally recognized engineering practices (e.g. ANSI. IEEE) and guidelines (e.g. (Federal Information Processing Standard (FIPS)) and correct obvious deficiencies in the AC power wiring and grounding configuration and correct poor wiring installation methods.

- Electromagnetic Shielding is the process whereby susceptible devices are encased in materials, usually metals to prevent stray RF from entering and interfering with the intended design of the device. In some instances, the rooms themselves are shielded that house a particular device from stray RF and also to prevent the device from interfering with other devices (e.g. MRI). This is usually designed by the manufacturer or the Biomedical Engineer to shield a component from stray RF (e.g. a TV monitor used in an MRI suite is being affected by the magnetic field, a properly designed box placed around the monitor can correct the situation).

Cooperation with other Agencies

a) Hospital Departments
b) Outside Agencies
c) Professional Societies

For total coverage in the hospital all departments must be on board as a source of information, information is a two way medium. Therefore your number one source of cooperation lies in your own institution. Outside agencies such as JCAHO, FDA, ECRI, etc. are also excellent sources of information and testing data. Again professional organizations such Engineering, Nursing and Medical societies are also avenues for assistance.

APPENDIX III

PROPOSED RULES

I. Part 2 of Title 47 of the Code of Federal Regulations is proposed to be amended as follows:

Part 2 - Frequency Allocations and Radio Treaty Matters; General Rules and Regulations

1. In Section 2.106, the Table of Frequency Allocations is amended by revising the entry for the 608-614 MHz band by adding the Wireless Medical Telemetry Service as co-primary and by revising the entries for the 1385-1390 MHz , and 1432-1435 MHz bands by adding the Wireless Medical Telemetry Service as co-primary.

II. Part 15 of Title 47 of the Code of Federal Regulations is proposed to be amended as follows:

Part 15 -

Section 15.242, subsection (a) is amended to read as follows:

§15.242 Operation in the bands 174-216 MHz and 470-668 MHz .

(a) The marketing and operation of intentional radiators under the provisions of this section is restricted to biomedical telemetry devices (i) for which either equipment authorization has been completed or, if applicable, an application for equipment authorization has been granted, and (ii) which is employed solely on the premises of health care facilities.

III. Part 90 of Title 47 of the Code of Federal Regulations is proposed to be amended as follows:

Part 90 -

Section 90.267(a)(5) is amended to read as follows:

§90.267 Assignment and use of frequencies in the 450-470 MHz band for low-power use.

(a) Any regularly assignable frequency in the 450-470 MHz band listed in the tables in Subparts B and C of this part may be designated by the frequency coordinators as a low-power channel in a defined geographic area. These channels are subject to the following conditions.

(5) A hospital or health care institution holding a license to operate a radio station under this part may operate a medical radio telemetry device with an output power not to exceed 20 milliwatts for which either equipment authorization has been completed or, if applicable, an application for equipment authorization has been granted. All licensees operating under this authority must comply with the requirements and limitations set forth in this section.

IV. [A new] Part __ of Title 47 of the Code of Federal Regulations is proposed as follows:

Part __ — Wireless Medical Telemetry Service

§ __.1 Scope. This part sets out the regulations for licensed Wireless Medical Telemetry Devices operating in the 608-614 MHz, 1385-1390 MHz , and 1432-1435 MHz frequency bands.

§ __.3 Definitions.

(a) Authorized health care professional. A physician or other individual authorized under state or federal law to provide health care services, or any health care facility operated by or employing individuals authorized under state or federal law to provide health care services, or any trained technician operating under the supervision and control of an individual or health care facility authorized under state or federal law to provide health care services.

(b) Health care facility. A health care facility includes hospitals and other establishments that offer services, facilities, and beds for use beyond 24 hours in rendering medical treatment and institutions and organizations regularly engaged in providing medical services through clinics, public health facilities, and similar establishments, including federal, state and local governmental entities and agencies for their own medical activities; but the term health care facility does not include an ambulance or other moving vehicle.

(c) Wireless medical telemetry transmitter. A transmitter which measures and records physiological parameters and other patient-related information via radiated bi or unidirectional electromagnetic signals in the 608-614 MHz , 1385-1390 MHz , and 1432-1435 MHz frequency bands.

§ __.5 Eligibility. Authorized health care professionals are permitted by rule to operate transmitters in the Wireless Medical Telemetry Service without an individual license issued by the FCC. Manufacturers of wireless medical telemetry devices and their representatives are authorized to operate wireless medical telemetry transmitters in this service solely for the purpose of developing and manufacturing such equipment for, demonstrating such equipment to, or installing and maintaining such equipment for, duly authorized health care professionals.

§ __.7 Authorized locations. The operation of a wireless medical telemetry transmitter under this Part is authorized anywhere within a health care facility. This authority does not extend to mobile vehicles, such as ambulances, even if those vehicles are associated with a health care facility.

§ __.9 Equipment authorization requirement.

(a) Wireless medical telemetry devices operating under this part be must be authorized under the Declaration of Conformity procedure prior to use or marketing, pursuant to the relevant sections in Part 2, Subpart J of this chapter. In addition to the requirements of § 2.1077 of this chapter, the manufacturer of a wireless medical telemetry device intended to operate under this Part must include in its Declaration of Conformity a statement that it will provide each user thereof with a compliance statement in accordance with §2.1077 and a Form __ [THE REGISTRATION FORM] that has been completed with at least the following information:

(1) the frequency range(s) used by the transmitter (for wideband devices) or the center frequency of the transmitter (for narrowband devices);
(2) the modulation scheme used; and
(3) the field strength or the effective radiated power of the device.
(4) the name and address the designated frequency coordinator for the Wireless Medical Telemetry Service.

(b) The following statement shall be placed in a prominent location in the instruction or user's manual furnished with the device, or, alternatively, shall be placed in at least __ point print on the container in which the device is marketed, or may appear on a label conspicuously placed on, and permanently affixed to, the device:

> Installation and operation of this equipment requires the prior registration with the frequency coordinator designated by the Federal Communications Commission for the Wireless Medical Telemetry Service.

§ __.11 Registration.

(a) Prior to operation, any authorized health care provider who desire to use a wireless medical telemetry device must first submit a registration form (FCC Form ___) with the frequency coordinator designated by the Federal Communications Commission for the Wireless Medical Telemetry Service. The registration form must contain the following information:

(1) frequency range(s) used (for wideband devices) or the center frequency of the transmitter (for narrowband devices);
(2) modulation scheme used;

(3) effective radiated power or field strength of the device;
(4) number of transmitters for which registration is being requested;
(5) legal name of the authorized health care provider;
(6) location of transmitter (coordinates, street address, building);
(7) point of contact for the authorized health care provider (name, title, office).

(b) An authorized health care provider shall notify the frequency coordinator by submitting FCC Form ___ whenever a medical telemetry device is permanently taken out of service, unless such device is replaced with another transmitter utilizing substantially the same technical characteristics as those reported on the effective registration. An authorized health care provider shall maintain the information contained in each registration current in all material respects, and shall notify the frequency coordinator when any change is made in the location or operating parameters previously reported which is material.

(c) The registration of wireless medical telemetry equipment shall be effective for a term of 5 years from the date of registration (which shall be the date on which the registration information is entered into the frequency coordinator's database). Any registration may be renewed for additional 5 year periods by submitting a FCC Form ___ with the frequency coordinator.

§ __.13 Frequency coordination.

(a) _____ is designated to coordinate the usage of the 608-614 MHz , 1385-1390 MHz, and 1432-1435 MHz bands for operation of medical telemetry devices.

(b) The frequency coordinator shall process registration forms submitted by authorized health care providers and maintain a central data base of all information submitted by authorized users which shall be available for public inspection at all reasonable business hours, and at any other time as the frequency coordinator may allow.

(c) It shall be the sole responsibility of each authorized user of a wireless medical telemetry device operating in the 608-614 MHz , 1385-1390 MHz and 1432-1435 MHz bands to determine by reference to the database maintained by the frequency coordinator for this service that there are no other licensed systems whose operations could affect, or could be affected by, the proposed wireless medical telemetry operations. To the extent that an authorized user determines by reference to the database maintained by the frequency coordinator for this service that other licensed systems will affect, or are likely to be affected by, the proposed wireless medical telemetry operations, such authorized user shall take reasonable steps to contact the operator of any such licensed systems, as identified in the database, and to resolve any anticipated interference problems with such licensed operator <u>before</u> initiating service on the proposed medical telemetry system.

(d) Any health care provider or health care facility that fails to register a wireless medical telemetry device operating in the 608-614 MHz, 1385-1390 MHz and 1432-1435 MHz bands in accordance with the provisions of this Section shall be responsible to take reasonable steps, and shall bear any costs or expenses, necessary to resolve any interference problems that may be created with any other licensed operator, even if the other operator initiated service on the proposed medical telemetry system after the non-registered system was already in operation.

§ __.15 General technical requirements.

(a) Power limits.

(1) In the 608-614 MHz band, the maximum allowable field strength is 370 mV per meter as measured at a distance of 3 meters, using a quasi-peak detector.

(2) In the 1385-1390 MHz and 1432-1435 MHz band, the maximum allowable field strength is 740 mV per meter as measured at a distance of 3 meters, using an averaging detector at a 1 MHz bandwidth.

(3) Field strength should be measured over the entire occupied bandwidth of the device.

(b) Limits on undesirable emissions.

(1) In the 608-614 MHz band, out-of-band transmissions are limited to 200 μV/m, as measured at a distance of 3 meters, using a quasi-peak detector. Manufacturers should note that a quasi-peak detector function indicates field strength per 120 kHz of bandwidth ± 20 kHz. Accordingly, the total signal level over the band operation may be higher than 200 μV/m.

(2) In the 1385-1390 MHz and 1432-1435 MHz band, out-of-band transmissions are limited to 500 μV/m as measured at a distance of 3 meters using an averaging detector at a 1 MHz bandwidth.

(c) Emission types. A wireless medical telemetry device may transmit any emission type appropriate for communications in this service.

(d) Channel use.

(1) In the 1385-1390 MHz and 1432-1435 MHz bands, no specific channels are specified. Wireless medical telemetry devices may operate on any channel within the bands authorized for wireless medical telemetry use in this part.

(2) In the 608-614 MHz band, wireless medical telemetry devices utilizing broadband technologies such as spread spectrum shall be capable of operating within one or more channels of 1.5 MHz each, up to a maximum of 6 MHz, and shall operate on the minimum number of such channels necessary to avoid harmful interference to any other wireless medical telemetry devices.

(3) Channel usage is on a co-primary shared basis only and channels will not be assigned for the exclusive use of any entity.

(4) Authorized health care professionals, in conjunction with the equipment manufacturers, must cooperate in the selection and use of frequencies in order to reduce the potential for interference with other wireless medical telemetry devices, or other co-primary users.

(e) Frequency stability. Manufacturers of wireless medical telemetry devices are responsible for ensuring frequency stability such that an emission is maintained within the band of operation under all of the manufacturer's specified conditions.

(f) Wireless medical telemetry devices are subject to the radiofrequency radiation exposure requirements specified in § § 1.1307(b), 2.1091, and 2.1093 of this chapter, as appropriate. All equipment shall be considered to operate in a "general population/uncontrolled" environment.

§ __.17 Type of communications.

(a) All types of communications are permitted, on both a unidirectional and bidirectional basis, including voice, data, video and telecommand, provided that all such communications are related to the provision of medical care.

(b) Operations that comply with the requirements of this part may be conducted under manual or automatic control, and on a continuous basis.

§ __.19 Specific requirements for wireless medical telemetry devices operating in the 608-614 MHz band. For a wireless medical telemetry device operating within the frequency range 608-614 MHz and that will be located within 32 km of the very long baseline array (VLBA) stations or within 80 km of any of the other radio astronomy observatories noted in footnote US 311 of § 2.106 of this chapter, operation is not permitted until the frequency coordinator specified in § __.11(a) has, upon receipt of a registration Form ____, coordinated with, and obtain the written concurrence of, the director of the affected radio astronomy observatory. Upon obtaining such concurrence, the frequency coordinator shall notify the end user that operation is permissible. The National Science Foundation point of contact for coordination is:

Spectrum Manager, Division of Astronomical Sciences, NSF Room 1045, 4201 Wilson Boulevard, Arlington, VA 22230; tel. no. (703) 306-1823.

§ __.21 Specific requirements for wireless medical telemetry devices operating in the 1385-1390 MHz and 1432-1435 MHz bands. Due to the critical nature of the communications transmitted under this part, no authorized user may operate a wireless medical telemetry device in the 1385-1390 MHz and 1432-1435 MHz bands unless it has first determined by reference to the database maintained by the frequency coordinator for this service that there are no federal government radar systems whose operations could affect, or could be affected by, the proposed wireless medical telemetry operations. It is the responsibility of each licensee to make such determination prior to operation.

APPENDIX IV

FREQUENCY COORDINATION IN THE WIRELESS MEDICAL TELEMETRY SERVICE

Consistent with the provisions of Section 332(b) of the Communications Act, the Commission has recognized the value of utilizing frequency coordinators for each radio service, group or pool of frequencies in the PLMR Service to check applications for completeness, accuracy and compliance with the applicable FCC rules; identify the most appropriate frequency for the operation of the respective transmitters; and make recommendations of such frequency to the FCC, which would review the materials and issue the license. Because the applicants for spectrum will typically receive a "protected service area" with their license, and therefore the application process has the potential to be adversarial in determining the availability of appropriate spectrum, a strong frequency coordination process is critical to spectrum management. Indeed, coordinators in the PLMR Service typically are called upon to assist the Commission in resolving post-licensing conflicts, and to provide a single, nationwide point of contact with the Commission for licensees in the services for which they are the coordinator.

For a number of reasons, the Task Force does not anticipate that users of Wireless Medical Telemetry devices will require such a strong, centralize coordination process. Rather, the Task Force believes that frequency coordination in the Wireless Medical Telemetry Service should be limited to the maintenance of a centralized database, with each user, aided by the manufacturer of the devices being operated by that user, responsible for determining in the first instance that its proposed operations will not create interference to other licensees already registered with the designated frequency coordinator. The Task Force believes that such a "register/database check/install" approach, managed through a centralized database management system, can be extremely effective in preventing interference to licensees in these bands, particularly in light of the very low powered transmissions that characterize the devices operating in this service. The goal of this unique coordination system would be to accommodate all reasonable uses of the available spectrum in a variety of closely-spaced health care facilities, while avoiding unacceptable interference to neighboring health care providers and/or other licensed services.

The frequency coordinator's key responsibility would be to maintain an accurate engineering database of "licensed" wireless medical telemetry transmitters, identified by number, location, emission type and output power. No user of a medical telemetry device operating in the Wireless Medical Telemetry Service could operate that device unless, and until, it had filed a registration with the frequency coordinator. Each user would be responsible for determining, in advance of installation, whether its new devices were likely to cause or be susceptible to interference from devices already registered in the coordination database; the Task Force is convinced that health care practitioners will be highly motivated by their desire to avoid interference to assure that this determination is made.

If, on review of the information in the database, interference was likely to occur from or to other registered devices, the proponent of the newly registered device would bear the responsibility of coordinating with existing users to avoid the interference. This may include the exchange of information between the proponent and existing licensees and associated manufacturers of methodologies and software for use in performing studies and engineering evaluations of potentially conflicting technologies, to assist in determining appropriate criteria to be applied in calculating the potential for interference at particular locations.

However, if interference occurred to any device that was not registered in advance with the frequency coordinator database, the operator of that device would have no protection from newly installed transmitters, and in fact would be required to resolve any interference problem at its own expense. The Task Force believes that this penalty will act as a significant deterrent to non-registration, as the failure to register would, in effect, lower the licensee's status to a "secondary" nature as to any subsequent installations within its area.

Consistent with the approach used with other land mobile frequency coordinators the frequency coordinator would be subject to certain rules for the processing of registrations, to assure that all health care facilities and providers were able to obtain non-discriminatory service at fair and reasonable fees. In this regard, the Task Force believes that any fees charged by the frequency coordinator must be subject to review by the Commission upon any complaint that suggests that the fees do not reasonably reflect the cost of providing the services envisioned for the frequency coordinator.

The Task Force recognizes that establishing a frequency coordinator to perform even the limited database management functions contemplated herein could implicate the Federal Advisory Committee Act (FACA). However, the statute by which Congress authorized the Commission to use frequency coordinators in the private mobile and fixed services area provides that "[a]ny advisory coordinating committee which furnishes assistance to the Commission under this subsection shall not be subject to the provisions of the FACA." We believe that the proposed frequency coordinator falls squarely under the provisions of this statute, and it should be clearly created pursuant to Section 332(b) to avoid any inference to the contrary.

APPENDIX B

May 31, 2000

EX PARTE

Magalie R. Salas, Secretary
Federal Communications Commission
The Portals Building
445 12th Street, SW TW-A325
Washington, D.C. 20554

JUN 1 2000

Re: ET Docket 99-255

Dear Ms. Salas:

In the Notice of Proposed Rulemaking ("NPRM") in the above-referenced proceeding, the Commission has proposed to allocate spectrum, including a portion of the 1427-1432 MHz band, to a Wireless Medical Telemetry Service ("WMTS"). In a separate proceeding (RM-9854), Itron, Inc. ("Itron") has filed a Petition for Rulemaking requesting that the Commission allocate the 1427-1432 MHz band for automatic meter reading and utility telemetry operations.

As a result of the potential for conflict between these two proposals, discussions have been held between manufacturers representing members of the American Hospital Association ("AHA") Task Force on Medical Telemetry and the medical telemetry community, and Itron, representing the critical infrastructure industries ("CII"). The purpose of these meetings has been to develop a framework by which WMTS and CII could utilize the entire 1427-1432 MHz band on a co-primary basis, thereby increasing the efficient use of the band for both types of service. Although final technical details of such an arrangement still must be explored, the parties are optimistic that a basis for such sharing can be developed. Indeed, both parties recognize the benefits of sharing a band with licensees with generally compatible approaches, rather than facing potentially debilitating interference from some of the less compatible radio services and uses that have also been proposed for this frequency band.

Accordingly, and having no desire to forestall action in the WMTS proceeding, the undersigned support the following actions by the Commission:

- Proceed expeditiously to issue a Report and Order allocating spectrum, including a portion of the 1427-1432 MHz band, to WMTS on a primary basis.
- State in that Report and Order the optimism of the medical telemetry community and CII that a technical and administrative basis for sharing the 1427-1432 MHz band on a co-primary basis can be developed, and state a commitment to issue

expeditiously a Further Notice of Proposed Rulemaking in the docket soliciting comments concerning such a sharing arrangement.

- Act expeditiously to adopt a Second Report and Order implementing the co-primary status of both types of uses in the entire 1427-1432 MHz band with an appropriate sharing arrangement between WMTS and CII uses.

Questions with respect to this filing should be directed to the undersigned.

Respectfully,

AMERICAN HOSPITAL ASSOCIATION

By: Mary Beth Savary Taylor

Mary Beth Savary Taylor
Director, Executive Branch Relations
American Hospital Association
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ITRON, INC.

By: Russell N. Fairbanks, Jr.

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APPENDIX C

JOINT STATEMENT OF POSITION BY THE
AMERICAN HOSPITAL ASSOCIATION
TASK FORCE ON MEDICAL TELEMETRY AND ITRON, INC.

I. This Joint Statement of Position expresses the intent of the undersigned parties to adopt a sharing plan for the assignment of licenses in the 1427-1432 MHz band, to present the plan to the Federal Communications Commission ("FCC") , to propose the adoption of this band sharing plan and its codification into regulations by the FCC in ET Docket No. 00-221, and to take additional actions in furtherance of such plan.

II. The parties to this Joint Statement of position are the American Hospital Association Task Force on Medical Telemetry ("AHA Task Force") acting in the interests of users and manufacturers of medical telemetry devices and systems and Itron, Inc. ("Itron") acting in the interests of users and manufacturers of utility telemetering devices and networks in the electric, gas, and water utility industries.

III. Itron and several electric and gas utilities presently hold licenses to operate on a secondary basis in the 1427-1432 MHz band to provide utility telemetry, including automated meter reading ("AMR"). The FCC has allocated the 1429-1432 MHz band on a primary basis to the Wireless Medical Telemetry Service ("WMTS").

IV. The FCC has issued a Notice of Proposed Rulemaking in ET Docket No. 00-221 (the "NPRM") seeking comment on alternative allocation proposals for the 1427-1432 MHz band. The parties have determined that it serves the parties whose interests they represent for the FCC to allocate the 1427-1432 MHz band exclusively for "Utility Telemetry", being AMR and other utility industry telemetry use on the one hand, and for WMTS use, on the other, with priority of use and technical characteristics set forth below. Therefore:

A. The parties agree that each will propose in its filings regarding the NPRM, and cooperate to support during the course of the proceeding in Docket 00-221, that the 1427-1432 MHz band will be allocated to WMTS and Utility Telemetry on a co-primary basis *vis-à-vis* other uses. The parties further will propose that the FCC codify into the FCC rules the Frequency Management Plan, setting forth the primary and secondary status of WMTS and Utility Telemetry *vis-à-vis* one another throughout the United States, and the technical characteristics that will govern such use, all as set forth below.

B. Frequency Management Plan:

1. Except as set out in subsection B.3. below, licensees for Utility Telemetry will have primary status in 1429.5-1432 MHz ("Utility Band"). Licensees for WMTS may operate in this band only on a secondary, non-interference basis to Utility Telemetry.

2. Except as set out in subsection B.3. below, licensees for WMTS will have primary status in 1427-1429.5 MHz ("WMTS Band"). Licensees for Utility Telemetry may operate in this band only on a secondary, non-interference basis to WMTS.

3. Notwithstanding the frequency designations set out above, in the following geographic areas ("Utility Defined Areas"), in each of which Utility Telemetry have systems operating on or before February 1, 2001, the Utility Band will be the bands 1427-1429 MHz and 1431.5-1432 MHz and the WMTS band will be the band 1429-1431.5 MHz:

    a. Areas in which Utility Telemetry systems will continue to use the 1427-1429 band indefinitely:

        i. Pittsburgh, Pennsylvania market (Westmoreland, Washington, Beaver, Allegheny, and Butler counties)

        ii. Springfield, Virginia market (Montgomery, Prince William, Fairfax, Prince George's, and Charles counties, Alexandria City, District of Columbia)

        iii. Richmond, Virginia market (Goochland, Powhatan, Hanover, and Henrico counties, Richmond City)

        iv. Norfolk, Virginia market (Hampton City, Virginia Beach City, Chesapeake City, Portsmouth City, and Suffolk City)

        v. Austin and Georgetown, Texas market (Williamson and Travis counties)

        vi. Battle Creek, Michigan market (Calhoun County)

        vii. Detroit, Michigan market (Oakland county)

        viii. Spokane, Washington market (Spokane county)

b. Areas in which Utility Telemetry Systems will continue to use the 1427-1429 band on a primary basis until February 1, 2006. Such systems may not expand outside of the designated areas or add channels or frequencies. During this period, licensees for WMTS may operate in this band on a secondary, non-interference basis to such Utility Telemetry Systems, subject to the provisions described in subsection B.4 below. After February 1, 2006, such Utility Telemetry Systems shall be treated as secondary users in the WMTS Band, subject to the provisions described in subsection B.4 below, and WMTS licensees shall be treated as primary:[1]

i. Baltimore, MD.

Base Station A located at 39.308731N, -76.564498W, 139' above the ground, with 1 watt EIRP; service area #1 is a one mile radius centered around 39.2934N -76.5756W; service area #2 is a one mile radius centered around 39.3268N -76.5497W.

Base Station B located at 39.336944N -76.733333W, 284' above the ground, with 1 watt EIRP; service area is a one a one mile radius centered around 39.2969N -76.7391W.

ii. Santa Ana, CA.

Base Station located at 33.706669N - 117.789068W, 125' above the ground, with 1 watt EIRP; service area is a one mile radius centered around 33.69187N - 117.78234W.

iii. Long Island, N.Y.

Base Station located at 40.608778N - 73.762433W, 150' above the ground with 1 watt EIRP, service area is a one mile radius centered around 40.60249N - 73.76198W.

4. Co-channel use of the Utility Band by WMTS Licensees and co-channel use of the WMTS Band by Utility Telemetry Licensees will be permitted on a secondary, non-interference basis to any existing or future primary licensee of that band, as follows:

   a. The co-channel users must be located at a sufficient distance apart to maintain a field strength of < 150uV/m, H and V,

[1] Within 90 days of the date of execution of this joint statement of position, Itron will provide a list of the exact frequencies used in these Utility Telemetry Systems.

measured over any 1 MHz with an averaging detector as measured at the interfered site.

b. In the event of any dispute between the primary and secondary users, such dispute shall be resolved by reference to an industry-standard propagation study conducted at the expense of the secondary user and approved by the frequency coordinator/manager specified in Section III.C. below.

5. The maximum transmitter output power for Utility Telemetry shall be no greater than 1 watt EIRP in the 1429.5-1430.5 MHz band, no greater than 10 watts EIRP in the 1430.5-1431.5 MHz band, and no greater than 100 watts EIRP in the 1431.5-1432 MHz band, *provided, however,* that in the Utility Defined Areas set out above, the maximum transmitter output power for Utility Telemetry shall be no greater than 100 watts EIRP in the 1427-1428 MHz band, 10 watts in the 1428- 1428.5 band, 1 watt in the 1428.5-1429 MHz band, and 10 watts in the 1431.5-1432 MHz band. The maximum transmitter output power (expressed in field strength) for WMTS shall be not greater than those limits specified in Part 95 of the FCC rules 740mV/m at 3 meters over 1 MHz (160mW EIRP). The maximum level of "out-of-band" emissions between Utility Telemetry use and WMTS use and between WMTS use and Utility Telemetry use shall be no greater than 150uV/m, H and V, measured over any 1 MHz with an averaging detector as measured at the interference site.

C .In accordance with the Frequency Management Plan set forth in Section B above, specific assignments in the Utility Band will be subject to prior frequency coordination by the designated Utility Telemetry frequency coordinator. Registration of licensed WMTS users in the WMTS Band into the frequency coordination database for the WMTS will be implemented through the American Society of Health Care Engineers ("ASHCE"). Secondary uses of the bands must be coordinated/registered with the appropriate frequency coordinator/manager prior to installation and operation. The parties shall urge the Commission to require ASHCE and the utility coordinator to provide access to each others data bases and to encourage communication and cooperation between them in carrying out their duties.

D. The parties agree to cooperate in proposing this band plan to the FCC and to take such additional actions as may be reasonably necessary in connection with seeking FCC adoption and codification of the band plan and frequency management plan described above, and to take such other action as shall not

prejudice either party's ability to retain the primary rights to at least 2.5 MHz of spectrum in the 1427-1432 MHz band. Neither party will seek to implement other sharing of these channels with users and for uses not contemplated in this joint statement of position, without discussing it with the other party and giving such party the opportunity to participate fully in such discussions. . The parties agree to negotiate in good faith concerning any additional terms that may be required to implement the understandings in this joint statement of position.

E. This joint statement of position may be executed in multiple counterparts. Each counterpart shall be deemed an original, and collectively the counterparts shall constitute a single instrument

IN WITNESS WHEREOF, the parties have executed this joint statement of position as of this 8th day of March, 2001.

Itron, Inc.

By: /s/ Russ Fairbanks
Russ Fairbanks
Vice President & General Counsel

American Hospital Association
Task Force on Medical Telemetry

By: /s/ Mary Beth Savary Taylor
Mary Beth Savary Taylor
Director
Executive Branch Relations