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September 16, 1999

Ms. Magalie Salas
Secretary
Federal Communications Commission
445 12th Street, S.W.
Washington, D.C. 20554

Re: ET Docket 99-255, Amendment of Parts 2 and 95 of the Commission's Rules to Create a Wireless Medical Telemetry Service

Dear Ms. Salas:

Transmitted herewith, on behalf of GE Marquette Medical Systems, Inc., are an original and nine copies of the "Comments of GE Marquette Medical Systems, Inc." submitted in the above-referenced rule making proceeding.

Under separate cover, a diskette copy of these comments is being submitted to Mr. Hugh L. Van Tuyl, Office of Engineering and Technology, FCC.

In the event there are any questions concerning this matter, please contact the undersigned.

Very truly yours,

Arthur B. Goodkind

Enclosure

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Before The
Federal Communications Commission
Washington, D.C. 20554

In the Matter of	)	ET Docket 99-255
	)	
Amendment of Parts 2 and 95	)	
of the Commission's Rules to	)	
Create a Wireless Medical	)	
Telemetry Service	)	

To: The Commission

COMMENTS OF GE MARQUETTE MEDICAL SYSTEMS, INC.

Arthur B. Goodkind
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September 16, 1999

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SUMMARY

GE Marquette Medical Systems, Inc. ("GE Marquette"), which is a leading manufacturer of medical telemetry equipment, strongly supports the Commission's proposal to establish a new Part 95 Medical Telemetry Service and to allocate Channel 37 and 1.4 GHz band frequencies for primary or co-primary medical telemetry use. GE Marquette also supports the Commission's proposal to establish a frequency coordinator for the new service.

The proposed primary frequency allocations for medical telemetry are highly desirable and will clearly be the first choice for future medical telemetry uses. It will not be possible or practical to utilize the primary frequencies in all cases, however, and the primary frequencies may also not be sufficient to meet all future demands for medical telemetry equipment by large health care facilities.

Accordingly, GE Marquette urges the Commission to continue to permit, without end date, the certification, manufacture, marketing and use of dual-capacity medical telemetry equipment capable of operating in at least one of the primary Part 95 frequency bands and, under Part 15 regulations, on some or all of

the Channel 7-46 frequencies presently used under Part 15. As explained in these comments, the concentration of most new medical telemetry uses in the Part 95 frequencies and the establishment of a new medical telemetry database by the frequency coordinator will essentially eliminate the possibility of future frequency conflicts between medical telemetry and television uses.

Before the
Federal Communications Commission
Washington, D.C. 20554

In the Matter of	)	ET Docket 99-255
	)	
Amendment of Parts 2 and 95 of the Commission's Rules to Create a Wireless Medical Telemetry Service	)	

To: The Commission

COMMENTS OF GE MARQUETTE MEDICAL SYSTEMS, INC.

GE Marquette Medical Systems, Inc. ("GE Marquette"), files herewith, by its attorneys, its Comments in response to the Commission's Notice of Proposed Rule Making ("NPRM") released July 16, 1999 in the above-captioned matter.

As set forth below, GE Marquette strongly supports the Commission's proposal to allot specific frequencies on a primary or co-primary basis for use by medical telemetry devices. GE Marquette urges, however, that the Commission also provide for instances in which the new primary frequencies may not be usable or may not afford sufficient capacity by continuing to approve dual-capacity medical telemetry devices that will be capable of operating both on the new primary frequencies under proposed Part 95 of the Rules and on other frequencies under the provisions of Part 15 of the Rules.

INTRODUCTION AND STATEMENT OF POSITION

GE Marquette is a leading developer, manufacturer and distributor of medical telemetry devices. Its medical telemetry equipment is presently in use in a very large number of hospitals and other health care facilities throughout the United States. A more complete description of some of the services provided by GE Marquette's telemetry devices is provided in the materials appended as Attachment A to these Comments. Over the past five years, the use of GE Marquette's devices and similar equipment produced by GE Marquette's competitors has increased dramatically.

The beneficiaries of medical telemetry devices have been patients. Medical telemetry permits continuous monitoring of various physiologic functions, such as heart rate, blood pressure, pulse oximetry, etc., as well as of the functioning of medical equipment connected to patients. Medical telemetry permits rapid medical intervention where indicated by the monitoring system and, of least equal importance, permits patients to get up and move about free of the need to be attached to the wires necessary for systems not employing wireless technology. The ability to achieve early patient ambulation has increasingly been recognized as an important factor in the

recovery process. Finally, the use of medical telemetry devices reduces staffing requirements and thereby helps reduce the cost of health care.

GE Marquette participated as a member of the American Hospital Association Task Force on Medical Telemetry (the "AHA Taskforce") and joined in its recommendations submitted to the FCC earlier this year.[1] The Commission has responded positively to that report by initiating this proceeding and GE Marquette applauds that action. More specifically, GE Marquette supports all of the affirmative proposals in the NPRM, including the following:

(1) The allotment of 608-614 MHZ for wireless medical telemetry use on a primary basis, subject to non-interference to radio astronomy.

(2) The allotment of additional primary frequency space for wireless medical telemetry in the 1.4 GHz band.

(3) The establishment of a new Part 95 of the Rules to govern operations of medical telemetry devices operating on the

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[1] Report of the American Hospital Association Taskforce on Medical Telemetry, April 15, 1999. The Commission has made the AHA Taskforce Report part of the record in this proceeding.

primary medical telemetry frequencies, as well as the eligibility, technical and other service rules proposed in the NPRM for the new Part 95. GE Marquette specifically supports the power limitation proposed in the NPRM for medical telemetry operations on Channel 37 frequencies.[2]

(4) The proposal to establish a frequency coordinator for wireless medical telemetry uses.

Notwithstanding its general support for the NPRM's proposals, GE Marquette urges modification of those proposals in two respects:

(1) We agree with the NPRM's proposals that Part 15 medical telemetry equipment certified prior to a cut-off date (proposed to be two years after the effective date of the new rules) may

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[2] GE Marquette's experience has been that a properly designed medical telemetry system operating with the power limit presently permitted in the Channel 7-46 frequency range (which is the same limit proposed for Channel 37 under new Part 95) permits highly reliable data links without unnecessarily increasing the cost of the system. Use of higher power would further limit use of Channel 37 in the vicinity of radio astronomy sites and would increase the possibility of mutual interference between different medical telemetry systems using Channel 37. GE Marquette also believes that further studies should be undertaken to establish that higher power levels can be used without compromising patient safety, in view of the fact that the radiating element in a medical telemetry device is frequently in direct contact with a patient's body.

continue to be manufactured, marketed and used indefinitely, and that "permissive changes" in such equipment may continue to be made consistent with the provisions of Section 2.1043(b) of the Rules. However, GE Marquette opposes the further suggestion in the NPRM that a cut-off date might be established after which the manufacture or importation of such pre-certified equipment would be prohibited.

(2) The Commission should continue to authorize, without future end date, any new dual-capacity medical telemetry equipment that will utilize one or both of the primary medical telemetry frequencies allotted through this rule making and which is also able to utilize all or some of the channel 7 - 46 frequencies presently available under Part 15.

GE Marquette's comments that follow are limited to the modifications it suggests in the Commission's proposals.[3]

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[3] GE Marquette is familiar with the separate Comments being filed in this proceeding by the AHA Taskforce. GE Marquette concurs with those Comments with the single exception of the Taskforce's support for higher permissible power on Channel 37.

We note that the AHA's Comments also include recommendations with respect to both Part 15 and Part 90 medical telemetry devices that are similar to those being made here by GE Marquette with respect to Part 15 devices operating in the Channel 7-46 range. GE Marquette has no different view with respect to other Part 15 and Part 90 medical telemetry devices, but focuses its comments here on Part 15 devices in the channel 7-46 range

(continued...)

I. ALTHOUGH ALLOTMENT OF THE NEW PRIMARY FREQUENCIES IS HIGHLY DESIRABLE, SUCH FREQUENCIES WILL NOT BE ADEQUATE TO FILL MEDICAL TELEMETRY NEEDS IN ALL CASES.

A. Channel 37 Frequencies Cannot Meet The Needs of All Health Care Providers.

Channel 37, 608-614 MHZ, is already authorized for use under Part 15 of the Rules. Because equipment has been developed for use in that frequency range, Channel 37 will almost certainly be the first Part 95 UHF frequency utilized by the suppliers of medical telemetry equipment. Since Channel 37 is to be allotted on a primary basis (subject only to non-interference with radio astronomy), it will also be an obvious initial choice for health care administrators in areas in which its use is feasible.

Use of Channel 37 will nonetheless be subject to a number of limitations. First, as specified in proposed Section 95.1119 of the Rules, Channel 37 frequencies cannot be used in the vicinity of a number of radio astronomy observatories. Second, use of some of the frequencies will also be curtailed in some areas by television stations broadcasting on adjacent channels 36 and 38. Third, the number of patients at a single health care facility that can be served using Channel 37 frequencies is limited.

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[3](...continued)
because its own experience has been primarily with such devices.

Given typical state-of-the-art channelization formats presently utilized or contemplated and the number of parameters typically monitored per patient, the number of patients per location capable of being monitored using Channel 37 frequencies will be far lower than the 600 patients referred to in the NPRM as possibly requiring concurrent monitoring at some locations.[4]

More efficient frequency utilization architectures will likely be developed in the future. The timing of such developments is at best uncertain, however, and the increased capacities thus made available are also likely to be used at least in part to monitor both a greater number of parameters per patient and to monitor more comprehensively some parameters being monitored today.[5] These factors will therefore limit any future increase in the number of patients per location that can be served using Channel 37.

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[4] NPRM, at paragraph 12, referring to a prior AHA survey. In its present Comments, the AHA Taskforce refers to further survey results indicating that within ten years medium to large hospitals will use an average of 1000 patient-connected transmitting devices.

[5] New parameters not generally monitored now by telemetry may include those such as respiration and temperature. More comprehensive monitoring of existing parameters may include, for example, an increase in the number of ECG vectors monitored.

Third, different medical telemetry manufacturers will likely utilize different channelization or spread spectrum schemes for Channel 37 telemetry devices. The use of different modulation schemes and/or incompatible communications protocols may make the coexistence of medical telemetry devices of different suppliers impossible at a given location. And finally, in large urban areas with multiple health care facilities in relative close proximity, use of the same Channel 37 frequencies may not be possible at adjacent facilities.

In sum, the allotment of Channel 37 for co-primary medical telemetry use is an extremely desirable step, but Channel 37 frequencies alone will not be adequate to address all medical telemetry needs in all cases.

B. The Allotment of 1.4 GHz band Frequencies for Primary Medical Telemetry Use is Also a Desirable Step, But Medical Telemetry Use of Such Frequencies Is Unlikely to Be a Practical Alternative at Many Locations For Many Years.

GE Marquette strongly supports the Commission's proposal to carve out a dedicated 1.4 GHz band frequency allotment for medical telemetry in addition to the allotment of Channel 37 frequencies. The 1.4 GHz band frequency proposal is, however,

also subject to various factors that may limit the use of such frequencies for a number of years.

First, there continues to be uncertainty as to whether the specific 1.4 GHz band frequency allotments proposed in the NPRM will be made. Pending legislation before Congress affecting the allotment of frequencies in the 1385-1390 MHZ range[6] and the demands of other frequency users should such legislation become law could result in further delays in making a final allocation of 1.4 GHz band frequencies to medical telemetry. Until such time as the allotment of specific frequencies in the 1.4 GHz band to medical telemetry appears to be assured, the manufacturers of medical telemetry equipment are unlikely to undertake the expensive design and developmental work necessary to produce equipment operating on those frequencies.

Second, even if the 1.4 GHz band allotment issue is promptly settled, the development, testing, FDA approval process and marketing of devices using 1.4 GHz band frequencies will almost certainly take substantially longer than two years, as indicated by the AHA Taskforce in its April 1999 report. The pace at which such equipment will be placed into operation will also be slowed by the budgeting and acquisition process of health care

[6] See concurrently filed comments of the AHA .

administrators. Apart from the delays inherent in any administrative equipment acquisition process, particularly where newly developed equipment is involved, 1.4 GHz band equipment is likely to be more expensive to acquire and to operate, at least during its early years, owing to amortization of equipment development costs and higher battery costs anticipated for operation in the 1.4 GHz band.

Third, some of the 1.4 GHz band channels will continue to be used by government military tracking radars until as late as the year 2009, making such frequencies unusable for medical telemetry purposes at locations near those specified in footnotes USyyy and Uszzz of proposed Section 2.106 of the Rules.

There will thus be instances in which the specific Channel 37 and 1.4 GHz band frequencies proposed for primary or co-primary medical telemetry use will either not be available for such use or may not be practical to use. The future demand for medical telemetry equipment may also exceed currently accepted projections as health care facilities, under continually increasing pressure to contain costs, turn to telemetry as the most cost-effective means of patient monitoring. Given the critical nature of the service provided by medical telemetry, the Commission should therefore modify its proposals as suggested

below to insure that there will continue to be sufficient medical telemetry frequency capacity.

II. THE COMMISSION SHOULD CONTINUE TO PERMIT MEDICAL TELEMETRY USES UNDER PART 15 TO ACCOMMODATE CASES IN WHICH USE OF PRIMARY MEDICAL TELEMETRY FREQUENCIES IS IMPOSSIBLE OR IMPRACTICAL.

There are strong public interest reasons for permitting the authorization, manufacture, marketing and use of dual-capacity telemetry equipment capable of operating in at least one of the primary Part 95 frequency bands and, on a secondary basis, on some or all of the Channel 7-46 frequencies presently used under Part 15.

As set forth above, operation of medical telemetry devices on frequencies designated for primary medical telemetry use may be impossible or impractical in a significant number of cases. On the other hand, equipment capable of operating on Channel 37 and other Channels in the 7-46 range has been developed and is in current use under the existing rules. Indeed, the development of such equipment was further encouraged and stimulated by the Commission's 1997 action enlarging the number of UHF channels available for Part 15 wireless medical telemetry use to include channel 30-46 frequencies for the first time.

Under the new rules now proposed, such equipment capable of operating on Channel 37 should be able to obtain certification for operation on Channel 37 as a Part 95 device. Upon Part 95 certification, health care facilities using such equipment would then operate under a blanket, primary license for Channel 37, subject only to non-interference to radio astronomy, making Channel 37 a likely initial first choice when its use is practical. For similar reasons, 1.4 GHz band frequencies allocated on a primary basis for medical telemetry would also become a primary choice at such point in the future as 1.4 GHz band equipment becomes available and in cases in which operation on 1.4 GHz frequencies is possible and practical.

For cases in which use of the primary medical telemetry frequencies is not possible or practical or in which still additional capacity is required, there is no reason not to permit continued Part 15 use of other frequencies in the Channel 7-46 range. Given the extremely low operating power of medical telemetry devices, there is little possibility of significant interference from wireless medical telemetry to reception of television stations, LPTV stations or TV translators. The problem that precludes use of many such frequencies for medical telemetry at any given location is instead the interference that would be received from television stations operating on such

frequencies. But in the limited number of instances in which Channel 7-46 medical telemetry uses will be necessary, that problem is fully manageable.

Any responsible supplier of medical telemetry equipment such as GE Marquette customarily undertakes an advance channel use and channel allotment study as well as on-site monitoring at the location of a proposed installation to determine whether any television signals exist or are proposed for future operation (including DTV allotments) that would create a frequency conflict with the proposed medical telemetry system. Television operations are fixed uses and the interference they cause or would cause is thus constant and predictable. No medical telemetry system involving a known frequency conflict with a television use will in the future be installed by a responsible manufacturer or purchased by a responsible health care provider. It has been GE Marquette's experience thus far that there have always been non-conflicting frequencies in the Channel 7-46 range that are available for use at the sites of its proposed installations.

Possible future conflicts will be limited to those that could occur upon the activation of the relatively limited number of new television stations commencing operation on channels <u>not</u>

now included in the NTSC or DTV Tables of Allotment (i.e., channels allotted through future rule makings) or upon the activation of new or changed LPTV or television translator stations. Owing to their much lower authorized power, LPTV and translator conflicts involve relatively small geographic areas. Such conflicts may be avoided with respect to full service television stations simply by continuing the same notification procedures the Commission has already established for new DTV stations prior to their commencing operation -- notification procedures that must be continued in any event to preclude conflicts with the large existing installed base of medical telemetry facilities already operating under Part 15 on Channels 7-46. In such cases, GE Marquette has found that the retuning of medical frequency devices to a non-conflicting frequency is not difficult to accomplish.[7]

GE Marquette does urge, however, that the Commission's notification requirements be extended (for appropriately smaller geographic areas) to new or changed LPTV and television translator stations. To assure that the permittees of such stations have access to information concerning the location of health care facilities using medical telemetry devices, GE

[7] GE Marquette's equipment is frequency agile and easily tunable.

Marquette concurs with the AHA's recommendations that (a) existing Part 15 and Part 90 medical telemetry users be encouraged to register with the frequency coordinator and (b) that the frequency coordinator's database should be available to all parties. By making the database available on the Internet, health care providers, medical telemetry equipment suppliers, and future television, LPTV and television translator licensees would all have access to information that will minimize the chances of frequency use conflicts.

CONCLUSION

The Commission should adopt the affirmative proposals in the NPRM for a new Part 95 Medical Telemetry Service, utilizing dedicated Channel 37 and 1.4 GHz band frequencies. It should modify those proposals so as to permit, without end date, continued certification, manufacture, sale and use of dual-capacity medical telemetry devices that can operate both in one or more of the Part 95 frequency bands and, under Part 15, on any or all of the frequencies in the Channel 7-46 range.

Respectfully submitted,

GE MARQUETTE MEDICAL SYSTEMS, INC.

By: Arthur B. Goodkind

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September 16, 1999

Attachment A

Description of GE Marquette
Medical Telemetry Equipment

marquette

Attachment B

DECLARATION OF JAMES W. BRINSFIELD

I am the Engineering Manager of the Wireless and Telemetry development unit at GE Marquette Medical Systems, Inc.

I have reviewed the "Comments of GE Marquette Medical Systems, Inc.," which have been prepared for filing on September 16, 1999 in Federal Communications Commission ET Docket 99-255. To the extent that statements of fact in those Comments are based on the experience of GE Marquette Medical Systems, Inc., such statements are within my personal knowledge and are correct.

This Declaration is made under penalty of perjury on this 14th day of September, 1999.

James W. Brinsfield

James W. Brinsfield

Attachment A

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