

ORIGINAL

Before the
Federal Communications Commission
Washington, DC 20554

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Federal Communications Commission
Office of Secretary

In the Matter of

Amendment of Parts 2 and 95 of the
Commission's Rules To Establish The
Medical Data Service at 401-402 and 405-
406 MHz

RM No. _____

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PETITION FOR RULEMAKING

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SUMMARY

This petition asks the FCC to promulgate regulations establishing the Medical Data Service (“MEDS”) at 401-402 and 405-406 MHz. The MEDS would be an ultra-low-power, private land mobile radio service supporting short-range data communications from implanted, body-worn, and associated external medical devices. The MEDS would operate in Part 95 of the Commission’s rules on a non-interference basis with the primary users, namely the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services (collectively “METAIDS”). In this way, the proposed new service offers a unique opportunity to provide improved medical care to millions of Americans using spectrum that will continue to serve essential government functions. As a Part 95 service, MEDS would be “licensed by rule” and not through individual station licenses.

The MEDS would complement the existing Medical Implant Communications Service (“MICS”) at 402-405 MHz, which uses smart radio technology (*i.e.*, listen before transmitting, “LBT,” and frequency agility) to enable communications from implanted medical devices performing life-critical functions. Like the MICS, the MEDS would incorporate the smart radio model for medical applications that make intensive use of the spectrum.

Unlike the MICS, the MEDS would allow lower power (relative to the maximum permitted power), transmit-only medical device communications so long as the device operates with a low duty cycle. Limiting such operations to a low duty cycle and lower power level minimizes the interference impact to other users of the MEDS band. In this way, the MEDS band would support wireless telemetry applications for certain types of implants and external sensors communicating non-time-sensitive medical data. Such applications include the transmission of status information, such as blood glucose levels, blood pressure, blood oxygen levels, etc., where the health and safety of the patient are not compromised if information

delivery is delayed. Indeed, recent requests for waiver of the MICS smart radio rules illustrate the need for licensed spectrum similar to the MICS band that will permit transmit-only operations away from implanted MICS devices that are communicating time-sensitive, life-critical medical data.

The new service would provide lower-cost medical data collection and therapy in hospital rooms, nursing facilities, and patient homes. It would allow physicians to adjust parameters of internal and external medical devices, such as neural stimulators and insulin pumps, with greater ease and accuracy. Remote monitoring, diagnosis, and therapy by medical providers via the lower-cost MEDS applications would allow many more individuals to live independently for a longer period of time and offer peace of mind to patients, family members, and health care professionals. Keeping otherwise healthy individuals out of hospital beds and nursing facilities, with lower-cost alternatives made possible by the MEDS, will lower substantially the cost of medical care and greatly benefit the U.S. economy.

And, because the frequency of operation would be adjacent to the MICS band, MEDS devices could take advantage of the recent advances in miniaturized and low-power smart radio technology that have made MICS-compliant transceivers a reality. This will reduce the time-to-market for MEDS devices using smart radio technology as well as low-cost transmit-only technology.

Due to advances in medical sensor technology and the expected proliferation of such devices, the Commission should establish a separate spectrum allocation for lower-cost medical monitoring and non-emergency reporting applications. Medtronic requests that the FCC promptly issue a Notice of Proposed Rulemaking proposing to adopt the rules set forth in Appendix A to this petition.

CONTENTS

SUMMARY	I
I. THE FCC SHOULD ALLOCATE THE 401-402 AND 405-406 MHZ BANDS FOR THE MEDICAL DATA SERVICE.	2
A. Additional Spectrum Is Needed To Support 21st Century Medical Needs.....	2
1. The Benefits of Wireless Connectivity.....	3
2. The Emergence of Wireless Medical Applications.....	6
3. The Inevitable Growth of the Wireless Medical Equipment Market.....	10
B. The MEDS Would Be Required To Share Spectrum.....	11
1. The MEDS Would Be Compatible With International Allocations.	12
2. The Proposed Bands Are Optimal For The MEDS.	13
3. The FCC and International Regulatory Bodies Have Recognized The Need for Reliable, Interference-Free Medical Communications.....	13
C. Proposed Rules.....	16
CONCLUSION	17
APPENDIX A.....	A-1

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Medtronic, Inc., hereby files this petition pursuant to Section 1.401 of the FCC's Rules¹ asking the Commission to initiate a rulemaking proceeding to establish the Medical Data Service ("MEDS") at 401-402 and 405-406 MHz.² The new service would facilitate wireless communications among medical devices worn by or implanted in patients and external monitoring and control equipment in hospital rooms, physicians' offices, assisted living facilities, and patient homes.³ The MEDS would be an ultra-low-power, private land mobile radio service used for medical data communications and would operate on a non-interference basis to current incumbent operations. In this way, the MEDS would use spectrum that has the

¹ See 47 C.F.R. § 1.401.

² Headquartered in Minneapolis, MN, Medtronic is an internationally recognized pioneer and leader in the development of numerous medical devices, including cardiac pacemakers and defibrillators, infusion pumps, and neural stimulators.

³ In contrast, the existing Wireless Medical Telemetry Service ("WMTS") in Part 95 of the Commission's rules, which supports higher power (and thus longer distance) communications links at 608-614 MHz, 1395-1400 MHz and 1427-1432 MHz, and is limited to operations within health care facilities.

potential for worldwide harmonization to provide improved medical care to many millions of Americans and continue to support vital incumbent operations. In short, it is a “win-win” proposal.

The MEDS would allow simple transmit-only RF medical devices for monitoring and reporting applications so long as the devices operate with a low duty cycle and lower transmit power level. Medical device applications that require increased reliability or use the spectrum more intensively would need to implement smart radio technology, *i.e.*, listen before transmitting (“LBT”) and frequency agility, based on the standard established for the Medical Implant Communications Service (“MICS”).

Today’s implanted and body-worn medical devices monitor and adjust blood glucose levels, regulate heart activity, treat epilepsy, obesity, incontinence, and even depression. A MEDS allocation would improve these applications and spur the introduction of new lower cost wireless medical data services, greatly enhancing medical care and patient quality of life.

I. THE FCC SHOULD ALLOCATE THE 401-402 AND 405-406 MHZ BANDS FOR THE MEDICAL DATA SERVICE.

A. Additional Spectrum Is Needed To Support 21st Century Medical Needs.

The FCC should promptly allocate the 401-402 and 405-406 MHz bands for the MEDS to enable short-range wireless medical connectivity. There is a pressing need for coordinated communications among multiple implanted and body-worn medical devices and external equipment. Almost every aspect of a patient’s health can now be monitored or regulated by implanted and body-worn sensors.⁴ Thus, the MEDS would enable “Patient Area Networks,”

⁴ See Ake Sivard, et al., *The Challenge of Designing In-body Communications*, EMBEDDED.COM, Oct. 26, 2004, available at <http://www.embedded.com/shared/printableArticle.jhtml?articleID=51200651> last accessed July 15, 2005.

ultra-low-power personal wireless hot spots exclusively for medical monitoring and therapy, while keeping the MICS band available for life-critical, time-sensitive data communications from medical implants.

Based on current estimates, the 21st Century will see the first time in human history that the elderly will outnumber the young. Hence, the applications for the MEDS are likely to grow rapidly and will have to evolve to serve the growing needs of our aging population. The flexible rules proposed herein will allow the MEDS to meet these needs.

1. The Benefits of Wireless Connectivity

The expanded use of short-range medical wireless connectivity would improve the quality of patient care and bring needed efficiencies to the practice of medicine when compared to the current wired technologies. Wireless implantable and body-worn MEDS devices would offer patients added comfort, more responsive and lower-cost therapy, more accurate diagnoses, enhanced mobility, peace of mind, higher quality of service, and protection from human error.⁵

Today, physicians continue to rely upon unwieldy wired communications links for many routine medical procedures that could be performed much more efficiently by the MEDS. Oftentimes, medical tests have to be repeated when wires connected to patients shift position and data are not properly recorded. Wireless connectivity to implanted and body-worn sensors would allow physicians to administer therapy and collect diagnostic data with improved accuracy, and greater ease and speed. MEDS wireless links would allow data downloads to

⁵ Accuracy of medical data and prevention of human error is especially critical. Each year nearly 200,000 Americans reportedly die in hospitals due to medical errors. *See In Hospital Deaths from Medical Errors at 195,000 per Year USA*, Medical News Today, Aug. 9, 2004 available at <http://www.medicalnewstoday.com/medicalnews.php?newsid=11856> last accessed July 15, 2005.

storage and processing equipment and lessen the time it takes to set up and conduct routine medical procedures.

The MEDS would take advantage of recent advances in medical and wireless technology to allow devices to store more information and transmit updates to physicians in between visits. Thus, the MEDS would improve the quality of patient care and permit early detection of medical problems. In addition, since physicians will have increased access to relevant patient data, patients likely will spend less time in doctors' offices. Remote review of relevant data could allow a patient to skip an appointment if conditions are normal or prompt a physician to request that the patient come to the office or hospital if an irregularity is detected.

The new service also would permit detection of medical problems of a transient nature. Thus, "[a] sudden slowing of the heart rate that leads to a fainting spell, for example, may last less than a minute and occur only once or twice a week [and is] often enough to make driving a car dangerous but not frequent enough for a doctor to spot during a checkup or even by using a portable 24-hour electrocardiogram (ECG) recorder, called a Holter monitor."⁶ Wireless sensors that detect a potentially harmful change, such as a slowing of the heart rate, could be used to communicate such information.

FCC allocation of the 401-402 and 405-406 MHz bands for the MEDS would further encourage worldwide harmonization of a service band that the ITU-R has already found to be compatible with incumbent users.⁷ Harmonized spectrum would allow patients using MEDS to

⁶ Philip E. Ross, *Managing Care Through the Air, Growing Old in a Wireless World Will Mean Not Just Keeping Your Body Healthy But Keeping it Online*, IEEE SPECTRUM, Dec. 2004 at 26-31. Mr. Ross explains that remote health care monitoring may be the best answer to managing the care of next generation of older people.

⁷ In fact, the ITU-R has determined that ultra-low-power medical systems do not pose a threat of interference to METAIDS systems at 401-406 MHz. *See Recommendation ITU-R (Continued)*

be able to receive medical care when traveling overseas. It also would allow medical device makers to sell the same medical sensors, implants, and external monitoring and control equipment in countries outside the U.S., thus lowering cost to manufacturers permitting savings to be passed on to the patient and medical insurers.

Wireless communications from patient medical devices also would increase administrative efficiencies and save costs.⁸ For example, vital sign data can be locally collected, automatically integrated into the patient record, and used for real-time care in hospital rooms and in physician's offices. Remote monitoring applications enabled by the MEDS also would decrease the cost of long-term medical care and benefit the U.S. economy. It may even reshape today's reactive healthcare approach into a more proactive system and further reduce long-term medical costs.

SA.1346, Sharing Between The Meteorological Aids Service and Medical Implant Communications Systems (MICS) Operating in the Mobile Service In the Frequency Band 401-406 MHz.

⁸ As President Bush has stated:

One of the amazing discrepancies in American society today is we're literally changing how medicine is delivered in incredibly positive ways, and yet docs are still spending a lot of time writing things on paper — and sometimes it's hard to read their handwriting. ... Sometimes it's difficult to have the spread of accurate information so that doctors can make good decisions.

President George W. Bush *quoted in* Richard Benedetto, *Bush Advocates Electronic Medical Record-keeping*, USA TODAY, May 27, 2004.

In April 2004, President Bush announced a health information technology ("IT") plan to guide the nationwide implementation of health IT in the public and private health care sectors to improve quality, prevent medical errors, and enhance overall health care value. The Secretary of Health and Human Services was charged with carrying out the plan. *See HEALTH INFORMATION TECHNOLOGY - HHS Is Taking Steps to Develop a National Strategy*, U.S. Government Accountability Office Report to the Chairman, Committee on the Budget, House of Representatives, May 2005.

2. The Emergence of Wireless Medical Applications

Medical applications that could use the MEDS are growing daily. Indeed, physicians are only beginning to learn of the benefit of wireless connectivity via MICS-compliant devices.⁹ While there are undoubtedly countless future uses for the MEDS and MICS waiting to be discovered, many time-sensitive and non-time-sensitive medical applications can be readily enhanced through expanded use of ultra-low-power wireless links.

Today, body-worn and implanted medical devices are used to: (i) monitor vital signs; (ii) administer insulin and other pharmaceuticals; (iii) regulate heart activity; (iv) control incontinence; and (v) provide spinal cord and nerve stimulation for the control of chronic pain and management of epilepsy and Parkinson's disease.¹⁰ Wireless communications with such devices, made possible via the MEDS, would improve functionality and lower the cost of diagnoses and therapy.

First and foremost, the MEDS would have a huge impact on the management of diabetes. More than 18 million Americans have diabetes, and more than 1 million new cases are diagnosed

⁹ The MEDS allocation at 401-402 and 405-406 MHz would complement the existing Medical Implant Communications Service ("MICS") at 402-405 MHz. Whereas the MICS supports time-sensitive, life-critical communications from implanted devices, the MEDS would support low-cost monitoring applications involving implanted and body-worn medical devices.

¹⁰ See, e.g., *Applications of Wearable Computers in Health Care* available at <http://www.iis.ee.ic.ac.uk/~frank/surp99/report/jcl197/apps.html> last accessed July 15, 2005; see also Roger Allen, *Medtronic Sets The Pace With Implantable Electronics*, ELECTRONIC DESIGN, Oct. 23, 2003, available at <http://www.elecdesign.com/Articles/Print.cfm?ArticleID=5951> last accessed July 15, 2005.

At least ten medical device manufacturers make or are developing neurostimulator products for a wide variety of applications from stroke rehabilitation to back pain treatment to eliminating the need for mechanical ventilators. See James Cavuoto, *Neural Engineering's Image Problem - Despite a string of successes, implanted prostheses remain in the shadows*, IEEE SPECTRUM, Apr. 2004 at 32-37.

each year.¹¹ Of these individuals, approximately 1.5 million suffer from Type 1, or insulin-dependent, diabetes. “In order to survive, people with Type 1 diabetes must have insulin delivered by a pump or injections.”¹²

The MEDS would allow a glucose sensor placed in or on the body to transmit to an internal or external insulin pump or glucose monitor for automatic “on-demand” adjustment of patient levels. Such adjustment would free the patient from having to administer insulin manually, and, in most cases, could be done before the patient enters the precarious condition of realizing that such adjustment is needed. In fact, diabetes is “a serious metabolic disorder that places patients at increased risk of coronary and vascular disease, as well as debilitating conditions such as retinopathy [*i.e.*, blindness], nephropathy [*i.e.*, kidney disease], and neuropathy [*i.e.*, nerve damage].”¹³ Better blood glucose control made possible via the MEDS lowers substantially the risk of these long-term complications.

Leading-edge medical technologies also would greatly benefit from the proposed MEDS allocation. For example, the *IEEE Spectrum* reported that implanted vagus nerve stimulators are now being used to treat chronic or recurrent depression in patients that do not respond to prescribed drugs, such as Paxil and Prozac.¹⁴ Some four million “treatment-resistant” Americans

¹¹ See American Diabetes Association, *National Diabetes Fact Sheet*, General information and national estimates on diabetes in the United States, 2002, available at <http://www.diabetes.org/diabetes-statistics/national-diabetes-fact-sheet.jsp> last accessed July 15, 2005.

¹² *Id.* Some Type 2 diabetics also rely on insulin administration.

¹³ See Jay S. Skyler, MD, *The Economic Burden of Diabetes and the Benefits of Improved Glycemic Control: The Potential Role of a Continuous Glucose Monitoring System*, *Diabetes Technology & Therapeutics*, Dec 2000, Vol. 2, No. supplement 1: 7-12.

¹⁴ See Samuel K. Moore, *Zapping Away The Blues, A pacemakerlike device to treat depression takes a giant step forward*, *IEEE SPECTRUM*, May 2005 at 16-17 available (Continued)

who suffer from depression could benefit from this technology. Scientists expect to use nerve stimulation to treat anxiety, bulimia, and chronic headache.¹⁵ A MEDS allocation would enable real-time therapy via wireless communications among these implanted devices and external monitoring and control equipment.

The *Washington Post* recently profiled another example. Implanted medical sensors in the brain of a paralyzed person are being used, in a laboratory setting, to translate the person's thoughts into action by artificial limbs.¹⁶ Medical scientists expect that this technology will, within our lifetime, allow paralyzed individuals to walk. The article reported that the implanted sensors are wired to a computer via an external jack on the side of the individual's head. Wireless connectivity from the person to his computer-controlled limbs via the MEDS would offer a much-needed improvement to the current wired configuration.

Finally, the MEDS would improve the level of care in hospital emergency rooms and other facilities or locations where trained medical personnel are in attendance. Wireless vital sign sensors could be affixed to a patient during triage to alert medical staff when the patient's condition worsens and/or collect data for later review.¹⁷

electronically at <http://www.spectrum.ieee.org/WEBONLY/resource/may05/0505ncyber.html> last accessed July 15, 2005.

¹⁵ *See id.*

¹⁶ *See Joel Garreau, *Inventing Our Evolution, We're almost able to build better human beings. But are we ready?* WASHINGTON POST, May 16, 2005, at A1, A9 (noting that the U.S. National Science Foundation is focusing efforts on the human body as the "next frontier"; the technology focus is turning inward to improve human life).*

¹⁷ *See Thaddeus R.F. Fulford-Jones, et al., *A Portable Low-Power, Wireless Two Lead EKG System*, PROCEEDINGS OF THE 26TH ANNUAL INTERNATIONAL CONFERENCE OF THE IEEE EMBS, Sept. 1-5, 2004, at 2141-44.*

These and many other applications would be readily realizable in the proposed MEDS using low-cost transmit-only communication systems and/or smart-radio systems developed for MICS. Because the MEDS would operate in bands adjacent to the MICS, the MEDS could take full advantage of low-power miniaturized RF technology developed for the MICS.¹⁸ Indeed, transceiver chips that comply with the FCC's MICS spectrum sharing rules are now available.

Chip manufacturers Cambridge Consultants¹⁹ and Zarlink Semiconductor²⁰ recently introduced miniaturized low-power drain smart radio transceivers that comply fully with the FCC's MICS rules. Another chipmaker, AMI Semiconductor announced that it is partnering with cardiac device maker Interventional Rhythm Management to develop MICS-compliant medical devices.²¹ The investment in MICS technology by medical device manufacturers and RF

¹⁸ See proposed revisions to FCC Rule Section 95.628 in Appendix A.

¹⁹ See David Manners, *Low power radio for in-body medicine*, ELECTRONICSWEEKLY.COM, Jan. 18, 2005, available at <http://www.electronicweeklly.co.uk/Article38546.htm> last accessed July 15, 2005.

²⁰ See Susan Taylor, *Zarlink Unveils Wireless Chip For Medical Implants*, WASHINGTONPOST.COM, May 31, 2005 ("Zarlink's high-speed chip transmits about ten times the data of rival products, while consuming about 20 percent of the power The chip's minuscule appetite for power means it can deliver additional features without significantly draining a device's battery.").

Zarlink Introduces World's First Wireless Chip Designed Specifically for In-Body Communication Systems; Merging RF and ultra low-power expertise, ZL™70100 transceiver chip fully complies with MICS (Medical Implant Communication Service) standard; Applications include implanted pacemakers, defibrillators, neurostimulators and blood glucose sensors, Press Release, May 31, 2005, available at <http://news.zarlink.com/archive/2005/May/31/May31-ZL70100-English.htm.en> last accessed July 15, 2005.

²¹ See AMI Semiconductor Agreement With Interventional Rhythm Management, Inc. Will Deliver Mixed-Signal Semiconductors for Next-Generation Implantable Defibrillators and Pacemakers – Turnkey ASIC Solutions for Cardiac Electrophysiology Devices Will Meet Requirements for Low Power Operation and Low Data Rate MICS Wireless Communications, AMI Press Release, Apr. 18, 2005, available at
(Continued)

transceiver chipmakers over the past several years, and the associated lessons learned, will prove useful in the development of MEDS products, including medical device communications systems that integrate MEDS and MICS technology.

3. The Inevitable Growth of the Wireless Medical Equipment Market

Today, millions of individuals rely upon implanted medical devices. Many more use body worn sensors for routine medical tests, such as the *monitoring of heart activity and fetal vital signs during birth*. Over the coming decades, as the average age of the population increases, millions more patients will rely upon medical implants and body-worn sensors to evaluate, support, and improve the quality of their lives.

The applications noted above are merely a subset of the vast opportunities that the MEDS would offer. The additional spectrum that this petition requests, coupled with the existing MICS band, would enable countless short-range medical device applications that relay both non-time-sensitive (MEDS) and time-sensitive (MICS) medical data from body-worn and implanted medical devices to external equipment for physician review and action. The MEDS also would support self-sustaining "Patient Area Networks."²² The FCC should swiftly propose allocating the MEDS spectrum, as requested herein.

http://www.amis.com/news/releases/2005/Q2/050418_irm.html last accessed July 15, 2005. Their initial product is going to be an intravascular defibrillator designed to prevent sudden cardiac death.

²² Zarlink is developing ultra low-power medical communications systems for Patient Area Networks, as part of the "Healthy Aims" project – a European initiative currently comprised of twenty-six medical device manufacturers developing products and applications for aged and disabled individuals. See <http://www.healthyaims.org/>.

B. The MEDS Would Be Required To Share Spectrum.

The MEDS would be required to share spectrum with other MEDS and METAIDS users of the 401-402 and 405-406 MHz bands. As medical device makers deploy implanted and body-worn sensor technology that increasingly relies upon wireless connectivity, the likelihood that multiple MEDS and MICS devices will be in close proximity increases greatly. Indeed, use of the MEDS band in hospitals and physician's offices and around certain individuals would be intense.

The proposed MEDS rules include a two-tiered spectrum access structure that would support a broad range of medical applications and successful spectrum sharing among uncoordinated devices. Specifically, devices that operate with transmit power of up to 25 microwatts EIRP would be required to implement smart radio technology and follow the spectrum access criteria in Section 95.628(a) – the same access criteria, which has been successfully implemented in the MICS.²³ Devices that make intensive use of the spectrum or require increased reliability would need to implement smart radio technology to avoid interference from and to other MEDS devices. Devices that operate with lower power, *i.e.*, 250 nanowatts EIRP, and with a duty cycle no greater than 0.1 percent, *i.e.*, no greater than 3.6 seconds of total transmission time in any one hour period (hereinafter lower power, low duty cycle, or “LPLDC” devices), could operate on a transmit-only basis. These LPLDC devices would support medical monitoring functions, where the patient's health or safety is not impacted if the delivery of information is delayed.²⁴

²³ See proposed FCC Rule Section 95.628 in Appendix A.

²⁴ Last year, the Commission granted a three-year conditional waiver under the MICS regulations to permit operation of a device that could be authorized under the MEDS. See Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical (Continued)

1. The MEDS Would Be Compatible With International Allocations.

Like the MICS, the MEDS allocation would be compatible with international allocations.²⁵ The same two-tiered spectrum access structure proposed herein was incorporated into ETSI TR 102 343 (V1.1.1) for ultra-low power medical implant applications in the 401-402 and 405-406 MHz bands.²⁶ International harmonization would serve the public interest by offering the international traveler with implanted or body-worn medical device technology an enhanced degree of freedom by ensuring that the traveler can receive appropriate medical attention whether at home or abroad. And, for the medical device manufacturers, international compatibility would allow development costs to be spread among multiple national markets.

Implant Communications Service Rules, *Order*, 19 FCC Rcd. 4208 (2004). The Commission explained that it granted the waiver, in part, because other spectrum options, such as Part 15 unlicensed spectrum, were not suitable. *See id.* at ¶ 14.

The FCC noted presciently that “advances in technology may improve the operability and availability of listen-before-talk implantable devices” and obviate the need for future waivers. *Id.* at ¶ 19. Indeed, as explained above, there are now multiple vendors that make devices that comply fully with the MICS rules.

²⁵ The 402-405 MHz MICS band has emerged as the worldwide standard for active medical implant communications. Aside from the FCC, ETSI, and the ITU, Industry Canada has adopted the MICS spectrum sharing requirements in its Radio System Specification 243. *See Active Medical Implant Communications System Devices in the 402-405 MHz Band*, Industry Canada, Spectrum Management and Telecommunications Policy, Radio Standards Specification, RSS-243, Issue 1, July 2004 available at [http://strategis.ic.gc.ca/epic/internet/insmt-gst.nsf/vwapj/rss243e.pdf/\\$FILE/rss243e.pdf](http://strategis.ic.gc.ca/epic/internet/insmt-gst.nsf/vwapj/rss243e.pdf/$FILE/rss243e.pdf) last accessed July 15, 2005. The New Zealand Ministry of Economic Development also has proposed the allocation at 402 to 405 MHz for low-power biomedical telemetry applications. *See Short Range Devices Discussion Paper, Summary of Submissions and Conclusions*, Dec. 2004, New Zealand Ministry of Economic Development, Radio Spectrum Policy and Planning, available at <http://www.med.govt.nz/rsm/planning/srd/submissions-summary/submissions-summary.pdf> last accessed July 15, 2005.

²⁶ *See* ETSI TR 102 343 V1.1.1 (2004-07), Electromagnetic compatibility and Radio spectrum Matters (ERM); Ultra Low Power Active Medical Implants (ULP-AMI) operating in the 401 MHz to 402 MHz and 405 MHz to 406 MHz bands; System Reference Document.

2. The Proposed Bands Are Optimal For The MEDS.

The 401-406 MHz band is an optimal band for medical transmissions for at least five separate reasons. First, it is a relatively low noise portion of the spectrum, as the only incumbent operations in the U.S. are the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services (collectively "METAIDS"). Second, signals in this frequency band propagate acceptably through human tissue. Third, as just noted, the band has already been recommended internationally for medical use under the mobile service allocation.²⁷ Fourth, medical devices operating at 400 MHz can be designed with small antennas. Fifth, the band can reliably support high-data rate transmissions,²⁸ and the band allows for circuit designs with very low-power drain, which translates into lighter-weight devices with small batteries.

3. The FCC and International Regulatory Bodies Have Recognized The Need for Reliable, Interference-Free Medical Communications.

FCC regulations, European standards (*i.e.*, the *de facto* regulations in Europe)²⁹ and the International Telecommunications Union ("ITU") Recommendation³⁰ recognize that interference to medical devices from primary METAIDS and other users will occur. To address this likelihood of interference and to protect the health and safety of the patient, these regulatory

²⁷ See ITU-R SA.1346.

²⁸ In fact, high-data rate capability is needed to minimize battery power drain over the life of the implant. See ETSI TR 102 343 V1.1.1, Annex B, § B.2.3.

²⁹ See European Standard ETSI EN 301 839 V1.1.1 (2002-06), *Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio Equipment in the frequency range 402 MHz to 405 MHz for Ultra Low Power Active Medical Implants and Accessories; Part 1* at 29-38.

³⁰ See ITU-R SA.1346.

bodies call for ultra-low-power medical devices to incorporate interference avoidance mechanisms – especially when they are communicating vital medical data.

In promulgating the MICS rules covering 402-405 MHz operations, the FCC and NTIA³¹ recognized that the spectrum environment would vary greatly by location and that not all of the channels would be available for medical implant communications.³² The agencies were aware that the spectrum contains signals from METAIDS and broadband noise sources, which are particularly acute in medical facility environments, and could interfere with life-critical communications from medical implants. The Commission also recognized that implanted medical devices would need to transmit with less power than the maximum permitted under the MICS regulations to conserve battery power.³³ Therefore, to ensure that communications would be successful, MICS systems were required to sense the spectrum environment and select an open channel prior to transmitting.³⁴ The FCC was so concerned that the band may be occupied fully by METAIDS, other MICS users, and broadband noise sources that it added a provision to

³¹ Because the federal government uses the 401-406 MHz band for the Meteorological Aids, the Meteorological Satellite, and Earth Exploration Satellite Services (collectively, “METAIDS”), FCC regulations establishing the MEDS at the lower and upper 1 MHz bands would need to be coordinated with NTIA. The FCC and NTIA successfully collaborated in establishing the MICS at 402-405 MHz.

³² See Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band, *Report and Order*, 14 FCC Rcd. 21040 (1999) (“*MICS Report and Order*”).

³³ Indeed, while external MICS programmer controllers typically operate with near maximum power and relatively narrow bandwidths, implanted MICS devices must use substantially less power to limit battery drain along with wider bandwidths to increase throughput.

³⁴ See 47 C.F.R. § 95.628(a); see also § 95.1211 (“Those using MICS transmitters must cooperate in the selection and use of channels in order to reduce interference and make the most effective use of the authorized facilities. Channels must be selected in an effort to avoid interference to other MICS transmissions.”).

the MICS regulations to permit medical devices to transmit on the least interfered channel when the noise level exceeds the monitoring threshold across the entire band.³⁵ Because METAIDS radiosondes are launched and landed in many parts of the United States on a regular basis, NTIA also was concerned with the “potential difficulties that might arise if the radiosondes interfered with the reception of critical medical data.”³⁶

Furthermore, the International Telecommunications Union has recommended that interference mitigation techniques “be used by Medical Implant Communications Systems to protect their operation;”³⁷ that is, to “avoid interferers and support the simultaneous operation of multiple devices in the same area (such as clinics with multiple rooms).”³⁸ The ITU explained that “[i]nternational spectrum studies have shown that even with 3 MHz available only one or two channels will be usable in many environments.”³⁹

As physicians and other medical professionals take advantage of the greater ease of use and effectiveness of wireless connectivity, their primary focus must be on the administration of therapy to patients and the analysis of medical data from patient devices. The FCC and other international standards bodies understood that implementation of channel sensing and frequency

³⁵ See 47 C.F.R. § 95.628(a)(4).

³⁶ Letter from Fredrick R. Wentland, Associate Administrator, NTIA Office of Spectrum Management, to Edmond J. Thomas, Chief, FCC Office of Engineering and Technology, May 22, 2003, ET Docket No. 03-92. NTIA stated that the risk of interference from the METAIDS to ultra-low-power medical devices operating at 401-406 MHz that do not use smart radio technology is “very real.” *Id.*

³⁷ Rec. ITU-R SA.1346. See also *id.*, Annex 1, Section 4.2 (“Narrow-band interferers will be avoided by MICS equipment through use of frequency agility ... and channelization.”).

³⁸ *Id.* at Annex 1, Section 2.2.

³⁹ *Id.*, Annex 1, Section 2.2.

agility in the MICS band are reliable, self-regulating approaches that promote spectrum efficiency and provide the necessary flexibility to support expanded medical applications.⁴⁰

Thus, the two-tiered MEDS rules proposed herein represent smart spectrum policy.⁴¹ They incorporate the smart radio model developed for MICS for medical applications that make intensive use of the spectrum or require a higher degree of reliability, and allow for lower power, low-duty-cycle, transmit-only operation for applications involving non-time-sensitive data.

C. Proposed Rules

Medtronic proposes a new Subpart M for the MEDS in Part 95 of the FCC's Rules. The new service would operate on a secondary non-interference basis to primary METAIDS users. MEDS devices would be permitted to operate without an individual station license issued by the FCC; that is, the MEDS would be licensed by rule. Proposed regulations establishing the MEDS are set forth in detail in Appendix A to this petition.

⁴⁰ Wireless links must be sufficiently reliable to support the intended application. "For a medical communication scheme to be usable, it must be both reliable and timely." *Ex Parte* Letter of Steven Greenberg, M.D., ET Docket No. 03-92, Dec. 13, 2003 (filed Jan. 8, 2004). Interference to time-sensitive communications from medical implants could delay emergency care with potentially fatal consequences. For instance, when a defibrillator with MICS capability is being implanted a communication channel typically will be obtained at the start of the surgical procedure. In this case, "a reliable communication scheme is critical if the operation of the implanted device must be modified to respond to an episode of ventricular fibrillation." *Id.*

⁴¹ The proposed rules are fully consistent with the recommendations of the Commission's Spectrum Policy Task Force and subsequent Commission actions effecting those recommendations. *See* FCC Spectrum Policy Task Force Report, Nov. 1, 2002, ET Docket No. 02-135; *see also* Cognitive Radio Technologies and Software Defined Radios, *Report and Order*, FCC 05-57, Mar. 11, 2005. The Spectrum Task Force explained that "[s]ufficient interference protection is a necessary and fundamental building block in any spectrum policy. Indeed, without adequate interference management, new spectrum-based services could be prematurely thwarted and, correspondingly, mature services might not be able to reach their full potential." SPTF Report at 25. Smart radio technology, which can avoid the creation and receipt of interference, is a sound and realizable interference management mechanism. *See* SPTF Report at 14, 20-21.

CONCLUSION

The FCC should promptly issue a Notice of Proposed Rulemaking to solicit comment on the proposed MEDS rules. The proposed spectrum sharing approach for the MEDS supports the stated goals of Memorandum of Understanding between the FCC and NTIA to “promote the efficient use of spectrum, including spectrum management techniques to promote increased shared use of the spectrum that does not cause harmful interference, as a means of increasing commercial access.”⁴² Indeed, as President Bush has recognized: “We must unlock the economic value and entrepreneurial potential of U.S. spectrum assets while ensuring that sufficient spectrum is available to support critical Government functions.”⁴³ The proposed MEDS rules offer this opportunity. The MEDS would provide improved, cost-effective medical care to millions of Americans by sharing spectrum used for important government functions.

Respectfully submitted,

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July 15, 2005

⁴² Memorandum of Understanding Between the FCC and the NTIA, Jan. 31, 2003. *See also* 47 U.S.C. § 157(a) (“It shall be the policy of the United States to encourage the provision of new technologies and services to the public.”).

⁴³ George W. Bush, Presidential Memo on Spectrum Policy, Memorandum for the Heads of Executive Departments and Agencies, Subject: Spectrum policy for the 21st Century, June 5, 2003, *available at* <http://www.whitehouse.gov/news/releases/2003/06/20030605-4.html> *last accessed* July 15, 2005.

Certificate of Service

The undersigned hereby certifies that, on the date below, the foregoing Petition for Rulemaking was filed with the Office of the Secretary, and courtesy copies were sent via electronic mail to the following individuals:

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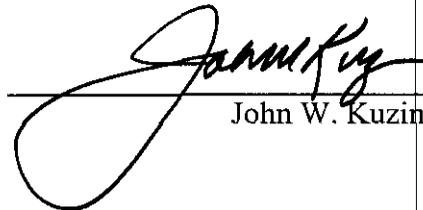
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APPENDIX A

**PROPOSED RULE CHANGES TO ESTABLISH THE MEDICAL DATA SERVICE
AT 401-402 AND 405-406 MHZ**

This appendix shows changes proposed for Parts 1, 2 and 95 of the Commission's Rules. A new subpart M to Part 95 is proposed. Additions are shown in **double-underlined bold** text. Any deletions are shown with ~~strikethrough~~ text.

Parts 1, 2 and 95 of Title 47 of the Code of Federal Regulations are amended as follows:

PART 1 – PRACTICE AND PROCEDURE

1. Section 1.1307 is amended by revising paragraph (b)(2) to read as follows:

§ 1.1307 Actions which may have a significant environmental effect, for which Environmental Assessments (EAs) must be prepared.

* * *

(b) * * *

(2) * * * Equipment authorized for use in the Medical Implant Communications Service (MICS) **or the Medical Data Service (MEDS)** as a medical implant **or body-worn** transmitter (as defined in Appendix 1 to Subpart E of Part 95 of this chapter) is subject to routine environmental evaluation for RF exposure prior to equipment authorization, as specified in § 2.1093 of this chapter by ~~finite difference time domain computational modeling or laboratory measurement~~ **other techniques accepted by the Commission.** Where a showing is based on computational modeling, the Commission retains the discretion to request that specific absorption rate measurement data be submitted. All other mobile, portable, and unlicensed transmitting devices are categorically excluded from routine environmental evaluation for RF exposure under §§ 2.1091, 2.1093 of this chapter except as specified in paragraphs (c) and (d) of this section.

* * *

**PART 2 – FREQUENCY ALLOCATIONS AND RADIO TREATY MATTERS;
GENERAL RULES AND REGULATIONS**

2. Section 2.106, the Table of Frequency Allocations, is amended by adding new entries showing the Medical Data Service (MEDS) as secondary at 401-402 and 405-406 MHz and adding footnote US### in numerical order to read as follows:

UNITED STATES (US) FOOTNOTES

* * *

US### In the 401-402 and 405-406 MHz bands the mobile, except mobile aeronautical, service is allocated on a secondary basis and is limited to, with the exception of military tactical mobile stations, Medical Data Service (MEDS) operations. MEDS stations are authorized by rule on the condition that harmful interference is not caused to stations in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services, and that MEDS stations accept interference from stations in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services.

* * *

3. Section 2.1204 is amended by adding paragraph (a)(9) to read as follows:

§ 2.1204 Import conditions.

* * *

(a) * * *

(9) The radio frequency device is a medical implant transmitter inserted in a person **or a transmitter worn on the body of the person, for the purpose of collecting diagnostic data or providing therapy to the person,** granted entry into the United States or is a medical implant programmer/controller transmitter **or other radio frequency device** associated with such an implanted **or body-worn** transmitter, provided, however that the transmitters covered by this provision otherwise comply with the technical requirements applicable to transmitters authorized to operate in the Medical Implant Communications Service **and/or the Medical Data Service** under Part 95 of this chapter. Such transmitters are permitted to be imported without the issuance of a grant of equipment authorization only for the personal use of the person in whom the medical implant transmitter has been inserted **or on whom the body-worn transmitter is applied.**

PART 95 - PERSONAL RADIO SERVICES

4. Section 95.401 is amended by adding paragraph (h) to read as follows:

§ 95.401 (CB Rule 1) What are the Citizens Band Radio Services?

* * *

(h) The Medical Data Service (MEDS) - an ultra-low power radio service that supports the transmission of non-voice data for the purpose of facilitating diagnostic and/or therapeutic functions involving medical devices worn by or implanted in patients. The rules for this service are contained in subpart M of this part.

5. Section 95.601 is amended by revising the last sentence in the text to read as follows:

§ 95.601 Basis and purpose.

* * * The Personal Radio Services are the GMRS (General Mobile Radio Service)--Subpart A, the Family Radio Service (FRS)--Subpart B, the R/C (Radio Control Radio Service)--Subpart C, the CB (Citizens Band Radio Service)--Subpart D, the Low Power Radio Service (LPRS)--Subpart G, the Wireless Medical Telemetry Service (WMTS)--Subpart H, the Medical Implants Communication Service (MICS)--Subpart I, the Multi-Use Radio Service (MURS)--Subpart J, ~~and~~ Dedicated Short-Range Communications Service On-Board Units (DSRCS-OBUs)--Subpart L, **and the Medical Data Service (MEDS)--subpart M.**

6. Section 95.603 is amended by revising paragraph (g) to read as follows:

§ 95.603 Certification required.

* * *

(h) Each Medical Implant Communications Service transmitter (a transmitter that operates or is intended to operate in the MICS) **and each Medical Data Service transmitter (a transmitter that operates or is intended to operate in the MEDS)** must be certificated except for ~~medical-implant~~ transmitters that are not marketed for use in the United States, but which otherwise comply with the MICS **or MEDS** technical requirements and are operated in the United States by individuals who have traveled to the United States from abroad. Medical implant transmitters (as defined in Appendix 1 to Subpart E of Part 95 of this chapter) are subject to the radiofrequency radiation exposure requirements specified in §§ 1.1307 and 2.1093 of this chapter, as appropriate. Applications for equipment authorization of devices operating under this section must contain a finite difference time domain (FDTD) computational modeling report **or a report based on another technique accepted by the Commission** showing compliance with these provisions for fundamental emissions. The Commission retains the discretion to request the submission of specific absorption rate measurement data.

7. Section 95.605 is amended by revising the first paragraph of the text to read as follows:

§ 95.605 Certification procedures.

Any entity may request certification for its transmitter when the transmitter is used in the GMRS, FRS, R/C, CB, IVDS, LPRS, MURS, or MICS or MEDS following the procedures in Part 2 of this chapter. Medical implant transmitters shall be tested on an open area test site for emissions and EIRP limit compliance while enclosed in a medium that simulates human body tissue in accordance with the procedures in §95.639(g). All external and body-worn transmitters shall be tested on an open area test site. Frequency stability testing for MICS or MEDS transmitters shall be performed over the temperature range set forth in §95.628. Dedicated Short-Range Communications Service On-Board Units (DSRCS-OBUs) must be certified in accordance with Subpart L of this part and Subpart J of Part 2 of this chapter.

8. Section 95.628 is revised to read as follows:

§ 95.628 Spectrum Sharing Requirements for MICS and MEDS Transmitters.

(a) Frequency monitoring. Except as provided in (b) below, MICS Medical implant programmer/control transmitters and MEDS system transmitters must be controlled by a system transmitter that incorporates a mechanism for monitoring the channel or channels that the MICS-system devices transmitter or transmitters intend to occupy, as detailed in the numbered paragraphs below in this subsection (a). The monitoring system antenna shall be the antenna normally used by the programmer/control transmitter monitoring system transmitter for a communications session. ~~Before a medical implant programmer/control transmitter initiates a MICS communications session, the following access criteria must be met:~~

(1) The monitoring system bandwidth measured at its 20 dB down points must be equal to or greater than the emission bandwidth of the intended transmission.

(2) Within 5 seconds prior to initiating a communications session, circuitry associated with a medical implant programmer/control the MICS or MEDS monitoring system transmitter must monitor the channel or channels the MICS-system transmitter devices intends to occupy for a minimum of 10 milliseconds per channel.

(3) Based on use of an isotropic monitoring system antenna, the monitoring threshold power level must not be more than $10\log B(\text{Hz}) - 150 \text{ (dBm/Hz)} + G(\text{dBi})$ where B is the emission bandwidth of the MICS or MEDS ~~communication session~~ transmitter having the widest emission and G is the ~~medical implant programmer/control transmitter~~ monitoring system antenna gain relative to an isotropic antenna. For purposes of showing compliance with the above provision, the above calculated threshold power level must be increased or decreased by an amount equal to the monitoring system antenna gain above or below the gain of an isotropic antenna, respectively.

(4) If no signal in a MICS or MEDS channel above the monitoring threshold power level is detected, the ~~medical implant programmer/control~~ monitoring system transmitter may initiate a MICS communications session involving transmissions to and from a medical implant device, a body-worn device, or other device external to the body on that channel. The MICS or MEDS communications session may continue as long as any silent period between consecutive data transmission bursts does not exceed 5 seconds. If a no spectrum channel within the permitted band of operation meeting the criteria in paragraph (a)(3) of this section is ~~un~~available, the channel with the lowest ambient power level (i.e., the least interfered channel, or LIC) may be accessed.

(5) When a channel is selected prior to a MICS or MEDS communications session, it is permissible to select an alternate channel for use if communications is interrupted, provided that the alternate channel selected is the next best choice using the above criteria. The alternate channel may be accessed in the event a communications session is interrupted by interference. The following criteria must be met:

(i) Before transmitting on the alternate channel, the channel must be monitored for a period of at least 10 milliseconds.

(ii) The detected power level during this 10 millisecond or greater monitoring period must be no higher than 6 dB above the power level detected when the channel was chosen as the alternate channel.

(iii) In the event that this alternate channel provision is not used by the MICS or MEDS system or if the criteria in (i) and (ii) above are not met, a channel must be selected using the access criteria specified in paragraphs (a)(1)-(a)(4) of this section.

(6) As used in this section, the following definitions apply:

(i) Emission bandwidth - Measured as the width of the signal between the points on either side of carrier center frequency that are 20 dB down relative to the maximum level of the modulated carrier. Compliance will be determined using instrumentation employing a peak detector function and a resolution bandwidth approximately equal to 1% of the emission bandwidth of the device under test.

(ii) MICS channel or MEDS channel - Any continuous segment of spectrum in the MICS band or MEDS bands, respectively, that is equal to the emission bandwidth of the device with the largest bandwidth that is to participate in a MICS or MEDS communications session. (Note: The rules do not specify a channeling scheme for use by MICS or MEDS systems.)

(iii) MICS or MEDS communications session - A collection of transmissions, that may or may not be continuous between or among MICS or MEDS system devices.

(b) **Exceptions to Access Criteria in (a).** (1) MICS communications sessions initiated by a medical implant event are not required to use the access criteria set forth in paragraph (a) of this section. (2) **Transmissions from a MEDS device are not required to use the access criteria set forth in paragraph (a) of this section so long as the transmit power is not greater than 250 nanowatts EIRP and the duty cycle for such transmissions does not exceed 0.1%, based on the total transmission time during a one-hour interval. A MEDS device operating under the exception in this subsection (b)(2) may not transmit for more than 3.6 seconds in any one hour.**

(c) **Operating Frequency.** MICS stations may operate on any of the frequencies in the band 402.000 - 405.000 MHz, provided that the out-of-band emissions are attenuated in accordance with § 95.635. **MEDS stations may operate on any of the frequencies in the bands 401.000-402.000 and 405.000-406.000 MHz, provided that the out-of-band emissions are attenuated in accordance with § 95.635.**

(d) **Authorized Bandwidth.** The authorized bandwidth of the emission from a MICS station shall not exceed 300 kHz, and no communications session involving MICS stations shall use more than a total of 300 kHz of bandwidth during such a session. Note: This provision does not preclude full duplex or half duplex communications provided that the total amount of bandwidth utilized by all of the MICS channels employed in such a MICS communications session does not exceed 300 kHz. **The authorized bandwidth of the emission from a MEDS station shall not exceed 100 kHz. Further, no medical data communications session involving MEDS stations shall use more than a total of 100 kHz of bandwidth during such a session inclusive of time division duplex (TDD) and/or frequency division duplex (FDD) techniques.**

(e) **Frequency Stability.** Each transmitter in the MICS **or MEDS** service must maintain a frequency stability of +/- 100 ppm of the operating frequency over the range:

(1) 25°C to 45°C in the case of medical implant transmitters; and

(2) 0°C to 55°C in the case of medical implant programmer/control transmitters **and MEDS transmitters that are not implanted in a patient.**

(f) **Shared Access.** The provisions of this section shall not be used to extend the range of spectrum occupied over space or time for the purpose denying fair access to spectrum for other MICS **or MEDS** systems.

9. Section 95.631 is amended by adding paragraph (k) to read as follows:

§ 95.631 Emission types.

* * *

(k) A MEDS station may transmit any emission type appropriate for communications in this service, except for voice communications.

10. Section 95.633 is amended by adding paragraph (h) to read as follows:

§ 95.633 Emission bandwidth.

* * *

(h) For transmitters in the MEDS:

(1) The maximum authorized emission bandwidth is 100 kHz.

(2) Lesser emission bandwidths may be employed, provided that the unwanted emissions are attenuated as provided in § 95.635 and that the power radiated in any 100 kHz bandwidth does not exceed 25 microwatts EIRP. See §§ 95.605 and 95.639(i) regarding power measurement procedures. For MEDS transmissions that do not comply with the requirements in Section 95.628(a), the power radiated in any 100 kHz bandwidth shall not exceed 250 nanowatts EIRP.

(3) Emission bandwidth will be determined by measuring the width of the signal between two points, one below and one above the theoretical carrier center frequency, that are 20 dB down relative to the maximum level of the modulated carrier. Compliance with the emission bandwidth limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

11. Section 95.635 is amended by revising paragraph (b) and adding paragraph (g) to read as follows:

§ 95.635 Unwanted radiation.

* * *

(b) The power of each unwanted emission shall be less than TP as specified in the applicable paragraphs listed in the following table:

Transmitter	Emission type	Applicable paragraphs (b)
* * * <u>MEDS</u>	* * * <u>As specified in paragraph (g)</u>	* * *
* * *		

* * *

(g) For transmitters designed to operate in the MEDS, emissions shall be attenuated in accordance with the following:

(1) Except for emissions in the MICS band (402.000 – 405.000 MHz), emissions more than 100 kHz outside of the MEDS bands (401.000 MHz - 402.000 MHz and 405.000 MHz - 406.000 MHz) and all emissions in the Emergency Position Indicating Radiobeacon (EPIRB) station band (406.000 – 406.100 MHz) shall be attenuated to a level no greater than the following field strength limits:

<u>Frequency (MHz)</u>	<u>Field strength (μV/m)</u>	<u>Measurement distance (m)</u>
<u>30-88</u>	<u>100</u>	<u>3</u>
<u>88-216</u>	<u>150</u>	<u>3</u>
<u>216-960</u>	<u>200</u>	<u>3</u>
<u>960 and above</u>	<u>500</u>	<u>3</u>
<u>NOTE - At band edges, the tighter limit applies.</u>		

(2) Emissions in the MICS band (402.000 – 405.000 MHz), shall be attenuated to a field strength level of 100 μ V/m at 3 meters.

(3) The emission limits shown in (1) and (2) above are based on measurements employing a CISPR quasi-peak detector except that above 1 GHz, the limit is based on measurements employing an average detector. Measurements above 1 GHz shall be performed using a minimum resolution bandwidth of 1 MHz. See also § 95.605.

(4) The emissions from a MEDS transmitter must be measured to at least the tenth harmonic of the highest fundamental frequency designed to be emitted by the transmitter.

(5) Emissions within the MEDS bands (401-402 and 405-406 MHz) more than 50 kHz away from the center frequency of the spectrum the transmission is intended to occupy, shall be attenuated below the transmitter output power by at least 20 dB except as noted in (1) and (2) above. Compliance with this limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution

bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

(6) Emissions 100 kHz or less below 401 MHz shall be attenuated below the maximum permitted output power by at least 20 dB. Compliance with this limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

12. Section 95.639 is amended by adding paragraph (j) to read as follows:

§ 95.639 Maximum transmitter power.

* * *

(j) In the MEDS the following limits apply:

(1) The maximum EIRP for MEDS transmitter stations that comply with the access criteria of Section 95.628(a) is 25 microwatts. The maximum EIRP for a MEDS transmitter that operates under Section 95.628(b) is 250 nanowatts. The antenna associated with any MEDS transmitter must be supplied with the transmitter and shall be considered part of the transmitter subject to equipment authorization. Compliance of any MEDS transmitter with the applicable EIRP limit may be determined by measuring the radiated field from the equipment under test at 3 meters and calculating the EIRP. Compliance is based on measurements using a peak detector function and measured over an interval of time when transmission is continuous and at its maximum power level. In lieu of using a peak detector function, instrumentation techniques set forth in ANSI C63.17-1998, Section 6.1.2.2.1 or Section 6.1.2.2.2 may be used in determining compliance with the above specifications.

(2) For a MEDS transmitter intended to be implanted in a human body, the following test fixture must be used to simulate operation of the implant under actual operating conditions. See § 95.605.

(i) For measurement purposes to determine compliance with emission limits, the radiating characteristics of an implant transmitter placed in a test fixture should approximate those of an implant transmitter placed in a human body. An appropriate human torso simulator for testing medical implant transmitters consists of a cylindrical Plexiglas container with a size of 30 cm by 76 cm with a sidewall thickness of 0.635 cm. It must be completely filled with a material that is sufficiently fluidic that it will flow around the implant without any voids. The dielectric and conductivity properties of this material must match the dielectric and conductivity properties of human muscle tissue at 403.5 MHz. All emissions measurements shall be made using the above specification at a nominal temperature of 20-25°C. Simple saline solutions do not meet the above criteria. A mounting grid for the implant inside the container must be provided that permits the

radiating element or elements of the implant to be positioned vertically and horizontally. The grid should also support any additional implant leads associated with the therapeutic function in a fixed repeatable manner. The implant must be mounted 6 cm from the sidewall and centered vertically within the container. The above fixture shall be placed on a turntable such that the implant transmitter will be located at a nominal 1.5-meter height above ground and at a 3-meter distance from the measurement antenna. Radiated emissions measurements shall then be performed to insure compliance with the applicable technical specifications.

(ii) A formula for a suitable tissue substitute material is defined in the paper "Simulated Biological Materials for Electromagnetic Radiation Absorption Studies" by G. Hartsgrove, A. Kraszewski, and A. Surowiec as published in "Bioelectromagnetics 8:29-36 (1987)".

(3) For a body-worn MEDS transmitter, the measured field strength on an open area test site shall be reduced by 4 dB to account for body absorption effects on radiated power.

13. Section 95.649 is amended by revising the text to read as follows:

§ 95.649 Power capability.

No CB, R/C, LPRS, FRS, MICS, MURS or WMTS, or MEDS unit shall incorporate provisions for increasing its transmitter power to any level in excess of the limits specified in §95.639.

14. Section 95.651 is amended by revising the text to read as follows:

§ 95.651 Crystal control required.

All transmitters used in the Personal Radio Services must be crystal controlled, except an R/C station that transmits in the 26-27 MHz frequency band, a FRS unit, a LPRS unit, a MURS unit, a MICS transmitter, or a WMTS unit, or a MEDS transmitter.

15. APPENDIX 1 TO SUBPART E TO PART 95 - GLOSSARY OF TERMS is revised to read as follows:

The definitions used in part 95, Subpart E are:

Authorized bandwidth. Maximum permissible bandwidth of a transmission.

Body-worn transmitter. A MEDS transmitter intended to be placed on or in very close proximity (i.e., 6 centimeters or less) to the human body used to facilitate communications with other medical communications devices for purposes of delivering medical therapy to a patient or collecting medical diagnostic information from a patient.

Carrier power. Average TP during one unmodulated RF cycle.

CB. Citizens Band Radio Service.

CB transmitter. A transmitter that operates or is intended to operate at a station authorized in the CB.

Channel frequencies. Reference frequencies from which the carrier frequency, suppressed or otherwise, may not deviate by more than the specified frequency tolerance.

Crystal. Quartz piezo-electric element.

Crystal controlled. Use of a crystal to establish the transmitted frequency.

dB. Decibels.

EIRP. Effective Isotropic Radiated Power. Antenna input power times gain for free-space or in-tissue measurement configurations required by MICS or MEDS, expressed in watts, where the gain is referenced to an isotropic radiator.

FCC. Federal Communications Commission.

Filtering. Refers to the requirement in § 95.633(b).

FRS. Family Radio Service.

GMRS. General Mobile Radio Service.

GMRS transmitter. A transmitter that operates or is intended to operate at a station authorized in the GMRS.

Harmful interference. Any transmission, radiation or induction that endangers the functioning of a radionavigation or other safety service or seriously degrades, obstructs or repeatedly interrupts a radiocommunication service operating in accordance with applicable laws, treaties and regulations.

Mean power. TP averaged over at least 30 cycles of the lowest modulating frequency, typically 0.1 seconds at maximum power.

Medical Implant Communications Service (MICS) transmitter. A transmitter authorized to operated in the MICS.

Medical implant device. Apparatus that is placed inside the human body for the purpose of performing diagnostic or therapeutic functions.

Medical implant event. An occurrence or the lack of an occurrence recognized by a medical implant device, or a duly authorized health care professional, that requires the transmission of data from a medical implant transmitter in order to protect the safety or well-being of the person in whom the medical implant transmitter has been implanted.

Medical implant programmer/control transmitter. A MICS transmitter that operates or is designed to operate outside of a human body for the purpose of communicating with a receiver connected to a medical implant device.

Medical implant transmitter. A MICS or ME DS transmitter that operates or is designed to operate within a human body for the purpose of facilitating communications from a medical implant device.

Medical Data Service (ME DS) transmitter. A transmitter authorized to operated in the ME DS.

MICS. Medical Implant Communications Service.

ME DS. Medical Data Service.

MURS. Multi-Use Radio Service.

Peak envelope power. TP averaged during one RF cycle at the highest crest of the modulation envelope.

R/C. Radio Control Radio Service.

R/C transmitter. A transmitter that operates or is intended to operate at a station authorized in the R/C.

RF. Radio frequency.

TP. RF transmitter power expressed in W, either mean or peak envelope, as measured at the transmitter output antenna terminals.

Transmitter. Apparatus that converts electrical energy received from a source into RF energy capable of being radiated.

W. Watts.

16. New Subpart M is added to read as follows:

Subpart M - Medical Data Service (MEDS)

§ 95.1601 Eligibility

Operation in the MEDS is permitted by rule and without an individual license issued by the FCC. Duly authorized health care professionals are permitted to operate MEDS transmitters. Persons may also operate MEDS transmitters to the extent the transmitters are incorporated into medical devices that are used by the person at the direction of a duly authorized health care professional; this includes medical devices that have been implanted in that person or placed on the body of that person by a duly authorized health care professional. Manufacturers of medical devices that include MEDS transmitters and their representatives are authorized to operate transmitters in this service for the purpose of demonstrating such equipment to duly authorized health care professionals. No entity that is a foreign government or which is acting in its capacity as a representative of a foreign government is eligible to operate a MEDS transmitter. The term "duly authorized health care professional" means a physician or other individual authorized under state or federal law to provide health care services. Operations that comply with the requirements of this part may be conducted under manual or automatic control.

§ 95.1603 Authorized locations.

MEDS operation is authorized anywhere CB station operation is authorized under § 95.405.

§ 95.1605 Station Identification.

A MEDS station is not required to transmit a station identification announcement.

§ 95.1607 Station inspection.

Any non-implanted MEDS transmitter must be made available for inspection upon request by an authorized FCC representative. Persons operating implanted MEDS transmitters shall cooperate reasonably with duly authorized FCC representatives in the resolution of interference.

§ 95.1609 Permissible communications.

(a) MEDS stations may transmit non-voice data only as permitted below:

(1) Except for the purposes of testing and for demonstrations to health care professionals, MEDS transmitters may transmit only operational, diagnostic and therapeutic information associated with a medical device used by a medical patient at the direction of a duly authorized health care professional.

(2) MEDS transmitters may transmit in accordance with the provisions of Section 95.628(a) for the purpose of facilitating MEDS system operation for no more than 5 seconds without the communications of data. MEDS transmitters may transmit in accordance with the provisions of Section 95.628(b) for the purpose of facilitating MEDS system operation for no more than 3.6 seconds in total within a one hour time period without the communications of data.

(3) MEDS transmitters may be interconnected with other telecommunications systems including the public switched telephone network.

(b) MEDS transmitters may not be used to relay information to a receiver that is not associated with the MEDS.

§ 95.1611 Channel use policy.

(a) The channels authorized for MEDS operation by this part of the FCC Rules are available on a shared basis only and will not be assigned for the exclusive use of any entity.

(b) To reduce interference and make the most effective use of the authorized facilities, MEDS transmitters must share the spectrum in accordance with Section 95.628.

(c) MEDS operation is subject to the condition that no harmful interference is caused to stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services. MEDS stations must accept any interference from stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services.

§ 95.1613 Antennas.

No antenna for a MEDS transmitter shall be configured for permanent outdoor use, provided, however, that any antenna used outdoors shall not be affixed to any structure for which the height to the tip of the antenna will exceed three (3) meters (9.8 feet) above ground.

§ 95.1615 Disclosure policies

(a) Manufacturers of MEDS transmitters must include with each transmitting device the following statement:

“This transmitter is authorized by rule under the Medical Data Service (47 C.F.R. Part 95) and must not cause harmful interference to stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired

operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Data Service. Operations are limited to non-voice data. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.”

§ 95.1617 Labeling requirements.

(a) MEDS transmitters shall be labeled as provided in Part 2 of this chapter and shall bear the following statement in a conspicuous location on the device:

This device may not interfere with stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

The statement may be placed in the instruction manual for the transmitter where it is not feasible to place the statement on the device.

(b) Where a MEDS transmitter is constructed in two or more sections connected by wire and marketed together, the statement specified in this section is required to be affixed only to the main control unit.

(c) MEDS transmitters shall be identified with a serial number. The FCC ID number associated with the transmitter and the information required by Section 2.925 of the FCC Rules may be placed in the instruction manual for the transmitter and on the shipping container for the transmitter, in lieu of being placed directly on the transmitter.

§ 95.1619 Marketing limitations.

Transmitters intended for operation in the MEDS may be marketed and sold only for the permissible communications described in § 95.1609 of this part.