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

SEP 19 2006

In the Matter of	)	
	)	
Investigation of the Spectrum Requirements for Advanced Medical Technologies	)	ET Docket No. 06-135
	)	
Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radio Communications Service at 401-402 and 405-406 MHz	)	RM-11271
	)	
DexCom, Inc. Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules	)	ET Docket No. 05-213
	)	
Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules	)	ET Docket No. 03-92

NOTICE OF PROPOSED RULEMAKING
NOTICE OF INQUIRY
AND ORDER

Adopted: July 13, 2006 **Released: July 18, 2006**

Comment Date: October 31, 2006
Reply Comment Date: December 4, 2006

By the Commission: Chairman Martin and Commissioners Copps, Tate and McDowell issuing separate statements.

TABLE OF CONTENTS

Heading Paragraph #

I. INTRODUCTION 1
II. BACKGROUND 6
III. NOTICE OF PROPOSED RULEMAKING 11
IV. ORDER 35
V. NOTICE OF INQUIRY 36
VI. INTERAGENCY COLLABORATION, INDUSTRY EDUCATION AND DEVICE IMMUNITY 45
VII. PROCEDURAL MATTERS 50
VIII. ORDERING CLAUSES 57
APPENDIX A - PARTIES FILING PLEADINGS IN RM-11271
APPENDIX B - INITIAL REGULATORY FLEXIBILITY ANALYSIS

I. INTRODUCTION

1. In this proceeding, the Commission intends to modify its rules to accommodate the development and use of a variety of new medical devices that rely on radiocommunication for critical aspects of their functionality.[1] These devices use wireless technologies for increasingly sophisticated and salutary health care applications. It is fair to say that quantum leaps in advanced medical technologies are revolutionizing treatment for a wide variety of medical conditions and, even more fundamentally, creating new health care models serving to improve quality of life for all Americans. For example, some of the more advanced research anticipates a time when implanted or body-worn devices could enable paralyzed individuals to control artificial limbs by thought through wireless interfaces between brain, nerve and muscle,[2] or the vision-impaired might have some degree of visual ability restored with the help of a microchip placed in the back of the eye.[3] Even today, implanted vagus nerve stimulators that send electric pulses to the brain are being used to treat severe chronic depression.[4] Tremors related to Parkinson's disease are being treated with deep brain stimulation implants.[5] With other new types of implants, such as insulin pumps, physicians could wirelessly retrieve data and then make operating parameter adjustments with greater ease and accuracy than with the more traditional wired connection technologies, and in some cases, changes can be effected immediately by computer control.[6] For health care providers and patients, such wireless implant monitoring technologies have the potential to lower medical costs by extending the time between hospital visits and surgical procedures.[7]

2. The Commission presently has rules in place for wireless medical radiocommunication technologies that were based on initial devices and their applications. It now appears, however, that the pace and nature of development of newer, more capable, and more sophisticated devices may be inadequately accommodated by those rules. Some current developments and devices are familiar to us, and the nature of the rule changes necessary to better provide for them seem readily apparent. We are also expectant, however, that there will be following generations of devices with which we are not yet

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[1] *See* Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Data Service at 401-402 MHz and 405-406 MHz, Petition for Rulemaking, filed by Medtronic, Inc., received by the Commission's Office of the Secretary on July 15, 2005, which initiated RM-11271 (Medtronic petition).

[2] For example, the biomedical engineering research projects at the Alfred Mann Institute foresee progress toward implantable BIONic neurons (BIONs) that could provide precise interfaces between electronic controllers and muscles. Available online at http://ami.usc.edu/projects/ami/projects/bion/. *See also* Raja Mishra, *Implant Could Free Power of Thought for the Paralyzed,* The Boston Globe, October 9, 2004, available at http://www.wireheading.com/misc/implant.html.

[3] In this concept, a tiny microchip containing thousands of microscopic solar cells converts light into electrical signals that travel through the optic nerve to the brain and are interpreted as an image. *See* Dan Roberts, *Microchip Implantation,* Macular Degeneration Support, March 2005. http://www.mdsupport.org./library/chip.html.

[4] Samuel K. Moore, *Psychiatry's Shocking New Tools*, IEEE Spectrum, March 2006.

[5] *Id.*

[6] *See New Devices May Free Diabetics From Constant Monitoring*, Washington Post, April 23, 2006, p. A1. *See also,* Chappell Brown, *Real-World Implants Are Arriving,* EE Times, Sept. 12, 2005, available at http://www.eetimes.com/news/latest/showArticle.jhtml?articleID=170701430 ("In the near term, electrodes that can be implanted and communicate with the nervous system are being used in products marketed by Medtronic Inc. (Minneapolis). Applications include controlling Parkinson's tremors, alleviating pain and controlling heart rhythms to avoid attacks."). *See also,* Ciaran Buckley, *SFI Invests EUR16.5m In Bio-Chip Research,* ENN ElectricNews.net, Sept. 7, 2005, available at http://www.electricnews.net/news.html?code=9636454. ("[B]io-chips will be used for cancer detection and assessing cardiac health, and will also be used in systems that monitor the coagulation of blood... [D]iagnostic medical devices being developed at the centre would help to make medicine more pro-active, helping health professionals and individuals to identify health issues before they become chronic problems.")

[7] Henry Higgins, *Making Medical Diagnosis an Out-of-Body Experience,* March 2005, available at http://europe.elecdesign.com/Articles/ArticleID/10023/10023.html.

adequately familiar, and whose needs should be taken into consideration to the extent they can be anticipated.

3. Accordingly, we hereby initiate a two-fold undertaking. We first propose certain modifications to our rules to better accommodate new medical devices immediately and imminently available. In particular, we propose to allocate two megahertz of spectrum for use by implanted and body-worn medical radio transmitting devices in the 401-402 MHz and 405-406 MHz bands that would be governed by rules generally similar in nature to those for the existing Medical Implant Communication Service (MICS) allocation in the 402-505 MHz band, but also would provide for the operation of certain low-power, low duty cycle medical devices without listen-before-talk (LBT) capability. We also address two current rule waivers that permit the operation of low power, low duty cycle medical devices without LBT in the existing 402-405 MHz MICS band. We next seek comment on whether implanted medical devices that rely upon inductive signal coupling should be permitted to operate in the 90-110 kHz band.

4. We also begin an inquiry into additional developments that are anticipated in the medical devices field and their likely spectrum requirements that will enable us to subsequently develop proposals for additional rules as may be appropriate for their operation, based on the input we receive. More specifically, we seek detailed comment on new implant and body-worn medical radiocommunication technologies and how the Commission could anticipate and proactively address the challenging array of RF spectrum sharing issues raised by their increasing use, including the protection of user health and safety when implants receive interference from primary allocated services in the band. We seek comment on the relative benefits and tradeoffs that should be considered with respect to both licensed and unlicensed approaches to authorizing the operation of these devices. Finally, we also seek comment on collaborative efforts between this Commission (FCC) and the U.S. Food and Drug Administration (FDA) regarding options for better educating device manufacturing industry leaders and RF wireless technology leaders about medical radio device electromagnetic compatibility (EMC) coexistence issues in an RF environment.[8] Our goal is to create an environment that fosters continuing advances in medical devices through flexible RF spectrum allocations with the minimum FCC regulatory requirements that are necessary for efficient use of the spectrum and to ensure patient safety.

5. Our focus in this proceeding is on implanted and body-worn medical radiocommunication devices that serve to actively manage and maintain body functions and/or health conditions, and the spectrum needs and appropriate operational protocols for such devices.[9] We note that the medical community also uses basic telemetry transmission for many other communications purposes, but these uses are distinct in their needs and means of accommodation.[10] We do not seek comment here on operations permitted by the wireless medical telemetry service (WMTS) under Part 95 of our Rules. Parties may comment, however, on whether the concerns and issues raised herein are also applicable to any particular medical telemetry functions that should be similarly accommodated.

II. BACKGROUND

6. The Commission has a long history of providing for the reliability of communications related to medical care. In 1973, for example, the Commission authorized the use of 18 frequencies in the 460-470 MHz band on a licensed basis under Part 90 of our rules for low-power biomedical telemetry

[8] The FDA is a public health service agency within the United States Department of Health and Human Services. The FDA assures the safety of foods and cosmetics, and the safety and efficacy of pharmaceuticals, biological products, and medical devices. Additional information on the FDA is available at http://www.fda.gov, and for device requirements at http://www.fda.gov/cdrh/emc/index.html.

[9] Part 95 of the Commission's rules define "medical implant transmitter" as a ". . . transmitter that operates or is designed to operate within the human body for the purpose of facilitating communications from a medical implant device."[9] *See Appendix 1 to Subpart E of Part 95 – Glossary of Terms* (following 47 C.F.R. § 95.673).

[10] Telemetry is the use of telecommunication for automatically indicating or recording measurements at a distance from the measuring instrument. 47 C.F.R. § 2.1.

operations in hospitals, other medical facilities, and convalescent centers.[11] As medical telemetry increased and its spectrum needs expanded, the Commission, in the year 2000, allocated 14 megahertz of spectrum in the 608-614 MHz, 1395-1400 MHz, and 1429-1432 MHz bands for the wireless medical telemetry service (WMTS) under Part 95 of its Rules, for the transmission of patient medical information to a central monitoring location in a hospital or other medical facility.[12]

7. With the development of increasing numbers and kinds of medical radio devices, the Commission responded to advances in medical implant technology by establishing the Medical Implant Communication Service (MICS) within Part 95 of its Rules in 1999.[13] Therein, the Commission set aside three megahertz of spectrum, at 402-405 MHz, on a licensed-by-rule basis expressly for allowing physicians to establish high speed, easy-to-use, short-range wireless links between ultra-low power medical implant transmitters and their associated programmer/control equipment.[14] The MICS service was anticipated to transmit data in support of the diagnostic and/or therapeutic functions associated with implanted medical devices to enable individuals and medical practitioners to utilize potential life-saving medical technology without causing interference to other users of the spectrum. Current examples of such implant devices include cardiac pacemakers and defibrillators that also monitor and report heart condition.

8. More recently, the Commission granted petitions for waivers of the MICS rules to accommodate new medical radio devices that use technology less sophisticated, but no less therapeutic, than contemplated when the rules were adopted.[15] Subsequent to these petitions for waiver, Medtronic, Inc. (Medtronic), a manufacturer of implantable medical radio devices, filed a petition for rulemaking seeking to amend our rules to accommodate additional numbers and types of implanted and body-worn medical radio devices, including such as those which required rule waivers in order to operate.[16] Several parties filed responsive pleadings. More recently, Biotronik, Inc. (Biotronik, see n. 15, *supra*) filed a petition for rulemaking that addresses the same issues.[17]

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[11] *First Report and Order* in Docket No. 19478 and RM-1842 (Amendment of Parts 2 and 91 of the Commission's Rules to Permit Medical Telemetry and Other Low-Power Uses of Offset Frequencies in the Business Radio Service), 41 F.C.C.2d 8 (1973).

[12] *Report and Order* in ET Docket No. 99-255 and PR Docket No. 92-235 (Amendment of Parts 2 and 95 of the Commission's Rules to Create a Wireless Medical Telemetry Service), 15 FCC Rcd 11206 (2000) (*WMTS Order*). 47 C.F.R. § 95.401(e). (Voice and video communications are expressly prohibited in the WMTS bands. However, the Commission decided that, for the purposes of its service definition, waveforms such as electrocardiograms (ECGs) would not be considered video.)

[13] *Report and Order* in WT Docket No. 99-66 (Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band), 14 FCC Rcd 21040 (1999) (*MICS Order*). 47 C.F.R. Part 95, Subpart I (Medical Implant Communications), and Subpart E (Technical Regulations).

[14] *See MICS Order* at para. 3.

[15] *Order* in ET Docket No. 03-92 (Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules), 19 FCC Rcd 4208 (2004) (*Biotronik Waiver*); *Order* in ET Docket No. 05-213 (DexCom, Inc. Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules), FCC 06-1, released January 18, 2006 (*DexCom Waiver*). We additionally note that the Laboratory Division of the Commission's Office of Engineering and Technology also works closely with equipment and device manufacturers on an ongoing basis to facilitate grant of equipment certifications and authorizations for medical device transmitters operating on either a licensed and unlicensed basis, and to provide guidance on how to take measurements for compliance with the Commission's standards on human exposure to RF emissions.

[16] *See* n. 1, *supra*.

[17] Petition for Rule Making of Biotronik, Inc., filed June 16, 2006. This petition has been added to the record of this proceeding.

9. In addition to these licensed uses, manufacturers of medical radio devices (as well as manufacturers of medical telemetry equipment) can market products that operate on an unlicensed basis under Part 15 of our rules. Indeed, from the records on our equipment authorization database, we see that the great majority of all medical radio devices authorized to date operate on an unlicensed basis under Part 15. Among the frequencies used by medical radio devices on an unlicensed basis are 9-315 kHz, 13.553-13.556 MHz (13 MHz ISM band), 174-216 MHz (TV channels 7-13), 218-222 MHz, 293-320 MHz, 410-450 MHz, 512-608 MHz (TV channels 14-36), 614-668 MHz (TV channels 38-46), 902-928 MHz (915 MHz ISM band), 2400-2483.5 MHz (2.45 GHz ISM band), and 5725-5875 MHz (5.8 GHz ISM band).[18] In 2002, however, the Commission decided that equipment approval would no longer be available for in-hospital medical telemetry equipment operating in the 174-216 MHz and 470-668 MHz bands under the provisions of Part 15 or Part 90 (except in the 1427-1432 MHz band).[19] Since that time, approval for new medical telemetry equipment must be sought pursuant to the WMTS rules in Part 95.[20] Certain medical devices also operate on an unlicensed basis using inductive techniques at low frequencies. However, some inductive devices may produce RF energy in restricted frequency bands that were established to protect against interference to services that are used for safety or low-signal operations.[21] In that connection, Guidant Corporation (Guidant) filed a petition for rulemaking to allow unlicensed operation by medical implant devices that employ inductively coupled signals for data communication in the 90-110 kHz restricted frequency band. Guidant asks that this authority be provided by inclusion in the MICS rules by specification of this additional band, or by exception to the restricted frequency band rule for unlicensed devices.[22]

10. The suggestions in the Medtronic and Guidant petitions and the pleadings filed in response to them, as well as our own experience in regulating medical implant devices, comprise the basis for our specific proposals, as follows.

III. NOTICE OF PROPOSED RULEMAKING

11. *MICS Rules.* The Commission adopted the MICS rules to provide for the transmission of operational, diagnostic, and therapeutic information associated with a medical implant device.[23] MICS operations, as originally envisioned, include a matched pair of devices. The medical implant transmitter is implanted in the body to sense body functions and/or conditions and to transmit corresponding data; its function is initiated by an external non-radio device or by an implant programmer/control transmitter,[24] which receives the data from the implant transmitter and can record or pass on the data via interconnection with an external telecommunications system.[25] The technical standards for MICS are designed to ensure compatibility among multiple uncoordinated MICS transmitters.[26] Among other requirements, MICS devices are limited to a very low maximum EIRP of 25 microwatts in order to avoid potential harmful interference to other in-band operations.[27] The rules require that the

[18] *See* 47 C.F.R. § 15.242 and 47 C.F.R. § 15.241.

[19] 47 C.F.R. §§ 15.37(i), 90.203(a)(1).

[20] 47 C.F.R. § 95.1101-1129.

[21] *See* 47 C.F.R. § 15.205

[22] *See* Petition to Amend the Medical Implant Communications Service (MICS) Rules to add Inductive Telemetry at 90-110 KHz, filed February 21, 2006.

[23] 47 C.F.R. § 95.1209(a).

[24] The rules also provide for immediate transmission initiated by the medical implant transmitter in the case of a "medical implant event." 47 C.F.R. § 95.1209(b).

[25] *See* Medtronic Petition, Appendix A, at proposed section §§ 1.1307, 95.603(f).

[26] *MICS Order* at 14 FCC Rcd 21055-21057, 21066.

[27] 47 C.F.R. § 95.628, *et seq*

programmer/control transmitter incorporate a frequency monitoring (*viz.*, "listen-before-talk") mechanism to determine whether a channel is available for operation.[28] Furthermore, MICS channels are available on a shared basis only, and 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 authorized facilities.[29]

12. In adopting the MICS rules, the Commission selected the 402-405 MHz band for MICS operations due to its signal propagation characteristics in the human body, the relative dearth of other users of the band, the compatibility of the MICS service with incumbent federal government meteorological operations, and the use of these frequencies internationally for this purpose.[30] The allocation was made secondary in order to protect incumbent Federal Government meteorological operations in the band.[31]

13. In 2004 and again in 2006, the Commission granted temporary waivers for certain medical implant transmitters to operate in the 402-405 MHz MICS band.[32] The data transmissions from these devices occur on a periodic basis rather than in response to recurring query from a programmer/control transmitter or other external device, and they each operate on a single channel without the requisite frequency monitoring capability. However, they operate with very low power and low duty cycles in order to minimize the likelihood that they would cause interference. The Commission granted the waivers for limited periods of time based on showings by Biotronik and DexCom that the devices could not presently be made to comply with the MICS rules, but would pose a negligible risk of interference to other medical radiocommunication devices or primary users in the MICS band, and would provide significant medical benefits for patients.[33] In granting the waivers, the Commission anticipated the need to revisit its rules for medical devices, and conditioned those waivers on the outcome of such rulemaking.

14. *Medtronic Rulemaking Petition and Responsive Comments.* On July 15, 2005, Medtronic filed a Petition for Rulemaking (Medtronic petition) proposing to establish a new service for implantable and body-worn medical radiocommunication devices in two megahertz of spectrum (at 401-402 MHz and 405-406 MHz) adjacent to the existing MICS 402-405 MHz band.[34] Medtronic states that this new allocation would complement the existing MICS allocation and support advances in medical sensor technology and the expected proliferation of such devices, especially those used for lower-cost medical monitoring and non-emergency reporting applications.[35]

15. As requested by Medtronic, this new allocation would provide for a "two-tiered" service of ultra-low power radio devices that would support short-range data communications from implanted, body-worn, and associated external medical devices. The first tier service would include implantable devices substantially identical to those permitted under the existing MICS rules, as well as body-worn medical radiocommunication devices. Devices operating with relatively higher power in this first tier would be required to employ frequency-monitoring technology. The second tier service would permit the operation of devices with very low power and low duty cycle that do not employ frequency monitoring,

[28] 47 C.F.R. § 95.628. This rule also authorizes MICS transmitters to operate on any frequency within the 402-405 MHz band, and limits the emission bandwidth from a MICS device to 300 kHz.

[29] 47 C.F.R. § 95.1211.

[30] *MICS Order* at 21042-43.

[31] 47 C.F.R. § 2.106, footnote US 345

[32] These devices were an implanted cardiac pacemaker manufactured by Biotronik, Inc. (Biotronik) and an implanted blood glucose monitor manufactured by DexCom, Inc. (DexCom). *See Biotronik Wavier, supra,* and *DexCom Waiver, supra.*

[33] *Id.*

[34] *See* n.1 *supra.*

[35] *Id.* at i - ii. *et seq.*

and would otherwise be prohibited in the MICS bands. Medtronic asserts that this new allocation could, among other benefits, foster the development of an array of new medical devices that would improve the quality of health care. Medtronic also asserts that this "would further encourage worldwide harmonization of a [medical] service band that the ITU-R has already found to be compatible with incumbent uses."[36]

16. On August 24, 2005, the Commission released a *Public Notice* seeking comment on Medtronic's petition.[37] DePuy Orthopaedics, Intel Corporation (Intel), Medtronic, Transoma Medical (Transoma), and Zarlink Semiconductor Inc. (Zarlink) submitted comments generally supporting the Medtronic Petition, while DexCom and Dr. W.G. Scanlon (Scanlon) offer partial support.[38] Biotronik opposes the Medtronic request.[39] As noted above, on June 16, 2006, Biotronik also filed a petition for rulemaking, with proposals that conflict with those in the Medtronic petition, which will be considered herein.[40]

17. Intel and others note that the requested new allocation would allow for the development of consumer medical sensing devices that could be used for monitoring outside of clinical environments.[41] Intel states that there are multiple manufacturers that could readily modify their MICS designs to produce compliant products under Medtronic's two-tiered plan. Transoma and Zarlink state that devices permitted by such an allocation would allow physicians to determine the status of the patient's condition in real time by communicating medical status information.[42] They argue that this would provide for early detection of events that may threaten the patient's life or lead to hospitalization and allow physicians to adjust internal and external medical radio devices with improved efficiency and accuracy.

18. DexCom states that it does not oppose the allocation of additional new spectrum for use by medical implant devices on general principles. However, both DexCom and Biotronik oppose any plan for the 402-405 MHz MICS band that would eventually force any currently deployed devices to move to new spectrum and/or to operate with reduced power levels.[43] DexCom also opposes a two-tiered system wherein some devices in any particular frequency band would be subject to more stringent technical requirements than others. Instead, both DexCom and Biotronik generally prefer rule changes that would more flexibly accommodate low power, low duty cycle devices in the existing MICS band.

19. Finally, Biotronik opposes the creation of a new allocation as suggested by Medtronic. Biotronik argues that the record does not support Medtronic's proposal. In particular, Biotronik argues that the MICS band is not crowded and that, as a result, a variety of devices (including low power, low duty cycle devices not having frequency monitoring technology) can coexist - particularly where the risk of interference is so low.[44] It argues that the current rules limit the utility of the band for some

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[36] Medtronic Petition at 4, referring to Recommendation ITU-R, SA.1346, *Sharing Between the Meteorological Aids Service and Medical Implant Communications Service (MICS) Operating in the Mobile Service in the Frequency Band 401-406 MHz.*

[37] *Public Notice*, August 24, 2005, Report No. 2725 (RM-11271). A list of the parties filing comments and reply comments is attached as Appendix A.

[38] *See* DePuy Orthopaedics Comments at 1; Intel Reply Comments at 2 and 5; Medtronic Comments at 5; Medtronic Reply Comments at 1 and 14; Scanlon Comments at 1; Transoma Medical Comments at 1; Zarlink Comments at 1; DexCom Comments at 1.

[39] *See* Biotronik Reply Comments at 2.

[40] *See* n. 17, *supra*.

[41] *Id.* at 3.

[42] *See* Transoma Comments at 1. *See* Zarlink Comments at 2.

[43] *See* DexCom Reply Comments at 1-2.

[44] *See* Biotronik Reply Comments at 2.

applications due to increased complexity and power drain required by compliance. Biotronik recommends that, instead of creating a new allocation, the Commission consider changes in the present MICS regime in the 402-405 MHz band to accommodate a wider range of devices, including devices that do not meet the current frequency monitoring requirements. Biotronik specifically proposes that the rules accommodate devices without frequency monitoring and agility if they maintain a maximum duty cycle of 0.1% per hour and a maximum power level of 100 nW effective radiated power. Furthermore, in its rulemaking petition, Biotronik proposes that a specific 300 MHz channel be set aside for such devices at 403.65 MHz +/- 150 kHz; and notes that this would be consistent with worldwide MICS allocations. It also suggests that this channel could be used as a "beacon" channel to initiate communication sessions for listen-before-talk devices in an efficient manner by avoiding repeated polling by the external device. It also argues that its proposal is consistent with the direction in which the European Telecommunications Standards Institute is moving, referring to a proposal by the ETSI Technical Committee Electromagnetic Compatibility and Radio Spectrum Matters, Task Group TG30.[45]

20. *Proposal for Amending MICSs.* As demonstrated by the response to the Medtronic petition for rulemaking, there is significant interest in using the 401-406 MHz MICS band for new diagnostic, therapeutic, and monitoring medical technologies. Based on the information provided by all parties, we are proposing to add two additional megahertz of spectrum for implanted and body-worn medical transmitters to the existing MICS allocation at 402-405 MHz. We specifically propose to add the 401-402 MHz and 405-406 MHz ("wing" bands) to the existing MICS allocation. In effect, this would make the entire 401-406 MHz (MedRadio) band available for both implanted and body-worn devices, while preserving the core 402-405 MHz (existing MICS) band for devices which, as discussed more fully below, have a frequency agility capability. These new "wing" bands appear well-suited for implanted and body-worn medical radio devices for the same reasons 402-405 MHz was originally designated for MICS, *i.e.*, propagation characteristics, availability, and compatibility with other users.[46] We also believe that

[45] Biotronik Petition for Rule Making at 2, 5.

[46] In the United States, the 401-406 MHz band is allocated to the meteorological aids service (METAIDS) on a primary basis for Federal and non-Federal use and transmissions are limited to radiosondes and associated ground transmitters. (The METAIDS is a radiocommunication service used for meteorological, including hydrological, observation and exploration. A radiosonde is an automatic radio transmitter in the METAIDS usually carried on an aircraft, free balloon, kit or parachute, and which transmits meteorological data. Radiosondes worldwide are launched each day to provide soundings data that contribute to global reports of air movement, pressure, and temperature. Computer models use this information to produce weather forecasts. While the 401-406 MHz band is allocated to the METAIDS on a primary basis in all Regions in the ITU *Radio Regulations*, transmissions are not limited to radiosondes and associated ground transmitters.) The Departments of Commerce (National Weather Service), Defense, and Energy are the primary users of this METAIDS allocation. (As of January 7, 2006, NTIA has authorized 52 radiosonde station assignments, 47 radiosonde ground station assignments, and 12 radar beacon precipitation gauge station assignments in the 401-406 MHz band. Non-Federal use of this METAIDS allocation has been limited to experimental license applications.) The 401-403 MHz band is also allocated to the meteorological-satellite (METSAT) and Earth exploration-satellite services (Earth-to-space) on a primary basis for Federal use and on a secondary basis for non-Federal use. As of January 7, 2006, NTIA has authorized 5,094 Federal assignments for transmitting earth stations in the METSAT and 18 Federal assignments for transmitting earth stations in the Earth Exploration Satellite Service (EESS). While the FCC has issued several hundred experimental licenses for non-Federal earth stations in the METSAT that transmit to Federal space stations in the 401-403 MHz band, no licenses have been issued in the EESS. *See* http://www.nws.noaa.gov/oh/hads/. This METSAT allocation is used by Federal and non-Federal earth stations (known as data collection platforms) that transmit weather information to Federal space stations (*e.g.*, National Oceanic and Atmospheric Administration and Geostationary Operational Environmental Satellite space stations). With regard to TT&C (tracking, telemetry and command) use of the 401-402 MHz band, the FCC has issued two licenses for NGSO space stations and four licenses for earth stations (each receive a 60 kHz emission centered on 401.5 MHz). (Specifically, Orbital Imaging Corporation (Orbimage) operates a high-resolution satellite imagery system in low-Earth orbit (LEO); space telemetry is received at earth stations in Barrow, AK (call sign E980376) and Dulles, VA (call sign E980375). EarthWatch Incorporated operates a LEO remote-sensing satellite system; space telemetry is received at earth stations in Fairbanks, AK (call sign E950499) and Longmont, CO (call sign E950498). NTIA has authorized one (continued....)

the provision of contiguous spectrum will provide for the maximum efficiency of design and operation. We propose to maintain much of the existing MICS rules in this spectrum, but not on an exclusive basis, and we also propose to continue to license use of MICS devices by rule. We further propose to permit non-implanted transmitters, such as those that are worn on the body ("body worn"), that are connected to implanted devices under these rules. Accordingly, we will henceforth refer to this service as "Medical Device Radiocommunication Service," ("MedRadio") - rather than MICS - to eliminate the implication that it is intended exclusively for implanted radios or implanted devices. We seek comment on whether the various current MICS rules would continue to be appropriate for operations under the new allocation, on the explicit inclusion of non-implanted transmitters, and on whether certain medical devices as contemplated herein would be better served by a licensed operation regime.

21. We note that Medtronic suggests limiting the maximum authorized channel bandwidth for all devices to 100 kHz in the new bands as contrasted with the 300 kHz channel bandwidth permitted for the MICS center band,[47] and more stringent emission limits for the wing bands than the present MICS limits.[48] Medtronic also recommends that the measured field strength limits for body-worn transmitters be reduced by 4 dB to account for the lack of body absorption of radiated power that occurs with implanted transmitters.[49] We seek comment on whether there are some functions for which a narrower bandwidth is appropriate, and why, and whether there is sufficient justification for the more stringent attenuation limits described in the Medtronic petition. Commenters supporting emission limits other than those currently in the rules should provide technical analysis and practical rationale explaining why other limits would be more appropriate, and the relative difficulty or cost of compliance associated with their proposed limits. Commenters proposing a reduced field strength for body-worn transmitters should also provide technical analysis supporting their position.

22. The United States, Canada, France, and the Russian Federation are active participants in the development of the international Search and Rescue Satellite (COSPAS-SARSAT) system. The system is made up of SARSAT and COSPAS satellites, terrestrial emergency transmitters, local ground stations, mission control centers (MCC) and rescue coordination centers (RCC). The COSPAS-SARSAT system determines the position of a distressed aircraft, ship, or other vehicle from the low-powered emission of an automatic distress beacon. The COSPAS-SARSAT system is composed of three main subsystems, the distress beacon, the satellite repeater/processor, and the ground receiver processor. The low-powered

(Continued from previous page)
assignment for space stations in non-geostationary orbit (NGSO) transmitting telemetry to earth stations in this band.) In addition, the 401-402 MHz band is allocated to the space operation service (space-to-Earth) on a primary basis for Federal and non-Federal use. (In the ITU *Radio Regulations*, the 401-406 MHz band is allocated to the mobile except aeronautical mobile service on a secondary basis in all Regions. 47 C.F.R. § 2.106.) The 402-405 MHz band is allocated to the MICS on a secondary basis as indicated above. The 402-406 MHz band is allocated to the mobile except aeronautical mobile service on a secondary basis. This allocation is codified in footnotes US345 and G6 to the Commission's Table of Frequency Allocations, which also limits the use of the allocation to Federal and non-Federal MICS stations in the 402-405 MHz band and to "military tactical fixed and mobile operations" in the 403-406 MHz band. (47 C.F.R. § 2.106, footnotes US345, G6.) We are unaware of any airborne use of the 403-406 MHz band and have requested that NTIA investigate this matter with view toward the deletion of the aeronautical mobile service. In the context of military tactical fixed operations, NTIA has informed us that this term actually means temporary fixed.)

[47] *See* Medtronic Petition, Appendix A, at proposed rule sections 95.633(h). For MICS transmitters, the maximum authorized emission bandwidth is 300 kHz. 47 C.F.R. § 95.633(e).

[48] The Medtronic petition suggests a standard by which emissions more than 50 kHz away from the fundamental emission would need to be attenuated by at least 20 dB; and emissions outside of the designated bands would need to be attenuated to 200 μV/m at 3 meters in the frequency ranges 216-400.9 MHz and 406-960 MHz. This is similar to the rules adopted for MICS transmitters, except that the field strength limit of 200 μV/m at 3 meters would have to be achieved in within a narrower 100 kHz span (400.9-401 MHz), instead of the 250 kHz span under the MICS rules.

[49] *See* Medtronic Petition, Appendix A, at proposed rule sections 95.639(i).

distress signal is transmitted by the Emergency Locator Transmitter (ELT) or the maritime equivalent Emergency Position Indicating Radio Beacon (EPIRB). The signal is detected by the receiver on the spacecraft and data is transmitted back to a Local User Terminal (LUT) on the ground, where the appropriate MCC and/or RCC is alerted. The processed data system is available only for the 406.025 MHz ELT/EPIRB signals. These signals contain data as to the type of platform, country of origin, identification of ship or aircraft, and type of emergency. The signals are recovered, detected and identified by processing on the spacecraft. The 406.025 MHz emergency frequency has been designated internationally for distress use only. The international COSPAS-SARSAT Program announced that it will terminate satellite processing of distress signals from 121.5 MHz and 243 MHz EPIRBs and ELTs as of February 1, 2009. The implication of this decision is that users of EPIRBs and ELTs that send distress alerts on 121.5 MHz and 243 MHz should begin using EPIRBs and ELTs operating on 406.025 MHz if the alerts are to be detected and relayed via satellites. Mariners, aviators, and other persons will have to switch to EPIRBs and ELTs that operate on 406.025 MHz. Given the importance of this frequency to public safety around the world, it must be adequately protected. Accordingly, we seek comment on what out-of-band emission level in the 406-406.1 MHz band is necessary to protect COSPAS-SARSAT satellite receivers.

23. We also propose to adopt rules for the 401-402 MHz and 405-406 MHz bands that would permit body-worn and implant transmitters having low-power and low duty cycles to operate without frequency monitoring capability as suggested by Medtronic and supported by several commenters. Because such devices would pose a small risk of causing harmful interference, we believe that permitting the operation of such devices without frequency monitoring could simplify device designs, reduce their size, and extend their operational life. This could help lower the cost of medical data collection and therapy in both the care center and home environments, as well as provide physicians with an easy and accurate way to make routine adjustments to internal and external medical radio devices such as neural stimulators and insulin pumps. We further believe that providing additional spectrum for deployment of these devices could prove beneficial in keeping otherwise healthy individuals out of hospital beds and nursing facilities and allow many more individuals to live independently for a longer period of time. We seek comment on the potential benefits of expanding the authority for operation of 400 MHz medical devices that do not employ LBT frequency monitoring capabilities.

24. We believe that allowing devices that do not employ frequency monitoring in the 401-402 MHz and 405-406 MHz bands, as argued by Medtronic and others, would preserve a block of spectrum at 402-405 MHz for the more critical devices and any others that employ frequency monitoring both to protect their function and to reduce the risk that they would be subject to interference. This could become increasingly important as spectrum use intensifies, for critical devices to avoid becoming more susceptible to harmful interference from other non-implanted devices and those that transmit without prior frequency monitoring. Furthermore, the MICS device industry itself is still in its nascent stages and, absent compelling reasons, we would be reluctant to upset the existing MICS rules for operation in the 402-405 MHz band in light of research and development that has taken place in reliance on our rules, and the products that are and will soon be available to the public as a result. In this light, we are not proposing the modifications to the MICS rules suggested by Biotronik in its rulemaking petition that suggest permanently allowing the use of certain devices without frequency agility within the 402-405 MHz band or setting aside one 300 kHz channel in that band for such use. However, in order to foster a full exploration of options for the entire 401-406 MHz band, we invite comment on the potential benefits or disadvantages of Biotronik's proposals.

25. Specifically, we propose to allow medical implant or body-worn devices and associated control station devices that operate without frequency monitoring to operate at 401-402 MHz and 405-406 MHz, and to limit such devices to an EIRP that does not exceed 250 nanowatts (nW) and a duty cycle that does not exceed 0.1% during any one-hour interval. Based on the information available to us, this proposal appears to reflect a reasonable balance between the operational capabilities needed for devices to

function properly and the need to minimize the risk of interference to other devices in the band.[50] We seek comment on this proposal, including whether other power and duty cycle thresholds would be more *appropriate, and what trade-offs they would entail.*

26. We also note Biotronik's contention that there is ample capacity in the current MICS allocation for a variety and large number of devices, and seek additional comment on whether the additional spectrum we propose is needed for future medical devices, or whether such devices should be accommodated in the existing 402-405 MHz allocations, with appropriate modifications to the operational rules, such as those proposed by Biotronik in its rulemaking petition. We also invite comment on whether the 401-406 MHz band should be apportioned differently among the various types of operation than as proposed above, both in relative amounts of spectrum designated, and in the specific frequencies permitted for each type of operation. For instance, should a portion of spectrum be exclusively designated for non-frequency-monitoring devices, and if so, how much? Can the provision of exclusive spectrum for frequency monitoring devices be made unnecessary by appropriate restrictions on other devices? Is additional spectrum beyond that proposed above needed for implanted and body-worn medical radio devices? Comments suggesting the allocation of additional spectrum should discuss the basis for projecting future types of uses and needs.

27. It is apparent from the devices we have examined, as well as the comments submitted, that our rules need to be clear as to the significance, if any, of the location of the transmitter (in particular, the antenna) associated with the medical device. While our present MICS rules can be read to have assumed that an implant transmitter would be part of a fully implanted device, it is now apparent that the transmitter and/or antenna portion of implanted devices can, in many cases, be located on (or just below) the surface of the skin.[51] Additionally, it appears that there are body-worn devices that can perform critical diagnostic, therapeutic, and monitoring functions, and we propose to accommodate such devices in our rules. In either case, it is the location of the antenna that determines a device's communication capability and its interference potential; and, thus its location should dictate the operational parameters set forth in the rules. Accordingly, we propose to modify our rules to clarify that the transmitter/antenna portion of a MedRadio device need not be implanted, but may also be body-worn (including placement on, or subcutaneously injected just below, the skin). We also seek comment on whether and what different rules or frequency bands should be applied to body-worn and implanted antennae. We also seek comment on Medtronic's proposed definition of a body-worn transmitter as one "intended to be placed on or in very close proximity (six centimeters or less) to the human body used to facilitate communications from a medical body-worn or implanted device.[52]

28. We note that Medtronic requests that we also amend Section 95.603(f) of the rules in order to provide manufacturers with an alternative means of demonstrating compliance with the Commission's RF safety exposure limits for their medical implant devices.[53] We do not discuss this issue herein because we believe that it is more appropriate to address it in the context of our ongoing RF safety proceeding (ET

[50] By comparison, one of the devices permitted by the *Biotronik Waiver* transmits in bursts of up to 280 milliseconds, repeated ten times per day, at a maximum power of 100 nanowatts on a single 40 kHz bandwidth channel. The blood glucose monitor permitted by the *DexCom Waiver* also operates on only one frequency with a 120 kHz bandwidth, with a power of 10 microwatts (-20dBm) and for only 6-9 milliseconds every five minutes.

[51] *See DexCom Order* at para 18.

[52] *See* Medtronics petition, proposed Appendix 1 to Subpart E to Part 95 - Glossary of Terms.

[53] Section 95.603(f) presently requires that applications for equipment authorization must contain a "finite difference time domain (FDTD) computational modeling report." Medtronic's proposal would also allow, as an alternative to the FDTD requirement, "a report based on another technique accepted by the Commission." *See* Medtronic Petition, Appendix A, at proposed section §§ 1.1307, 95.603(f).

Docket No. 03-137) that anticipates dealing with proposed changes in the Commission's Rules regarding *human exposure to RF electromagnetic fields in a more comprehensive fashion.*[54]

29. The rules we propose herein focus on providing the flexibility in the use of spectrum for implanted and body-worn medical radio devices. We note that the Medtronic petition suggests distinctions depending upon factors such as whether a device uses spectrum intensively or is used for life-critical applications. We believe that it is neither the role, nor the area of expertise, of the Commission to adopt rules that would define operating criteria based upon such determinations. Instead, we believe that medical device manufacturers should be cognizant of the potential health and safety risks that could arise if implanted or body-worn medical radiocommunication devices are subjected to various levels of RF interference in a dynamic and unpredictable RF environment, and design their products with appropriate safeguards and robustness as is appropriate to their function. We further believe that such concerns are more appropriately taken into consideration and evaluated as part of the FDA medical device approval process. Therefore, we decline to propose any rules based upon such criteria. We seek comment on this position.

30. Our intention in proposing these rules is to provide for more efficient and intensive spectrum use in the near term by advanced medical technologies that feature implantable and body-worn transmitters. Our deliberations will be informed by the current activity, development, and knowledge in this area. We particularly seek information regarding the development of such devices, their stage of development, their function, and their spectrum requirements and reliability needs. We will also take into consideration, to the extent practical, information provided in response to our Inquiry, as indicated below, regarding anticipated future developments in implanted and body-worn medical devices that may rely, in varying degrees, on radiocommunication for their functionality.

31. *Inductive Telemetry.* Guidant Corporation manufactures medical devices for cardiac patients, including implantable pacemakers, implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy (CRT) devices that use inductive coupling to communicate heart information between patients and doctors. Inductive medical devices must be coupled to external programmers or readers by means of low level magnetic pulses.[55] Magnetic coupling requires very close spacing between the implanted device in the patient and external monitoring/control equipment, often requiring body contact for proper operation.[56] The inductive magnetic pulses generated by these inductive devices also produce RF energy. The Guidant devices produce RF energy in the 90-110 KHz band as a consequence of its inductive coupling technique.

32. Part 15 of our rules restricts radiation from unlicensed devices in certain frequency bands ("restricted bands") to spurious emissions only.[57] The 90-110 kHz band is included among the restricted bands in order to protect incumbent the Loran-C operations.[58]

33. Guidant states that it is unclear how induction devices fit under the Commission's restricted band prohibition of Section 15.205.[59] While acknowledging that its devices produce RF energy in the 90-

[54] Proposed Changes in the Commission's Rules Regarding Human Exposure to Radiofrequency Electromagnetic Fields, ET Docket No. 03-137, *Notice of Proposed Rule Making*, 18 FCC Rcd 13187 (2003), available at http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC-03-132A1.doc.

[55] See *MICS Order* at para 3.

[56] *Id.*

[57] 47 C.F.R. § 15.205.

[58] The 90-110 kHz band is allocated for Radionavigation (Loran-C) service by both Federal and non-Federal use on a shared, primary basis. (47 C.F.R. §2.106.) Non-federal use in this band consists of aviation and Private Land Mobile services under Parts 87 and 90 respectively.

[59] Guidant petition at 5. Guidant further states that their medical devices produce radiated emissions in the 90-110 kHz band as a 'by-product' of the inductive coupling technique employed to communicate with the devices.[59] (continued....)

110 KHz band, Guidant also argues that these emissions could be considered spurious under our rules.[60] In that regard, Guidant argues that its devices rely upon the magnetic pulses rather than the RF energy produced in order to function. Furthermore, Guidant argues that since the RF energy produced by its devices could be suppressed without affecting its inductive communications ability, the RF component could nevertheless be deemed a spurious emission.[61] Guidant also states the emission levels from its devices are so low that there is little risk of interference being caused to any other devices or services in the band. Accordingly, Guidant asks the Commission to amend the Part 95 Rules to include medical implant devices such as those made by Guidant that use inductive telemetry in the 90-110 kHz band. More specifically, it requests that the Commission provide a narrow exception to the Part 15 restricted band prohibitions for medical implants or, preferably, amend the MICS rules to expressly include all implants, including those that operate inductively in the 90-110 kHz band. Guidant urges that making a provision in the rules for these devices would be beneficial because the alternative of being required to modify its devices to suppress the RF energy would only result in added device cost and complexity with no discernable interference reduction benefit.

34. We seek comment on whether inductive devices such as those made by Guidant should be authorized to operate if they produce RF energy in the 90-110 kHz band. We ask commenters to address the advantages and disadvantages of allowing or prohibiting such operation, including the resulting interference potential. If such operation were to be permitted, what approach should be taken? For example, similar to the modified MedRadio rules proposed herein, a secondary allocation for inductively coupled medical devices could be created in the 90-110 kHz band on a licensed-by-rule basis under Part 95. Another option would be to provide an exception to the restricted band spurious emission limits for unlicensed medical devices that use inductive coupling in the 90-110 kHz band. Alternatively, a waiver could be granted that would permit manufacture, sale, and use of such devices for a limited period of time until devices fully compliant with the present rules can be developed. We invite commenters to address the relative merits these options, and to suggest any other options.[62] We also seek comment on the more general question raised by Guidant concerning how to address emissions from medical implant devices that employ inductive coupling technology for communicating with associated external devices.

IV. ORDER

35. As previously noted, two families of noncompliant devices are currently authorized for use in the MICS band.[63] The DexCom waiver is effective until January 19, 2009 (or until one year after the completion of any rulemaking the Commission may undertake, whichever is later). In granting the DexCom waiver, the Commission anticipated both the need to undertake the instant rulemaking, as well as further developments in medical technology. The Biotronik waiver is effective until February 26, 2007. In light of the need for physicians and patients to reasonably anticipate the availability of such critical products, Biotronik has already filed a request for extension of its waiver.[64] Given the importance of these devices and the fact that we have thus far found no instances of interference involving their use, we hereby grant Biotronik's request for extension of its waiver, pending adoption of new MedRadio rules as proposed today. To the extent the Biotronik device is not compliant with the forthcoming rules, we will require that Biotronik modify its device to ensure compliance within one year of the effective date of

(Continued from previous page)

However, Guidant further states that the level of emissions from these inductive implants is typically 50-90 dB below the limits of Section 15.209.

[60] *See* Guidant petition generally.

[61] Guidant petition at 5.

[62] We note that we would seek the concurrence of the National Telecommunications and Information Administration (NTIA) before any action, such as those suggested in this paragraph, that would impact a restricted band allocated for Federal Government use.

[63] *See* para 8. *supra.*

[64] *Request for Extension of Waiver*, December 12, 2005.

such rules. Our intent is to render consistent the Biotronik waiver with that granted to DexCom (which, as noted earlier, provides one year beyond completion of the instant rulemaking), as well as to ensure adequate transition time for modification of the subject devices as may be necessary. We will, however, also retain the option to permit the continued manufacture and use of either the DexCom or Biotronik devices for an additional period, or indefinitely, depending on considerations such as the availability of technology and parts for compliant equipment at the time we adopt our new MedRadio rules. Finally, we note that parties may comment on the propriety of further extending the Biotronik and DexCom waivers beyond the extension provided herein.

V. NOTICE OF INQUIRY

36. As noted in the Introduction, above, it appears that the health care industry has reached the beginning of a wave of breakthroughs in providing care and rehabilitation that will use radiocommunication technologies in a variety of ways. There is already development in such medical devices to assist in everything from motor function to eyesight, significantly mitigating the effects of once debilitating injuries or diseases. For instance, we understand that at least one research organization, the Alfred E. Mann Foundation, is working on RF-powered microstimulators for nerves and muscles and other applications.[65] More and more sophisticated devices are also being developed to monitor various health conditions and to control the medication for a wide variety of ailments and diseases, leading to better management of these conditions to reduce their morbidity, their effects on overall health, and patients' quality of life and life expectancy. We must also be aware of medical devices that do not directly utilize radio communication, but can affect or be affected by the RF environment. As one example, researchers at the Massachusetts Institute of Technology (MIT), Vivo Metrics, and other research centers are developing a vest (and other clothing articles) with a surface that is completely electrically conductive, so that a variety of sensors can be placed at locations as appropriate for individual patients and wirelessly feed medical information back to a data collection point on the vest.[66] Thus, we seek information on evolving trends in medical radio device development to determine the long-term adequacy of the Medical Device Radiocommunication Service rules proposed herein and, if so guided by the comments and information received in response to this Inquiry, to propose additional rules and/or additional spectrum for the operation of such devices. Because increasing numbers of implanted and body-worn medical devices rely upon wireless radiocommunication technologies, we seek to develop a comprehensive record concerning the present and future RF spectrum requirements as well as device immunity issues with respect to these medical radio devices in order to better inform our current rulemaking effort and to provide a basis for further rule changes.

37. In order to gain a more informed perspective on the evolving spectrum needs for implanted and body-worn medical radio devices that will use spectrum, or other devices that will affect or be affected by MedRadio devices, we seek information on existing devices as well as those that might be outside the scope of the rules proposed above. Commenters should include any available information on the developmental status and anticipated market deployment timelines for planned and envisioned future devices. From the manufacturing and deployment perspective, we seek comment on the extent to which existing and planned devices have spectrum operating needs different from each other and different from those that will be accommodated by the rules adopted in response to the proposals above, and what those needs might be. For example, we invite commenters to address whether some frequency bands are preferable for use due to physiological characteristics with respect to RF propagation through body tissue. Would it be beneficial to separate certain types of implanted and body-worn medical radio devices into specific operating frequency bands where they would be less likely to be interfered with by other types of medical radio devices? We ask whether any of the newer devices will require exclusive spectrum or can share spectrum with existing users. We seek input about the nature and function of the devices, particularly if such devices incorporate life supporting or critical functions, and their potential

[65] *See, e.g.*, Alfred E. Mann Foundation at http://www.aemf.org/index.html.

[66] *See, e.g.*, http://www.media.mit.edu/wearables/; http://www.vivometrics.com/site/system.html.

susceptibility to RF interference from other medical and non-medical RF emitters. What techniques will, or can, such devices employ to ensure an adequate level of robustness and with what types of other operations can they feasibly share spectrum? What power levels and duty-cycles will these new devices require? Could additional changes in the rules governing the frequency bands already allocated for medical radio devices prove beneficial? If so, what would be the impact of such changes, positive or negative, on existing services in the band?

38. With respect to spectrum management, we seek comment on whether there are ways in which we could anticipate, and proactively avoid, RF interference between various medical radio devices, as well as with non-medical devices sharing the same spectrum, before they occur. Could different rules than those proposed above eventually provide greater flexibility to encourage technological advancement while fostering more intensive spectrum use and, if so, how? If additional spectrum will be needed for new devices, what spectrum is suitable and available?

39. The Commission's rules in some instances specify the emission type or modulation schemes that are permitted in particular frequency bands;[67] for example, a MICS station may transmit any emission type appropriate for communications in that service, except that voice communications are prohibited.[68] Should all emission types be permitted within any particular band, or should some restrictions be imposed to address interference concerns, channelization, spectrum efficiency or related concerns? What criteria should be used for identifying emission types that would either be permitted or prohibited? What types of devices should be allowed to operate in the spectrum identified for medical radio use? Should any restrictions be placed on the locations in which these devices should operate? Should some form of spectrum-sharing etiquette be considered in certain frequency bands? Would it be beneficial if a medical radio device were permitted to use its primary operating frequency to enable networked communications with other devices or systems in the same frequency band? How could such use best be accomplished, and what would be the tradeoffs in terms of spectrum sharing and possibly increased RF congestion? Parties may also wish to comment on any other related issues or approaches not mentioned herein so that we may develop the most comprehensive record possible.

40. We also recognize that international harmonization of the operating frequencies for medical radio devices could be beneficial. This could foster a more expeditious deployment of medical radio devices using the same basic device designs over wider international markets and at reduced costs. In addition, persons with implanted or body-worn medical radio devices would be able to travel internationally with greater confidence that their medical radio devices would continue to operate properly and have greater compatibility with device support infrastructure in other countries. Thus, we seek comment on how domestic RF allocations could or should be better harmonized with international RF allocations.

41. We seek comment on any medical device manufacturing industry standards work that has been done domestically or internationally on medical radio devices, and the results of such activities. We are interested in evaluating how important standardization will be for all or certain medical radio devices, both for manufacturing ease and/or economy and for patient safety and medical device effectiveness when traveling. We are also interested in the cost or difficulty in achieving such standardization in any respects. Among other matters, commenters should address what, if any, international standards should be investigated for possible consideration in the United States to facilitate the development of medical radio devices for a global marketplace. What aspects of these international standards might prove to be beneficial domestically? Why would they be beneficial? What are the disadvantages? What steps should the Commission take to encourage this work? Are there other standards bodies involved in similar activities?

[67] *See, e.g.*, 47 C.F.R. § 95.631 ("Emission Types").

[68] 47 C.F.R. § 95.631 (h)

42. As explained above, under our current rules a wide range of frequencies between 9 kHz and 2483.5 MHz *may be used under our current rules by medical devices - some on a licensed, and others on* an unlicensed basis. As a general condition of operation, Part 15 devices may not cause harmful interference to authorized radio services and must accept any interference that they receive.[69] Consequently, medical devices operating under Part 15 may be more likely to experience harmful interference, particularly from other authorized non-medical devices sharing the same RF spectrum.

43. We note that this is not the first time we have addressed these concerns. For example, as previously noted, the Commission established the WMTS in response to a reported case of interference to unlicensed biomedical telemetry operations under Part 15 on a previously vacant TV channel that occurred when a new digital television (DTV) station began test transmissions on the same channel.[70] The Commission also sought to address the potential for harmful interference to biomedical telemetry devices from co-frequency, high power private land mobile radio (PLMR) operations in the 460-470 MHz band.[71] In 2002, the Commission decided that equipment approval would no longer be available for in-hospital medical telemetry equipment operating in the 174-216 MHz and 470-668 MHz bands under the provisions of Part 15 or Part 90 (except in the 1427-1432 MHz band).[72] Since that time, approval for new medical telemetry equipment must be sought pursuant to the WMTS rules in Part 95.[73]

44. Accordingly, we seek comment on the relative merits of licensed versus unlicensed approaches for authorization of new types of medical radio devices, especially with regard to addressing the potential for harmful interference to such devices. Are there situations, such as life-critical applications, where a licensed approach would be more beneficial? If so, how would "life-critical" be defined or a "life-critical" threshold determination be made, and by whom? Would certain wireless networking technologies, such as Wi-Fi, or others provide a more flexible and readily deployable infrastructure to support medical radio devices if utilized for medical purposes on an unlicensed basis? Should the operation of medical radio devices under Part 15 for medical applications on frequencies that are shared with other non-medical devices or services be discouraged or prohibited? If so, what measures would be appropriate? How would such alternative approaches be implemented and managed by regulators and industry? We also ask, in a similar fashion to the approach adopted by the Commission for unlicensed personal communications service (UPCS) devices, whether defining or restricting certain frequency bands exclusively for operation of certain type of medical radio devices on either an unlicensed or licensed-by-rule basis could address these needs.[74] What would be the benefits and disadvantages of such an approach? Are there any other regulatory approaches, including hybrids between licensed and unlicensed devices that should be considered?

VI. INTERAGENCY COLLABORATION, INDUSTRY EDUCATION, AND DEVICE IMMUNITY

45. Implantable and body-worn devices will occasionally be brought into unpredictable electromagnetic environments, both within and beyond the health care setting. In such settings, a medical device could be adversely affected if the environmental RF exposure exceeds its EMC immunity design and test level, or if effects of RF interference cannot be efficiently mitigated.[75] For example, even while

[69] 47 C.F.R. § 15.5.

[70] See *WMTS Order*, 15 FCC Rcd 11206, at para 6.

[71] *Id.* at para 3.

[72] 47 C.F.R. §§ 15.37(i), 90.203(a)(1).

[73] 47 C.F.R. § 95.1101-1129.

[74] FCC Part 15, Subpart D, 47 C.F.R. §§ 15.301 through 15.323.

[75] We note, however, that some researchers and practitioners continue to debate whether concerns about interference in settings such as hospitals, for example, from devices like pagers and cell phones, have been overestimated. *See No hazard to hospitals? Fear that cell phones cause failure of vital machines in medical facilities is a myth, says* (continued....)

confined inside a health care facility, the proper operation of a medical device may be impaired when brought into proximity to other medical equipment such as magnetic resonance imaging (MRI), diathermy, or X-ray equipment. In addition, many patients with implanted or body-worn medical radio devices could also congregate in a health care facility, resulting in a particularly high local density of use. In the outside world, concerns may arise when implanted medical devices are in close proximity to microwave ovens and other electronic equipment that may be either intentional or unintentional radiators of RF energy.

46. This Commission and the FDA presently work together concerning various aspects of the medical radio devices issues discussed in this Inquiry. The Commission's primary efforts focus on promulgating regulations that allocate RF spectrum for their particular use, and that set operational limits on the RF emissions they generate to achieve efficient and effective utilization of the spectrum. The FDA addresses device safety and effectiveness, including EMC issues, as part of its regulation of medical devices.[76] Furthermore, officials of both agencies periodically meet to discuss matters of concern related to the spectrum use and immunity issues discussed here. Thus, this Commission and the FDA play individual and complementary roles in the authorization and regulation of medical radio devices.

47. We seek comment, especially from parties with experience before both agencies, on how the two agencies might enhance their collaborative efforts toward better educating medical radio devices manufacturers and industry alike about RF interference and device EMC issues. How can the FCC better meet the challenge and work with the FDA to keep pace with evolving technologies? To what extent should such efforts be directed toward planning pre-deployment device design requirements versus resolving issues that arise after a device is developed or even deployed? For example, would it be beneficial to provide an FCC web site on which manufacturers or the general public could find informational documents on RF allocation and immunity issues, or where problems of interference between medical radio devices and other radiocommunication devices could be reported?[77]

48. Should other approaches be explored in cooperation with regulatory agencies and manufacturing trade groups to raise the awareness of manufacturers and applicants of what is expected (both in submission materials and other technical criteria) by the regulatory agencies in their respective approval processes concerning electromagnetic compatibility (EMC) and electromagnetic interference (EMI), including RF interference (RFI)? Should the Commission's medical radio device rules cross-reference related FDA rules? We also seek comment on whether manufacturers are generally aware that they must get approval from the FCC, and in most cases the FDA as well, before distributing or selling medical radio devices. If not, what method of knowledge sharing should be used to distribute this information throughout the medical industry? We seek input on any change in FCC procedures that might be useful to the industry in this regard. We intend to coordinate the comments and suggestions responsive to this NOI with FDA as part of our continuing efforts in this area.

49. Finally, we seek comment and suggestions for approaches to addressing any other related issues not specifically discussed above. Commenters should provide detailed descriptions of such issues, including a detailed discussion of the potential benefits and difficulties associated with any suggested approach for addressing them.

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author of new study, Newsday.com, Health/Science, by Delthia Ricks, February 6, 2006, available at http://www.newsday.com/news/health/ny-hsfone064615861feb06,0,2835197.story.

[76] We also note that the National Institute of Standards and Technology (NIST) has certain programs designed to assist the healthcare industry in the evaluation and application of wireless technologies for medical applications. *See* http://w3.antd.nist.gov/Health.shtml.

[77] We note that such a site already exists for medical devices and adverse event reports to FDA, which is required of medical device manufacturers (and certain health care facilities or clinicians) in cases of serious injury or death. http://www.fda.gov/medwatch/how.htm.

VII. PROCEDURAL MATTERS

50. *Initial Regulatory Flexibility Analysis for the Notice of Proposed Rule Making.* As required by Section 603 of the Regulatory Flexibility Act, 5 U.S.C. § 603, the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities of the proposals suggested in this document. The IRFA is set forth in Appendix B.

51. *Initial Paperwork Reduction Analysis.* The *Notice of Proposed Rule Making* and *Order* contain proposed new or modified information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995, Public Law 104-13. Public and agency comments are due 60 days after the date of publication in the Federal Register. Comments should address: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. In addition, pursuant to the Small Business Paperwork Relief Act of 2002,[78] we seek specific comment on how we might "further reduce the information collection burden for small business concerns with fewer than 25 employees."

52. In addition to filing comments with the Secretary, a copy of any comments on the information collections contained herein should be submitted to Judith Boley Herman, Federal Communications Commission, 445 12th Street, S.W., Room 1-C804, Washington, D.C. 20554, or via the Internet to <Judith-B.Herman@fcc.gov>, and to Kristy LaLonde, Policy Analyst, Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB), Docket Library, Room 10234, New Executive Office Building (NEOB), 725 17th Street, N.W., Washington, D.C. 20503, or via the Internet at <LaLonde@omb.eop.gov>.

53. *Comments.* Pursuant to Sections 1.415 and 1.419 of the Commission's rules, 47 C.F.R. §§ 1.415, 1.419, interested parties may file comments on or before October 31, 2006, and reply comments on or before December 4, 2006. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings*, 63 Fed. Reg. 24121 (1998).

54. Comments filed through the ECFS can be sent as an electronic file via the Internet to http://www.fcc.gov/e-file/ecfs.html. Generally, only one copy of an electronic submission must be filed. If multiple docket or rulemaking numbers appear in the caption of this proceeding, however, commenters must transmit one electronic copy of the comments to each docket or rulemaking number referenced in the caption. In completing the transmittal screen, commenters should include their full name, U.S. Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions for e-mail comments, commenters should send an e-mail to ecfs@fcc.gov, and should include the following words in the body of the message, "get form <your e-mail address>." A sample form and directions will be sent in reply. Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, commenters must submit two additional copies for each additional docket or rulemaking number.

55. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although we continue to experience delays in receiving U.S. Postal Service mail). The Commission's contractor,

[78] Public Law 107-198, *see* 44 U.S.C. 3506(c)(4).

Natek, Inc., will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S. Postal Service first-class mail, Express mail, and Priority Mail should be addressed to 445 12th Street, SW., Washington, DC 20554.

56. *Further Information.* For further information, contact Bruce Romano, Office of Engineering and Technology, at (202) 418-2124, or via the Internet at bruce.romano@fcc.gov; or Gary Thayer, Office of Engineering and Technology, at (202) 418-2290, or via the Internet at gary.thayer@fcc.gov.

VIII. ORDERING CLAUSES

57. IT IS ORDERED that pursuant to Sections 1, 4(i), 7(a), 301, 303(f), 303(g), 303(r), 307(e) and 332 of the Communications Act of 1934, as amended, 47 U.S.C. Sections 151, 154(i), 157(a), 301, 303(f), 303(g), 303(r), 307(e), and 332, this *Notice of Proposed Rule Making, Notice of Inquiry, and Order* IS ADOPTED.

58. IT IS FURTHER ORDERED that the Biotronik *Request for Extension of Waiver*, referenced above, is granted until one year from the effective date of final rules adopted in this proceeding.

59. IT IS FURTHER ORDERED that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, SHALL SEND a copy of this *Notice of Inquiry, Notice of Proposed Rule Making, and Order*, including the Initial Regulatory Flexibility Analysis to the Chief Counsel for Advocacy of the Small Business Administration.

FEDERAL COMMUNICATIONS COMMISSION

Marlene H. Dortch

Marlene H. Dortch
Secretary

APPENDIX A

PARTIES FILING PLEADINGS IN RM-11271

Comments:

1. Biotronik, Inc. (Biotronik)
2. (DePuy): late-filed (September 26, 2005)
3. DexCom, Inc. (DexCom)
4. Medtronic, Inc. (Medtronic)
5. Scanlon, Dr. W. G. (Scanlon): late-filed (September 29, 2005)
6. Transoma Medical: late-filed (September 27, 2005)
7. Zarlink Semiconductor Inc. (Zarlink)

Reply Comments:

1. Biotronik
2. DexCom
3. Intel Corporation (Intel)
4. Medtronic

APPENDIX B

INITIAL REGULATORY FLEXIBILITY ANALYSIS

As required by the Regulatory Flexibility Act of 1980, as amended (RFA),[79] the Commission has prepared this present Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in this *Notice of Proposed Rule Making* (*NPRM*). Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments provided in paragraph 53 of this *NPRM*. The Commission will send a copy of this *NPRM*, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA).[80] In addition, the *NPRM* and IRFA (or summaries thereof) will be published in the Federal Register.[81]

A. Need for, and Objectives of, the Proposed Rules

In this proceeding, the Commission explores future spectrum requirements for advanced medical devices that use wireless radiocommunication technologies. Wireless technologies are increasingly being used in medical devices for a variety of purposes ranging from basic telemetry transmission to more sophisticated health care applications.[82] Our focus in this proceeding is primarily on implanted and body-worn medical radiocommunication devices (MRDs) that serve to actively manage and maintain body function/health conditions.[83] Technological advances in this field are revolutionizing health care for the benefit of all Americans. Our goal is to create an environment that fosters continuing advances through flexible RF spectrum allocations and reduced regulatory requirements.

Based on the responses we have received to a Petition for Rulemaking from Medtronic, Inc., we believe that there is need for additional spectrum in the 400 MHz range for implanted and body-worn MRDs. Thus, in the Rulemaking portion of this proceeding, we propose to allocate two megahertz of spectrum for use by MRDs in the 401-402 MHz and 405-406 MHz bands that are adjacent to the existing Medical Implant Communication Service (MICS) allocation in the 402-505 MHz band. We seek comment on establishing a new Medical Data Service (MEDS) that would encompass all MRDs operating in the entire 401-406 MHz band

B. Legal Basis

The proposed action is authorized under Sections 1, 4(i), 7(a), 301, 303(f), 303(g), 303(r), 307(e) and 332 of the Communications Act of 1934, as amended, 47 U.S.C. Sections 151, 154(i), 157(a), 301, 303(f), 303(g), 303(r), 307(e), and 332.

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[79] *See* 5 U.S.C. § 603. The RFA, *see* 5 U.S.C. §§ 601 - 612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Pub. L. No. 104-121, Title II, 110 Stat. 847 (1996).

[80] *See* 5 U.S.C. § 603(a).

[81] *Id.*

[82] Telemetry is the use of telecommunication for automatically indicating or recording measurements at a distance from the measuring instrument. 47 C.F.R. § 2.1.

[83] Part 95 of the Commission's rules define "medical implant transmitter" as a " . . . transmitter that operates or is designed to operate within the human body for the purpose of facilitating communications from a medical implant device."[83] *See Appendix 1 to Subpart E of Part 95 – Glossary of Terms* (following 47 C.F.R. § 95.673). The term "body-worn" is not defined by our current rules, however, as discussed in Rulemaking herein, we propose to adopt an analogous definition for medical body-worn transmitters namely, a "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 from a medical body-worn or implanted device."

C. Description and Estimate of the Number of Small Entities To Which the Proposed Rules Will Apply

The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted.[84] The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction."[85] In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act.[86] A small business concern is one which: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.[87]

Nationwide, there are a total of approximately 22.4 million small businesses, according to SBA data.[88] A "small organization" is generally "any not-for-profit enterprise which is independently owned and operated and is not dominant in its field."[89] Nationwide, as of 2002, there were approximately 1.6 million small organizations.[90] The term "small governmental jurisdiction" is defined generally as "governments of cities, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand."[91] Census Bureau data for 2002 indicate that there were 87,525 local governmental jurisdictions in the United States.[92] We estimate that, of this total, 84,377 entities were "small governmental jurisdictions."[93] Thus, we estimate that most governmental jurisdictions are small.

Personal Radio Services. We are proposing to place the MEDS within Part 95 of our rules ("Personal Radio Services"). Personal radio services provide short-range, low power radio for personal communications, radio signaling, and business communications not provided for in other services. The Personal Radio Services include spectrum licensed under Part 95 of our rules.[94] Many of the licensees in these services are individuals, and thus are not small entities. In addition, due to the mostly unlicensed and shared nature of the spectrum utilized in many of these services, the Commission lacks direct information other than the census data above, upon which to base an estimation of the number of small entities under an SBA definition that might be directly affected by the proposed rules.

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[84] 5 U.S.C. § 603(b)(3).

[85] 5 U.S.C. § 601(6).

[86] 5 U.S.C. § 601(3) (incorporating by reference the definition of "small business concern" in 15 U.S.C. § 632). Pursuant to the RFA, the statutory definition of a small business applies "unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the Federal Register." 5 U.S.C. § 601(3).

[87] Small Business Act, 15 U.S.C. § 632 (1996).

[88] *See* SBA, Programs and Services, SBA Pamphlet No. CO-0028, at page 40 (July 2002).

[89] 5 U.S.C. § 601(4).

[90] Independent Sector, The New Nonprofit Almanac & Desk Reference (2002).

[91] 5 U.S.C. § 601(5).

[92] U.S. Census Bureau, Statistical Abstract of the United States: 2006, Section 8, page 272, Table 415.

[93] We assume that the villages, school districts, and special districts are small, and total 48,558. *See* U.S. Census Bureau, Statistical Abstract of the United States: 2006, section 8, page 273, Table 417. For 2002, Census Bureau data indicate that the total number of county, municipal, and township governments nationwide was 38,967, of which 35,819 were small. *Id.*

94 47 CFR Part 90.

Wireless Service Providers. The SBA has developed a small business size standard for wireless firms within the two broad economic census categories of "Paging"[95] and "Cellular and Other Wireless Telecommunications."[96] Under both categories, the SBA deems a wireless business to be small if it has 1,500 or fewer employees. For the census category of Paging, Census Bureau data for 2002 show that there were 807 firms in this category that operated for the entire year.[97] Of this total, 804 firms had employment of 999 or fewer employees, and three firms had employment of 1,000 employees or more.[98] Thus, under this category and associated small business size standard, the majority of firms can be considered small. For the census category of Cellular and Other Wireless Telecommunications, Census Bureau data for 2002 show that there were 1,397 firms in this category that operated for the entire year.[99] Of this total, 1,378 firms had employment of 999 or fewer employees, and 19 firms had employment of 1,000 employees or more.[100] Thus, under this second category and size standard, the majority of firms can, again, be considered small.

Public Safety Radio Services. Public Safety radio services include police, fire, local government, forestry conservation, highway maintenance, and emergency medical services.[101] For small businesses in this category, the above small business size standard applies to 1500 or fewer employees. There are a total of approximately 127,540 licensees in these services. Governmental entities[102] as well as private businesses comprise the licensees for these services. All governmental entities with populations of less than 50,000 fall within the definition of a small entity.[103]

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[95] 13 C.F.R. § 121.201, NAICS code 517211.

[96] 13 C.F.R. § 121.201, NAICS code 517212.

[97] U.S. Census Bureau, 2002 Economic Census, Subject Series: "Information," Table 5, Employment Size of Firms for the United States: 2002, NAICS code 517211 (issued Nov. 2005).

[98] *Id.* The census data do not provide a more precise estimate of the number of firms that have employment of 1,500 or fewer employees; the largest category provided is for firms with "1000 employees or more."

[99] U.S. Census Bureau, 2002 Economic Census, Subject Series: "Information," Table 5, Employment Size of Firms for the United States: 2002, NAICS code 517212 (issued Nov. 2005).

[100] *Id.* The census data do not provide a more precise estimate of the number of firms that have employment of 1,500 or fewer employees; the largest category provided is for firms with "1000 employees or more."

101 With the exception of the special emergency service, these services are governed by Subpart B of part 90 of the Commission's Rules, 47 C.F.R. §§ 90.15-90.27. The police service includes approximately 27,000 licensees that serve state, county, and municipal enforcement through telephony (voice), telegraphy (code) and teletype and facsimile (printed material). The fire radio service includes approximately 23,000 licensees comprised of private volunteer or professional fire companies as well as units under governmental control. The local government service that is presently comprised of approximately 41,000 licensees that are state, county, or municipal entities that use the radio for official purposes not covered by other public safety services. There are approximately 7,000 licensees within the forestry service which is comprised of licensees from state departments of conservation and private forest organizations who set up communications networks among fire lookout towers and ground crews. The approximately 9,000 state and local governments are licensed to highway maintenance service provide emergency and routine communications to aid other public safety services to keep main roads safe for vehicular traffic. The approximately 1,000 licensees in the Emergency Medical Radio Service (EMRS) use the 39 channels allocated to this service for emergency medical service communications related to the delivery of emergency medical treatment. 47 CFR §§ 90.15-90.27. The approximately 20,000 licensees in the special emergency service include medical services, rescue organizations, veterinarians, handicapped persons, disaster relief organizations, school buses, beach patrols, establishments in isolated areas, communications standby facilities, and emergency repair of public communications facilities. 47 CFR §§ 90.33-90.55.

102 47 CFR § 1.1162.

103 5 U.S.C. § 601(5).

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

We propose a licensing approach for the 401-402 MHz and 405-406 MHz wing bands identical to that used for the existing MICS center band. Thus, rather than require individual transmitter licensing, we propose to authorize operation by rule within the Citizens Band (CB) Radio Service under Part 95 of our Rules and pursuant to Section 307(e) of the Communications Act.[104] Under this proposal, licensing would be accomplished through adherence to applicable technical standards and other operating rules (unlicensed operations). We tentatively conclude that this approach is beneficial because it would minimize the administrative burden on prospective licensees as compared with an individual licensing. We seek comment on this proposal. Commenters are invited to address whether other licensing approaches should be considered and discuss the relative benefits and disadvantages compared to our proposal.

E. Steps Taken to Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.[105]

We propose to establish a new Medical Data Service (MEDS) under Part 95 that would encompass all medical devices permitted to operate in the entire 401-406 MHz band. We seek comment on options concerning whether and how the five megahertz of spectrum that would comprise this proposed MEDS band could be divided among the evolving varieties of implanted and body-worn medical transmitters, including low-power, low-duty-cycle (LPLDC) devices without listen-before-talk (LBT).

For example, should both implantable and body-worn transmitters be permitted to operate in all, or just selected portions, of the five megahertz of the proposed 401-406 MHz MEDS band? Should the same technical standards that govern the existing MICS center band transmitters be applied uniformly across the entire band? Should an adjustment in the permissible operating power of body-worn transmitters be made to account for difference in body tissue attenuation as compared with implantable devices? Similarly, should LPLDC devices without LBT be permitted to operate throughout the entire five megahertz of the proposed MEDS band or be limited to segments such as the 401-402 MHz and 405-406 wing bands? Why or why not? Commenters should explain the rationale, and corresponding benefits and disadvantages, for whatever approach is recommended. Are there any other factors that should be considered with respect to distinguishing the applicable rules for implantable, body-worn devices, and LPLDC transmitters? Should other types of medical radiocommunication devices be considered for operation in this proposed MEDS band? We especially seek small entity comment on these issues.

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[104] *See* Medtronic Petition at i, 16, and Appendix A, at proposed section § 95.1601. We note that 47 U.S.C. § 307(e)(3) provides that the term "citizens band radio service" shall have the meaning given it by the Commission by rule. 47 U.S.C. § 307(e)(1) provides that upon determination by the Commission that an authorization serves the public interest, convenience, and necessity, the Commission may by rule authorize the operation of radio stations without individual licenses in the citizens band radio service.

[105] *See* 5 U.S.C. § 603(c).

F. Federal Rules that May Duplicate, Overlap, or Conflict With the Proposed Rule

None.

STATEMENT OF
CHAIRMAN KEVIN J. MARTIN

Re: Investigation of the Spectrum Requirements for Advanced Medical Technologies; Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radio Communications Service at 401-402 and 405-406 MHz; DexCom, Inc. Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules; Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules; *Notice of Proposed Rulemaking, Notice of Inquiry and Order*

The use of wireless technologies in implantable and body-worn medical devices is improving and extending patients' lives. Today's item supports continued development and deployment of these devices by proposing the allocation of additional spectrum and greater flexibility for medical radio devices. As demand for more advanced medical devices increases, we should also be prepared to facilitate next-generation solutions and to work with the Food and Drug Administration and other agencies that play a role in their evolution. Our requests for information on new medical radio technologies and inter-agency collaboration will help us better anticipate future developments in this field of medicine and thereby provide the best healthcare possible for patients today and tomorrow.

STATEMENT OF COMMISSIONER MICHAEL J. COPPS

Re: Investigation of the Spectrum Requirements for Advanced Medical Technologies; Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radio Communications Service at 401-402 and 405-406 MHz; DexCom, Inc. Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules; Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules; *Notice of Proposed Rulemaking, Notice of Inquiry and Order*

Few uses of our spectrum could be more important than supporting new medical technologies that can extend and improve lives. Already, our nation's medical researchers have developed extraordinary body-worn and implanted devices that control heart rhythms to prevent attacks, mitigate the tremors of neurological patients, and help control the delivery of insulin to patients with diabetes. Around the corner are a whole host of equally awe-inspiring technologies – devices that can restore movement in paralyzed persons, improve sight among the visually-impaired, and control artificial limbs by direct interfaces with the brain and nervous system. We all owe these scientists a great measure of gratitude for their heroic efforts.

Wireless technologies are likely to play a key role in the development of these and other medical devices. The use of radiofrequencies allows doctors to send signals to and recover data from subcutaneous and implanted devices without the use of wires that are prone to infection and other forms of failure. Today's item seeks comment on how the Commission can make spectrum available for these critically important tasks, and I am happy to support it. I would like to give special thanks to our Office of Engineering and Technology, as well as our colleagues at the Food and Drug Administration (FDA) and the National Telecommunications and Information Administration (NTIA), for their hard work in crafting this excellent and timely item.

STATEMENT OF COMMISSIONER DEBORAH TAYLOR TATE

Re: Investigation of the Spectrum Requirements for Advanced Medical Technologies; Amendment of *Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radio* Communications Service at 401-402 and 405-406 MHz; DexCom, Inc. Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules; Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules; *Notice of Proposed Rulemaking, Notice of Inquiry and Order*

Imagine a world in which:

- A quadriplegic can again move her arms and legs;
- A person with chronic depression never needs a pill;
- The visually impaired can see with the assistance of a microchip; and,
- An array of conditions such as Parkinson's disease, bipolar disorder, obsessive compulsive disorder, and even bulimia can be conquered with relative ease.

What once was possible only in science fiction is rapidly becoming science fact through breakthroughs occurring in biomedical engineering almost everyday.

The Commission's task in this item is about improving the quality of life. Throughout my professional career and as a lifelong community volunteer, I have tried to serve as an advocate for services which heal the body, mind, and spirit. I am glad that I have another opportunity to continue that commitment to healthier living in my role as a Commissioner.

While medical devices that use the spectrum are not a brand new concept, it is clear that greater and greater achievements lie ahead. Thus, this item is critical to ensure that we properly facilitate the promises of biomedical engineering in a manner that protects patients while still giving doctors and innovators the flexibility they need to continue to make even more stunning advances in the future.

STATEMENT OF
COMMISSIONER ROBERT M. McDOWELL

Re: *Investigation of the Spectrum Requirements for Advanced Medical Technologies*, Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radio Communications Service at 401-402 and 405-406 MHz; DexCom, Inc. Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules; Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules, *Notice of Proposed Rulemaking, Notice of Inquiry and Order*

I am pleased that the Commission is undertaking this effort to reexamine the spectrum requirements for advanced medical technologies, and I thank the staff of the Office of Engineering and Technology for its work on this item. Our goal – to create an environment that fosters continuing improvements in medical devices through flexible spectrum allocations and minimum regulatory requirements – is laudable.

I am delighted that the Commission will play a role in working to bring cutting-edge technologies to fruition in order to improve the quality of life for all Americans. The horizon is exciting.

- For those with heart disease: these new technologies offer the promise of improved cardiac pacemakers and defibrillators that monitor and report on heart functions with increased sophistication;
- for patients with sleep disorders, depression or other mental illnesses: the development of vests worn on the body that capture cardiopulmonary and other medical data and facilitate wireless transmission of the readings to health care providers in real-time;
- for those with diabetes: the promise of implanted blood glucose sensors that would not only monitor and wirelessly transmit readings directly to health care providers, but would directly manage medications; and
- for patients with eye disorders such as macular degeneration: the real potential for increased eye function through microchip technologies.

I am also pleased that the Commission seeks to permit multiple players to operate in the medical device spectrum band. While we must be mindful of the need to avoid potential harmful interference to other in-band operations, facilitating competition in the medical device market is particularly important given the ageing U.S. population (76 million baby boomers will reach retirement age within the next decade), and the corresponding need for an increased number of our citizens to participate in more frequent health monitoring. I am hopeful that a proliferation of devices will lead to decreased health care prices and improved quality of care, while also allowing patients the ability to lead more independent lives.

I look forward to working closely with the Chairman and all of my Commission colleagues as we move forward. And, I encourage all interested parties to join us in this exciting work.