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

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 Radiocommunication 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 of the Medical Implant Communications Service Rules	)	ET Docket No. 03-92

REPORT AND ORDER

Adopted: March 19, 2009 **Released: March 20, 2009**

By the Commission: Acting Chairman Copps, and Commissioners Adelstein and McDowell issuing separate statements.

I. INTRODUCTION

1. By this Report and Order, we establish a new Medical Device Radiocommunication Service (MedRadio Service) under Part 95 of the Commission's rules.[1] This new service incorporates the existing Medical Implant Communications Service (MICS) "core" band at 402-405 MHz, and also includes two megahertz of newly designated spectrum in the adjacent "wing" bands at 401-402 MHz and 405-406 MHz. Altogether, the MedRadio Service will provide a total of five megahertz of contiguous spectrum on a secondary basis and non-interference basis for advanced wireless medical radiocommunication devices used for diagnostic and therapeutic purposes in humans. The MedRadio Service will accommodate the operation of body-worn as well as implanted medical devices, including those using either listen-before-talk ("LBT") frequency monitoring or non-LBT spectrum access methods, in designated portions of the 401-406 MHz band.

2. Significant advances in wireless implanted and body-worn 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. As demonstrated by the

[1] Part 95 governs the Personal Radio Services, including General Mobile Radio Service, Radio Control Service and Citizens Band (CB) Radio Service. The CB Radio Service, in turn, covers a number of specialized services such as Family Radio Service, Low Power Radio Service, Medical Implant Communications Service, Wireless Medical Telemetry Service, Multi-Use Radio Service, and Dedicated Short-Range Communications Service.

record in this proceeding, implanted and body-worn medical devices that rely upon wireless technologies are being used even today to treat a variety of cardiac and diabetic conditions.[2] For example, wireless implanted cardiac devices serve as defibrillators and pacemakers without the need for external wired connections; while other radio-equipped devices, such as blood glucose monitors and insulin pumps, support more timely treatment for diabetic patients and allow physicians to wirelessly retrieve data and then make operating parameter adjustments with greater ease and accuracy than with more traditional wired connection technologies.[3] Some examples of newer generations of devices that could benefit from the use of wireless technologies include implanted vagus nerve stimulators that send electric pulses to the brain to treat severe chronic depression,[4] and deep brain stimulators used to treat tremors related to Parkinson's disease.[5] Such advances have the potential to significantly improve the quality of life and sophistication of therapy for countless Americans living with a variety of medical conditions and, in turn, could result in lower medical costs and extend the time between hospital visits and surgical procedures.[6]

3. Also, we extend a waiver granted to DexCom, Inc. (Dexcom) that will allow it to continue marketing and operating glucose monitoring devices in the 402-405 MHz band for four years from the effective date of rules adopted herein.[7]

II. BACKGROUND

4. The MICS was established in 1999 to accommodate the development of increasing numbers and kinds of implantable medical devices that rely upon radiocommunication technologies.[8] For this new service, the Commission set aside three megahertz of spectrum at 402-405 MHz and adopted service rules under Part 95 of the Commission's rules.[9] The Commission selected this band for MICS operations due

[2] *See, e.g.,* Comments of Medtronic, Biotronik and DexCom.

[3] *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.").

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

[5] *Id*.

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

[7] DexCom, Inc. Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, ET Docket No. 05-213, *Order,* 21 FCC Rcd 875 (2006) (*DexCom Waiver*).

[8] *See* Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band, WT Docket No. 99-66, RM-9157, *Report and Order*, 14 FCC Rcd 21040 (1999) (*MICS Order*). 47 C.F.R. Part 95, Subpart I (Medical Implant Communications), and Subpart E (Technical Regulations).

[9] As indicated above, the MICS is identified as a CB Radio Service under the rules, and as such operation of MICS devices is permitted by rule and without an individual license issued by the FCC – otherwise known as license-by-rule. *See* 47 U.S.C. § 307 (e) (the Commission may authorize operation of radio stations in the CB radio service by rule rather than by individual license and shall determine the meaning of the term CB radio service). Under the current rules, a person is permitted to operate medical implant transmitters connected to medical implant devices that have been implanted in that person by a duly authorized health care professional and medical implant programmer/control transmitters associated with their medical implant transmitter(s). *See* 47 C.F.R. § 95.1201.

to favorable signal propagation characteristics in the human body of frequencies in this band, the compatibility of the MICS service with incumbent federal government operations, and the use of these frequencies internationally for the same medical purposes.[10] The designation was made secondary in order to protect incumbent Federal Government operations in the band.[11]

5. Typical MICS operations include a medical implant device that includes a radiofrequency (RF) transmitter, which operates in conjunction with an associated external programmer/control transmitter.[12] After initiating a MICS transmission session, the external device receives stored data from the medical implant transmitter and can record the data or pass it on via interconnection with an external telecommunications system. Some of the more familiar examples of MICS devices include cardiac pacemakers and defibrillators that incorporate monitoring and reporting functions, as well as devices used for diabetic glucose monitoring and control.

6. The technical standards for the MICS are designed to ensure efficient spectrum sharing and compatibility among multiple uncoordinated MICS transmitters and to reduce instances of harmful interference from services that are allocated on a primary basis.[13] Thus, among other requirements, MICS devices are limited to a maximum effective isotropic radiated power (EIRP) of 25 microwatts.[14] The rules also require that the programmer/control transmitter incorporate a LBT frequency monitoring mechanism to select a suitable least-interfering-channel for operation.[15] Furthermore, MICS channels are available on a shared basis only and those parties 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.[16]

7. In 2004 and 2006, the Commission granted waivers to Biotronik, Inc. (*Biotronik Waiver*) and DexCom, Inc., (*DexCom Waiver*), respectively, to accommodate specific models of medical radiocommunication devices that do not have the LBT frequency monitoring capability required by the MICS rules.[17] These non-LBT devices typically operate with reduced power and low duty cycle (LP-LDC) on a single channel.[18] More specifically, the *Biotronik Waiver* authorizes a low power implanted transmitter that operates in conjunction with certain Biotronik cardiac pacemakers to facilitate data communication from the implanted device to a radio receiver in close proximity to the patient that, in

[10] *See MICS Order*, *supra* at n 7.

[11] *See* 47 C.F.R. § 2.106, footnote US 345.

[12] Typically, the medical implant device transmits in response to a signal from the external programmer/control transmitter. However, the MICS 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). As an additional requirement, medical implant programmer/control transmitters in the MICS may transmit only operational, diagnostic and therapeutic information associated with a medical implant device that has been implanted in a human patient by a duly authorized health care professional. *See* 47 C.F.R. §§ 95.401(d), 95.628(a)(4) and 95.1209(a).

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

[14] In practice, the actual output power of a medical implant device varies from device to device depending upon the application and, in order to extend battery life, is generally well below the maximum permitted 25 microwatts.

[15] *See* 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 kilohertz.

[16] *See* 47 C.F.R. § 95.1211.

[17] *See* Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules, ET Docket No. 03-92, *Order*, 19 FCC Rcd 4208 (2004) (*Biotronik Waiver*); and DexCom, Inc. Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, ET Docket No. 05-213, *Order,* 21 FCC Rcd 875 (2006) (*DexCom Waiver*).

[18] For convenience in this proceeding, we will generally use the term 'non-LBT' as a shorthand reference for medical device transmitters that do not employ listen-before-talk frequency monitoring.

turn, relays the data to a physician. The *DexCom Waiver* authorizes certain blood glucose monitoring sensors implanted in the body that are combined with a low power transmitter applied to the surface of the skin to provide periodic information on blood glucose levels. In both cases, the Commission determined that these devices were unlikely to cause harmful interference to other users of the band because they operate on only one channel, at low power and with a low duty cycle. The Commission also determined that granting these two waivers served the public interest because these devices could be made available for immediate use. It subjected them to specific conditions on their use to reduce the potential for interference[19] and limited the duration of the waivers to, at most, one year after completion of any rulemaking addressing changes to the medical implant rules that might accommodate their continued operation in the 402-405 MHz band.[20] In addition, with respect to the *DexCom Waiver*, the Commission noted but deferred for future consideration an issue raised regarding whether DexCom's patient-worn transmitter would be considered an implanted device under the MICS rules.[21]

8. In July 2005, Medtronic, Inc., (Medtronic) a manufacturer of implantable medical devices used in the existing MICS band, filed a petition for rulemaking arguing that additional spectrum is needed – specifically, in the 401-402 MHz and 405-406 MHz wing bands – for a new "medical data service" that would accommodate the increasing numbers and types of implanted and body-worn medical devices that rely upon radiocommunication technologies.[22] Medtronic requested that, in addition to implanted devices, this new service permit the operation of other types of devices that are not currently permitted in the MICS core band at 402-405 MHz. In particular, this proposal included body-worn devices, and those implanted and body-worn devices using non-LBT spectrum access methods such as those covered by the *Biotronik* and *DexCom Waivers*. Medtronic also recommended that the new wing bands should be designated for use by devices that serve non-time-sensitive, non-life-critical functions. In conjunction with such designation, Medtronic further argued that the existing MICS core band should be reserved for implanted devices that are required to use LBT frequency monitoring, and which support time-sensitive, life-critical functions.

9. In July 2006, in response to this petition as well as the comments it elicited, and in light of the continuing developments in medical device technology, we adopted a Notice of Proposed Rulemaking (NPRM), Notice of Inquiry (NOI) and Order – collectively, the *MedRadio Notice*.[23] In the NPRM

[19] The Biotronik waiver applies only to devices whose transmissions do not exceed 280 milliseconds ten times per day, with a maximum output power of 100 nanowatts, transmitting at 403.66 MHz (+/- 75kilohertz). The DexCom waiver applies only to devices operating nominally with a power level of -20dBm (*i.e.* 10 microwatts), and whose transmissions do not exceed 10 milliseconds each, that employ a duty cycle not exceeding one transmission every five minutes, and which occupy a channel bandwidth no greater than 120 kilohertz at 402.142 MHz +/- 40 kilohertz. *See Biotronik* and *DexCom* waivers at ¶¶ 20 and 22, respectively.

[20] The *DexCom Waiver* was granted for three years, expiring January 19, 2009; or until one year after the completion of any rulemaking the Commission may undertake regarding medical implant devices, whichever is later; and the *Biotronik Waiver* was set to expire on February 26, 2007, but was later extended by *Order* in the *MedRadio Notice* pending adoption of the new MedRadio rules. By that *Order*, the expiration of the *Biotronik Waiver* was made consistent with that of the *DexCom Waiver*, namely to expire one year from the effective date of the final rules adopted in this proceeding. *See MedRadio Notice*, n. 22, at ¶¶ 35 and 58.

[21] *DexCom Waiver*, 21 FCC Rcd at 881, ¶ 18.

[22] *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., filed July 15, 2005, Public Notice released August 24, 2005 (RM-11271) (Medtronic petition).

[23] *See* 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, ET Docket No. 06-135, RM-11271, *Notice of Proposed Rulemaking and Notice of Inquiry and Order,* (*MedRadio Notice*) 21 FCC Rcd 8164 (2006).

portion of the *MedRadio Notice*, we proposed to establish a new service for medical radiocommunication devices to better accommodate the varieties of new implantable and body-worn medical devices such as those described in the Medtronic petition. We also proposed to designate two additional megahertz of spectrum for use by body-worn as well as implanted medical transmitters in the adjacent 401-402 MHz and 405-406 MHz wing bands. For the existing MICS core band, we proposed to modify the rules to permit the operation of body-worn devices (in addition to the implantable devices currently authorized), and sought comment on whether non-LBT spectrum access should also be permitted.

10. We also sought comment on issues raised in a separate petition for rulemaking filed by Biotronik, which was included in this docket, and that asks the Commission to identify a single 300 kilohertz wide channel centered at 403.65 MHz in the existing MICS band where non-LBT access would be permitted by devices operating with a maximum effective isotropic radiated power (EIRP) of 100 nanowatts.[24] We further proposed that these new frequency bands at 401-402 MHz and 405-406 MHz would be governed by rules similar in nature to those for the existing MICS designation, but provide greater flexibility by permitting both LBT and non-LBT spectrum access methods.[25]

11. In the inquiry portion of the *MedRadio Notice*, we sought comment in a broader context on anticipated developments in the medical devices field and resulting spectrum requirements. Thus, we asked for detailed comment in the NOI 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. We sought 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 asked for comment on collaborative efforts between the Commission 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) issues in an RF environment.[26]

12. More than 100 comments were filed in response to the *MedRadio Notice*. The comment record demonstrates broad support for designating additional spectrum to support the growing use of medical implant and body-worn devices; for establishing a new medical device radiocommunication service spanning the 401-406 megahertz band that would accommodate both LBT and non-LBT devices; and, to the extent possible, adopting rules that harmonize with international standards. In particular, the record demonstrates an increasing interest by manufacturers and practitioners in wireless medical devices that could be worn on the body in order to provide additional, and oftentimes less invasive, patient treatment options. Finally, we observe that the interest sparked by this proceeding has resulted in the filing of two additional petitions for rulemaking - one by Alfred Mann Foundation (AMF) and one by GE Healthcare – both seeking the designation of additional spectrum at different frequencies to support other

[24] In its petition, Biotronik argues that the interference potential from such devices would be negligible due to their ultra low operating power and low duty cycle, and thus could coexist with LBT devices on the same frequencies. *See* Petition for Rule Making, filed by Biotronik, Inc., on June 16, 2006. *See also MedRadio Notice* at ¶ 8, n. 17 and ¶ 24.

[25] With respect to a separate matter, we also sought comment on whether, and on what terms, inductive medical devices operating in the 90-110 kHz band, such as those manufactured by Boston Scientific, Inc., should be authorized.[25] We do not address this latter issue herein, but intend to do so later in a separate proceeding. *See* Petition for Rule Making filed by Guidant Corporation on February 22, 2006. *See also MedRadio Notice*, at ¶¶ 31-34.

[26] 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).

types of medical radiocommmunication needs.[27] We intend to address these two petitions later in separate proceedings.

III. DISCUSSION

13. Since the inception of MICS in 1999, the availability of dedicated spectrum with desirable biological propagation characteristics in the existing MICS band at 402-405 MHz has fostered continuing advances in wireless medical radiocommunication devices used with human patients for a variety of beneficial therapeutic and diagnostic purposes. As we observed in the *MedRadio Notice*, however, the existing MICS rules only permit the operation of medical implant devices and their associated external programmer/control units. We find that the record overwhelmingly supports the designation of additional spectrum and the establishment of a new service for medical implant and body-worn devices. More specifically, the record informs us that recent advances in the medical device field – particularly the development of body-worn medical devices – dramatically expand the treatment options for an increasing variety of medical conditions.[28] The new Medical Device Radiocommunication Service, or MedRadio Service, will span the 401-406 MHz band. This spectrum encompasses the existing MICS "core" band at 402-405 MHz and an additional two megahertz of spectrum in the adjacent "wing" bands at 401-402 MHz and 405-406 MHz. This will provide a total of five megahertz of spectrum for implanted and body-worn medical devices that rely upon wireless technologies for critical aspects of their functionality.

14. As we discuss in detail below, the service and technical rules that we adopt in this Order for the MedRadio Service are based upon the existing MICS rules, and include modified spectrum sharing requirements in the new wing bands. More specifically, the new rules will permit the use of medical implant devices that are LBT-enabled across the entire 401-406 MHz band. Medical body-worn devices that are LBT-enabled will be, with one exception, permitted to operate only in the new wing bands at 401-402 MHz and 405-406 MHz. As an exception to this general rule and subject to certain restrictions, we will permit the operation on any frequency in the 402-405 MHz core band of temporary body-worn transmitting devices that are used solely during a limited patient evaluation period in order to determine the suitability of a fully implanted device, provided that they fully comply with all other MedRadio rules applicable to the band. Both implant and body-worn devices using non-LBT spectrum access methods (with reduced EIRP and duty cycle limits) will also be permitted in the new MedRadio wing bands. In the core band, however, non-LBT operation will be limited to medical implant devices operating with a total channel emission bandwidth not exceeding 300 kilohertz centered at 403.65 MHz.

15. Among other considerations, these new MedRadio sharing rules are designed to provide a greater degree of flexibility than is permitted by the existing medical implant rules, while also assuring spectrum use compatibility among different device types. The new designation in the wing bands will provide the additional shared spectrum that commenters tell us is urgently needed for operation of both

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[27] *See* Petition for Rulemaking, filed by Alfred Mann Foundation on September 5, 2007, "In the Matter of Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Micropower Network Service in the 413-457 MHz Band", and *Public Notice* in RM-11404, (Report No. 2835), released October 3, 2007. *See also, w*ith respect to the GE Healthcare (GEHC) petition, "Office of Engineering and Technology to Treat *Ex Parte* Comments of GE Healthcare as Petition for Rule Making and Seeks Comments", *Public Notice* in ET-Docket No. 08-59 (DA 08-953), released April 24, 2008. AMF requests that spectrum be made available for new generations of artificial nervous systems using injectible devices called 'BIONs' which together are designed to replace or improve the function of an impaired nervous system by performing "functional electric stimulation" or FES. The spectrum identified by AMF as well suited for this technology includes the 413-419 MHz, 426-432 MHz, 438-444 MHz and 451-457 MHz bands. The GEHC petition seeks use of the 2360-2400 MHz band by wireless body sensor network (BSN) technologies used primarily for patient monitoring and which make use of uncoordinated localized networks or point-to-point communications that require more throughput and continuous communications than that proposed under the 400 MHz MedRadio rules. GEHC requests that BSN devices be licensed-by-rule to eligible health care providers, like current MICS devices, but that operations be permitted both inside and outside of medical facilities.

[28] *See*, *generally*, comments of October 31, 2006, file by Medtronic, GEHC, Alfred Mann, Zarlink, and others.

implant and body-worn devices (including LBT and non-LBT varieties). To ensure that devices can share this spectrum in an efficient manner, the new rules impose conservative EIRP and duty cycle limits on the operation of non-LBT devices. In addition, this should maintain the interference potential from other MedRadio devices at negligible levels and reduce instances of harmful interference from federal systems that are allocated on a primary basis. We believe that the MedRadio rules adopted in this Order should encourage the continuing use of the legacy MICS core band predominantly for life-critical applications, such as those served by the existing population of medical implant devices presently used therein.

16. Finally, we believe that the additional spectrum and enhanced flexibility afforded in the new rules will promote the accelerated development of newer generations of advanced medical device technologies. These advances, in turn, will herald dramatic improvements in therapeutic/diagnostic patient care and quality of life for countless individuals. Furthermore, the MedRadio designation and rules adopted in this Order are harmonized for the most part in their general approach with European Telecommunication Standards Institute (ETSI)[29] standards relating to use of the 401-406 MHz band by medical implant and body-worn devices in other regions of the world. As with the existing MICS band rules, we believe that such harmonization will serve the public interest by offering Americans greater confidence of reliable device operation while traveling abroad, and conversely, by offering similar confidence for foreign visitors to the United States. Moreover, economies of scale resulting from harmonized rules for domestic manufacturers seeking to compete in the world market should foster a reduction of device prices, thus making the benefits of such technologies more widely available and affordable for the American public.

A. Frequency Designation

17. As the number and kinds of medical devices have increased, so has the demand for additional spectrum. Thus, in the *MedRadio Notice*, we proposed to broaden the existing MICS by designating new spectrum for medical implant and body-worn devices in the 401-402 MHz and 405-406 MHz bands. Commenters join Medtronic in arguing that this additional spectrum is urgently needed due to the increasing numbers and types of devices used for an ever-increasing array of diagnostic and therapeutic purposes.[30] Indeed, no commenter opposed designating this additional spectrum in the wing bands for these purposes. We find that these arguments make a persuasive case and, consistent with our proposal in the *MedRadio Notice*, we designate the frequency bands 401-402 MHz and 405-406 MHz to the MedRadio Service for use by both implant and body-worn medical devices on a secondary basis.

18. 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 Departments of Commerce (National Weather Service), Defense, and Energy are the primary users of this METAIDS allocation. 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. 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.[31] The 402-405 MHz

[29] The latest version of the ETSI standards include those contained in "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Medical Data Service Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz" (Parts 1 & 2), ETSI EN 302 537-1 & ETSI EN 302 537-2, v1.1.2 (2007-12), and "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz (Parts 1 & 2), ETSI EN 301 839-1 & ETSI EN 301 839-2, v1.2.1 (2007-07), available on the Internet at (http://www.etsi.org).

[30] *See e.g.,* comments filed October 31, 2006, of GEHC, Alfred Mann, Partners HealthCare, ON Semiconductor, and others.

[31] 47 C.F.R. § 2.106.

band is designated for use by the MICS on a secondary basis. 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.[32]

19. We find that the spectrum at 401-402 MHz and 405-406 MHz is well suited for use on a secondary basis by the medical implant and body-worn devices covered by this Order. Among other factors, these frequencies offer the same propagation, availability, and compatibility characteristics that were found to be favorable for the MICS in the 402-405 MHz core band.[33] In addition, this new designation will result in a continuous span of spectrum (from 401-406 MHz) that matches the five-megahertz of spectrum that is also designated internationally for similar use by medical implant and body-worn devices.

20. We further conclude that the potential for interference to incumbent operations in the 401-402 MHz and 405-406 MHz bands is negligibly small as it is in the 402-405 MHz band previously designated for medical implant devices. In the United States, the 401-406 MHz band is allocated for various Federal and non-Federal uses on a primary basis, and the 402-405 MHz band is allocated for mobile, except mobile aeronautical, service on a secondary basis, with use limited to MICS. Given the ultra low power limits and intermittent operating modes that will be used by these medical devices, and the expectation of large separation distances, there is little likelihood that these medical devices could cause harmful interference to incumbent operations.

21. As with devices used in the existing MICS, it is also of key importance that MedRadio devices should employ sufficiently robust designs to deal with potentially harmful effects of received interference. For example, with respect to potential interference from the higher-powered federal systems operating in the band,[34] MedRadio medical devices, particularly those devices used for life critical and time-sensitive applications, might need to employ a variety of error detection and correction techniques, frequency monitoring capabilities, and re-transmission protocols.[35]

B. Service Rules

22. We discuss in this section the service rules for devices operating in the MedRadio Service at 401-406 MHz with respect to licensing, types of permissible devices, authorized frequencies, permissible communications, and operator eligibility.

23. *Licensing*. In the *MedRadio Notice*, we proposed to apply the license-by-rule approach of the existing MICS to the entire 401-406 MHz band. We also sought comment on whether other licensing approaches should be considered, or whether certain medical devices would be better served by alternative licensing regimes.[36] The MICS was originally established under Part 95 of our Rules, and that

[32] 47 C.F.R. § 2.106, footnotes US345, G6.

[33] *See MICS Order* at ¶¶ 6-8.

[34] Throughout the United States, Federal use includes more than 20,000 Data Collection Platforms transmitting to meteorological satellites in the 401-403 MHz band, and 94 radiosonde stations and their associated airborne transmitters in the 401-406 MHz band.

[35] Annex 1 of 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*.provides a more detailed discussion of the interference mitigation techniques that can be used by MedRadio devices to avoid possible interference from federal systems.

[36] See *MedRadio Notice* at ¶20.

operation is authorized by rule pursuant to Section 307(e) of the Communications Act (Act).[37]

24. The commenters that address the licensing issue support the license-by-rule approach as reflected by the present MICS rules. For example, Partners HealthCare and Medtronic, among others, note the reduced regulatory requirements for licensees and overall success of this approach in the core MICS band. We agree.

25. Consistent with the existing MICS licensing scheme, we decide that the new MedRadio service at 401-406 MHz will be governed under Part 95 of the Commission's rules, thus providing for license-by-rule operation throughout the 5 megahertz band. As the Commission determined when it adopted the original MICS rules, we conclude that this approach minimizes regulatory procedures and will facilitate the more expeditious deployment of new generations of beneficial wireless medical devices in these bands that can improve the quality of life for countless Americans, thus serving the public interest, convenience and necessity. Furthermore, the operation of medical devices in the MedRadio band will be on a secondary, non-interference basis with respect to other authorized services and as such they must accept harmful interference from the systems operating in those services. MedRadio devices will operate on a shared, non-exclusive basis with respect to each other.

26. *Definitions – Implant and Body-worn Devices*. In the *MedRadio Notice,* we proposed to adopt rules that define implant and body-worn medical devices for use in the MedRadio Service.[38] Our existing rules only include definitions for medical implant devices, which are located within a human body for diagnostic or therapeutic purposes.[39] To this end, we anticipated definitions that would turn upon the location of the transmitting antenna used by the patient device as a line of demarcation between implant and body-worn devices. In this regard, we sought comment on a definition for body-worn transmitters suggested by Medtronic in its original petition.[40]

27. GE Healthcare and Biotronik, among others, agree that clear definitions are needed to distinguish between implant and body-worn devices.[41] In addition, no commenter raises significant objection to the definition for body-worn devices suggested by Medtronic.

28. In order to be deemed a *medical body-worn device* or *medical body-worn transmitter*, we will require that the antenna of the associated patient-worn device be placed upon or in very close proximity (*e.g.,* within a few centimeters) to the body.[42] This closely parallels the ETSI definition for body-worn

[37] *See* 47 C.F.R.§ 95.401 (d). *See, also*, *MICS Order* at ¶ 2. Under Section 307(e) of the Act, the Commission may authorize the operation of radio stations by rule without individual licenses in certain specified radio services when the Commission determines that such authorization serves the public interest, convenience, and necessity. *See* 47 USC Section 307(e)(1). The services set forth in this provision for which the Commission may authorize operation by rule include: 1) the Citizens Band Radio Service, 2) the Radio Control Service, 3) the Aviation Radio Service, and 4) the Maritime Radio Service.

[38] *See MedRadio Notice* at ¶ 27.

[39] Our existing rules contain the following definitions: "*Medical implant device.* Apparatus that is placed inside the human body for the purpose of performing diagnostic or therapeutic functions." "*Medical implant transmitter.* A MICS transmitter that operates or is designed to operate within a human body for the purpose of facilitating communications from a medical implant device." *See* Appendix 1 to Subpart E of Part 95 (*Glossary of Terms*).

[40] See *MedRadio Notice* at ¶27. Medtronic suggests the following formulation for body-worn devices, namely those "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."

[41] *See, e.g., Medtronic Petition*; Biotronik comments of October 31, 2006, at 14; GEHC comments of November 1, 2006, at 14-15.

[42] *See* Final Rules, Appendix A, attached hereto. These terms are not defined in our present rules.

devices.[43] MedRadio devices falling into this category may operate only in the 401-402 MHz and 405-406 MHz wing bands with an exception for certain temporary body-worn devices discussed below.

29. In order to be classified as a medical implant transmitter or medical implant device, we will require that the transmitting antenna of the patient device must itself be implanted wholly within the body – which would include any point below the skin, or more deeply within the body. We thus retain the existing definitions for medical implant devices. MedRadio devices falling into this category may operate across the entire 401-406 MHz MedRadio band pursuant to the technical rules for medical implant devices adopted herein.

30. *Authorized Frequencies for Implant and Body-worn Devices.* In the *MedRadio Notice*, we proposed to allow the operation of both implant and body-worn devices in the new 401-402 MHz and 405-406 MHz wing bands. We also sought comment on whether to permit the operation of both types of devices in the existing 402-405 MHz core band. In response, commenters express broad support for a flexible approach in the wing bands at 401-402 MHz and 405-406 MHz that would permit the operation of both body-worn and implant devices.[44] Such flexibility, they argue, would foster advances in device technology that would ultimately result in improved health care and quality of life for patients. For the existing core band, Medtronic and other commenters favor limiting operation to implanted devices.[45] Subsequently, St. Jude Medical (St. Jude) filed *ex parte* comments arguing that some provision for temporary operation of body-worn devices should be made.[46]

31. There is no dispute in the record that implanted devices should be permitted in both the existing MICS core band at 402-405 MHz, as well as in the wing bands at 401-402 MHz and 405-406 MHz. We concur because doing so would provide flexibility and promote the development of a wider variety of therapeutic implants. Thus, we will allow medical implant devices to operate anywhere in the 401-406 MHz band – but subject to different technical requirements in the core and wing bands as set forth below.

32. We will permit body-worn devices, with one exception discussed below, to operate only in the wing bands at 401-402 MHz and 405-406 MHz. Thus, in the new MedRadio wing bands, both implant and body-worn devices will be allowed to operate, under common technical requirements for each, throughout both the 401-402 MHz and 405-406 MHz frequency range. The technical rules we are adopting for the wing bands will provide a greater degree of operational flexibility than is available in the legacy MICS core band. In addition, as noted above, we anticipate that manufacturers will find the wing bands to be more suitable for use by devices that might not have the same quality of service demands as those life critical implants operating in the core band.[47]

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[43] ETSI defines a body-worn device as "a medical sensor, handheld device, or other medical device intended to be operated in close proximity to the human body, and is used to sense and/or transfer, via means of radio frequency transmission, human physiological parameters or system programming information." *See* "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Medical Data Service Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; Part 1: Technical characteristics and test methods", ETSI EN 302 537-1 V1.1.2 (2007-12).

[44] *See,* comments of GEHC, Zarlink, Medtronic, and others, filed Oct 31, 2006.

[45] *See, e.g.,* reply comments of Medtronic at 20-21, and AdvaMed letter of December 4, 2006. Early in this proceeding, and prior to the adoption by ETSI of standards that also do not provide for body-worn devices in the core band, a few other commenters voiced general support for the overall approach initially proposed in the *MedRadio Notice* which would have permitted such operation. As discussed above, no other commenters apart from St. Jude have subsequently come forward to argue a case for allowing body-worn devices in the core band.

[46] *See ex parte* letters of St. Jude submitted July 18 and August 25, 2008.

[47] For example, such devices might employ longer duration transmission times, or data could be retransmitted without significantly compromising patient care or safety.

33. We believe this approach will serve to accommodate a greater variety of implant and body-worn devices. Moreover, by preserving the core band at 402-405 MHz primarily for communications involving implanted devices, we anticipate that it will continue to be used largely for life-critical medical devices such as cardiac defibrillators and the like. Our approach carefully balances the potential benefits and risks of accommodating the operation of body-worn devices in the existing MICS core band, which heretofore has been reserved for implanted devices alone; and also provides for a greater degree of flexibility for both types of medical devices in the wing bands.

34. As an exception to the general rule for body-worn devices, we will permit the operation in the core band of temporary body-worn devices that are used to evaluate the efficacy of an implanted medical device. St Jude cites significant patient benefits that can be derived from using a temporary body-worn device to evaluate the efficacy of a fully implanted medical device before subjecting the patient to an invasive implantation procedure.[48] St. Jude also argues that temporary body-worn devices will pose little or no risk of adverse impact on implanted devices because they will meet the technical requirements for the band and are intended to be replaced by a fully implanted permanent device after a brief evaluation period. From the outset of this proceeding, however, Medtronic has cautioned against the potential risk of shortened implant battery life that could result from competing with body-worn devices in the same spectrum.[49] Notwithstanding these concerns, Medtronic recognizes that allowing such temporary body-worn devices to operate in the core band could serve beneficial purposes, and further accedes that such operation could be accommodated in the core band without imperiling the operation of implanted devices, provided that temporary external devices are subject to certain conditions.[50]

35. We agree with St. Jude and Medtronic on this matter, and further conclude that allowing the operation of temporary body-worn devices that meet the technical requirements for the band and are intended to be replaced by a fully implanted permanent device will serve the public interest. Among other benefits, permitting such operation will enhance the therapeutic and diagnostic options available to patients. In particular, this will allow physicians to better evaluate the efficacy of proposed treatments involving implanted devices prior to actual device implantation. Accordingly, we will permit the operation of such temporary body-worn devices on any frequency in the 402-405 MHz core band provided that: (1) such external operation is limited solely to evaluating with a patient the efficacy of a fully implanted permanent medical device that is intended to replace the temporary body-worn device; (2) RF transmissions from the external device must cease following the patient evaluation period, which may not exceed 30 days, except where a health care practitioner determines that additional time is necessary due to unforeseen circumstances; (3) the maximum output power of the external, temporary body-worn device shall not exceed 200 nW EIRP; and (4) the external device must comply fully with all other MedRadio rules described below throughout the core 402-405 MHz band.[51]

36. We decline to explicitly limit the core band to life-critical and time-sensitive applications, or the wing bands to non-life-critical, non-time sensitive applications, as the comments of some parties

[48] *See* St. Jude *ex parte* letter of July 16, 2008. St. Jude explains that using a temporary body-worn device to evaluate the efficacy of certain therapies, such as spinal cord stimulation, is medically provident since it enables patients and health care providers to arrive at a better-informed decision whether to undergo implantation of a permanent device.

[49] Medtronic argues that such competition for spectrum with other devices could result in LBT-enabled devices needing to retransmit data and therapeutic instructions, resulting in prematurely depleted battery power reserves. The undesired consequence of shortened battery life, Medtronic argues, would be the need for more frequent device replacement involving the attendant risks and inconvenience to the patient of an invasive surgical procedure. *See, generally,* Medtronic petition, comments and reply comments

[50] *See* Medtronic *ex parte* letter of August 6, 2008.

[51] This exception for temporary body-worn devices in the 402-405 MHz band applies to both LBT and non-LBT devices provided they satisfy the frequency and relevant technical requirements for their use in the band.

suggest might be done.[52] Nevertheless, we believe that our decision to limit the core band primarily to communications involving implanted devices, coupled with the technical rules we are adopting for use of the core and wing bands will achieve much the same result. In particular, and as discussed more fully below, the 300 kilohertz emission bandwidth that we currently permit for the core band appears to be particularly well suited for implants, where shorter transmissions with relatively higher data rates are a major factor in preserving battery life. By comparison, the relatively narrower 100 kilohertz emission bandwidth that we adopt for the wing band frequencies is expected to be better suited for non-life-critical devices, namely those with less severe battery life constraints that might be tailored for operation with lower bandwidth data streams and that might require a relatively greater number of longer data transmission sessions. Thus, we conclude that the approach we take here will provide greater flexibility for device manufacturers and practitioners. We also believe that leaving the ultimate decision on these matters to health care professionals and medical device manufactures, in concert with FDA-required risk management processes, will result in better and more flexible use of this scarce spectrum resource.

37. *Permissible Communications and Operator Eligibility*. Among other service and eligibility requirements, the existing MICS rules provide that a medical implant device may be used by persons for diagnostic and therapeutic purposes, but only when provided to a human patient under the direction of a duly authorized health care professional.[53] Furthermore, the existing MICS is defined as a service intended for the transmission of non-voice data.[54] The existing MICS rules also do not allow medical implant programmer/control transmitters to relay information on MICS frequencies to a receiver that is not included with a medical implant device.[55] These requirements are central to maintaining the originally intended character and utility of this spectrum, which has proven to be of significant benefit to many patients over the years. Thus, in the *MedRadio Notice*, we proposed that the MedRadio service would be governed by generally the same rules.

38. Based upon the entirety of the record in this proceeding, we continue to believe that applying the existing MICS permissible communications and operator eligibility requirements to the new MedRadio service will result in a more beneficial use of the spectrum than alternative approaches. To the extent that alternative uses might be considered, we note that the Alfred Mann and GE Healthcare petitions cited above, which have been placed on public notice, could provide an avenue to consider new applications for other types of medical devices in other frequency bands.

39. Some commenters, including Intel, GE Healthcare, Advanced Medical Technology Association (AdvaMed), and Partners HealthCare Systems (Partners) urge that we maintain the original MICS requirements for the MedRadio spectrum, particularly with respect to mandating diagnostic and therapeutic use with human patients under the direction of a health care professional. ON Semiconductor Corporation (ON Semi) (formerly AMI Semiconductor) requests that we permit the aggregation of three contiguous 100 kilohertz emission bandwidth channels in the upper MedRadio wing band at 405-406 MHz to accommodate the operation of wireless hearing aid devices that require an emission bandwidth of 300 kilohertz.[56] Next, Transoma asks us to permit use of the entire MedRadio spectrum from 401-406

[52] *See, e.g.,* Partners HealthCare comments at 8-9, and Medtronic reply comments at 8.

[53] *See* 47 C.F.R. § 95.1201.

[54] *See* 47 C.F.R. § 95.401

[55] *See* 47 C.F.R. § 95.1209 (e). Under this provision, wireless retransmission of information by a medical implant programmer/control transmitter shall be conducted using other radio services that operate in spectrum outside the MedRadio band.

[56] ON Semi proposes that all use be confined to a single 300 kilohertz band. *See* ON Semi comments received October 22, 2007; and *ex parte* presentation of February 6, 2008.

MHz for applications involving non-human test subjects in research laboratory settings.[57] Transoma argues that no other frequency band meets its needs.[58] It states that the Industrial, Scientific and Medical (ISM) bands are already heavily used in laboratories, and thus present a high risk of interference; that operation under the Wireless Medical Telemetry Service (WMTS) (Part 95, Subpart H) is limited to authorized health care providers within health care facilities; that approvals for operation as biomedical telemetry devices (under §§ 5.241 & 15.242) are no longer granted pursuant to § 15.37(i); and that periodic operation under § 15.231 requires power/duty cycle limitations that are incompatible with telemetry. Medtronic, in response to these requests, argues that, given the nascent stage of medical device deployment in the MICS band, now is not the time to expand the types of allowable uses beyond what the rules currently permit, and urges that the entire MedRadio band should be reserved for non-voice data applications only, and that the wing band rules should be maintained as originally proposed with 100 kilohertz channel bandwidths.[59]

40. In the course of arriving at this determination, we carefully considered the requests by ON Semi and Transoma, both of which involve significant departures from the existing service and eligibility requirements. We recognize the potential benefits of new wireless hearing aid technologies for improving the quality of life for people with hearing disabilities. ON Semi's proposal raises a number of important issues. In contrast to MICS devices that would operate intermittently for short periods of time, wireless hearing aids can be expected to operate continuously. Such operation increases the potential that devices could be operating simultaneously in close proximity causing mutual interference. While ON Semi asserts that such interference is unlikely because the hearing aids would use extremely low power and would operate in only a portion of the spectrum allocated for medical devices, the analysis of potential interference in the record thus far is limited, and does not yet provide sufficient basis for our necessary assessment of potential interference concerns.

41. We also note that some commenters have expressed concerns that the operation of wireless hearing aids in this spectrum could have a detrimental impact on MICS devices, possibly reducing the life of implanted devices and requiring more frequent replacement. Given the consequences if these concerns are accurate, we believe more thorough analyses are needed before we can move forward, particularly to evaluate the long term impact as the population of such devices grows in the future. As discussed above, we expect the intermittent nature of non-voice data associated with the MedRadio devices to enable compatibility with the Federal incumbents, but are not yet convinced that the continuous operation associated with ON Semi's hearing aid proposal would be similarly compatible, and would require additional investigation in conjunction with NTIA and the Federal users. In light of these considerations, at this time, we decline to adopt ON Semi's proposal to amend the rules to provide for wireless hearing aids. In recognition of the important public interest benefits associated with ON Semi's proposal, however, the Commission welcomes additional technical submissions or revisions to address whether this or some other band(s) could accommodate the types of hearing aid devices that ON Semi or others might propose, and would consider developing a record through a notice of proposed rulemaking to more fully analyze these matters.

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[57] *See ex parte* letters from Transoma dated August 23, 2007, and September 28, 2007. We further note that, in February 2007, the Commission's Wireless Telecommunications Bureau (Wireless Bureau), by delegated authority, denied, in substance, a request by Transoma for an interpretation of the MICS rules that would permit such use. In that action, the Wireless Bureau affirmed the plain language reading of the MICS rules, as further explained in the original *MICS Order*, that devices used on these frequencies must be installed in *human* patients by duly authorized health care professionals for diagnostic or therapeutic purposes. *See* Transoma Medical, Inc., Request for Interpretation of Medical Implant Communication Service Rules, *Order*, DA 07-801, FCC Rcd 3765 (2007) (*Transoma Order*).

[58] *See* Transoma *ex parte* letter of April 10, 2008.

[59] *See ex parte* letter from Medtronic to Marlene H. Dortch, Secretary, Federal Communications Commission, filed November 15, 2007.

42. We will not allow the use of MedRadio devices with animal test subjects in the course of human drug research, as requested by Transoma. Such testing would not, in and of itself, directly perform any diagnostic or therapeutic function for a human patient. Since its creation, the MICS has been explicitly reserved for use by devices performing diagnostic and therapeutic functions with human patients and only when such use has been duly authorized by a health care professional. Changing the eligibility requirements to permit animal test subject use would constitute a major departure from this underlying guiding principle and that such a departure is not warranted.[60] In the *MedRadio Notice*, we neither proposed, nor sought comment on, modifying these basic service and eligibility provisions.[61] We particularly did not address the specific question at issue here of whether use of the MICS/MedRadio frequencies should be extended to animal testing. To the contrary, in the *MedRadio Notice*, we generally conveyed an intention to carry forward the basic service and eligibility rules of the MICS. While there was some response to Transoma's proposal, we have an insufficient procedural or substantive record upon which to address this question.

C. Technical rules

43. In this section, we discuss the technical rules for devices operating in the MedRadio Service at 401-406 MHz with respect to channel bandwidth, frequency monitoring, operating power, out-of-band emission limits, and other related matters. These technical rules generally follow the framework of the existing core MICS band rules with modified sharing requirements to accommodate implant, body-worn and non-LBT devices in specified portions of the MedRadio band.

44. *MedRadio channels.* As indicated above, in the *MedRadio Notice* we indicated our intent to generally carry forward the MICS rules into the new MedRadio Service. Thus, we did not seek specific comment about whether the MedRadio band should be channelized in any particular fashion. Under the existing rules, no particular channeling scheme is specified for the operation of MICS devices.[62] Instead, the rules define a "(MICS) channel" simply as any continuous segment of spectrum used by a medical device. Thus, a device may transmit on any center frequency so long as the maximum authorized emission bandwidth is not exceeded and all emissions remain within the designated MICS band. We continue to believe that this approach is beneficial. For example, as demonstrated by the current generations of cardiac and diabetic therapy devices that use LBT frequency monitoring, as well as the non-LBT devices operating under the *Biotronik Waiver*, manufacturers tend to design devices that operate with a variety of emission bandwidths that are less than the maximum permitted. This approach will continue to provide the greater flexibility that device manufacturers now use as compared with a rigid channeling scheme.

45. *Emission Bandwidth.* The maximum authorized emission bandwidth for implanted devices operating in the existing MICS 402-405 MHz core band is 300 kilohertz.[63] Medtronic requests that we limit the maximum authorized emission bandwidth to 100 kilohertz in the 401-401 MHz and 405-406 MHz wing bands, as this would provide up to 20 channels in the wing bands to meet the expected proliferation of MedRadio devices that could be used, such as body area networks comprised of multiple sensors.[64] To further explore this matter, we sought comment in the *MedRadio Notice* on whether there

[60] We also have concerns as to how the time and place of use (*e.g.*, near health care facilities and the like) for such animal test devices could be adequately controlled in order to avoid interference with MedRadio devices used with human patients. Further, it is unclear whether such devices might need to operate with higher EIRP and channel bandwidths than some human-use MICS/MedRadio devices that typically operate with EIRPs reduced far below the 25 microwatt limit for LBT devices to conserve battery life.

[61] We are required by the Administrative Procedure Act to provide adequate notice to the public of significant rule changes in any rulemaking proceeding. *See* 5 U.S.C. § 533.

[62] *See* 47 C.F.R. § 95.628 (a) (6) (ii).

[63] 47 C.F.R. § 95.633 (e).

[64] *See Medtronic Petition*; *See also* Medtronic *ex parte* letter of May 18, 2006.

are some functions for which a narrower bandwidth such as that suggested by Medtronic would be appropriate.[65]

46. Prior to ETSI's adoption of a 100 kilohertz emission standard, a few commenters initially expressed support for wider emission bandwidths in the wing bands. They have since been silent on this matter and have not addressed it in their more recent pleadings. Biotronik, for example, indicates in an early submission that a uniform 300 kilohertz maximum emission bandwidth should span the entire 401-406 MHz MedRadio band.[66] Guidant suggests that fixed frequency implants be allowed to use a 300 kilohertz emission bandwidth in the core band and to aggregate multiple channels of such bandwidth in the adjacent wing bands to support high speed downloads. It also argues that frequency-agile implants that employ LBT frequency monitoring should have no bandwidth restrictions since they are inherently non-interfering.[67] Medtronic, on the other hand, has continued to actively support a uniform 100 kilohertz emission bandwidth throughout the wing bands, citing the potential for higher spectrum utilization and the benefits of harmonization with standards recently adopted by ETSI for medical devices in the 401-402 MHz and 405-406 MHz bands.[68]

47. On balance, we conclude that a 100 kilohertz maximum authorized emission bandwidth in the limited space of the one-megahertz wide wing bands at 401-402 MHz and 405-406 MHz will foster more intensive spectrum utilization by a greater number of devices as compared with a 300 kilohertz maximum bandwidth. For example, the two megahertz of spectrum in the wing bands could support 20 devices, each using a 100 kilohertz bandwidth without overlapping each other. By comparison, the three megahertz of spectrum in the core band can support, at most, ten devices, each using a 300 kilohertz bandwidth without overlapping each other.[69] The smaller bandwidth allows more devices to use the wing bands on non-overlapping spectrum. This situation will also serve to minimize interference potential from other MedRadio devices, particularly in light of the fact that both LBT and non-LBT devices will share the entire wing bands.

48. Nonetheless, we will allow up to a 150 kilohertz maximum authorized emission bandwidth at 401.85-402 MHz. We recognize that some body worn devices, such as the glucose monitoring devices manufactured by DexCom that are now operating in the core band under a waiver, need a slightly wider emission bandwidth (*see infra* paragraphs 66-70). Our decision here to allow a slightly wider emission bandwidth at the upper edge of the 401-402 MHz wing band will facilitate DexCom's ability to transition its operating freuquency out of the core band. The slightly wider emission bandwidth also would provide flexibility for other manufacturers designing medical devices in these bands.

49. Maximizing the potential number of devices that can use the wing bands should also foster a wider deployment of therapeutic and diagnostic devices serving to improve the quality of medical care for all Americans. In addition, we observe that the narrower bandwidth for the wing bands, as indicated earlier, is expected to be better suited for non-life-critical devices - namely, those with less severe battery life constraints that are tailored for operation with lower bandwidth data streams utilizing a relatively greater number of longer data transmission sessions as compared with devices used in the core band.

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[65] *See MedRadio Notice* at ¶21.

[66] *See* Biotronik reply comments at 6.

[67] *See* Guidant comments at 9. Guidant seeks these aggregation rules in conjunction with its request that we significantly expand the overall bandwidth available for MedRadio applications. In any case, Guidant asks that aggregation of a minimum of three channels be permitted "regardless of allocation."

[68] *See* Medtronic ex parte letter of May 18, 2006, at 3.

[69] As we noted in the *MedRadio Notice*, some implants now used in the core band transmit on channels less than 100 kilohertz wide even though the maximum authorized bandwidth of 300 kilohertz is significantly higher. *See MedRadio Notice* at fn. 50 (one of the devices permitted by the *Biotronik Waiver* transmits on a single 40 kilohertz wide channel).

50. For the core band at 402-405 MHz, we are maintaining the existing maximum authorized emission bandwidth of 300 kilohertz. Relative to the 100 kilohertz bandwidth we adopt for the wing bands, this 300 kilohertz bandwidth will better facilitate more data-intensive transmissions of shorter duration – which as Medtronic indicates, tend to be more energy efficient, and thus prolong battery life for implants. This will also support higher data transmission rates than could be accommodated by the maximum authorized emission bandwidth of 100 kilohertz channels of the wing bands, and thus may be more desirable for certain applications. Such characteristics are especially beneficial in extending the battery life of deep implant devices.

51. Guidant requests that we allow the aggregation of multiple transmission channels in a MedRadio device. We reject this proposal insofar that it would result in a single MedRadio communications session that exceeds a total of 100 kilohertz in the wing bands, or 300 kilohertz in the core band. This increased bandwidth would make the spectrum unavailable to other implanted and body-worn MedRadio devices used for non-voice, diagnostic and therapeutic purposes, which is contrary to our goal of providing greater opportunity for such devices and their applications. However, we will not preclude full duplex or half duplex communications if the total amount of bandwidth used by all of the MedRadio channels employed by a MedRadio device during a MedRadio communications session does not exceed the maximum authorized emission bandwidth (*i.e.* 100 kilohertz in the wing bands and 300 kilohertz in the core band). Moreover, smaller bandwidths may be employed by a single MedRadio device so long as the device adheres to all other EIRP and unwanted emission limits. For example, a single MedRadio device operating in the wing bands could be designed to operate nominally on two channels, each having a maximum emission bandwidth of 50 kilohertz, because the communications session would, in aggregate, be 100 kilohertz. In essence, these provisions carry forward the existing channel use provisions of the MICS rules into the new MedRadio rules.[70]

52. *Frequency monitoring requirement*. In the *MedRadio Notice*, we proposed to permit the operation of non-LBT medical devices – that is, those that do not employ listen-before-talk frequency monitoring - in the new MedRadio wing bands at 401-402 MHz and 405-406 MHz.[71] We also sought comment on whether to permit the operation of non-LBT devices on a single channel in the existing MICS core band.[72]

53. The current MICS rules require that the programmer/control transmitter associated with a medical implant device in the 402-405 MHz band must incorporate a frequency monitoring mechanism to monitor the channel or channels that the medical device transmitters intend to occupy.[73] In effect, this requirement imposes a listen-before-talk spectrum access protocol by which the external programmer/control transmitter samples the available spectrum and selects a non-occupied channel upon which to operate. Thus, under the current MICS rules, a medical implant transmitter is generally permitted to transmit only in response to a triggering signal from an external programmer/control device.[74]

54. Many commenters submit that the LBT frequency monitoring requirement should apply throughout the entire MedRadio 401-406 MHz band. Some of these parties argue that non-LBT operation be allowed for devices that employ sufficiently low duty-cycles and reduced EIRP. Medtronic, Boston Scientific, Biotronik, DexCom, and others argue that non-LBT devices should be permitted in the new

[70] *See* 47 C.F.R. § 95.628 (d) and. *See also* 47 C.F.R. § 95.633 (e) (2).

[71] *See MedRadio Notice* at ¶ 23.

[72] *See Id.* at ¶ 24.

[73] *See* 47 C.F.R. §§ 95.628(a) and 95.1209 (b).

[74] One exception to this requirement is provided in the rules. Under the "medical implant event" exception, an implant device may initiate a transmission without regard to the LBT frequency monitoring requirement. *See* 47 C.F.R. §§ 95.628 (b).

MedRadio wing bands. The most significant debate among the commenters is whether we should permit non-LBT operation in the core MICS band.[75]

55. We believe that an LBT frequency monitoring requirement is beneficial because it facilitates spectrum sharing among many uncoordinated devices and can reduce the likelihood of harmful interference from federal systems that are allocated on a primary basis. Thus, except as described below, we will maintain the current LBT frequency monitoring protocol as a general requirement for implant devices permitted throughout the entire 401-406 MHz band, as well as for body-worn devices permitted in the wing bands. The protocol that we adopt is identical to that for the existing MICS band, and we will retain the same LBT monitoring threshold limits specified in the present MICS rules.[76] In addition, we also extend the "medical implant event" exception of the current rules to LBT-enabled implant devices operating throughout the 401-406 MHz MedRadio band. [77]

56. We also recognize the potential advantages of non-LBT spectrum access methods for certain low power, low duty cycle (LP-LDC) devices - particularly, in terms of extended battery life, reduced complexity, and lower cost to patients in treating a wide variety of medical conditions where such simpler devices are adequate for the purpose. Thus, we will permit the use of non-LBT spectrum access methods in the wing bands by both implant and body-worn devices subject to the EIRP and duty cycle limits discussed below. We also will permit the use of non-LBT spectrum access methods for implant devices that operate with an emission bandwidth not exceeding 300 kilohertz centered at 403.65 MHz in the existing core band, as discussed below. Finally, as previously discussed, we will also permit operation on any of the frequencies in the 402-405 MHz band of temporary body-worn transmitting devices that are used solely during a limited patient evaluation period in order to determine the suitability of a fully implanted device, provided that they fully comply with all other MedRadio rules applicable to the band.. This decision is consistent with our anticipation that the rules we adopt herein will preserve the core band for the type of life-critical and time-sensitive applications served by LBT-enabled implant devices. In order to maintain reliable operation of these LBT implant devices, we will generally prohibit the operation of non-LBT devices in the core band except for the one designated portion of the core band that LBT devices can more readily avoid to reduce the potential for any adverse interactions.

57. *Transmitter power and duty cycle.* We will limit the maximum EIRP of LBT-enabled implant devices throughout the 401-406 MHz band and LBT-enabled body-worn medical devices in the wing bands to 25 microwatts EIRP. As with the original MICS rules, this limit is intended to ensure efficient spectrum sharing and compatibility among multiple uncoordinated devices. Furthermore, the 25 microwatt limit will maintain continuity with the present EIRP limit and LBT frequency monitoring requirement for the core band (which we also maintain under the new MedRadio rules) that has served well for spectrum access.

58. With respect to access to the 402-405 MHz band by non-LBT devices, we find that the convergence of comments in the record, particularly subsequent to the adoption by ETSI of similar

[75] *See,* generally, the comments of Biotronik, Medtronic, and others.

[76] *See* 47 C.F.R. §95.628 (a). Medtronic seeks in later-filed *ex parte* submissions to have the LBT threshold modified to include a correction factor of 1 dB higher for every 1 dB the EIRP of the monitoring system transmitter is below the maximum permitted level of 25 microwatts EIRP. *See* Medtronic *ex parte* letter, January 10, 2008. Medtronic argues that the modified threshold would result in agreement with the LBT threshold in recently adopted ETSI standards. We note that the question of possibly modifying the LBT threshold that appears in the present MICS rules was not raised in the *MedRadio Notice*, and thus there is insufficient notice and little substantive basis in the record for departing from the status quo.

[77] *See* 47 C.F.R. §95.628 (b). A medical implant event exception is not needed for implant devices using non-LBT spectrum access methods because non-LBT devices may, by definition, initiate a transmission session at will, provided that the EIRP and duty cycle requirements adopted in this Order are met. As a practical matter, this will permit a non-LBT implant device to transmit essentially whenever a medical event might occur.

standards, supports permitting operation by such devices with a total emission bandwidth not exceeding 300 kilohertz, centered at 403.65 MHz, with a maximum EIRP of 100 nanowatts and with maximum duty-cycle and transmission session limits of 0.01% and ten per hour, respectively.[78] We believe that permitting such non-LBT access in the legacy MICS core band will be useful and serves to promote the public interest

59. Our decision is informed by the increasingly widespread adoption of standards internationally that provide for non-LBT spectrum access methods in the 402-405 MHz band. ETSI, as noted just above, has adopted standards that allow non-LBT implant devices to operate with 100 nanowatts on a single channel centered at 403.65 MHz.[79] Furthermore, based upon our prior experience with single-channel non-LBT devices operating under the *Biotronik Waiver* in the core MICS band – particularly, the absence of complaints of interference arising between any MICS or non-LBT devices – we conclude that these EIRP and duty cycle limits are sufficiently conservative to permit efficient spectrum sharing between LBT enabled and non-LBT devices that choose to operate at 403.65 MHz.

60. For devices using non-LBT spectrum access methods in the new MedRadio wing bands at 401-402 and 405-406 MHz, we adopt power and duty cycle limits that match our proposals in the *MedRadio Notice*, namely a maximum EIRP of 250 nanowatts, together with a maximum duty cycle limit of 0.1% and a maximum limit of 100 communication sessions per hour.[80] We agree with those commenters who generally support these technical limits as being sufficiently conservative to enable coexistence with other LBT devices in the wing bands. Furthermore, we believe that permitting the higher EIRP of 250 nanowatts for non-LBT operation in the wing bands, as compared with the 100 nanowatts adopted above for non-LBT operation in the core band, will serve to encourage use of the wing bands for the majority of non-LBT applications.

61. Nonetheless, we will allow a maximum of 25 microwatts EIRP for devices using non-LBT spectrum access methods at 401.85-402 MHz. We recognize that some body worn devices, such as the glucose monitoring devices manufactured by DexCom that are now operating in the core band under a waiver, need more power (*see infra* paragraphs 66-70). Our decision here to allow more power for non-LBT devices at the upper edge of the 401-402 MHz wing band will facilitate DexCom's ability to transition its operating freuquency out of the core band. The higher power also would provide flexibility for other manufacturers designing medical devices in these bands.

62. *Unwanted emissions*. The existing Part 95 rules set forth limits on unwanted emissions from transmitters operating in the MICS, and include limits on both in-band and out-of-band emissions.[81] We sought comment on the general topic of emissions in the *MedRadio Notice*,[82] and there is relatively sparse comment in the record with respect thereto. In its petition, Medtronic supplied a prospective rules appendix that includes wing band emission mask limits and related in-band/out-of-band emission limits,

[78] These requirements are incorporated in the new MedRadio technical rules set forth in 'Appendix A' attached to this Order.

[79] *See* ETSI EN 301 839-1, v1.2.1 (2007-07), available online at (http://www.etsi.org).

[80] The term "[MICS] communication session" is defined in the present rules as "[A] collection of transmissions, that may or may not be continuous, between MICS system devices." *See* 47 C.F.R. 95.628(a)(6)(iii).

[81] *See* 47 C.F.R. 95.635(d). Generally, emissions more than 250 kilohertz outside the MICS band must meet specified field strength limits that depending on the frequency, emissions within the MICS band for than 150 kilohertz away from the intended center frequency are subject to attenuation below the transmitter power by at least 20 dB, and emissions 250 kilohertz or less that are above and below the MICS band must be attenuated below the maximum output power by at least 20 dB. While this rule section, which applies to numerous Part 95 services, is titled "Unwanted radiation," for purposes of discussion we are using the more familiar term "emission" herein.

[82] See *MedRadio Notice* at ¶ 21, n. 48.

which in some respects are stricter than the corresponding limits for devices operating in the core band.[83] In response, Biotronik says that it opposes more stringent in-band, out-of-band, or spurious emission limits for any portion of the 401-406 MHz band, whether accomplished with narrower guard bands or lower absolute limits.[84] ORBCOMM, submits that whatever out-of-band emission limits are adopted should afford sufficient protection to avoid harmful interference to its satellite operations in the lower adjacent band below 401 MHz.[85]

63. We believe that the existing Part 95 limits on unwanted radiation have served well in the MICS. Thus, we retain without modification the existing in-band and out-of-band emission limits for the MedRadio core band frequencies at 402-405 MHz. For the new MedRadio wing bands at 401-402 MHz and 405-406 MHz, we adopt an emission mask having the same form as the emission mask that already exists for the core band, but modified to apply over the narrower 100 kilohertz maximum authorized emission bandwidth of the wing band. Thus, we will require that emissions from devices operating within the MedRadio wing bands more than 50 kilohertz away from the center frequency of a transmission be attenuated below the actual transmitter output power by at least 20 dB. In addition, we will require emissions 100 kilohertz or less below 401 MHz, or above 406 MHz, to be attenuated below the maximum permitted output power by at least 20 dB. Finally, for out-of-band emissions at more than 100 kilohertz outside the 401 MHz and 406 MHz MedRadio band edges, we adopt generally the same field strength limits on emissions that presently apply to the core band.[86]

64. We decline to impose more restrictive limits on emissions from MedRadio wing band devices into the existing core band in the manner indicated by Medtronic in its petition.[87] Under such an approach, wing band devices would be burdened with more stringent limits on radiation into the core band as compared to core band devices. We find no compelling reason to place wing band devices on such an unequal footing with core band devices, particularly if such a limit were to be set below the existing general emission limits contained in Section 15.209 as suggested by Medtronic. Manufacturers must design core band devices under the assumption that RF energy will be encountered in the core band from the in-band and spurious emissions of other authorized services as well as emissions from a wide variety of unlicensed electronic devices, (*e.g*., personal computers, CD players, etc). Medical implant devices that are designed to operate in such an electromagnetic environment should not need greater protection from spurious emissions from wing band devices. We are confident that manufacturers of wing band devices are capable of designing their products to be compatible with and to protect core band devices, especially when both types of devices are used by the same patient.

65. We conclude that the emission limits we adopt are more than adequate to foster efficient spectrum sharing within the MedRadio bands and to guard against harmful interference to out of band operations. In particular, these limits will minimize the potential overlap of wing band devices that transmit on channels that use the full 100 kilohertz maximum emission bandwidth and will minimize the potential for spill-over from wing band devices into the existing core band. Because the limits we adopt

[83] *See* attachment to *Medtronic Petition*. Medtronic proposed rule section 95.635(d).

[84] *See* Biotronik comments received October 31, 2007, at 8.

[85] *See* ORBCOMM comments filed December 5, 2006. ORBCOMM requests that the Commission ensure that any new designation in the wing bands not cause interference to the downlink operations of its Non-Voice, Non-Geostationary Mobile Satellite Service (NVNG MSS – also known as 'Little LEO') operations in the adjacent 400-401 MHz band. ORBCOMM further states that it is currently using the 400-400.15 MHz band for timing downlinks, and notes that other portions of the 400.15-401 MHz band have been allocated to the NVNG MSS.

[86] *See* 47 C.F.R. 95.635 (d) (1).

[87] *See* Medtronic *ex parte* letter of September 3, 2008. Medtronic seeks a limit on wing band device emissions into the core band of 100 μV/m at 3 m. By comparison, under the rules we adopt herein, the radiation from wing band devices into the core band will be limited to 200 μV/m at 3 meters, which is the general limit on emissions between 216-960 MHz that also presently applies to core band devices.

are consistent with the emission limits as discussed in the *MedRadio Notice*, we also conclude that they address ORBCOMM's comments and that they will afford sufficient protection to satellite operations on frequencies below 401 MHz adjacent to the lower MedRadio wing band.[88]

66. *RF safety and EIRP compliance*. We maintain unchanged the basic requirements in the current rules and related provisions in other Parts as they apply RF safety and EIRP compliance requirements for implanted devices.[89] Of course, the existing MICS rules do not address body-worn devices; and we did not seek comment in the *MedRadio Notice* about how these matters should be addressed with respect to such body-worn devices. However, to the extent feasible, body-worn MedRadio devices will be governed by the same requirements as other hand-held transmitting devices set forth elsewhere in our rules for the purposes of demonstrating compliance with RF safety and EIRP limits.[90]

67. Medtronic's original petition and subsequent *ex parte* filings request two related modifications or additions to the MICS/MedRadio rules that were not addressed in the *MedRadio Notice*. One issue involves whether and when open-area test sites or body-torso simulator measurements should be performed, and whether a 4 dB EIRP correction factor should be applied between implant and body-worn devices to account for the absorption of radio energy by body tissue that can be associated with implanted devices. A second issue involves whether unspecified "other techniques" (beyond the finite difference time domain (FDTD) technique cited in the existing rules) could be used for equipment authorization and RF exposure evaluation purposes.

68. We conclude that insufficient notice was provided in the *MedRadio Notice* on these particular questions raised by Medtronic to form a basis for departing from the current rules. On a substantive basis, we further note that the modifications sought by Medtronic would appear to have significant applicability beyond the narrow scope of medical devices considered herein, particularly with respect to other body-worn or hand-held devices such as cell phones and the like - all of which operate in close proximity to the human body. We have another ongoing proceeding concerning RF exposure that is better suited to address several of these concerns in a more comprehensive context.[91] Accordingly, we decline to adopt these changes suggested by Medtronic herein and, instead, defer further consideration to the RF exposure proceeding.

69. *Disposition of Biotronik and DexCom Waivers*. The Biotronik and DexCom waivers permit the manufacture and marketing in the United States of certain models of cardiac and diabetic therapy devices that do not possess the LBT frequency monitoring capability required by the present MICS rules for the core band at 402-405 MHz.[92] Both waivers are valid for one year from the effective date of the final MedRadio rules adopted in this proceeding.[93]

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[88] *See* ORBCOMM reply comments at 5-6 (stating that "[I]f the Commission adopts the out-of-band emission limits suggested in the [*MedRadio Notice*], then these new devices are unlikely to cause harmful interference to ORBCOMM's operations in the adjacent band.").

[89] *See* existing 47 C.F.R. 1.1307, and new Section 95.1221 adopted herein. In addition, by this Order, we move certain provisions regarding EIRP measurement procedures from the existing Section 95.639 to a more logical location in new Section 95.628.

[90] *See* 47 C.F.R. 2.1093.

[91] *See* "Proposed Changes in the Commission's Rules Regarding Human Exposure to Radiofrequency Electromagnetic Fields" (ET Docket No. 03-137), *Notice of Proposed Rulemaking*, 18 FCC Rcd 13187 (2003).

[92] *See* ¶ 6, *supra*.

[93] *See MedRadio Notice* at ¶¶ 35 & 58.

70. The technical parameters of the cardiac devices authorized by the *Biotronik Waiver*[94] are now encompassed within the provisions of the new MedRadio rules adopted herein - which provide for non-LBT operation by low power, low duty cycle implants operating between 403.5-403.8 MHz in the 402-405 MHz core band. Consequently, the *Biotronik Waiver* will be rendered moot upon the effective date of the MedRadio rules adopted herein and ET Docket No. 03-92 will be terminated.

71. On the other hand, the devices authorized by the *DexCom Waiver* operate at 402.142 MHz instead of within the 403.5-403.8 MHz frequency range specified by the rules adopted herein for non-LBT spectrum access in the core band, and also operate with a significantly higher EIRP than that permitted under the new rules.[95] Because the technical parameters of the relevant DexCom devices fail to comply with the provisions of the MedRadio rules adopted herein, the *DexCom Waiver* would, by its own terms, expire one year from the effective date of the MedRadio rules adopted herein. After that time, pursuant to the terms of the *DexCom Waiver* Order, the LTS (long term) model devices that have already been installed may continue to operate, but use of the STS (short term) model devices must cease, and no additional LTS devices can be installed in patients.

72. During the course of this proceeding, DexCom filed a request for extension of its waiver that would allow it to continue marketing and operating devices under the terms of the *DexCom Waiver* for five years from the effective date of the MedRadio rules adopted herein.[96] DexCom argues that its non-LBT devices cannot meet the technical requirements for such devices that are being considered for the core band at 402-405 MHz (where it currently operates) nor the wing bands at 401-402 MHz and 405-406 MHz.[97] If it must consider transitioning out of the core band, DexCom asserts that it needs five years to develop, test and receive regulatory approvals for new devices. DexCom also claims that, even if operations within the core band greatly increase over the next five years, the interference potential between its devices and others would remain small given the low power and low duty cycle employed by its devices and the unlikelihood that its devices would operate in close proximity to others operating in the band.[98]

73. We will extend DexCom's waiver for four years from the effective date of the MedRadio rules adopted herein. This should provide DexCom with sufficient time to come into compliance with the new MedRadio rules and to obtain the required FDA approval. In this regard, we observe that the DexCom devices would be considered to be body-worn (and thus prohibited in the core band under the

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[94] *See* n. 18, *supra*.

[95] The *DexCom Waiver* permits non-LBT manufacture and use of the STS and LTS models of blood glucose monitoring systems on a single channel, with a maximum 120 kHz bandwidth, at 402.142 MHz (+/- 40 kilohertz) with power levels of approximately -20 dBm conducted. *See DexCom Waiver* at ¶ 16. The STS uses a separate injectible probe that must be replaced every several days (the transmitter to which it is attached is more permanent); the LTS is a more complete monitoring unit that is fully implanted and remains for up to one year. *See DexCom Waiver* at n.17.

[96] *See* Request for Extension of Waiver, filed by DexCom on September 23, 2008. DexCom states that it is working with other manufacturers to integrate its glucose monitoring devices with insulin pumps, and hopes to introduce a new device under the current waiver in mid-2009. *Id.* at 2-3.

[97] DexCom states that its devices operate "at a power level close to 10 uW EIRP (-20dBm) EIRP [sic], while the apparent consensus proposal would allow non-LBT devices to operate at power levels no greater than 100 nW ERP on the main MICS band and 250 nW EIRP on the side bands." *Id.* at 4. We note that LBT devices in the wing bands can operate at 25 uW EIRP, well above the power level used by the DexCom devices.

[98] The DexCom devices operate with a total duty cycle of 0.003% (compared to a 0.01% total duty cycle being considered for non-LBT devices in the core band and a 0.1% total duty cycle in the wing bands). *Id*. at 6. The DexCom devices operate on a 120 kilohertz channel (*see DexCom Waiver* at ¶ 16) which is, we note, well within the 300 kilohertz maximum emission bandwidth permitted in the core band but slightly greater than the 100 kilohertz maximum emission bandwidth we are adopting for the wing bands.

new MedRadio rules) because the transmitter/antenna portion of the device is applied to the top of the skin. We find that operation of the DexCom non-LBT devices in the core band, particularly at the higher power levels they use, could in the long term prove problematic for other rules-compliant devices - especially those used for life-critical applications - as the number of either of these types of devices grow. Further, the new MedRadio rules provide a single channel in the center of the core band for non-LBT devices, consistent with international standards. We also observe that the wing bands provide adequate spectrum for both LBT and non-LBT body-worn devices and that DexCom's devices may reasonably be accommodated under the new MedRadio rules for these bands. We recognize that Dexcom's devices will need to be redesigned to conform to the new rules and that new FDA approval will be required. However, we are not persuaded that the relatively small move in operating frequency, while maintaining emission bandwidth, power and duty cycle specifications, will require 5 years. We encourage DexCom to transition to the newly designated spectrum as soon as practicable. While we have concerns about the interference risks of non-compliant devices in the core band over the long term, we believe that the limited proliferation of DexCom's devices over the next few years will not pose a significant interference risk. Moreover, we find it is in the public interest to ensure that these devices continue to be available without interruption. Accordingly, we find that the extension of DexCom's waiver, as modified above, is warranted.

D. Other Issues – NOI Related

74. We received a variety of comments in response to the notice of inquiry portion of the *MedRadio Notice*. Among the matters that we believe can be addressed in the near term, several commenters favor making information about medical radiocommunication devices more readily available to the general public and other interested parties. We agree with commenters that making such information readily available, particularly via the Internet, could be beneficial. Thus, we intend to explore options for creating a MedRadio page on the Commission's official web site that could serve this purpose, while endeavoring to monitor new developments in the field.

IV. PROCEDURAL MATTERS

75. *Final Regulatory Flexibility Analysis.* As required by Section 603 of the Regulatory Flexibility Act, 5 U.S.C. § 603, the Commission has prepared a Final Regulatory Flexibility Analysis (FRFA) of the possible significant economic impact on small entities of the final rules adopted in this document. The FRFA is set forth in Appendix C.

76. *Paperwork Reduction Act.* This document contains no new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104-13. In addition, therefore, it does not contain any new or modified "information collection burden for small business concerns with fewer than 25 employees," pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107-198, *see* 44 U.S.C. 3506(c)(4*)*.

77. *Congressional Review Act.* The Commission will send a copy of this Report and Order in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

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

V. ORDERING CLAUSES

79. Accordingly, IT IS ORDERED that pursuant to the authority contained in Sections 4(i), 301, 302, 303(e), 303(f) and 303(r) of the Communications Act of 1934, as amended, 47 USC Sections 154(i), 301, 302, 303(e), 303(f) and 303(r), this Report and Order IS ADOPTED and Parts 2 and 95 of the Commission's Rules ARE AMENDED as set forth in Appendix A effective 90 days after publication in the Federal Register.

80. IT IS FURTHER ORDERED that we GRANT IN PART, consistent with the terms of this order, DexCom, Inc.'s request for extension of waiver, and otherwise DENY the request in all other respects.

81. IT IS FURTHER ORDERED that ET Docket No. 03-92 IS TERMINATED.

82. IT IS FURTHER ORDERED that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, SHALL SEND a copy of this Report and Order, including the Final Regulatory Flexibility Analysis in Appendix C, to the Chief Counsel for Advocacy of the Small Business Administration.

FEDERAL COMMUNICATIONS COMMISSION

Marlene H. Dortch
Secretary

APPENDIX A

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 C.F.R. parts 1, 2, and 95 as follows:

PART 1—PRACTICE AND PROCEDURE

1. The authority citation for part 1 continues to read as follows:

AUTHORITY: 15 U.S.C. 79 et seq.; 47 U.S.C. 151, 154(i), 154(j), 155, 157, 225, 303(r), and 309.

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

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

* * * * *

(b) * * *

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

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

3. The authority citation for part 2 continues to read as follows:

AUTHORITY: 47 U.S.C. 154, 302a, 303, and 336, unless otherwise noted.

4. Section 2.106, the Table of Frequency Allocations, is amended as follows:

a. Revise page 24.

b. In the list of United States (US) footnotes, revise footnote US345.

§ 2.106 Table of Frequency Allocations.

* * * * *

The revisions read as follows:

399.9-400.05 MOBILE-SATELLITE (Earth-to-space) 5.209 5.224A RADIONAVIGATION-SATELLITE 5.222 5.224B 5.260 5.220	399.9-400.05 MOBILE-SATELLITE (Earth-to-space) US319 US320 RADIONAVIGATION-SATELLITE 5.260		Satellite Communications (25)
400.05-400.15 STANDARD FREQUENCY AND TIME SIGNAL-SATELLITE (400.1 MHz) 5.261 5.262	400.05-400.15 STANDARD FREQUENCY AND TIME SIGNAL-SATELLITE (400.1 MHz) 5.261		
400.15-401 METEOROLOGICAL AIDS METEOROLOGICAL-SATELLITE (space-to-Earth) MOBILE-SATELLITE (space-to-Earth) 5.208A 5.209 SPACE RESEARCH (space-to-Earth) 5.263 Space operation (space-to-Earth) 5.262 5.264	400.15-401 METEOROLOGICAL AIDS (radiosonde) US70 METEOROLOGICAL-SATELLITE (space-to-Earth) MOBILE-SATELLITE (space-to-Earth) US319 US320 US324 SPACE RESEARCH (space-to-Earth) 5.263 Space operation (space-to-Earth) 5.264	400.15-401 METEOROLOGICAL AIDS (radiosonde) US70 MOBILE-SATELLITE (space-to-Earth) US319 US320 US324 SPACE RESEARCH (space-to-Earth) 5.263 Space operation (space-to-Earth) 5.264	Satellite Communications (25)
401-402 METEOROLOGICAL AIDS SPACE OPERATION (space-to-Earth) EARTH EXPLORATION-SATELLITE (Earth-to-space) METEOROLOGICAL-SATELLITE (Earth-to-space) Fixed Mobile except aeronautical mobile	401-402 METEOROLOGICAL AIDS (radiosonde) US70 SPACE OPERATION (space-to-Earth) EARTH EXPLORATION-SATELLITE (Earth-to-space) METEOROLOGICAL-SATELLITE (Earth-to-space) US345 US384	401-402 METEOROLOGICAL AIDS (radiosonde) US70 SPACE OPERATION (space-to-Earth) Earth exploration-satellite (Earth-to-space) Meteorological-satellite (Earth-to-space) US345 US384	MedRadio (95I)
402-403 METEOROLOGICAL AIDS EARTH EXPLORATION-SATELLITE (Earth-to-space) METEOROLOGICAL-SATELLITE (Earth-to-space) Fixed Mobile except aeronautical mobile	402-403 METEOROLOGICAL AIDS (radiosonde) US70 EARTH EXPLORATION-SATELLITE (Earth-to-space) METEOROLOGICAL-SATELLITE (Earth-to-space) US345 US384	402-403 METEOROLOGICAL AIDS (radiosonde) US70 Earth exploration-satellite (Earth-to-space) Meteorological-satellite (Earth-to-space) US345 US384	
403-406 METEOROLOGICAL AIDS Fixed Mobile except aeronautical mobile	403-406 METEOROLOGICAL AIDS (radiosonde) US70 US345 G6	403-406 METEOROLOGICAL AIDS (radiosonde) US70 US345	
406-406.1 MOBILE-SATELLITE (Earth-to-space) 5.266 5.267	406-406.1 MOBILE-SATELLITE (Earth-to-space) 5.266 5.267		Maritime (80) Aviation (87) Personal Radio (95)
406.1-410 FIXED MOBILE except aeronautical mobile RADIO ASTRONOMY 5.149	406.1-410 FIXED US13 MOBILE RADIO ASTRONOMY US74 US117 G5 G6	406.1-410 RADIO ASTRONOMY US74 US13 US117	Private Land Mobile (90)

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UNITED STATES (US) FOOTNOTES

* * * * *

US345 In the band 401–406 MHz, the mobile, except mobile aeronautical, service is allocated on a secondary basis and is limited to, with the exception of military tactical mobile stations, Medical Device Radiocommunication Service (MedRadio) operations. MedRadio stations are authorized by rule on the condition that harmful interference is not caused to stations in the meteorological aids, meteorological-satellite, and earth exploration-satellite services, and that MedRadio stations accept interference from stations in the meteorological aids, meteorological-satellite, and earth exploration-satellite services.

* * * * *

5. Section 2.1093 is amended by revising paragraph (c) to read as follows:

§ 2.1093 Radiofrequency radiation exposure evaluation: portable devices.

* * * * *

(a) * * *

(b) * * *

(c) Portable devices that operate in the Cellular Radiotelephone Service, the Personal Communications Service (PCS), the Satellite Communications Services, the General Wireless Communications Service, the Wireless Communications Service, the Maritime Services, the Specialized Mobile Radio Service, the 4.9 GHz Band Service, the Wireless Medical Telemetry Service (WMTS) and the Medical Device Radiocommunication Service (MedRadio), authorized under subpart H of part 22 of this chapter, parts 24, 25, 26, 27, 80 and 90 of this chapter, subparts H and I of part 95 of this chapter, and unlicensed personal communication service, unlicensed NII devices and millimeter wave devices authorized under subparts D and E, §§15.253, 15.255 and 15.257 of this chapter are subject to routine environmental evaluation for RF exposure prior to equipment authorization or use. All other portable transmitting devices are categorically excluded from routine environmental evaluation for RF exposure prior to equipment authorization or use, except as specified in §§1.1307(c) and 1.1307(d) of this chapter. Applications for equipment authorization of portable transmitting devices subject to routine environmental evaluation must contain a statement confirming compliance with the limits specified in paragraph (d) of this section as part of their application. Technical information showing the basis for this statement must be submitted to the Commission upon request.

* * * * *

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

§ 2.1204 Import conditions.

* * * * *

(a) * * *

(9) The radio frequency device is a medical implant transmitter inserted in a person or a medical body-worn transmitter as defined in Part 95, granted entry into the United States or is a control transmitter associated with such an implanted or body-worn transmitter, provided, however that the transmitters covered by this provision otherwise comply with the technical requirements applicable to transmitters authorized to operate in the Medical Device Radiocommunication Service (MedRadio) under part 95 of this chapter. Such transmitters are permitted to be imported without the issuance of a grant of equipment authorization only for the personal use of the person in whom the medical implant transmitter has been inserted or on whom the medical body-worn transmitter is applied.

* * * * *

PART 95 – PERSONAL RADIO SERVICES

7. The authority citation for part 95 continues to read as follows:

AUTHORITY: Sections 4, 303, 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 303

8. Section 95.401 is amended by revising paragraph (d) to read as follows:

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

* * * * *

(d) The Medical Device Radiocommunication Service (MedRadio) — an ultra-low power radio service, for the transmission of non-voice data for the purpose of facilitating diagnostic and/or therapeutic functions involving implanted and body-worn medical devices. The rules for this service are contained in subpart I of this part.

* * * * *

9. Section 95.601 is amended by revising the last sentence to read as follows:

§ 95.601 Basis and purpose.

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

10. Section 95.603 is amended by revising paragraph (f) to read as follows:

95.603 Certification required.

* * * * *

(f) Each Medical Device Radiocommunication Service (MedRadio) transmitter (a transmitter that operates or is intended to operate in the MedRadio service) must be certificated except for such transmitters that are not marketed for use in the United States, but which otherwise comply with the MedRadio Service technical requirements and are operated in the United States by individuals who have traveled to the United States from abroad.

* * * * *

11. Section 95.605 is revised to read as follows:

§ 95.605 Certification procedures.

Any entity may request certification for its transmitter when the transmitter is used in the GMRS, FRS, R/C, CB, 218-219 MHz Service, LPRS, MURS, or MedRadio Service following the procedures in part 2 of this chapter. Dedicated Short-Range Communications Service On-Board Units (DSRCS-OBUs) must be certified in accordance with subpart L of this part and subpart J of part 2 of this chapter.

12. Section 95.628 is amended by revising the title and paragraphs (a) through (f), and by adding a new paragraph (g) to read as follows:

§ 95.628 MedRadio transmitters.

(a) *Frequency monitoring*. Except as provided in (b) below, all MedRadio programmer/control transmitters operating in the 401-406 MHz band must operate under the control of a monitoring system that incorporates a mechanism for monitoring the channel or channels that the MedRadio system devices

intend to occupy. The monitoring system antenna shall be the antenna normally used by the programmer/control transmitter for a communications session. Before the monitoring system of a MedRadio programmer/control transmitter initiates a MedRadio communications session, the following access criteria must be met:

(1) * * *

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

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

(4) If no signal in a MedRadio channel above the monitoring threshold power level is detected, the MedRadio programmer/control transmitter may initiate a MedRadio communications session involving transmissions to and from a medical implant or medical body-worn device on that channel. The MedRadio communications session may continue as long as any silent period between consecutive data transmission bursts does not exceed 5 seconds. If a channel meeting the criteria in paragraph (a)(3) of this section is unavailable, the channel with the lowest ambient power level may be accessed.

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

(i) * * *

(ii) * * *

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

(6) * * *

(i) * * *

(ii) *MedRadio channel*—Any continuous segment of spectrum in the MedRadio band that is equal to the emission bandwidth of the device with the largest bandwidth that is to participate in a MedRadio communications session. (Note: The rules do not specify a channeling scheme for use by MedRadio systems.)

(iii) *MedRadio communications session*—A collection of transmissions, that may or may not be continuous, between MedRadio system devices.

(b) *Exceptions to frequency monitoring criteria.* MedRadio devices or communications sessions that meet any one of the following criteria are not required to use the access criteria set forth in paragraph (a) of this section:

(1) MedRadio communications sessions initiated by a medical implant event.

(2) MedRadio devices operating in either the 401-401.85 MHz or 405-406 MHz bands, provided that the transmit power is not greater than 250 nanowatts EIRP and the duty cycle for such transmissions does not exceed 0.1%, based on the total transmission time during a one-hour interval.

(3) MedRadio devices operating in the 401.85-402 MHz band, provided that the transmit power is not greater than 25 microwatts EIRP and the duty cycle for such transmissions does not exceed 0.1%, based on the total transmission time during a one-hour interval.

(4) MedRadio devices operating with a total emission bandwidth not exceeding 300 kHz centered at 403.65 MHz, provided that the transmit power is not greater than 100 nanowatts EIRP and the duty cycle for such transmissions does not exceed 0.01%, based on the total transmission time during a one-hour interval.

(c) *Operating frequency.* MedRadio stations authorized under this Part may operate on frequencies in the 401-406 MHz band as follows provided that the out-of-band emissions are attenuated in accordance with §95.635:

(1) MedRadio stations associated with medical implant devices, which incorporate a frequency monitoring system as set forth in paragraph (a) of this section, may operate on any of the frequencies in the 401-406 MHz band,

(2) MedRadio stations associated with medical implant devices, which do not incorporate a frequency monitoring system as set forth in paragraph (a) of this section, may operate on any frequency in 401-402 MHz or 405-406 MHz bands, or at 403.65 MHz in the 402-405 MHz band.

(3) MedRadio stations associated with medical body-worn devices, regardless of whether a frequency monitoring system as set forth in paragraph (a) this section is employed, may operate on any of the frequencies in the 401-402 MHz or 405-406 MHz bands.

(4) MedRadio stations that are used externally to evaluate the efficacy of a more permanent medical implant device, regardless of whether a frequency monitoring system as set forth in paragraph (a) of this section is employed, may operate on any of the frequencies in the 402-405 MHz band, provided that:

(i) Such external body-worn operation is limited solely to evaluating with a patient the efficacy of a fully implanted permanent medical device that is intended to replace the temporary body-worn device;

(ii) RF transmissions from the external device must cease following the patient evaluation period, which may not exceed 30 days, except where a health care practitioner determines that additional time is necessary due to unforeseen circumstances;

(iii) The maximum output power of the temporary body-worn device shall not exceed 200 nW EIRP; and

(iv) The temporary body-worn device must comply fully with all other MedRadio rules applicable to medical implant device operation in the 402-405 MHz band.

(d) *Authorized bandwidth.* The authorized bandwidth of the emission from a MedRadio station operating between 402-405 MHz shall not exceed 300 kHz, and no communications session involving MedRadio stations shall use more than a total of 300 kHz of bandwidth during such a session. The authorized bandwidth of the emission from a MedRadio station operating between 401-401.85 MHz or 405-406 MHz shall not exceed 100 kHz, and no communications session involving MedRadio stations shall use more than a total of 100 kHz of bandwidth during such a session. The authorized bandwidth of the emission from a MedRadio station operating between 401.85-402 MHz shall not exceed 150 kHz, and no communications session involving MedRadio stations shall use more than a total of 150 kHz of bandwidth during such a session. Note: This provision does not preclude full duplex or half duplex communications provided that the total amount of bandwidth utilized by all of the MedRadio channels employed in such a MedRadio communications session does not exceed 300 kHz in the 402-405 MHz band, or 100 kHz in the 401-402 MHz and 405-406 MHz bands.

(e) *Frequency stability*. Each transmitter in the MedRadio service must maintain a frequency stability of ±100 ppm of the operating frequency over the range:

(1) * * *

(2) 0°C to 55°C in the case of MedRadio programmer/control transmitters and MedRadio body-worn transmitters.

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

(g) *Measurement procedures.*

(1) MedRadio transmitters shall be tested for frequency stability, radiated emissions and EIRP limit compliance in accordance with paragraphs (g)(2) and (g)(3) below.

(2) Frequency stability testing shall be performed over the temperature range set forth in (e) above.

(3) Radiated emissions and EIRP limit measurements limit may be determined by measuring the radiated field from the equipment under test at 3 meters and calculating the EIRP. The equivalent radiated field strength at 3 meters for 25 microwatts, 250 nanowatts, and 100 nanowatts EIRP is 18.2, 1.8, or 1.2 mV/meter, respectively, when measured on an open area test site; or 9.1, 0.9, or 0.6 mV/meter, respectively, when measured on a test site equivalent to free space such as a fully anechoic test chamber. Power measurements for transmissions by stations authorized under this section may be made either in accordance with a Commission-approved peak power technique, or the following. Peak transmit power must be measured over any interval of continuous transmission using instrumentation calibrated in terms of an rms-equivalent voltage. The measurement results shall be properly adjusted for any instrument limitations, such as detector response times, limited resolution bandwidth capability when compared to the emission bandwidth, sensitivity, etc., so as to obtain a true peak measurement for the emission in question over the full bandwidth of the channel.

(i) For a transmitter intended to be implanted in a human body, radiated emissions and EIRP measurements for transmissions by stations authorized under this section may be made in accordance with a Commission-approved human body simulator and test technique. A formula for a suitable tissue substitute material is defined in OET Bulletin 65 Supplement C (01-01).

(ii) For a transmitter intended to be body-worn, and for programmer/control transmitters, use standard ANSI C63.4 test setup and test method.

13. Section 95.631 is amended by revising paragraph (h) to read as follows:

§ 95.631 Emission types.

* * * * *

(h) A MedRadio station may transmit any emission type appropriate for communications in this service. Voice communications, however, are prohibited.

* * * * *

14. Section 95.633 is amended by revising paragraph (e) to read as follows:

§ 95.633 Emission bandwidth.

* * * * *

(e) For transmitters in the MedRadio Service:

(1) For stations operating in 402-405 MHz, the maximum authorized emission bandwidth is 300 kHz. For stations operating in 401-401.85 MHz or 405-406 MHz, the maximum authorized emission bandwidth is 100 kHz, and stations operating in 401.85-402 MHz, the maximum authorized emission bandwidth is 150 kHz.

(2) Lesser emission bandwidths may be employed, provided that the unwanted emissions are attenuated as provided in § 95.635. See §§ 95.628(g) and 95.639(f) regarding maximum transmitter power and measurement procedures.

* * * * *

15. Section 95.635 is amended by revising paragraphs (b) and (d) to read as follows:

§ 95.635 Unwanted radiation.

* * * * *

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

Transmitter	Emission type	Applicable paragraphs (b)
* * *	* * *	* * *
MedRadio	As specified in paragraph (d)	
* * *		

* * * * *

(d) For transmitters designed to operate in the MedRadio service, emissions shall be attenuated in accordance with the following: (Subparagraphs 1 through 5 pertain to MedRadio transmitters operating in the 402-405 MHz band; subparagraphs 6 through 10 pertain to MedRadio transmitters operating in the 401-402 MHz or 405-406 MHz bands)

(1) Emissions from a MedRadio transmitter more than 250 kHz outside of the 402–405 MHz band shall be attenuated to a level no greater than the following field strength limits:

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

(2) * * *

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

(4) Emissions within the 402–405 MHz band more than 150 kHz away from the center frequency of the spectrum the transmission is intended to occupy will be attenuated below the transmitter output power by at least 20 dB. Compliance with this limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

(5) Emissions 250 kHz or less that are above and below the 402–405 MHz band will be attenuated below the maximum permitted output power by at least 20 dB. Compliance with this limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

(6) Emissions from medical device transmitters operating in the 401-402 MHz or 405-406 MHz bands at more than 100 kHz outside of the MedRadio bands (401-406 MHz) and all emissions in the band 406.000-406.100 MHz shall be attenuated to a level no greater than the following field strength limits:

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

(7) The emission limits shown in (6) above are based on measurements employing a CISPR quasi-peak detector except that above 1 GHz, the limit is based on measurements employing an average detector. Measurements above 1 GHz shall be performed using a minimum resolution bandwidth of 1 MHz. See also § 95.605.

(8) The emissions from a medical device transmitter operating in the MedRadio bands (between 401-402 MHz or 405-406 MHz) must be measured to at least the tenth harmonic of the highest fundamental frequency designed to be emitted by the transmitter.

(9) Emissions within the MedRadio bands more than 50 kHz away from the center frequency of the spectrum the transmission is intended to occupy, shall be attenuated below the transmitter output power by at least 20 dB except as noted in (7) above. Compliance with this limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

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

* * * * *

16. Section 95.639 is amended by revising paragraph (f) to read as follows:

§ 95.639 Maximum transmitter power.

* * * * *

(f) In the MedRadio Service for transmitters that are not excepted under § 95.628(b) from the frequency monitoring requirements of § 95.628(a), the maximum radiated power in any 300 kHz bandwidth by MedRadio transmitters operating at 402-405 MHz, or in any 100 kHz bandwidth by MedRadio transmitters operating at 401-402 MHz or 405-406 MHz shall not exceed 25 microwatts EIRP. For transmitters that are excepted under § 95.628(b) from the frequency monitoring requirements of § 95.628(a), the power radiated by any station operating in 402-405 MHz shall not exceed 100 nanowatts EIRP confined to a maximum total emission bandwidth of 300 kHz centered at 403.65 MHz. For transmitters that are excepted under § 95.628(b) from the frequency monitoring requirements of § 95.628(a), the power radiated by any station operating in 401-401.85 MHz or 405-406 MHz shall not exceed 250 nanowatts EIRP in any 100 kHz bandwidth and in 401.85-402 MHz shall not exceed 25 microwatts in the 150 kHz bandwidth. See §§ 95.633(e). The antenna associated with any MedRadio transmitter must be supplied with the transmitter and shall be considered part of the transmitter subject to equipment authorization. Compliance with these EIRP limits may be determined as set forth in § 95.628(g).

17. Section 95.649 is revised to read as follows:

§ 95.649 Power capability.

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

18. Section 95.651 is revised to read as follows:

§ 95.651 Crystal control required.

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

19. Appendix 1 to Subpart E of Part 95—Glossary of Terms is amended by removing the definition of "Medical Implant Communications Service (MICS) transmitter", "MICS" and "MICS programmer/control transmitter"; and by revising the definitions of "EIRP", "Medical implant transmitter"; and by adding the definitions of "Medical body-worn device", "Medical body-worn transmitter", "MedRadio programmer/control transmitter", "MedRadio Service" and "MedRadio transmitter" in alphabetical order to read as follows:

APPENDIX 1 TO SUBPART E OF PART 95—GLOSSARY OF TERMS

* * * * *

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

* * * * *

Medical body-worn device. Apparatus that is placed on or in close proximity to the human body (e.g., within a few centimeters) for the purpose of performing diagnostic or therapeutic functions.

Medical body-worn transmitter. A MedRadio transmitter intended to be placed on or in close proximity to the human body (e.g., within a few centimeters) used to facilitate communications with other medical communications devices for purposes of delivering medical therapy to a patient or collecting medical diagnostic information from a patient.

* * * * *

Medical implant transmitter. A MedRadio transmitter in which both the antenna and transmitter device are designed to operate within a human body for the purpose if facilitating communications from a medical implant device.

MedRadio programmer/control transmitter. A MedRadio transmitter that operates or is designed to operate outside of a human body for the purpose of communicating with a receiver, or for triggering a transmitter, connected to a medical implant device or to a medical body-worn device used in the MedRadio Service; and which also typically includes a frequency monitoring system that initiates a MedRadio communications session.

MedRadio Service. Medical Device Radiocommunication Service.

MedRadio transmitter. A transmitter authorized to operate in the MedRadio service.

* * * * *

20. The title of Subpart I is revised to read as follows:

Subpart I—Medical Device Radiocommunication Service (MedRadio)

* * * * *

21. Section 95.1201 is revised to read as follows:

§ 95.1201 Eligibility.

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

22. Section 95.1203 is revised to read as follows:

§ 95.1203 Authorized locations.

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

23. Section 95.1205 is revised to read as follows:

§ 95.1205 Station identification.

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

24. Section 95.1207 is revised to read as follows:

§ 95.1207 Station inspection.

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

25. Section 95.1209 is amended by revising paragraphs (a) through (e) to read as follows:

§ 95.1209 Permissible communications.

(a) Except for the purposes of testing and for demonstrations to health care professionals, MedRadio programmer/control transmitters may transmit only non-voice data containing operational, diagnostic and therapeutic information associated with a medical implant device or medical body-worn device that has been implanted or placed on the person by or under the direction of a duly authorized health care professional.

(b) Except in response to a medical implant event, or except as provided in § 95.628(b)(3), in the 402-405 MHz band no medical implant transmitter shall transmit except in response to a transmission from a medical implant programmer/control transmitter or in response to a non-radio frequency actuation signal generated by a device external to the body in which the medical implant transmitter is implanted or is to be implanted.

(c) MedRadio programmer/control transmitters may be interconnected with other telecommunications systems including the public switched telephone network.

(d) For the purpose of facilitating MedRadio system operation during a MedRadio communications session, as defined in § 95.628, MedRadio transmitters may transmit in accordance with the provisions of § 95.628(a) for no more than 5 seconds without the communications of data.; MedRadio transmitters may transmit in accordance with the provisions of § 95.628(b)(3) for no more than 3.6 seconds in total within

a one hour time period without the communications of data; MedRadio transmitters may transmit in accordance with the provisions of § 95.628(b)(2) for no more than 360 milliseconds in total within a one hour time period without the communications of data.

(e) MedRadio programmer/control transmitters may not be used to relay information to a receiver that is not included with a medical implant or medical body-worn device. Wireless retransmission of information intended to be transmitted by a MedRadio programmer/control transmitter or information received from a medical implant or medical body-worn transmitter shall be performed using other radio services that operate in spectrum outside of the MedRadio band.

26. Section 95.1211 is amended by revising paragraphs (a) through (c) to read as follows:

§ 95.1211 Channel use policy.

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

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

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

27. Section 95.1213 is revised to read as follows:

§ 95.1213 Antennas.

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

28. Section 95.1215 is amended by removing the parenthetical letter "(a)" at the beginning of the text and revising the remainder of the text to read as follows:

§ 95.1215 Disclosure polices.

Manufacturers of MedRadio transmitters must include with each transmitting device the following statement:

"This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150-406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference."

29. Section 95.1217 is amended by revising paragraphs (a) through (c) to read as follows:

§ 95.1217 Labeling requirements.

(a) MedRadio programmer/control transmitters shall be labeled as provided in part 2 of this chapter and shall bear the following statement in a conspicuous location on the device:

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

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

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

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

30. Section 95.1219 is revised to read as follows:

§ 95.1219 Marketing limitations.

Transmitters intended for operation in the MedRadio Service may be marketed and sold only for the permissible communications described in § 95.1209 of this part.

31. Subpart I is amended by adding a new section 95.1221 to read as follows:

§ 95.1221 RF exposure.

MedRadio medical implant or medical body-worn transmitters (as defined in appendix 1 to subpart E of part 95 of this chapter) are subject to the radiofrequency radiation exposure requirements specified in §§ 1.1307 and 2.1093 of this chapter, as appropriate. Applications for equipment authorization of implant devices operating under this section must contain a finite difference time domain (FDTD) computational modeling report showing compliance with these provisions for fundamental emissions. The Commission retains the discretion to request the submission of specific absorption rate measurement data.

APPENDIX B

Parties Filing Comments In RM-11271

AdvaMed
Advanced Bionics
Alfred Mann Foundation
American Association of People with Disabilities or AAPD
AMI Semiconductors, Inc. (now "ON Semiconductor Corp.")
Apostolos P. Georgopoulos, MD, PhD
Argonne National Laboratory
Biogenic Research Corporation
Bioness Inc.
Biotronik, Inc.
Bosley
Brenda J. Arndt
Carlana Stone Lawson
College of the Canyons
Cyberkinetics Neutrotechnology Systems, Inc.
Dana Brown
David A. Larson
Department of the Army
Department of Veteran Affairs
DexCom, Inc.
Doheny Eye Institute
Donald Garretson
Donald W. Nielsen, Ph.D.
Dr Richard Mellish, Medicines & Healthcare Products Regulatory Agency
Dr. Arthur Prochazka
Dr. Jane Burridge
Dr. Joseph P. Pancrazio
Elbert E. Hardeman
Electronic Technology Solutions
F. Terry Hambrecht, M.D.
Gad Alon Ph.D., PT
GE Healthcare
George H. Crossley III, M.D.
Guidant Corporation
Henry G. Stifel
Henry Mayo Newhall Memorial Hospital
Herb Schorr, Ph.D.
HMRI
House Ear Institute
Implanted Acoustics
International Functional Electrical Stimulation Society
J. Thomas Mortimer, Ph.D.
James R. Buckett
James S. Walter, PhD
John W. McDonald, M.D., Ph.D.
Julia M. Olson
Kenneth Rodgers
Kent Kresa
Leidner & Leidner, A.P.C.
Lucinda L. Baker PT, PhD
MannKind Corporation
Margaret Giannini
Mark A. Liker, M.D.
Medtronic, Inc.
Michael C Harris
National Institute on Disability and Rehabilitation
Neural Signals Inc
NeuroSystec Corporation
Neurotech Network
Northwestern University
ORBCOMM Inc.
Paralyzed Veterans of America
Partners HealthCare System
Peter Pitsch
Pritzker Institute of Biomedical Science & Engineering
Professor Roger Briggs
Quallion LLC
Richard Andersen, Ph.D.
Richard B. North, MD
Robert B. Strother, Jr.
Robert R. Myers, Ph.D.
Roger D. Madison, Ph.D.
Ross Davis, M.D.
Roundtrip LLC
RTI International
Scot Decristofaro
Second Sight
Shepherd Center
Shriners Hospitals for Children
St. Jude Medical
Stellar Microelectronics, Inc.
STMicroelectronics, Inc.
The Los Angeles Gerontology Research Group
The Media Laboratory
Themis R. Kyriakides, Ph.D.
Timex Corporation
Transoma
Tulane University
United Cerebral Palsy
University of California, Los Angeles
University of California, Santa Cruz
University of Pittsburgh
University of Utah
UWEB
V. Reggie Edgerton, Ph.D.
W. Dean Baker, PhD
Zarlink Semiconductor Inc.

APPENDIX C

Final Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act (RFA),[1] an Initial Regulatory Flexibility Analysis (IFRA) was incorporated in the *Notice of Proposed Rulemaking, Notice of Inquiry and Order (MedRadio Notice)* in ET Docket No. 06-135.[2] The Commission sought written public comment on the proposals in the *MedRadio Notice,* including comment on the IRFA. This present Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.

A. Need for and Objectives, of the Report and Order.

The Report and Order establishes the Medical Device Radiocommunication Service (MedRadio) under Part 95 of the Commission's rules. This new service will incorporate the existing Medical Implant Communications Service (MICS) "core" band at 402-405 MHz, and include two megahertz of newly designated spectrum in the adjacent "wing" bands at 401-402 MHz and 405-406 MHz. Altogether, the MedRadio Service will provide a total of five megahertz of contiguous spectrum for advanced wireless medical radiocommunication devices to be used for diagnostic and therapeutic purposes in humans. Among other benefits, the MedRadio Service will accommodate the operation of body-worn as well as implanted medical devices, including those using either LBT or non-LBT spectrum access methods, in designated portions of the 401-406 MHz band.

Significant advances in wireless implanted and body-worn 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. As demonstrated by the comment record in this proceeding, implanted and body-worn medical devices that rely upon wireless technologies are being used even today to treat a variety of cardiac and diabetic conditions. For example, wireless implanted cardiac devices serve as defibrillators and pacemakers without the need for external wired connections; while other radio-equipped devices, such as blood glucose monitors and insulin pumps, support more timely treatment for diabetic patients and allow physicians to wirelessly retrieve data and then make operating parameter adjustments with greater ease and accuracy than with the more traditional wired connection technologies. Some examples of newer generations of devices that could benefit from the use of wireless technologies include implanted vagus nerve stimulators that send electric pulses to the brain to treat severe chronic depression, and deep brain stimulators used to treat tremors related to Parkinson's disease.[3] Such advances have the potential to significantly improve the quality of life and sophistication of therapy for countless Americans living with a variety of medical conditions; and, in turn, could result in lower medical costs and extend the time between hospital visits and surgical procedures.

B. Summary of Significant Issues Raised by Public Comments in Response to the IRFA.

There were no comments filed that specifically addressed the rules and policies proposed in the IRFA.

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[1] *See* 5 U.S.C. § 603. The RFA, *see* 5 U.S.C. § 60-612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1966 (SBREFA), Public Law No. 104-121, Title II, 110 Stat. 857 (1996).

[2] 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, ET Docket No. 06-135, RM-11271, *Notice of Proposed Rulemaking and Notice of Inquiry and Order,* (*MedRadio Notice*) 21 FCC Rcd 8164 (2006).

[3] *Id*.

C. Description and Estimate of the Number of Small Entities to Which the 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.[4] The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction."[5] In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act.[6] 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.[7]

Nationwide, there are a total of approximately 22.4 million small businesses, according to SBA data.[8] A "small organization" is generally "any not-for-profit enterprise which is independently owned and operated and is not dominant in its field."[9] Nationwide, as of 2002, there were approximately 1.6 million small organizations.[10] 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."[11] Census Bureau data for 2002 indicate that there were 87,525 local governmental jurisdictions in the United States.[12] We estimate that, of this total, 84,377 entities were "small governmental jurisdictions."[13] Thus, we estimate that most governmental jurisdictions are small.

Personal Radio Services. The Medical Device Radio Communications Service are being placed 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 and covers a broad range of uses.[14] Many of the licensees in these services are individuals, and thus are not small entities. In addition, due to the fact that licensing of operation under Part 95 is accomplished by rule (rather than by issuance of individual license), and due to the shared nature of the spectrum utilized by some 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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[4] 5 U.S.C. § 603(b)(3).

[5] 5 U.S.C. § 601(6).

[6] 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).

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

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

[9] 5 U.S.C. § 601(4).

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

[11] 5 U.S.C. § 601(5).

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

[13] 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.*

[14] 47 CFR Part 90.

We do note, however, that the designation for the two megahertz of spectrum for the Medical Device Radio Communications Service would be limited to use by medical implant and body-worn medical devices and, thus, would not be shared with other non-Federal Governmental uses. To date, there are only a small number of manufacturers (i.e., less than ten – maybe five or so) that produce these devices, and FDA approval must be secured before such devices are brought to market. Due to the stringent FDA approval requirements, the small number of existing medical device manufacturers tends to focus very narrowly on this highly specialized market niche.

Wireless Communications Equipment Manufacturers. The Census Bureau does not have a category specific to medical device radiocommunication manufacturing. The appropriate category is that for wireless communications equipment manufacturers. The Census Bureau defines this category as follows: "This industry comprises establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment. Examples of products made by these establishments are: transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment." The SBA has developed a small business size standard for Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, which is: all such firms having 750 or fewer employees.[15] According to Census Bureau data for 2002, there were a total of 1,041 establishments in this category that operated for the entire year. Of this total, 1,010 had employment of under 500, and an additional 13 had employment of 500 to 999. Thus, under this size standard, the majority of firms can be considered small.[16]

Wireless Service Providers. The SBA has developed a small business size standard for wireless firms within the two broad economic census categories of "Paging"[17] and "Cellular and Other Wireless Telecommunications."[18] 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.[19] Of this total, 804 firms had employment of 999 or fewer employees, and three firms had employment of 1,000 employees or more.[20] 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.[21]

[15] NAICS code 334220.

[16] NAICS code 11210.

[17] 13 C.F.R. § 121.201, NAICS code 517211.

[18] 13 C.F.R. § 121.201, NAICS code 517212.

[19] 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).

[20] *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."

[21] 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).

Of this total, 1,378 firms had employment of 999 or fewer employees, and 19 firms had employment of 1,000 employees or more.[22] 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.[23] 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[24] 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.[25]

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

We are using the licensing approach for the entire 401-406 MHz MedRadio band that is identical to that used for the existing MICS band at 402-405 MHz. Thus, rather than require individual transmitter licensing, the Commission authorizes 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.[26] Licensing will be accomplished through adherence to applicable technical standards and other operating rules (unlicensed operations). We conclude that this approach is beneficial because it would minimize the administrative burden on prospective licensees as compared with an individual licensing scheme.

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[22] *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."

23 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.

24 47 CFR § 1.1162.

25 5 U.S.C. § 601(5).

[26] *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.

E. Steps Taken to Minimize the 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.[27]

In the Report and Order we are establishing a new Medical Device Radiocommunication Service (MedRadio Service) under Part 95, which will encompass all medical devices permitted to operate in the 401-406 MHz band. We sought comment on the options concerning whether and how the five megahertz of spectrum that would comprise this MedRadio band could be divided among the evolving varieties of both implanted and body-worn medical transmitters, including low-power, low-duty-cycle (LPLDC) devices that do not employ "listen-before-talk" (LBT) frequency monitoring spectrum access techniques.

Report to Congress: The Commission will send a copy of the Report and Order, including this FRFA, in a report to be sent to Congress pursuant to the Congressional Review Act.[28] In addition, the Commission will send a copy of the Report and Order, including this FRFA, to the Chief Counsel for Advocacy of the SBA. A copy of the Report and Order and FRFA (or summaries thereof) will also be published in the Federal Register.[29]

[27] *See* 5 U.S.C. § 603(c).

[28] *See* 5 U.S.C. § 801(a)(1)(A).

[29] *See* 5 U.S.C. § 604(b).

STATEMENT OF
ACTING CHAIRMAN MICHAEL J. COPPS

RE: ***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 Radiocommunication 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 of the Medical Implant Communications Service Rules, ET Docket No. 03-92***

Few uses of our spectrum could be more important than supporting new medical technologies that can extend and improve lives. Our nation's medical researchers continue to develop extraordinary body-worn and implanted devices that are used to treat a variety of health conditions with less invasive patient treatment options. Today's order takes us another major step forward with the establishment of a new Medical Device Radiocommunication Service, which incorporates the existing Medical Implant Communications Service band with additional spectrum for advanced wireless medical radiocommunication devices used for diagnostic and therapeutic purposes. Among other things, these devices are used to control heart rhythms to prevent attacks, mitigate the tremors of neurological patients, and control the delivery of insulin to patients with diabetes.

I am always pleased to support these kinds of achievements. Once again I thank our Office of Engineering and Technology, working in conjunction with the National Telecommunications and Information Administration (NTIA), for developing these new rules.

STATEMENT OF
COMMISSIONER JONATHAN S. ADELSTEIN

RE: ***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 Radiocommunication 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 of the Medical Implant Communications Service Rules, Report and Order ET Docket No. 03-92***

With the approval of the new Medical Device Radiocommunication Service, the Commission is helping to facilitate exciting new medical technologies that will improve our lives. The addition of two megahertz of spectrum to the Medical Implant Communications Service band will be used for advance diagnostic, monitoring, and therapeutic wireless radiocommunication devices that can help doctors better treat their patients and benefit the health and comfort of so many. I hope that the order will spark more research and new medical applications so that we may continue to make strides in health care. For these reasons, I am pleased to support this order. I thank the National Telecommunication and Information Administration and our Office of Engineering and Technology for their work in crafting these rules.

STATEMENT OF
COMMISSIONER ROBERT M. McDOWELL

RE: ***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 Radiocommunication 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 of the Medical Implant Communications Service Rules, ET Docket No. 03-92***

It is with great pleasure that I vote to approve this order, which establishes a new Medical Device Radio Communications Service and provides five megahertz of contiguous spectrum to power advanced diagnostic and therapeutic wireless devices. Our action today provides direct help to millions of people suffering from a variety of medical conditions such as diabetes, Parkinson's disease, depression and cardiac ailments, to name a few.

I am excited about the notices of proposed rulemaking that will result from our decision in this proceeding. The Alfred Mann Foundation has undertaken pioneering research that harnesses wireless technology to provide medical treatment and therapy to patients suffering from paralysis. In addition, GE Medical Systems is developing advanced body sensing technologies that would allow continuous patient monitoring whether the patient is located within or outside of a hospital setting. Similarly worthwhile is the proposal submitted by ON Semiconductor, which has the potential to deliver new and innovative services to the hearing impaired community. I am pleased that we will consider moving forward to develop a record through a notice of proposed rulemaking to more fully analyze the relevant issues.

Many thanks to our team in the Office of Engineering and Technology, and our colleagues at the National Telecommunications and Information Administration, for your dedication and diligence. I look forward to learning about future scientific breakthroughs that result from your work, that of the private sector, as well as the important action taken by the Commission today.