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

In the Matter of	)	
	)	
Amendment of Parts 2 and 95 of the	)	ET Docket No. 09-36
Commission's Rules to Provide Additional	)	
Spectrum for the Medical Device	)	RM-11404
Radiocommunication Service	)	
in the 413-457 MHz band	)	
	)	

REPORT AND ORDER

Adopted: November 30, 2011 **Released: November 30, 2011**

By the Commission: Chairman Genachowski and Commissioners Copps, McDowell, and Clyburn issuing separate statements.

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I. INTRODUCTION

1. By this Report and Order, we expand the Medical Device Radiocommunication (MedRadio) Service under Part 95 of the Commission's rules to permit the use of new wideband medical implant devices that employ neuromuscular microstimulation techniques to restore sensation, mobility, and other functions to paralyzed limbs and organs.[1] These medical devices hold enormous promise to advance the state of medical care, lower health costs, and improve the quality of life for countless Americans. The rules we adopt will allow these new types of MedRadio devices to access 24 megahertz of spectrum in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands on a secondary basis.

2. Each year, millions of Americans, including injured U.S. soldiers, suffer from spinal cord

[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 Device Radiocommunication Service, Wireless Medical Telemetry Service, Multi-Use Radio Service, and Dedicated Short-Range Communications Service.

injuries, traumatic brain injuries, strokes, and various neuromusculoskeletal disorders. The devices that we anticipate will operate under our new rules are designed to provide artificial nervous system functions for these patients.

3. Our action is part of a larger effort to recognize and facilitate the significant advances in wireless medical technologies that are revolutionizing treatment for a wide variety of medical conditions and creating new health care models to benefit all Americans. 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.[2] The devices that we expect to be deployed under the rules we adopt herein hold the promise of safer, less invasive, and more effective treatment options than those available under current medical practice.

II. BACKGROUND

4. The Commission has long recognized the importance of providing access to spectrum for wireless medical communications technologies. Vital medical devices such as telemetry equipment that transmit a patient's pulse and respiration rates, implant devices that regulate heart rates, administer medication, and treat neurological tremors; and sensor network systems that monitor physiological parameters from multiple patients would not work without access to the electromagnetic spectrum. Our support of the evolving needs of the medical radiocommunications community is equally longstanding. Nearly forty years ago, the Commission authorized the use of the 460-470 MHz band for low-power biomedical telemetry operations in medical facilities and convalescent centers. The Commission later designated spectrum in the 608-614 MHz, 1395-1400 MHz, and 1429-1432 MHz bands for the Wireless Medical Telemetry Service (WMTS) under Part 95 of its Rules in response to increased use of medical telemetry and expanding spectrum challenges.[3]

5. The continued development of new medical radio devices, including increasing numbers of implanted devices, also led the Commission to establish the Medical Implant Communication Service (MICS) in 1999.[4] For the MICS, the Commission set aside three megahertz of spectrum at 402-405 MHz on a license-by-rule basis under Part 95 expressly for short-range wireless links between ultra-low power medical implant transmitters and associated programmer/control equipment.[5] These rules supported the development of implant devices such as cardiac pacemakers and defibrillators that also monitor and report cardiac condition. Most recently, the Commission created the MedRadio Service in the 401-406 MHz

[2] Americans spent approximately $73.7 billion in 2010 for stroke-related medical costs and disability; a comprehensive study of the economic burden of injury estimated that, for traumatic brain injuries incurred in the U.S. over a one year period, the lifetime direct and indirect costs of those injuries totaled approximately $60 billion; and the estimated average lifetime costs for a person with cerebral palsy are approximately $921,000. *See* Alfred Mann Foundation *ex parte*, ET Docket No. 09-36, filed November 15, 2011 at 1-2 (citing American Stroke Association and Centers for Disease Control and Prevention).

[3] Amendment of Parts 2 and 95 of the Commission's Rules to Create a Wireless Medical Telemetry Service, ET Docket No. 99-255, PR Docket No. 92-235, *Report and Order,* 15 FCC Rcd 11206 (2000). 47 C.F.R. § 95.401(e). "Wireless medical telemetry" is defined in the rules governing WMTS as "the measurement and recording of physiological parameters and other patient-related information via radiated bi-or unidirectional electromagnetic signals." *See* 47 C.F.R. § 95.1103 (c). Voice and video communications are expressly prohibited in the WMTS bands. However, the Commission decided that, for the purposes of its service definition, waveforms such as electrocardiograms (ECGs) would not be considered video communications. 47 C.F.R. § 95.1117(a).

[4] 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, *Report and Order*, 14 FCC Rcd 21040 (1999) (*MICS R&O*); 47 C.F.R. Part 95, Subpart E (Technical Regulations) and Subpart I (Medical Implant Communications).

[5] *See MICS R&O* at 21043-46 paras. 8, 10, 15.

band.[6] MedRadio, which includes legacy MICS operations, represents an umbrella framework to regulate the operation of both implanted and body-worn wireless medical devices used for diagnostic and therapeutic purposes in humans.

6. The WMTS and MedRadio services, together with unlicensed medical applications developed and operated under our general Part 15 rules, have supported countless vital therapeutic and diagnostic medical applications. We recognize, however, that the dynamic nature of medical technology means that our existing rules may need to evolve to keep pace with the newest cutting edge therapies. Thus, the Commission included in the *MedRadio Proceeding* a notice of inquiry seeking information in a broader context relating to future spectrum needs for wireless medical technologies.[7] On September 5, 2007, the Alfred Mann Foundation for Scientific Research (AMF or Alfred Mann) filed a petition for rulemaking that serves as the basis of this proceeding.[8]

7. In its petition, Alfred Mann asked the Commission to designate up to 24 megahertz of spectrum in the 413-457 MHz range to support new medical micro-power networks (MMNs) consisting of implantable neuromuscular microstimulation devices and associated external control units. Alfred Mann's petition was based on its research dating to 1989 on implantable medical devices to treat neurological injuries and disorders.[9] Since 2005, AMF has conducted extensive work under the authority of an experimental license from the Commission to operate its devices in the 400-470 MHz band.[10] Alfred Mann's wideband MMN equipment is designed to replace damaged nerve connections by performing functional electric stimulation (FES) to activate and monitor nerves and muscles in order to restore sensation, mobility, and other functions to nonfunctioning limbs and organs.[11]

8. The Commission released a *Notice of Proposed Rulemaking* (*NPRM*) on March 20, 2009, that proposed to allocate 24 megahertz of spectrum in four segments of the 413-457 MHz band for MMN devices.[12] In the *NPRM*, we sought comment on providing access to spectrum in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands under the umbrella of the MedRadio Service on a secondary basis for the operation of bandwidth intensive wireless medical devices. We proposed to adopt

[6] *See* Investigation of the Spectrum Requirements for Advanced Medical Technologies, ET Docket Nos. 06-135, 05-213, and 03-92, *Report and Order,* 24 FCC Rcd 3474 (2009) (*MedRadio R&O*).

[7] Investigation of the Spectrum Requirements for Advanced Medical Technologies, ET Docket Nos. 06-135, 05-213, 03-92, *Notice of Proposed Rulemaking, Notice of Inquiry, and Order*, 21 FCC Rcd 8164 (2006). In response to this *Notice of Inquiry*, AMF filed comments describing its work with implanted microstimulator devices. Comments of Alfred Mann Foundation, ET Docket No. 06-135, filed Oct. 31, 2006.

[8] Petition for Rulemaking, Alfred Mann Foundation, RM-11404, filed September 5, 2007 (*AMF Petition*).

[9] *See* Alfred Mann Foundation, *Neuromuscular Disorders*, at http://aemf.org/our-research/current-focus/neuromuscular-disorders/.

[10] *See* Alfred Mann Foundation, Experimental License, Call Sign WD2XLW, issued in 2005 and renewed in 2009.

[11] Examples of FES applications include allowing paraplegics to stand, restoring hand grasp function for quadriplegics, and restoring patient's bowel and bladder function. FES can also be used for treatment of numerous debilitating medical conditions that are not responsive to pharmaceutical treatment, such as arthritis, pain, and migraine headache.

[12] *See generally* Amendment of Parts 2: and 95 of the Commission's Rules to Provide Additional Spectrum for the Medical Device Radiocommunication Service in the 413-457 MHz band, ET Docket No. 09-36, RM-11404, *Notice of Proposed Rulemaking*, 24 FCC Rcd 3445 (2009) (*NPRM*). The *NPRM* followed an October 3, 2007 Public Notice in which the Commission sought comment on AMF's petition. Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Micropower Network Service in the 413-457 MHz band, RM-11404, *Public Notice*, Report No. 2835 (Oct. 3, 2007). Commenters responding to the *Public Notice* had expressed broad support for the proposal and agreed that AMF's work could revolutionize the treatment of neurological injuries and diseases.

rules that would provide spectrum access for wireless MMNs that would be comprised of multiple networked implanted devices that employ wideband FES techniques.

9. The Commission received 63 comments and 3 reply comments in response to the *NPRM*, and the record was broadly supportive of the MMN concept. For example, a diverse group of 55 commenters (including members of Congress, universities, the medical community, and veterans associations) expressed general support for the proposed rules.[13] Other commenters, generally representing entities with license interests in the 413-457 MHz band, objected to allocation of spectrum in the 413-457 MHz band for MMNs while expressing concern that secondary medical device users would be unable to successfully co-exist with primary users in the bands.[14] While generally supportive of the *NPRM*'s goals, the parties are concerned that if the medical devices receive harmful interference from the incumbent radio services then incumbent users could be asked to modify or downgrade their systems to protect the health of patients using MMN devices.[15] The record also includes detailed testing reports and analysis commissioned by AMF that examined whether MMN devices could co-exist with incumbent systems in the 413-457 MHz band.

III. DISCUSSION

10. The work that AMF has done with the Veterans Administration and other hospitals under its experimental license has proven the potential benefits of MMNs. We strongly believe that widespread MMN deployment can foster important advancements in medical care by, for example, significantly improving the quality of life for the many Americans suffering from spinal cord injuries, traumatic brain injuries, and strokes.[16] However, we also recognize that MMNs represent a new type of radio communication which does not readily fit into any of the existing spectrum allocations. Because of the significant benefits that MMNs are poised to deliver, we conclude that the public interest warrants modifying our rules to allow their use. First, we discuss the characteristics of MMN operations and conclude that this service is best accommodated by modifying and expanding our existing Part 95 MedRadio rules. Second, we evaluate the frequency allocations necessary to support MMN operations and provide a secondary allocation in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands for use by MMNs as proposed. This means these devices cannot cause interference to and must accept interference from stations of a primary service.[17] This restriction ensures that the potential for interference– *i.e.*, the only cost that would be imposed on other parties – is negligible. Finally, we set forth the service and technical rules that will allow MMNs operating on a secondary basis to share these bands with incumbent services.

11. Our decision to allow MMNs to share spectrum with existing services supports the Commission's commitment to promoting efficient spectrum use to meet growing demand. In the March

[13] *See e.g.,* Comments of Injured Marine Semper Fi Fund, ET Docket No. 09-36, filed July 9, 2009; Comments of Rehabilitation Institute of Chicago, ET Docket No. 09-36, filed July 14, 2009; Comments of Harvard Medical School, ET Docket No. 09-36, filed Aug. 11, 2009; and Letter from Congressman John F. Kerry, ET Docket No. 09-36, Oct. 14, 2009.

[14] *See e.g.,* Comments of ARRL, the National Association for Amateur Radio, ET Docket No. 09-36, filed Aug. 11, 2009, at 7-8 (*ARRL Comments*); Comments of the Land Mobile Communications Council, ET Docket No. 09-36, filed Aug. 11, 2009, at, 2, 5 (*LMCC Comments*); Comments of Engineers for the Integrity of Broadcast Auxiliary Services Spectrum, ET Docket No. 09-36, filed June 25, 2010, at 3 (*EIBASS Comments*).

[15] *See e.g.,* Comments of the Society of Broadcast Engineers, ET Docket No. 09-36, filed Aug. 11, 2009, at 3-6 (*SBE Comments*).

[16] We note that any future MMN equipment will have to undergo an independent testing and approval process by the Food and Drug Administration (FDA) before being used for medical purposes.

[17] *See* 47 C.F.R. § 2.105(c)(2). The primary uses of this spectrum are discussed *infra* at paras. 25-27.

2010 *National Broadband Plan,* the Commission underscored the importance of expanding opportunities for innovative spectrum access models made possible by advanced technologies.[18] The Commission sought to promote the development of such technologies through its dynamic spectrum use technologies *Notice of Inquiry*.[19] MMNs, which make use of advanced technology such as spectrum sensing, dynamic frequency selection, and notching out of interference signals to share spectrum with other services, demonstrate one such spectrum access model.[20] These techniques will allow MMNs to use available spectrum to provide life-changing health benefits without impairing the ability of other licensed users in these frequency bands to continue providing service.

A. Medical Micro-Power Networks (MMNs)

12. In the *NPRM,* we sought comment on authorizing MMN devices to operate in the 413-457 MHz band as an extension of our existing Part 95 MedRadio rules.[21] As a Part 95 MedRadio service, MMNs would qualify for license-by-rule operation[22] pursuant to Section 307(e) of the Communications Act (Act).[23] Under this approach, medical devices would operate in the band on a shared, non-exclusive basis with respect to each other. AMF supports the license-by-rule framework and no one objects to this approach or suggests alternative licensing methods.[24]

13. As discussed in the NPRM, we will authorize MMN operations under the existing Part 95 MedRadio rules. For MedRadio devices, the Commission determined that the license-by-rule approach minimized regulatory procedures and would facilitate more expeditious deployment of new generations of beneficial wireless medical devices.[25] Also, MMNs share many characteristics with devices that operate in the existing MedRadio service. The core MedRadio band from 402-405 MHz is restricted to communication between an implanted medical device and an external programmer/controller.[26] This is the same architecture employed for AMF's MMNs. As with MedRadio implant devices, the MMN implant devices are sophisticated medical devices that are intended to be deployed by or under the direction of a duly authorized health care professional.[27] The power levels proposed by AMF for MMN

[18] *See Connecting America: The National Broadband Plan*, Federal Communications Commission, March 2010, Section 5.6, at 94-96.

[19] Promoting More Efficient Use of Spectrum Through Dynamic Spectrum Use Technologies, ET Docket No. 10-237, *Notice of Inquiry*, 25 FCC Rcd 16632 (2010).

[20] We will not require MMNs to implement interference mitigation techniques such as automatic power control, geolocation, etc. because they are designed to be extremely low power devices that operate with a maximum power of one milliwatt. We expect that future technologies that use dynamic spectrum access techniques may require such interference mitigation techniques.

[21] *NPRM* at 3445 para. 1.

[22] *See* 47 C.F.R. § 95.1201.

[23] 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. 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. *See* 47 U.S.C. § 307(e)(1).

[24] Comments of the Alfred Mann Society, ET Docket No. 09-36, filed Aug. 11, 2009, at 14 (*AMF Comments*).

[25] *MedRadio R&O* at 3482 para. 25.

[26] Body-worn medical devices may also be used in the 402-405 MHz band for a limited patient evaluation period. *MedRadio R&O* at 3483-84 para. 32-35.

[27] 47 C.F.R. § 95.1209; *MedRadio R&O* at 3485 paras. 37-38.

devices are on par with the power levels used by MedRadio devices.[28] Additionally, both MedRadio devices and MMN systems are designed to operate in the 400 MHz frequency range, although MMNs require greater bandwidth than is available under the existing MedRadio rules.[29] For the reasons provided above, we believe that the MedRadio license-by-rule framework is the best way to structure our MMN rules.

14. Based on the history of this proceeding and the record developed over its course, we find it appropriate to rely heavily on AMF's MMN system design when crafting our rules. Although we sought comment on other types of functional electrical stimulation applications that would be consistent with MMN operations and that would similarly require the wider emission bandwidths proposed, no commenter identified other specific applications, devices, or architectures that we should take into consideration.[30] Instead, the record is concentrated on AMF's specific MMN proposal and research in this area. The work AMF has performed demonstrates that the benefits that MMNs can deliver are substantially greater – in both qualitative and quantitative terms – than the developmental and per-patient deployment costs associated with the rules we adopt.[31] Thus, we think it represents the appropriate starting point for our authorization of this new type of MedRadio service, and it does not appear that doing so would inhibit the development of additional therapeutic devices for these or similar purposes.

15. Under its experimental license, AMF developed an MMN system that consists of a wireless network of implantable microstimulators that produce electrical pulses to elicit muscle contractions and neural responses. The components of this system include an external programmer/controller (P/C) that coordinates the activities of all other system components;[32] separate miniature, battery-powered, implantable microstimulators capable of sensing body signals or generating stimulation pulses; and a recharging subsystem consisting of an external charger and coil assemblies.[33] Depending upon the nature

[28] Under the existing rules, MedRadio devices in the 402-405 MHz band that meet the frequency monitoring requirements of 47 C.F.R. § 95.628(a) may transmit with a maximum power of 25 microwatts EIRP in a 300 kHz bandwidth. This would be equivalent to 0.5 milliwatts in a 6 MHz bandwidth, which is on par with the maximum power levels proposed by AMF. 47 C.F.R. § 95.639(f); *AMF Comments* Appendix B at 5.

[29] *See MICS R&O* at 21043-44 para. 8.

[30] *NPRM* at 3453 para. 26.

[31] *See* footnote 2, *supra*. AMF estimates that the costs of providing an initial model of an MMN system (consisting of a master control unit, or "MCU," and five to six microstimulator implants) to a patient in compliance with the proposed rules would total approximately $50,000. AMF expects that these costs will decrease as economies of scale and scope are achieved. Additionally, it notes that these estimated costs exclude their sunk investment costs, such as costs attributable to initial research and development of interference mitigation techniques (approximately $2.2 million) and independent laboratory testing of those techniques (approximately $190,000). *See* Alfred Mann Foundation *ex parte*, ET Docket No. 09-36, filed November 15, 2011 at 2.

[32] The P/C is a portable device that may he carried by the patient or placed in a convenient location within a few meters of the patient. It is the communication and control hub that transmits and receives signals to and from all implanted devices in the system. Specifically, it coordinates the activity of the implanted devices by receiving sensing data from the implanted devices, processing that data, and creating a stimulation pattern in the appropriate implant devices by transmitting instructions based on the processed data to the implanted devices. It also serves as the basic user interface for the patient, providing system activation, alarms, program selection, and limited parameter control. *AMF Petition* at 4 n.1.

[33] According to AMF, the charger generates a magnetic field at 127 kHz with the external coil worn only when recharging the batteries in the implanted devices. The external coil includes a faraday shield to limit emissions levels in compliance with the FCC emission limits. The P/C communicates with each implant device to determine which device requires recharging and when a device is fully charged. The recharging subsystem includes a temperature sensor that halts the recharging process if the external coil temperature were to rise above a (continued….)

and extent of the neurological condition, AMF envisions that one to 100 microstimulators would be used for any given patient, although an average of two to 12 microstimulators is estimated for the typical patient. Each of the implanted microstimulators is cylindrical and measures approximately 3.4 mm in diameter and 25 mm long, making them fully implantable into the human body by injection or other minor surgical procedure. Their small size, however, permits only limited battery power.

16. AMF designed its MMN system to operate on 5 MHz channels in the 413-457 MHz band. These design choices take advantage of favorable signal propagation in the human body.[34] MMNs that operate on these frequencies, AMF states, can transmit at low power (*e.g.*, less than 1 milliwatt) using the small batteries that are integral to the implanted microstimulators.[35] Additionally, the five megahertz wide channels allow MMNs to send large amounts of heavily encoded data very quickly.[36]

17. MMNs must also operate in a congested frequency environment and use a number of sophisticated techniques to mitigate the harmful effects of interference from incumbent co-channel services.[37] AMF designed its MMN system to occupy only one of the four proposed frequency bands at any given time. The P/C has the ability to continuously assess the quality of the frequency band and switch the MMN system to another of the four available bands if necessary, allowing the MMN to make robust use of the available spectrum and respond to changing spectrum conditions. Additionally, the wideband nature of the MMN signals will make them less susceptible to interference from narrowband signals in general, and AMF has specifically designed the P/C to filter out narrowband interference signals, (*i.e*. it "notches out" the signals).[38] This feature, coupled with the error correction coding techniques, minimizes system susceptibility to interference from narrowband signals. Additionally, because MMN transmissions are only a few microseconds long, interference from other short duration transmissions from incumbent users is less likely to occur.[39] In the event that all four bands are unusable despite the interference mitigation techniques, AMF's MMN system is designed to enter a "graceful shutdown" mode to protect the person in whom the devices are implanted.[40]

18. In the *NPRM* we sought comment on a number of definitions that AMF proposed be added to the Part 95 MedRadio Service rules for devices operating in the 413-457 MHz band.[41] These definitions were for a Medical Micropower Network (MMN), MMN control transmitter, MMN implant transmitter,

(Continued from previous page)

predetermined level. *Id*. at 4 n.2. We presume that the charger functions in a manner similar to chargers used for MedRadio devices under our previous rules. We emphasize that the charger must operate in compliance with our rules for Part 18 devices. 47 C.F.R. §§ 18.101-311.

[34] Reply Comments of the Alfred Mann Foundation, ET Docket No. 09-36, filed Sept. 10, 2009, at 5-7 (*AMF Reply*); *See* paragraph 24, *infra*.

[35] According to AMF, the small battery size imposes constraints on power consumption, which increases with operating frequency. *AMF Comments* at 6.

[36] *Id.* at 8.

[37] *Id.* at 10-13. *See also ARRL Comments* at 10-12 (discussing how specific elements of AMF's system design work to mitigate potential interference from incumbent operations).

[38] As AMF notes, implanted devices operate in a lower radiofrequency noise environment due to attenuation by the human body. Alfred Mann Foundation *ex parte*, ET Docket No. 09-36, filed Aug. 15, 2011, at 2 (*AMF 8/15/11 ex parte*).

[39] As described below, one such Federal Government use in the bands under consideration is for pulse modulated radar transmissions.

[40] Alfred Mann Foundation *ex parte*, *ET* Docket No. 09-36, filed June 8, 2011, at 2. The graceful shutdown or fail-safe mode executes a pre-programmed, customized sequence of actions to allow the implant to operate independently of the P/C for a brief period. *AMF ex parte 8/15/11* at 3.

[41] *NPRM* at 3453-54 para. 30.

and MMN transmitter. Few commenters addressed these proposals. One of these parties, Mark Sienkiewicz, suggests that the MMN definition not be specifically limited to FES because research into biotechnology may discover other uses for implanted medical device networks in the future.[42] He also questions the limitation of MMN transmissions to non-voice data because he thought there might be medical applications for voice data. Sienkiewicz also asks that the definition of an MMN control transmitter not be limited to operations outside the body because future devices could become implantable. The Cleveland FES Center requests that the MMN definition be modified to allow networks of implants that are not under the control of an MMN control transmitter.[43]

19. We adopt a single definition for MMN, as follows:

> Medical Micropower Network (MMN): An ultra-low power wideband network consisting of a MedRadio programmer/control transmitter and medical implant transmitters, all of which transmit or receive non-voice data or related device control commands for the purpose of facilitating functional electric stimulation, a technique using electric currents to activate and monitor nerves and muscles.

This definition tracks AMF's proposal in substance, with some word alterations to be consistent with the other MedRadio definitions. It is important to make these frequency bands available for medical applications such as AMF's MMNs that cannot be accommodated in other frequency bands and to avoid use of the band by non-medical devices or for non-medical purposes. The definition we adopt accomplishes this goal. Because the existing MedRadio definitions in Part 95 of our rules for MedRadio programmer/control transmitter, Medical implant transmitter, and MedRadio transmitter can also describe the functions of the MMN control transmitter, MMN implant transmitter, and MMN transmitter, respectively, we will not adopt MMN-specific definitions for these devices.[44]

20. We decline to adopt the more expansive definitions proposed by Sienkiewicz and the Cleveland FES Center or to substantially deviate from the framework we proposed in the *NPRM*. We recognize that the existing programmer/control transmitter definition does not permit use of implanted programmer/control transmitters or the deployment of an MMN that functions without a programmer/control transmitter, as Sienkiewicz and the Cleveland FES Center have suggested should be permitted for MMNs.[45] The record in this proceeding is largely based on AMF's MMN system, which uses an external programmer/control transmitter which implements a number of interference mitigation techniques to allow the MMN to share spectrum with other services in these bands and which has been subject to extensive testing. We have no information at this time to determine whether an MMN without an external programmer/controller could mitigate the effects of interference and successfully coexist in these bands. Other use of these frequency bands such as for non-FES medical applications or allowing transmission of voice data is speculative at this point.[46] No one has provided guidance on what alternative specifications would appropriately accommodate other uses while not compromising the potential of MMNs. Further modification to the rules may be readily sought if and when a need arises.

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[42] Comments of Mark Sienkiewicz, ET Docket No. 09-36, filed July 13, 2009, at 2 (*Sienkiewicz Comments*).

[43] Comments of the Cleveland FES Center, ET Docket No. 09-36, filed Aug. 10, 2009, at 2 (*Cleveland FES Comments*).

[44] 47 C.F.R. Appendix 1 to Subpart E of Part 95.

[45] *See Sienkiewicz Comments* at 3; *Cleveland FES Comments* at 2.

[46] In the MedRadio preceeding we rejected allowing wireless hearing aids to use the MedRadio band because they would be expected to operate continuously and therefore would have an increased likelihood of causing interference to other MedRadio devices. *MedRadio R&O* at 3486 para. 40. Allowing MMNs to transmit voice data would raise similar concerns.

21. Based on this definition and the rules we adopt under it, we can be sure that all MMNs will be designed with sufficient interference mitigation techniques and design elements to be able to operate on a secondary basis under our Part 95 Rules. At the same time, and because we want parties to be able to tap the vast potential MMN technologies have to transform lives and advance the state of medical care, we reject those comments that would have us bind our rules too tightly to AMF's specific equipment design. For example, ARRL urges the Commission not to allow the operation of MMNs or similar devices with parameters different than the AMF design.[47] SBE notes that the only devices addressed in the *NPRM* are AMF's and that other MMN devices may have different interference characteristics.[48] Because manufacturers may develop new MMN devices with different interference mitigation techniques, we do not think it is appropriate to require that all MMN devices function in an identical fashion to AMF's devices. Future systems, for example, may rely on technologies that have an even greater capability to reject interference than AMF's current design, and we will evaluate individual devices as part our equipment authorization process.

22. Finally, we sought comment in the *NPRM* on the service and technical rules that would apply to medical devices in the 413-457 MHz band. Our discussion generally followed the framework of the MedRadio Service rules with, for example, modified power and emission bandwidth requirements to accommodate the proposed MMNs.[49] While we did not include a separate appendix of proposed rules, the *NPRM* stated that we were seeking comment on allowing additional spectrum to be used under the MedRadio Service in Part 95 of the Commission's rules, referenced new rules that AMF had proposed in its filing, and discussed specific service and technical issues at length.[50] For this reason parties have had ample opportunity to provide meaningful comments on our proposals, and we reject suggestions to the contrary.[51] Because we are including MMNs within the existing framework of the MedRadio Service, we will apply the existing MedRadio service and technical regulations to MMNs to the extent possible and only amend the rules in Part 95, Subparts E and I, as necessary to distinguish between MMNs and other MedRadio devices. As we observed in the *NPRM*, such an approach "is desirable as it would maintain consistency with rules applicable to wireless medical devices, particularly for implanted and related therapeutic devices."[52]

B. Frequency Bands

23. Although we conclude that it is appropriate to license MMNs as a MedRadio service, it does not follow that it is feasible for MMNs to operate on the existing MedRadio frequencies. This is because MMNs are different from existing MedRadio applications in important technical and design elements. For example, a typical MMN is expected to contain multiple implant devices, which will require the transmission of much more data than the MedRadio devices operating under the existing rules. Moreover, due to their small size, MMN implant devices must be even more energy efficient than typical MedRadio implants. This efficiency is achieved by using short transmissions, which necessitate the use

[47] *ARRL Comments* at 15. We note that ARRL is also known as the American Radio Relay League, Incorporated. *Id*. at 1.

[48] *SBE Comments* at 2 n.1.

[49] *NPRM* at 3453 para. 27.

[50] *NPRM* at 3445, 3453-59 paras. 1, 27-56.

[51] *See ARRL Comments* at 2 n.1 (suggesting that the Commission did not have sufficient information about MMN devices to proceed with an NPRM and that the Commission should have published and sought comment on actual proposed rules); *SBE Comments* at 2 n.1 (claiming that "[t]hose who wish to comment on specific rules that might substantially affect the interference potential or interference susceptibility of these devices are precluded from doing so.").

[52] *NPRM* at 3453 para 27.

of much wider bandwidth signals than the 300 kHz currently permitted in the existing MedRadio bands.[53] This limit was put in place to maximize the number of medical devices that can use the 5 megahertz available in the 401-406 MHz band and is consistent with the operational needs of existing MedRadio applications. By contrast, MMNs are designed to operate with a 5 megahertz emission bandwidth. Thus, the current MedRadio frequencies are insufficient to support MMN operation.

24. In the *NPRM* we sought comment on the suitability of four segments of the 413-457 MHz band for use by MMNs on a secondary basis—*i.e*., 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz. According to AMF, this band—which is in close proximity to the 401-406 MHz band used by the MedRadio service—is within the range of frequencies that is most suitable for propagation in the human body.[54] According to AMF, optimal signal propagation within the human body is essential to allow MMNs to transmit at low power using small batteries and wide bandwidth signals to send large amounts of data in a short timeframe.

25. The 413-419 MHz band is allocated for Federal fixed, mobile, and space research services and is used primarily by federal agencies for non-tactical land mobile operations.[55] These land mobile operations include base, mobile, and hand-held portable stations operating on both conventional (single channel) and trunked (shared multiple channel) systems. The band is heavily used by Federal public safety agencies. Non-Federal use of this band is limited to fixed stations that transmit hydrological and meteorological data in cooperation with Federal agencies and may not cause harmful interference to Federal stations.[56]

26. The 426-432 MHz and 438-444 MHz bands are allocated for Federal radiolocation services on a primary basis and for (non-Federal) Amateur services on a secondary basis.[57] Radiolocation services include Federal ground-based, airborne, and shipborne radar systems.[58] These radar systems transmit pulsed signals that may operate on a wide bandwidth over a portion of the band or transmit across the entire band using spread spectrum frequency hopping techniques. These radar systems are used for very

[53] *MedRadio R&O* at 3488-89 paras. 47-50. An even narrower maximum bandwidth – 100 kHz – is permitted in a 2 megahertz portion of the band.

[54] Reply Comments of the Alfred Mann Foundation, ET Docket No. 09-36, filed Sept. 10, 2009, at 5-7 (*AMF Reply*). AMF states that tissue tests confirm that frequencies in the lower 400 MHz band are optimal for RF signal propagation through body tissue. *Id.* at 6-7. In addition, Medtronic – a manufacturer of implantable MedRadio devices – has conducted research and analysis that also reaches this conclusion. *Id.* at 6-7; *See also* Comments of Cedric F. Walker, Tulane Univ., ET Docket No. 09-36, filed Aug. 11, 2009.

[55] *See* 47 C.F.R. § 2.106; *See also* National Telecommunications and Information Administration, Federal Long-Range Spectrum Plan, at 77 (Sept. 2000) (*NTIA Spectrum Plan*), http://www.ntia.doc.gov/osmhome/LRSP/Final-LRSP.pdf.

[56] Under footnote US13 of the Table of Frequency Allocations, 12.5 kHz-wide channels within the band are available for assignment to non-government fixed stations for transmitting hydrological and meteorological data in cooperation with federal agencies. *See* 47 C.F.R. § 2.106 n.US13.

[57] *See* 47 C.F.R. § 2.106. Under footnote US230 of the Table of Frequency Allocations, non-government land mobile radio services are also permitted to operate on certain frequencies within the 422-430 MHz band, but these operations are limited to areas within 80.5 kilometers (50 miles) of Buffalo, New York; Detroit, Michigan; and Cleveland, Ohio. *See* 47 C.F.R. § 2.106 n.US230. Under footnote US269, non-Federal pulse-ranging radiolocation systems may be authorized along the shoreline of the conterminous United States and Alaska and non-Federal spread spectrum radiolocation systems may be authorized within the United States and Alaska. These non-Federal radiolocation systems have secondary status. 47 C.F.R. § 2.106 n.US269. No one has commented on these radiolocation systems.

[58] *See NTIA Spectrum Plan*, at 77-79. The 426-432 MHz and 438-444 MHz bands also may be used by the military and the National Aeronautics and Space Administration for telemetry and telecommand. *Id.*

long range detection, identification, and tracking of objects and typically employ megawatt transmitters and high antenna gains resulting in very high equivalent isotropically radiated power (EIRP) levels. The radar receivers are also extremely sensitive so that they can detect weak returns from targets. In addition, the Federal Government operates the Enhanced Position Location Reporting System (EPLRS) in these bands, which is a secure communications network employing a frequency hopping, spread spectrum method that is used primarily for data distribution and position location and reporting.

27. The 451-457 MHz band is allocated on a primary basis for non-Federal Land Mobile services. Within this range, the band segments 454-455 MHz and 456-457 MHz also include a primary allocation for non-Federal Fixed service.[59] This band is heavily used by both public safety agencies and private businesses for private land mobile communications systems.[60] These systems use one- and two-way radio transmissions for coordinating people and materials, dispatching workers and vehicles, and communicating with first responders. The public mobile service also operates in this band.[61] Portions of the band are also used by the broadcast auxiliary service (BAS) for remote pickup (RPU) stations which are used to send audio to and from remote locations such as news events or live sporting events and serve as communication links between radio and TV studios and news crews in the field.

28. *Decision.* Consistent with our proposal, we will allocate the 24 megahertz of spectrum in four segments of the 413-457 MHz band for MMN use on a secondary basis, *i.e.*, 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz. As described by AMF, the propagation characteristics of the 400 MHz band make it particularly well suited to host MMN devices, and the band is already used for other MedRadio implanted devices. Further, because these four band segments will allow for the wide bandwidth signals required to transmit large amounts of data in a short amount of time, they will provide the emission bandwidth that MMNs require. As explained below, we do not believe operation on a secondary basis will detrimentally impact the development or deployment of MMNs as they are designed to be able to operate on a secondary basis.

29. We also conclude that allocating four band segments for MMN use is necessary to ensure that an MMN has sufficient spectrum to operate while avoiding causing interference to or receiving interference from primary users in the band. An MMN will occupy only one band segment at any given time. By having a variety of authorized frequency bands available and employing protocols that will allow MMNs to quickly migrate from band to band, an MMN licensee will be able to make robust use of the available spectrum and respond to changing spectrum conditions. For example, ARRL, in its analysis of how the MMN channel-switching design can protect patients, states that it is "critical for patient protection" that we make all four channels identified in the *NPRM* available for MMN use.[62] In addition, the four band segments serve a mix of Federal and non-Federal use. By permitting MMN use of all four segments, we will give MMNs more flexibility to operate in differing RF interference environments. Commenters expressed concern that heavy band use situations could render a particular frequency band unavailable to MMNs for extended periods of time.[63] However, we do not believe that such a possibility

[59] *See* 47 C.F.R. § 2.106. Use of this spectrum is limited by various footnotes to the Table of Allocations to specific types of operations under Parts 22, 74, 80, and 90 of the Commission's Rules.

[60] Licensed under Part 90 of the Commission's rules.

[61] Licensed under Part 22 of the Commission's rules.

[62] *ARRL Comments* at 12.

[63] The Association of Public-Safety Communications Officers-International (APCO) and Engineers for the Integrity of the Broadcast Auxiliary Service Spectrum (EIBASS) state that the use of co-channel public safety radios in close proximity to people with implanted microstimulator devices will result in debilitating levels of interference. *See* Comments of the Public-Safety Communications Officers-International, ET Docket No. 09-36, filed Aug. 11, 2009, at 2-3 (*APCO Comments*); Engineers for the Integrity of Broadcast Auxiliary Services Spectrum *ex parte*, ET Docket No. 09-36, filed May 19, 2011, at 1-2 (*EIBASS 5/19/11 ex parte*). The Association for Maximum Service (continued….)

should categorically preclude us from allocating the four proposed frequency bands. Similarly, the fact that certain interference mitigation techniques might work in some situations but not in others is not a reason to prevent MMNs from being authorized to operate in all four frequency bands.[64] Even in a worst-case situation, we can expect that many patients with MMN implants will still be able to make effective use of at least one of the allocated frequency segments.[65]

30. We will implement this allocation by modifying footnote US345 to the Table of Allocations for the MedRadio service to add a secondary mobile, except aeronautical mobile, allocation for the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz frequency bands and renumbering this footnote as US64.[66] This allocation will be in addition to the existing allocations in these four frequency bands and will be limited to use solely by MedRadio operations. We are making this allocation through a footnote rather than a direct entry in the Table for consistency with the existing MedRadio allocation and to emphasize the limited nature of this allocation.

31. We will place this footnote in both the Federal Table and non-Federal Table for each of these four frequency bands to allow use in a variety of settings such as in health care facilities operated by the Department of Veterans Affairs or the United States military, as well as non-Federal health care facilities.[67] Even though this allocation will be both a Federal and non-Federal allocation, we do not expect any changes in the primary use of any of these frequency bands. The 413-419 MHz band will continue to be used primarily for Federal mobile and space research services. The 451-457 MHz band will continue to be used primarily for non-Federal land mobile services. The 426-432 MHz and 438-444 MHz bands will continue to be shared by the Federal radiolocation service and the non-Federal Amateur service.[68] Because MedRadio use of these bands will be on a secondary basis, MedRadio stations will not be allowed to cause interference to and must accept interference from primary services sharing the

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Television (MSTV) states that breaking news stories are likely to take place in hospitals and other locations where individuals with MMNs would be present, thus affecting MMN operations in the 450-456 MHz range. *See* Comments of The Association for Maximum Service Television , ET Docket no. 09-36, filed Aug. 11, 2009, at 2 (*MSTV Comments*).

[64] *See, e.g.,* Comments of Motorola Inc., ET Docket No. 09-36, filed Aug. 11, 2009, at 8 (*Motorola Comments*) (stating that reducing the MMN bandwidth from 5 MHz to 3 MHz would still likely overlap a large number of land mobile channels, making it difficult if not impossible for the medical device to find open spectrum).

[65] Because MMN devices will operate on one channel at a time, any potential that a particular frequency band will experience higher levels of interference to MMNs actually bolsters the argument for authorizing MMN operation in as many channels as practical – including more heavily encumbered ones. Doing so will provide the system with a wider variety of potential channels in which to operate. Accordingly we allocate for MMN use all 24 megahertz of spectrum that we identified in the *NPRM.*

[66] The MedRadio band at 401-406 MHz is allocated on a secondary basis to the Mobile, except aeronautical mobile, service by footnote US345 to the Table. *See* 47 C.F.R. § 2.106 n.US345. Stations of a secondary service cannot cause interference to and must accept interference from stations of a primary service, even if the primary service stations begin operation after the secondary service station has been established. *See* 47 C.F.R. § 2.105(c)(2). The new footnote, US64, will apply the provisions of the prior US345 to the 401-406 MHz band while adding provisions for the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz frequency bands.

[67] The Table is further divided into the Federal Table of Frequency Allocations (Federal Table) and the non-Federal Table of Frequency Allocations (non-Federal Table). The National Telecommunications and Information Administration (NTIA) authorizes Federal stations in allocations listed in the Federal Table, and the Commission issues licenses to non-Federal stations in allocations listed in the non-Federal Table.

[68] The NTIA and Commission jointly manage shared Federal/non-Federal bands in accordance with a Memorandum of Understanding (MOU) that governs how rules will be developed and frequency use will be authorized in shared bands. *See* Memorandum of Understanding between the Federal Communications Commission and the National Telecommunications and Information Administration, January 31, 2003, available at http://hraunfoss.fcc.gov/edocs_public/attachmatch/DOC-230835A2.pdf.

bands.[69] Consequently, there is no reason for any changes to the current coordination procedures between FCC and NTIA for these frequency bands. NTIA will continue to manage the 413-419 MHz band, the FCC will continue to manage the 451-457 MHz band, and both agencies will continue to share management responsibilities of the 426-432 MHz and 438-444 MHz bands.

32. We also note that the spectrum we are adding to the MedRadio Service is allocated to similar services in both the United States Table and in all regions of the world in the International Table. Thus, we believe that MMN devices designed to be compatible with U.S. radiocommunications services will be equally compatible with the services found elsewhere in the world. However, we are not aware of any other administrations that have made provisions for MMNs. Although individuals using MMNs should not encounter significantly different electromagnetic environments when traveling abroad, the use of MMNs may be restricted in other countries.[70] We find that the benefits promised by MMNs as well as the ability for MMNs to coexist with the radiocommunications services already allocated internationally in the bands under consideration support our decision to adopt the proposed allocation.[71]

33. We reject other frequency band suggestions made by commenters and find that they would not be suitable for MMN use. We reject suggestions by the National Association for Amateur Radio (ARRL), the Land Mobile Communications Council (LMCC), the Enterprise Wireless Alliance (EWA), and Motorola that the WMTS bands are more appropriate for MMNs.[72] In the MedRadio proceeding, the Commission stated that frequencies below 216 MHz and above 470 MHz are "outside the range of spectrum generally considered to be the most suitable for propagation of radio signals within the human body."[73] Because implanted MMN devices must operate with minimal power, efficient propagation of signals through the human body is extremely important for their operation. The WMTS bands from 608-614 MHz, 1395-1400 MHz, and 1429-1432 MHz are far above the suitable range for signal propagation in the human body. While the use of additional power might overcome the decreased propagation of signals in the human body in these bands as compared to the 400 MHz band, it appears that it is not practical to substantially increase the size of batteries in the MMN implant devices. In addition, the 608-614 MHz WMTS band is heavily used in medical facilities and could complicate reliable MMN service in such close proximity. We therefore conclude that the WMTS bands are not a practical alternative for use by MMNs.

[69] The 426-432 MHz, 438-444 MHz bands are also allocated on a secondary basis to the non-Federal Amateur service and on a primary basis to the Federal Radiolocation service. Hence these two bands are currently shared Federal/non-Federal bands. The Amateur service has equal status with MedRadio operations in these bands.

[70] We recognize that under the existing allocations, patients with MMN devices potentially would not be able to operate the devices when traveling internationally. Given that MMNs are expected to, among other things, restore sensation, mobility, and other functions to paralyzed limbs and organs, we believe that the benefits of MMN use would far outweigh any potential inconvenience associated with such travel restrictions.

[71] We believe that, as U.S. patients begin to realize the benefits of MMNs, there will likely be interest in other parts of the world where MMNs can bring significant improvements to the quality of life of similarly situated patients. MMN compatibility with international allocations would be expected to promote the growth of these technologies globally.

[72] *ARRL Comments* at 15; *LMCC Comments* at 4-5; Reply Comments of the Enterprise Wireless Alliance, ET Docket No. 09-36, filed Sept. 10, 2009, at 3 (*EWA Reply*); *Motorola Comments* at 9.

[73] *See MICS R&O* at 21042-43 para. 6. ARRL expresses dissatisfaction with AMF's contention that frequencies above 470 MHz have unsuitable within-body propagation. *ARRL Comments* at 5 n.4. However, this contention is consistent with the Commission's previous conclusions. *See also NPRM* at 3451 para. 21 (noting AMF's submission that "WMTS spectrum is unsuitable for wideband MMN devices because frequencies above 470 MHz are outside the preferred range of spectrum for propagation of radiofrequency ("RF") signals within the human body.")

34. We also do not believe that Motorola's suggestion that MMNs can use the 902-928 MHz band is viable given the diminutive size of the implanted MMN devices and corresponding limited available power. Similar to the WMTS bands, this band is outside the range of frequencies with favorable propagation characteristics. Motorola suggests that the use of additional power may be able to overcome the decreased propagation of signals in the human body as compared with the 400 MHz band.[74] We do not find this argument convincing. AMF has conducted tests that show that implanted devices would not be able to transmit a strong enough signal at 915 MHz to communicate with an external control unit, and we reject the possible use of larger batteries to produce greater power for the reasons discussed above. [75]

35. Parties that object to MMN operations in the 413-457 MHz band focus mostly on the potential for interference between MMNs and incumbent services. Some parties also question whether MMNs should be authorized on a secondary basis in this or any band since a secondary service must not cause interference to primary users and must accept interference from primary users. We address these concerns below.

36. Our *NPRM* envisioned, and AMF has designed, MMNs that are capable of operating on a secondary basis in frequency bands with existing, established incumbent use. Through the use of harmful interference mitigation techniques, operations on multiple frequency bands, and pre-established shutdown protocols in the event that no frequency bands are available, MMNs will be able to operate successfully in the lower 400 MHz band.[76] We are further encouraged by the fact that the MMN concept is not just theoretical: AMF has engaged in prototype development under an experimental license that it has held since January 2005[77] and in actual evaluation and testing in cooperation with Federal stakeholders. AMF notes that it has developed prototype programmer/controllers that implement these interference mitigation techniques and points out that these techniques have been independently tested and shown to be effective against a wide range of potential interference signals.[78]

37. On April 8, 2011, AMF submitted interference analyses, test reports, and technical studies that it had commissioned to evaluate MMN use in the identified bands.[79] These materials were the

[74] *Motorola Comments* at 9-10. Motorola makes this same suggestion regarding the 608-614 MHz WMTS band which we reject for the same reason.

[75] *AMF Reply* at 7; *See also* Richard Scanlon, Brian Burns, and Noel E. Evans, *Radiowave Propagation from a Tissue-Implanted Source at 418 MHz and 916.5 MHz*, 47 IEEE Transactions of Biomedical Engineering, 527-34, 533 (April 2000) (concluding that the propagation of signals in the body are expected to be 6 dB worse at 916 MHz as compared with 418 MHz); A. Alomainy, Y. Hao, Y. Yuan, Y. Liu, *Modeling and Characterization of Radio Propagation from Wireless Implants at Different Frequencies*, Proceedings of the 9th European Conference on Wireless Technology, 199-122 (2006) (illustrating the differences in within-body propagation loss between 402 MHz, 868 MHz, and 2.4 GHz).

[76] *AMF Reply* at 14; Alfred Mann Foundation *ex parte*, ET Docket No. 09-36, filed June 8, 2011, at 2 (*AMF 6/8/11 ex parte*); *AMF Comments* at 10-13. EIBASS claims that many of these techniques are not effective since they are only implemented in the P/C and not the implanted MMN devices. Engineers for the Integrity of Broadcast Auxiliary Services Spectrum *ex parte*, ET Docket No. 09-36, filed May 19, 2011, at 5 (*EIBASS 5/19/11 ex parte*). AMF responds that implant devices operate in a lower interference environment because of shielding by the human *body* and, consequently, the Commission's MedRadio rules require interference mitigation capabilities only in the P/C, not the implants. Alfred Mann Foundation *ex parte*, ET Docket No. 09-36, filed Aug. 15, 2011, at 2 (*AMF 8/15/11 ex parte*).

[77] *AMF Comments* at 3-4.

[78] Alfred Mann Foundation *ex parte*, ET Docket No. 09-36, filed July, 7 2011, at 1-2 (*AMF 7/7/11 ex parte*). The results of these tests are described in para. 40, *infra*.

[79] Alfred Mann Foundation *ex parte*, ET Docket No. 09-36, filed April 8, 2011 (*AMF 4/8/11 ex parte*); Electromagnetic Compatibilty Analysis of the Alfred Mann Foundation Medical Microprocessor Network, Defense Information Systems Agency, Joint Spectrum Center, Jan. 6, 2011, ET Docket No. 09-36, filed by AMF on April 8, (continued….)

product of a process that began in August 2009, when AMF and the Joint Spectrum Center (JSC) (a field office within the U.S. Defense Spectrum Organization that provides spectrum planning and support for U.S. military interests) entered into a memorandum of agreement (MOA) for JSC to conduct a technical analysis to determine whether MMN devices could co-exist with incumbent government systems in the 413-457 MHz band. As background, NTIA had filed comments in response to the *NPRM* questioning whether there would be electromagnetic compatibility issues associated with the proposed MMN devices and current and future federal systems operating in the band and suggesting that coordinated measurement efforts with the incumbent federal spectrum users would be necessary.[80]

38. Pursuant to the MOA, JSC directed a contractor, ITT, to collect, validate, and evaluate technical data regarding MMN devices and incumbent government systems. The resulting report (JSC Report) contained a theoretical analysis to evaluate the electromagnetic compatibility (EMC) of incumbent government system receivers in the presence of radiofrequency (RF) emissions from MMN transmitters and the EMC of MMN receivers of both the programmer/controller (P/C) and implanted microstimulator devices— in the presence of RF emissions from incumbent systems.[81] The JSC reviewed the report and approved it for publication in October 2010.

39. The JSC Report concluded that, with respect to the MMN-to-government system interference potential, (1) "relatively small [required separation distances] result from the low EIRP and duty cycle of the MMN transmitters combined with the low antenna heights of the MMN," and (2) MMN systems "should be operationally compatible and not cause unacceptable interference into [incumbent government] systems currently authorized to operate in the 410-450 MHz band."[82]

40. In addition, AMF commissioned Aerospace Corporation (the operator of a federally funded research and development center and provider of comprehensive technical service to national security space programs) to conduct laboratory tests to determine whether MMNs could successfully operate in the presence of incumbent users.[83] To evaluate the performance of the MMN network in the 413-457 MHz band, the Aerospace testers conducted a wired simulation of the frequency bands.[84] Specifically they tested signals representing Federal mobile radio (data and voice), radar (ground and airborne), and the Enhanced Position Location Reporting System, as well as non-Federal amateur television.[85] The tests specifically targeted four MMN interference mitigation techniques: spectral excising of narrowband

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2011 (*JSC Report*); Alfred Mann Foundation (AMF) Medical Micropower Network (MMN) Wired Test Report, Aerospace Corp., Nov. 3, 2010, ET Docket No. 09-36, filed by AMF on April 8, 2011 (*Aerospace Report*); ITT Corp. Memorandum, March 1, 2011, ET Docket No. 09-36, filed by AMF on April 8, 2011 (*IIT Memo*).

[80] National Telecommunications Information Administration, ET Docket No. 09-36, filed March 25, 2009, 1, 11.

[81] The EMC analysis was performed by establishing interference criteria for both MMN and incumbent systems for testing purposes and then calculating the required separation distances (RSD) predicted to preclude the potential for harmful interference between MMNs and incumbent systems. *JSC Report* at 1-2.

[82] *JSC Report* at 27.

[83] *See also Aerospace Report* at 15, 20, 27, 28 (listing the specific test objectives).

[84] In this project, they performed an initial study that used documentation from the National Telecommunications and Information Administration (NTIA) and the Telecommunications Industry Association (TIA) as a reference to evaluate signals present in this band. *Aerospace Report* at 4. They digitally generated all of the signals used for the MMN evaluation in a personal computer using Matlab®. They then uploaded the signals to a pair of arbitrary waveform generators (AWG) and up-converted them to the system's carrier frequency. This methodology enabled the generation of a large number of different signals within the bands of interest. The study used one signal generator to inject MMN signals into the frequency band being tested and a second AWG to simulate interferers on the other three available frequency bands within the bands of interest.

[85] *Aerospace Report* at 13-14.

incumbent signals; changing frequency bands without suspending critical functions; shutting down in a communication link loss scenario; and incumbent signal level sensing to avoid interference. The resulting report (Aerospace Report) concluded that the AMF MMN System performs according to its specifications and can successfully operate in presence of incumbent users.

41. In conjunction with the Aerospace Report, AMF provided the JSC with an internal AMF engineering test report entitled "Uplink Path Loss of Four-Wire Antenna Connection in Simulated FEBPM Implant," as well as other AMF technical documents describing additional test results and MMN technical and operational characteristics.[86] Together, these documents were responsive to the JSC Report's recommendation that testing be conducted to determine the effectiveness of MMN interference mitigation techniques and to validate the body loss calculations used in the analysis. ITT evaluated AMF's additional submissions for the JSC and determined that the Aerospace Report adequately demonstrated the effectiveness of MMN interference mitigation techniques; that AMF's tests validate the body loss measurements that were used in the analysis and were adequate; and that the documents, collectively, offered additional substantiation of the electromagnetic compatibility results reported in the JSC Report.[87]

42. The JSC Report and Aerospace Report offer detailed evaluations of specific interference scenarios involving a broad spectrum of incumbent operations backed up by testing with actual equipment. Based on these reports, we conclude that the record demonstrates that MMNs can operate on a compatible secondary basis with primary Federal operations in the 413-419 MHz, 426-432 MHz, and 438-444 MHz band segments.

43. We are also convinced that MMNs can operate on a compatible secondary basis with primary non-Federal operations**.** The findings of the JSC Report, which focused on Federal systems, and the simulations conducted by AMF and the Aerospace Corporation, which looked at a wider variety of high-powered signals, support this conclusion. In this regard, non-Federal fixed and land mobile radio systems in the 451-457 MHz frequency band use the same technologies as Federal fixed and land mobile radio systems in the 420-450 MHz frequency band.[88] Moreover, the mitigation techniques that the Aerospace Report examined have broad applicability. For example a P/C that incorporates "notching" techniques could filter out a 100 kHz RPU signal from a BAS operator.[89]

44. Many parties stated that additional testing would be needed to determine whether MMNs could operate in conjunction with high power, co-channel incumbent operations.[90] We believe that the

[86] Alfred Mann Foundation, ET Docket No. 09-36, filed April 8, 2011 at 51 (filed in same document as the *Aerospace Report*).

[87] *IIT Memo* at 4-5.

[88] *See* AMF *4/8/11 ex parte* at 4. (stating that "most of these non-government systems are virtually identical to their government counterparts and are supplied from the same manufacturers"); *LMCC Comments* at 3 (stating that "land mobile technology in these NTIA bands is similar to that used in the 451-457 MHz band"). Notably, Motorola, which supplies land mobile radio equipment to both Federal and non-Federal users, does not make it clear in its comments whether it is discussing one or both types of users when it claims land mobile use is incompatible with MMNs. *Motorola Comments at 2-9.*

[89] RPU signals in the 451-457 MHz band are, at a maximum, 100 kHz wide. Many RPU signals may actually have smaller bandwidth. 47 C.F.R. § 74.402(b)-(d). ARRL, in its comments analyzing the AMF system, notes that the MMN filters are designed to implement numerous notches, up to 250 kHz each, within a particular channel. *ARRL Comments* at 11.

[90] *SBE Comments* at 3, 7 (claiming that, based on the information that was available at the time of its filing, it was unlikely that MMNs will be able to operate without endangering patients); *ARRL Comments* at 10 (stating that no rules for MMN devices should be enacted without a comprehensive series of field tests that assure patient safety in the presence of typical RF fields in the bands under consideration); *EWA Reply* at 2 (suggesting that not enough (continued….)

JSC Report, Aerospace Report, and associated materials filed by AMF are responsive to these concerns.[91] In addition, because these materials provide extensive technical details about the interference mitigation techniques employed by AMF's MMN devices,[92] we disagree with the contention of the Engineers for the Integrity of the Broadcast Auxiliary Service Spectrum (EIBASS) that AMF has provided insufficient technical details about its interference mitigating protocols.[93]

45. A number of parties claim that incumbent operators could receive harmful interference from MMN devices. Motorola, for example, claims that AMF's interference calculations show an unacceptably high level of interference to land mobile systems in the 451-457 MHz band.[94] We disagree. Several factors serve to reduce any risk that MMNs could cause harmful interference. First, the JSC Report concluded that the MMN systems would not cause unacceptable interference into government systems in the 413-419 MHz, 426-432 MHz, and 438-444 MHz bands.[95] Again, because the non-Federal land mobile systems in the 451-457 MHz are virtually identical to the types of government systems considered in the JSC Report, there is no basis for us to expect interference to non-Federal land mobile systems.[96] Such non-Federal land mobile systems must overcome interference caused by the high-powered operations of other incumbents in the band. For this reason, they are well equipped to tolerate the presence of any signals they might receive from an MMN system operating at a much lower power.[97] The Aerospace Report, which tested actual prototype MMN devices and concluded that incumbent services would not receive significant interference, further bolsters our conclusion.[98] We further note that

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work had been done to determine whether the 451-457 MHz band satisfies the non-interference criterion necessary for secondary MMN operations); *LMCC Comments* at 5 (suggesting extensive testing should be done before allowing MMNs in 451-457 MHz band); *See also Motorola Comments* at 3 (stating that each of the four proposed band segments present "significant challenges" for MMNs to either avoid receiving interference from or preventing interference to incumbent services).

[91] Our analysis focuses on the technical feasibility of deploying MMN systems and, to a lesser extent, the broad public interest in advancing the state of medical technologies that use the public airwaves. Additionally, MMN equipment will have to undergo an independent testing and approval process.

[92] *Aerospace Report* at 1-2, 15-17, 20, 23, 27-28; *JSC Report* at 5-8, 10-12, 23-25.

[93] Engineers for the Integrity of Broadcast Auxiliary Services Spectrum *ex parte*, ET Docket No. 09-36, filed Aug. 26, 2010, at 3 (*EIBASS 8/26/10 ex parte*) (arguing that AMF has "not discussed at length the technical details of its claimed interference mitigating protocols" and that "AMF has made sweeping claims about dynamic channel switching, spectral exclusion/notching, and "signal coding" but has offered no technical details to back up its claims") *See also SBE Comments* at 8.

[94] *Motorola Comments* at 6-9. Motorola also argues that a number of erroneous assumptions that AMF made in its calculations mean that the actual interference levels will be even higher. AMF has responded that the calculations it submitted in the petition were an extremely conservative worst-case scenario based on free-space loss that does not take into account other factors that would result in greater losses, the JSC Report uses an alternate approach, and Motorola's analysis is fatally flawed. *AMF Reply* at 11-13. *See also APCO Comments* at 2 (recommending further testing to ensure that MMN devices do not cause interference to public safety radios).

[95] *JSC Report* at 27.

[96] Motorola's concerns were based on the analysis submitted with AMF's petition. We believe that the JSC Report offers a more detailed and accurate interference analysis and therefore serves as a more appropriate frame of reference. Motorola has not commented on the JSC report or AMF's associated filings.

[97] We are permitting MMN devices, whether programmer/controllers or implanted devices, to transmit at a maximum output power level of one milliwatt. In comparison, the output power levels of land mobile systems in the 413-419 MHz and 451-457 MHz bands are typically 10 to 90 watts and radar systems in the 426-432 MHz and 438-444 MHz bands are typically 1 to 5 megawatts. National Telecommunications and Information Administration *ex parte*, ET Docket No. 09-36, filed March 25, 2009, at 2-4.

[98] *Aerospace Report* at 3, 13-31.

some commenters have rejected the likelihood of interference from MMN devices to their services which, like land mobile systems, operate at much higher powers than MMNs.[99] Finally, we adopt service rules that will require an MMN to switch to another frequency if it appears that there is an incumbent operating in close proximity.[100]

46. A second concern for many commenters is whether MMNs will be able to tolerate the interference caused by non-Federal operations in the bands. This is because, as secondary users, MMN licensees must be prepared to accept any interference received from incumbent operations. The Enterprise Wireless Alliance, the Land Mobile Communications Council (LMCC), and Motorola all state that high-power land mobile transmitters that are heavily deployed throughout the 451-457 MHz band are likely to interfere with MMN device operation.[101] APCO points out that public safety organization use of the 426-430 MHz spectrum for portable and mobile communications may interfere with MMN use of the spectrum in some areas.[102] The Society of Broadcast Engineers (SBE), the Association for Maximum Service Television (MSTV), and EIBASS claim that use of portions of the 451-457 MHz band by BAS remote pick-up operation (RPU) would prevent MMN operation.[103]

47. As discussed above, the studies commissioned by AMF show that MMNs are able to function with a significant amount of interference from incumbent operations.[104] As such, we are not persuaded by those comments that claim that MMNs are incompatible with incumbent non-Government licensees. Incumbent systems that operate in the bands under consideration share the same high-powered operational attributes that MMNs have been specifically designed to tolerate.[105]

48. To the extent that these objections focus on the fact that a transmitter of a particular service may cause interference when operating in close proximity to an MMN device, commenters fail to acknowledge that the MMN system design anticipates such a scenario. There is no dispute that MMN devices may not be able to function in one or more of the four bands at a particular moment because of interference. AMF's MMN devices are capable of switching among the four different bands and are designed to operate on one band at a time, and the Aerospace Report found that this design feature worked as planned.[106] Moreover, because MMNs are designed to operate in a variety of bands with a

[99] *ARRL Comments* at 2; *EIBASS 5/19/11 ex parte* at 1 (concluding that MMN devices are unlikely to cause interference to amateur operations and RPU BAS operations, respectively).

[100] *See* paragraph 60, infra.

[101] *EWA Reply* at 4; *LMCC Comments* at 4; *Motorola Comments* at 3-4.

[102] *APCO Comments* at 2; *See also LMCC Comments* at 3 (noting that non-Federal licensees use the 426-430 MHz spectrum).

[103] The 450-451 MHz and 455-456 MHz spectrum is used by BAS Remote Pickup stations under Part 74, Subpart D of the Commissions rules. *SBE Comments* at 5; *MSTV Comments* at 2; Comments of Thomas R. Spencer, ET Docket 09-36, filed March 24, 2009 (*Spencer Comments*); Comments of Engineers for the Integrity of Broadcast Auxiliary Services Spectrum, ET Docket No. 09-36, filed June 25, 2010, at 3 (*EIBASS Comments*).

[104] *ITT Memo* at 3-5.

[105] Some commenters may not fully understand the nature and characteristics of implanted medical radio devices. For example, EIBASS claims that many of the interference techniques used by AMF's MMNs are not effective since they are only implemented in the P/C and not the implanted MMN devices. *EIBASS 5/19/11 ex parte* at 5. AMF responds that implant devices operate in a lower interference environment because of shielding by the human body, and consequently, the Commission's MedRadio rules require interference mitigation capabilities only in the P/C, not the implants. Alfred Mann Foundation *ex parte*, ET Docket No. 09-36, filed Aug. 15, 2011, at 2. We agree and see no reason to deviate from the existing MedRadio rules.

[106] SBE notes that the only devices addressed in the *NPRM* are AMF's and that other MMN devices may have different interference characteristics. *SBE Comments* at 2 n.1. The testing AMF has done illustrates that it is possible to build MMN devices that have a high degree of interference immunity in these bands.

diverse set of Government and non-Government users, a band that is rarely available for use in a particular place or at a specific time may be uncongested in other situations.[107] Under this reasoning, we are not troubled by EIBASS's claim that the tests submitted by AMF did not specifically consider RPU operations, a claim AMF refutes.[108] EIBASS states that RPU broadcasts are distinct because they often employ a long duty cycle and postulates a scenario where extended RPU operations would take place at a health care facility.[109] In such a case, the MMNs operating in that place and time would simply not be able to access the portion of the MedRadio band that is being used by the RPU operator.

49. Several parties argue that it would be inappropriate for us to permit medical devices—and MMNs in particular—to operate on a secondary basis.[110] Parties raise variations of this issue in their comments. For example, Motorola cautions against relying on secondary status and asks whether abnormal operation of the devices due to interference could negatively affect patients, while MSTV warns that there may be unintended negative consequences from allowing medical devices to use spectrum used on a primary basis by other services.[111] EIBASS, which strongly asserts that secondary medical operation is an inappropriate policy, takes the position that "[i]f the application is for an important medical purpose, then the use of RF spectrum for that purpose needs to be on a primary, protected, basis."[112] It also claims

[107] *See* paragraph 29, *supra*; *See also ARRL Comments* at 5-6 (claiming that amateur radio television transmitters would cause interference on par with what MMNs would experience in the 450-470 MHz band, a band AMF has rejected due to interference concerns). Even if amateur television operations are similar to the types of operations that led AMF to not pursue the use of frequencies above 457 MHz, it does not automatically follow that such operations are so pervasive as to raise the same level of interference concerns for successful MMN operation.

[108] Engineers for the Integrity of Broadcast Auxiliary Services Spectrum *ex parte*, ET Docket No. 09-36, filed July 15, 2011, at 1 (*EIBASS 7/15/11 ex parte*); *See also* Society of Broadcast Engineers *ex parte*, ET Docket No. 09-36, filed June 17, 2011, at 1; Alfred Mann Foundation *ex parte*, ET Docket No. 09-36, filed Aug. 15, 2011 at 1-2. We also discuss paragraph 43, *supra* how MMNs can mitigate interference with BAS RPUs.

[109] *EIBASS 7/15/11 ex parte* at 2 (discussing a remote broadcast in support of a "Jump Rope for Health" or similar fundraising event taking place in a hospital setting). EIBASS also points out that the AMF website contains a section called "commercializing your idea" to indicate AMF has a profit motive for developing the MMN technology. *See* Engineers for the Integrity of Broadcast Auxiliary Services Spectrum *ex parte*, ET Docket No. 09-36, filed June 25, 2010 at 1. We do not see how this relates to the technical arguments under consideration here.

[110] Commenters offer two examples to illustrate why secondary status for medical devices is not appropriate. Prior to 2000, WMTS operations in the 450-470 MHz band operated on a secondary basis under Part 90 to primary land mobile operations. The Commission decided to cease authorizing WMTS operations in this band because of interference concerns and allocated spectrum elsewhere for WMTS. Because the incumbent operations in 451-457 MHz that we are designating for MMNs are the same as in the 460-470 MHz band previously used by WMTS, LMCC argues that the Commission should prevent MMNs from operating in the band to avoid a similar situation in the future. *See LMCC Comments* at 4-5. Other commenters point to interference that WMTS devices experienced from television stations during the digital television transition, when some wireless medical telemetry devices operating on an unlicensed basis on the television bands experienced disabling interference in conjunction with the launch of new digital stations operating on previously unused channels. *See SBE Comments* at 6. We note that, unlike WMTS, MMN devices will be frequency agile and can avoid interference situations in this band. In the case of wireless telemetry operation in the television bands, the expectation that no television stations would operate on a co-channel basis with medical telemetry devices was upset by the digital television transition. Moreover, none of the bands identified for MMN use contain a broadcasting allocation or are used for over-the-air television broadcasting.

[111] *Motorola Comments* at 5; *MSTV Comments* at 1; *See also ARRL Comments* at 7 (stating that Amateur operators have a "practical inability" to protect patients with MMN implants); *Spencer Comments* at 1 (questioning the viability of any medical device "which much be 100 percent reliable under any conditions" under the proposed secondary allocation).

[112] Engineers for the Integrity of Broadcast Auxiliary Services Spectrum *ex parte*, ET Docket No. 09-36, filed Aug. 26, 2010, at 4-5.

that patients can potentially be put at risk if the MMN devices must shut down because they cannot communicate because of interference.[113]

50. We disagree with parties that argue that we should never allocate spectrum to medical devices on a secondary basis. As a general matter, we take many factors into account in deciding whether a given service should operate with a primary or secondary status in a designated frequency band or even whether a device should operate on an unlicensed basis under Part 15 of our rules. Each case is evaluated on its own merits. This is also true of our allocations for medical devices. At the present time, the Commission's rules allow medical devices to operate on a primary basis, on a secondary basis, and on an unlicensed basis.[114] We find in this order that the characteristics of the MMN devices at issue here warrant operation on a secondary basis. The MMN devices that will be deployed under the rules that we adopt herein will be frequency agile and can switch to other frequency bands when interference occurs. Thus, the MMN devices will be designed with capabilities that enable them to share spectrum with primary services successfully. Rigorous testing has shown that MMN devices can perform as intended.

51. We acknowledge that there may be instances when MMN devices cannot operate due to interference on all frequency bands. However, we also note that AMF has accounted for this possibility by designing its MMN devices to shut down in a controlled, pre-planned manner that is designed to avoid harm to the patient or others if interference in all four frequency bands prevents successful reception of signals by the MMN system.[115] We reject the notion that the potential for such a shutdown should categorically bar us from designating spectrum for MMNs and, thus, deny the benefits associated with these devices.[116] The Food and Drug Administration (FDA), as part of its independent review process,

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[113] *EIBASS 5/19/11ex parte* at 3; *EIBASS 7/15/11 ex parte* at 3. EIBASS also claims that a 2010 *Order on Reconsideration* that refused to allow secondary use of the 1.427-1.432 GHz band for WMTS implies that secondary use of the 451-457 MHz band for MMNs should not be allowed. Engineers for the Integrity of Broadcast Auxiliary Services Spectrum *ex parte*, ET Docket No. 09-36, filed May 14, 2010, at 1-3 (*EIBASS 5/14/10 ex parte*) (*see* Amendment of Part 90 of the Commission's Rules, WP Docket No. 07-100, *Order on Reconsideration*, 25 FCC Rcd 5105 (2010) (*WMTS Recon Order*)). However, that order clearly states that secondary WMTS was not being permitted in the band because the record there did not reflect that it is possible to develop appropriate and effective measures to detect and avoid harmful interference. *WMTS Recon Order* at 5106 para. 4. That is not the case here. Furthermore, the *WMTS Recon Order* clearly states that it applies only to WMTS, takes into account the unique technical characteristics of the service, the lack of safeguards in our rules to promote safe secondary operations, and the operations with which WMTS shares spectrum. *Id*.

[114] For example, WMTS operates on a primary basis and MedRadio operates on a secondary basis. For recent examples of unlicensed wireless medical devices see, for example, Boston Scientific Corp., Request for Waiver of Section 15.205 of the Commission's Rules to Permit the Marketing and Operation of Certain Medical Communications Devices that Operate in the 90-110 kHz band, ET Dkt. No. 05-331, *Order*, DA 11-1427, 26 FCC Rcd 11405 (2011) (waiver of Part 15 rule to allow marketing and unlicensed operation of implanted cardiac devices in restricted bands); Letter to Mitchell Lazarus from Julius P. Knapp, Chief, Office of Engineering and Technology, DA 09-2425, 24 FCC Rcd 13795 (2009) (waiver of Part 15 emission limits to permit the marketing and unlicensed operation of an implanted device in the 6.78 MHz band used for treating gastro-intestinal disorders); Office of Engineering and Technology Declares the Second Sight Medical Products Inc. Request for Waiver of Rule Section 15.209(a) to be a "Permit-but-Disclose" Proceeding for *Ex Parte* Purposes and Request Comment, ET Docket 11-123, *Public Notice*, 26 FCC Rcd 10286 (2011) (pending waiver for a retina prosthesis system for unlicensed operation under Part 15).

[115] *AMF 8/15/11 ex parte* at 3. *See also ARRL Comments* at 12 (describing how the implants are designed to "function in such a way as to permit the neuron triggering on a low-level basis that apparently allows, for example, limb movement").

[116] Furthermore, we do not consider such a shutdown to be a "malfunction," as EIBASS suggests. *See EIBASS Comments* at 2. We also reject EIBASS's inference that it is not in the public interest to authorize a medical implant device unless it is able to deliver active therapy at all times in all cases. Therapeutic needs vary greatly between (continued….)

will take into account these "graceful shutdowns" when it determines when and how MMN use can be prescribed. Further, we will require that MMN devices be authorized under the direction of a duly authorized health care professional who will inform patients of the risks associated with MMN use, including "graceful shutdowns."

52. We must balance the cost of allowing MMNs to operate on a secondary basis in these bands against the benefits that patients could potentially receive from their use. Given the extremely low risk of incumbent services suffering interference from MMNs and the yet lower risk of a harmful result from any such interference, the potential benefits of establishing a secondary allocation and adopting rules to allow MMN operation outweigh the slight risk to incumbent services. Because of the great potential of MMNs to improve the lives of people who suffer from a range of illnesses such as spinal cord injuries, traumatic brain injuries, strokes, and various neuromusculoskeletal disorders, we recognize the enormous potential benefit of allowing MMNs to become a reality. The benefits of making this secondary allocation and adopting rules to facilitate MMN operations therefore far exceed any potential costs.

53. Lastly, we address several commenters' overarching concerns that new MedRadio applications must remain truly secondary – neither interfering with incumbent operations nor creating an expectation that MMNs must be protected from the types of interference that higher-powered primary uses may legitimately cause. For example, EIBASS claims that when medical devices operating on a secondary basis receive interference from a primary user, the primary user is likely to receive the blame and have to take action to protect the medical device.[117] We fully intend that MMN devices will operate within the constraints of their secondary status, and we do not adopt here any limitations on the operations of incumbent primary services in these bands for the benefit of MMN operation. Because AMF has designed its MMNs to anticipate interference and to operate in a challenging spectrum environment, we are confident that they will remain secondary in both rule and practice.[118] We also clarify that MMNs, the Amateur Radio Service, and the non-Federal radiolocation service — all of which operate under a secondary allocation in the 426-432 MHz and 438-444 MHz bands—will have equal status.[119] Given that MMN devices are expected to implement measures to mitigate the effects of interference, it is reasonable to expect the MMN devices to tolerate some interference from the Amateur Service or to move to another frequency band as needed. As ARRL concedes, MMN devices are "unlikely generally" to cause interference to Amateur Radio communications in these bands.[120]

C. Service and Technical Rules

54. In the *NPRM* the Commission asked about the service and technical rules that should apply to medical devices in the 413-457 MHz band. The discussion generally followed the framework of the existing MedRadio Service rules and proposed to modify specific rules, such as those pertaining to power and emission bandwidth requirements, to accommodate the proposed MMNs. The Commission also noted that the service and technical rules discussed in the *NPRM* were essentially consistent with recommendations made in the Alfred Mann petition.

55. We adopt the overall approach proposed in the *NPRM*. Thus, rather than creating a new rule subpart for MMNs, we will only amend the service and technical rules contained in Part 95 Subparts E

(Continued from previous page)
patients and between therapies and efficacy is best evaluated by the FDA. Such an absolute standard would curtail the deployment of MMNs, as well of many other beneficial medical applications.

[117] *EIBASS Comments* at 4; *See also SBE Comments* at 3.

[118] The rules we adopt specifically require that MedRadio programmer/control transmitters shall have the ability to operate in the presence of other primary and secondary users. See Appendix A rule Section 95.628(d), *infra*.

[119] 47 C.F.R. § 2.106.

[120] *ARRL Comments* at 8.

and I of our rules to the extent necessary. We also adopt service and technical rules that are based on the research undertaken for AMF's MMN devices. This approach offers incumbent operators greater certainty as to the types and characteristics of MedRadio devices that may be deployed in the band and, because it is backed by extensive testing, provides greater certainly that MMNs and other new medical technologies will be able to thrive on a secondary basis in these frequencies. We are confident that the state of medical radiocommunication technology will evolve and improve over time, as will mitigation techniques that maximize sharing potential on a secondary basis. Further development and testing of future generations of MMNs may allow us to adopt service rules that provide even greater flexibility while still protecting incumbent services. However, the service and technical rules we adopt here are appropriate based on the record before us today.

56. *Interference Mitigation.* Because MMNs will operate under the secondary MedRadio Service, they must be designed to function in the presence of signals from other services operating in the same frequency bands. The interference analysis, test reports, and technical studies that AMF submitted have demonstrated that it is possible to build MMNs that are highly resistant to interference, and as technology continues to advance, we believe it will be possible to build MMN devices that are even more capable of functioning in the presence of interference. To ensure future flexibility for equipment designers, we will not require that MMNs include all of the types of interference mitigation techniques that AMF has employed in its MMN devices. Instead, we will adopt the general requirement that P/C transmitters have the ability to operate in the presence of other users in the 413-457 MHz band, and we will incorporate several basic interference mitigation provisions into our rules. We expect that MMN technology developed in the future will be at least as capable of co-existing with other services as the system AMF has demonstrated.

57. Regardless of the interference mitigation techniques employed, we expect that there will be instances where MMNs will not be able to function in a particular frequency band because of a high level of interference from other stations. To provide a greater probability that an MMN will continue to function in the presence of interference, we adopt the requirement that all MMNs be capable of operating in any of the four frequency bands and that they be able to switch to another frequency band when the band on which they are operating becomes unavailable due to interference. We conclude that these requirements will not increase the cost of equipment unreasonably or be burdensome for manufacturers to meet. As AMF has noted, these four bands are nearly adjacent in frequency and thus incorporation of a multi-channel operating capability requires no significant change in antenna or transmitter design and "imposes no undue economic burden."[121] Only a single transmitter and one antenna are necessary to cover these four bands. Components to enable manufacturers of MMNs to meet this requirement should be readily available since equipment is currently designed to operate across the Federal mobile bands between 406.1 MHz and 450 MHz and non-Federal mobile bands between 450 MHz and 512 MHz.[122] Thus, we conclude that the improved robustness of MMNs that will result from these requirements will more than offset the expected minimal cost of implementing them.

58. We also note that AMF has proposed several rules regarding interference mitigation techniques for MMNs.[123] These suggested rules are based on AMF's experience in building and testing MMN systems. Because of AMF's expertise in this area and the lack of input from other parties on this issue, we are adopting technical provisions to add assurance that any MMN technology developed in the future will be able to operate successfully in the heavily used 413-457 MHz frequency range.

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[121] *See* Alfred Mann Foundation *ex parte*, ET Docket No. 09-36, filed Nov. 15, 2011 at 2.

[122] A staff search of the FCC's equipment authorization database reveals several hundred certifications for radios capable of operating across both the Federal and non-Federal mobile bands.

[123] Alfred Mann Foundation *ex parte*, ET Docket No. 09-36, filed Sept. 12, 2011 (*AMF 2011 Rules*); Alfred Mann Foundation *ex parte*, ET Docket No. 09-36, filed Sept. 26, 2011.

59. To be able to switch to another frequency band when an existing band becomes unavailable due to high levels of interference, it will be necessary for an MMN to be aware of the potential for interference in all four frequency bands. To that end, we adopt the requirement suggested by AMF that the programmer/controller (P/C) of an MMN monitor all four available frequency bands. For the band in which the MMN is operating, the P/C must check at least once a second for interference so as to be able to switch frequency bands to avoid disabling amounts of interference.[124] Because most of the potential interferers in these bands such as land mobile, BAS, and amateur stations, typically transmit far longer than one second, a once-a-second monitoring interval should be sufficient to detect interfering signals.[125] The P/C must be capable of determining when either direction of the communication link between the P/C and the implanted devices is becoming degraded to the extent that communication is likely to be lost for more than 45 milliseconds. As suggested by AMF, we will require the P/C to move the MMN to another frequency band upon making this determination. As suggested by AMF, we will require the P/C to monitor the other frequency bands often enough such that when it must switch frequency bands it has determined which frequency band is available based on monitoring of that band during the two second period prior to switching. According to AMF, incorporating a requirement to monitor MMN channels prior to executing a channel change "will not materially increase production costs."[126] This is not surprising considering that radios now operating in these bands also have a requirement to monitor channels prior to transmitting on them[127] and that the technology and techniques to accomplish spectrum monitoring in these bands are well established. Thus, we conclude that the benefits of these monitoring requirements far outweigh the expected costs to comply.

60. Because the MMN devices operate with such low power, we do not believe that they will cause interference to other stations sharing the same frequency bands. However, out of an abundance of caution we will adopt one additional monitoring requirement to further reduce the risk of interference. We will require the P/C to switch to another frequency band if during the monitoring of the occupied frequency band it determines that there is a received signal with power greater than -60 dBm in any 12.5 kHz bandwidth being used by the MMN device that persists for at least fifty milliseconds.[128] A received signal of this strength is likely to be caused by a station in close proximity to the P/C. We are using a measurement bandwidth of 12.5 kHz for this determination because this is the signal bandwidth used by all Federal land mobile stations. Non-Federal land mobile operations are currently undergoing a migration from using 25 kHz channels to 12.5 kHz channels, and consequently, in the near future the majority of licensees will also be limited to signal bandwidths of 12.5 kHz.[129] We are choosing this measurement bandwidth based on land mobile stations because they are the most numerous stations that

[124] AMF proposed that the P/C have a mechanism for monitoring the channel or channels that the MMN intends to occupy. *AMF Comments* appendix B, at 2.

[125] Most of the radar signals present in these bands are pulse radars with short duration signals. Because we are requiring that MMN P/Cs only transmit at most three percent of the time, the MMNs should be able to operate in the presence of these radars without switching to another frequency band. *See* paragraph 81, *supra*.

[126] *See* Comments of Alfred Mann Foundation *ex parte*, ET Docket No. 09-36, filed Nov. 15, 2011 at 2-3.

[127] *See*, *e.g.*, 47 C.F.R. § 90.403(e).

[128] AMF and the United States Department of Defense agreed to the -60 dBm threshold and fifty millisecond signal duration. Alfred Mann Foundation *ex parte*, ET Docket No. 09-36, filed Nov. 17, 2011 (*AMF 11/17/11 ex parte*).

[129] Implementation of Sections 309(j) and 337 of the Communications Act of 1934 as Amended, WT Docket No. 99-87, *Second Report and Order and Second Notice of Proposed Rulemaking*, 18 FCC Rcd 3034, 3038-39 para. 12 (2003); 47 C.F.R. § 90.209(b)(5). We note that licensees may still use 25 kHz channels if they employ a technology that achieves the narrowband equivalent of at least one channel per 12.5 kHz of channel bandwidth for voice and transmission rates of at least 4800 bits per second per 6.25 kHz for data systems operating with bandwidths greater than 12.5 kHz (narrowband-equivalent technology).

will share these frequency bands with MMNs.[130] This requirement should prevent the unlikely occurrence of interference from an MMN device to another service sharing the same frequency band.

61. There may occasionally be instances when MMNs may not be able to function because of high levels of interference in all four frequency bands. To account for these infrequent occurrences, the rules we adopt will require that all MMN transmitters incorporate a programmable means to implement a system shutdown process in the event of a communication failure or on command from the P/C. Because MMNs are used to provide therapeutic benefits to patients, such as providing them with a means to move muscles that they would not otherwise be able to move, it is important that we require the MMNs to incorporate a means to implement a pre-defined system shutdown process.[131] We believe that this requirement offers vital benefits to patients and is integral to the success of the MMN system design. Because MMNs are sophisticated electronic devices and the programming necessary to implement a system shutdown process should represent only a portion of the overall design costs, we conclude that the benefits of a system shutdown requirement far outweigh any associated costs. As suggested by AMF, we will require that this shutdown process commence within 45 milliseconds after loss of the communication link or receipt of the shutdown command from the P/C.[132]

62. *Contention Protocol Requirement*. In the *NPRM,* the Commission sought comment on a number of questions related to contention protocols, such as whether a contention protocol should be applied to MMN transmitting devices, what kinds of contention protocols should or should not be used, and how a contention protocol might be developed.[133] A contention protocol would be aimed at allowing multiple MMN systems to share the specified frequency bands without causing interference to each other. This approach differs from the interference mitigation techniques that AMF's MMN devices employ. These techniques are designed to allow the MMNs to function in the presence of interference from other services sharing the same frequency bands. Commenters supported the idea of MMNs using a contention protocol, but no one specified a particular contention protocol that we could adopt. For example, AMF proposed rules that include a requirement that all MMN stations employ the same contention-based protocol but did not define a specific contention-based protocol.[134] The Cleveland FES Center (CFC) encourages the use of an open-source contention protocol, but it offers no particulars regarding the characteristics such a protocol should have, while AMF argues that CFC's proposal is too vague and indefinite to include in the rules.[135] Sienkiewicz points out that if devices use different protocols they may be unable to effectively share the frequency band and stresses the need for one protocol to be used by all devices.[136] He suggests it may be in the public interest to require that a protocol be developed by a particular date.[137] Strother, on the other hand, encourages the Commission to consider adopting general

[130] It is important not to choose a bandwidth greater than 12.5 kHz because this would potentially aggregate the power from multiple stations and result in meeting the -60dBm limit even when the MMN is not in close proximity to any of the stations. We note that other stations operating in these bands such as amateur and BAS stations should also have enough power concentrated within a 12.5 kHz bandwidth to trigger this threshold when in close proximity to an MMN, even though they use larger bandwidth signals.

[131] We will not specify a specific shutdown routine as that will necessarily depend on the function the MMN is designed to perform (*e.g*. restore sensitivity vs. enable movement).

[132] *See* paragraph 51, *supra*.

[133] *NPRM* at 3455-56 paras. 37-39.

[134] *AMF Comments* Appendix B at 5, 6. Motorola states that without details of the contention protocol it cannot provide an opinion as to the effectiveness of the protocol used in the AMF MMNs. *Motorola Comments* at 9.

[135] *Cleveland FES Comments* at 2.

[136] *Sienkiewicz Comments* at 6-7

[137] *Id*. at 11. According to Sienkiewicz, the typical approach to developing a protocol is to form a working group to develop it. *Id*. at 7.

performance requirements, which would allow for the implementation of multiple protocols that might have specific advantages for different applications while ensuring spectrum sharing across device manufacturers and applications.[138]

63. We appreciate that requiring MMNs to use a common contention protocol would enable MMNs to more efficiently share the available spectrum. However, as no commenters have suggested a specific contention protocol, we cannot adopt a requirement for use of a specific contention protocol at this time.[139] We also will not require the development of a contention protocol by a particular date as suggested by Sienkiewicz. Given the novelty of MMN technologies, we are not able to predict when entities other than AMF will develop MMNs for use in these bands and therefore have no grounds to speculate on how and in what timeframe a contention protocol may be developed. We do encourage manufacturers of MMN devices to cooperate in the development of a contention protocol so that the MMN devices may more effectively share the limited available spectrum.[140] If, in the future, parties establish a specific contention protocol that they believe should be applied to these bands, they are welcome to file a Petition for Rulemaking to bring such information to our attention.

64. In the *NPRM,* the Commission also sought comment on using the listen-before-talk (LBT) approach of the existing MedRadio service rules to share spectrum between different MMNs. Under this approach, a transmitting device must monitor a frequency band for the presence of other MedRadio transmitters before beginning transmissions in that frequency band.[141] If a signal with power above a certain threshold is detected, the transmitting device is not allowed to transmit in that frequency band. As we described above, we have adopted a similar requirement with a high power threshold (-60 dBm in a 12.5 kHz bandwidth) to help guard against the unlikely occurrence of interference from MMNs to other services sharing the same frequency band.[142] Use of this high threshold will not be effective in facilitating MMN-to-MMN sharing because MMNs transmit such low power over a wide bandwidth. We will not adopt a similar requirement with a lower LBT threshold because it would interfere with the functioning of the interference mitigation techniques employed by AMF's MMN devices.[143] The MMN devices would not be able to determine whether a detected signal with a power above the LBT threshold is from another MMN or is a signal from another service sharing the same frequency band. Because MMNs should be designed to operate in the presence of a certain level of interference from other services operating in the same frequency band, not transmitting when signals above a lower LBT threshold are present would lead to MMNs not making use of the available spectrum effectively.

65. *Permissible Communications and Operator Eligibility.* In the *NPRM,* the Commission sought comment on restricting implant devices for use by persons only for diagnostic and therapeutic

[138] Comments of Bob Strother, ET Docket 09-36, filed Aug. 12, 2009, at 3 (*Strother Comments*). The performance requirements can include maximum continuous message duration, minimum listen-before-talk monitor intervals, maximum allowable delay between listen-before-talk monitoring intervals, etc.

[139] Considering the fact that AMF has proposed a rule requiring that all MMNs use the same contention protocol, we presume that their MMNs employ such a protocol. However, they have not revealed this protocol in the record. In the *NPRM* the Commission also sought comment on adopting the general definition of contention-based protocol that is used under Part 90 of the rules in the 3650 MHz band. *NPRM* at 3455-56 para. 37. Because we are not requiring use of a contention protocol, we have no need to adopt a definition of a contention-based protocol.

[140] We agree with Sienkiewicz that any common contention protocol that is developed should be available to everyone (*i.e*. published and not encumbered by intellectual property). *Sienkiewicz Comments* at 7.

[141] *See* 47 C.F.R. § 95.628(a); *NPRM* at 3456 para. 38.

[142] *See* paragraph 60, *supra*.

[143] Sienkiewicz questions the appropriateness of a listen-before-talk protocol because of the potentially time critical data in a medical device network. *Sienkiewicz Comments* at 6.

purposes and only to the extent that such devices have been provided to a human patient under the direction of a duly authorized health care professional. This requirement is present in our existing MedRadio rules[144] and is consistent with how we expect MMNs to be used. No one has raised an objection to this requirement. We will therefore apply this restriction for MMNs.

66. The Commission also sought comment on prohibiting the medical implant programmer/controller (P/C) from relaying information to a receiver that is not included with a medical implant device. This prohibition is included in the existing MedRadio rules. AMF states that the restriction preventing MedRadio programmer/controllers from relaying information to a receiver not included in a medical implant device should not apply to MMNs so that different MMNs can exchange information to mitigate potential interference between the MMNs.[145] Sienkiewicz agrees that different programmer/controllers should be able to communicate with each other.[146]

67. We will allow P/Cs in different MMNs to communicate with each other for the purposes of coordination of the use of the spectrum resource. This differs from our existing MedRadio rules, which prohibit controller-to-controller communication. We expect that each MMN will use a spectrum band for short periods of time as is the case for AMF's MMNs.[147] Because of this, multiple MMNs should be able to share a frequency band without causing interference to each other. If the P/Cs for different MMNs from the same manufacturer are able to communicate with each other, they can coordinate their networks' respective transmissions to avoid transmitting at the same time in the same frequency bands.

68. While we will allow P/C-to-P/C communications to facilitate sharing of the scarce spectrum resource, we will not permit P/Cs to communicate with non-implanted devices for other purposes. This will prevent the 413-457 MHz spectrum from being used as backhaul to move data from an MMN to devices outside the network. This is the rule currently in place for MedRadio devices under our existing rules and is needed because the 413-457 MHz band remains reserved only for those medical applications that cannot be achieved in other spectrum and allowing other transmissions would cause undesirable spectrum congestion.[148]

69. The Commission also sought comment in the *NPRM* on whether implant-to-implant communications should be allowed, whether each programmer/controller must always control the transmitters implanted in a single patient, and whether all implants in a patient must be controlled by a single programmer/controller. Bob Strother (Strother) and the Cleveland FES Center suggest that we adopt rules permitting implant-to-implant communication.[149] Sienkiewicz agrees, noting that there is substantial research into how multiple independent units can cooperate without a central control system.[150] AMF disagrees because this would be a significant departure from the MedRadio rules, which AMF argues properly serve to manage RF transmissions to and from implant devices.[151] Sienkiewicz also suggests that multiple MMNs with separate controllers should be allowed in a single patient and that a

[144] 47 C.F.R. § 95.1201.

[145] *AMF Comments* at 15.

[146] *Sienkiewicz Comments* at 3.

[147] *See* discussion of maximum duty cycle in paragraph 81, *supra*. *AMF 2011 Rules* at 2.

[148] 47 C.F.R. § 95.1209(e). The transmission of data from a P/C to devices outside the body does not require the use of the 413-457 MHz band with its favorable in-body propagation characteristics because the transmissions will occur outside of the human body.

[149] *Cleveland FES Comments* at 2; *Strother Comments* at 2.

[150] *Sienkiewicz Comments* at 3-4.

[151] *AMF Reply* at 15.

single programmer/controller should be able to control implants in more than one patient.[152]

70. We will not permit implant-to-implant communications. In making the decision to allow MMNs to use spectrum in the 413-457 MHz band, we have been favorably impressed by the interference mitigation techniques that AMF has demonstrated in the independent test described in the Aerospace Report. The system tested relied on a P/C external to the body to schedule the implant transmissions in accordance with these mitigation techniques. We have no evidence on the record that MMNs can successfully mitigate the effects of interference if implants are permitted to communicate with each other outside the control of a P/C. As a result, we cannot reach the conclusion that such a network would be able to function in these bands with the incumbent services.

71. We will allow multiple MMNs to exist within a single patient with each network having its own separate P/C. The configuration of the networks for a particular patient should be determined by the medical needs of the patient and the limits of existing technology. This may require the use of different networks to accomplish different functions. On the other hand, we will not permit a P/C to control implanted devices in multiple patients. Given the power limits of the MMN devices, we expect that the P/C will have to be within a few meters of the patient at all times. Allowing a single P/C to control implants in more than one patient would require the patients to remain in close proximity at all times, which does not appear to be practical. No commenter has suggested a scenario for which such an accommodation would be useful.

72. *Emission Bandwidth*. In the *NPRM,* we sought comment on the maximum emission bandwidth that should be allowed for MMN devices.[153] Each of the four segments of the 413-457 MHz band allocated in this proceeding for use by MMN devices occupies six megahertz of spectrum. Alternatively, we also sought comment on whether a smaller maximum emission bandwidth (*e.g.,* three megahertz) might be sufficient for MMN purposes and might further improve spectrum use and efficiency.

73. AMF has submitted proposed rules that specify a five-megahertz maximum emission bandwidth.[154] Sienkiewicz states that there is no point to having a six-megahertz band limited to five megahertz signals and that the rules should not be limited to the minimum requirements for AMF's devices.[155] Strother believes that a three-megahertz bandwidth is reasonable for any application conceivable at this time.[156]

74. We shall adopt a maximum emission bandwidth of six megahertz. We see no reason to limit the emission bandwidth to three or five megahertz considering that we are allocating six megahertz bands for use by MMNs. This will provide flexibility for future, more efficient system design. We note that the maximum emission bandwidth of the MMN signals will also be constrained by the unwanted emission limits that we are adopting.[157]

75. *Channelization*. In the *NPRM,* the Commission suggested that one approach to channelization would be to adopt rules that do not specify any particular channeling plan, thereby

[152] *Sienkiewicz Comments* at 3-4.

[153] *NPRM* at 3454 para. 35.

[154] *AMF Comments* Appendix B at 3.

[155] *Sienkiewicz Comments* at 5.

[156] *Strother Comments* at 2.

[157] *See* paragraph 82, *infra*.

following the approach used with the existing MedRadio Service.[158] We sought comment on whether we should require a specific channel plan.

76. In the rules that AMF proposed, the MMN devices would transmit with a specified center frequency and channel boundaries in each of the four proposed frequency bands.[159] The Cleveland FES Center suggests that the Commission not specify a channel plan.[160] Sienkiewicz points out that channelization can lead to more efficient use of spectrum, but only if devices are designed to cooperate in the use of the channels.[161] He states that if the four frequency bands are subdivided into channels this will raise the issue of what to do with devices that need more bandwidth than a single channel.

77. No parties have suggested a channelization plan other than AMF's proposal for centering the signals in each of the four bands. Given that no parties have suggested a channelization plan, we have no grounds for adopting one, nor do we see any reason to specify that emissions be based around a center frequency in each of the four bands as AMF has proposed. Because MMN manufacturers will have to design equipment to operate on specific frequencies, we recognize that there would be little or no added equipment design cost if we were to specify a particular channel plan or center frequency. Nevertheless, we see no benefit in doing so, as it would limit the flexibility available for future system design. Accordingly, we will not adopt rules specifying a channelization plan for MMN devices.

78. *Transmitter Power*. In the *NPRM,* the Commission sought comment on the appropriate transmitted power for MMNs.[162] AMF suggested in its petition that each implantable microstimulator could be limited to a maximum EIRP of 200 microwatts and each P/C transmitter could be limited to a maximum EIRP of 1 milliwatt. In the draft rules it submitted with its petition, AMF proposed transmitter power limits that did not distinguish between implant and P/C maximum power levels. These rules would require that the MedRadio transmitters be limited to a maximum EIRP of the lesser of 1 milliwatt or (10 log B – 6.866) dBm, where B is the 20 dB emission bandwidth of the transmitted signal in MHz and that the peak power spectral density shall not exceed 800 microwatts per MHz in any 1 MHz band. No commenters specifically addressed AMF's proposed power limits. The *NPRM* also sought comment on what measurement methods would be appropriate for establishing compliance with the EIRP limits, whether there should be an upper limit on the number of devices in an MMN, whether the EIRP of devices should be aggregated in some manner, and if we should consider any other operational factors.

79. We shall adopt the transmitter power limits in AMF's proposed rules with one minor change to reflect the fact that we are allowing MMNs to use a six megahertz maximum emission bandwidth instead of a five megahertz emission bandwidth as AMF proposed. We will limit the maximum EIRP of any MMN transmitter to the lesser of 1 mW or (10 log B – 7.782) dBm where B is the 20 dB emission bandwidth of the transmitted signal in MHz. As discussed above, we believe that these devices transmitting at these power limits will not cause interference to other services in the 413-457 MHz band. The rules we adopt will apply the same transmitter power limits to both implanted transmitters and the P/C transmitter. We see no reason to apply a stricter power limit to implanted transmitters considering that the signals from these devices will be attenuated by body tissue. For this reason an implanted transmitter is even less likely to cause interference than a P/C transmitter operating at the same power level. We will also not place a limit on the number of devices in an MMN network or aggregate the powers of the devices. No one has suggested a limit on the number of devices or how the power of

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

[159] *AMF Comments* Appendix B at 2.

[160] *Cleveland FES Comments* at 2.

[161] *Sienkiewicz Comments* at 6.

[162] *NPRM* at 3456-57 paras. 41-42.

multiple devices may be aggregated. We note that because the implant devices in an MMN will only transmit under the control of the P/C, as a practical matter only one implant device in an MMN would transmit at any one time.[163] Consequently, we see no need to aggregate the powers of the multiple devices in the MMN for purposes of establishing a transmitter power limit.

80. *Duty Cycle.* In the NPRM, the Commission sought comment on the appropriate duty cycle requirements for MMNs.[164] In its petition AMF stated that "each implanted microstimulator transmits data for approximately *5* microseconds every 11 milliseconds and receives data for approximately 6 microseconds every 11 milliseconds (*i.e.,* less than 0.05 percent transmit duty cycle). For a system with 10 to 20 implanted microstimulators, the transmit duty cycle of the MCU is approximately 3 percent."[165] AMF made a similar statement in its comments filed subsequent to the NPRM when describing the operation of its prototype MMNs, but it did not include a duty cycle specification in the rules it concurrently proposed.[166] In a recent *ex parte* submission, AMF indicated that it had reached agreement with the United States Department of Defense that a 3 percent maximum duty cycle for P/Cs would be appropriate.[167]

81. We find that it is important to specify a maximum duty cycle for MMNs. Because each P/C will occupy a frequency band for a fraction of the time, other MMNs will be able to make use of the frequency band during the remainder of the time, thus facilitating sharing among multiple MMNs. Specifying a maximum duty cycle will also help the MMNs share the frequency bands with pulse radars with short duration signals that are present in the 426-432 MHz and 438-444 MHz bands.[168] As discussed above, based on the JSC Report and Aerospace Report, we have concluded that the record demonstrates that MMNs can operate on a compatible secondary basis with primary Federal systems in these bands.[169] The JSC Report assumed a P/C duty cycle of 3 percent in conducting the analysis that concluded that MMNs would be operationally compatible and not cause interference to Federal systems.[170] Because we have no information on how the conclusions of the JSC Report would be affected if the P/C duty cycle were allowed to rise above 3 percent, and in recognition of the concurrence of AMF and the Department of Defense that a 3 percent maximum duty cycle is appropriate for MMNs, we adopt rules that specify a maximum duty cycle of 3 percent for P/Cs.

82. *Unwanted Emissions*. The existing MedRadio rules under Part 95 set limits on unwanted emissions from medical transmitting devices operating in the 401-406 MHz band.[171] As delineated therein, these provisions include limits on both in-band and out-of-band radiation. AMF has proposed

[163] Even in cases where multiple MMNs are operating in close proximity (such as two MMNs in the same person), these devices would still be implanted, small in number, and would not necessarily be operating simultaneously.

[164] *NPRM* at 3456-57 paras. 41-43. Duty cycle is the proportion of time during which a device is operated. The duty cycle can be expressed as a ratio or as a percentage.

[165] *AMF Petition* at 17.

[166] *AMF Comments* at 9. AMF also did not include a duty cycle specification with the rules it proposed when it submitted its petition. In a subsequent submission, it proposed a maximum duty cycle for P/Cs of 10 percent but did not discuss how it arrived at this number. *See AMF 2011 Rules* at 2.

[167] *AMF 11/17/11 ex parte.*

[168] Letter from the National Telecommunications Infrastructure Administration, WT Docket 09-36, filed Feb. 27, 2009, at 2-5.

[169] *See* paragraph 42, *supra*.

[170] *JSC Report* at 13.

[171] *See* 47 C.F.R. § 95.635(d).

emissions limits that are similar to the existing MedRadio rules.[172] No parties commented on the unwanted emissions limits. The rule we adopt applies these emissions limits to these frequency bands. Under this approach, in the first 2.5 megahertz beyond any of the frequency bands authorized for MMN operation, the EIRP level associated with any unwanted emission must be attenuated within a 1 megahertz bandwidth by at least 20 dB relative to the maximum EIRP level within any 1 megahertz of the fundamental emission.[173] In addition, emissions more than 2.5 megahertz outside of the authorized bandwidth must meet the frequency-dependent set of electric field strength limits of new Section 95.635(d)(1)(iv) of the rules as set forth in Appendix A.[174]

83. *Frequency Stability*. In the *NPRM,* we sought comment on whether each MMN transmitter should be required to maintain a frequency stability as specified in the current MedRadio rules of +/- 100 ppm of the operating frequency over the range: (1) 25°C to 45°C in the case of MMN implant transmitters; and (2) 0°C to 55°C in the case of MMN programmer/control transmitters. AMF suggested extending this existing frequency stability criterion in its rulemaking petition.[175] Sienkiewicz argues that a frequency stability requirement is unnecessary if there is no channelization scheme and that devices from different manufacturers do not need to talk to each other (*i.e*., if there is no common contention protocol). Even if a frequency stability criterion is needed, he thinks that the criterion can be ten times more relaxed than the suggested standard, but he acknowledges that the +/- 100 ppm standard is common in off-the-shelf oscillators.[176]

84. The +/- 100 ppm frequency stability criterion is the standard for MedRadio devices in the current rules and represents good engineering practice. As Sienkiewicz acknowledges, oscillators that meet this standard are readily available. AMF, which has built functioning equipment, believes it is an appropriate standard. We agree and see no reason to depart from the current MedRadio frequency stability criterion. We will apply this standard to MMN devices.

85. *Antenna Locations*. In the *NRPM,* we sought comment on applying the existing MedRadio requirement that no antenna for a control transmitter be configured for permanent outdoor use.[177] No one objected to this proposal, and we will retain this rule for MMNs. Additionally, ARRL stated that only portable, body-worn MMN devices should be permitted and that no fixed antenna is appropriate in this frequency range.[178] The rules we adopt permit only MMNs that contain implanted devices and a programmer/controller transmitter to operate in the MedRadio Service in these frequency bands and the limited transmit power permitted under our rules will limit the programmer/controller to locations on or in close proximity to the patient. Because the rules will effectively restrict MMNs to portable body-worn devices and preclude the use of fixed antennas, we conclude that it is unnecessary for us to adopt a new

[172] *AMF Comments* Appendix B at 4-5. We note that AMF proposed different frequency ranges for these unwanted emission limits when it filed its petition. *AMF Petition* Appendix A at 5. We mentioned these earlier proposed frequency ranges in the *NPRM*. *NRPM* at 3457 at para. 46. We are basing our adopted rules on AMF's later submitted proposed rules.

[173] For example, for the 413-419 MHz band, emissions below 410.5 MHz and above 421.5 MHz would have to be at least 20 dB below the transmitter output power.

[174] These frequency dependent limits are the same frequency dependent field strength limits presently specified in Section 95.635(d)(1) for the MedRadio Service.

[175] *AMF Petition* Appendix A at 4.

[176] *Sienkiewicz Comments* at 9-10.

[177] Under the existing MedRadio rules, any MMN control transmitter used outdoors would not be allowed to 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. 47 C.F.R. § 95.1213.

[178] *ARRL Comments* at 15.

rule containing these restrictions..

86. *RF Safety.* In the *NPRM,* the Commission noted that portable devices are subject to Section 2.1093 of its rules, pursuant to which an environmental assessment must be prepared under Section 1.1307, and that these rule sections also govern existing MedRadio devices.[179] The Commission further noted that its ongoing RF safety proceeding (ET Docket No. 03-137) anticipated dealing with proposed changes in the Commission's rules regarding human exposure to RF electromagnetic fields in a more comprehensive fashion. The *NPRM* only sought comment on whether MMN implant and programmer/controller transmitters should be deemed portable devices subject to Sections 2.1093 and 1.1307 of the existing rules. No commenters addressed this issue. Because existing MedRadio devices are considered portable devices and we have no reason to treat MMN devices differently, we shall deem MMN devices to be portable devices subject to sections 2.1093 and 1.1307 of our rules.[180]

87. The ARRL stated that "no rules should be enacted without a comprehensive series of field tests that assure patient safety in the presence of typical RF fields in the bands at issue in this proceeding."[181] To the extent that these comments relate to RF safety matters, they are misplaced.[182] Given the ongoing Commission proceeding on RF safety in ET Docket 03-137, the *NPRM* did not request duplicative comment in this proceeding. Rather, the only question we raised in the *NPRM* that implicated RF safety concerns was the categorization issue, *i.e.*, whether MMN devices should be subject to the RF exposure limits applicable to portable devices, as are other MedRadio devices,[183] or the limits applicable to mobile devices.[184] Consequently, because matters concerning RF safety are more appropriately addressed in ET Docket 03-137 and not here ARRL should raise any specific concerns it has regarding RF safety directly in ET Docket 03-137.

88. *Miscellaneous Provisions*. In the *NPRM,* we sought comment on a number of provisions regarding equipment certification, authorized locations, station identification, station inspection, disclosure policy, labeling requirements, and marketing limitations that mirror the existing MedRadio rules.[185]

89. As the Commission proposed in the *NPRM*, we will require each MMN transmitter authorized to operate in the 413-457 MHz band to be certificated.[186] This requirement will not apply to transmitters that are not marketed for use in the United States, are being used in the United States by individuals who have traveled to the United States from abroad, and comply with the applicable technical

[179] *NPRM* at 3458 para. 49.

[180] The AMF petition proposed that references to MMNs be added to sections 1.1307 and 2.1093 of our rules regarding environmental assessments and radiofrequency radiation exposure, respectively. *AMF Petition* Appendix A at 1-2. Because MMNs are treated as part of the MedRadio Service and MedRadio is listed in these sections, we do not need to amend these rules.

[181] *ARRL Comments* at 10.

[182] Because ARRL's reference to "patient safety" is in a portion of its comments that address the interference susceptibility of MMNs, it is not clear whether it is raising specific RF safety concerns. Insofar as ARRL is only talking about the ability of MMNs to operate as designed (and therefore avoid harm to patients), we are convinced that they will be able to do so. *See* footnote 90, *supra*.

[183] *See NPRM*, 24 FCC Rcd at 3458 para. 49. *See also* 47 C.F.R. §§ 2.1093, 1.1307, 95.1221. Section 2.1093 defines "portable devices" as devices that are used within 20 cm of the body of the user.

[184] *See* 47 C.F.R. §§ 2.1091. Section 2.1091 defines "mobile devices" as devices other than those to be operated at a fixed location and are used more than 20 cm away from the body of the user.

[185] *NPRM* at 3458-59 paras. 50-55; 47 C.F.R. §§ 95.1203-07, 95.1215-19.

[186] 47 C.F.R. § 95.603(f).

requirements. We will also adopt the proposals in the *NPRM* that MedRadio devices in the 413-457 MHz band be authorized to operate anywhere CB station operation is authorized under § 95.405 and not be required to transmit a station identification announcement.[187] In addition, we will apply the existing MedRadio rule that requires that all non-implanted MMN transmitters be made available for inspection upon request by an authorized FCC representative.[188] Under this provision, persons operating implanted MMN transmitters are required to cooperate reasonably with duly authorized FCC representatives in the resolution of interference. These requirements are all the same as the existing MedRadio rules for the 401-406 MHz band. No commenters objected to any of these proposals.

90. In the *NPRM,* the Commission sought comment on whether to require the manufacturers of MMN transmitters to include with each transmitting device the following disclosure statement:

> This transmitter is authorized by rule under the MedRadio Service (47 C.F.R. Part 95). This transmitter must not cause harmful interference to stations authorized to operate on a primary basis in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands, 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 MedRadio 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.[189]

The Commission also sought comment on requiring that MMN programmer/control transmitters be labeled and bear the following statement in a conspicuous location on the device:

> This device may not interfere with stations authorized to operate on a primary basis in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands, and must accept any interference received, including interference that may cause undesired operation.[190]

The Commission did not propose an analogous labeling requirement for implant transmitters but instead sought comment on whether to require that the implant transmitters be identified with a serial number.[191]

91. The ARRL argues that the certification process should include regulation of the written information that should be provided to patients and medical providers regarding the interference susceptibility of the devices.[192] According to the ARRL, the disclosure and labeling language proposed in the *NPRM* are insufficient and are an abdication of the Commission's obligation to patients to place MMN devices in a band where they will not receive harmful interference or malfunction in the presence of strong RF signals. SBE complains that Part 15 type disclaimers as proposed in the *NPRM* are useless once the devices are implanted.[193] SBE considers the proposed notices an abdication of the Commission's obligation to make spectrum allocations based on a finding that the interference potential is predictably low and that merely stating there is no guarantee a device will function correctly is

[187] 47 C.F.R. §§ 95.1203, 95.1205. CB radio operation is operation is permitted in any area of the world where radio services are regulated by the Commission. 47 C.F.R. § 95.405.

[188] 47 C.F.R. § 95.1207. For MMNs this provision will apply only to programmer/control transmitters.

[189] See *NPRM* at 3458 para. 53; 47 C.F.R. § 95.1215.

[190] See *NPRM* at 3459 para. 54; 47 C.F.R. § 95.1217. The Commission's rules require that any equipment covered in an application for equipment authorization bear a nameplate or label that contains an FCC identifier and any other statement or labeling imposed by the rules. 47 C.F.R. § 2.925(a).

[191] *See* 47 C.F.R. § 95.1217(c).

[192] *ARRL Comments* at 14.

[193] *SBE Comments* at 7.

unacceptable. Sienkiewicz believes that the proposed notice may not be blunt enough for the average user and proposes text that is not "legal-sounding."[194] He suggests that the regulations require that users be warned that interference may occur, even if it is unlikely, and that MMNs must be operated so that they do not pose a risk to others.

92. Both ARRL and SBE base their opposition to our proposed notice and labeling requirements at least in part on the fact that the MMN devices cannot be guaranteed to function at all times because of possible interference from other services in these bands. We have addressed this concern above and therefore have no need to discuss this issue further.[195] We also do not believe that the proposed labeling will be "useless" once the implanted MMN devices are placed within the body because only the P/C transmitter will bear a label, and it will not be implanted in the body. The proposed disclosure and labeling statements are based on the requirements for the MedRadio Services (and the MICS before that) that have been in place since 1999.[196] These notices have served us well since that time, and we see no reason to change them now. We note that MMN devices are medical devices which will be used only under the direction of knowledgeable medical personnel. As such, the notices are not aimed at consumers but instead at medical professionals who are in the best position to give appropriate patient advice. We therefore believe that the notice and labeling requirements are sufficient and will adopt them as proposed. These disclosure and labeling requirements provide an important benefit to medical professionals by warning of the secondary status of the MMN devices. These requirements are consistent with those that are in place for similar medical devices that are authorized under the Commission's rules, and so the costs should be similar. Therefore, we see no reason why disclosure and labeling requirements should be more burdensome in the case of MMNs.

93. No one commented on the proposal that implant transmitters be identified with a serial number. This is the same requirement that MedRadio devices must meet under our existing rules. We therefore adopt this requirement. Doing so will make it easier to identify particular MMN implant devices, and this information is limited enough to be placed on tiny devices. As proposed, we will allow the FCC ID number associated with the transmitter and the information required by Section 2.925 of the FCC Rules to be placed in the instruction manual for the transmitter in lieu of being placed directly on the transmitter.

94. In the *NPRM* the Commission also proposed to provide that MMN transmitters intended for operation in any portions of the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands may be marketed and sold only for those permissible uses described above.[197] No one objected to this proposal, which currently is part of the existing MedRadio rules. Given our expressed intent to limit use of these frequency bands to MedRadio applications that cannot be achieved in other spectrum, we believe that this requirement is necessary, and we therefore adopt it.

IV. PROCEDURAL MATTERS

95. *Further Information*: For further information, contact Peter Georgiou, Office of Engineering and Technology, at (202) 418-8130, or Nicholas Oros, Office of Engineering and Technology, at (202) 418-0636, Federal Communications Commission, 445 12th Street, SW, Washington, DC 20554; or via the Internet at Peter.Georgiou@fcc.gov or Nicholas.Oros@fcc.gov, respectively.

[194] *Sienkiewicz Comments* at 9.

[195] *See* paragraphs 49-52, *supra*.

[196] The MICS rules were adopted in 1999 and were replaced by the MedRadio rules in 2009. *MICS R&O*; *MedRadio R&O*; 47 C.F.R. §§ 95.1215, 95.1217.

[197] 47 C.F.R. § 95.1219.

96. *Regulatory Flexibility Analysis.* A Final Regulatory Flexibility Analysis has been prepared for this Report and Order and is included in Appendix B.

97. *Paperwork Reduction Act.* This document does not contain proposed information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104-13.[198] 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).

V. ORDERING CLAUSES

98. Accordingly, IT IS ORDERED that pursuant to the authority contained in Sections 4(i), 301, 302, 303(e), 303(f), 303(r), and 307(e) of the Communications Act of 1934, as amended, 47 USC Sections 154(i), 301, 302, 303(e), 303(f), 303(r), and 307(e), 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 30 days after publication in the Federal Register.

99. 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 B, to the Chief Counsel for Advocacy of the Small Business Administration.

FEDERAL COMMUNICATIONS COMMISSION

Marlene H. Dortch
Secretary

[198] The proposed labeling and disclosure requirements do not qualify as information collections under the PRA. 5 C.F.R. § 1320.3(c)(2).

APPENDIX A

Final Rules

For the reasons discussed above, the Federal Communications Commission amends title 47 of the Code of Federal Regulations, Parts 2 and 95, as follows:

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

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

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

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

a. Pages 26-28 are revised.

b. In the list of United States (US) Footnotes, footnote US64 is added and footnote US345 is removed.

§ 2.106 Table of Frequency Allocations.

The revisions and additions 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 5.208B 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) US320 US324 SPACE RESEARCH (space-to-Earth) 5.263 Space operation (space-to-Earth) 5.264 US319	Satellite Communications (25)
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UNITED STATES (US) FOOTNOTES

* * * * *

US64 (a) In the band 401-406 MHz, the mobile, except aeronautical mobile, 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.

(b) The bands 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz are also allocated on a secondary basis to the mobile, except aeronautical mobile, service. The use of this allocation is limited to MedRadio operations. MedRadio stations are authorized by rule and operate in accordance with 47 CFR part 95.

* * * * *

PART 95 – PERSONAL RADIO SERVICES

SUBPART E – TECHICAL REGULATIONS

3. The authority citation for Part 95 continues to read as follows:

Authority: Secs. 4, 303, 48 Stat, 1068, 1032, as amended; 47 U.S.C. 154, 303.

4. Section 95.627 is redesignated as Section 95.626, and Section 95.628 is redesignated as Section 95.627.

§ 95.626 FRS unit channel frequencies.

* * * * *

5. Newly redesignated Section 95.627 is amended by revising the heading and introductory text to read as follows:

§ 95.627 MedRadio transmitters in the 401-406 MHz band.

The following provisions apply only to MedRadio transmitters operating in the 401-406 MHz band.

* * * * *

6. New Section 95.628 is added to read as follows:

§ 95.628 MedRadio transmitters in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands.

The following provisions apply only to MedRadio transmitters operating in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands as part of a Medical Micropower Network (MMN).

(a) *Operating frequency.* Only MedRadio stations that are part of an MMN may operate in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz frequency bands. Each MedRadio station that is part of an MMN must be capable of operating in each of the following frequency bands: 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz. All MedRadio stations that are part of a single MMN

must operate in the same frequency band. A MedRadio station authorized under this part must have out-of-band emissions that are attenuated in accordance with §95.635.

(b) *Frequency monitoring.* MedRadio programmer/control transmitters must incorporate a mechanism for monitoring the authorized bandwidth of the frequency band that the MedRadio transmitters intend to occupy. The monitoring system antenna shall be the antenna used by the programmer/control transmitter for a communications session.

(1) The MedRadio programmer/control transmitter shall be capable of monitoring any occupied frequency band at least once every second and monitoring alternate frequency bands within two seconds prior to executing a change to an alternate frequency band.

(2) The MedRadio programmer/control transmitter shall move to another frequency band within one second of detecting a persistent (*i.e.,* lasting more than 50 milliseconds in duration) signal level greater than -60 dBm as received by a 0 dBi gain antenna in any 12.5 kHz bandwidth within the authorized bandwidth.

(3) The MedRadio programmer/control transmitter shall be capable of monitoring the authorized bandwidth of the occupied frequency band to determine whether either direction of the communications link is becoming degraded to the extent that communications is likely to be lost for more than 45 milliseconds. Upon making such a determination the MedRadio programmer/control transmitter shall move to another frequency band.

(c) MedRadio transmitters shall incorporate a programmable means to implement a system shutdown process in the event of communication failure, on command from the MedRadio programmer/control transmitter, or when no frequency band is available. The shutdown process shall commence within 45 milliseconds after loss of the communication link or receipt of the shutdown command from the MedRadio programmer/control transmitter.

(d) MedRadio programmer/control transmitters shall have the ability to operate in the presence of other primary and secondary users in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands.

(e) *Authorized bandwidth*. The 20 dB authorized bandwidth of the emission from a MedRadio station operating in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands shall not exceed 6 MHz.

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

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

(2) 0 °C to 55 °C in the case of MedRadio programmer/control transmitters

(g) *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.

(h) *Measurement procedures.* (1) MedRadio transmitters shall be tested for frequency stability, radiated emissions and EIRP limit compliance in accordance with paragraphs (h)(2) and (h)(3) of this section.

(2) Frequency stability testing shall be performed over the temperature range set forth in (f) of this

section.

(3) Radiated emissions and EIRP limit measurements 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 1 milliwatt, 25 microwatts, 250 nanowatts, and 100 nanowatts EIRP is 115.1, 18.2, 1.8, or 1.2 mV/meter, respectively, when measured on an open area test site; or 57.55, 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. Compliance with the maximum transmitter power requirements set forth in §95.639(f) shall be based on measurements using a peak detector function and measured over an interval of time when transmission is continuous and at its maximum power level. In lieu of using a peak detector function, measurement procedures that have been found to be acceptable to the Commission in accordance with §2.947 of this chapter may be used to demonstrate compliance.

(A) 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).

7. 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. For stations operating in 401.85–402 MHz, the maximum authorized emission bandwidth is 150 kHz. For stations operating in 413- 419 MHz, 426-432 MHz, 438-444 MHz, or 451-457 MHz, the maximum authorized emission bandwidth is 6 megahertz.

(2) Lesser emission bandwidths may be employed, provided that the unwanted emissions are attenuated as provided in §95.635. See §§95.627(g), §95.628(h), and 95.639(f) regarding maximum transmitter power and measurement procedures.

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

* * * * *

8. Section 95.635 is amended by revising paragraph (d) to read as follows:

95.635 Unwanted radiation.

* * * * *

(d) For transmitters designed to operate in the MedRadio service, emissions shall be attenuated in accordance with the following:

(1) Emissions from a MedRadio transmitter shall be attenuated to a level no greater than the field strength limits shown in the following table when they:

(i) Are more than 250 kHz outside of the 402–405 MHz band (for devices designed to operate in the 402-405 MHz band);
(ii) Are more than 100 kHz outside of either the 401–402 MHz or 405–406 MHz bands (for devices designed to operate in the 401–402 MHz or 405–406 MHz bands);
(iii) Are in the 406.000-406.100 MHz band (for devices designed to operate in the 401–402 MHz or 405–406 MHz bands); or
(iv) Are more than 2.5 MHz outside of the 413-419 MHz, 426-432 MHz, 438-444 MHz, or 451-457 MHz bands (for devices designed to operate in the 413-457 MHz band).

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) The emission limits shown in the table of paragraph (d)(1) 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.

(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) For devices designed to operate in the 402-405 MHz band: Emissions within the band more than 150 kHz away from the center frequency of the spectrum the transmission is intended to occupy and emissions 250 kHz or less below 402 MHz or above 405 MHz band will be attenuated below the maximum permitted output power by at least 20 dB.

(5) For devices designed to operate in the 401–402 MHz or 405–406 MHz bands: Emissions between 401–401.85 MHz or 405–406 MHz within the MedRadio bands that are more than 50 kHz away from the center frequency of the spectrum the transmission is intended to occupy (or more than 75 kHz away from the center frequency of MedRadio transmitters operating between 401.85–402 MHz) and emissions 100 kHz or less below 401 MHz or above 406 MHz shall be attenuated below the maximum permitted output power by at least 20 dB.

(6) For devices designed to operate in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands: In the first 2.5 megahertz beyond any of the frequency bands authorized for MMN operation, the EIRP level associated with any unwanted emission must be attenuated within a 1 megahertz bandwidth by at least 20 dB relative to the maximum EIRP level within any 1 megahertz of the fundamental emission.

(7) Compliance with the limits described in subparagraphs (4) through (6) are 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.

* * * * *

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

§95.639 Maximum transmitter power.

* * * * *

(f) In the MedRadio Service:

(1) For transmitters operating in the 401-406 MHz band that are not excepted under § 95.627(b) from the frequency monitoring requirements of § 95.627(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 § 95.627(b) from the frequency monitoring requirements of § 95.627(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, 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 the power radiated by any station operating in 401.85-402 MHz shall not exceed 25 microwatts in the 150 kHz bandwidth. See §§ 95.633(e).

(2) For transmitters operating in 413-419 MHz, 426-432 MHz, 438-444 MHz, or 451-457 MHz bands, the peak EIRP over the frequency bands of operation shall not exceed the lesser of 1 mW or 10 log B – 7.782 dBm, where B is the 20 dB emission bandwidth in MHz; and the peak power spectral density shall not exceed 800 microwatts per megahertz in any 1 megahertz band.

(3) 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 § 95.627(g) or § 95.628(h), as applicable.

* * * * *

10. Appendix 1 is amended by adding the new definition " Medical Micropower Network" to the definitions list in alphabetical order:

Appendix 1 to Subpart E of Part 95—Glossary of Terms

Medical Micropower Network (MMN). An ultra-low power wideband network consisting of a MedRadio programmer/control transmitter and medical implant transmitters, all of which transmit or receive non-voice data or related device control commands for the purpose of facilitating functional electric stimulation, a technique using electric currents to activate and monitor nerves and muscles.

Subpart I – Medical Device Radiocommunications Service (MedRadio)

11. Section 95.1209 is amended by revising paragraphs (b), (d), and (e) and by adding new paragraphs (f) and (g) to read as follows:

§95.1209 Permissible communications.

* * * * *

(b) Except as provided in §95.627(b) no MedRadio implant or body-worn transmitter shall transmit except in response to a transmission from a MedRadio programmer/control transmitter or in response to a non-radio frequency actuation signal generated by a device external to the body with respect to which the MedRadio implant or body-worn transmitter is used.

* * * * *

(d) For the purpose of facilitating MedRadio system operation during a MedRadio communications session, as defined in § 95.627, MedRadio transmitters in the 401-406 MHz band may transmit in accordance with the provisions of § 95.627(a) for no more than 5 seconds without the communications of data; MedRadio transmitters may transmit in accordance with the provisions of § 95.627(b)(2) and (b)(3) for no more than 3.6 seconds in total within a one hour time period; and MedRadio transmitters may transmit in accordance with the provisions of § 95.627(b)(4) for no more than 360 milliseconds in total within a one hour time period.

(e) MedRadio programmer/control transmitters may not be used to relay information in the 401-406 MHz band 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 401-406 MHz band.

(f) MedRadio programmer/control transmitters and medical implant transmitters may not be used to relay information in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands to a receiver that is not part of the same Medical Micropower Network. Wireless retransmission of information to a receiver that is not part of the same Medical Micropower Network must be performed using other radio services that operate in spectrum outside of the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands. Not withstanding the above restrictions, a MedRadio programmer/control transmitter of an MMN may communicate with the MedRadio programmer/control transmitter of another MMN to coordinate transmissions so as to avoid interference between the two MMNs.

(g) MedRadio programmer/control transmitters operating in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands shall not transmit with a duty cycle greater than 3 percent.

12. Section 95.1211 is amended by revising paragraphs (b) and (c) as to read as follows:

§ 95.1211 Channel use policy.

* * * * *

(b) To reduce interference and make the most effective use of the authorized facilities, MedRadio transmitters must share the spectrum in accordance with §§ 95.627 or 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, or to other authorized stations operating in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands. 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, and from other authorized stations operating in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands.

13. Section 95.1215 is amended to read as follows:

§ 95.1215 Disclosure policies.

(a) Manufacturers of MedRadio transmitters operating in the 401-406 MHz band 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."

(b) Manufacturers of MedRadio transmitters operating in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands must include with each transmitting device the following statement:

"This transmitter is authorized by rule under the MedRadio Service (47 C.F.R. Part 95). This transmitter must not cause harmful interference to stations authorized to operate on a primary basis in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands, 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 MedRadio 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."

14. Section 95.1217 is amended by revising paragraph (a) to read as follows:

§ 95.1217 Labeling requirements.

(a) (1) MedRadio programmer/control transmitters operating in the 401-406 MHz band 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

(2) MedRadio programmer/control transmitters operating in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands 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 authorized to operate on a primary basis in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands, 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.

* * * * *

APPENDIX B

Final Regulatory Flexibility Analysis

1. As required by the Regulatory Flexibility Act of 1980, as amended (RFA),[1] an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the Notice of Proposed Rulemaking (*NPRM*).[2] The Commission sought written public comment on the proposals in the *NPRM*, including comment on the IRFA. No comments were received addressing the IRFA. This present Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.[3]

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

2. The Report and Order (*R&O*) expands the Medical Device Radiocommunication (MedRadio) Service under Part 95 of the Commission's rules to enable the operation of medical micro-power networks (MMNs) consisting of implantable medical devices and associated external programmer/controllers (P/C). These MMNs will employ functional electric stimulation (or FES) techniques to serve as an artificial nervous system to restore sensation, mobility, and function to paralyzed limbs and organs. The *R&O* establishes a secondary allocation in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands for MedRadio with use limited to MMNs.

3. The *R&O* adopts technical and service rules to govern the operation of MMNs in these four frequency bands. Because MMNs will operate on a secondary basis, they must accept interference from and not cause interference to primary services operating in these frequency bands. Consequently, these rules must prevent MMNs from causing interference to the other services operating in these bands. Since MMNs will be used for medical purposes, the rules must also provide assurance that they can reliably function in these frequency bands in the presence of signals from primary services operating these bands. For the most part the adopted rules mirror the existing rules that apply to MedRadio in the 401-406 MHz band in Part 95 of the Commission's rules with modifications to account for the MMN's wider bandwidth, higher transmission power, and need to operate in the presence of other primary services.

4. The proposed action is authorized under Sections 4(i), 301, 302, 303(e), 303(f), 303(r), and 307(e) of the Communications Act of 1934, as amended, 47 USC Sections 154(i), 301, 302, 303(e), 303(f), 303(r), and 307(e).

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

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

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

6. 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 rules and policies adopted herein.[4] The RFA

[1] *See* 5 U.S.C. § 603. The RFA, *see* 5 U.S.C. § 601 – 612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Pub. L. No. 104-121, Title II, 110 Stat. 857 (1996).

[2] In the Matter of Amendment of Parts 2: and 95 of the Commission's Rules to Provide Additional Spectrum for the Medical Device Radiocommunication Service in the 413-457 MHz band, ET Docket No. 09-36, RM-11404, *Notice of Proposed Rulemaking*, 24 FCC Rcd 3445, 3463 (2009)

[3] *See* 5 U.S.C. § 604.

[4] 5 U.S.C. § 603(b)(3).

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 27.5 million small businesses, according to the SBA.

7. **Personal Radio Services**. The Medical Device Radio Communications Services are being placed within Part 95 of our rules ("Personal Radio Services"). The Commission has not developed a small business size standard specifically applicable to these services. Therefore, for purposes of this analysis, the Commission uses the SBA small business size standard for the category Wireless Telecommunications Carriers (except Satellite), which is 1,500 or fewer employees.[8] Census data for 2007 show that there were 1,383 firms that operated that year.[9] Of those 1,368 had fewer than 100 employees. 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 cover a broad range of uses.[10] 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 adopted herein.

8. **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.[11] According to Census bureau data for 2007, there were a total of 919 firms in this category that operated for the entire year. Of this total, 771 had fewer than 100 employees and 148 had more than

[5] 5 U.S.C. § 601(6).

[6] 5 U.S.C. § 601(3) (incorporating by reference the definition of "small-business concern" in the Small Business Act, 15 U.S.C. § 632). Pursuant to 5 U.S.C. § 601(3), 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."

[7] 15 U.S.C. § 632 (1996).

[8] *See* 13 C.F.R. § 121.201, NAICS code 517210.

[9] U.S. Census Bureau, 2007 Economic Census, Sector 51, 2007 NAICS code 517210 (rel. Oct. 20, 2009), http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-fds_name=EC0700A1&-_skip=700&-ds_name=EC0751SSSZ5&-_lang=en.

[10] 47 CFR Part 90.

[11] 13 C.F.R. § 121.201 NAICS code 334220.

100 employees.[12] Thus, under this size standard, the majority of firms can be considered small.

9. We do note, however, that the allocation for the twenty-four megahertz of spectrum in four frequency bands for the Medical Device Radio Communications Service would be limited to use by MMNs. To date no entities are producing MMNs on a commercial basis. However, one entity, the Alfred Mann Foundation (AMF), has produced prototype MMN devices. We have no data on the size of AMF in terms of number of employees or revenue, but we presume that AMF is a small entity. In general, there are only a small number of manufacturers who produce wireless implanted medical devices (less than ten), 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 tend to focus very narrowly on this highly specialized niche market.

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

10. The *R&O* adopts no reporting or record keeping requirements. However, the R&O does adopt a number of service and technical rules that apply to all entities who manufacture and use MMN devices in the four frequency bands. Under the adopted rules the MMNs will not require individual licenses but instead will qualify for license-by-rule operation[13] pursuant to Section 307(e) of the Communications Act (Act).[14] The rules generally require that MMNs be able to operate in the presence of other primary and secondary users in these frequency bands.[15] MMNs must be capable of operating on any of the four allocated frequency bands.[16] The programmer/controller (P/C) in the MMN will be required to monitor the frequency band in which the MMN is operating at least once a second and must monitor the other frequency bands often enough that when it does switch frequency bands it has monitored the band it is switching to in the two seconds prior to switching.[17] The P/C must be capable of determining when either direction of the communication link between the P/C and the implanted devices is becoming degraded to the extent that communication is likely to be lost for more than 45 milliseconds. When the P/C makes this determination the MMN is required to move to another frequency band. The P/C will also be required to switch to another frequency band if during the monitoring of the occupied frequency band it determines that there is a received signal with power greater than -60 dBm in any 12.5 kHz bandwidth that persists for at least fifty milliseconds.[18] The MMN transmitters must incorporate a programmable means to implement a system shutdown process within 45 milliseconds of a communication failure or on command from the P/C.[19]

11. MMN use shall be restricted for use by persons only for diagnostic and therapeutic purposes and only to the extent that such devices have been provided to a human patient under the direction of a

[12] *See* http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-fds_name=EC0700A1&-_skip=4500&-ds_name=EC0731SG3&-_lang=en

[13] *See* 47 C.F.R.§ 95.1201.

[14] 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. 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. *See* 47 USC § 307(e)(1).

[15] *See* paragraph 56, *supra*.

[16] *See* paragraph 57, *supra*.

[17] *See* paragraph 59, *supra*.

[18] *See* paragraph 60, *supra*.

[19] *See* paragraph 61, *supra*.

duly authorized health care professional.[20] P/Cs in different MMNs may communicate with each other for the purposes of coordination of the use of the spectrum resource.[21] However, P/Cs may not communicate with non-implanted devices for other purposes.[22] Implanted MMN devices may not communicate directly with other MMN implanted devices. Multiple MMNs may be present within one patient with each MMN having its own P/C.[23] However, a P/C may not control implanted devices in multiple patients.

12. MMNs may transmit in a maximum emission bandwidth of six megahertz. MMN transmitters may transmit with a maximum EIRP of lesser of 1 mW or (10 log B – 7.782) dBm where B is the 20 dB emission bandwidth of the transmitted signal in MHz.[24] The P/C of an MMN may transmit with a maximum duty cycle of 3 percent.[25] The MMN must meet specific limits on both in-band and out-of-band emissions.[26]

13. MMN transmitters will be required to maintain a frequency stability as specified in the current MedRadio rules of +/- 100 ppm of the operating frequency over the range: (1) 25°C to 45°C in the case of MMN implant transmitters; and (2) 0°C to 55°C in the case of MMN programmer/control transmitters.[27]

14. MMN transmitters must be certificated except for such transmitters that are not marketed for use in the United States, are being used in the United States by individuals who have traveled to the United States from abroad, and comply with the applicable technical requirements.[28] MMNs may be operated anywhere that CB station operation is authorized under § 95.405 and not be required to transmit a station identification announcement.[29] All non-implanted MMN transmitters must be made available for inspection upon request by an authorized FCC representative. Manufacturers of MMN transmitters must include with each transmitting device a disclosure statement and each MMN programmer/controller must be labeled with a statement.[30] MMN transmitters must be labeled with a serial number, but this serial number may be placed in the instruction manual for the transmitter in lieu of being placed directly on the transmitter.[31]

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

15. The RFA requires an agency to describe any significant alternatives that it has considered in developing its 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

[20] *See* paragraph 65, *supra*.

[21] *See* paragraph 67, *supra*.

[22] *See* paragraph 68, *supra*.

[23] *See* paragraph 70, *supra*.

[24] *See* paragraph 79, *supra*.

[25] *See* paragraph 81, *supra*.

[26] *See* paragraph 82, *supra*.

[27] *See* paragraphs 83-84, *supra*.

[28] *See* paragraph 89, *supra*.

[29] *See* paragraph 89, *supra*.

[30] *See* paragraph 92, *supra*.

[31] *See* paragraph 93, *supra*.

resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such 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 such small entities."[32]

16. We are adopting a license-by-rule approach for MMN operations. This should decrease the cost of MMN use for small entities as compared to a licensing approach because they will not be subject to the expense of obtaining a license.

17. We have adopted a requirement that MMNs be capable of operating in any of the four allocated frequency bands. We do not believe this requirement will increase the cost of equipment unreasonably or be burdensome for manufacturers to meet. We note that these four bands are relatively close in frequency and thus only a single transmitter and one antenna are necessary to cover these four bands. We believe that the components to enable manufacturers of MMNs to meet this requirement should be readily available since equipment is currently designed to operate across the Federal mobile bands between 406.1 MHz and 450 MHz and non-Federal mobile bands between 450 MHz and 512 MHz.

18. As described above we have adopted requirements that the P/C of an MMN monitor the frequency bands and switch frequency bands under certain circumstances. We considered not imposing any frequency monitoring requirements on MMNs. However, we believe that this requirement is necessary because MMNs will operate in frequency bands where other services will operate on a primary basis. The MMNs must therefore be capable of detecting signals from these other services and taking steps to minimize the effects of these signals on MMN operations or switching frequency bands. Because MMNs will be used for medical purposes, they must be reliable and therefore these frequency monitoring requirements are necessary. We do not believe this monitoring requirement will add significant cost to MMN equipment since radios now operating in these bands also have a requirement to monitor channels prior to transmitting on them.[33]

19. The requirement that MMN transmitters maintain a frequency stability of +/- 100 ppm will not impose significant costs on small entities because oscillators that meet this standard are readily available.

20. We have adopted various provisions regarding equipment certification, authorized locations, station identification, station inspection, disclosure policy, labeling requirements and marketing limitations that mirror the existing MedRadio rules. We note that the certification and inspection requirements apply to a broad range of wireless devices within the Commission's jurisdiction and are a necessary part of insuring that the Commission's technical rules are followed. We therefore did not consider alternatives to these requirements. The disclosure and labeling requirements inform interested parties about limitations on use of the MMN devices, such as the fact that they may not cause interference to and must accept interference from other stations operating on a primary basis in these bands. We therefore believe that the disclosure and labeling requirements are useful and that they will not have a significant cost. The marketing limitation permits MMNs to be marketed and sold only for the types of communication that are permitted under the rules the Commission has adopted. We do not believe this will impose significant costs on small entities.

21. Report to Congress: The Commission will send a copy of the Report and Order, including this FRFA, in a report to Congress pursuant to the Congressional Review Act.[34] In addition, the

[32] 5 U.S.C. § 603(c)(1) – (c)(4).

[33] *See* paragraph 59, *supra.*

[34] See 5 U.S.C. § 801(a)(1)(A).

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 the FRFA (or summaries thereof) will also be published in the Federal Register.[35]

[35] *See* 5 U.S.C. § 604(b).

STATEMENT OF
CHAIRMAN JULIUS GENACHOWSKI

Re: Amendment of Parts 2 and 95 of the Commission's Rules to Provide Additional Spectrum for the Medical Device Radiocommunication Service in the 413-457 MHz band, ET Docket No. 09-36

This may seem like science fiction, but it's not. A veteran who recently participated in a study conducted at the Walter Reed Medical Center had a spinal cord injury that paralyzed his lower limbs. The patient was treated with an early version of the technology we are further advancing today, Medical Micropower Networks. Thanks to this technology, the patient recovered use of his limbs, and five months later he could perform rehabilitation exercises without using the microstimulators.

Anyone wondering why we have made unleashing mobile innovation one of the FCC's highest priorities need look no further than this example, testimonials included in the record in this proceeding, and the stories we heard in the video during the Bureau's presentation. As we saw, new wireless networks have the potential to enable paraplegics to stand and to facilitate other breakthrough treatments for victims of spinal cord injuries, traumatic brain injuries, and strokes. These broadband-enabled technologies are life-changing, impacting individuals, families, and communities in ways we can only begin to imagine.

This may be the most dramatic step we've taken to harness the benefits of communications technology for health care, but it's not the first. In our National Broadband Plan we identified health care as an enormous area of opportunity. We pointed to ways that broadband can improve health care quality and reduce costs – including remote medical monitoring. Wireless devices can help diabetes patients track their glucose levels or heart disease patients monitor cardiovascular data.

And as part of our mobile broadband agenda, the Commission has already taken a number of actions to seize the opportunities of mHealth. We entered an unprecedented partnership with the Food and Drug Administration to help ensure that communications-related medical innovations can swiftly and safely be brought to market. We've also taken steps to facilitate spectrum sharing and to improve and expand our experimental licensing program, proposing to ease testing restrictions on universities and research organizations, and proposing a new program to speed development of new health-related devices that use spectrum.

Today's order to enable Medical Micropower Networks builds on this work and promises to dramatically improve the lives of the millions of Americans who suffer from spinal cord injuries, traumatic brain injuries, strokes, and various neuromusculoskeletal disorders. These debilitating injuries severely impair quality of life and impose significant medical costs. Americans incurred costs of approximately $73.7 billion in 2010 for stroke-related disabilities and $60 billion in 2000 for traumatic brain injuries. Of course, the true cost of these injuries to these victims is immeasurable.

The devices that we expect to be deployed under the rules the Commission adopts today hold the promise of safer, less invasive, and more effective treatment options than those available under current medical practice. We're talking about medical miracles: allowing paraplegics to stand and restoring hand grasp function for quadriplegics. The implications for veterans, accident victims and people born with disabilities are incredible. Medical Micropower Networks can restore their mobility.

Medical Micropower Networks have been shown to reliably operate in spectrum shared with other services and are a model for making more efficient use of radio spectrum by using advanced technologies such as monitoring the quality of the radio link, switching frequency bands, notching out of interfering signals, and error correction coding. Testing also demonstrates that the Medical Micropower

Network devices developed by the Alfred Mann Foundation are able to operate reliably in spectrum shared with federal government and commercial services.

The Commission's action today is only a first step in our efforts to advance the health care agenda. Early next year, I expect that we will act with respect to Medical Body Area Networks for wireless patient monitoring in health care facilities and make changes to our experimental licensing program to facilitate research and development of wireless medical devices.

I'm also pleased to announce that today the FCC's Office of Engineering and Technology is issuing an order allowing Second Sight Medical Products, Inc. to market a retinal prosthesis that will help restore functional sight for individuals with certain eye diseases. Second Sight's Argus II retinal prosthesis is a medical implant system designed to treat blind people suffering from advanced retinal degenerative diseases. The system consists of a neurostimulator surgically implanted on the eye, a pair of eyeglasses housing a miniature video camera, and an external video processing unit connected to the eyeglasses via cable.

The video camera captures images that are converted into instructional signals by the video processing unit and are sent back to the eyeglasses to be wirelessly transmitted to the implant. OET's order will permit the device to exceed the Part 15 limits for intentional radiators when the data signals are transmitted from the eyeglasses to the implant.

Helping a blind person to see. Empowering a paraplegic to stand. That's the power of wireless technology. And that's why the FCC will continue working around the clock to harness this power to improve the lives of the American people.

I want to recognize and thank the staff in our Office of Engineering and Technology who worked on today's item, particularly Julie Knapp, Geraldine Matise, Jamison Prime, Nicholas Oros and Peter Georgiou. I'd also like to thank Amy Levine of my office for her excellent work shepherding through this item.

STATEMENT OF
COMMISSIONER MICHAEL J. COPPS

Re: Amendment of Parts 2 and 95 of the Commission's Rules to Provide Additional Spectrum for the Medical Device Radiocommunication Service in the 413-457 Band, ET Docket No. 09-36

Discussions of spectrum use can sometimes get a little abstract and hung up on issues like competition, data rates, and interoperability. But every once in a while—and today is one of those "once in a whiles"—we get a chance to talk about improving everyday lives in really direct ands meaningful ways.

I am pleased - more than pleased—delighted—that we are taking action that will dramatically improve the lives of potentially very many of our sisters and brothers who suffer from neuromuscular disorders. The devices we help enable today can serve as artificial nervous systems to restore sensation, mobility, and function to paralyzed limbs and organs, traumatic brain injury, stroke, cerebral palsy, and multiple sclerosis.

Today's action allocates 24 megahertz of spectrum in four band segments for the MedRadio service on a secondary basis. The band here—400 MHz—is well suited for propagation inside the body. These devices employ the latest techniques for efficient use of spectrum and interference mitigation—tools like spectrum sensing and dynamic frequency selection. The devices' low power means that they themselves won't pose interference to their neighbors. So there is a lot to like about today's order—the good it will do to restore critical functions for the injured, the innovative interference mitigation techniques, and the strong federal coordination with our partners at NTIA and the Joint Spectrum Center.

I salute the Alfred Mann Foundation for its work with the Veterans Administration and other hospitals under its experimental license, and its exhaustive research that has paved the way for our action today.

My hope and expectation is that we will soon build on today's action by addressing related proposals for Medical Body Area Networks which have the capability to track peoples' health status and which can prove hugely helpful in a number of scenarios, one such being emergency situations.

I want to pay special thanks to my friend, Commissioner McDowell—and salute him—for the leadership role he performed in getting this item moving initially. We wouldn't be here doing this without him. It was an item he brought to my attention as soon as I became Acting Chairman back in 2009 and together we got it teed up then. I also thank the Chairman for following through and getting us to the finish line this morning, and other colleagues past and present who helped move it along in the interim. Thanks in addition to Julie Knapp and his talented team for putting together such a welcome and thorough Order that will no doubt change many lives for the better for years to come.

STATEMENT OF
COMMISSIONER ROBERT M. McDOWELL

RE: ***Amendment of Parts 2 and 95 of the Commission's Rules to Provide Additional Spectrum for the Medical Device Radiocommunication Service in the 413-457 Band, ET Docket No. 09-36***

Today's Commission action represents the best of government performing a core mission: helping others in need. Sadly, it has taken the government far too long to act in this important proceeding. Regrettably, bureaucratic delay literally forced disabled patients to wait much longer than necessary to benefit from some amazing emerging technologies. Nonetheless, I have had the privilege to work closely with the Alfred Mann Foundation (AMF) throughout this challenging process on the regulatory aspects of its groundbreaking research, and I am delighted that this day has finally come.

Neuromuscular injuries and disorders impose tremendous physical, psychological and financial burdens. After years of investment and research, AMF produced remarkable technologies that allow paralyzed people to regain use of their limbs. Such a vision was imaginable only in the texts of science fiction a few years ago. Yet AMF has made it a reality for stroke victims, people paralyzed in accidents and America's wounded veterans.

AMF's miraculous inventions, however, require low power use of specific wireless frequencies; hence, the need for government approval. From a technical standpoint, we are implementing a sharing technique that maximizes efficiency and employs spectrum in a dynamic manner, important policies for which I have advocated for some time. It has been a lengthy process, yet worth the wait – AMF is poised to revolutionize medical treatments and therapies to improve the lives of millions of people, and to bring a measure of comfort and peace of mind to their families and friends.

Congratulations to AMF for its perseverance and commitment. Thank you to Chairman Genachowski for bringing this order to a vote and also to then-Acting Chairman Copps for moving forward on the notice of proposed rulemaking after an unnecessarily lengthy delay. I remember vividly our conversation in January of 2009 that led to this day. So thank you for your leadership. Thank you also to our dedicated and talented Office of Engineering and Technology staff for your important work.

Most importantly, congratulations to the paralyzed patients who now have more than hope to support them – they will have the power of their own bodies. To you I also offer the apology of your government for consuming nearly half a decade to reach this point.

STATEMENT OF
COMMISSIONER MIGNON L. CLYBURN

RE: ***Amendment of Parts 2 and 95 of the Commission's Rules to Provide Additional Spectrum for the Medical Device Radiocommunication Service in the 413-457 Band, ET Docket No. 09-36***

One of this Commission's key goals is to remove unnecessary regulatory barriers to the development and deployment of products and services that have the potential of improving the lives of the people we serve. So often, when we make substantial strides in this direction, that action fails to receive the level of attention it deserves, because it seems difficult to construct a flashy headline, or hard to generate the type of controversy which would carry on into another news cycle. But in my opinion, this Order is one of the most important the Commission has adopted during my tenure, because the innovation it unleashes—medical micro power networks—has the potential to greatly improve the lives of those who are faced with some of today's most difficult medical challenges.

In 2009, the Christopher and Dana Reeve Foundation published a report estimating that 5.6 million Americans suffer from some form of paralysis. The medical micro power networks, which the Alfred Mann Foundation has developed, use implant devices to employ micro-stimulation techniques that can restore sensation, mobility, and other vital functions, to limbs and organs. This is an exciting innovation that could lead to incredible breakthroughs for the millions of Americans that suffer from paralysis and other debilitating neuromuscular injuries or disorders. As the Order explains, the beneficial impact of these micro-power networks could also reach beyond the medical field. Because of the growing demand for wireless spectrum, we must promote more efficient use of allocated spectrum, and as the Notice of Inquiry this Commission adopted last November makes clear, dynamic spectrum use technologies could greatly advance this policy goal. Because the micro power networks leverage advanced spectrum use technologies, such as spectrum sensing and dynamic frequency location, they are also providing another business case for use of dynamic spectrum technologies.

But this technological innovation did not come easy or cheap. The Alfred Mann Foundation has already spent approximately 115 million dollars and it has taken eleven years to develop this technology. I commend the ingenuity, effort, and sacrifice that were necessary to create these important medical treatment devices and services. And I wish to take another opportunity to applaud Julie Knapp, and the talented OET staff, for working through the technical issues in this proceeding.

This day also represents an opportunity to highlight the potential the relevant federal agencies have to ensure efficient approval of important technological innovations in the future. For example, the Alfred Mann Foundation had to receive the necessary federal regulatory approvals not only from the FCC, but also from the Veterans Administration, NTIA, and several agencies in the Department of Defense at a cost of millions of dollars in administrative expenses. Enhanced interagency collaboration has the potential to reduce the time and the economic resources it takes get such a valuable product on the market, and I am looking forward to being a part of an ever-improving collaborative engagement. That is why I was particularly pleased that last November, the FCC initiated a rulemaking proceeding, on the medical program experimental licenses, which seeks to promote ways that the FCC, and other relevant federal agencies, can help speed the development and deployment of wireless medical services to consumers. I encourage the industry to provide us with a clear record on how we can further improve in this area.

So this is a good news day, a significant news day for the FCC, as the Commission is taking an affirmative measure to reduce barriers to deploy new wireless medical services and improve the lives of millions.