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

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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 operation²² 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 be 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.

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 proceeding 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 2005⁷⁷ 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 Compatibility 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 (*ITT 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 *ITT 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 Commission's 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,

¹¹³ *EIBASS 5/19/11 ex 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 users 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 certainty 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.

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 them¹²⁷ 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 rules¹⁴⁴ 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.