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

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

NOTICE OF PROPOSED RULEMAKING

Adopted: March 17, 2009 **Released: March 20, 2009**

Comment Date: [90 days from date of publication in the Federal Register]
Reply Comment Date: [120 days from date of publication in the Federal Register]

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

I. INTRODUCTION

1. In this proceeding, the Commission seeks comment on the feasibility of allowing up to 24 megahertz of spectrum in the 413-457 MHz band to be used on a secondary basis under the Medical Device Radiocommunication Service (MedRadio Service) in Part 95 of the Commission's rules.[1] We take this action in response to a petition for rulemaking filed by Alfred Mann Foundation (Alfred Mann or AMF) and numerous supportive comments concerning groundbreaking advances in implantable neuromuscular microstimulation devices using wireless technologies.[2] As described by Alfred Mann, a number of these implanted devices could be surgically injected in a patient and configured along with an external control unit to function as a wideband medical micro-power network – or MMN (pluralized herein for multiple networks as MMNs). MMNs using functional electric stimulation (or FES) techniques could serve as an artificial nervous system to restore sensation, mobility, and function to paralyzed limbs and organs.[3]

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[1] *See* "Investigation of the Spectrum Requirements for Advanced Medical Technologies, ET Docket No. 06-135; Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radiocommunication Service at 401-402 and 405-406 MHz, RM-11271; DexCom, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, ET Docket No. 05-213; Biotronik, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, ET Docket No. 03-92, *Report and Order*, adopted March 19, 2009, released March 20, 2009, FCC 09-23.

[2] *See* "Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Micropower Network Service in the 413-457 MHz band", Petition for Rulemaking, filed September 5, 2007 by Alfred Mann Foundation, placed on *Public Notice* for comment October 3, 2007, (Report No. 2835; RM-11404) (*AMF Petition*).

[3] "Functional electric stimulation" - often abbreviated as FES - is the generic terminology commonly used in reference to techniques using electrical currents to either generate or suppress activity in the nervous system. Such techniques can produce and control the movement of otherwise paralyzed limbs, activate visceral body functions, (continued….)

2. This proceeding reflects our ongoing effort to foster the development and deployment of advanced medical devices using wireless technologies that benefit the health and well-being of the American public. More specifically, large numbers of Americans, including U.S. service men and women returning each year from military service, suffer from spinal cord injuries, traumatic brain injuries, strokes, and various neuromusculoskeletal disorders.[4] For these persons, the prospect of recovering some degree of sensation, mobility, and other functions for paralyzed limbs and organs offers new hope for improved quality of life.[5] Furthermore, these individuals could be provided with safer, less-invasive, and more effective treatment options as compared with existing wired therapeutic approaches.

II. BACKGROUND

3. The Commission has a long history of providing access to spectrum on a licensed basis for the use of wireless medical communications technologies.[6] In 1973, for example, the Commission authorized the use of 18 frequencies in the 460-470 MHz band on a license-by-rule basis under Part 90 of its rules for low-power biomedical telemetry operations in hospitals, other medical facilities, and convalescent centers.[7] In addition, medical radio device manufacturers have for many years been able to market products that operate on an unlicensed basis.

4. As medical telemetry use increased and its spectrum needs expanded, the Commission designated 14 megahertz of spectrum in the 608-614 MHz, 1395-1400 MHz, and 1429-1432 MHz bands for the Wireless Medical Telemetry Service (WMTS) under Part 95 of its Rules.[8] WMTS is used for the transmission of patient-related telemetric medical information to a central monitoring location in a hospital or other medical facility.[9] The Commission established the WMTS because existing medical telemetry devices operating in other frequency bands were receiving interference from incumbent users in those bands. The Commission decided that new equipment approvals would no longer be available for medical telemetry equipment operating on an unlicensed basis in the 174-216 MHz and 470-668 MHz bands under the provisions of Part 15 or for in-hospital medical telemetry equipment operating under Part

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create perceptions such as skin sensibility, arrest undesired pain or spasm, and facilitate natural recovery and accelerate motor relearning. *See, e.g.*, "FES Resource Info" and "FES Center Resource Guide" at http://fescenter.org/index.php. Alfred Mann also uses the substantially equivalent phrase "functional electric stimulation and sensing" - which it abbreviates as FESS. For simplicity herein, we shall use the shorter phrase "functional electric stimulation" interchangeably along with the acronym FES.

[4] *See AMF Petition* at ii.

[5] *See Id.*

[6] Among the frequencies used by medical radio devices on an unlicensed basis under Part 15 of our rules are the 9-315 kHz, 13.553-13.556 MHz (13 MHz ISM band), 174-216 MHz (TV channels 7-13), 218-222 MHz, 293-320 MHz, 410-450 MHz, 512-608 MHz (TV channels 14-36), 614-668 MHz (TV channels 38-46), 902-928 MHz (915 MHz ISM band), and 2400-2483.5 MHz (2.45 GHz ISM band) bands. Certain medical devices also operate on an unlicensed basis using inductive techniques at low frequencies. *See* 47 C.F.R. § 15.242 and 47 C.F.R. § 15.241.

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

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

[9] "Wireless medical telemetry" is defined in the rules governing WMTS as "[T]he 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).

90 (except in the 1427-1432 MHz band).[10] Since that time, approvals for new medical telemetry equipment must be sought pursuant to the WMTS rules in Part 95.

5. With the development of increasing numbers and kinds of medical radio devices–particularly those of the implanted variety – the Commission in 1999 established the Medical Implant Communication Service (MICS) within Part 95 of its Rules.[11] For the MICS, the Commission set aside three megahertz of spectrum at 402-405 MHz, also on a license-by-rule basis, expressly for short-range wireless links between ultra-low power medical implant transmitters and associated programmer/control equipment.[12] Current examples of such implant devices include cardiac pacemakers and defibrillators that also monitor and report cardiac condition.

6. Recently, the Commission established the MedRadio Service in the 401-406 MHz band. This new service includes the legacy MICS at 402-405 MHz.[13] As presently formulated, the operation of both implanted and body-worn wireless medical devices used for diagnostic and therapeutic purposes in humans is accommodated under the umbrella framework of the present MedRadio Service.

7. In the *MedRadio Proceeding*, the Commission included a notice of inquiry seeking information in a broader context relating to future spectrum needs for wireless medical technologies. In response, Alfred Mann filed the petition for rulemaking that is the subject of this proceeding. Alfred Mann asks the Commission to designate up to 24 megahertz of spectrum in the 413-457 MHz range for a "medical micropower network" or MMN service to accommodate operation of implanted microstimulator devices using FES techniques. Alfred Mann states that such devices could serve as an artificial nervous system in individual patients to restore sensation, mobility, and other functions to paralyzed limbs and organs. Alfred Mann further states that it has developed and tested prototype equipment under an experimental authorization allowing operation in the 400-470 MHz band, and has conducted some clinical trials using an experimental version of a MMN in the United Kingdom.[14] On October 3, 2007, the Commission released a public notice seeking comment on this petition.[15]

8. We received numerous comments in response to the public notice that enthusiastically support the general concept of providing spectrum for use by advanced microstimulator devices that might serve as artificial nervous systems for those suffering from a wide array of debilitating disorders or injuries.[16] Commenters point out that this technology could revolutionize medical treatment and therapy

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[10] *See* 47 C.F.R. § 15.37(i), 90.203(a)(1) and 95.1101-1129. Furthermore, §15.37(j) eliminates all new equipment for medical telemetry, in-hospital or not, under Sections 15.241 and 15.242.

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

[12] *See MICS Order, supra,* at para. 3.

[13] *See* "Investigation of the Spectrum Requirements for Advanced Medical Technologies, ET Docket No. 06-135; Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radiocommunication Service at 401-402 and 405-406 MHz, RM-11271; DexCom, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, ET Docket No. 05-213; Biotronik, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, ET Docket No. 03-92 , *Report and Order*, adopted March 19, 2009, released March 20, 2009, FCC 09-23.

[14] Alfred Mann was granted an experimental authorization, which is valid from January 6, 2005 to November 16, 2009, for the 216-224.9995 MHz and 400-470 MHz bands. Permitted authorized power limits are 1 mW(ERP) and 200 uW (ERP). *See* File Number 0255-EX-PL-2004.

[15] *See* n1, *supra.*

[16] These comments are further augmented by over 60 additional comments filed in the *MedRadio Proceeding* that similarly support the Alfred Mann efforts and encourage the Commission to move forward with providing spectrum for such purposes.

for millions of people living with spinal cord injury and diseases such as multiple sclerosis, polio, cerebral palsy, and ALS, as well as numerous other neurological disorders.[17] Commenters also emphasize that this technology can provide an important tool in the medical treatment and care of numerous U.S. service men and women who suffered spinal cord, brain, and other serious injuries in Iraq, Afghanistan, and on other missions abroad.[18] Some commenters believe that wireless implant technology has the potential to enhance the quality of life for patients who find current wired implant technologies to have limited effectiveness, to be painful, and to require them to seek assistance from others to attach or remove the devices.[19]

III. DISCUSSION

9. We undertake this proceeding to explore the feasibility of providing access to spectrum for the operation of bandwidth intensive wireless medical devices, under the umbrella of the MedRadio Service, on a secondary basis in four segments of the 413-457 MHz band, *i.e.*, 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz. In particular, we are interested in providing access to spectrum for wireless MMNs that would be comprised of multiple networked implanted devices that employ wideband functional electrical stimulation - or FES - techniques.

10. Alfred Mann notes that such techniques have been implemented successfully in devices such as cardiac pacemakers to monitor and regulate the heart and cochlear implants to restore hearing. Alfred Mann claims that functional electric stimulation has not been widely adopted as a means of rehabilitating paralyzed limbs and organs because of the limitations of the current commercially available equipment, which utilizes cumbersome wire electrodes that must be placed on the skin or partially or fully implanted underneath the skin. The existing FES technology used with paralyzed/impaired limbs and organs thus typically requires highly invasive surgery which carries an increased risk of infection. Alfred Mann notes that other devices that can be placed on the skin (rather than implanted) are not as effective because the electrodes cannot be placed directly on the neural sites.

11. Alfred Mann indicates that it has been engaged in researching and developing wireless FES networks to activate and monitor nerves and muscles to restore sensation, mobility and other functions to paralyzed limbs and organs. According to Alfred Mann, FES technology can be adapted to create a network of multiple implanted sensors - referred to as a medical micro-power network or MMN - that would serve as an artificial nervous system to improve or replace the function of an impaired nervous system, thus providing therapeutic and functional benefits for millions of disabled persons. The miniature, battery-powered micro-stimulators would be fully implantable by injection or other minor surgical procedure, and create within the body a wireless network capable of both delivering electrical stimulation and acting as sensors of various in-body attributes and functions. Depending upon the nature and extent of the neurological damage, approximately one to 100 micro-stimulators are envisioned for any given patient, although an average of two to 12 micro-stimulators is estimated for the typical patient. Each of these micro-stimulators is a cylinder that is approximately 3.4 mm in diameter and 25 mm long. Each injection should require only a fraction of the time required to implant existing, commercially available wired systems. Their small size and lack of wires render the micro-stimulators minimally invasive, thus typically avoiding the need for major surgery and its associated risk and costs.

12. An external master control unit (MCU) would coordinate the activities of all network components and also would include an external recharging subsystem. The MCU, which is portable, transmits to and receives signals from all implanted devices in the network and coordinates their activity

[17] *See generally* comments of Paralyzed Veterans of America (PVA), a Congressionally-chartered national veteran's service organization; Shriners Hospitals for Children (Shriners); Case Western Reserve University (Case Western); and United Cerebral Palsy (UCP).

[18] *See generally* comments of Shriners and National Institute on Disability and Rehabilitation Research (NIDRR).

[19] *See generally* comments of Case Western.

to stimulate nerves and muscles to produce the desired therapy or function.[20] The MCU also serves as the patient interface for system activation and other types of system control. Unlike cardiac pacemakers, which are typically a single implanted device using relatively narrow emission bandwidths to accomplish the desired therapy and function, these medical micro-power networks are distinguished by their coordination of the activity of multiple implanted devices using a relatively wide emission bandwidth to produce the desired therapy or function.

13. If successfully implemented, we believe that wireless medical micro-power networks could offer new hope of improved quality of life for vast numbers of Americans. For example, Alfred Mann calls attention in its petition to the fact that millions of Americans each year suffer from spinal cord injuries, traumatic brain injuries, strokes, and neuromusculoskeletal disorders. Among these are: cerebral palsy, osteoporosis, disuse atrophy, spasticity, cardiopulmonary dysfunction, epileptic seizures, muscle and joint contractures, arthritis, facial paralysis, debilitating migraine headache, urinary incontinence, and loss of muscle endurance and metabolic function. Alfred Mann claims that wireless devices using FES microstimulation techniques could be used for brain and spinal cord injuries and neuromusculoskeletal disorders, and also could be used in conjunction with next-generation prosthetic limbs to provide wireless sensation and control to the prostheses, thus significantly reducing the weight of the prostheses. Alfred Mann cites recent estimates that approximately 700,000 Americans suffer from strokes each year, and that Americans were predicted to pay approximately $62.7 billion in 2007 for stroke-related medical costs.[21]

14. In addition, we take due notice of the immense physical toll and monetary expense involved with a variety of debilitating conditions. For example one source indicates that approximately 250,000 to 400,000 Americans suffer from spinal cord injuries, and, each year, approximately 11,000 U.S. residents sustain new spinal cord injuries.[22] Sources report that, depending upon the level of injury and age at the time of injury, the estimated lifetime costs that are directly attributable to a spinal cord injury can be as much as $2.9 million (in 2006 dollars).[23] Alfred Mann claims that these new wireless FES devices would offer a revolutionary technology that could fundamentally improve the quality of life for millions of seriously disabled people, as well as significantly alleviate the impact of skyrocketing medical costs.

15. We also believe that wireless MMNs would offer a number of other practical patient benefits. For example, the lack of wires implanted in the body also means that there would be no connections to break and that the implanted devices would be less susceptible to infection. If an implanted device were to become infected, the infection likely would not spread to other implanted devices because there would be no wires along which the infection can spread. Furthermore, implantable microstimulators would be powered by batteries which would eliminate the need for patients to wear an external device to transmit power and data to the implanted device, thereby improving acceptance of the technology by patients, enhancing the reliability of the system, and enabling the mobility of patients uninhibited by cumbersome external wires and coils. Finally, we note Alfred Mann's comments regarding the risks of presently available systems, namely hours of invasive surgery to implant devices connected through wires that, in many cases, are placed partly or entirely within the body.

16. In light of all the foregoing, we believe that the record supports our consideration of additional spectrum in the 413-457 MHz band for the MedRadio Service under Part 95 of our rules to accommodate the bandwidth intensive wireless MMNs described by Alfred Mann or other similar bandwidth intensive medical implant networks.

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[20] According to Alfred Mann, the MCU could be carried by the patient or placed in a convenient location within a few meters of the patient. *See* Alfred Mann petition at 4.

[21] *See* American Stroke Association, Impact of Stroke, http://www.strokeassociation.org/presenter.jhtml?identifier=1033.

[22] *See* About Spinal Cord Injury, http://www.spinalcord.org/html/injury.php.

[23] This estimate does not include indirect costs such as losses in wages, fringe benefits, and productivity. *See* Spinal Cord Injury: Facts and Figures at a Glance, http://images.main.uab.edu/spinalcord/pdffiles/Facts06.pdf.

A. Frequency Allocation

17. We seek comment on the suitability of four segments of the 413-457 MHz band requested by Alfred Mann—*i.e.*, 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz—for use by medical micro-power networks or other similar bandwidth intensive medical implant networks that require a high degree of operational reliability.

18. The spectrum from 410-450 MHz is allocated on a primary basis for Federal operations with only limited non-Federal use allowed. More specifically, the 410-420 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.[24] 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.[25] Additionally, the 420-450 MHz band is allocated for Federal radiolocation services on a primary basis and for non-Federal Amateur services on a secondary basis.[26] Within the 426-432 MHz and 438-444 MHz band segments, radiolocation services include Federal ground-based, airborne and shipborne radar systems for long-range surveillance that operate with very high power and wide bandwidths.[27] The radar systems transmit pulsed signals that may operate on a single frequency over a wide frequency range or transmit across the entire band using spread spectrum frequency hopping techniques. These radar systems are used for very long range detection, identification, and tracking of objects and typically employ Mega Watt transmitters and high antenna gains resulting in very high equivalent isotropically radiated power (EIRP) levels.[28] The radar receivers are also extremely sensitive in order to detect weak returns from targets. In addition, the Federal Government operates the Enhanced Position Location Reporting System (EPLRS) in the 420-450 MHz band, 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.

19. The 450-460 MHz band is allocated on a primary basis for non-Federal Land Mobile services. Within this range, the band segments 454-455 MHz and 456-460 MHz also include a primary allocation for non-Federal Fixed service.[29]

20. According to Alfred Mann, medical micro-power networks would require at least 5 megahertz emission bandwidth for reliable operation. Because MMNs would operate on a secondary and non-harmful interference basis, Alfred Mann believes that at least four channels should be available for MMNs use so that at least one channel will be available and to avoid harmful interference if the other

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[24] *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.

[25] Under footnote US13 of the Table of Frequency Allocations, 12.5 kHz-wide channels within the band also 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.

[26] *See* 47 C.F.R. § 2.106. Under footnote US230 of the Table of Frequency Allocations, non-government land mobile radio services are permitted to operate on certain frequencies within the 422-430 MHz band, but these operations are limited to areas within 50 miles of Buffalo, New York; Detroit, Michigan; and Cleveland, Ohio. *See* 47 C.F.R. § 2.106 n.US230.

[27] *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.*

[28] A Mega Watt is 1 million watts.

[29] *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, 90 and 95 of the Commission's Rules.

three channels are unavailable in a given area. Thus, it submits that, in order to provide sufficient operational flexibility and reliability, four blocks of spectrum totaling up to 24 megahertz in the 413-457 MHz band should be made available for MMN use. Further, Alfred Mann states that permitting operation at frequencies near 400 MHz is optimal for RF signal propagation through body tissue. Alfred Mann notes that, because power consumption increases with the operating frequency, operation in the upper 400 MHz band, above would consume substantially more power than is acceptable. They further state that this spectrum also is desirable because it would allow battery-powered implant devices to conserve battery power and prolong battery life, all of which inure to the benefit of the patient, who will enjoy long-lasting, long-functioning systems. Thus, they claim that three band segments identified below 450 MHz, *i.e*., 413-419 MHz, 426-432 MHz, and 438-444 MHz, are the most favorable locations for MMN operations. Alfred Mann notes that designating a fourth channel for MMN at 451-457 MHz could mitigate any concerns regarding potential harmful interference to federal government radiolocation operations below 450 MHz by providing an additional non-Federally-allocated channel upon which each MMN could transmit.[30]

21. Alfred Mann argues in its petition that no other suitable spectrum is now available to accommodate the operation of MMNs.[31] According to AMF, the spectrum generally available for wireless medical devices on a licensed basis primarily consists of (a) 14 megahertz of spectrum in the 608-614 MHz, 1395-1400 MHz, and 1429-1432 MHz bands for wireless medical telemetry service ("WMTS") under Part 95; (b) 5 megahertz of spectrum in the 401-406 MHz band for the MedRadio Service under Part 95; and (c) frequencies in the 450-470 MHz band for low-power biomedical telemetry operations under Part 90 of the Commission's rules. AMF submits 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. According to AMF, WMTS and Part 90 spectrum above 450 MHz is also congested and populated with commercial, high-power transmitters that could preclude reliable operation of lower-power, wireless medical implant devices. Additionally, AMF argues that the spectrum available under the MedRadio Service at 401-406 MHz is insufficient to accommodate new wireless medical implant devices that require much larger bandwidths and higher power levels to support much more complex functions.[32] NIDRR similarly notes that, although the Commission has allocated some spectrum for medical telemetry operations and for medical implant communications services, that spectrum is not suitable for FES devices, which require larger bandwidths to perform more complex functions.[33] UCP cautions that the benefits of FES cannot be realized unless the Commission allocates sufficient spectrum and establishes service rules to facilitate their deployment.[34] We invite commenters to address the validity of Alfred Mann's arguments above in support of permitting MMN operations in the specified segments of the 413-457 MHz band rather than in the other frequency bands, which it asserts are either unavailable or undesirable.

22. We further note that the 413-450 MHz band is used by federal agencies for land mobile radio and radar operations. In particular, the National Telecommunications and Information Administration

[30] *See* AMF petition at 15.

[31] *See* AMF petition at 11 *et seq*.

[32] AMF also explains that, although Parts 15 and 18 of the Commission's rules permit wireless medical devices to operate using various frequencies on an unlicensed basis, the technical restrictions under those rules prevent deployment of higher-power, wideband MMN devices. Specifically, according to AMF, the emission limits under Sections 15.209(a) and 18.305(b) of the Commission's rules are too stringent for wideband MMNS systems, which require higher power levels. Additionally, AMF says that although Section 18.305(a) permits industrial, scientific, and medical equipment to operate at unlimited emission levels on certain frequencies, these frequencies are located below 41 MHz and above 900 MHz, which it argues are outside the preferred range of spectrum for RF signal propagation within the human body. *See* AMF petition at 12, n22.

[33] *See* NIDRR Comments at 1.

[34] *See* UCP Comments at 1.

(NTIA) has made available information which provides greater detail concerning federal operations in the band, as well as a discussion of technical issues related to electromagnetic compatibility between medical devices and federal systems in this band.[35] Use of this band for non-Federal operations would require agreement with NTIA. In concert with such agreement, we would propose to allow MMNs to operate in this band on a secondary basis at 413-419 MHz, 426-432 MHz, and 438-444 MHz, subject to the further condition that harmful interference not be caused to Federal operations in the band. We would further propose to provide for such use by including a U.S. footnote to the Table of Allocations in Part 2 of the Rules for the specific band segments.[36] We seek comment on this approach. We also seek comment on allowing MMNs to operate in the 451-457 MHz band on a secondary basis by including a U.S. footnote to the Table of Allocations.

23. We seek comment on whether permitting MMNs to operate in these bands would cause interference to incumbent users, as well as whether transmissions from incumbent stations could adversely affect the operation of such medical devices, possibly resulting in adverse effects to the patient. Given the low transmitter power and duty cycle limits that would typically be used by either the implanted MMN device or the external MCU, we expect that the risk of interference from MMNs to incumbent operations in these frequency bands would be negligibly small. Because MMNs typically would be operating at much lower power than an incumbent station, the latter should be able to overcome any interference received from any MMN device. The risk of interference to incumbent operations also would likely be mitigated by other factors such as separation distances from a MMN to an incumbent station, and only a small amount of energy from a wideband MMN would be received by a narrowband land mobile station.[37] We seek comment on these observations as well as other factors that should be considered in assessing potential interference from MMNs to the incumbent systems. For example, given the potentially large number of implanted devices that a MMN might use, is there a potential for interference to incumbent systems from the simultaneous operation of multiple implanted devices?

24. Given the diverse range of incumbent operations in the 410-460 MHz band, we believe that there is some potential for high power incumbent stations to cause interference to MMNs. In addition to high power, other factors such as separation distances and field of view could compromise MMN operations. As we discuss further below, MMNs could employ various techniques to overcome noisy RF environments. For example, implant devices would, by their nature of use, operate at very close range to an external master control unit (on the order of a few meters, or less – where undesired RF sources that are expected to be weak would be masked beneath the desired signal), and could employ sophisticated error detection and correction techniques, frequency monitoring capabilities, and re-transmission protocols that can successfully overcome, or recover from, undesired signals that might be encountered. [38] We seek comment on these observations as well as other factors that should be considered in assessing potential interference from incumbent stations to MMNs.

25. Finally, we seek comment on whether allowing use of the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz frequency bands on a secondary basis for new MMN devices would be consistent with international spectrum allocations and operations. We observe that in all or substantial portions of the three International Telecommunication Union regions, the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands are allocated to mobile, except aeronautical mobile, services on a

[35] *See* NTIA letter to Julius Knapp, Chief, Office of Engineering and Technology, dated February 27, 2009.

[36] *See* 47 C.F.R. § 2.106.

[37] Alfred Mann computed distance separations between an MMN MCU and a federal land mobile receiver to preclude potential interference making certain assumptions regarding MCU transmitter, land mobile receiver and the anticipated background noise levels. *See* AMF petition at 19. We note that Alfred Mann did not attempt to assess the risk of harmful interference to Federal Government radiolocation and radar operations because the technical specifications for these systems are not publicly available. *Id*. at 18, n.32.

[38] For pulsed signals the interference tolerance of a digital receiver is directly related to the ratio of the pulse length to the information signal length.

primary basis.[39] International harmonization of this spectrum could serve to expedite global deployment of new wireless wideband medical devices at reduced costs and could allow patients using these devices to travel domestically and internationally with greater assurance that the devices will operate properly and within legal guidelines wherever they may be.

B. Service and Technical Rules

26. We discuss in this section the service and technical rules that would apply to medical devices in the 413-457 MHz band. For the purposes of discussion, our central focus herein is on MMNs used to provide FES therapeutic treatment and the kinds of devices that would be part of these networks as described by Alfred Mann. We also invite comment, however, on other types of FES applications that would be consistent with MMN operations and that would similarly require the wider emission bandwidth afforded in this spectrum, which is not available in other spectrum currently identified for wireless medical devices.

27. Many of the service and technical rules discussed below generally follow the framework of the MedRadio Service rules with, for example, modified power and emission bandwidth requirements to accommodate the anticipated wider bandwidth and higher EIRP needs of MMNs. We believe that this approach is desirable as it would maintain consistency with rules applicable to wireless medical devices, particularly for implanted and related therapeutic devices. Thus, the service and technical rules discussed below are essentially consistent with recommendations made in the Alfred Mann petition. We note that the AMF petition includes an appendix that sets forth one possible framework for the service and technical rules as a separate subpart of Part 95. To the extent that the discussion below deviates from Alfred Mann's suggested approach for service and technical rules, we also invite comment on the suggestions in Alfred Mann's petition.

1. Service Rules

28. *Licensing*. We seek comment on whether medical device operations in the 413-457 MHz band should be authorized, like other medical devices in the MedRadio Service under Part 95 of our Rules, thus providing for license-by-rule operation[40] pursuant to Section 307(e) of the Communications Act (Act).[41] Under this approach, medical devices would operate in the band on a shared, non-exclusive basis with respect to each other. As the Commission determined when it adopted the MedRadio Service rules, we continue to believe that this approach minimizes regulatory burdens and facilitates the expeditious deployment of new generations of beneficial wireless medical devices that can improve the quality of life for countless Americans, thus serving the public interest, convenience and necessity.

29. We seek comment on whether this license-by-rule framework would provide the most beneficial approach for MMN devices. Would other approaches be preferable? If so, how would those alternative approaches be structured, and why? What would be the relative benefits and disadvantages compared with the license-by-rule approach?

30. *Definitions*. We seek comment on what definitions should be added to Part 95 and the MedRadio Service rules for medical devices operating in the 413-457 MHz band. Alfred Mann recommends broad definitions for various component devices using FES techniques that are generally modeled after the existing definitions for analogous MedRadio devices. We seek comment on the following definitions:

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[39] *See* 47 C.F.R. § 2.106, n.5.276.

[40] *See* 47 C.F.R.§ 95.401 (d).

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

- Medical Micro-power Network (MMN): An ultra-low power radio service for the transmission of non-voice data to and from medical implant devices for the purpose of facilitating functional electric stimulation and sensing, a technique using electric currents to activate and monitor nerves and muscles. A MMN is comprised of multiple medical implant devices under the control of a MMN control transmitter.
- MMN control transmitter: A MMN transmitter that operates or is designed to operate outside of a human body for the purpose of communicating with a receiver connected to a MMN implant device or to another MMN transmitter associated with a MMN implant device, and is sometimes referred to as a Master Control Unit (MCU).
- MMN implant transmitter: A MMN transmitter that operates or is designed to operate within a human body for the purpose of facilitating communication from a medical implant device.
- MMN transmitter: A transmitter authorized to operate as part of a MMN.

31. Are these definitions too broad or too narrow or should alternative definitions be used? Should other components of wireless MMN networks also be identified and defined? Do any current definitions included in the MedRadio Service rules need to be modified to accommodate wireless medical devices operating at 413-457 MHz?

32. *Permissible Communications and Operator Eligibility.* We seek comment on requirements for permissible communications and operator eligibility that are generally the same as those in place for the MedRadio Service. The MedRadio rules provide that a medical implant device may be used by persons for diagnostic and therapeutic purposes, but only to the extent that such devices have been provided to a human patient under the direction of a duly authorized health care professional.[42] Furthermore, transmissions are limited to non-voice data signals.[43] We believe that applying these same requirements here is central to maintaining the intended use of this spectrum primarily for devices that could serve as artificial nervous systems or components thereof. We seek comment on whether these requirements would be appropriate for MMNs.

33. We note that the present MedRadio Service rules do not allow medical implant programmer/control transmitters to relay information to a receiver that is not included with a medical implant device.[44] However, the MedRadio Service rules do allow medical implant programmer/control transmitters to be interconnected with other telecommunications systems including the public switched telephone network. We seek comment on whether, and why, similar requirements should also apply here.

34. More specifically, we also seek comment on whether implant-to-implant communication should be allowed, and whether there should be a requirement that each external master control unit (or MCU) must always control the transmitters implanted within a single patient. Should all implants in a single patient be controlled by a single MCU, thus comprising a single network, even if the implants control different functions within the patient? Or should implants that perform different functions within the patient be organized into separate networks, each controlled by its own MCU? Could one MCU control multiple implants in more than one patient? What is the impact if multiple MCUs are used for a single patient?

2. Technical Rules

35. *Emission Bandwidth.* We seek comment on the maximum emission bandwidth that should be permitted for MMN devices. Each of the four segments of the 413-457 MHz band under review in this

[42] *See* 47 C.F.R. §§ 95.1201, 95.1209(a).

[43] *See* 47 C.F.R. § 95.401

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

proceeding for use by MMN devices occupies 6 megahertz of spectrum. Thus, specifying a maximum emission bandwidth of 6 megahertz would appear to be a reasonable option. The obvious benefit of this approach would be to allow each MMN device to fully utilize the available spectrum in each band segment. By comparison, Alfred Mann suggests limiting the maximum emission bandwidth of MMNs to approximately 5 megahertz. Thus, 6 megahertz would afford some degree of flexibility for manufacturers in identifying the center frequency of MMN transmissions but it also could have an adverse impact on spectrum use efficiency. Alternatively, we also seek comment on whether a smaller maximum emission bandwidth (*e.g.,* 3 megahertz) might be sufficient for MMN purposes and might further improve spectrum use efficiency. We seek comment on these observations. Commenters should address these questions in the context of the following expected operational needs of MMN devices: (1) to transmit large amounts of data necessary to perform complex biomedical functions; (2) to transmit heavily coded messages necessary to permit detection and correction of errors; and (3) to conserve battery power while minimizing the size of the battery and thus the size of the implantable microstimulator.[45] In addition, commenters should address the potential impact of any particular emission bandwidth with respect to the potential for increased or decreased compatibility with incumbent users. For example a wider transmission bandwidth will require a larger receiver bandwidth, which could make MMN devices more susceptible to interference from wideband pulsed radar signals.

36. *Channelization.* One approach to channelization would be to adopt rules that do not specify any particular channeling plan, thereby following the approach used with the MedRadio Service.[46] Under this model, a transmission 'channel' occupied by a MMN device would be loosely defined as any continuous portion of spectrum that is equal to the bandwidth of the device with the largest bandwidth that is to participate in a given MMN communications session. In this context, a MMN communication session would be defined (as with the MedRadio Service) as a collection of transmissions that may or may not be continuous and that take place between MMN devices.[47] One benefit of this approach would be that a MMN device could transmit on any center frequency within the MMN band so long as the maximum emission bandwidth out-of-band, and spurious emission limits are met. This approach would also afford the flexibility for MMN devices to subdivide the available 6 megahertz of each MMN band segment into multiple 'channels' of reduced emission bandwidth tailored to specific device needs on an ad-hoc basis. For example, a single MMN device might be designed to transmit on three center frequencies, with each transmission occupying two megahertz (*i.e.*, 3 channels totaling 6 megahertz occupied bandwidth). If such an approach were followed, would the potential benefit of more efficient spectrum use be outweighed by an increased risk of adverse mutual interactions between MMN devices using differing center frequencies and bandwidths? What other factors should be considered under this option? We seek comment on whether specific channeling plans might be considered.

37. *Contention protocol requirement*. We seek to ensure that all users will have a reasonable opportunity to operate without mutual interference and so that no operator can block others' access to the spectrum. We recognize that low power operation and spread spectrum or similar technology may enable MMN devices to operate in very close proximity without any mutual interference and mitigate the potential for blocking others access to the spectrum. We invite comment on this premise and whether any rules should be adopted to ensure such sharing. In particular, we seek comment on whether a contention protocol should be applied to MMN transmitting devices, and if so, how such a protocol might be developed. If we were to adopt a requirement for a contention based protocol, we invite comment as to whether we should, rely upon the general definition of *contention-based protocol* recently adopted by the Commission for the operation of wireless devices under Part 90 of the rules in the 3650 MHz band,

[45] *See* AMF petition at 12.

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

[47] *See* 47 C.F.R. § 95.628 (a) (6) (iii) for the analogous definition of "MICS communications session" under the present rules.

which reads as follows.[48]

> "*Contention-based protocol.* A protocol that allows multiple users to share the same spectrum by defining the events that must occur when two or more transmitters attempt to simultaneously access the same channel and establishing rules by which a transmitter provides reasonable opportunities for other transmitters to operate. Such a protocol may consist of procedures for initiating new transmissions, procedures for determining the state of the channel (available or unavailable), and procedures for managing retransmissions in the event of a busy channel."

38. Depending upon the transmit/receive reliability, or quality of service requirements of a particular use, contention protocols could take a variety of forms, such as listen-before-talk (LBT) frequency monitoring, time slot synchronization, or frequency hopping among others. The system described by Alfred Mann in its petition, for example, appears to depend upon time slot sharing to avoid interference with individual microstimulator devices and associated device networks. We seek comment on the advantages and disadvantages of such an approach. Would a time slot synchronization protocol of this nature present compatibility issues with respect to other protocols that might be used by alternative MMN devices? Another option would be to follow the existing approach of the MedRadio service whereby the medical transmitting device must incorporate a LBT frequency monitoring mechanism to monitor the channel or channels that the medical device transmitters intend to occupy.[49] One potential benefit of this latter approach would be that the LBT protocol of the MedRadio Service is already clearly defined in the rules and appears to be successful in allowing a number of uncoordinated devices to share the same spectrum. We seek comment on the desirability of either of these protocols.

39. More generally, we encourage commenters supporting implementation of a contention based protocol to discuss what kinds of contention protocols should or should not be utilized, and to explain in detail why or why not. How should such protocols be defined? Would the protocol be open-source or proprietary? Would more than one protocol be permitted? Should the same protocol be required for all devices, and how would this be accomplished? How should such protocols be established - by rule, by industry standard setting procedures, or other approaches?[50] Would any of these protocols be expected to interact either favorably or adversely with incumbent users?

40. We also seek comment on the technical parameters associated with frequency monitoring protocols that can be used to facilitate sharing with the incumbent federal users. How should the frequency monitoring threshold power level be established? How should the minimum time for monitoring a channel for an incumbent signal be established? What effect will the different types of incumbent signals have on frequency monitoring capabilities? Once a channel; is determined to be occupied by an incumbent should a minimum time be established before the channel can be monitored? Can a single frequency monitoring capability be implemented that can detect both pulsed radar signals and non-pulsed analog and digital land mobile radio signals?

41. *Transmitter power and duty cycle.* Based upon prototype MMN devices presently undergoing experimental testing, Alfred Mann states that each implantable microstimulator could be limited to a maximum EIRP of 200 microwatts; and each external master control unit could be limited to operate at a maximum EIRP of 1 milliwatt.[51] With respect to anticipated duty cycle requirements, Alfred Mann further states that each implanted MMN transmitter would be expected to transmit data for approximately 5 microseconds every 11 milliseconds and receive data for approximately 6 microseconds

[48] *See* 47 C.F.R. § 90.7.

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

[50] Alfred Mann indicates that it is exploring the establishment of an industry-led standards committee to define an appropriate communications protocol that could be used by all micorstimulation devices to mitigate the risk of interference and to maximize use of spectrum. *See* AMF petition at 21.

[51] More specifically, MCUs would be limited to a maximum EIRP of the lesser of 1 mW or 10 log B – 6.866 dBm where B is the 20 dB emission bandwidth in MHz. *See* AMF petition at 17.

every 11 milliseconds (*i.e.,* less than 0.05 percent transmit duty cycle). Thus, for a system with 10 to 20 implanted microstimulators, the transmit duty cycle of the master control unit would be approximately 3 percent.

42. We seek comment on whether the MMN rules should reflect these EIRP and duty cycle specifications suggested by Alfred Mann. Should other power limits and duty cycle constraints be considered? Should the same, or different, limits be applied to both implanted MMN devices and external or body-worn master control units? We also seek comment on what measurement methods would be appropriate for establishing compliance with maximum EIRP limits for MMN devices. More fundamentally, and with particular regard to implanted microstimulators, we seek comment on whether other approaches, such as conducted power limits in lieu of more traditional EIRP limits, would be either more, or less, appropriate. For example, given the extremely small form factor of implanted microstimulators, would it be impractical to specify a conducted power approach?

43. With respect to the potential for interference to federal operations, we seek specific comment on several issues: Should more stringent duty cycle limits than those just described above be imposed, or would the inherent duty cycle characteristics of MMN devices be sufficient to minimize the potential for interference to those incumbent systems? In assessing the potential impact on incumbent systems, what other operational factors should be considered? Should there be an upper limit on the number of devices that might comprise a single MMN network, or should the individual EIRP of a significant number of devices be aggregated in some manner? Are there any other interference mitigation factors that should be considered in this regard?

44. With respect to the potential for interference to MMN devices from federal government operations, we seek specific comment on what interference mitigation techniques could be employed with a sufficiently high degree of confidence by systems using FES or other similar techniques. We are particularly interested in comments relating to techniques such as error detection and correction coding, dynamic channel switching, and spectral notching that could be used by MMN devices and whether any of these, or other such techniques, would be effective, either alone or in combination.

45. *Unwanted emissions*. The existing MedRadio rules under Part 95 set forth limits on unwanted emissions from medical transmitting devices operating in the 401-406 MHz band.[52] As delineated therein, these provisions include limits on both in-band and out-of-band radiation. Following this framework, we seek comment on such limits that would be applied to MMN devices operating in the 413-457 MHz band.

46. Under this approach, emissions 500 kHz or less above or below the any particular authorized bandwidth must be attenuated by at least 20 dB below the transmitter output power. In addition, emissions more than 500 kHz outside of the authorized bandwidth must attenuated to a level no greater than the following signal strengths at 3 m: a) between 30-88 MHz, 100 μV/m, b) between 88-216 MHz, 150 μV/m, c) between 216-960 MHz, 200 μV/m, and d) 960 MHz and above, 500 μV/m.[53] We seek comment on the suitability of these proposed limits on out-of-band and spurious emissions and whether they would be adequate to protect incumbent operations, while fostering efficient spectrum use by MMN devices.

47. *Frequency stability*. We seek comment on whether each MMN transmitter should be required to maintain a frequency stability of +/- 100 ppm of the operating frequency over the range: (1) 25°C to 45°C in the case of MMNS implant transmitters; and (2) 0°C to 55°C in the case of MMNS control transmitters.

48. *Antenna locations*. We seek comment on whether to require that no antenna for a MMN

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

[53] These limits generally reflect the same field strength limits presently specified in Section 95.635 (d)(1) for the MICS

control transmitter may be configured for permanent outdoor use. Under such a provision, any MMN control transmitter used outdoors would not be allowed to be affixed to any structure for which the height to the tip of the antenna will exceed three (3) meters (9.8 feet) above ground. This would replicate the same requirement that applies to the MedRadio Service.

49. *RF safety*. We note that portable devices are subject to Section 2.1093 of the rules, pursuant to which an environmental assessment must be prepared under Section 1.1307. These rule sections also govern existing MedRadio devices. Devices covered by these rules are subject to routine environmental evaluation for RF exposure prior to equipment authorization of use.[54] We further note, however, that our ongoing RF safety proceeding (ET Docket No. 03-137) anticipates dealing with proposed changes in the Commission's rules regarding human exposure to RF electromagnetic fields in a more comprehensive fashion.[55] Thus, for the purposes of the instant proceeding, and pending Commission action in the RF safety proceeding in ET Docket 03-137, we only seek comment here on whether MMN implant and control transmitters should be deemed as portable devices subject to Sections 2.1093 and 1.1307 of the existing rules.

50. *Miscellaneous provisions*. We also seek comment on various provisions regarding equipment certification, authorized locations, station identification, station inspection, disclosure policy, labeling requirements and marketing limitations that mirror the existing MedRadio rules.

51. First, we seek comment on whether we should require that each MMN transmitter authorized to operate in the 413-457 MHz band must be certificated except for such transmitters that are not marketed for use in the United States, but which otherwise comply with the applicable technical requirements and are operated in the United States by individuals who have traveled to the United States from abroad.

52. For authorized locations, we seek comment on whether we should require that operation would be authorized anywhere CB station operation is authorized under § 95.405. With respect to station identification, we seek comment on providing that a MMN station would not be required to transmit a station identification announcement. We also seek comment on whether to provide that all non-implanted MMN transmitter apparatus be made available for inspection upon request by an authorized FCC representative. Under such a provision, persons operating implanted MN transmitters would be required to cooperate reasonably with duly authorized FCC representatives in the resolution of interference. We seek comment on all of these options.

53. We seek comment on whether to require that manufacturers of MMN transmitters include with each transmitting device the following disclosure statement: "This transmitter is authorized by rule under the MedRadio Service (47 C.F.R. Part 95). This transmitter must not cause harmful interference to stations authorized to operate on a primary basis in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands, and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the MedRadio Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference." We seek comment on this language, which tracks the existing MICS/MedRadio requirement.

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[54] *See* §2.1093 (c). The limits to be used for evaluation are based generally on criteria published by the American National Standards Institute (ANSI) for localized specific absorption rate ("SAR") in Section 4.2 of "IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz," ANSI/IEEE C95.1–1992, Copyright 1992 by the Institute of Electrical and Electronics Engineers, Inc., New York, New York 10017. *See* §2.1093 (d).

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

54. We further seek comment on whether to require that MMN control transmitters be labeled and shall bear the following statement in a conspicuous location on the device: "This device may not interfere with stations authorized to operate on a primary basis in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands, and must accept any interference received, including interference that may cause undesired operation." Where a MMN control transmitter is constructed in two or more sections connected by wire and marketed together, the statement specified in this section would be required to be affixed only to the main control unit. We also seek comment on whether to require that MMN implant transmitters be identified with a serial number. Under that plan, we would allow the FCC ID number associated with the transmitter and the information required by Section 2.925 of the FCC Rules to be placed in the instruction manual for the transmitter in lieu of being placed directly on the transmitter.

55. Finally, with respect to marketing limitations, we seek comment on requiring that MMN transmitters intended for operation in any portions of the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands may be marketed and sold only for those permissible uses described above.

56. We seek comment on all of the matters discussed above, and encourage commenters to address any other relevant matters of concern that might serve to illuminate the record in this proceeding.

IV. PROCEDURAL MATTERS

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

58. *Initial Paperwork Reduction Analysis.* The *Notice of Proposed Rule Making* and *Order* contain proposed new or modified information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995, Public Law 104-13. Public and agency comments are due 60 days after the date of publication in the Federal Register. Comments should address: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. In addition, pursuant to the Small Business Paperwork Relief Act of 2002,[56] we seek specific comment on how we might "further reduce the information collection burden for small business concerns with fewer than 25 employees."

59. In addition to filing comments with the Secretary, a copy of any comments on the Paperwork Reduction Act information collections requirements contained herein should be submitted to the Federal Communications Commission via email to PRA@fcc.gov and to Nicholas A. Fraser, Office of Management and Budget via email to Nicholas_A._Fraser@omb.eop.gov or via fax at (202) 395-5167.

60. *Comments.* Pursuant to Sections 1.415 and 1.419 of the Commission's rules, 47 C.F.R. §§ 1.415, 1.419, interested parties may file comments on or before the dates indicated on the first page of this document. Comments may be filed using: (1) the Commission's Electronic Comment Filing System (ECFS), (2) the Federal Government's eRulemaking Portal, or (3) by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings*, 63 Fed. Reg. 24121 (1998).

- Electronic Filers: Comments may be filed electronically using the Internet by accessing the ECFS: http://www.fcc.gov/cgb/ecfs/ or the Federal eRulemaking

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

Portal: http://www.regulations.gov. Filers should follow the instructions provided on the website for submitting comments.

- For ECFS filers, if multiple docket or rulemaking numbers appear in the caption of this proceeding, filers must transmit one electronic copy of the comments for each docket or rulemaking number referenced in the caption. In completing the transmittal screen, filers should include their full name, U.S. Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions, filers should send an e-mail to ecfs@fcc.gov, and include the following words in the body of the message, "get form." A sample form and directions will be sent in response.

- Paper Filers: Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

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

- The Commission's contractor will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE, Suite 110, Washington, DC 20002. The filing hours at this location are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building.

- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.

- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street, SW, Washington DC 20554.

People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an e-mail to fcc504@fcc.gov or call the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (tty).

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

V. ORDERING CLAUSES

62. IT IS ORDERED that pursuant to Sections 4(i), 301, 302, 303(e), 303(f) and 303(r) of the Communications Act of 1934, as amended, 47 USC Sections 154(i), 301, 302, 303(e), 303(f) and 303(r), this *Notice of Proposed Rule Making* IS ADOPTED.

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

FEDERAL COMMUNICATIONS COMMISSION

Marlene H. Dortch
Secretary

APPENDIX A

Parties Filing In Response To Public Notice

Case Western Reserve University
Great Batch, Inc
Henry Mayo Newhall Memorial Hospital
Huntington Medical Research Institues - HMRI
Kent Kresa
Neurotech Network
Paralyzed Veterans of America
Shriners Hospitals for Children
Tulane University
United Cerebral Palsy
National Institute on Disability and Rehabilitation Research (United States Department of Education)
Walter Reed Army Medical Center

APPENDIX B

Initial Regulatory Flexibility Analysis

1. As required by the Regulatory Flexibility Act (RFA),[1] the Commission has prepared this present Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities by the policies and rules proposed in this *Notice of Proposed Rule Making* (*NPRM*). Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments provided in paragraph 60 of this *NPRM*. The Commission will send a copy of this *NPRM*, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA).[2] In addition, the *NPRM* and IRFA (or summaries thereof) will be published in the Federal Register.[3]

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

2. The Commission seeks comment on the feasibility of allowing up to 24 megahertz of spectrum in the 413-457 MHz band to be used on a secondary basis under the Medical Device Radiocommunication Service (MedRadio Service) in Part 95 of the Commission's rules.[4] We take this action in response to a petition for rulemaking filed by Alfred Mann Foundation (Alfred Mann or AMF) and numerous supportive comments concerning groundbreaking advances in implantable neuromuscular microstimulation devices using wireless technologies.[5] As described by Alfred Mann, a number of these implanted devices could be surgically injected in a patient and configured along with an external control unit to function as a wideband medical micro-power network – or MMN (pluralized herein for multiple networks as MMNs). MMNs using functional electric stimulation (or FES) techniques could serve as an artificial nervous system to restore sensation, mobility, and function to paralyzed limbs and organs.

B. Legal Basis

3. The proposed action is authorized under Sections 4(i), 301, 302, 303(e), 303(f), 303(r), 304 and 307 of the Communications Act of 1934, as amended, 47 U.S.C. Sections 154(i), 301, 302, 303(e), 303(f), 303(r), 304 and 307.

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

4. The RFA directs agencies to provide a description of and, where feasible, an estimate of the

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

[2] *See* 5 U.S.C. § 603(a).

[3] *Id.*

[4] *See* "Investigation of the Spectrum Requirements for Advanced Medical Technologies, ET Docket No. 06-135; Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radiocommunication Service at 401-402 and 405-406 MHz, RM-11271; DexCom, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, ET Docket No. 05-213; Biotronik, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, ET Docket No. 03-92 , *Report and Order*, adopted March 19, 2009, released March 20, 2009, FCC 09-23.

[5] *See* "Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Micropower Network Service in the 413-457 MHz band", Petition for Rulemaking, filed September 5, 2007 by Alfred Mann Foundation, placed on *Public Notice* for comment October 3, 2007, (Report No. 2835; RM-11404) (*AMF Petition*).

number of small entities that may be affected by the proposed rules, if adopted.[6] The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction."[7] In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act.[8] A small business concern is one which: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.[9]

Nationwide, there are a total of approximately 22.4 million small businesses, according to SBA data.[10] A "small organization" is generally "any not-for-profit enterprise which is independently owned and operated and is not dominant in its field."[11] Nationwide, as of 2002, there were approximately 1.6 million small organizations.[12] The term "small governmental jurisdiction" is defined generally as "governments of cities, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand."[13] Census Bureau data for 2002 indicate that there were 87,525 local governmental jurisdictions in the United States.[14] We estimate that, of this total, 84,377 entities were "small governmental jurisdictions."[15] Thus, we estimate that most governmental jurisdictions are small.

Personal Radio Services. The Medical Device Radio Communications Services are being placed within Part 95 of our rules ("Personal Radio Services"). Personal radio services provide short-range, low power radio for personal communications, radio signaling, and business communications not provided for in other services. The Personal Radio Services include spectrum licensed under Part 95 of our rules and covers a broad range of uses.[16] Many of the licensees in these services are individuals, and thus are not small entities. In addition, due to the fact that licensing of operation under Part 95 is accomplished by rule (rather than by issuance of individual license), and due to the shared nature of the spectrum utilized by some of these services, the Commission lacks direct information other than the census data above, upon which to base an estimation of the number of small entities under an SBA definition that might be directly affected by the proposed rules.

We do note, however, that the designation for the two megahertz of spectrum for the Medical Device Radio Communications Service would be limited to use by medical implant and body-worn

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[6] 5 U.S.C. § 603(b)(3).

[7] 5 U.S.C. § 601(6).

[8] 5 U.S.C. § 601(3) (incorporating by reference the definition of "small business concern" in 15 U.S.C. § 632). Pursuant to the RFA, the statutory definition of a small business applies "unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the Federal Register." 5 U.S.C. § 601(3).

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

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

[11] 5 U.S.C. § 601(4).

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

[13] 5 U.S.C. § 601(5).

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

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

[16] 47 CFR Part 90.

medical devices and, thus, would not be shared with other non-Federal Governmental uses. To date, there are only a small number of manufacturers (i.e., less than ten – maybe five or so) that produce these devices, and FDA approval must be secured before such devices are brought to market. Due to the stringent FDA approval requirements, the small number of existing medical device manufacturers tends to focus very narrowly on this highly specialized market niche.

Wireless Communications Equipment Manufacturers. The Census Bureau does not have a category specific to medical device radiocommunication manufacturing. The appropriate category is that for wireless communications equipment manufacturers. The Census Bureau defines this category as follows: "This industry comprises establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment. Examples of products made by these establishments are: transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment." The SBA has developed a small business size standard for Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, which is: all such firms having 750 or fewer employees.[17] According to Census Bureau data for 2002, there were a total of 1,041 establishments in this category that operated for the entire year. Of this total, 1,010 had employment of under 500, and an additional 13 had employment of 500 to 999. Thus, under this size standard, the majority of firms can be considered small.[18]

Wireless Service Providers. The SBA has developed a small business size standard for wireless firms within the two broad economic census categories of "Paging"[19] and "Cellular and Other Wireless Telecommunications."[20] Under both categories, the SBA deems a wireless business to be small if it has 1,500 or fewer employees. For the census category of Paging, Census Bureau data for 2002 show that there were 807 firms in this category that operated for the entire year.[21] Of this total, 804 firms had employment of 999 or fewer employees, and three firms had employment of 1,000 employees or more.[22] Thus, under this category and associated small business size standard, the majority of firms can be considered small. For the census category of Cellular and Other Wireless Telecommunications, Census Bureau data for 2002 show that there were 1,397 firms in this category that operated for the entire year.[23] Of this total, 1,378 firms had employment of 999 or fewer employees, and 19 firms had employment of 1,000 employees or more.[24] Thus, under this second category and size standard, the majority of firms can, again, be considered small.

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[17] NAICS code 334220.

[18] NAICS code 11210.

[19] 13 C.F.R. § 121.201, NAICS code 517211.

[20] 13 C.F.R. § 121.201, NAICS code 517212.

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

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

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

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

Public Safety Radio Services. Public Safety radio services include police, fire, local government, forestry conservation, highway maintenance, and emergency medical services.[25] For small businesses in this category, the above small business size standard applies to 1500 or fewer employees. There are a total of approximately 127,540 licensees in these services. Governmental entities[26] as well as private businesses comprise the licensees for these services. All governmental entities with populations of less than 50,000 fall within the definition of a small entity.[27]

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

5. We seek comment on whether medical device operations in the 413-457 MHz band should be authorized, like other medical devices in the MedRadio Service under Part 95 of our Rules, thus providing for license-by-rule operation[28] pursuant to Section 307(e) of the Communications Act (Act).[29] Under this approach, medical devices would operate in the band on a shared, non-exclusive basis with respect to each other. As the Commission determined when it adopted the MedRadio Service rules, we continue to believe that this approach minimizes regulatory burdens and facilitates the expeditious deployment of new generations of beneficial wireless medical devices that can improve the quality of life for countless Americans, thus serving the public interest, convenience and necessity.

6. We also seek comment on whether this license-by-rule framework would provide the most beneficial approach for MMN devices. Would other approaches be preferable? If so, how would those alternative approaches be structured, and why? What would be the relative benefits and disadvantages compared with the license-by-rule approach?

7. We also seek comment on various provisions regarding equipment certification, authorized locations, station identification, station inspection, disclosure policy, labeling requirements and marketing limitations that mirror the existing MedRadio rules.

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

[26] 47 CFR § 1.1162.

[27] 5 U.S.C. § 601(5).

[28] *See* 47 C.F.R.§ 95.401 (d).

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

8. We seek comment on whether to require that manufacturers of MMN transmitters include with each transmitting device the following disclosure statement: "This transmitter is authorized by rule under the MedRadio Service (47 C.F.R. Part 95). This transmitter must not cause harmful interference to stations authorized to operate on a primary basis in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands, and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the MedRadio Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference." We seek comment on this language, which tracks the existing MICS/MedRadio requirement.

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

9. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.[30]

10. We further seek comment on whether to require that MMN control transmitters be labeled and shall bear the following statement in a conspicuous location on the device: "This device may not interfere with stations authorized to operate on a primary basis in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands, and must accept any interference received, including interference that may cause undesired operation." Where a MMN control transmitter is constructed in two or more sections connected by wire and marketed together, the statement specified in this section would be required to be affixed only to the main control unit. We also seek comment on whether to require that MMN implant transmitters be identified with a serial number. Under that plan, we would allow the FCC ID number associated with the transmitter and the information required by Section 2.925 of the FCC Rules to be placed in the instruction manual for the transmitter in lieu of being placed directly on the transmitter.

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

None.

[30] *See* 5 U.S.C. § 603(c).

STATEMENT OF
ACTING CHAIRMAN MICHAEL J. COPPS

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

I am pleased to support this Notice of Proposed Rulemaking, which examines the possible allocation of additional spectrum and service rules for use by advanced wireless devices that could significantly enhance the quality of life of many Americans that suffer from a wide array of neuromuscular disorders. In particular, this proceeding explores whether 24 megahertz of spectrum in the 400 MHz band could accommodate wideband medical micropower network devices that could serve as artificial nervous systems to restore sensation, mobility, and function to paralyzed limbs and organs. Among the many Americans that could benefit are men and women who, in providing service and sacrifice to this nation, are experiencing combat-related brain and spinal cord injuries.

I would like to give thanks to our Office of Engineering and Technology and the National Telecommunications and Information Administration (NTIA) for working closely together in crafting this important Notice.

STATEMENT OF
COMMISSIONER JONATHAN S. ADELSTEIN

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

I am pleased to approve this Notice of Proposed Rulemaking because the medical technologies benefiting from this item will have a deep impact on the health and lives of Americans. It represents new hope for those who suffer from neuromuscular disorders as it brings us a step closer to an artificial nervous system that can help restore sensation and function to paralyzed limbs and organs. Coupled with the establishment of the new Medical Radio Communication Service, the Commission is taking great strides in adopting wireless policies that facilitate health care.

This notice is the result of the combined efforts of the Alfred Mann Foundation, the National Telecommunications and Information Administration and our own Office of Engineering and Technology, and I commend them on their good work.

STATEMENT OF
COMMISSIONER ROBERT M. McDOWELL

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

I am delighted to finally be able to vote to approve this notice of proposed rulemaking, which was originally filed with the Commission in September 2007. Acting Chairman Copps deserves praise for bringing this exciting proposal forward and giving it the attention it deserves. Our action today takes another step to improve the quality of life for millions of Americans with impaired mobility and paralysis.

In addition, I thank the Alfred Mann Foundation (AMF) not only for its groundbreaking work, but for its perseverance in navigating the regulatory approval process. I wish AMF the best of luck as the Commission moves forward to more closely analyze its important proposal.

Finally, I want to note my appreciation for Acting Chairman Copps' pledge to promptly move forward on a similarly interesting proposal submitted by GE Medical Systems. I am committed to doing my part to ensure that we complete our work in these two proceedings expeditiously. Our fellow Americans living with chronic health conditions deserve no less.