Commission on Environmental Quality (TCEQ), 12100 Park S. Circle, Austin TX 78753–3087, (512) 239–6079. Comments may also be submitted electronically or through hand delivery/courier; please follow the detailed instructions in the **ADDRESSES** section of the immediate final rule which is located in the Rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Alima Patterson (214) 665–8533.

SUPPLEMENTARY INFORMATION: For additional information, please see the immediate final rule published in the ''Rules and Regulations''section of this **Federal Register**.

Dated: April 22, 2009.

Lawrence E. Starfield,

Acting Regional Administrator, Region 6.

[FR Doc. E9–11189 Filed 5–12–09; 8:45 am]

BILLING CODE P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2 and 95

[ET Docket No. 09–36, RM–11404; FCC 09–20]

Additional Spectrum for the Medical Device Radiocommunication Service

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document 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 umbrella of the existing Medical Device Radiocommunication Service. This action reflects the Commission's 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.

DATES: Comments must be filed on or before August 11, 2009 and reply comments must be filed on or before September 10, 2009.

FOR FURTHER INFORMATION CONTACT: Gary Thayer, Office of Engineering and Technology, (202) 418–2290, e-mail: *Gary.Thayer@fcc.gov,* TTY (202) 418–2989.

ADDRESSES: You may submit comments, identified by ET Docket No. 09–36, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Federal Communications Commission's Web Site: http://www.fcc.gov/cgb/ecfs/.* Follow the instructions for submitting comments.
- *E-mail:* [Optional: Include the E-mail address only if you plan to accept comments from the public]. Include the docket number(s) in the subject line of the message.
- *Mail:* [Optional: Include the mailing address for paper, disk, or CD–ROM submissions needed/requested by your Bureau or Office. Do not include the Office of the Secretary's mailing address here.]
- *People With Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rule Making,* ET Docket No. 09–36, FCC 09–20, adopted March 17, 2009, and released March 20, 2009. The full text of this document is available for public inspection and copying during regular business hours in the Commission's Reference Information Center, Portals II, 445 12th Street, SW., (Room CY–A257), Washington, DC 20554. The complete text of this document also may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., Portals II, 445 12th Street, SW., Room, CY–B402, Washington, DC 20554, telephone (202) 488–5300, facsimile (202) 488–5563 or via e-mail *FCC@BCPIWEB.com.* The full text may also be downloaded at: *http://www.fcc.gov.*

Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply 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 FR 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 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 a.m. to 7 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 should 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).

Summary of Notice of Proposed Rulemaking

1. In this *Notice of Proposed Rule Making,* 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 existing Medical Device Radiocommunication Service (MedRadio Service) framework in part 95 of the Commission's rules. This action is taken in response to a petition for rulemaking filed by Alfred Mann Foundation (Alfred Mann or AMF). Numerous commenters also support the general concept espoused by Alfred Mann of providing spectrum for use by advanced microstimulator devices that might service as artificial nervous systems for those suffering from a wide array of debilitating disorders or injuries.

2. This *Notice of Proposed Rule Making* also reflects the Commission's 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. For example, 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. 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. Furthermore, these individuals could be provided with safer, less-invasive, and more effective treatment options as compared with existing wired therapeutic approaches.

3. In light of these potential health benefits, the Commission proposes in this *Notice of Proposed Rule Making* to provide access to spectrum for wireless micro-power networks that would be comprised of multiple networked implanted devices that employ wideband functional electrical stimulation techniques.

Frequency Allocation

4. The Commission concludes that the record supports its consideration of additional spectrum in the 413–457 MHz band for the MedRadio Service under part 95 of our rules. Accordingly, the Commission seeks comment on the suitability of four segments of the 413–457 MHz band (413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz) that Alfred Mann requested be made available for use by medical micro-power networks (MMN) or other similar bandwidth intensive medical implant networks that require a high degree of operational reliability.

5. In its petition for rulemaking, Alfred Mann argues 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. To explore this assertion more fully, the Commission invites 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 Alfred Mann asserts are either unavailable or undesirable.

6. The Commission further notes that the 413–450 MHz band is presently used by federal agencies for land mobile radio and radar operations. The National Telecommunications and Information Administration (NTIA) has made available information that has been incorporated into ET Docket No. 09–36 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. The Commission observes that use of this band for non-Federal operations would require agreement with NTIA. To lay the groundwork for considering the ramifications of such a prospective agreement, the Commission proposes 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 should not be caused to Federal operations in the band. The Commission further proposes 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. It seeks comment on this approach. The Commission also seeks 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.

7. The Commission also seeks 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 patients using the medical devices. Given the low transmitter power and duty cycle limits that would typically be used by either the implanted MMN device or the external MCU, the Commission states that it expects 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. The Commission seeks 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?

8. Finally, the Commission seeks 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. In this regard, the Commission observes that 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 primary basis in all or substantial portions of the three International Telecommunication Union regions.

Service and Technical Rules

9. The Commission states that the central focus in this *Notice of Proposed Rule Making* is on MMNs that would be used to provide FES therapeutic treatment and the kinds of devices that would be part of these networks as described by Alfred Mann. Thus, the Commission invites comment on other types of functional electric stimulation (FES) applications that would be consistent with MMN operations and that would similarly require the wider emission bandwidth that might be accommodated in this spectrum, and which is not available in other spectrum currently identified for wireless medical devices. The Commission also notes 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 and invites comment on the suggestions in Alfred Mann's petition.

10. *Licensing.* The Commission seeks comment on whether the operation of MMN devices in the 413–457 MHz band should be authorized in the same manner as other medical devices in the MedRadio Service—namely, under part 95 of the rules, and thus providing for

license-by-rule operation pursuant to Section 307(e) of the Communications Act (Act).

11. The Commission further seeks comment on whether this license-by-rule framework would provide the most beneficial approach for MMN devices, but also asks whether other approaches would 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?

12. *Definitions.* The Commission seeks comment on what definitions should be included in its rules for MMN medical devices operating in the 413–457 MHz band. In addition, the *Notice of Proposed Rule Making* proposes the following definitions:

- *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.

13. The Commission seeks comment on whether these definitions are suitable. Are they too broad or too narrow? Should alternative definitions be used? For example, should other components of wireless MMN networks also be identified and defined? would any current definitions included in the MedRadio Service rules need to be modified to accommodate wireless medical devices operating at 413–457 MHz?

14. *Permissible Communications and Operator Eligibility.* The Commission seeks comment on adopting requirements for permissible MMN communications and MMN operator eligibility that are generally the same as those in place for the MedRadio Service. For example, the existing 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. Furthermore, transmissions are limited to non-voice data signals. In this *Notice of Proposed Rule Making,* the Commission states its belief that applying these same requirements would be central to maintaining the intended use of this spectrum primarily for devices that could serve as artificial nervous systems or components thereof. The Commission thus seeks comment on whether these same requirements would be appropriate for MMNs.

15. The Commission also notes 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. However, it observes that the MedRadio Service rules do allow medical implant programmer/control transmitters to be interconnected with other telecommunications systems including the public switched telephone network. The Commission seeks comment on whether, and why, similar requirements should also apply to the proposed MMN operations.

16. The Commission seeks 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. The Commission also asks several related questions. 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 would be the impact if multiple MCUs were to be used for a single patient?

Technical Rules

17. *Emission Bandwidth.* The Commission seeks comment on the maximum emission bandwidth that should be permitted for MMN devices. The Commission notes that each of the four segments of the 413–457 MHz band under consideration in this *Notice of Proposed Rule Making* for use by MMN devices occupies six megahertz of spectrum. Thus, it tentatively concludes that specifying a maximum emission bandwidth of six megahertz would appear to be a reasonable option because it would be to allow each MMN device to fully utilize the available spectrum in each band segment. By comparison, however, Alfred Mann suggests limiting the maximum emission bandwidth of MMNs to approximately five megahertz. The Commission notes that a six megahertz maximum emission bandwidth 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. Thus, in the alternative, the Commission seeks comment on whether an even smaller maximum emission bandwidth (e.g., three megahertz) would be sufficient for MMN purposes and might serve to further improve spectrum use efficiency. In this regard, the Commission asks commenters to 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. Commenters are also invited to address the potential impact of any particular emission bandwidth with respect to the potential for increased or decreased compatibility with incumbent users.

18. *Channelization.* The Commission proposes to adopt rules that do not specify any particular channeling plan for MMN device operation, thereby following the approach used with the MedRadio Service. Under this approach, a ''channel'' would be loosely defined as the maximum bandwidth occupied by the transmissions from a MMN device in the course of a MMN communications session. The Commission seeks comment on whether the potential benefit of more efficient spectrum use under this approach would be outweighed by an increased risk of adverse mutual interactions between MMN devices using differing center frequencies and bandwidths. The Commission seeks comment on what other factors should be considered under this option, and whether other more specific channeling plans might be considered.

19. *Contention protocol requirement.* The Commission seeks comment on whether a contention protocol should be applied to MMN transmitting devices, and if so, how such a protocol might be

developed. In particular, it seeks comment on whether a contention protocol should be applied to MMN transmitting devices, and if so, how such a protocol might be developed. The Commission also invites comment on whether it should rely upon the general definition of *contention-based protocol* recently adopted by the Commission in another rulemaking proceeding for the operation of wireless devices under part 90 of the rules in the 3650 MHz band Thus, the proposed definition would reads as follows.

''*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.''

20. The Commission observes that, depending upon such factors as the transmit/receive reliability, or quality of service requirements of a particular use, a practical contention protocol 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. The Commission seeks 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. The Commission notes that 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.

21. In this regard, The Commission encourages commenters to discuss what kinds of contention protocols should or should not be utilized, and seeks detailed responses to the following questions. If implemented, 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? Would any of these protocols be expected to interact either favorably or adversely with incumbent users?

22. The Commission also seeks 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?

23. *Transmitter power and duty cycle.* The Commission seeks comment on what measurement methods would be appropriate for establishing compliance with maximum EIRP limits for MMN devices. With respect to the potential for interference to federal operations, the Commission seeks specific comments on several issues: What, if any, duty cycle limits should 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?

24. With respect to the potential for interference to MMN devices from federal government operations, the Commission seeks 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. The Commission states that it is particularly interested in comments relating to 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.

25. *Unwanted emissions.* The Commission observes that the existing MedRadio rules under part 95 set forth limits on unwanted emissions (including limits on both in-band and out-of-band radiation) from medical transmitting devices operating in the 401–406 MHz band. Following this framework, the Commission seeks comment on whether such limits should be applied to MMN devices operating in the 413–457 MHz band.

26. Under this approach, emissions 500 kHz or less above or below 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. The Commission seeks 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.

27. *Frequency stability.* The Commission seeks 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.

28. *Antenna locations.* The Commission seeks comment on whether to require that no antenna for a MMN 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.

29. *RF safety.* In this proceeding, the Commission only seeks comment 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.

The Commission notes 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.

Miscellaneous Provisions

30. Finally, the Commission seeks 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.

31. *Equipment Certification.* First, the Commission seeks comment on whether it 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.

32. *Authorized Locations, Station Identification, and Inspections.* For authorized locations, the Commission seeks comment on whether it should require that operation would be authorized anywhere CB station operation is authorized under § 95.405. With respect to station identification, the Commission seeks comment on providing that a MMN station would not be required to transmit a station identification announcement. It also seeks 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 MNN transmitters would be required to cooperate reasonably with duly authorized FCC representatives in the resolution of interference. The Commission seeks comment on all of these options.

33. *Disclosure Statement.* The Commission seeks 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 CFR 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.'' The Commission notes that this language tracks the existing MedRadio disclosure requirement.

34. *Labeling.* The Commission further seeks 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. The Commission also seeks comment on whether to require that MMN implant transmitters be identified with a serial number. Under that plan, the Commission would allow the FCC ID number associated with the transmitter and the information required by § 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.

35. *Marketing Limitations.* Finally, with respect to marketing limitations, the Commission seeks 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.

Initial Regulatory Flexibility Analysis

36. 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]

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

37. 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. The Commission takes 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.[3] 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. 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

38. 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

[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). Public Law 104–121, Title II, 110 Stat. 857 (1996).

[2] *See* 5 U.S.C. 603(a).

[3] *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*). *See also* ''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. (setting forth rules for the MedRadio Service).

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

39. The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted.[4] The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' [5] In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act.[6] A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.[7]

40. Nationwide, there are a total of approximately 22.4 million small businesses, according to SBA data.[8] A ''small organization'' is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' [9] Nationwide, as of 2002, there were approximately 1.6 million small organizations.[10] The term ''small governmental jurisdiction'' is defined generally as ''governments of cities, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.'' [11] Census Bureau data for 2002 indicate that there were 87,525 local governmental jurisdictions in the United States.[12] We estimate that, of this total, 84,377 entities were ''small governmental jurisdictions.'' [13] Thus, we estimate that most governmental jurisdictions are small.

41. *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.[14] Many of the licensees in these services are individuals, and thus are not small entities. In addition, due to the fact that licensing of operation under part 95 is accomplished by rule (rather than by issuance of individual license), and due to the shared nature of the spectrum utilized by some of these services, the Commission lacks direct information other than the census data above, upon which to base an estimation of the number of small entities under an SBA definition that might be directly affected by the proposed rules.

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

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

44. *Wireless Service Providers.* The SBA has developed a small business size standard for wireless firms within the two broad economic census categories of ''Paging'' [17] and ''Cellular and Other Wireless Telecommunications.'' [18] Under both categories, the SBA deems a wireless business to be small if it has 1,500 or fewer employees. For the census category of Paging, Census Bureau data for 2002 show that there were 807 firms in this category that operated for the entire year.[19] Of this total, 804 firms had employment of 999 or fewer employees, and three firms had employment of 1,000 employees or more.[20] Thus, under this category and associated small business size standard, the majority of firms can be considered small. For the census category of Cellular and Other Wireless Telecommunications, Census Bureau data for 2002 show that there were 1,397 firms in this category that operated for the entire year.[21] Of this total, 1,378 firms had employment of 999 or fewer employees, and 19 firms had employment of 1,000 employees or more.[22] Thus, under this second

[4] 5 U.S.C. 603(b)(3).

[5] 5 U.S.C. 601(6).

[6] 5 U.S.C. 601(3) (incorporating by reference the definition of ''small business concern'' in 15 U.S.C. 632). Pursuant to the RFA, the statutory definition of a small business applies ''unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the Federal Register.'' 5 U.S.C. 601(3).

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

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

[9] 5 U.S.C. 601(4).

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

[11] 5 U.S.C. 601(5).

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

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

[14] 47 CFR Part 90.

[15] NAICS code 334220.

[16] NAICS code 11210.

[17] 13 CFR 121.201, NAICS code 517211.

[18] 13 CFR 121.201, NAICS code 517212.

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

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

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

[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.''

category and size standard, the majority of firms can, again, be considered small.

45. *Public Safety Radio Services.* Public Safety radio services include police, fire, local government, forestry conservation, highway maintenance, and emergency medical services.[23] For small businesses in this category, the above small business size standard applies to 1500 or fewer employees. There are a total of approximately 127,540 licensees in these services. Governmental entities [24] as well as private businesses comprise the licensees for these services. All governmental entities with populations of less than 50,000 fall within the definition of a small entity.[25]

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

46. The Commission seeks 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 its rules, thus providing for license-by-rule operation [26] pursuant to Section 307(e) of the Communications Act (Act).[27] 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, it continues 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.

47. The Commission also seeks 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?

48. The Commission also seeks 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.

49. The Commission seeks 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 CFR 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.'' The Commission seeks comment on this language, which mirrors the existing MedRadio requirement.

50. The Commission also seeks 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. It also seeks 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 § 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.

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

51. 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.[28]

52. In this proceeding, the Commission notes that the ''license by rule'' approach of the MedRadio service (and the related equipment certification, disclosure, and labeling requirements discussed above) that it proposes here for MMN operation already afford the benefit of minimal regulatory and economic impact on prospective users, including small entities. Nevertheless, in this Notice of Proposed Rulemaking, the Commission seeks further comment on whether the existing MedRadio regulatory framework should be retained, or whether any other approaches should be considered.

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

[24] 47 CFR 1.1162.

[25] 5 U.S.C. 601(5).

[26] *See* 47 CFR 95.401(d).

[27] 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).

[28] *See* 5 U.S.C. 603(c).

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

53. None.

Ordering Clauses

54. Pursuant to Sections 4(i), 301, 302, 303(e), 303(f) and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 301, 302, 303(e), 303(f) and 303(r), this *Notice of Proposed Rule Making* is adopted.

55. 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.

[FR Doc. E9–11066 Filed 5–12–09; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 73 and 74

[MB Docket No. 09–52; FCC 09–30]

Policies To Promote Rural Radio Service and To Streamline Allotment and Assignment Procedures

AGENCY: Federal Communications Commission.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: In this document, the Commission adopted a Notice of Proposed Rulemaking (NPRM), seeking comment on a number of procedures designed to streamline the process of allocating new FM channels and AM frequency assignments, with an emphasis on encouraging policies that foster new and modified channel assignments favoring smaller communities, rural areas, and Native American and Alaska Native tribal areas. The Commission proposes a number of rule and procedural changes addressing channel assignment and allotment priorities under Section 307(b) of the Communications Act of 1934, as amended, including proposing a new priority for Native American and Alaska Native tribes and their members seeking to provide new radio service to tribal lands. The Commission also proposes a number of smaller but significant procedural changes designed to make the allotment and assignment of radio channels more efficient.

DATES: Comments may be filed no later than July 13, 2009 and reply comments may be filed no later than August 11, 2009. Written comments on the Paperwork Reduction Act proposed information collection requirements must be submitted by the public, Office of Management and Budget (OMB) and other interested parties on or before July 13, 2009.

ADDRESSES: You may submit comments, identified by MB Docket No. 09–52, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Federal Communications Commission's Web site: http://www.fcc.gov/cgb/ecfs/.* Follow the instructions for submitting comments.
- *E-mail: ecfs@fcc.gov.* Include the docket number in the subject line of the message. See the **SUPPLEMENTARY INFORMATION** section of this document for detailed information on how to submit comments by e-mail.
- *Mail:* 445 12th Street, SW., Washington, DC 20554.
- *People With Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Peter Doyle, Chief, Media Bureau, Audio Division, (202) 418–2700; Thomas Nessinger, Attorney-Advisor, Media Bureau, Audio Division, (202) 418–2700.

For additional information concerning the Paperwork Reduction Act information collection requirements contained in this document, contact Cathy Williams at 202–418–2918, or via the Internet at *Cathy.Williams@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rulemaking (NPRM), FCC 09–30, adopted April 7, 2009, and released April 20, 2009.

Initial Paperwork Reduction Act of 1995 Analysis

This NPRM contains proposed information collection requirements. It will be submitted to the Office of Management and Budget (OMB) for review under section 3507(d) of the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13, 109 Stat 163 (1995). The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and OMB to comment on the proposed information collection requirements contained in this NPRM, as required by the PRA. Public and agency comments on the PRA proposed information collection requirements are due July 13, 2009. 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, Public Law 107–198, 116 Stat 729 (2002), *see* 44 U.S.C. 3506(c)(4), the Commission seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

The following existing information collection requirements would be modified if the proposed rules contained in the NPRM are adopted.

OMB Control Number: 3060–0996.

Title: AM Auction Section 307(b) Submissions.

Form Number: Not applicable.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; not-for-profit institutions; State, local or Tribal government.

Estimated Number of Respondents and Responses: 153 respondents; 153 responses.

Estimated Time per Response: 0.5 hours to 3 hours.

Frequency of Response: On occasion reporting requirement.

Estimated Total Annual Burden: 354 hours.

Estimated Total Annual Costs: $43,050.00.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for this information collection is contained in Sections 154(i), 307(b) and 309 of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Impact Assessment: No impact(s).

Needs and Uses: Applicants in AM broadcast filing windows whose