

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

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

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

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

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

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

¹⁶⁵ AMF Petition at 17.

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

¹⁶⁷ AMF 11/17/11 *ex parte*.

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

¹⁶⁹ See paragraph 42, *supra*.

¹⁷⁰ JSC Report at 13.

¹⁷¹ See 47 C.F.R. § 95.635(d).

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

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

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

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

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

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

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

¹⁷⁵ *AMF Petition* Appendix A at 4.

¹⁷⁶ *Sienkiewicz Comments* at 9-10.

¹⁷⁷ Under the existing MedRadio rules, any MMN control transmitter used outdoors would not be allowed to be affixed to any structure for which the height to the tip of the antenna will exceed three (3) meters (9.8 feet) above ground. 47 C.F.R. § 95.1213.

¹⁷⁸ *ARRL Comments* at 15.

rule containing these restrictions..

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

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

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

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

¹⁷⁹ *NPRM* at 3458 para. 49.

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

¹⁸¹ *ARRL Comments* at 10.

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

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

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

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

¹⁸⁶ 47 C.F.R. § 95.603(f).

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

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

This transmitter is authorized by rule under the MedRadio Service (47 C.F.R. Part 95). This transmitter must not cause harmful interference to stations authorized to operate on a primary basis in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands, and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the MedRadio Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.¹⁸⁹

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

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

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

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

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

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

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

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

¹⁹¹ See 47 C.F.R. § 95.1217(c).

¹⁹² *ARRL Comments* at 14.

¹⁹³ *SBE Comments* at 7.

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

92. Both ARRL and SBE base their opposition to our proposed notice and labeling requirements at least in part on the fact that the MMN devices cannot be guaranteed to function at all times because of possible interference from other services in these bands. We have addressed this concern above and therefore have no need to discuss this issue further.¹⁹⁵ We also do not believe that the proposed labeling will be “useless” once the implanted MMN devices are placed within the body because only the P/C transmitter will bear a label, and it will not be implanted in the body. The proposed disclosure and labeling statements are based on the requirements for the MedRadio Services (and the MICS before that) that have been in place since 1999.¹⁹⁶ These notices have served us well since that time, and we see no reason to change them now. We note that MMN devices are medical devices which will be used only under the direction of knowledgeable medical personnel. As such, the notices are not aimed at consumers but instead at medical professionals who are in the best position to give appropriate patient advice. We therefore believe that the notice and labeling requirements are sufficient and will adopt them as proposed. These disclosure and labeling requirements provide an important benefit to medical professionals by warning of the secondary status of the MMN devices. These requirements are consistent with those that are in place for similar medical devices that are authorized under the Commission’s rules, and so the costs should be similar. Therefore, we see no reason why disclosure and labeling requirements should be more burdensome in the case of MMNs.

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

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

IV. PROCEDURAL MATTERS

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

¹⁹⁴ *Sienkiewicz Comments* at 9.

¹⁹⁵ See paragraphs 49-52, *supra*.

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

¹⁹⁷ 47 C.F.R. § 95.1219.

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

97. *Paperwork Reduction Act.* This document does not contain proposed information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104-13.¹⁹⁸ Therefore, it does not contain any new or modified “information collection burden for small business concerns with fewer than 25 employees,” pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107-198, *see* 44 U.S.C. § 3506(c)(4).

V. ORDERING CLAUSES

98. Accordingly, IT IS ORDERED that pursuant to the authority contained in Sections 4(i), 301, 302, 303(e), 303(f), 303(r), and 307(e) of the Communications Act of 1934, as amended, 47 USC Sections 154(i), 301, 302, 303(e), 303(f), 303(r), and 307(e), this Report and Order IS ADOPTED and Parts 2 and 95 of the Commission’s Rules ARE AMENDED as set forth in Appendix A effective 30 days after publication in the Federal Register.

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

FEDERAL COMMUNICATIONS COMMISSION



Marlene H. Dortch
Secretary

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

APPENDIX A**Final Rules**

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

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

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

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

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

a. Pages 26-28 are revised.

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

§ 2.106 Table of Frequency Allocations.

The revisions and additions read as follows:

* * * * *

399.9-400.05 MOBILE-SATELLITE (Earth-to-space) 5.209 5.224A RADIONAVIGATION-SATELLITE 5.222 5.224B 5.260 5.220	399.9-400.05 MOBILE-SATELLITE (Earth-to-space) US319 US320 RADIONAVIGATION-SATELLITE 5.260		Satellite Communications (25)
400.05-400.15 STANDARD FREQUENCY AND TIME SIGNAL-SATELLITE (400.1 MHz) 5.261 5.262	400.05-400.15 STANDARD FREQUENCY AND TIME SIGNAL-SATELLITE (400.1 MHz) 5.261		
400.15-401 METEOROLOGICAL AIDS METEOROLOGICAL-SATELLITE (space-to-Earth) MOBILE-SATELLITE (space-to-Earth) 5.208A 5.208B 5.209 SPACE RESEARCH (space-to-Earth) 5.263 Space operation (space-to-Earth) 5.262 5.264	400.15-401 METEOROLOGICAL AIDS (radiosonde) US70 METEOROLOGICAL-SATELLITE (space-to-Earth) MOBILE-SATELLITE (space-to-Earth) US319 US320 US324 SPACE RESEARCH (space-to-Earth) 5.263 Space operation (space-to-Earth) 5.264	400.15-401 METEOROLOGICAL AIDS (radiosonde) US70 MOBILE-SATELLITE (space-to-Earth) US320 US324 SPACE RESEARCH (space-to-Earth) 5.263 Space operation (space-to-Earth) 5.264 US319	Satellite Communications (25)
401-402 METEOROLOGICAL AIDS SPACE OPERATION (space-to-Earth) EARTH EXPLORATION-SATELLITE (Earth-to-space) METEOROLOGICAL-SATELLITE (Earth-to-space) Fixed Mobile except aeronautical mobile	401-402 METEOROLOGICAL AIDS (radiosonde) US70 SPACE OPERATION (space-to-Earth) EARTH EXPLORATION-SATELLITE (Earth-to-space) METEOROLOGICAL-SATELLITE (Earth-to-space) US64 US384	401-402 METEOROLOGICAL AIDS (radiosonde) US70 SPACE OPERATION (space-to-Earth) Earth exploration-satellite (Earth-to-space) Meteorological-satellite (Earth-to-space) US64 US384	MedRadio (95I)
402-403 METEOROLOGICAL AIDS EARTH EXPLORATION-SATELLITE (Earth-to-space) METEOROLOGICAL-SATELLITE (Earth-to-space) Fixed Mobile except aeronautical mobile	402-403 METEOROLOGICAL AIDS (radiosonde) US70 EARTH EXPLORATION-SATELLITE (Earth-to-space) METEOROLOGICAL-SATELLITE (Earth-to-space) US64 US384	402-403 METEOROLOGICAL AIDS (radiosonde) US70 Earth exploration-satellite (Earth-to-space) Meteorological-satellite (Earth-to-space) US64 US384	
403-406 METEOROLOGICAL AIDS Fixed Mobile except aeronautical mobile	403-406 METEOROLOGICAL AIDS (radiosonde) US70 US64 G6	403-406 METEOROLOGICAL AIDS (radiosonde) US70 US64	
406-406.1 MOBILE-SATELLITE (Earth-to-space) 5.266 5.267	406-406.1 MOBILE-SATELLITE (Earth-to-space) 5.266 5.267		Maritime (EPIRBs) (80V) Aviation (ELTs) (87F) Personal Radio (95)
406.1-410 FIXED MOBILE except aeronautical mobile RADIO ASTRONOMY 5.149	406.1-410 FIXED MOBILE RADIO ASTRONOMY US74 US13 US117 G5 G6	406.1-410 RADIO ASTRONOMY US74 US13 US117	Private Land Mobile (90)

International Table			United States Table		FCC Rule Part(s)
Region 1 Table	Region 2 Table	Region 3 Table	Federal Table	Non-Federal Table	
410-420 FIXED MOBILE except aeronautical mobile SPACE RESEARCH (space-to-space) 5.268			410-420 FIXED MOBILE SPACE RESEARCH (space-to-space) 5.268 US13 US64 G5	410-420 US13 US64	Private Land Mobile (90) MedRadio (95I)
420-430 FIXED MOBILE except aeronautical mobile Radiolocation 5.269 5.270 5.271			420-450 RADIOLOCATION G2 G129	420-450 Amateur US270	Private Land Mobile (90) MedRadio (95I) Amateur Radio (97)
430-432 AMATEUR RADIOLOCATION 5.271 5.272 5.273 5.274 5.275 5.276 5.277	430-432 RADIOLOCATION Amateur 5.271 5.276 5.277 5.278 5.279				
432-438 AMATEUR RADIOLOCATION Earth exploration-satellite (active) 5.279A 5.138 5.271 5.272 5.276 5.277 5.280 5.281 5.282	432-438 RADIOLOCATION Amateur Earth exploration-satellite (active) 5.279A 5.271 5.276 5.277 5.278 5.279 5.281 5.282				
438-440 AMATEUR RADIOLOCATION 5.271 5.273 5.274 5.275 5.276 5.277 5.283	438-440 RADIOLOCATION Amateur 5.271 5.276 5.277 5.278 5.279				
440-450 FIXED MOBILE except aeronautical mobile Radiolocation 5.269 5.270 5.271 5.284 5.285 5.286					
450-455 FIXED MOBILE 5.286AA			450-454 5.286 US64 US87	450-454 LAND MOBILE 5.286 US64 US87 NG112 NG124	Remote Pickup (74D) Low Power Auxiliary (74H) Private Land Mobile (90) MedRadio (95I)
5.209 5.271 5.286 5.286A 5.286B 5.286C 5.286D 5.286E			454-456	454-455 FIXED LAND MOBILE US64 NG12 NG112 NG148	Public Mobile (22) Maritime (80) MedRadio (95I)
455-456 FIXED MOBILE 5.286AA 5.209 5.271 5.286A 5.286B 5.286C 5.286E	455-456 FIXED MOBILE 5.286AA MOBILE-SATELLITE (Earth-to-space) 5.286A 5.286B 5.286C 5.209	455-456 FIXED MOBILE 5.286AA 5.209 5.271 5.286A 5.286B 5.286C 5.286E	US64	455-456 LAND MOBILE US64	Remote Pickup (74D) Low Power Auxiliary (74H) MedRadio (95I)

456-459 FIXED MOBILE 5.286AA 5.271 5.287 5.288			456-459 5.287 5.288 US64			456-460 FIXED LAND MOBILE 5.287 5.288 US64 NG12 NG112 NG124 NG148			Public Mobile (22) Maritime (80) Private Land Mobile (90) MedRadio (95i)		
459-460 FIXED MOBILE 5.286AA 5.209 5.271 5.286A 5.286B 5.286C 5.286E			459-460 FIXED MOBILE 5.286AA 5.209 5.271 5.286A 5.286B 5.286C 5.286E			459-460					
460-470 FIXED MOBILE 5.286AA Meteorological-satellite (space-to-Earth)			460-470 Meteorological-satellite (space-to-Earth)			460-462.5375 FIXED LAND MOBILE 5.289 US201 US209 NG124 462.5375-462.7375 LAND MOBILE 5.289 US201 462.7375-467.5375 FIXED LAND MOBILE 5.287 5.289 US73 US201 US209 NG124 467.5375-467.7375 LAND MOBILE 5.287 5.289 US201 467.7375-470 FIXED LAND MOBILE 5.288 5.289 US73 US201 NG124			Private Land Mobile (90) Personal Radio (95) Private Land Mobile (90) Personal Radio (95) Maritime (80) Private Land Mobile (90)		
5.287 5.288 5.289 5.290			5.287 5.288 5.289 US73 US201 US209			470-512 BROADCASTING Fixed Mobile 5.292 5.293			470-585 FIXED MOBILE BROADCASTING 5.291 5.298		
470-790 BROADCASTING			470-512 BROADCASTING Fixed Mobile 5.292 5.293			470-585 FIXED MOBILE BROADCASTING 5.291 5.298			470-608 FIXED LAND MOBILE BROADCASTING NG5 NG14 NG66 NG115 NG149		
512-608 BROADCASTING 5.297			512-608 BROADCASTING 5.297			512-608 BROADCASTING NG5 NG14 NG115 NG149			Broadcast Radio (TV)(73) LPTV, TV Translator/Booster (74G) Low Power Auxiliary (74H)		
608-614 RADIO ASTRONOMY Mobile-satellite except aeronautical mobile-satellite (Earth-to-space)			608-614 RADIO ASTRONOMY RADIONAVIGATION 5.149 5.305 5.306 5.307			608-614 LAND MOBILE (medical telemetry and medical telecommand) RADIO ASTRONOMY US74			Personal Radio (95)		
614-698 BROADCASTING Fixed Mobile 5.149 5.291A 5.294 5.296 5.300 5.302 5.304 5.306 5.311A 5.312			614-698 BROADCASTING Fixed Mobile 5.293 5.309 5.311A 5.149 5.305 5.306 5.307 5.311A 5.320			614-698 BROADCASTING NG5 NG14 NG115 NG149			Broadcast Radio (TV)(73) LPTV, TV Translator/Booster (74G) Low Power Auxiliary (74H)		

UNITED STATES (US) FOOTNOTES

US64 (a) In the band 401-406 MHz, the mobile, except aeronautical mobile, service is allocated on a secondary basis and is limited to, with the exception of military tactical mobile stations, Medical Device Radiocommunication Service (MedRadio) operations. MedRadio stations are authorized by rule on the condition that harmful interference is not caused to stations in the meteorological aids, meteorological-satellite, and Earth exploration-satellite services, and that MedRadio stations accept interference from stations in the meteorological aids, meteorological-satellite, and Earth exploration-satellite services.

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

PART 95 – PERSONAL RADIO SERVICES**SUBPART E – TECHICAL REGULATIONS**

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

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

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

§ 95.626 FRS unit channel frequencies.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

section.

(3) Radiated emissions and EIRP limit measurements may be determined by measuring the radiated field from the equipment under test at 3 meters and calculating the EIRP. The equivalent radiated field strength at 3 meters for 1 milliwatt, 25 microwatts, 250 nanowatts, and 100 nanowatts EIRP is 115.1, 18.2, 1.8, or 1.2 mV/meter, respectively, when measured on an open area test site; or 57.55, 9.1, 0.9, or 0.6 mV/meter, respectively, when measured on a test site equivalent to free space such as a fully anechoic test chamber. Compliance with the maximum transmitter power requirements set forth in §95.639(f) shall be based on measurements using a peak detector function and measured over an interval of time when transmission is continuous and at its maximum power level. In lieu of using a peak detector function, measurement procedures that have been found to be acceptable to the Commission in accordance with §2.947 of this chapter may be used to demonstrate compliance.

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

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

§ 95.633 Emission bandwidth.

* * * * *

(e) For transmitters in the MedRadio Service:

(1) For stations operating in 402–405 MHz, the maximum authorized emission bandwidth is 300 kHz. For stations operating in 401–401.85 MHz or 405–406 MHz, the maximum authorized emission bandwidth is 100 kHz. For stations operating in 401.85–402 MHz, the maximum authorized emission bandwidth is 150 kHz. For stations operating in 413- 419 MHz, 426-432 MHz, 438-444 MHz, or 451-457 MHz, the maximum authorized emission bandwidth is 6 megahertz.

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

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

* * * * *

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

95.635 Unwanted radiation.

* * * * *

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

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

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

Frequency (MHz)	Field strength ($\mu\text{V/m}$)	Measurement distance (m)
30–88	100	3
88–216	150	3
216–960	200	3
960 and above	500	3

Note—At band edges, the tighter limit applies.

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

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

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

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

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

(7) Compliance with the limits described in subparagraphs (4) through (6) are based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

* * * * *

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

§95.639 Maximum transmitter power.

* * * * *

(f) In the MedRadio Service:

(1) For transmitters operating in the 401-406 MHz band that are not excepted under § 95.627(b) from the frequency monitoring requirements of § 95.627(a), the maximum radiated power in any 300 kHz bandwidth by MedRadio transmitters operating at 402-405 MHz, or in any 100 kHz bandwidth by MedRadio transmitters operating at 401-402 MHz or 405-406 MHz shall not exceed 25 microwatts EIRP. For transmitters that are excepted under § 95.627(b) from the frequency monitoring requirements of § 95.627(a), the power radiated by any station operating in 402-405 MHz shall not exceed 100 nanowatts EIRP confined to a maximum total emission bandwidth of 300 kHz centered at 403.65 MHz, the power radiated by any station operating in 401-401.85 MHz or 405-406 MHz shall not exceed 250 nanowatts EIRP in any 100 kHz bandwidth and the power radiated by any station operating in 401.85-402 MHz shall not exceed 25 microwatts in the 150 kHz bandwidth. See §§ 95.633(e).

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

(3) The antenna associated with any MedRadio transmitter must be supplied with the transmitter and shall be considered part of the transmitter subject to equipment authorization. Compliance with these EIRP limits may be determined as set forth in § 95.627(g) or § 95.628(h), as applicable.

* * * * *

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

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

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

Subpart I – Medical Device Radiocommunications Service (MedRadio)

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

§95.1209 Permissible communications.

* * * * *

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

* * * * *

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

(e) MedRadio programmer/control transmitters may not be used to relay information in the 401-406 MHz band to a receiver that is not included with a medical implant or medical body-worn device. Wireless retransmission of information intended to be transmitted by a MedRadio programmer/control transmitter or information received from a medical implant or medical body-worn transmitter shall be performed using other radio services that operate in spectrum outside of the 401-406 MHz band.

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

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

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

§ 95.1211 Channel use policy.

* * * * *

(b) To reduce interference and make the most effective use of the authorized facilities, MedRadio transmitters must share the spectrum in accordance with §§ 95.627 or 95.628.

(c) MedRadio operation is subject to the condition that no harmful interference is caused to stations operating in the 400.150-406.000 MHz band in the Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services, or to other authorized stations operating in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands. MedRadio stations must accept any interference from stations operating in the 400.150-406.000 MHz band in the Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services, and from other authorized stations operating in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands.

13. Section 95.1215 is amended to read as follows:

§ 95.1215 Disclosure policies.

(a) Manufacturers of MedRadio transmitters operating in the 401-406 MHz band must include with each transmitting device the following statement:

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

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

“This transmitter is authorized by rule under the MedRadio Service (47 C.F.R. Part 95). This transmitter must not cause harmful interference to stations authorized to operate on a primary basis in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands, and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the MedRadio Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.”

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

§ 95.1217 Labeling requirements.

(a) (1) MedRadio programmer/control transmitters operating in the 401-406 MHz band shall be labeled as provided in part 2 of this chapter and shall bear the following statement in a conspicuous location on the device:

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

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

(2) MedRadio programmer/control transmitters operating in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands shall be labeled as provided in part 2 of this chapter and shall bear the following statement in a conspicuous location on the device:

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

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

* * * * *

APPENDIX B**Final Regulatory Flexibility Analysis**

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

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

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

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

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

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

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

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

6. The RFA directs agencies to provide a description of, and, where feasible, an estimate of the number of small entities that may be affected by the rules and policies adopted herein.⁴ The RFA

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

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

³ See 5 U.S.C. § 604.

⁴ 5 U.S.C. § 603(b)(3).

generally defines the term “small entity” as having the same meaning as the terms “small business,” “small organization,” and “small governmental jurisdiction.”⁵ In addition, the term “small business” has the same meaning as the term “small business concern” under the Small Business Act.⁶ A “small business concern” is one which: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.⁷ Nationwide, there are a total of approximately 27.5 million small businesses, according to the SBA.

7. Personal Radio Services. The Medical Device Radio Communications Services are being placed within Part 95 of our rules (“Personal Radio Services”). The Commission has not developed a small business size standard specifically applicable to these services. Therefore, for purposes of this analysis, the Commission uses the SBA small business size standard for the category Wireless Telecommunications Carriers (except Satellite), which is 1,500 or fewer employees.⁸ Census data for 2007 show that there were 1,383 firms that operated that year.⁹ Of those 1,368 had fewer than 100 employees. Personal radio services provide short-range, low power radio for personal communications, radio signaling, and business communications not provided for in other services. The Personal Radio Services include spectrum licensed under Part 95 of our rules and cover a broad range of uses.¹⁰ Many of the licensees in these services are individuals and thus are not small entities. In addition, due to the fact that licensing of operation under Part 95 is accomplished by rule (rather than by issuance of individual license), and due to the shared nature of the spectrum utilized by some of these services, the Commission lacks direct information other than the census data above upon which to base an estimation of the number of small entities under an SBA definition that might be directly affected by the proposed rules adopted herein.

8. Wireless Communications Equipment Manufacturers. The Census Bureau does not have a category specific to medical device radiocommunication manufacturing. The appropriate category is that for wireless communications equipment manufacturers. The Census Bureau defines this category as follows: “This industry comprises establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment. Examples of products made by these establishments are: transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment.” The SBA has developed a small business size standard for Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, which is: all such firms having 750 or fewer employees.¹¹ According to Census bureau data for 2007, there were a total of 919 firms in this category that operated for the entire year. Of this total, 771 had fewer than 100 employees and 148 had more than

⁵ 5 U.S.C. § 601(6).

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

⁷ 15 U.S.C. § 632 (1996).

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

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

¹⁰ 47 CFR Part 90.

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

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

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

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

10. The R&O adopts no reporting or record keeping requirements. However, the R&O does adopt a number of service and technical rules that apply to all entities who manufacture and use MMN devices in the four frequency bands. Under the adopted rules the MMNs will not require individual licenses but instead will qualify for license-by-rule operation¹³ pursuant to Section 307(e) of the Communications Act (Act).¹⁴ The rules generally require that MMNs be able to operate in the presence of other primary and secondary users in these frequency bands.¹⁵ MMNs must be capable of operating on any of the four allocated frequency bands.¹⁶ The programmer/controller (P/C) in the MMN will be required to monitor the frequency band in which the MMN is operating at least once a second and must monitor the other frequency bands often enough that when it does switch frequency bands it has monitored the band it is switching to in the two seconds prior to switching.¹⁷ The P/C must be capable of determining when either direction of the communication link between the P/C and the implanted devices is becoming degraded to the extent that communication is likely to be lost for more than 45 milliseconds. When the P/C makes this determination the MMN is required to move to another frequency band. The P/C will also be required to switch to another frequency band if during the monitoring of the occupied frequency band it determines that there is a received signal with power greater than -60 dBm in any 12.5 kHz bandwidth that persists for at least fifty milliseconds.¹⁸ The MMN transmitters must incorporate a programmable means to implement a system shutdown process within 45 milliseconds of a communication failure or on command from the P/C.¹⁹

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

¹² See http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-fds_name=EC0700A1&-skip=4500&-ds_name=EC0731SG3&-lang=en

¹³ See 47 C.F.R. § 95.1201.

¹⁴ Under Section 307(e) of the Act, the Commission may authorize the operation of radio stations by rule without individual licenses in certain specified radio services when the Commission determines that such authorization serves the public interest, convenience, and necessity. The services set forth in this provision for which the Commission may authorize operation by rule include: 1) the Citizens Band Radio Service; 2) the Radio Control Service; 3) the Aviation Radio Service; and 4) the Maritime Radio Service. See 47 USC § 307(e)(1).

¹⁵ See paragraph 56, *supra*.

¹⁶ See paragraph 57, *supra*.

¹⁷ See paragraph 59, *supra*.

¹⁸ See paragraph 60, *supra*.

¹⁹ See paragraph 61, *supra*.

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

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

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

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

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

15. The RFA requires an agency to describe any significant alternatives that it has considered in developing its approach, which may include the following four alternatives (among others): “(1) the establishment of differing compliance or reporting requirements or timetables that take into account the

²⁰ See paragraph 65, *supra*.

²¹ See paragraph 67, *supra*.

²² See paragraph 68, *supra*.

²³ See paragraph 70, *supra*.

²⁴ See paragraph 79, *supra*.

²⁵ See paragraph 81, *supra*.

²⁶ See paragraph 82, *supra*.

²⁷ See paragraphs 83-84, *supra*.

²⁸ See paragraph 89, *supra*.

²⁹ See paragraph 89, *supra*.

³⁰ See paragraph 92, *supra*.

³¹ See paragraph 93, *supra*.

resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.”³²

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

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

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

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

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

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

³² 5 U.S.C. § 603(c)(1) – (c)(4).

³³ See paragraph 59, *supra*.

³⁴ See 5 U.S.C. § 801(a)(1)(A).

Commission will send a copy of the Report and Order, including this FRFA, to the Chief Counsel for Advocacy of the SBA. A copy of the Report and Order and the FRFA (or summaries thereof) will also be published in the Federal Register.³⁵

³⁵ See 5 U.S.C. § 604(b).

**STATEMENT OF
CHAIRMAN JULIUS GENACHOWSKI**

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

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

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

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

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

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

The devices that we expect to be deployed under the rules the Commission adopts today hold the promise of safer, less invasive, and more effective treatment options than those available under current medical practice. We're talking about medical miracles: allowing paraplegics to

stand and restoring hand grasp function for quadriplegics. The implications for veterans, accident victims and people born with disabilities are incredible. Medical Micropower Networks can restore their mobility.

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

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

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

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

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

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

STATEMENT OF
COMMISSIONER MICHAEL J. COPPS

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

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

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

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

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

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

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

**STATEMENT OF
COMMISSIONER ROBERT M. McDOWELL**

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

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

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

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

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

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

**STATEMENT OF
COMMISSIONER MIGNON L. CLYBURN**

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

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

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

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

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

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