APPENDIX A

APPENDIX A

Proposed Rules for the Medical Micropower Network Service

1. Section 1.1307 is amended by revising paragraph (b)(2) to read as follows:

§ 1.1307 Actions that may have a significant environmental effect, for which Environmental Assessments (EAs) must be prepared.

* * * * *

(b) * * * * *

(2) Mobile and portable transmitting devices that operate in the Cellular Radiotelephone Service, the Personal Communications Services (PCS), the Satellite Communications Services, the Wireless Communications Service, the Maritime Services (ship earth stations only), the Specialized Mobile Radio Service, and the 3650 MHz Wireless Broadband Service authorized under Parts 22, 24, 25, 27, 80, and 90 of this chapter are subject to routine environmental evaluation for RF exposure prior to equipment authorization or use, as specified in §§ 2.1091 and 2.1093 of this chapter. Unlicensed PCS, unlicensed NII and millimeter wave devices are also subject to routine environmental evaluation for RF exposure prior to equipment authorization or use, as specified in §§ 15.253(f), 15.255(g), 15.319(i), and 15.407(f) of this chapter. Portable transmitting equipment for use in the Wireless Medical Telemetry Service (WMTS) is subject to routine environment evaluation as specified in §§ 2.1093 and 5.1125 of this chapter. Equipment authorized for use in the Medical Implant Communications Service (MICS) or Medical Micropower Network Service (MMNS) as a medical implant transmitter or MMNS implant transmitter (as defined in Appendix 1 to Subpart E of Part 95 of this chapter) is subject to routine environmental evaluation for RF exposure prior to equipment authorization, as specified in § 2.1093 of this chapter by finite difference time domain computational modeling or laboratory measurement techniques. Where a showing is based on computational modeling, the Commission retains the discretion to request that specific absorption rate measurement data be submitted. All other mobile, portable, and unlicensed transmitting devices are categorically excluded from routine environmental evaluation for RF exposure under §§ 2.1091, 2.1093 of this chapter except as specified in paragraphs (c) and (d) of this section.

2 Section 2.1093 is amended by revising paragraph (c) to read as follows:

§ 2.1093 Radiofrequency radiation exposure evaluation: portable devices.

* * * * *

(c) Portable devices that operate in the Cellular Radiotelephone Service, the Personal Communications Service (PCS), the Satellite Communications Services, the General Wireless Communications Service, the Wireless Communications Service, the Maritime Services, the Specialized Mobile Radio Service, the 4.9 GHz Band Service, the Wireless Medical Telemetry

Service (WMTS), the Medical Implant Communications Service (MICS), and the Medical Microwpower Network Service (MMNS), authorized under subpart H of part 22 of this chapter, parts 24, 25, 26, 27, 80 and 90 of this chapter, subparts H, I and M of part 95 of this chapter, and unlicensed personal communication service, unlicensed NII devices and millimeter wave devices authorized under subparts D and E, §§ 15.253, 15.255 and 15.257 of this chapter are subject to routine environmental evaluation for RF exposure prior to equipment authorization or use. * * * * *

3. The Table of Frequency Allocations in Section 2.106 is amended by revising the entries for 410-420 MHz, 420-450 MHz, 450-454 MHz, 454-455 MHz, 455-456, and 456-460 MHz, and adding footnote US399 to read as follows:

International Table	United States Table		FCC Rule Part(s)
* * * * *	Federal Table (MHz)	Non-Federal Table (MHz)	
* * * * *	410-420 FIXED US13 MOBILE SPACE RESEARCH (space-to-space) 5.268 G5 US399	410-420 US13 US399	Private Land Mobile (90) Personal (95)
* * * * *	420-450 RADIOLOCATION US217 G2 G129 5.286 US7 US87 US230 US397 G8 US399	420-450 Amateur US7 NG135 5.282 5.286 US87 US217 US230 US397 US399	Private Land Mobile (90) Amateur (97) Personal (95)
* * * * *	450-454 5.286 US87 US399	450-454 LAND MOBILE 5.286 US87 US399 NG112 NG124	Auxiliary Broadcasting (74) Private Land Mobile (90) Personal (95)
* * * * *	454-456	454-455 FIXED LAND MOBILE US399 NG12 NG112 NG148	Public Mobile (22) Maritime (80) Personal (95)
		455-456 LAND MOBILE US399	Auxiliary Broadcasting (74) Personal (95)
* * * * *	456-460 5.287 5.288 US399	456-460 FIXED LAND MOBILE 5.287 5.288 US399 NG112 NG124 NG148	Public Mobile (22) Maritime (80) Private Land Mobile (90) Personal (95)

* * * * *

UNITED STATES (US) FOOTNOTES

* * * * *

US399 In the 413-419 MHz band, the mobile, except mobile aeronautical, service is allocated on a secondary basis for non-Federal use and is limited to Medical Micropower Network Service

(MMNS) operations. MMNS operations also are permitted in the 426-432 MHz, 438-444 MHz, and 451-457 MHz bands on a secondary basis. MMNS stations are authorized by rule on the condition that they do not cause harmful interference to, and must accept interference from, stations authorized to operate on a primary basis in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands.

4. Section 95.401 is amended by adding paragraph (h) to read as follows:

§ 95.401 (CB Rule 1) What are the Citizens Band Radio Services?

* * * * *

(h) Medical Micropower Network Service (MMNS) – a wideband, ultra-low power radio service for the transmission of non-voice data to and from implanted medical devices for the purpose of facilitating functional electric stimulation and sensing, a technique using electric currents to activate and monitor nerves and muscles. The rules for this service are contained in subpart M of this part.

5. Section 95.601 is amended by revising the last sentence in the text to read as follows:

§ 95.601 Basis and purpose.

* * * * *

The Personal Radio Services are the GMRS (General Mobile Radio Service)—subpart A, the Family Radio Service (FRS)—subpart B, the R/C Radio Control Radio Service)—subpart C, the CB (Citizens Band Radio Service)—subpart D, the Low Power Radio Service (LPRS)—subpart G, the Wireless Medical Telemetry Service (WMTS)—subpart H, the Medical Implants Communication Service (MICS)—subpart I, the Multi-Use Radio Service (MURS)—subpart J, Dedicated Short-Range Communications Service On-Board Units (DSRCS-OBUs)—subpart L, and Medical Micropower Network Service (MMNS)—subpart M.

6. Section 95.603 is amended by adding paragraph (i) to read as follows:

§ 95.603 Certification required.

* * * * *

(i) Each MMNS transmitter must be certificated, except for MMNS transmitters that are not marketed for use in the United States, but which otherwise comply with the MMNS technical requirements and are operated in the United States by individuals who have traveled to the United States from abroad. MMNS transmitters are subject to the radiofrequency radiation exposure requirements specified in Sections 1.1307 and 2.1093 of this chapter, as appropriate. Applications for equipment authorization of devices operating under this section must contain a finite difference time domain (FDTD) computational modeling report showing compliance with these provisions for fundamental emissions. The Commission retains the discretion to request the submission of specific absorption rate measurement data.

7. Section 95.605 is amended by revising the text to read as follows:

Any entity may request certification for its transmitter when the transmitter is used in the GMRS, FRS, R/C, CB, IVDS, LPRS, MURS, MICS, or MMNS following the procedures in part 2 of this chapter. * * * * *

8. Section 95.626 is added to read as follows:

§ 95.626 MMNS Transmitter Frequencies

(a) Stations may operate on any of the frequencies in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands, provided that the out-of-band emissions are attenuated in accordance with § 95.635.

(b) Each MMNS transmitter 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 MMNS implant transmitters; and

(2) 0°C to 55°C in the case of MMNS control transmitters.

9. Section 95.631 is amended by adding paragraph (l) to read as follows:

§ 95.631 Emission types.

* * * * *

(l) An MMNS station may transmit any emission type appropriate for communications in this service. Voice communications, however, are prohibited.

10. Section 95.633 is amended by adding paragraph (h) to read as follows:

§ 95.633 Emission bandwidth.

* * * * *

(h) For transmitters in the MMNS:

(1) The maximum authorized emission bandwidth is 5 MHz.

(2) Lesser authorized emission bandwidths may be employed, provided that the unwanted emissions are attenuated as provided in § 95.635 and the transmitter power complies with the limits specified in § 95.639(j).

(3) Emission bandwidth will be determined by measuring the width of the signal between two 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.

11. Section 95.635 is amended by revising paragraph (b) and adding paragraph (e) to read as follows:

§ 95.635 Unwanted radiation.

* * * * *

(b) The power of each unwanted emission shall be less than TP as specified in the applicable paragraphs listed in the following table:

Transmitter	Emission type	Applicable paragraphs (b)
* * * * *	* * * * *	* * * * *
MMNS	As specified in paragraph (g)	
* * * * *	* * * * *	* * * * *

* * * * *

(g) For transmitters designed to operate in the MMNS, emissions shall be attenuated in accordance with the following:

(1) Emissions more than 250 kHz outside of the MMNS bands (413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz) shall be attenuated to a level no greater than the following field strength limits:

Frequency (MHz)	Field strength (μV/m)	Measurement distance (m)
30-88	100	3
88-216	150	3
216-960	200	3
960 and above	500	3
Note – At band edges, the tighter limit applies.		

(2) The emission limits shown in the above table 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 Sec. 95.605.

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

(4) Emissions within the MMNS bands (413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz) more than 2.5 MHz away from the center frequency of the spectrum the transmission is intended to occupy, will be attenuated below the transmitter output power by at least 20 dB. Compliance with this 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.

(5) Emissions 500 kHz or less that are above and below the MMNS bands (413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz) will be attenuated below the maximum permitted output power by at least 20 dB. Compliance with this 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.

12. Section 95.639 is amended by adding paragraph (j) to read as follows:

§ 95.639 Maximum transmitter power.

* * * * *

(j) In the MMNS the following limits apply:

(1) For MMNS transmitters, the maximum EIRP over the frequency bands of operation shall not exceed the lesser of 1 mW or 10 log B – 6.866 dBm, where B is the 20 dB emission bandwidth in MHz. In addition, the peak power spectral density shall not exceed 800 microwatts per MHz in any 1 MHz band.

(2) The antenna associated with any MMNS transmitter must be supplied with the transmitter and shall be considered part of the transmitter subject to equipment authorization. Compliance is based on measurements using a peak detector function and measured at its maximum power level.

(3) The maximum EIRP and peak power spectral density may be determined by measuring the radiated field from the equipment under test at 3 meters using a calibrated antenna and calculating the radiated power. Alternative techniques acceptable to the Commission may be used. Measurements are made over a bandwidth of 1 MHz or the 20 dB emission bandwidth of the device, whichever is less. A resolution bandwidth less than the measurement bandwidth can be used, provided that the measured power is integrated to show total power over the measurement bandwidth. If the resolution bandwidth is approximately equal to the measurement bandwidth, and much less than the emission bandwidth of the equipment under test, the measured results shall be corrected to account for any difference between the resolution bandwidth of the test instrument and its actual noise bandwidth.

(4) For a transmitter intended to be implanted in a human body, the following test fixture must be used to simulate operation of the implant under actual operating conditions. See § 95.605.

(i) For measurement purposes to determine compliance with emission limits, the radiating characteristics of an implant transmitter placed in a test fixture should approximate those of an implant transmitter placed in a human body. An appropriate human torso simulator for testing MMNS implant transmitters consists of a cylindrical Plexiglas or polyethelene container with a size of 30 cm by 76 cm with a sidewall thickness of 0.635 cm. or less. It must be completely filled with a material that is sufficiently fluidic that it will flow around the implant without any voids. The dielectric and conductivity properties of this material must match the dielectric and conductivity properties of human muscle tissue at 403.5 MHz. All emissions measurements will be made using the above specification at a nominal temperature of 20-25°C. Simple saline solutions do not meet the above criteria. A mounting grid for the implant inside the container must be provided that permits the radiating element or elements of the implant to be positioned vertically and horizontally. The grid should also support any additional implant leads associated with the therapeutic function in a fixed repeatable manner. The implant must be mounted 6 cm from the sidewall and centered vertically within the container. The above fixture shall be placed on a turntable such that the implant transmitter will be located at a nominal 1.5-meter height above ground and at a 3-meter distance from the measurement antenna. Radiated emissions measurements shall then be performed to insure compliance with the applicable technical specifications.

(ii) A formula for a suitable tissue substitute material is defined in the paper "Simulated Biological Materials for Electromagnetic Radiation Absorption Studies" by G. Hartsgrove, A. Kraszewski, and A. Surowiec as published in "Bioelectromagnetics 8:29-36 (1987)."

13. Section 95.649 is amended by revising the text to read as follows:

§ 95.649 Power capability.

No CB, R/C, LPRS, FRS, MICS, MURS, WMT, or MMNS unit shall incorporate provisions for increasing its transmitter power to any level in excess of the limits specified in § 95.639.

14. Appendix 1 to Subpart E of Part 95—Glossary of Terms is revised to read as follows:

The definitions used in part 95, Subpart E are:

* * * *

Common restricted contention-based protocol. A contention-based protocol that can avoid co-frequency interference with devices using the same contention-based protocol.

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.

MMNS. Medical Micropower Network Service.

MMNS control transmitter. An MMNS transmitter that operates or is designed to operate outside of a human body for the purpose of communicating with a receiver connected to an MMNS implant device or to another MMNS transmitter associated with an MMNS implant device.

MMNS implant transmitter. An MMNS transmitter that operates or is designed to operate within a human body for the purpose of facilitating communications from a medical implant device.

MMNS transmitter. A transmitter authorized to operate in the MMNS.

* * * * *

15. Subpart M is added to read as follows:

Subpart M—Medical Micropower Network Service (MMNS)

§ 95.1601 Eligibility

Operation in the MMNS is permitted by rule and without an individual license issued by the FCC. A person is permitted to operate (i) MMNS implant transmitters connected to medical implant devices that have been implanted in that person by a duly authorized health care professional and (ii) MMNS control transmitters associated with their MMNS implant transmitters. Duly authorized health care professionals are permitted by rule to operate MMNS transmitters. Manufacturers of medical implant devices and MMNS transmitters and their representatives are authorized to operate MMNS transmitters for the purpose of demonstrating such equipment to duly authorized health care professionals. The term "duly authorized health care professional" means a physician or other individual authorized under state or federal law to provide health care services using medical implant devices. Operations that comply with the requirements of this part may be conducted under manual or automatic control.

§ 95.1603 Authorized locations.

MMNS operation is authorized anywhere CB station operation is authorized under § 95.405.

§ 95.1605 Station Identification.

An MMNS station is not required to transmit a station identification announcement.

§ 95.1607 Station inspection.

All non-implanted MMNS apparatus must be made available for inspection upon request by an authorized FCC representative. Persons operating implanted MMNS implant transmitters shall cooperate reasonably with duly authorized FCC representatives in the resolution of interference.

§ 95.1609 Permissible communications.

(a) MMNS transmitters may transmit data signals as permitted in this subpart. Voice communications are prohibited.

(b) Except for the purposes of testing and for demonstrations to health care professionals, MMNS control transmitters may transmit only operational, diagnostic, and therapeutic information associated with a medical implant device that has been implanted by a duly authorized health care professional.

(c) MMNS control transmitters may be interconnected with other telecommunications systems including the public switched telephone network.

§ 95.1611 Channel use policy.

(a) The channels authorized for MMNS operation by this part of the FCC Rules are available on a shared basis only and will not be assigned for the exclusive use of any entity.

(b) Those using MMNS transmitters must cooperate in the selection and use of channels in order to reduce interference and make the most effective use of the authorized facilities. Channels must be selected in an effort to avoid interference to other MMNS transmissions.

(c) Operation is subject to the condition that MMNS transmitters do not cause harmful interference to, and must accept interference from, stations authorized to operate on a primary basis in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands.

(d) All MMNS stations must employ a common restricted contention-based protocol.

(e) Frequency monitoring. MMNS control transmitters must incorporate a mechanism for monitoring the channel or channels that the MMNS devices intend to occupy. The monitoring system antenna shall be the antenna normally used by the MMNS control transmitter for a communications session.

§ 95.1613 Antennas.

No antenna for an MMNS control transmitter shall be configured for permanent outdoor use. Any MMNS control transmitter used outdoors shall not 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.

§ 95.1615 Disclosure policies.

Manufacturers of MMNS transmitters must include with each transmitting device the following statement: "This transmitter is authorized by rule under the Medical Micropower Network 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 Medical Micropower Network 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."

§ 95.1617 Labeling requirements.

(a) MMNS control transmitters 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."

(b) Where an MMNS control transmitter is constructed in two or more sections connected by wire and marketed together, the statement specified in this section is required to be affixed only to the main control unit.

(c) MMNS implant transmitters shall be identified with a serial number. The FCC ID number associated with the transmitter and the information required by Section 2.925 of the FCC Rules may be placed in the instruction manual for the transmitter in lieu of being placed directly on the transmitter.

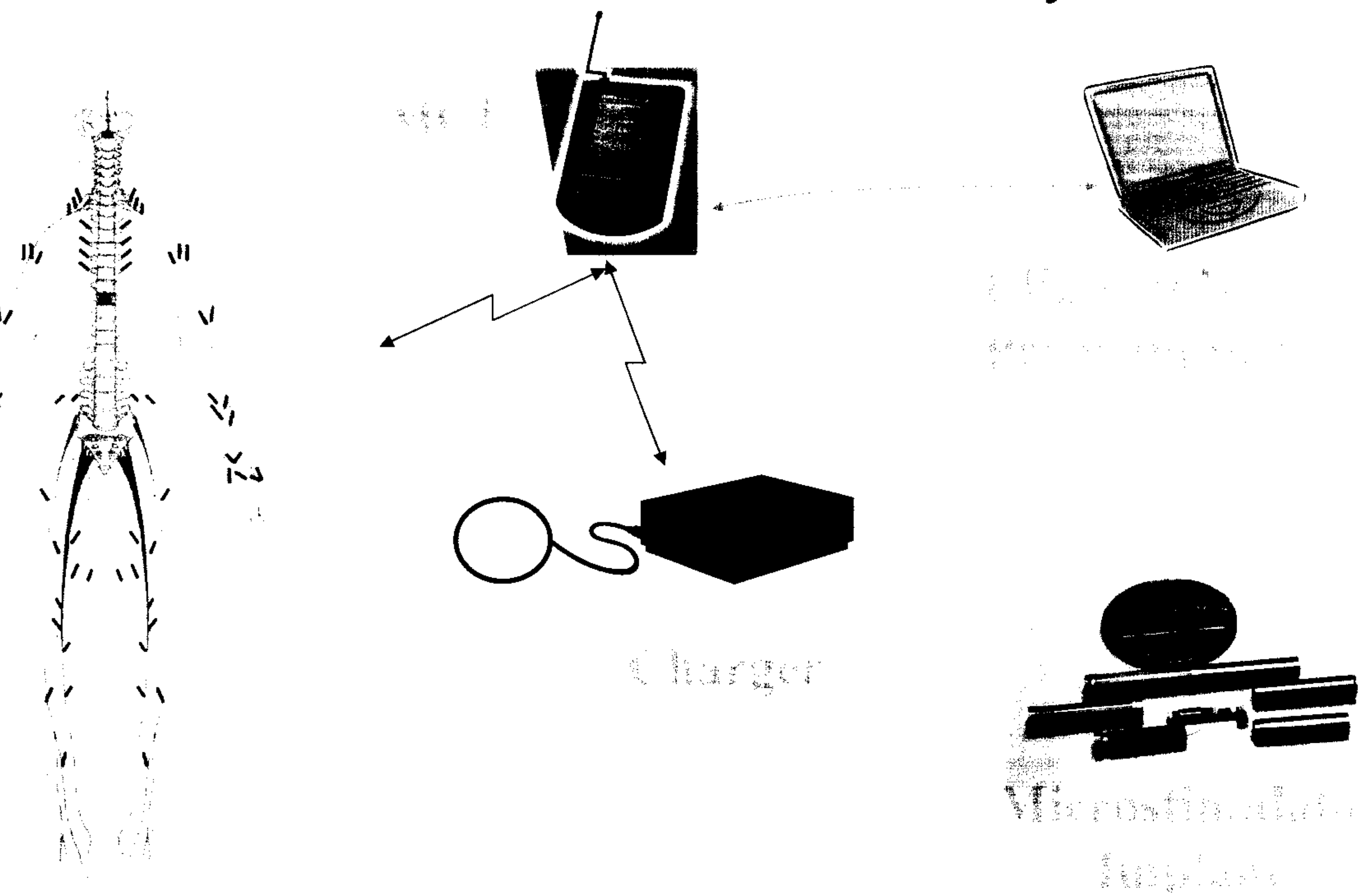
§ 95.1219 Marketing limitations.

Transmitters intended for operation in the MMNS may be marketed and sold only for those uses described in § 95.1609 of this part.

APPENDIX B

ED MANN FOUNDATION

Appendix B: Medical Micropower Network Service System



APPENDIX C

APPENDIX C

ENGINEERING STATEMENT OF JEFFREY BINCKES

I. INTRODUCTION

The Alfred Mann Foundation (AMF) in its petition for rulemaking has proposed to operate medical micro power network service (MMNS) devices, on a secondary basis, in four channels, each of which is 5 MHz wide, in the 413-457 MHz band, portions of which now are allocated, on a primary basis, to federal government fixed, mobile, radiolocation, and space research operations, as well as for non-government fixed and land mobile services. Portions of the 413-457 MHz band also are allocated, on a secondary basis, to amateur services. This study examines the potential for harmful interference from MMNS devices to other authorized services in the 413-457 MHz band, and concludes that MMNS devices can operate in the band with a very low probability of causing harmful interference to other authorized services.[1]

II. BACKGROUND

A. Technical Characteristics of MMNS Systems

In this study, only the highest power radiating element of the MMNS system, the master control unit (MCU), is analyzed in terms of its potential to cause interference to other authorized services. An analysis of the interference potential of the implantable microstimulators is unnecessary because the microstimulators transmit signals at much lower power and duty cycle than the MCU, and because body tissues further attenuate emissions from the microstimulators.

The parameters used for the analysis of MCU links are those of a classic interference link budget, such as EIRP, range to the 'victim' receiver, free space losses, duty cycle, mobile/fixed receiver front-end bandwidth, and equivalent thermal noise of the 'victim' receiver front-end (based upon receiver sensitivity). The values for these parameters are shown in the Summary Table of Section III(B) below. This study assumes a *co-channel existence* between the MCU's transmission and any given type of radio whose tuning range would permit overlap with one or more of the MCU's transmission frequency channels.

B. Technical Characteristics of Mobile, Fixed, and Amateur Radio Receivers

Based upon a general review of the technical specifications for various fixed, mobile, and amateur radio transceivers operating in the 413-457 MHz band, this study assumes that the most common types of fixed, mobile, and amateur two-way radios are, with the

[1] This analysis does not address MCU interference into Government surveillance radars as the characteristics of these radiolocation systems are not publicly available. However, due to the very low power levels of the MCU emissions and separation distances involved, radar video signals are highly unlikely to be impaired.

exception of the available UHF channel(s) tuning range and certain band-specific features, of very similar RF performance—most notably in terms of their front-end sensitivity and RF noise bandwidth. Thus, although this study is based upon the average value of technical specifications for representative mobile radio receivers in the 413-457 MHz band, the results of the study and conclusions drawn are equally applicable to mobile, fixed, and amateur radio receivers in the 413-457 MHz band.

Accordingly, an interference link budget was developed to calculate the interference levels that would accrue *from* the MCU's transmissions, using its *maximum* radiated carrier power (EIRP = 0 dBm or 1 milliwatt) at the *center* of each of the four proposed MMNS frequency bands: 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz. The interference levels are evaluated at the mobile radio receiver at various ranges: 3 meters, 30 meters, 300 meters, 3000 meters (3 km) and 30,000 meters (30 km). At each of these path distances, *only* free space losses (FSL) were applied to determine the attenuation of the MCU's signals; that is, those losses due to inverse-square propagation (**FSL = λ^2 / (4π)^2 R^2**; where **λ = the wavelength** and **R = the range** between the MCU and the Mobile Radio).

Consequently, because the interference analysis does not account for terrain or other environmental conditions that ordinarily would mitigate interference, it is expected to yield overly conservative results that would occur only in worst-case interference scenarios. In any real-world operating environment, terrain profile (*e.g.*, hills and mountains) as well as natural foliage and man-made obstacles can provide considerably more attenuation of the signal over and above the theoretical FSL. Additionally, most MCU transmissions are expected to occur indoors; and, therefore additional attenuation would be present in the link due to signal loss through building walls, typically 15- 20 dB for outside walls. Furthermore, antenna misalignment and polarization loss would further diminish actual interference levels and these losses have not been taken into account here.

III. INTERFERENCE ANALYSIS

A. Methodology

Interference calculations presented herein are thus straight-forward and are most easily followed by reference to those that are set forth in an Excel spread sheet attached as Attachment 1. Nearly all the calculations are supplied in logarithmic form in order to simplify the math and to comply with normal engineering practice.

In the first pair of columns, **A & B,** the center or carrier MCU frequencies of the four proposed 5 MHz sub-bands: 416 MHz, 429 MHz, 441 MHz, and 454 MHz are listed and the equivalent operating wavelength, as calculated from: **λ = *c/f*;** where ***c*** **= the speed of light = 3 x 10^8 meters/second, and *f* = the transmitting frequency in MHz x 10^6.**

In the next column, **C,** the MCU's *maximum* effective isotropic radiated power (EIRP) is entered (the same for all four sub-bands) as -30 dBW or 1 milliwatt. The next column, **D,** gives the range between the MCU and Mobile Radio, in meters.

Corresponding to the range and the frequency (or wavelength) the free space losses are calculated, in dB, in column **E**. The equation for calculation of FSL ($\lambda^2/(4\pi)^2 R^2$), in decibel form is given by:

$$20*LOG(\lambda)-20*LOG(4\pi)-20*LOG(R); \text{ where } R = \text{range (meters)}$$

It is evident that the propagation losses for the four frequency sub-bands differ by less than 1 dB, as taken from the lowest to the highest frequency sub-band, because the wavelengths corresponding to this frequency range differ by about 9%.
Calculation of the MCU signal level, in dBm, instead of dBW, at the various ranges, using the logarithmic form of FSL is now very simply:

MCU signal level = EIRP (dBW)+FSL (dB)+30 dB (dBm); where 30 dB converts from dBW to dBm

These MCU interfering signal levels, shown in column **F**, represent the full 1 milliwatt power of the MCU integrated over the total 5 MHz bandwidth of the MCU transmission. However, land mobile radios, either the FM or Digital Mobile Radio receivers are programmed at the factory to tune to narrow-band channels with either a 12.5 kHz or 25/30 kHz channel spacing. Nevertheless, the front-end filtering of these receivers is less than the channel spacing: it is normally configured with only a 5 kHz band pass filter. Therefore, regardless of the channel to which it is tuned, the mobile radio receiver will intercept a level of interference power corresponding to the ratio of its band pass bandwidth (5 kHz) to the full bandwidth occupied by the MCU transmission (5 MHz); or:

Relative Level of MCU signal = 10*LOG(5*10^3/5*10^6) =10*LOG(.001)= -30dB (in a 5 kHz bandwidth)

Thus, the level of the MCU signal shown in column **G** is correspondingly 30 dB down from the level shown in column **F.** However, even this reduced value of the MCU signal represents an assumed, hypothetical duty cycle of 100% for the MCU transmission. In reality, the duty cycle of MCU is never 100%, but rather only 3% to 5%.

For a system with 10 to 20 implanted microstimulators, the transmit duty cycle of the MCU is approximately 3 percent. This duty cycle is reflected in column **H,** which for the typical mode of operation described above, is simply a reduction in the *average power* of the MCU signal, by virtue of the duty cycle, as taken in the 5 kHz pass band, at the mobile radio receiver by:

10*LOG(.03125) = -15.0 dB

The resulting interference power level from the MCU can be compared to the thermal noise at the mobile radio receiver to obtain the interference-to-noise ratio. The receiver's internal thermal noise, in turn, is a function of its noise figure or temperature. However, in reviewing manufacturers' specifications for mobile radios, it is found that the sensitivity of the receiver is most often expressed in voltage units, such as μV rather than noise power (kTB); and, as such, the following equation will be used to convert the sensitivity in *microvolts* to *average power*, in dBm:

dBm = 10*LOG(Vrms^2/Zo) +30;

where Vrms = receiver sensitivity in volts rms
Zo = receiver impedance (typically 50Ω)

In an examination of technical specifications for a wide variety of mobile radio receivers in the 400 MHz band, the most commonly stated value and indeed the average value for the sensitivity of analog UHF FM radios or even the newer digital radios was 0.25μV with a variance of +/-0.05μV. The receiver thermal noise level, expressed in dBm, can be given, as shown in column **I**, as:

10*LOG{ (0.25 * 10^-6)^2/50}+30 = -149+30 = -119 dBm

In the 413-457 MHz frequency band, there is also a significant level of *ambient, external RF noise, from both the local environment (power lines, machinery, etc) and unwanted radio signals.* Mobile radio receivers must contend with this noisy RF environment, usually accomplished with a so called "squelch" control which limits the level of residual hum and noise of the receiver. In any commercially available receiver the Automatic Gain Control (AGC) of the receiver will add gain as the level of the RF input is reduced—this extra receiver gain for low-level signals then amplifies the residual hum and noise, obscuring intelligibility of voice communications or causing bit errors unless the squelch control is activated to limit the RF gain and/or audio gain. Thus, while the ultimate sensitivity of the radio is driven by internal, thermal noise, the usable sensitivity of the receiver is limited by the sum of internal ***thermal noise*** plus ***ambient, external noise.***

The field experience of mobile radio operators, as well as some testing by organizations, such as the International Telecommunication Union,[2] which conduct their own evaluations of commercially available mobile radios in local RF environments, leads to the conclusion that the *average* ambient RF noise in the typical, narrow-band voice channels of UHF mobile radios—in urban areas—is typically about 20 dB above the thermal noise (kTB) of the receiver noise bandwidth. Therefore, in the computation of the Interference-to-Noise (I/N) ratio due to MCU interference to mobile radio, the thermal noise, -119 dBm, calculated above (as derived from the receiver sensitivity of 0.25μV) is used; and an *additional external* RF noise, equivalent to +20 dB over this value results in a *combined*, practical receiver noise floor of -99 dBm, as shown in column **J**.

---

[2] *See, e.g.*, International Telecommunication Union, Radiocommunication Study Groups, U.S. Input Document 7C/140-E, *Feasibility of Co-channel Sharing Between the Meteorological Aids and Ultra-low Power Implantable Medical Devices in the 401-406 MHz Band*, at 3 (May 26, 1997).

Finally, as shown in the last, active spread-sheet column **K**, the value of MCU interference at five different ranges (3, 30, 300, 3000, 30,000 meters) as compared to the Mobile Radio noise floor is calculated; i.e., the (I/N); N being kTB+20 dB.

B. Results

The following summary table sets forth the results of the relevant interference calculations.

SUMMARY TABLE: RESULTS OF INTERFERENCE STUDY

Center Frequency (MHz)	Range to LMR (meters)	Free Space Losses (dB)	Interference Level from MCU (dBm)	LMR Receiver Noise (dBm)	I/N Ratio (dB) Receiver N= (thermal+ambient)
429	3	-34.6	-79.6	-99.0	+19.4
429	30	-54.6	-99.6	-99.0	-0.6
429	300	-74.6	-119.6	-99.0	-20.6
429	3,000	-94.6	-139.6	-99.0	-40.6
429	30,000	-114.6	-159.6	-99.0	-60.6

The results in column **K** of Attachment 1 show that at ranges of 30 meters, 300 meters, 3,000 meters (3 km.), and 30,000 meters (30 km.), the interference level from MCU transmissions would be approximately -1 dB, -20 dB, -40 dB, or -60 dB *below* the receiver noise floor. Thus, the mobile radio receiver cannot discern the presence of the MCU signals, except possibly some minimal added background noise when the mobile radio is at a distance of 30 meters.

In other words, at a range of 300 meters, approximately 100 MCUs would be required to transmit simultaneously on the same channel to approach the mobile radio noise floor. Moreover, at ranges of 3 km. and 30 km., approximately 10,000 MCUs and 1,000,000 MCUs, respectively, would be required to transmit simultaneously on the same channel in order to equal the receiver noise floor. Furthermore, assuming that four radio channels are available for MMNS use, the total number of MCUs that can be accommodated would increase four-fold without breaching the noise floor of any mobile radio receiver.

At a range of only 3 meters, the interference level from MCU transmissions would exceed the mobile radio noise floor, as indicated by a positive I/N ratio of +19.4 dB. In the unlikely event that a mobile radio receiver would be within 3 meters of a person using an MCU, the interference could mitigated by (1) adjusting the orientation or alignment of the MCU or the mobile radio antenna; (2) increasing the distance between the MCU and the mobile radio receiver; or (3) creating an obstruction in the line of sight path, such as by moving the MCU closer to the patient's body. Furthermore, through its frequency monitoring capability, the MCU can shift to a less congested channel, thus further reducing the risk of harmful interference to nearby mobile radio receivers.

These calculations are based *__solely__* on free space losses, without any additional propagation attenuation for real, terrestrial links, which normally entail considerably more loss due to terrain and foliage, as well as polarization and antenna misalignment losses. *As such, these interference calculations are considered to be overly conservative.* Thus, MCU interference to mobile radio receivers would likely be imperceptible to mobile radio at ranges of 30 m., 300 m., 3 km., and 30 km.

IV. CERTIFICATION

I, Jeffrey Binckes, am a telecommunications engineer with more than 40 years of experience working on communications interference and regulatory issues. I have been retained by the Alfred Mann Foundation to examine the potential for harmful interference from MMNS devices to other authorized services in the 413-457 MHz band. The information contained herein is true and correct to the best of my knowledge.

Jeffrey Binckes

Date: September 5, 2007

ATTACHMENT 1

INTERFERENCE SCENARIO FOR MEDICAL MICROPOWER NETWORK SERVICE ("MMNS") DEVICES INTO MOBILE RADIOS ("MOBILE") IN 413-457 MHz BAND

ENCY z)	(B) WAVELENGTH λ (m)	(C) MMNS EIRP (dBW)	(D) RANGE BETWEEN MMNS AND MOBILE (meters)	(E) FREE SPACE PROPAGATION LOSS (dB)	(F) INTERFERENCE AT MOBILE (dBm)	(G) INTERFERENCE IN MOBILE FRONT END RF CHANNEL(dBm)	(H) NET INTERFERENCE TO MOBILE (dBm)	(I) MOBILE RECEIVER THERMAL NOISE (dBm)	(J) AMBIENT NOISE AT RECEIVER INPUT (dBm)	INTER TO-
	0.721153846	-30	3	-34.36606389	-34.36606389	-64.36606389	-79.36606389	-119	-99	
	0.721153846	-30	30	-54.36606389	-54.36606389	-84.36606389	-99.36606389	-119	-99	
	0.721153846	-30	300	-74.36606389	-74.36606389	-104.3660639	-119.3660639	-119	-99	
	0.721153846	-30	3000	-94.36606389	-94.36606389	-124.3660639	-139.3660639	-119	-99	
	0.721153846	-30	30,000	-114.3660639	-114.3660639	-144.3660639	-159.3660639	-119	-99	
	0.699300699	-30	3	-34.63334312	-34.63334312	-64.63334312	-79.63334312	-119	-99	
	0.699300699	-30	30	-54.63334312	-54.63334312	-84.63334312	-99.63334312	-119	-99	
	0.699300699	-30	300	-74.63334312	-74.63334312	-104.6333431	-119.6333431	-119	-99	
	0.699300699	-30	3000	-94.63334312	-94.63334312	-124.6333431	-139.6333431	-119	-99	
	0.699300699	-30	30,000	-114.6333431	-114.6333431	-144.6333431	-159.6333431	-119	-99	
	0.680272109	-30	3	-34.87296907	-34.87296907	-64.87296907	-79.87296907	-119	-99	
	0.680272109	-30	30	-54.87296907	-54.87296907	-84.87296907	-99.87296907	-119	-99	
	0.680272109	-30	300	-74.87296907	-74.87296907	-104.8729691	-119.8729691	-119	-99	
	0.680272109	-30	3000	-94.87296907	-94.87296907	-124.8729691	-139.8729691	-119	-99	
	0.680272109	-30	30,000	-114.8729691	-114.8729691	-144.8729691	-159.8729691	-119	-99	
	0.660792952	-30	3	-35.12531434	-35.12531434	-65.12531434	-80.12531434	-119	-99	
	0.660792952	-30	30	-55.12531434	-55.12531434	-85.12531434	-100.1253143	-119	-99	
	0.660792952	-30	300	-75.12531434	-75.12531434	-105.1253143	-120.1253143	-119	-99	
	0.660792952	-30	3000	-95.12531434	-95.12531434	-125.1253143	-140.1253143	-119	-99	
	0.660792952	-30	30,000	-115.1253143	-115.1253143	-145.1253143	-160.1253143	-119	-99	