

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.

(8) 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.

* * * * *

7. Section 95.639 is amended by redesignating existing paragraph (f)(3) as paragraph (f)(5) and adding new paragraphs (f)(3) and (f)(4) to read as follows:

§ 95.639 Maximum Transmitter Power.

* * * * *

(f) In the MedRadio Service:

* * * * *

(3) For transmitters operating in the 2360-2390 MHz band, the maximum EIRP over the frequency bands of operation shall not exceed the lesser of 1 mW or $10 \cdot \log(B)$ dBm, where B is the 20 dB emission bandwidth in MHz.

(4) For transmitters operating in the 2390-2400 MHz band, the maximum EIRP over the frequency bands of operation shall not exceed the lesser of 20 mW or $16 + 10 \cdot \log(B)$ dBm, where B is the 20 dB emission bandwidth in MHz.

(5) 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.

* * * * *

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

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

Medical Body Area Network (MBAN). An MBAN is a low power network consisting of a MedRadio programmer/control transmitter and multiple medical body-worn devices all of which transmit or receive non-voice data or related device control commands for the purpose of measuring and recording physiological parameters and other patient information or performing diagnostic or therapeutic functions via radiated bi- or uni-directional electromagnetic signals.

Subpart I – Medical Device Radiocommunications Service (MedRadio)

9. Section 95.1203 is revised to read as follows:

§ 95.1203 Authorized Locations.

MedRadio operation is authorized anywhere CB station operation is authorized under § 95.405, except that use of Medical Body Area Network devices in the 2360-2390 MHz band is restricted to indoor operation within a health care facility registered with the MBAN coordinator under § 95.1225. A health care facility includes hospitals and other establishments that offer services, facilities and beds for use beyond a 24 hour period in rendering medical treatment, and institutions and organizations regularly engaged in providing medical services through clinics, public health facilities, and similar establishments, including government entities and agencies such as Veterans Administration hospitals.

10. Section 95.1209 is amended by redesignating existing paragraph (g) as paragraph (h) and adding a new paragraph (g) to read as follows:

§ 95.1209 Permissible Communications

* * * * *

(g) Medical body-worn transmitters may only relay information in the 2360-2400 MHz band to a MedRadio programmer/control transmitter that is part of the same Medical Body Area Network (MBAN). A MedRadio programmer/control transmitter may not be used to relay information in the 2360-2400 MHz band to another MedRadio programmer/controller transmitter. Wireless retransmission of information to a receiver that is not part of the same MBAN shall be performed using other radio services that operate in spectrum outside of the 2360-2400 MHz band.

(h) 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.

11. Section 95.1211 is amended by revising paragraph (c) to read as follows:

§ 95.1211 Channel Use Policy

* * * * *

(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, 451-457, and 2360-2400 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, 451-457, and 2360-2400 MHz bands.

* * * * *

12. Section 95.1213 is revised to read as follows:

§ 95.1213 Antennas.

Except for the 2390-2400 MHz band, no antenna for a MedRadio transmitter shall be configured for permanent outdoor use. In addition, any MedRadio antenna 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.

13. Section 95.1215 is amended by adding paragraph (c) to read as follows:

§ 95.1215 Disclosure Policies.

* * * * *

(c) Manufacturers of MedRadio transmitters operating in the 2360-2400 MHz band 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 2360-2400 MHz band, 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 adding paragraph (a)(3) and revising paragraph (c) to read as follows:

§ 95.1217 Labeling Requirements.

* * * * *

(a) (3) MedRadio programmer/control transmitters operating in the 2360-2400 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 authorized to operate on a primary basis in the 2360-2400 MHz band, 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.

* * * * *

(c) MedRadio transmitters shall be identified with a serial number, except that in the 2360-2400 MHz band only the MedRadio programmer/controller transmitter shall be identified with a serial number. The FCC ID number associated with a medical implant transmitter and the information required by §2.925 of this chapter may be placed in the instruction manual for the transmitter and on the shipping container for the transmitter, in lieu of being placed directly on the transmitter.

15. New Section 95.1223 is added to read as follows:

§ 95.1223 Registration and frequency coordination in the 2360-2390 MHz Band.

(a) A health care facility must register all MBAN devices it proposes to operate in the 2360-2390 MHz band with a frequency coordinator designated under § 95.1225. Operation of these devices in the 2360-2390 MHz band is prohibited prior to the MBAN coordinator notifying the health care facility that

registration and coordination (to the extent coordination is required under paragraph (c)), is complete. The registration must include the following information:

- (1) Specific frequencies or frequency range(s) within the 2360-2390 MHz band to be used, and the capabilities of the MBAN equipment to use the 2390-2400 MHz band;
- (2) Effective isotropic radiated power;
- (3) Number of control transmitters in use at the health care facility as of the date of registration including manufacturer name(s) and model numbers and FCC identification number;
- (4) Legal name of the health care facility;
- (5) Location of control transmitters (*e.g.*, geographic coordinates, street address, building);
- (6) Point of contact for the health care facility (*e.g.*, name, title, office, phone number, fax number, e-mail address); and
- (7) In the event an MBAN has to cease operating in all or a portion of the 2360-2390 MHz band due to interference under § 95.1211 or changes in coordination under paragraph (c) of this rule section, a point of contact (including contractors) for the health care facility that is responsible for ensuring that this change is effected whenever it is required (*e.g.*, name, title, office, phone number, fax number, e-mail address). The health care facility also must state whether, in such cases, its MBAN operation is capable of defaulting to the 2390-2400 MHz band and that it is responsible for ceasing MBAN operations in the 2360-2390 MHz band or defaulting traffic to other hospital systems.

(b) A health care facility shall notify the frequency coordinator whenever an MBAN control transmitter in the 2360-2390 MHz band is permanently taken out of service, unless it is replaced with transmitter(s) using the same technical characteristics as those reported on the health care facility's registration. A health care facility shall keep the information contained in each registration current, shall notify the frequency coordinator of any material change to the MBAN's location or operating parameters, and is prohibited from operating the MBAN in the 2360-2390 MHz band under changed operating parameters until the frequency coordinator determines whether such changes require coordination with the AMT coordinator designated under § 87.305 of this chapter and, if so, the coordination required under paragraph (c) has been completed.

(c) Coordination procedures. The frequency coordinator will determine if an MBAN is within the line of sight of an AMT receive facility in the 2360-2390 MHz band and notify the health care facility when it may begin MBAN operations under the procedures below.

(1) If the MBAN is beyond the line of sight of an AMT receive facility, it may operate without prior coordination with the AMT coordinator, provided that the MBAN coordinator provides the AMT coordinator with the MBAN registration information and the AMT coordinator concurs that the MBAN is beyond the line of sight prior to the MBAN beginning operations in the band.

(2) If the MBAN is within line of sight of an AMT receive facility, the MBAN frequency coordinator shall achieve a mutually satisfactory coordination agreement with the AMT frequency coordinator prior to the MBAN beginning operations in the band. Such coordination agreement shall provide protection to AMT receive stations consistent with International Telecommunication Union (ITU) Recommendation ITU-R M.1459, "Protection criteria for telemetry systems in the aeronautical mobile service and mitigation techniques to facilitate sharing with geostationary broadcasting-satellite and mobile-satellite services in the frequency bands 1 452-1 525 and 2 310-2 360 MHz," adopted May 2000, as adjusted using generally accepted engineering practices and standards that are mutually agreeable to both coordinators to take into account the local conditions and operating characteristics of the applicable AMT and MBAN facilities, and shall specify when the device shall limit its transmissions to segments of the 2360-2390 MHz band or shall cease operation in the band. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 C.F.R. part 51. Copies of the recommendation may be obtained from ITU, Place des Nations, 1211 Geneva 20,

Switzerland, or online at <<http://www.itu.int/en/publications/Pages/default.aspx>>. Copies are available for inspection during normal business hours at the following locations: Federal Communications Commission, 445 12th Street, SW, Washington, DC 20554, or Office of the Federal Register, 800 North Capitol Street, N.W., Suite 700, Washington, DC. "Generally accepted engineering practices and standards" include, but are not limited to, engineering analyses and measurement data as well as limiting MBAN operations in the band by time or frequency.

(3) If an AMT operator plans to operate a receive site not previously analyzed by the MBAN coordinator to determine line of sight to an MBAN facility, the AMT operator shall consider using locations that are beyond the line of sight of a registered health care facility. If the AMT operator determines that non-line of sight locations are not practical for its purposes, the AMT coordinator shall notify the MBAN coordinator upon no less than 7 days' notice that the registered health care facility must cease MBAN operations in the 2360-2390 MHz band unless the parties can achieve a mutually satisfactory coordination agreement under paragraph (c)(2).

16. New Section 95.1225 is added to read as follows:

§ 95.1225 Frequency coordinator.

(a) The Commission will designate a frequency coordinator(s) to manage the operation of medical body area networks in the 2360 MHz -2390 MHz band.

(b) The frequency coordinator shall perform the following functions:

(1) Register health care facilities that operate an MBAN in the 2360-2390 MHz band, maintain a database of these MBAN transmitter locations and operational parameters, and provide the Commission with information contained in the database upon request;

(2) Determine if an MBAN is within line of sight of an AMT receive facility in the 2360-2390 MHz band and coordinate MBAN operations with the designated AMT coordinator as specified in § 87.305;

(3) Notify a registered health care facility when an MBAN has to change frequency within the 2360-2390 MHz band or to cease operating in the band consistent with a coordination agreement between the MBAN and the AMT coordinators;

(4) Develop procedures to ensure that registered health care facilities operate an MBAN consistent with the coordination requirements under § 95.1223; and

(5) Identify the MBAN that is the source of interference in response to a complaint from the AMT coordinator and notify the health care facility of alternative frequencies available for MBAN use or to cease operation consistent with the rules.

APPENDIX C

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 Objective of the Report and Order.

2. The Report and Order (*R&O*) expands our Part 95 Medical Device Radiocommunication Service (MedRadio) rules to permit the development of new Medical Body Area Network (MBAN) devices. MBAN devices will be linked into wireless networks of multiple body transmitters used for measuring and recording physiological parameters and other patient information or for performing diagnostic or therapeutic functions, primarily in health care facilities. By reducing the need to physically connect sensors to essential monitoring equipment by cables and wires, MBAN technology will enhance patient care and promote efficiencies that can in turn reduce overall health care costs.

3. The *R&O* concludes that the 2360-2400 MHz band is particularly well suited for MBAN use, given the propagation characteristics of these frequencies, the ability of MBAN devices to be able to share the band with incumbent users, and the ready availability of chipsets and technology that can be leveraged for MBAN development. The *R&O* establishes a 40 megahertz secondary allocation for MedRadio, with use limited to MBAN operations, through the addition of a footnote to the Table of Frequency Allocations (Table). Because MBAN operation is authorized on a secondary basis, an MBAN must accept interference from and not cause interference to primary services that share the 2360-2400 MHz band. The *R&O* adopts technical and service rules to govern MBAN operation. MBAN devices will operate under existing Part 95 MedRadio rules, as modified to account for device networking, wider bandwidth, and higher transmission power. The *R&O* adopts new registration and coordination rules to ensure protection of Aeronautical Mobile Telemetry (AMT) operations in the 2360-2390 MHz band.

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

4. No comments were filed in response to the IRFA in this proceeding. In addition no comments were submitted concerning small business issues.

C. Response to Comments by the Chief Counsel for Advocacy of the Small Business Administration

5. Pursuant to the Small Business Jobs Act of 2010, the Commission is required to respond to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration (SBA), and to provide a detailed statement of any change made to the proposed rules as a result of those comments.

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

² See Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Networks, ET Docket No. 08-59, Notice of Proposed Rulemaking (NPRM), 24 FCC Rcd 9589, 9615-18 (2009).

³ See 5 U.S.C. § 604.

The Chief Counsel did not file any comments in response to the proposed rules in this proceeding.

D. Description and Estimate of the Number of Small Entities to Which the Adopted 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 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. As an initial matter, we note that our decision will permit MBAN use of the 2390-2400 MHz band, which is also allocated to the Amateur Radio Service on a primary basis. Individuals who are the control operators of amateur radio stations are not “small entities,” as defined in the RFA.

7. Personal Radio Services. The MBAN devices will be subject to 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.

⁴ 5 U.S.C. § 603(b)(3).

⁵ 5 U.S.C. § 601(6).

⁶ 5 U.S.C. § 601(3) (incorporating by reference the definition of “small-business concern” in 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 C.F.R.C.F.R. Part 90.

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

9. Aeronautical Mobile Telemetry (AMT). Currently there are 9 AMT licensees in the 2360-2395 MHz band. It is unclear how many of these will be affected by our new rules. The Commission has not yet defined a small business with respect to aeronautical mobile telemetry 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.¹³ Census data for 2007 show that there were 1,383 firms that operated that year.¹⁴ Of those 1,368 had fewer than 100 employees. Thus, under this size standard, the majority of firms can be considered small. The rules we adopt provide the flexibility manufacturers, licensees and coordinators need to accommodate changes in both AMT and MBAN operations and assurance to AMT users that their future access to the spectrum will not be hampered.

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

10. Under the adopted rules, MBAN operators will not require individual licenses but instead will qualify for license-by-rule operation¹⁵ pursuant to Section 307(e) of the Communications Act (Act).¹⁶ While there is no requirement to file with the Commission, parties seeking to utilize the 2360-2390 MHz band must register with a frequency coordinator. The Commission will designate the MBAN frequency coordinator(s). The frequency coordinator will require the following information from an entity that seeks to operate an MBAN in the 2360-2390 MHz band:

- Specific frequencies or frequency range(s) within the 2360-2390 MHz band to be used, and

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

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

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

¹⁴ 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.

¹⁵ See 47 C.F.R. § 95.1201.

¹⁶ 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).

the capabilities of the MBAN equipment to use the 2390-2400 MHz band;

- Effective isotropic radiated power;
- Number of programmer/controller transmitters in use at the health care facility as of the date of registration including manufacturer name(s) and model numbers and FCC identification number;
- Legal name of the health care facility;
- Location of programmer/controller transmitters;
- Point of contact for the health care facility; and
- Contact information for the party that is responsible for ensuring that MBAN operations within the health care facility are discontinued or modified in the event such devices have to cease operating in all or a portion of the 2360-2390 MHz band due to interference or because the terms of coordination have changed. The health care facility also must state whether, in such cases, its MBAN operation is capable of defaulting to the 2390-2400 MHz band and that it is responsible for ceasing MBAN operations in the 2360-2390 MHz band or defaulting traffic to other hospital systems.

11. The Commission imposes these notification requirements in recognition that MBAN device operations have the potential to interfere with the sensitive receivers and high gain antennas used by the primary AMT licensees. The *Report and Order* also establishes a coordination procedure that will be used when the MBAN coordinator determines that MBAN devices in the 2360-2390 MHz band would be operating under conditions where such interference might occur – specifically, within the line-of-sight of AMT operations. The coordination process would allow the MBAN coordinator and the AMT coordinator to determine whether and under what circumstances MBAN equipment could be used without interfering with the primary AMT operations. The *Report and Order* concludes that the adoption of reasonable coordination requirements will adequately protect AMT operations while enabling MBAN devices to be widely deployed in health care facilities. The Commission concludes that the registration and coordination requirements effectively balance the interests of the interested parties and are preferable to other options, such as using alternate frequency bands or establishing large exclusion zones around AMT locations.

12. The *R&O* adopts service and technical rules that apply to all entities that manufacture and use MBAN devices. The rules generally require that MBAN devices be able to operate in the presence of other primary and secondary users in these frequency bands. MBAN operations in the 2360-2390 MHz are restricted to indoor locations to protect AMT operations. The MBAN programmer/controller must ensure that its network operates in the 2360-2390 MHz band only if it is in receipt of a control message. As directed by a control message, the MBAN programmer/controller must be capable of: (1) redirecting the MBAN to newly specified spectrum in the 2360-2390 MHz band; or (2) redirecting the MBAN to spectrum in the 2390-2400 MHz band. An MBAN programmer/controller that does not receive a control message within the timeframe programmed into the device by the manufacturer must ensure that its MBAN ceases operation in the 2360-2390 MHz band.¹⁷

13. MBAN 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

¹⁷ Paras. 48-49, *supra*.

duly authorized health care professional.¹⁸ An MBAN consists of only body-worn devices. A single MBAN programmer/controller may direct more than one MBAN. MBAN programmer/controller devices may not directly communicate with each other and MBAN component devices may not directly communicate with each other.¹⁹

14. An MBAN may transmit in an authorized bandwidth of 5 megahertz.²⁰ MBAN transmitters may transmit in the 2360-2390 MHz band, the maximum EIRP over the frequency bands of operation shall not exceed the lesser of 1 mW or $10 \cdot \log(B)$ dBm, where B is the 20 dB emission bandwidth in MHz. MBAN transmitters may transmit in the 2390-2400 MHz band, the maximum EIRP over the frequency bands of operation shall not exceed the lesser of 20 mW or $16 + 10 \cdot \log(B)$ dBm, where B is the 20 dB emission bandwidth in MHz.. The MBAN must meet specific limits on unwanted emissions.²¹ MBAN 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 0°C to 55°C.²²

15. MBAN 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. Manufacturers of MBAN transmitters must include with each transmitting device a disclosure statement and each MBAN programmer/controller must be labeled with a statement.²³ An MBAN may be operated anywhere that CB station operation is authorized under § 95.405 and not be required to transmit a station identification announcement. All non- MBAN transmitters must be made available for inspection upon request by an authorized FCC representative.²⁴

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

16. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.²⁵

17. We are adopting a license-by-rule approach for MBAN operations. This decision should decrease the cost of MBAN use for small entities as compared to a requirement that MBAN users apply for and obtain individual station licenses from the Commission because it will eliminate application expenses associated with the traditional licensing process.

¹⁸ Paras. 33-34, *supra*.

¹⁹ Paras. 35-38, *supra*.

²⁰ Paras. 44-45, *supra*.

²¹ Paras. 46-47, *supra*.

²² Para. 51, *supra*.

²³ Paras 41-42, *supra*.

²⁴ Para. 43, *supra*.

²⁵ See 5 U.S.C. § 603(c).

18. The registration and coordination process for operation in the 2360-2390 MHz band, as well as the requirement that MBAN devices be capable of receiving and complying with a control message, will maximize the ability of MBAN devices to share spectrum with primary AMT users. Alternative approaches, such as the use of exclusion zones, would have categorically prohibited MBAN use in certain areas, even if it would be technically possible to operate MBAN devices without interference to AMT users. Other options would have made it more difficult to accommodate new or modified use by the primary AMT licensees that can affect the ability for MBAN users to operate without causing interference.

19. Permitting operation in the 2360-2400 MHz band will enable MBAN manufacturers to easily adapt the wide variety of equipment that is already produced for operation in the adjacent 2.4 GHz band, thus reducing MBAN equipment costs. Alternative higher spectrum bands would require increased power to provide adequate coverage, which would result in shorter battery life. This, along with the lack of readily available chipsets, indicates that adopting the other allocation options considered in the proceeding would likely have resulted in higher costs for MBAN users.

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. Taken as a whole, these requirements will ensure that (1) MBAN operations comply with our technical rules, (2) MBAN users are aware of pertinent interference requirements, and (3) equipment manufacturers market and sell MBAN devices only for the types of communications permitted under the Commission's rules. Utilizing our existing regulatory framework, which is familiar to both health care providers and medical device manufacturers, enables us to authorize MBAN devices without implementing new rule subparts or codifying a significantly more complex system management scheme into our existing rules. Thus, we are able to provide for MBAN deployment in a manner that protects incumbent users without passing any undue costs or regulatory burdens onto prospective MBAN users, many of whom may be small entities.

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.²⁶ In addition, the 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.

²⁶ See 5 U.S.C. § 801(a)(1)(A).

**STATEMENT OF
CHAIRMAN JULIUS GENACHOWSKI**

Re: Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Network, First Report and Order and Further Notice of Proposed Rulemaking, ET Docket No. 08-59

This is the second of two items on today's agenda about major innovations to harness communications technology to save lives.

In his new book *The Creative Destruction of Medicine*, Dr. Eric Topol wrote, quote, "The emergence of powerful tools to digitize human beings with full support of [our Internet] infrastructure creates an unparalleled opportunity to forever change how health care is delivered."

At the FCC we have embraced the opportunities of communications technology to improve health care results and lower health care costs. The National Broadband Plan identified health care as an area of enormous promise for broadband-enabled innovation. The plan included many recommendations, which we have been implementing.

We entered into 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 proposed USF reforms, and easing testing restrictions on anchor institutions like universities and research organizations. I expect an order on this in the coming months.

And late last year, the Commission adopted an order to dedicate spectrum for Medical Micropower Networks, which have the potential - literally - to enable paraplegics to stand.

Today, we take the next step forward on our health communication agenda with new rules to allow greater use of spectrum for Medical Body Area Network, or MBAN, devices. As I saw last week at George Washington University Hospital, this technology has tremendous potential to untether patients from tubes and wires, and improve the quality of health care and ensure better outcomes for patients.

How much does monitoring matter? Unmonitored hospital patients have a 6% chance of surviving a cardiac arrest. For monitored hospital patients, the odds improve dramatically to 48%. And Philips estimates that, by decreasing hospital-acquires infections, MBAN monitoring can save an average of up to \$12,000 per patient.

Today's item will help maximize the potential of MBAN technology by providing access to relatively quiet spectrum where this technology can develop and flourish.

With this order, the U.S. becomes the first country in the world to dedicate spectrum for Medical Body Area Networks in hospitals, clinics, doctors' offices, as well as in homes.

Previously, this spectrum was used almost exclusively by commercial test pilots. This order represents a multi-industry effort to foster innovation in this spectrum band by allowing distinct but compatible users to share airwaves.

This item is a great example of how parties working together and with the FCC can achieve win-win outcomes for various industries and for the America people.

Thank you to all the parties – in particular our partners at NTIA and DoD, who helped address interference issues in the 2360 – 2400 MHz band through sharing, compromise, and good faith. This order would not have been possible without collaboration among public and private parties.

I would like to recognize GE Healthcare, Philips and the Aerospace and Flight Test Radio Coordinating Council, which all worked diligently with us to develop a framework for sharing, a goal the Commission is realizing today. We welcome other innovators to join their efforts.

This creative use of spectrum provides wireless health manufacturers with the certainty they need to streamline their product development, which for many years operated on a variety of frequencies.

I expect it will eventually lead to technologies not just for health care facilities, but also for in-home use.

This item also complements advances in machine-to-machine technology that allows anywhere, anytime medical monitoring over 3G, 4G and Wi-Fi networks.

Thank you to all the Commissioners for their input and enthusiasm. I'd like to particularly acknowledge Commissioner McDowell for his passion, interest and input on health-related issues like these.

Finally, thank you to the FCC staff who have been working on this issue – Josh Gottheimer and Charles Mathias in my office, and Julie Knapp, Bruce Romano, and Geraldine Matise in our Office of Engineering and Technology.

**STATEMENT OF
COMMISSIONER ROBERT M. McDOWELL**

Re: Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Network, First Report and Order and Further Notice of Proposed Rulemaking, ET Docket No. 08-59

I am happy to finally be able to vote to approve procedures for a new and innovative service: Medical Body Area Networks (MBANs). I remain as enthusiastic about the promise of this new technology as I was when first learning of it back in early 2007. Since then, I have made advancement of this proceeding an important priority. Although the government has taken far too long to get to this point, I am delighted that we are finally here. The FCC's action today will allow technologists to help medical patients in many profound and dramatic ways. At the same time, we are ensuring that these cutting-edge wireless technologies do not cause harmful interference with flight test operations. I thank Chairman Genachowski for bringing this order for a vote today.

Specifically, liberating innovators to allow them to create new wireless medical devices will end reliance on physically attached cables so patients can move sooner during the healing process. Furthermore, eliminating the need for potentially hazardous wires will increase patient safety. I suspect that new MBANs applications will result in lower health costs by leveraging commercial equipment designed for the 2.3 GHz Band already available in the marketplace. As a result, I am hopeful that all hospitals – whether large or small, urban or rural, for-profit or non-profit – will be able to take advantage of this service, to improve their patient care and lower their costs therefore benefitting consumers of medical services.

Thank you, Julie Knapp, and your exceptional group in the Office of Engineering and Technology. This has been a challenging task spanning many years. Your fortitude, patience, persistence, thoroughness and diligence have brought us to this day. Congratulations. I also thank all of the parties involved – for developing this exciting proposal forward and for joining together to work through the difficult technical issues.

**STATEMENT OF
COMMISSIONER MIGNON L. CLYBURN**

Re: Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Network, First Report and Order and Further Notice of Proposed Rulemaking, ET Docket No. 08-59

Before us this morning, is yet another example of the how the communications industry is working to address important needs in health care. According to the statistics filed in this proceeding, only 56% of staffed beds in acute care hospitals were actually monitored. In his remarks last week, Chairman Genachowski pointed out that the Institute of Healthcare Improvement reported that "a monitored hospital patient has a 48% chance of surviving a cardiac arrest." However, "unmonitored patients have only a 6% chance of survival." These statistics cry out for a solution, which would enable the health care industry to monitor more patients and improve those outcomes.

Medical Body Area Networks, or MBANs, have the capacity to significantly address this issue. In addition, these networks provide a "last meter" wireless link to eliminate the wires and cables that currently tether a patient to the monitor. This gives patients more freedom of movement, the enhanced ability to walk and exercise, which could result in more rapid recovery and discharge. This ultimately should improve patient care and reduce overall healthcare costs. With the rule changes contained in this Order, the Commission is also providing up to 40 megahertz of spectrum for medical care.

Today's Order, not only holds the promise of more speedy recovery and lower medical costs, it should also attract capital investment and spur business development and job creation, as the health care profession and the wireless industry again join forces in deploying MBANs nationwide. Although this Order largely tracks a Joint Proposal that GE, Phillips, and AFTRCC presented to the Commission, there are a number of equipment manufacturers and wireless carriers, that have demonstrated interest in offering devices and services, for the MBAN platform.

This proceeding also affirms what is possible, when members of our communications industry, work past initial disagreements. At first, there were several parties who hold primary licenses in the 2.3 GHz band that were opposed to the GE Petition. They were concerned that the development of Medical Body Area Networks would cause interference to their incumbent operations. I am glad that all relevant parties were able to collaborate and find a way to improve health care while maintaining protections for incumbent operations in these spectrum bands. Perhaps the details of their approach can be followed to promote sharing in other bands as well, and I am confident that this collaboration will continue, as we work through the remaining issues raised in the Further Notice portion of this item.

I join my colleagues in commending the talented staff of the Office of Engineering and Technology, for working through difficult technical issues, and for presenting us with a detailed and thorough item.

**STATEMENT OF
COMMISSIONER JESSICA ROSENWORCEL**

Re: Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Network, First Report and Order and Further Notice of Proposed Rulemaking, ET Docket No. 08-59

This is a decision with revolutionary potential. Today's Order makes the United States the first in the world to allocate spectrum for Medical Body Area Networks (MBANs).

The promise of this technology is extraordinary. By using small, low-powered sensors on the body, we can capture a wide range of physiological data. Information about blood pressure, glucose, oxygen concentration in the blood, and other medical metrics can then be sent along wirelessly to health care providers. This reduces the cost of patient monitoring. It frees patients from being tethered to a messy collection of wires and devices, both in the hospital and in the home. It makes way for medical care that is more accurate, more patient-centered, and more preventive. It will save lives.

Our action today would not be possible without the creative efforts of many people across multiple industries. I want to thank the health care providers, device manufacturers, and aeronautical industry for their willingness to hammer out a compromise in service of the greater good. By working through the complex technical and operational issues and developing a joint proposal for sharing in the 2360-2400 MHz band, they have done more than facilitate the further development and use of MBANs. They have served as a model for developing shared use policies for spectrum that address interference concerns while allowing new services to flourish. With the growing demand for spectrum resources, it is cooperative efforts like this that give us hope and faith.

As the Further Notice indicates our work is not done. We must establish registration and coordination procedures. I am hopeful that Commission staff, working with interested parties, will proceed quickly through the next stages of this proceeding so that MBAN devices will soon become available in our hospitals and homes.

More, too, can be done with other Commission programs that facilitate the use of technology in medical care. Building on its work in the Medical Radio Service, the Commission has already expanded it to include medical micro-power networks. It has a first of its kind memorandum of understanding with the Food and Drug Administration to promote the development of new medical devices. Going forward, the Commission may also need to update its universal service rural health care mechanism, which helps bring high-capacity broadband networks to rural health care providers.

Finally, let me thank the Commission's Office of Engineering and Technology. This effort is a testament to their abilities to wrestle with hard issues and see them through to resolutions that facilitate innovation and improve lives.

**STATEMENT OF
COMMISSIONER AJIT V. PAI**

Re: Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Network, First Report and Order and Further Notice of Proposed Rulemaking, ET Docket No. 08-59

However complex the technical details, this item's purposes are simple: to save lives and reduce health care costs. Through the use of Medical Body Area Network ("MBAN") devices, health care professionals will be better able to monitor their patients and can intervene at an earlier stage if warning signs emerge. Moreover, wireless MBAN devices can reduce the risk of infection, improve patient comfort and convenience, and even obviate the need for an initial or extended hospital admission. Thus, by establishing service rules and allocating spectrum for MBAN devices, the FCC today is enabling significant, positive impacts on Americans' health and on overall health care costs.

In terms of procedural history, the road to adoption has been long. Indeed, this proceeding resulted from a Notice of Inquiry issued by the Commission in the summer of 2006 seeking comment on the spectrum needs of wireless medical devices. Our ability to take definitive action at long last is due in large part to the efforts of the health care and flight testing communities. By working together cooperatively on a joint proposal for the sharing of spectrum, they set the stage for final Commission action. I hope that their approach will serve as a model for parties participating in current and future spectrum proceedings. As we seek to allocate spectrum and deploy technology for innovative uses in a timely manner, it will be necessary for stakeholders to come to the table in good faith and to be open to compromise. The perfect should not be the enemy of the good. The merits of this approach are made apparent in this item.

While today's vote marks an important milestone in this proceeding, our work is not yet done. In order to pave the way for the development and deployment of MBAN devices, we must respond quickly to the comments we receive in response to the Further Notice of Proposed Rulemaking, issue rules related to the selection of an MBAN coordinator, and then select that coordinator. In my view, these steps should be completed within a year. It is therefore encouraging that the item sets a target of final action by June 2013. Additionally, once MBAN devices begin to be deployed, we should assess their performance and see if there are opportunities to expand their use. While today's item appropriately takes a cautious view with respect to many issues, I am open to taking a more forward-leaning approach in the future if the evidence warrants.

Finally, I commend the Chairman for his leadership on this issue and the staff in the Office of Engineering and Technology for their fine work on this item. I look forward to casting many more votes in future meetings to facilitate the innovative use of spectrum and technology to improve the lives of Americans.

