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

In the Matter of	)	
	)	
Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Networks	)	ET Docket No. 08-59
	)	
	)	
	)	

FIRST REPORT AND ORDER AND FURTHER NOTICE OF PROPOSED RULEMAKING

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Comment Date: [45 days after date of publication in the Federal Register]
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By the Commission: Chairman Genachowski and Commissioners McDowell, Clyburn, Rosenworcel, and Pai issuing separate statements.

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I. INTRODUCTION

1. By this Report and Order and Further Notice of Proposed Rulemaking (Further Notice), we expand our Part 95 MedRadio rules to permit the development of new Medical Body Area Network (MBAN) devices in the 2360-2400 MHz band, and propose procedures for selecting a party to register and coordinate MBAN use of the 2360-2390 MHz portion of the band.[1] The MBAN technology will provide a flexible platform for the wireless networking of multiple body transmitters used for the purpose of measuring and recording physiological parameters and other patient information or for performing diagnostic or therapeutic functions, primarily in health care facilities. This platform will enhance patient safety, care and comfort by reducing the need to physically connect sensors to essential monitoring equipment by cables and wires. Our decision herein is the latest in a series of actions to expand the spectrum available for wireless medical use.[2] As the numbers and types of medical radio devices continue to expand, these technologies offer tremendous power to improve the state of health care in the United States.[3] The specific MBAN technology that can be deployed under our revised rules promises to enhance patient care as well as to achieve efficiencies that can reduce overall health care costs. We also find that the costs of permitting MBAN operation in these frequency bands are limited to the risk of increased interference, which we minimize by adopting rules to protect other licensed operations in these bands. We find that the risk of increased interference is minimal and is greatly outweighed by the benefits of the MBAN rules we adopt today.

2. As discussed in detail below, the *Report and Order* adopts rules for MBAN operations on a secondary, non-interference basis under our "license-by-rule" framework.[4] To address spectrum compatibility concerns with respect to incumbent operations under this approach, we establish a process by which MBAN users will register and coordinate the use of certain equipment, and in the Further Notice we propose the criteria for designating the frequency coordinator who will manage these activities. Notably, we base many of these procedures on a joint proposal by representatives of incumbent Aeronautical Mobile Telemetry (AMT) licensees and the MBAN proponents – parties that, when we issued the *Notice of Proposed Rulemaking* (*NPRM*) in this proceeding, strongly disagreed as to whether MBAN and AMT operations could successfully coexist in the same frequency band. Cooperative efforts such as this are beneficial in helping us realize the vital goal of promoting robust and efficient use of our limited spectrum resources.

II. BACKGROUND

3. Currently, there are multiple frequency bands available for different types of wireless

[1] Part 95 governs the Personal Radio Services, including General Mobile Radio Service, Radio Control Service and Citizens Band (CB) Radio Service. The CB Radio Service, in turn, covers a number of specialized services such as Family Radio Service, Low Power Radio Service, Medical Device Radiocommunication Service, Wireless Medical Telemetry Service, Multi-Use Radio Service, and Dedicated Short-Range Communications Service.

[2] *See, e.g.,* Investigation of the Spectrum Requirements for Advanced Medical Technologies Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radiocommunication Service at 401-402 and 405-406 MHz, ET Docket No. 06-135, *Report and Order,* 24 FCC Rcd 3474 (2009); *Erratum*, 24 FCC Rcd 4689 (2009); reconsideration granted in part, 25 FCC Rcd 10414 (2010) (collectively, *MedRadio Order*). *See also* 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, *Report and Order*, 26 FCC Rcd 16605 (2011) (*MMN Order*).

[3] *Connecting America: The National Broadband Plan*, Recommendation 10.3, p.206-207 (FCC, 2010). The National Broadband Plan is available at http:// www.broadband.gov/plan/.

[4] *See* footnote 8, *infra.*

medical device applications. The MedRadio service provides an umbrella framework to regulate the operation of both implanted and body-worn wireless medical devices[5] used for diagnostic and therapeutic purposes in humans. MedRadio uses spectrum in the 401-406 MHz, 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands, all on a secondary basis.[6] The Wireless Medical Telemetry Service (WMTS) allows for the transmission of patient-related telemetric medical information to a central monitoring location within a hospital or other medical facility.[7] WMTS operates in the 608-614 MHz, 1395-1400 MHz, and 1427-1432 MHz bands on a primary basis. Both the MedRadio service and WMTS are regulated under Part 95 of our Rules and operation of these medical devices is authorized by rule rather than by individual licenses, pursuant to Section 307(e) of the Communications Act (Act).[8] In addition, medical radio device manufacturers have for many years been allowed to market products which operate on a variety of frequencies on an unlicensed basis.[9]

4. The Commission initiated this proceeding in response to a specific proposal by GE Healthcare (GEHC) to allocate up to 40 megahertz of spectrum in the 2360-2400 MHz band for MBAN operations using body sensor devices.[10] GEHC filed its petition (hereinafter "GEHC Petition"), following the Commission's adoption of a Notice of Inquiry (NOI) that had sought broad comment on future spectrum needs for wireless medical technologies.[11] GEHC claimed that the existing spectrum that is available for medical radio applications is either too crowded or not appropriate for MBAN deployment, and that a new frequency allocation would be required to support MBAN spectrum needs. In an April 24, 2008 *Public Notice*, we sought comment on GEHC's proposal.[12]

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[5] A medical implant device is an apparatus that is placed inside the human body for the purpose of performing diagnostic or therapeutic functions. A medical body-worn device is an apparatus that is placed on or in close proximity to the human body (*e.g.*, within a few centimeters) for the purpose of performing diagnostic or therapeutic functions. Appendix 1 to Subpart E of Part 95 of the Commission's rules.

[6] These uses are described further in the *MedRadio Order* and the *MMN Order*.

[7] "Wireless medical telemetry" is defined in the rules governing WMTS as "[T]he measurement and recording of physiological parameters and other patient-related information via radiated bi-or unidirectional electromagnetic signals [. . .]." 47 C.F.R. § 95.1103(c). Voice and video communications are expressly prohibited in the WMTS bands. However, the Commission decided that, for the purposes of its service definition, waveforms such as electrocardiograms (ECGs) would not be considered video.

[8] 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 U.S.C. § 307(e)(1).

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

[10] GEHC, *ex parte,* filed December 27, 2007.

[11] *See* Investigation of the Spectrum Requirements for Advanced Medical Technologies Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radiocommunication Service at 401-402 and 405-406 MHz, ET Docket No. 06-135, *Notice of Proposed Rulemaking, Notice of Inquiry, and Order*, 21 FCC Rcd 8164 (2006).

[12] *See* Office of Engineering and Technology to Treat Ex Parte Comments of GE Healthcare as Petition for Rule Making and Seeks Comment, ET Docket No. 08-59, *Public Notice*, 23 FCC Rcd 6854 (2008).

5. Based on the record received in response to GEHC's proposal, the Commission issued a Notice of Proposed Rulemaking in June 2009.[13] Using the GEHC proposal as a starting point, the *NPRM* asked about allocating the 2360-2400 MHz band for MBAN use on a secondary basis, but also noted concerns raised by the Aerospace and Flight Test Radio Coordinating Council (AFTRCC) that MBAN devices would be unable to share the band with existing primary AMT operations.[14] We asked, for example, whether we should establish coordination procedures, exclusion zones, or operational restrictions (such as limiting MBAN use in the 2360-2390 MHz band to indoor-only use) to allow for shared use of the band.[15] We also sought comment on the potential for MBAN deployment in the 2300-2305 MHz, 2390-2395 MHz, and 2395-2400 MHz bands; the 2400-2483.5 MHz band; the 5150-5250 MHz band; and any other suitable frequency range. The *NPRM* further discussed how the MBAN concept could operate on a license-by-rule basis under Part 95 following the overall framework of the MedRadio service, but also sought comment on whether an MBAN could operate under other licensing structures.[16] It also asked how we should structure the service, including what definitions and service and technical rules would be appropriate for MBAN use.[17]

6. We received 24 comments and 5 reply comments in response to the *NPRM*. The proposal received support from professional associations with health care interests,[18] GEHC and other equipment and device manufacturers,[19] AT&T, Inc.,[20] and numerous individuals affiliated with the medical field.[21]

[13] *See* Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Networks, ET Docket 08-59, *Notice of Proposed Rulemaking*, 24 FCC Rcd 9589 (2009) (*NPRM*).

[14] AFTRCC is recognized by the Commission and the National Telecommunications and Information Administration (NTIA) as the non-government coordinator for flight test frequencies in the 2360-2395 MHz band. *NPRM* at 9592 para. 9. Both Federal and non-Federal users conduct AMT operations in the 2360-2395 MHz band under a primary Mobile allocation. Examples of telemetry use include aeronautical flight testing by the commercial aviation industry and flight testing of aircraft, spacecraft and missiles by the Federal Government. *NPRM* at 9594 para. 15.

[15] *NPRM* at 9597 para. 22.

[16] Specifically, we asked whether MBAN use should be on a licensed and non-exclusive basis under Part 90 or even on an unlicensed basis under Part 15. *See NPRM* at 9600-01 para. 36. In the *NPRM*, we asked whether we should implement the MBAN concept by modifying and expanding the existing MedRadio rules or if the rules should instead be in a new subpart, as GEHC suggested. *See id.* at 9600 para. 35.

[17] *NPRM* at 9600-01 paras. 35-38.

[18] Comments of the American Telemedicine Association, filed October 2, 2009, at 2 (*ATA Comments*) (stating that MBAN technology "has the potential of freeing up millions of homebound patients suffering from chronic diseases such as congestive heart failure, diabetes, and chronic obstructive pulmonary disease.") *See* also Comments of AdvaMed, filed October 6, 2009, at 1 (*AdvaMed Comments*); Comments of The American Society for Healthcare Engineering of the American Hospital Association, filed October 5, 2009, at 1-2 (*ASHE Comments*) (characterizing the MBAN concept as "an additional platform for the use of wireless technologies in health care facilities," that could improve patient care and safety, reduce costs, and enhance patient outcomes).

[19] *See* Comments of GE Healthcare, filed October 5, 2009 (*GEHC Comments*); Comments of Philips Healthcare Systems, filed October 6, 2009 (*Philips Comments*); Comments of Texas Instruments, Incorporated, filed October 5, 2009 (*TI Comments*); Comments of Toumaz Technology, Ltd., filed October 5, 2009 (*Toumaz Comments*); Zarlink Semiconductor Inc. *ex parte*, filed May 7, 2010 (listed as "Stephen J. Swift" in the Commission's Electronic Comment Filing System (ECFS)).

[20] Comments of AT&T, Inc., filed October 5, 2009 (*AT&T Comments*).

[21] Many of these pleadings consisted of brief statements of general support. *See, e.g.,* Comments of Amy L. Bush, filed October 29, 2009; Comments of Lamont Yoder, filed October 29, 2009.

In addition, the Local and Metropolitan Area Networks Standards Committee of the Institute of Electrical and Electronics Engineers (IEEE) filed in support of the MBAN proposal.[22] Although no parties disputed the benefits that could be derived from MBAN use, several filers raised concerns about the location and amount of spectrum that should be allocated for MBAN use. Aerospace-related entities reiterated their concerns that MBAN operations in the 2360-2395 MHz band would interfere with AMT receivers,[23] ARRL, the National Association for Amateur Radio (ARRL) claimed that MBAN operations could be incompatible with incumbent amateur licensee use,[24] and several parties questioned whether our alternative spectrum proposals would inhibit Wi-Fi, Bluetooth and other unlicensed devices that currently enjoy widespread popular use.[25]

7. On January 13, 2011, representatives of GEHC, Philips Healthcare (Philips), and AFTRCC, updated the record with an *ex parte* filing describing a means by which an MBAN could successfully operate on a secondary basis in the spectrum used on a primary basis for AMT operations.[26] Their *Joint Proposal* "represent[ed] the culmination of 15 months of discussion, analyses, and negotiation among and between the named parties," and updated the initial GEHC Proposal to set forth a comprehensive proposed set of rules to govern shared AMT-MBAN use.[27] No parties objected to the *Joint Proposal*. The Telecommunications Industry Association offered "strong support" for the plan, and reiterated its view that MBAN deployment could promote health care, spur innovation, and create jobs.[28] Additionally, two parties that had initially expressed concerns about MBAN operation but that were not direct signatories to the *Joint Proposal* filed to reflect their conditional support of the plan.[29]

[22] Comments of IEEE 802 Local and Metropolitan Area Networks Standards Committee, filed July 27, 2009.

[23] *See e.g.,* Comments of AFTRCC, filed October 5, 2009, at i-ii (*AFTRCC Comments*); Comments of the Boeing Company, filed October 5, 2009, at ii-iii (*Boeing Comments*).

[24] Specifically, ARRL was opposed to MBAN operation in the 2300-2305 MHz, 2390-2400 MHz, 2400-2402 MHz, and 2402-2417 MHz bands. *See* Comments of ARRL, the National Association for Amateur Radio, filed October 5, 2009 (*ARRL Comments*).

[25] See Comments of the Wi-Fi Alliance, filed October 2, 2009 (*Wi-Fi Alliance Comments)* and Comments of the Blue Tooth Special Interest Group filed August 31, 2009 (listed as "Mike Foley" in the ECFS). *See also* Comments of the Telecommunications Industry Association, filed October 5, 2009 (stating that the proposed MBAN use of the 2360-2400 MHz band should not go forward absent extensive interference tests).

[26] AFTRCC, Philips & GEHC ("Joint Parties") *ex parte*, filed January 14, 2011, Attachment B. The Joint Parties subsequently clarified and expanded upon this initial filing. We collectively refer to this record as the "*Joint Proposal*" in the discussion that follows.

[27] Joint Parties *ex parte,* filed January 14, 2011, at 1. Filings in the docket that pre-date the *Joint Proposal* demonstrate that interested parties had been working in good faith to find common ground. *See, e.g.,* Reply Comments of the Boeing Company, filed November 4, 2009, at 8-21 (indicating a receptiveness to the limited use of electronic means to ensure that MBAN operation occurs only where permitted); Reply Comments of the Aerospace and Flight Test Radio Coordinating Council, filed November 4, 2009, at 14-15 (stating that "the electronic key" technology suggested by Philips Healthcare Systems ("Philips") would represent "an interesting theoretical proposal to overcome the problems inherent with MBANS devices trying to share the 2360-2390 band with primary AMT operations").

[28] Telecommunications Industry Association *ex parte*, filed February 8, 2011, at 1.

[29] Boeing Company *ex parte*, filed May 24, 2011; Cessna Aircraft Company *ex parte*, filed June 9, 2011.

III. REPORT AND ORDER

8. As an initial matter, we conclude that there are significant public interest benefits associated with the development and deployment of new MBAN technologies. In the *NPRM*, we took note of the limitations and disadvantages of patient monitoring technologies that tether patients to monitoring devices by an array of hardwired cables.[30] These observations continue to hold true. Existing wired technologies inevitably result in reduced patient mobility and increased difficulty and delay in transporting patients. Caregivers, in turn, can spend inordinate amounts of time managing and arranging monitor cables, as well as gathering patient data. The introduction of Wireless Medical Telemetry Service (WMTS) in health care facilities has overcome some of the obstacles presented by wired sensor networks. Nonetheless, WMTS is an in-building network that is often used primarily for monitoring critical care patients in only certain patient care areas.[31] The MBAN concept would allow medical professionals to place multiple inexpensive wireless sensors at different locations on or around a patient's body and to aggregate data from the sensors for backhaul to a monitoring station using a variety of communications media.[32] We conclude that an MBAN represents an improvement over traditional medical monitoring devices (both wired and wireless) in several ways, and will reduce the cost, risk and complexity associated with health care. For example, a health care facility could monitor more patients, particularly in patient care areas where WMTS is not currently installed; an MBAN could be used outside the health care facility, *e.g.*, within patients' homes; and an MBAN could be used for both monitoring and therapeutic applications.[33] We also conclude that these benefits can be achieved with minimal cost. The only cost resulting from these new regulations is the risk of increased interference, and we have minimized that risk by adopting rules that permit an MBAN device to operate only over relatively short distances and as part of a low power networked system. This approach will permit us to provide frequencies where an MBAN can co-exist with existing spectrum users and engage in robust frequency re-use, which will result in greater spectral efficiency. As a result, we believe that the risk of increased interference is low and is greatly outweighed by the substantial benefits of this new technology.

9. The rules we adopt are based on and largely reflect the provisions of the *Joint Proposal* but differ from them in certain respects that we discuss below. The *Joint Proposal* is a comprehensive plan that draws from both the existing MedRadio and WMTS rules to specify MBAN operational requirements for body-worn sensors and hubs, but is drafted as a new subpart under Part 95 of our Rules.[34] It expands upon these rules, however, to include a detailed set of requirements for MBAN management within a health care facility. It also proposes that MBAN use in the 2360-2390 MHz band be limited mostly to indoor use and subject to specific coordination procedures and processes to protect AMT users in that band, whereas MBAN use in the 2390-2400 MHz band could occur at any location and without coordination. The *Joint Proposal* describes an MBAN as consisting of a master transmitter

[30] *NPRM* at 9592-93 para. 10.

[31] Traditional telemetry systems create a separate wireless link between each patient sensor and the remote monitoring system. If multiple functions are being monitored on the patient, multiple separate links are established. *NPRM* at 9593 para. 12.

[32] *NPRM* at 9593 para 11.

[33] Philips has noted that in 2008 only 56% of staffed beds in acute care hospitals were monitored and that studies have shown that patient monitoring outside of an intensive care unit (ICU) can identify patients who are rapidly failing before their condition worsens and require an ICU admission. Philips *ex parte* filed May 18, 2009, at 3 and 5. *See also* Comments of GEHC, filed May 27, 2008, at 4-6.

[34] Joint Parties *ex parte,* filed January 14, 2011, Attachment C. Updated proposed rules were included in attachments to the Joint Parties *ex parte* filed September 13, 2011 and the Joint Parties *ex parte* filed January 30, 2012.

(hereinafter referred to as a "hub"), which is included in a device close to the patient, and one or more client transmitters (hereinafter referred to as body-worn sensors or sensors), which are worn on the body and only transmit while maintaining communication with the hub that controls its transmissions.[35] The hub would convey data messages to the body-worn sensors to specify, for example, the transmit frequency that should be used. The hub and sensor devices would transmit in the 2360-2400 MHz band. The hub would aggregate patient data from the body-worn sensors under its control and, using the health care facility's local area network (LAN) (which could be, for example, Ethernet, WMTS or Wi-Fi links), transmit that information to locations where health care professionals monitor patient data. The hub also would be connected via the facility's LAN to a central control point that would be used to manage all MBAN operations within the health care facility.[36] To protect AMT operations from harmful interference, the *Joint Proposal* would have the Commission designate an MBAN frequency coordinator who would coordinate MBAN operations in the 2360-2390 MHz band with the AMT frequency coordinator. The control point would serve as the interface between the MBAN coordinator and the MBAN master transmitters to control MBAN operation in the 2360-2390 MHz band. The control point would receive an electronic key, which is a data message that specifies and enables use of specific frequencies by the MBAN devices.[37] The control point, in turn, would generate a beacon or control message to convey a data message to the hub via the facility's LAN that specifies the authorized frequencies and other operational conditions for that MBAN.[38]

10. Our rules are based on the basic framework set forth in the *Joint Proposal*, particularly that an MBAN is comprised of two component devices—one that is worn on the body (sensor)[39] and another that is located either on the body or in close proximity to it (hub)—that are used to monitor a patient's physiological functions and to communicate the data back to a monitoring station. Thus, we will specify an MBAN to be a low power network of body sensors controlled on a localized basis by a single hub device, and use this framework as the context for our discussions below. An MBAN shares many characteristics with other established medical radio services and applications. For example, MBAN devices would operate consistent with the definitions for body-worn devices in the MedRadio rules.[40]

[35] Joint Parties *ex parte*, filed November 21, 2011, at 1. The Joint Parties have used the term "slave" transmitter to describe the client device.

[36] *Id.* at 1-2. The *Joint Proposal* defines the control point as either a single device or application that conveys authorized frequency information to the hub devices. There may be one or more control points for a health care facility depending on the size and physical configuration of the facility and the number and location of MBAN master and client devices.

[37] The Joint Parties have specified two different types of electronic keys, "standard" and "time-limited," depending on whether the MBAN was within line-of-sight of and coordinated with an AMT receiver and the terms and the conditions of a coordination agreement. Joint Parties *ex parte,* filed January 30, 2012, Attachment § 95.1603. The Joint Parties recommend that "standard" electronic keys can be delivered by the MBAN coordinator to the facility's Control Point using any type of communication (*e.g.*, email, telephone, facsimile, postal mail) (termed "semi-automatic key delivery"), but that "time-limited" electronic keys should be deployed without any human intervention (*e.g.*, a secure Internet connection) (termed "automatic electronic key delivery"). Joint Parties *ex parte,* filed November 21, 2011, at 3.

[38] *Id.*

[39] We use the term "sensor" to describe the component located on a person's body for ease of reference, not to limit the device's application. As the Joint Parties note and our definition for body-worn medical transmitter provides, the body-worn device could be used either to collect patient diagnostic information (a sensor) or to deliver medical therapy (an actuator). *See* Joint Parties *ex parte,* filed November 21, 2011.

[40] *See* Appendix 1 to Subpart E of Part 95 ("Medical body-worn device. Apparatus that is placed on or in close proximity to the human body (e.g., within a few centimeters) for the purpose of performing diagnostic or therapeutic (continued….)

Also, the data transmitted over the wireless link from the body-worn sensors to the nearby controlling hub would consist of physiological readings and other patient-related information that is transmitted via radiated electromagnetic signals, which follows the definition of medical telemetry in the WMTS rules.[41] We are therefore authorizing MBAN operations under our existing Part 95 MedRadio rules, and the requirements we adopt are limited to the operation of MBAN devices within the 2360-2400 MHz band.

11. We adopt rules that focus primarily on the service and technical rules for operating MBAN sensors and hubs, as well as the registration and coordination requirements to protect primary AMT operations in the 2360-2390 MHz band and do not extend the rules to the communications links between the hubs and central control points and the MBAN hubs and the MBAN frequency coordinator. We recognize that MBAN users will have to consider additional factors when they deploy their systems – such as how to relay the data collected at the MBAN hubs to control points at remote locations by technologies that do not use the 2360-2400 MHz band, and what method they will use to establish communication links to an MBAN coordinator. However, we also recognize that each health care facility is unique and needs flexibility to decide how best to accomplish these backhaul/interface functions. Thus, we do not include here the *Joint Proposal's* recommendations to codify certain aspects of their vision – for example, requiring a health care facility to designate a central control point and specific communication procedures between the control point and the MBAN frequency coordinator or the hub. Instead, we expect that MBAN users, the frequency coordinators, and equipment manufacturers will work together cooperatively to utilize the technologies and procedures that will permit MBAN and AMT services to share spectrum while fully protecting AMT licensees' operations and while fully integrating MBAN use into the health care ecosystem.

12. In the Report and Order, we first discuss MBAN spectrum requirements and determine that a secondary allocation in the 2360-2400 MHz band is best suited to support MBAN operations. Second, we conclude that MBAN operations would be most efficiently implemented by modifying our existing Part 95 MedRadio rules. Third, we discuss the service and technical rules that will apply to MBAN operations. Finally, we discuss the registration and coordination requirements for MBAN operation in the 2360-2390 MHz band. As part of our analysis, we recognize that the *Joint Proposal* has been endorsed by parties that had previously objected to the original GEHC Petition, and that the record of this proceeding now contains conflicting pleadings by the same parties. In such cases, we will look to those pleadings associated with the *Joint Proposal* and will not address any earlier, inconsistent submissions by the same party, based on our assumption that the earlier filings have been superseded by the more recent filings.

A. Spectrum for MBAN Operation

13. *Notice of Proposed Rulemaking*. In the *NPRM*, the Commission proposed to allocate 40 megahertz of spectrum in the 2360-2400 MHz band on a secondary basis for MBAN use as suggested by

(Continued from previous page)

functions." "MedRadio programmer/control transmitter. A MedRadio transmitter that operates or is designed to operate outside of a human body for the purpose of communicating with a receiver, or for triggering a transmitter, connected to a medical implant device or to a medical body-worn device used in the MedRadio Service; and which also typically includes a frequency monitoring system that initiates a MedRadio communications session"). MBAN devices differ from other MedRadio body-worn devices in several ways, *e.g.*, they use a wider transmission bandwidths and data from multiple sensors are aggregated and backhauled to a monitoring station through a hub.

[41] *See* footnote 7, *supra.* MBAN devices differ from WMTS in several ways, *e.g.*, they require fewer links to a monitoring station because data from multiple sensors are aggregated and backhauled through a hub, and they use lower transmission power to collect patient data which promotes frequency re-use and allows for the deployment of multiple networks within a health care facility.

GEHC. This would be implemented by adding a new U.S. footnote to the Table of Allocations in Part 2 of the Rules. The footnote would also specify that an MBAN must not cause harmful interference to and accept interference from Federal and non-Federal stations operating in accordance with the Table of Frequency Allocations.[42] While the predominant use of these frequencies is for Federal and non-Federal AMT use at 2360-2395 MHz on a primary basis, this band also contains a primary allocation for the Amateur radio service at 2390-2400 MHz. In addition, the 2360-2390 MHz band is allocated to Federal users on a primary basis for radiolocation service and on a secondary basis for fixed service for Federal operations.[43] As a practical matter, the radiolocation allocation supports radio astronomy operations in Arecibo, Puerto Rico.[44] In the *NPRM*, we also sought comment on the possible use of frequencies at 2300-2305 MHz, 2400-2483.5 MHz, and 5150-5250 MHz for MBAN operations. The later two bands are heavily used by unlicensed devices, such as Wi-Fi equipment and Bluetooth devices.

14. *Decision*. We find that the best way to promote MBAN development is by allocating the entire 40 megahertz of spectrum in the 2360-2400 MHz band proposed in the *NPRM* for MBAN use, on a secondary basis. We do so by adding a new footnote to our Table of Frequency Allocations (Table) as proposed. We conclude that the 2360-2400 MHz band is particularly well suited for MBAN use, given the ability of MBAN devices to be able to share the band with incumbent users. We are also persuaded that the ready availability of chipsets and technology that can be applied to this band will promote quick development of low-cost MBAN equipment. This, in turn, will reduce developmental expenses, encourage multiple parties to develop MBAN applications, and will promote the widespread use of beneficial MBAN technologies. Such deployment will reduce health care expenses, improve the quality of patient care, and could ultimately save lives.

15. We note that the record reflects strong support for use of this band among those who would develop, deploy and operate MBAN equipment. For example, Texas Instruments (TI), a manufacturer of electronic chipsets, states that because existing low power 2.4 GHz band transceiver chips that it and other manufacturers have produced for use in Bluetooth, WiFi and similar applications can be easily modified to operate in the 2360-2400 MHz band, MBAN devices can be quickly deployed at cost-effective prices.[45] GEHC and AdvaMed also note that the ready availability of components will promote the development of MBAN devices in greater volumes and at lower price points.[46] The band would also offer contiguous spectrum, which AdvaMed claims is preferable for MBAN design.[47] In addition, researchers have previously noted that the 2360-2400 MHz band offers favorable conditions for

[42] *NPRM* at 9598 para. 25.

[43] Furthermore, frequencies in the 2360-2395 MHz range are periodically used, under special temporary authority (STA), to provide video coverage of short-term events, such as car races, golf matches, and political conventions. One such user, Broadcast Sports, Inc., (BSI) had opposed the GEHC proposal and suggested that the Commission create a secondary "Event Radio Service", in the 2360-2395 MHz AMT spectrum. *NPRM* at 9592 para. 9 (discussing BSI's March 4, 2009 "Comments and Counterproposal"). In the *NPRM*, we determined that the MBAN Proposal would not adversely affect BSI's ability to obtain STAs and found that allocating its proposed service would not be in the public interest nor would it represent an efficient use of spectrum. *NPRM* at 9611 para. 78. BSI did not challenge the Commission's finding in the *NPRM*, nor did it file any further comments in this proceeding.

[44] *NPRM* at 9594-95 para. 16. Research at Arecibo involves the exploration of the surface of planets and other solar system bodies, and in the detection of Near Earth Objects.

[45] *TI Comments* at 2-3. *See also Toumaz Comment*s at 2.

[46] *GEHC Comments* at 8. *AdvaMed Comments* at 2.

[47] *AdvaMed Comments* at 3.

communications between body-worn sensors and nearby hub devices.[48] Finally, it appears that the 2360-2400 MHz band holds potential for international harmonization. Both TI and GEHC note that the band is included in the technical requirements developed by a European standards group studying medical devices.[49]

16. We also conclude that the 40 megahertz of spectrum in the 2360-2400 MHz band we proposed to allocate in the *NPRM* is an appropriate allocation for MBAN use. Both GEHC and Philips discuss how peak MBAN deployments would require as much as 20 megahertz of spectrum to be available if on an exclusive basis, and assert that a full 40 megahertz allocation would maximize the opportunity for MBAN devices that operate on a secondary basis to avoid interference to and from primary users.[50] TI, Zarlink Semiconductor and AdvaMed offer similar assertions.[51] We find these arguments persuasive. Any MBAN device designed to operate in the 2360-2400 MHz band will also have to be designed to operate in a manner that will protect incumbent licensees, and a 40-megahertz allocation will provide sufficient spectrum flexibility to serve this goal. In addition, this allocation will enable greater frequency diversity and promote reliable MBAN performance.[52] This is particularly true given our decision, discussed below, to allow an MBAN device to operate with an emission bandwidth up to 5 megahertz.[53] Additionally, we find that the 40-megahertz allocation is appropriate because it will allow for reliable MBAN operations in high-density settings, such as waiting rooms, elevator lobbies, and preparatory areas, where multiple MBAN-equipped patients will congregate.[54] For example, AdvaMed notes that a smaller spectrum allocation might not allow for the use of devices by multiple vendors in the

[48] Comments of W.G. Scanlon, filed April 29, 2008, at 1 (citing papers he and other researchers published in 2007 and 2008 examining body-area communication in the 2.45 GHz range); Comments of Akram Alomainy, filed May 9, 2008, at 1 (stating that "[o]ur experience suggests that the allocation of a new frequency band at 2.360–2.400 GHz would help us to tackle issues such as interference and channel co-existence."). These comments were filed in response to the GEHC Petition.

[49] *TI Comments* at 3 (stating that "ETSI ERM TG30 – Medical Devices (TR 102 655) has also independently identified the 2360 – 2400 MHz band as a candidate band for wireless MBAN devices"); *GEHC Comments* at 8. We note that while Zarlink Semiconductor had initially suggested that another band might be an even stronger candidate for international harmonization, it now supports the 2360-2400 MHz band as best suited for MBAN deployment. Zarlink Semiconductor Inc. *ex parte*, filed May 7, 2010 at 2.

[50] *GEHC Comments* at 9-10 (stating that, because MBAN devices operating in the 2360-2400 MHz band would have to be designed to operate in the presence of signals from higher power incumbent services, "the MBAN allocation would still need to be large enough to provide a high likelihood of sufficient spectrum being available for opportunistic MBAN devices to successfully operate in the band."). *See also id.* at Appendix B (describing the specific parameters, such as frame sync preambles, media access control ("MAC") layer information, error detection and correction schemes, contention protocol inefficiencies, and modulation spectral efficiency that GEHC used to determine the appropriate MBAN spectrum requirements); *Philips Comments* at A-5.

[51] *TI Comments* at 3 (stating that a 40 megahertz allocation "will provide sufficient bandwidth to enable frequency diversity techniques, which will be necessary to combat multi-path and shadowing" and "avoid strong narrowband interference, or out-of-band emissions from the 2.4 GHz ISM band"); Zarlink Semiconductor Inc. *ex parte*, filed May 7, 2010 at 2; *AdvaMed Comments* at 2.

[52] *GEHC Comments* at 9 (noting that access to a 40 megahertz band would permit "meaningful frequency diversity" for MBAN devices without needing additional transmit power).

[53] We note that some of the comments addressing the need for a 40 megahertz allocation may have been based on GEHC's original discussion of a one megahertz-wide emission bandwidth, which would suggest an even greater need for a 40 megahertz allocation under the emission bandwidth limits we are adopting.

[54] *See, e.g.*, *GEHC Comments* at 9; *TI Comments* at 3.

same hospital and thereby drive up costs, and also claims that more limited spectrum access would not support all of the currently conceived MBAN device applications.[55] It is clear that such a scenario would increase costs by reducing competition and effectively limiting the use of multiple MBAN devices; this, in turn, could deprive many patients of the health care and cost-saving benefits that MBAN operations are poised to deliver. For all of these reasons, we agree with Philips that "[t]he less spectrum allocated, the more difficult it will be to avoid interference," and that the 40 MHz of spectrum we proposed in the *NPRM* "will maximize opportunities to avoid interference through frequency separation, support the coexistence of multiple and competitive MBAN networks, and provide the spectrum needed for future innovation."[56]

17. We further conclude that an MBAN will be able to share the 2360-2400 MHz band with incumbent users. The *Joint Proposal* offers a way for MBAN devices to operate in a manner compatible with incumbent AMT licensees. By proposing unrestricted use of the 2390-2400 MHz band segment and a coordination process for MBAN users in the 2360-2390 MHz portion of the band along with suggesting the use of established engineering guidelines to determine if MBAN use can occur within line-of-sight of an AMT site without causing interference, the *Joint Proposal* describes how MBAN users could successfully operate in the band on a secondary basis. We agree. As discussed in greater detail below, we conclude that it is necessary for us to establish a coordination process and related procedures and guidelines to ensure that the primary AMT operations in the band are adequately protected from MBAN users.

18. MBAN operators in the 2390-2400 MHz band will also have to account for amateur radio users, which are authorized on a primary basis in this spectrum. Both Philips and GEHC assert that interference from MBAN devices to amateur radio is unlikely, citing factors such as the low transmission power and low duty cycle proposed for MBAN devices, as well as geographic separation and the frequency agility of MBAN devices.[57] ARRL does not anticipate that an MBAN would cause "a significant amount of harmful interference" to amateur users, but it cautions that some amateur operations – such as weak signal communications, that occur on a "completely unpredictable basis"– could receive interference.[58] We believe that MBAN devices can successfully share the band with the amateur service. These frequencies are part of the larger "13 cm band" in which amateur radio operators already share the adjacent 2400-2450 MHz portion of the band with low-powered equipment authorized under Part 15 of our rules. We expect that the amateur service will likewise be able to share the 2390-2400 MHz portion of the band with MBAN devices because the power limits for MBAN operations will be even lower than that allowed for the unlicensed equipment that operates in the 2400-2450 MHz range. We further believe that MBAN and amateur operations are highly unlikely to occur in close proximity to each other. An MBAN, which will use very low transmitted power levels compared to the amateur service, is not intended for mass market types of deployment and instead will be used only under the direction of health care professionals. We also believe that the majority of MBAN operations in the 2390-2400 MHz band will be located indoors. We envision that the most likely outdoor use will occur in ambulances or while patients are otherwise in transit, thus we do not believe that prolonged outdoor use in a single location is likely. In such a situation, any interference that might occur would likely be transitory in nature and would not seriously degrade, obstruct or repeatedly interrupt amateur operations and thus would not be

[55] *AdvaMed Comments* at 1-2.

[56] *Philips Comments* at 5.

[57] *See, e.g.*, *Philips Comments* at 10-11.

[58] *ARRL Comments* at 8.

considered harmful under our definition of harmful interference.[59] In the unlikely event that an atypical scenario occurs where amateur operators do receive harmful interference from MBAN operations, we note that amateur operators would be entitled to protection from MBAN interference.

19. We also address the potential for interference from licensed amateur operations to MBAN operations. ARRL states that amateur operation in the band is unpredictable. The "substantial power levels and exceptionally high antenna gain figures used by radio Amateurs in the 2390-2400 MHz band will provide no reliability of MBANs in this segment whatsoever," it observes, calling the results of such interference "potentially disastrous."[60] MBAN proponents assert that MBAN devices will have built-in capabilities such as spectrum sensing techniques to detect in-band amateur signals and frequency agility capability to move MBAN transmissions to other available channels.[61] As to ARRL's concerns about MBAN's reliability and the risk presented by interference caused by amateur operation, GEHC acknowledges that "medical device manufacturers seeking to develop equipment consistent with the MBAN rules would need to build robust products in order to satisfy FDA requirements and to ensure customer acceptance,"[62] but does not view that as a barrier to its efforts to develop and deploy MBAN devices. We find that factors such as the incorporation of established techniques to avoid interference into MBAN devices, the use of low duty cycles, and the separation distances between MBAN devices and amateur operations that are likely to occur in real world situations will minimize any potential for interference to MBAN devices from amateur users. Nevertheless, MBAN operations will occur on a secondary basis and MBAN operators will thus be required to accept any interference they receive from primary amateur licensees operating in accordance with the rules.[63]

20. The 2370-2390 MHz band is used for radio astronomy operations in Arecibo, Puerto Rico.[64] Prior to the filing of the *Joint Proposal*, both GEHC and Philips suggested using an exclusion zone to protect the Arecibo site.[65] Subsequently, the Joint Parties suggested that MBAN users simply notify the Arecibo facility prior to operation in accordance with our existing rules.[66] We find that our existing MedRadio Rules, which provide a prior notification requirement, are sufficient to ensure protection of radio astronomy operations at the Arecibo site.[67]

21. Lastly, we observe that because MBAN operations will be permitted adjacent to other bands that host a variety of different services, MBAN users will have to take into account the operating characteristics of those adjacent-band services.[68] The upper end of the band, 2400 MHz, is immediately

[59] Harmful interference is "[i]nterference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radiocommunication service operating in accordance with [the ITU] Radio Regulations." 47 C.F.R. § 2.1.

[60] *ARRL Comments* at 9-10.

[61] *Philips Comments* at 11. *See also AdvaMed Comments* at 3.

[62] *GEHC Comments* at 18.

[63] *See* 47 C.F.R. § 95.1221(c).

[64] Para. 13, *supra.*

[65] *Philips Comments* at 11. *GEHC Comments* at 14.

[66] *See* Joint Parties' *ex parte,* filed July 5, 2011, at 1-2.

[67] 47 C.F.R. § 95.1203 (referencing 47 C.F.R. § 95.405). *See also* 47 C.F.R. § 1.924(d).

[68] Although amateur use of the 2400-2417 MHz band is authorized on a primary basis and AMT users operate in the 2345-2360 MHz band, we have discussed MBAN use vis-à-vis these services above and do not address them further here.

adjacent to the spectrum used by unlicensed devices – such as Wi-Fi and wireless local area network (WLAN) devices – as well as industrial, scientific and medical (ISM) equipment operating under Part 18 of our Rules, both of which are widely used in health care settings.[69] As MBAN users manage their facilities, they will need to consider the potential for adverse interaction between their MBAN, Wi-Fi, and ISM resources.[70]

22. MBAN equipment will also operate immediately adjacent to the Wireless Communications Service (WCS) at 2360 MHz. As with any new service, it is incumbent on MBAN developers to evaluate and account for the operational characteristics of adjacent band services – in this case, WCS – when designing receivers and associated equipment. As a practical matter, we find that it is unlikely WCS operations would preclude effective MBAN use given that MBAN operations near 2360 MHz will be in institutional settings under the control of a health care provider and because MBAN users will have a large swath of spectrum in which to place their operations.[71] Moreover, the record indicates that GEHC has already anticipated designing MBAN devices that use contention-based protocols and frequency agility to account for potential out of band emissions into the 2360-2400 MHz band.[72] For these reasons, and notwithstanding filings made by the Wireless Communications Association, International ("WCAI"), we find no reason to adopt specific rules relating to adjacent-band WCS operations.[73]

23. Accordingly, we will add a new footnote US101 to the Table of Allocations to provide a secondary mobile, except aeronautical mobile, allocation in the 2360-2400 MHz band for use by the MedRadio Service.[74] We are making this allocation through a unique footnote rather than a direct entry in the Table, or modification of the existing US276,[75] in order to provide consistency across the entire band and to emphasize the limited nature of this allocation.[76] We will place footnote US101 in both the

[69] *See, e.g.*, *Wi-Fi Alliance Comments* at 3 (noting that WLAN technology "is already deeply embedded in the healthcare industry" and is likely to continue to be part of health care IT infrastructure "for the foreseeable future").

[70] For example, because Wi-Fi channel 1 under the 802.11b standard occupies the 2401-2423 MHz band, it may prove difficult to operate on Wi-Fi channel 1 within close proximity of an MBAN device. Similarly, medical therapies that use ISM equipment may have difficulties coexisting with some MBAN uses. In such cases, health care providers may have to consider how they deploy their various resources to best overall advantage.

[71] We note that while an MBAN will operate within a 40 megahertz spectrum block, the maximum authorized bandwidth for a single MBAN is 5 megahertz. We discuss this and other service and technical rules in greater detail, below.

[72] GEHC *ex parte,* filed September 25, 2008, at 2.

[73] *See, e.g.*, WCAI *ex parte*, filed January 28, 2011 (suggesting specific modifications to the rules proposed by the Joint Parties to make clear that MBAN use would be secondary to all primary services, including those in adjacent bands).

[74] We note that although the footnote references MedRadio generally, the modifications we make to the Part 95 rules will authorize only MBAN operations in the 2360-2400 MHz band.

[75] The Joint Parties, in conjunction with the suggested rules they provided in the Joint Proposal, suggested modifying footnote US276, which describes flight testing operations authorized in the 2360-2395 MHz band, to permit secondary MBAN operations in the 2360-2390 MHz and 2390-2400 MHz bands. Joint Parties *ex parte,* filed January 14, 2011, Attachment C at 9.

[76] Our footnote varies slightly in language and location from that proposed by the Joint Parties. These differences are not matters of substance, but, rather a reflection of our decision *infra* to include the MBAN rules in the (continued….)

Federal Table and non-Federal Table to facilitate MBAN use in a variety of settings such as in health care facilities operated by the Department of Veterans Affairs or the United States military, as well as non-Federal health care facilities.[77] Because use of these frequencies will be on a secondary basis, MBAN stations will not be allowed to cause interference to and must accept interference from primary services, including AMT licensees operating under the primary mobile allocation in the 2360-2390 MHz and 2390-2395 MHz bands and Amateur Radio service licensees that operate on a primary basis in the 2390-2395 MHz and 2395-2400 MHz bands.

24. The *Joint Proposal* was based on secondary MBAN use of the 2360-2400 MHz band, and no commenters supporting either the 2360-2400 MHz band or any alternate spectrum proposals endorsed giving MBAN operations primary status.[78] Our decision to provide 40 megahertz of spectrum in the 2360-2400 MHz band for MBAN use is based on our decision above to require MBAN users to share the spectrum with incumbent users, as well as among different MBAN devices, and that, therefore MBAN devices require a larger spectrum block than would be the case if spectrum were allocated to MBAN use on an exclusive basis.[79] A secondary allocation is consistent with our approach. We are also confident that our decision to authorize MBAN service on a secondary basis will not adversely affect the usefulness of MBAN devices. We note that the supportive comments filed by numerous manufacturers indicate a readiness to produce devices capable of relaying essential patient data in a reliable manner within this regulatory framework.[80]

25. This action affirms the tentative conclusion from the *NPRM* that we should allocate spectrum not currently used by existing medical radio services to support new MBAN operations. Although ARRL suggests that MBAN devices could make use of spectrum currently used by the WMTS,[81] we agree with Philips that the WMTS bands are not suitable for MBAN devices because of the existing widespread use of WMTS applications in hospitals.[82] We do not believe that WMTS and MBAN devices would be able to successfully co-exist on the same frequencies simultaneously within the same facilities, leaving health care facilities with the dilemma of choosing between two valuable health care tools. A better course is to accommodate MBAN users in other frequencies. We further note that all of the other frequency bands identified in this proceeding for possible MBAN use have limitations that make them less desirable than the 2360-2400 MHz band. For example, Philips claims that the alternative bands are "substantially inferior to the 2360-2400 MHz band" for MBAN use, and predicts that "devices would be unlikely to succeed for both cost and technical reasons, and the opportunity to benefit from better

(Continued from previous page)
MedRadio service rather than establish a new service for MBAN use with separate rules in Part 95. *See* para. 30, *infra*.

[77] The Table is further divided into the Federal Table of Frequency Allocations (Federal Table) and the non-Federal Table of Frequency Allocations (non-Federal Table). The National Telecommunications and Information Administration (NTIA) authorizes Federal stations in allocations listed in the Federal Table, and the Commission issues licenses to non-Federal stations in allocations listed in the non-Federal Table.

[78] We had suggested that primary status for MBAN devices might be possible in the 2300-2305 and 2390-2400 MHz bands but, for reasons discussed below, we find these bands unsuitable for MBAN use.

[79] *See* para. 16, *supra*. For example, Philips states that 20 MHz of primary, exclusive use spectrum would be required for MBAN operations to provide viable service on par with that provided by a 40 MHz secondary allocation. *See Philips Comments* at 3-4.

[80] *See e.g., TI Comments* at 7; *Toumaz Comments* at 2.

[81] *ARRL Comments* at 2-3.

[82] *Philips Comments* at 12-13; Philips *ex parte,* filed July 27, 2010, at 7-8. *See also AdvaMed Comments* at 1.

healthcare using these devices likely would be substantially delayed or lost."[83] We agree, and briefly discuss each of the alternate band proposals below.

26. The proposal to allocate only the 2300-2305 MHz and 2390-2400 MHz bands would only provide MBAN users with 15 megahertz of spectrum, which would have to be shared with incumbent users. As AdvaMed notes, such a limited allocation would not be sufficient to satisfy high density use situations, such as in hospitals.[84] As TI observes,[85] such a non-contiguous arrangement would increase equipment design costs. The potential use of the 2300-2305 MHz band also drew objections from amateur radio operators, who operate on a secondary basis in the band, and by GEHC, which noted that it was not aware of any currently available transceiver chips designed for use in the band.[86]

27. The 2400-2483.5 MHz band is also unsuitable for widespread MBAN use, given the ISM equipment and unlicensed devices that operate in the band.[87] While GEHC and Philips discussed the benefits of employing low-power technology and chipsets that have been widely deployed in the 2.4 GHz band and which can be readily modified to use the adjacent 2360-2400 MHz spectrum, they emphatically rejected the possibility of deploying MBAN operations above 2400 MHz. GEHC notes that the 2.4 GHz band is heavily populated by unlicensed intentional radiators and ISM devices deployed by hospitals and carried by patients, visitors, doctors and staff.[88] The 5150-5250 MHz band which used by unlicensed national information infrastructure (U-NII) devices operating under Subpart E of the Commission's Part 15 rules, is even less desirable. As with the 2.4 GHz band, many unlicensed devices already intensively use the 5150-5250 MHz band in health care settings.[89] Moreover, as GEHC notes, use of 5150-5250 MHz band would require a higher transmit power and result in shorter battery life and it is not aware of readily available chipsets that could be incorporated into MBAN devices.[90]

B. Licensing Framework

28. *Notice of Proposed Rulemaking*. In the *NPRM,* we requested comment on whether MBAN medical devices should be eligible for license-by-rule operation pursuant to Section 307(e) of the Communications Act (Act).[91] Under this approach, an MBAN would be authorized pursuant to Part 95 of our Rules to operate in the band on a shared, non-exclusive basis with respect to each other and without the need for the MBAN to be individually licensed.[92] In the event that we determined the license-by-rule

[83] *Philips Comments* at 4.

[84] Reply Comments of AdvaMed, filed November 4, 2009, at 4-5 (*AdvaMed Reply Comments*).

[85] *TI Comments* at 4.

[86] *ARRL Comments* at 3; *GEHC Comments* at 10.

[87] As noted in the *NPRM*, portions of this band also host Amateur operations, Federal and non-Federal radiolocation service, and non-Federal fixed and mobile services. *See NPRM* at 9598 para. 27.

[88] *GEHC Comments* at 6. *See also AdvaMed Comments* at 4; *Toumaz Comments* at 2.

[89] *Wi-Fi Alliance Comments* at 3-6.

[90] *GEHC Comments* at 7.

[91] We also asked for comment on whether MBAN devices could operate on an unlicensed basis pursuant to Part 15 of the rules in the context of our alternate proposals relating to MBAN operation in the 2400-2483 MHz and 5150-5250 MHz band. *See NPRM* at 9598-99 paras 26-32. As we have already established that the 2360-2400 MHz band will be allocated for MBAN operation (*see* paras. 13-27, *supra*), we will not discuss the potential for unlicensed use in rejected band proposals any further.

[92] *NPRM* at 9600-01 paras. 35-36.

approach to be appropriate, we further sought comment as to whether the MBAN rules should be included in Subpart I of Part 95, which authorizes the MedRadio Service, or in a new subpart under Part 95. We also requested comment on alternative approaches including non-exclusive licensing under Part 90, both with or without coordination, and a regime similar to that applied to wireless broadband services in the 3650-3700 MHz band (wherein eligible entities would apply for non-exclusive nationwide licenses and subsequently register individual stations with the Commission.)[93] Finally, regarding licensing, we asked for specific comments on the comparative advantages and disadvantages and the processing involved in each approach.[94] The record reflects general support for the license-by-rule approach, but little discussion of the relative merits of the different licensing approaches discussed in the *NPRM*. For example, and as discussed above, the *Joint Proposal* is based on the license-by-rule framework, and includes proposed rules that would authorize MBAN operations under a new subpart of Part 95.[95]

29. *Decision.* We conclude that authorizing MBAN use on a license-by-rule basis within our Part 95 rules is the best approach. These devices share many characteristics with medical radiocommunications technologies that are already authorized under a license-by-rule approach, and we find that this framework can promote the rapid and robust development of MBAN devices without subjecting users to an unnecessarily burdensome individual licensing process.[96] Moreover, we are adopting appropriate technical rules and coordination procedures to ensure that MBAN devices can successfully operate on a secondary basis in the 2.3 GHz band without the need for individual licenses.

30. We next consider how we should structure the rules for MBAN operations. While an MBAN may be similar to WMTS in purpose –both involve the measurement and recording of physiological parameters and other patient-related information – we find that they are closer to MedRadio devices in their implementation. Like MedRadio devices, MBAN devices will be designed to operate at low power levels. Moreover, the two MBAN components – the body-worn sensor and the nearby hub – are functionally analogous to the medical body-worn device and associated MedRadio programmer/control transmitter that are provided for in our MedRadio rules.[97] Although we recognize that we could codify the MBAN rules as a separate rule subpart, we conclude that the best course is to modify our existing MedRadio rules. This is the same approach we recently took when providing for the development of new ultra-low power wideband networks consisting of multiple transmitters implanted in the body that use electric currents to activate and monitor nerves and muscles.[98] Moreover this approach avoids duplicating existing rules that logically apply to both MBAN and existing MedRadio devices.[99] This, in turn, will ensure that any future rules that affect MBAN and other MedRadio applications will be updated in a comprehensive and consistent manner. Also, because the MedRadio rules already distinguish between each of the various types of MedRadio devices when necessary by, for example,

[93] *See* 47 C.F.R. § 90.1307.

[94] *NPRM* at 9600-01 para. 36.

[95] Joint Parties *ex* parte, filed January 14, 2011, Attachment A at 4 and Attachment C. We note that two parties that now support the *Joint Proposal* – Boeing and AFTRCC – had previously expressed concerns about the use of a license-by-rule approach.

[96] *See also* 47 C.F.R. § 95.1211 (setting forth a channel use policy that allows for cooperative use of the MedRadio frequencies).

[97] *See* Appendix 1 to Subpart E of Part 95 – Glossary of Terms (codified immediately after 47 C.F.R. § 95.673).

[98] *MMN Order* at 16613 para. 22.

[99] Although the *Joint Proposal* suggests that we codify the MBAN rules in a new subpart of Part 95, many of the rules proposed by the Joint Parties appear to be directly based on existing MedRadio rules.

setting forth particular operational rules and authorized frequencies, we will still be able to add MBAN-specific rules when and where appropriate.

31. The *NPRM* sought comment on the definitions we should apply to an MBAN and its components, and proposed four terms that we could codify in our final rules. Because we have decided to authorize MBAN operations under our MedRadio rules, it is not necessary to adopt such a comprehensive set of definitions. We instead modify the Appendix to Subpart E of Part 95 of our Rules to add a single new definition – Medical body area network (MBAN) to read as follows:

> 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

This definition is slightly different from that proposed in the *NPRM*. It reflects appropriate MedRadio terminology and includes a description of the telemetry functions of an MBAN that were originally part of the separate definition we proposed for the term "Medical body area device." The other terms we had proposed to define are already encompassed within the existing MedRadio definitions. The existing definition for a MedRadio programmer/control transmitter is a transmitter that is designed to operate outside the human body for the purpose of communicating with a receiver connected to a body-worn device in the MedRadio Service. Because this definition already describes how an MBAN control transmitter functions, it is not necessary for us to adopt a separate definition for an "MBAN control transmitter." Although the MedRadio programmer/control transmitter definition is broadly written to permit other functions – such as communicating with implanted devices or acting as a programmer – we recognize that such features will not be necessary for MBAN operations and observe that a device that does not include them could still conform to the definition.[100] In a similar vein, we find that the existing definition for a Medical body-worn device already describes how an MBAN sensor operates and can be used in lieu of the proposed "Medical body area device." Finally, the existing "MedRadio transmitter" definition is analogous to our proposed "MBAN transmitter" term. We find that this overall approach to the MBAN definitions shares the same advantages as, and is consistent with, the decision to provide for MBAN operations as part of the existing MedRadio rules. We also note that while the Joint Parties proposed numerous definitions in conjunction with their draft rules, their focus was on specific technical and operational definitions.[101] We will not adopt these terms, as we agree with AdvaMed that it is not necessary to define other components of an MBAN because there will be different ways to meet the overall MBAN definition and we should afford manufacturers flexibility for innovation.[102]

[100] Similarly, the statement that a MedRadio programmer/control transmitter "also typically includes a frequency monitoring system that initiates a MedRadio communications session" is not relevant in the context of MBAN operations.

[101] Their proposed definitions, part of a proposed rule section, Section 95.1603, titled "Definitions," address matters of eligibility (paragraphs (a) and (c)), MBAN device operation (paragraphs (d) through (g)), and the information exchange between a health care facility and the MBAN coordinator (paragraphs (h) through (l)). Joint Parties *ex parte,* filed January 18, 2011, Attachment C at 1-3.

[102] *AdvaMed Comments* at 6. We address the technical and service rule matters that are the subject of the Joint Parties' proposed definitions, to the extent that they are relevant, in the "Service and Technical Rules" section, *infra.*

C. Service and Technical Rules

32. We now set forth the specific service and technical parameters that will define an MBAN. Because we have chosen to regulate MBAN devices under the MedRadio rules, we have analyzed those rules to determine which need to be modified for MBAN devices and which are already suitable for MBAN use.[103] Our discussion, below, focuses primarily on those service and technical rules that require further modification.

1. Service Rules

33. *Operator Eligibility.* In the *NPRM*, we proposed that MBAN use be subject to the same operator eligibility requirements that are in place for the MedRadio Service.[104] Section 95.1201 of our Rules permits operation of MedRadio transmitters by duly authorized health care professionals, by persons using MedRadio transmitters at the direction of a duly authorized health care professional, and by manufacturers and their representatives for the purpose of demonstrating such equipment to duly authorized health care professionals. We conclude that this rule should be applied to MBAN operations without further modification.

34. The Joint Parties ask that we expand MBAN eligibility to permit manufacturers and vendors (and their representatives) to operate MBAN transmitters for developing, demonstrating and testing purposes.[105] Although the Joint Parties state that this would mirror analogous provisions in the WMTS rules, in fact the WMTS rules permit manufacturers and their representatives to operate such equipment only for purposes of "demonstrating" such equipment.[106] There is similar language in the current MedRadio rules that permits operation of MedRadio equipment by manufacturers "and their representatives."[107] This language permits vendors to demonstrate MBAN equipment as representatives of a manufacturer. Thus, we do not need to modify the current rule to state this specifically. We further note that the current rule would not preclude authorized healthcare professionals from contracting for the services of third parties to operate an MBAN.[108] Additionally, for the reasons discussed below regarding the frequency coordinators' roles, we do not modify this rule to include frequency coordinators as eligible

[103] These rules are generally set forth in Subpart E of Part 95, which sets forth technical requirements that apply across all Personal Radio Services, and include : § 95.601 Basis and purpose; § 95.605 Certification procedures; § 95.631 Emission types; § 95.637 Modulation standards; § 95.645 Control accessibility; § 95.649 Power capability; § 95.651 Crystal control required; § 95.653 Instructions and warnings.

[104] *NPRM* at 9601-02 para. 39.

[105] Joint Parties, *ex parte,* filed January 30, 2012, at 4 and Attachment at 3. Joint Parties *ex parte* filed June 27, 2011, at 2. The Joint Parties also ask that the MBAN and AMT coordinators be allowed to operate MBAN devices under this rule. Among other things, the Joint Parties cite the need to "test MBANs equipment quickly with a minimum of paperwork and delay in the event equipment issues surface during the course of interference resolution." Joint Parties *ex parte,* filed January 27, 2012, at 4.

[106] Joint Parties *ex parte,* filed January 27, 2012, at 4. The WMTS rules provide: "Manufacturers of wireless medical telemetry devices and their representatives are authorized to operate wireless medical telemetry transmitters in this service solely for the purpose of demonstrating such equipment to, or installing and maintaining such equipment for, duly authorized health care providers." 47 C.F.R. § 95.1105.

[107] *See* 47 C.F.R. § 95.1201.

[108] We have a longstanding principle of holding specific licensees responsible for the acts and omissions of their employees and contractors. *See, e.g., Eure Family Limited Partnership,* 17 FCC Rcd 21861, 21863-64 (2002), citing *MTD, Inc.,* 6 FCC Rcd 34, 35 (1991) and *Wagenvoord Broadcasting Co.,* 35 FCC 2d 361 (1972). Here, we make clear that this principle applies to parties that are licensed by rule to operate certain equipment.

operators of MBAN equipment.[109] With respect to expanding the MedRadio rule to permit equipment operation by manufacturers for developing and testing purposes, we are not persuaded that such a rule revision is necessary. The Commission's experimental licensing rules provide the appropriate process for granting non-licensees operational authority for developing and testing MedRadio devices, including MBAN devices.[110]

35. *Permissible Communications.* In the *NPRM,* we observed that the existing rules allow a MedRadio device to be used for diagnostic and therapeutic purposes to relay non-voice data, and asked whether such requirements would be appropriate for MBAN operations.[111] The *NPRM* also asked how communications should be structured within a particular MBAN. Specifically, we asked whether communications between body-worn MBAN devices or communications between MBAN devices within one network with those in another should be allowed, and whether a single programmer/controller should be permitted to control body-worn devices associated with multiple MBAN networks simultaneously or those associated with more than one patient. As described below, we adopt communications rules that are generally consistent with the existing MedRadio provisions and modify Section 95.1209 of our Rules accordingly.

36. As an initial matter, no commenter objected to allowing an MBAN to communicate both diagnostic and therapeutic information. We will apply Section 95.1209(a) of our Rules, as written, to MBAN operations. While this rule provides considerable flexibility to provide data and visual information, it does not allow voice data, as requested by AT&T.[112] We believe that the MedRadio and WMTS rules offer a proven framework in which to base MBAN operations,[113] and note that AT&T's suggestion relates to general speculation about potential future MBAN functionality as opposed to a specific application it intends to deploy.[114]

37. We will require an MBAN to consist of a single programmer/control transmitter (or hub) that controls multiple (*i.e.*, non-implanted) sensor devices.[115] The intent of defining MBAN in this way is to prevent direct communications between programmer/controllers which would facilitate mesh type networks using MBAN controllers to potentially extend the range of an MBAN beyond the confines of the medical facility. Consequently, we will not permit direct communications between body-worn sensors or direct communication between programmer/control transmitters. Under existing Section 95.1209(c), programmer/control transmitters will be able to interconnect with other telecommunications systems. This will allow backhaul from a single patient-based MBAN control transmitter to a monitoring

[109] *See,* footnote 192, *infra.*

[110] 47 C.F.R. § 5.5 (Experimental authorizations).

[111] *NPRM* at 9601-02 para. 39.

[112] *AT&T Comments* at 6.

[113] The Commission prohibited voice transmissions in the WMTS due to a concern that allowing such transmissions could encourage the equipment to be used as a form of wireless intercom. Amendment of Parts 2 and 95 of the Commission's Rules to Create a Wireless Medical Telemetry Service, ET Docket 99-255, PR Docket 92-235, *Report and Order*, 15 FCC Rcd 11206, 11221 paras. 43-45 (2000).

[114] The low-power short distance nature of the MBAN architecture means that any voice communication that could be received by a sensor could also likely be received by the nearby controller. Moreover, the controller is permitted to connect to existing networks – including both wireless and wireline networks in which voice communication is permitted.

[115] This approach fits within the definition we are adopting for a Medical Body Area Network. *See* para. 31, *supra*.

station that receives and processes MBAN body sensor data from multiple patients using frequencies other than the 2360-2400 MHz band.[116] We recognize that some commenters would have us allow one programmer/control transmitter to be controlled by a separate programmer/control transmitter or permit direct communications between body-worn sensor devices.[117] We do not adopt these proposals. We believe that the rules we adopt provide more certainty that an MBAN will operate in compliance with our rules or a coordination agreement because each programmer/control transmitter and its associated body-worn sensors will operate in response to a control message received over the facility's LAN. As we gain further experience with MBAN operations, we may revisit these restrictions.

38. We believe that there is no need to specify that each MBAN control transmitter be limited to controlling the body sensor transmitters for a single patient, nor that specific protocols should be associated with such transmissions.[118] The low power levels permitted for MBAN transmitters will already limit the effective range for communications to a small number of patients, and thus such use does not raise any unique interference concerns. Consistent with the approach we have taken in the MedRadio proceeding, we also decline to restrict an MBAN from performing functions that are "life-critical" or "time-sensitive."[119] We continue to believe that these types of determinations are best made by health care professionals in concert with FDA-required risk management processes. Operators of MBAN systems and health care facilities are reminded that even the "life-critical" operations permitted on a secondary basis must accept interference from the primary spectrum users in the 2360-2400 MHz band.

39. *Authorized Locations.* We sought comment on whether it would be appropriate to restrict the use of MBAN transmitting antennas to indoor locations in certain frequency bands, and noted that our WMTS rules restrict antennas to indoor use only, while the MedRadio rules provide for the use of temporary outdoor antennas.[120] We are modifying Sections 95.1203 and 95.1213 of the MedRadio rules to provide for indoor-only MBAN operation in the 2360-2390 MHz band and MBAN operation at any location in the 2390-2400 MHz band.

40. Our decision on this issue is consistent with the approach suggested in the *Joint Proposal.* We find that limiting MBAN operation in the 2360-2390 MHz band to indoor locations within health care facilities is a reasonable and effective way to limit potential interference and promote sharing between MBAN and AMT users. It is also consistent with the coordination procedures we are adopting. Although AT&T suggests that any rule restricting use to indoors would limit the usefulness of an MBAN, we disagree and note that GEHC and other likely equipment developers have not been deterred by the prospect of indoor-only operation.[121] Moreover, in the 2390-2400 MHz band, where there are fewer AMT interference concerns,[122] we are able to provide MBAN users with the added flexibility of operating

[116] *NPRM* at 9602 para. 41. No commenter supported placing any specific restrictions on how backhaul between an MBAN and a monitoring location would be achieved. The application of Section 95.1209(c) to MBAN operations will permit the use of Ethernet connections, the telephone network, in-hospital wired systems, or any other suitable communication means to meet backhaul needs.

[117] *See, e.g.,* Joint Parties *ex parte*, filed November 21, 2011, at 4-5; *TI Comments* at 5.

[118] *Id. See also NPRM* at 9602 para. 42.

[119] *NPRM* at 9602 para. 40.

[120] *NPRM* at 9609 para. 70.

[121] *AT&T Comments* at 3.

[122] AMT operations at 2390-2395 MHz are not as extensive as they are in the 2360-2390 MHz band. *See* footnote 185, *infra.*

in any location. We reject the suggestion by the Joint Parties that we modify our rules to permit outdoor operation in the 2360-2390 MHz band in cases of a "medical emergency declared by duly authorized governmental authorities after emergency coordination with the AMT coordinator."[123] We find that the suggested exception does not clearly define "medical emergency" or "authorized governmental authorities" and would essentially delegate authority to unnamed third parties to determine when outdoor MBAN operation is permitted. Instead, we observe that there are other approaches that would as readily address this issue. Health care facilities can consider using MBAN devices that are capable of shifting to the 2390-2400 MHz band – where it is not necessary to receive prior approval to operate outdoors – in anticipation of situations where there may not be time to perform a quick coordination, such as an emergency in a part of the health care facility that requires some patients to be temporarily moved outdoors. For extraordinary circumstances involving outdoor use of the 2360-2390 MHz band, MBAN licensees will have to follow the same course of action as other licensees when emergencies occur, and ask the applicable licensing bureau (in this case, the Wireless Telecommunications Bureau) for a temporary waiver to permit such operation.[124] We expect that, in *bona fide* emergency situations, the MBAN and AMT licensees and the frequency coordinators will all cooperate to identify frequencies that can be made available for emergency MBAN operations as quickly as possible while ensuring flight safety.

41. *Equipment Authorization.* In the *NPRM*, we asked if each MBAN transmitter authorized to operate in the 2360-2400 MHz band should be required to be certificated, if manufacturers of MBAN transmitters should be subject to disclosure statement and labeling requirements that are analogous to those in the existing MedRadio rules (including the identification of MBAN transmitters with a serial number), and if MBAN transmitters should be required to be marketed and sold only for the permissible communications we allow for the service.[125] These provisions allow for the deployment and operation of existing MedRadio devices in a consistent and predictable manner, and we conclude that they will do the same for MBAN equipment. We therefore will apply the existing MedRadio provisions in Sections 95.603(f), 95.605, 95.1215, 95.1217, and 95.1219 of our rules to MBAN operations, modified as necessary to refer to MBAN devices and their associated frequency bands.

42. Although no commenter specifically addressed this issue, we note that the certification requirement in Section 95.603(f) of the rules does not apply to transmitters that are not marketed for use in the United States, but 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.[126] This provision will apply to MBAN devices. The disclosure statement and labeling requirements, which are similar to those

[123] Joint Parties, *ex parte,* filed January 27, 2012, Appendix § 95.1607.

[124] In order for us to evaluate requests for outdoor operation in the 2360-2390 MHz band, the health care facility must have first contacted the MBAN coordinator. This will allow the MBAN coordinator to notify the AMT coordinator so as not to endanger any ongoing AMT operations that have critical flight safety requirements, and will ensure that all parties have opportunity to discuss the terms and conditions for the proposed operations. The FCC has a 24-hour operations center ((202) 418-1122) that can issue authority in the case of unexpected emergencies that occur outside normal business hours. *See* 47 C.F.R. § 0.392(f).

[125] *NPRM* at 9610-11 paras. 73, 75-77. Certification requirements and procedures for MedRadio equipment are currently contained in 47 C.F.R. § 95.603(f) and 47 C.F.R. § 95.605, while disclosure policies, labeling requirements and marketing limitations are contained in 47 C.F.R. § 95.1215, 47 C.F.R. § 95.1217, and 47 C.F.R. § 95.1219 respectively.

[126] *NPRM* at 9610 para. 73. *See also* 47 C.F.R. § 95.603.

suggested in the *Joint Proposal*, are based on requirements that have been in place since 1999.[127] Although WCAI had expressed concern that similar labeling rules originally suggested by GEHC might be inadequate to notify MBAN users of their responsibilities as secondary licensees, we conclude that our proposed labeling rules are appropriate.[128] We have analyzed the potential for interference to and from MBAN devices – including in the adjacent-band scenarios of interest to WCAI – and determined that our rules will support MBAN operation on a secondary basis.[129] Moreover, because MBAN devices are similar to other MedRadio devices in that they will operate at low power and under the direction of a duly authorized health care professional, it is appropriate for us to apply the existing MedRadio labeling language for the programmer/controller transmitter that has served us well for many years.[130] However, we will modify the requirement for labeling a MedRadio transmitter with a serial number. The current rule requires that all MedRadio transmitters shall be identified with a serial number.[131] GEHC has stated that "…It would not be appropriate to require that individual MBAN transmitters be equipped with a unique serial number, given the fact that individual sensor nodes may be disposable."[132] Although we are not aware that this requirement has presented any problems for the manufacture and use of existing body-worn MedRadio devices, we will only require individual MBAN programmer/controller transmitters to be labeled with a unique serial number but not require individual MBAN body-worn sensor devices to be labeled this way due to their expected low-cost and disposable nature. Finally, as proposed in the *NPRM*, 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.[133] The size and placement of MBAN equipment may make it impractical to place this information directly on the transmitter, and the personnel responsible for overall MBAN operations within a health care facility are not likely to be physically located in patient care areas where MBAN transmitters will be used.

43. *Other Service Issues.* We will also adopt the proposals in the *NPRM* that MBAN devices not be required to transmit a station identification announcement, and that all MBAN transmitters be made available for inspection upon request by an authorized FCC representative.[134] These requirements are the same as the existing MedRadio rules, and no commenters objected to applying these provisions to MBAN users. We also update Section 95.1211 of our Rules ("Channel Use Policy") to reference the 2360-2400 MHz band.

2. Technical Rules

44. *Authorized Bandwidth and Channel Aggregation.* In the *NPRM*, we sought comment on

[127] *See MMN Order* at 16637 para. 92.

[128] *See* Comments of WCAI, filed October 5, 2009, at 2-5 (*WCAI Comments*); WCAI e*x parte*, filed January 28, 2011, at 2.

[129] We address the adjacent channel operational considerations raised by WCAI in paragraphs 21-22, *supra*.

[130] Our existing MedRadio labeling requirements specifically reference the band in which the MedRadio device is authorized to operate. While *NPRM* did not propose to reference the 2360-2400 MHz band specifically, we believe that it is appropriate to do so for purposes of consistency, and to avoid the suggestion that MBAN users are subject to different rights and responsibilities than other MedRadio users.

[131] 47 C.F.R. § 95.1217 (c).

[132] *See GE Comments* at 30.

[133] *NPRM* at 9611 para. 76.

[134] *NPRM* at 9610 paras. 72 and 74. These rules are codified at 47 C.F.R. §§ 95.1205 and 95.1207, respectively.

whether to apply the MedRadio approach of specifying only the maximum permitted bandwidth, but not any particular channel plan, with respect to MBAN devices in their authorized frequency band(s).[135] The record reflects broad support for this approach, and we are modifying Section 95.633 to specify a 5-megahertz maximum authorized bandwidth for MBAN devices as described below. This approach is consistent with the existing MedRadio rules.

45. Our decision to specify a 5 megahertz authorized bandwidth is also consistent with recommendations from the Joint Parties and other commenters.[136] Although the *NPRM* suggested a 1 megahertz limit, we agree with the Joint Parties and other commenters that 5 megahertz is a more appropriate limit.[137] By allowing the larger authorized bandwidth, we can still accommodate MBAN devices that use a 1 megahertz bandwidth, while also providing flexibility for the development of MBAN devices that can use higher data rates and that have higher throughput for applications that require larger amounts of data.[138] We will also permit device manufacturers to aggregate multiple transmission channels in a single device, so long as the total emission bandwidth used by all devices in any single patient MBAN communication session does not exceed the maximum authorized bandwidth of 5 megahertz.[139] This, too, is consistent with the existing channel use provisions of the MedRadio Service.

46. *Transmitter Operation and Power Limits.* In the *NPRM*, we sought comment on the appropriate maximum transmitter power for MBAN devices. We proposed to limit individual MBAN devices to a maximum transmit power of 1 mW equivalent isotropic radiated power (EIRP) measured in a 1 megahertz bandwidth, which followed GEHC's proposal.[140] The *Joint Proposal* suggested use of a maximum EIRP of 20 mW measured in a 5 megahertz bandwidth for the 2390-2400 MHz band, but maintained the original 1 mW EIRP maximum for the 2360-90 MHz band.[141] Based on the information provided in the record and our decision, discussed above, to adopt a maximum bandwidth of 5 megahertz, we will modify Section 95.639 of our Rules to specify the power limits in the *Joint Proposal*.

47. The need for a different power limit in the upper portion of the MBAN band was addressed by Philips. The 2390-2400 MHz portion of the MBAN spectrum will have no restrictions regarding location or mobile use, and thus all in-home MBAN use will occur in this band. Philips provides a detailed discussion of the differences between home and hospital MBAN use, and contends that there are unique circumstances – such as the possibility that an adverse health event could result in the patient falling on the MBAN transmitter and the need to provide patients with full mobility within their homes – that warrant a higher power level for this 10 megahertz band.[142] It also notes that the upper band's proximity to the ISM band means that the MBAN may have to overcome excess noise in some instances to ensure a reliable link budget.[143] AdvaMed echoes Philips in support of a 20 mW maximum

[135] *NPRM* at 9603 para. 44.

[136] Joint Parties *ex parte,* filed January 14, 2011, Attachment B at 5*; Philips Comments* at 14, Appendix A at A1-A2, and Appendix E at E-33; *AdvaMed Comments* at 11.

[137] *NPRM* at 9608 para. 65. We proposed 1 megahertz based on the GEHC Petition.

[138] Under our decision, an MBAN user may also choose to employ lesser emission bandwidths so long as the device complies with all applicable EIRP and unwanted emission limits.

[139] *NPRM* at 9608-09 para. 67.

[140] *NPRM* at 9608 para. 65.

[141] Joint Parties *ex parte,* filed January 14, 2011*,* Attachment B at 5.

[142] *Philips Comments*, Appendix D at D-1.

[143] *Philips Comments*, Appendix E at E25-E32.

EIRP in the 2390-2400 MHz band.[144] We find these arguments persuasive. Although all MBAN devices will operate within the framework of a low-power MedRadio service, there is good reason to make a distinction in the maximum power we authorize in the lower 2360-2390 MHz and in the upper 2390-2400 MHz bands.[145]

48. We are adopting additional transmitter operation rules for MBAN devices to implement other MBAN requirements. For example, as discussed above, MBAN devices may not operate outside the confines of a health care facility in the 2360-2390 MHz band. MBAN devices that operate in the 2360-2390 MHz band must comply with registration and coordination requirements, discussed below, and operate in the band consistent with the terms of any coordination agreement.[146] The Joint Parties proposed that these dual requirements — no outdoor use and compliance with a coordination agreement — could be met by requiring that the MBAN master transmitter receive a "beacon" signal or control message that conveyed the permitted scope of operation in the band and that the device cease operating in the band automatically if it could not receive the signal.[147] In their proposal, the control point in the health care facility would transmit this beacon or control message to the MBAN master transmitter using the facility's LAN.[148]

49. We generally agree with the Joint Parties' suggestions. We revise Section 95.628 of the rules, which specifies the technical requirements for MedRadio transmitters,[149] so that the MBAN programmer/controller transmitters must be capable of receiving and complying with a control message[150] specifying its particular operating parameters within the band. Specifically, an MBAN programmer/control transmitter may not commence operation and must automatically cease operating in the 2360-2390 MHz band if it does not receive a control message. It must also comply with a control message that directs it to limit its transmissions to segments of the band or to cease operation in the band. We note that the Joint Parties did not propose a specific period of time within which the MBAN transmitter must receive a control message to begin or continue operating. The proposal also did not

[144] *AdvaMed Comments* at 11. No commenter attempted to refute Philips assertions regarding the need for higher power in the 2390-2400 MHz band.

[145] We believe that MBAN operations at the slightly higher power in the 2390-2400 MHz band will not pose serious interference risk, as discussed at paras. 18-19 *supra*.

[146] For example, under the terms of a coordination agreement an MBAN may be permitted to transmit only on a specific sub-band; it may only transmit at certain times on certain days; or it may have to cease operations completely in the band. If no coordination is required because the MBAN is not within line-of-sight, it may be permitted to transmit anywhere within the band.

[147] The Joint Parties define a beacon as follows: "An electronic signal that must be received by MBANS master transmitters to convey authorized MBANS frequency information to all MBANS devices and to enable MBANS transmissions in the 2360-2390 MHz band. When an MBANS device cannot receive its associated beacon signal, it must automatically cease all radio transmissions in the 2360-2390 MHz band and operate only on default spectrum outside the 2360-2390 MHz band." Joint Parties *ex parte,* filed January 27, 2012, Attachment § 95.1603(g).

[148] Joint Parties *ex parte*, filed November 21, 2011, at 3.

[149] 47 C.F.R. § 95.628.

[150] We prefer the term "control message" because it better conveys the idea that there is associated data in addition to a basic beacon or signal function. Also, because the term "beacon" already appears in our Rules in various forms, we will refrain from using it in the MBAN context to avoid any potential confusion. *See, e.g.,* 47 C.F.R. Part 17 (describing beacons used for antenna structure lighting purposes); 47 C.F.R. § 87.5 (defining aviation terms, including racon (radar beacons) and radiobeacon stations); 47 C.F.R. Part 95, Subpart K (setting forth rules for Personal Locator Beacons); and 47 C.F.R. § 97.3(a)(9) (defining a "Beacon" in the amateur radio context).

prescribe a specific format or protocol for the control message. We will require applicants for equipment certification to attest that they comply with the requirement that MBAN equipment receive the control message by describing the protocols that the devices employ including the expected periodicity for reception of control messages that will allow the MBAN transmitter to begin or continue operating in the band.[151] Additionally, we expect that the control message will be an electronic message since it is expected to be sent using the health care facility's LAN. This helps to ensure that the MBAN meets the requirement for operating indoors on the 2360-2390 MHz band as discussed above, since it will have to be tethered to a wireline network or within signal range of a wireless network within the facility. Accordingly, our control message requirement offers a means by which an MBAN user can comply with our separate requirement that an MBAN that is moved outdoors (either intentionally or unintentionally) must stop operating in the 2360-2390 MHz band. Because each health care facility's communications infrastructure and physical layout will present unique capabilities and challenges, we do not establish any requirements for how control messages are distributed within a health care facility.

50. *Unwanted Emissions.* In the *NPRM,* we noted that the Part 95 MedRadio rules set forth limits on unwanted emissions from medical transmitting devices operating in the 401-406 MHz band and sought comment on the appropriateness of applying the same general limits to MBAN operations in the 2360-2400 MHz bands.[152] We find that the provisions in Section 95.635(d) of our Rules, which specify limits on unwanted emissions, are appropriate. Accordingly, we modify this rule to reflect the use of the 2360-2400 MHz band by MBAN devices.[153] We note that the Joint Parties' proposal supports using the proposed limits on unwanted radiation and no party objected to the use of these figures.[154] In addition, use of the MedRadio limits is consistent with our approach of accommodating MBAN operations under the existing MedRadio rules where practical.

51. *Frequency Stability.* In the *NPRM,* we proposed to require that MBAN transmitters comply with the MedRadio rules and maintain a frequency stability[155] of +/- 100 ppm of the operating frequency over the ambient environmental temperature range: 1) 25°C to 45°C in the case of MBAN transmitters; and 2) 0°C to 55°C in the case of MBAN control transmitters.[156] GEHC states that +/- 100 ppm is an acceptable limit for MBAN devices, but does not discuss the temperature range over which that stability should be required.[157] As described above, we are using the existing MedRadio definitions to regulate the MBAN sensor and hub devices. Under this construction, the existing temperature range for MedRadio programmer/control transmitters set forth in 95.628(d)(2) of our Rules will apply to MBAN

[151] Existing Section 95.603(f) requires certification for MedRadio Transmitters. 47 C.F.R. § 95.603(f).

[152] *NPRM* at 9609 para. 68.

[153] Under Section 95.635(d), emissions on frequencies 500 kHz or less above or below any particular authorized bandwidth are required to be attenuated by at least 20 dB below the transmitter output power. In addition, emissions more than 500 kHz above or below any particular authorized bandwidth are required to be attenuated to a level no greater than the following signal strengths at 3 m: a) between 30-88 MHz, 100 μV/m, b) between 88-216 MHz, 150 μV/m, c) between 216-960 MHz, 200 μV/m, and d) 960 MHz and above, 500 μV/m. *See* 47 C.F.R. § 95.635(d)(1).

[154] Joint Parties *ex parte*, filed January 30, 2012, Attachment § 95.635.

[155] Frequency stability is the maximum permissible departure by the characteristic frequency of an emission from the reference frequency. The frequency stability is typically expressed in parts per million.

[156] *NPRM* at 9609 para. 69.

[157] *GEHC Comments* at 29. Revised 47 C.F.R. § 95.628(d)(1) specifies a temperature range of 25 °C to 45 °C in the case of medical implant transmitters and revised 47 C.F.R. § 95.628(d)(2) specifies a temperature range of 0 °C to 55 °C in the case of MedRadio programmer/control transmitters.

hub devices without modification. Because no MBAN sensor will be implanted, we further conclude that the 25°C to 45°C range we have used for implanted devices should not apply to sensors. Instead we will use the broader 0°C to 55°C specification.[158]

52. *RF Safety.* In the *NPRM,* we noted that portable radiofrequency (RF) transmitting devices are subject to Section 2.1093 of the Rules, pursuant to which an environmental assessment concerning human exposure to RF electromagnetic fields must be prepared under Section 1.1307, and that these rule sections also govern existing MedRadio devices.[159] We also noted that the Commission has an open RF safety proceeding (ET Docket No. 03-137) in which it proposed to conduct a comprehensive review of its rules regarding human exposure to RF electromagnetic fields. Thus, the *NPRM* only sought comment on whether MBAN transmitters should be deemed portable devices. We will apply existing Section 95.1221 of our rules to MBAN devices, which will classify them as portable devices that are subject to Sections 2.1093 and 1.1307 of our rules. The record reflects support for treating MBAN devices in this manner.[160] We see no reason to treat MBAN devices differently than existing MedRadio devices with respect to RF safety matters.

53. *Frequency Monitoring.* In the *NPRM*, we sought comment on whether a frequency monitoring requirement should be required for MBAN devices to promote inter- and intra-service sharing and, if so, how we should develop such a protocol.[161] We noted that contention-based protocols could take a variety of forms, including listen-before-talk (LBT) frequency monitoring, time slot synchronization, and frequency hopping.[162] We encouraged commenters supporting implementation of a contention based protocol to discuss what kinds of contention protocols should or should not be utilized, and to explain in detail why or why not.[163]

54. We find that it is not necessary to specify protocols to ensure spectrum sharing among MBAN systems. We recognize that the record on this issue has evolved. Initial filings by GEHC as well as the Joint Parties indicated a desire to codify a sharing protocol requirement.[164] Several parties that support contention protocols nevertheless have urged us to avoid adopting specific rules.[165] In more recent pleadings, the Joint Parties state that while manufacturers believe that MBAN devices are likely to incorporate a mechanism to avoid interference in close proximity (such as within medical facilities), they do not wish for us to adopt detailed procedures that might inadvertently inhibit the development of innovative methods that would allow them to make more intensive use of the spectrum.[166] We believe

[158] We are modifying Section 95.628(d)(2) to specify that the 0°C to 55°C temperature range applies to Medical body-worn transmitters. This provision was omitted in our recent decision to authorize Medical Micro-power Networks because Medical Micro-power Networks cannot contain body-worn transmitters other than a programmer/control transmitter. *MMN Order* at Appendix A.

[159] *NPRM* at 9609-10 para. 71.

[160] *See Philips Comments* at A-16; *AdvaMed Comments* at 13; *GEHC Comments* at 29.

[161] *NPRM* at 9607 para. 61.

[162] *NPRM* at 9607 para. 62.

[163] *NPRM* at 9608 para. 64.

[164] *GEHC* Comments filed May 27, 2008 at 16.

[165] *AdvaMed Comments* at 10 ("this should just be defined as a high-level requirement with no specific details"). *See also TI Comments* at 7 and *Philips Comments* at A-8.

[166] Joint Parties *ex parte,* filed July 27, 2011, at 1-2.

that the best course is to refrain from mandating a sharing protocol requirement, particularly because it appears that these matters are already being addressed within the standards setting process.[167] In addition, we believe that the relatively low power levels used by MBAN transmitters make it possible that the use of sharing protocols might be unnecessary in many situations. We further conclude that MBAN manufacturers will determine the appropriate level of communications reliability through the risk management activities involved with medical device design that is subject to oversight by the Food and Drug Administration (FDA), and that they should be given the flexibility to meet that level of communications reliability through whatever means they find appropriate.[168] We also find that because we are requiring frequency coordination for MBAN and AMT sharing, described below, it is not necessary to adopt frequency monitoring rules to promote spectrum sharing between these services.

55. *Duty Cycle.* In the *NPRM*, we sought comment on whether we should adopt specific duty cycle limits for MBAN transmitters in our rules and whether such limits would be needed to allow the functioning of a contention-based protocol for achieving reliable MBAN system performance, or for other reasons.[169] We find that it is not necessary to specify a duty cycle in our rules. The record indicates that manufacturers are likely to employ duty cycles absent a specific requirement to do so because it will allow them to achieve important operational goals.[170] Moreover, we note that the Joint Parties' did not propose that we adopt a duty cycle.[171] Finally, while AdvaMed supports adoption of a mandatory duty cycle to be consistent with other international standards, we believe that the ongoing efforts of standards setting bodies to address MBAN use are adequate to address any relevant duty cycle considerations.[172]

D. Registration and Coordination for the 2360-2390 MHz band

56. *Notice of Proposed Rulemaking.* In the NPRM we sought comment on several approaches for facilitating sharing between MBAN systems and incumbent AMT operations. We sought comment on the establishment of exclusion zones around AMT test flight sites and whether they could be an effective means to protect those sites from harmful interference.[173] We noted that the GEHC Petition included a similar proposal to protect AMT receive sites in the 2360-2390 MHz band, and we asked for comment regarding the procedures and criteria for implementing such zones, acknowledging that these topics had generated much contention up to that point in the proceeding.[174] In particular, we sought comment on the interference criteria that should be used to determine whether harmful interference might

[167] For example, IEEE P802.15, the working group for Wireless Personal Area Networks (WPANs), is considering proposals to support MBAN operations in the 2360-2400 MHz band. *See* homepage for Task Group 4j, available at http://www.ieee802.org/15/pub/TG4j.html.

[168] *See* Joint Parties *ex parte,* filed June 27, 2011, at 2.

[169] *NPRM* at 9608 para. 66.

[170] *See Philips Comments* at A-12 and A-16 (discussing power management and RF safety considerations). Philips also notes that the 5 megahertz maximum bandwidth – which we are adopting – will allow for a shorter duty cycle than would be possible under the 1 megahertz limit we proposed in the *NPRM*. *Id.* at A-14. *See also, NPRM* at para. 66 (discussing the 25 percent duty cycle factor assumed in GEHC's original proposal).

[171] Joint Parties *ex parte,* filed January 30, 2012.

[172] *AdvaMed Comments* at 11. *See also*, footnote 163, *supra*.

[173] *NPRM* at 9605-06 paras. 52-55.

[174] *Id.* at 9596, 9603-06 paras. 19, 46-55.

occur;[175] the criteria that should be used to identify which AMT sites need interference protection; and the procedures to be used to identify future AMT sites that should be protected from an operational MBAN.[176] We also asked whether limiting MBAN operations in the 2360-2390 MHz band to indoor use within health care facilities (as defined in the WMTS[177]) would further reduce the likelihood of interference to AMT facilities by relying on building structures to further attenuate MBAN signals.[178]

57. We also sought comment on whether coordination of MBAN devices and AMT operations is needed and should be required and, if so, under what circumstances.[179] We specifically requested comments addressing the potential benefits of requiring registration of MBAN devices similar to the approach used for WMTS registration,[180] and the advantages and disadvantages of requiring coordination procedures rather than specifying exclusion zones where MBAN operations would not be permitted. We asked parties to address the criteria that would be used to determine if a MBAN system could operate without causing interference, the type of information that should be contained in a database, and how the Commission would designate a database administrator.[181]

58. *Decision.* We adopt registration and coordination rules for MBAN operations in the 2360-2390 MHz band.[182] As explained below, registration and coordination are two separate but related processes. A health care facility that intends to operate an MBAN in the 2360-2390 MHz band must register the MBAN with a frequency coordinator ("the MBAN coordinator") that the Commission will designate. The registration requirement will ensure that the locations of all MBAN operations in the 2360-2390 MHz band are recorded in a database. As part of the coordination process, the MBAN coordinator will first determine if a proposed MBAN in the 2360-2390 MHz band will be within line-of-sight of an AMT receiver. If the MBAN transmitter is within line-of-sight of an AMT receive site, the MBAN and AMT coordinators will work cooperatively to assess the risk of interference between the two operations and determine the measures that may be needed to mitigate interference risk. The MBAN coordinator will notify the health care facility when coordination is complete and the MBAN must operate consistent with the terms of any agreement reached by the coordinators. If no agreement is reached, the MBAN will not be permitted to operate in the band. The health care facility may not operate

[175] *Id.* at 9604-05 paras. 51-52. GEHC suggested an interference-to-noise ratio (I/N) of ≤ -3 dB; AFTRCC, the AMT coordinator, suggested a power-flux density (PFD) level of -180 dB Watts/m² in a 4 kHz bandwidth. The I/N criteria examines the power of an interfering signal relative to the noise level of the receiver, and the PFD criteria measures power received at a given location, usually on the ground. Both of these criteria are employed in ITU-R Recommendation M.1459 that addresses AMT systems operating in the 1425-1525 and 2310-2360 MHz bands and compatibility with broadcasting-satellite and mobile-satellite services.

[176] *NPRM* at 9605 para. 54. GEHC and AFTRCC disagreed on the number of AMT test sites, including those that were in use and the number of sites "entitled" to use the 2360-2390 MHz band. *See id.* at 9605 footnote 69.

[177] Section 95.1103(b) of the Commission's rules provides: "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; except the term health care facility does not include an ambulance or other moving vehicle. 47 C.F.R. § 95.1103 (b).

[178] *NPRM* at 9597 para. 22.

[179] *Id.* at 9606 paras. 56-58.

[180] *Id.* at 9606 paras. 57-58. *See also* 47 C.F.R. §§ 95.1111, 95.1113.

[181] *NPRM* at 9606 para. 58.

[182] Operation in the 2390-2400 MHz band may occur without registration or coordination.

the MBAN in the band until it receives the appropriate operating parameters from the MBAN coordinator. We also adopt procedures to accommodate new AMT receive sites as well as changes to MBAN deployment and operations.

59. The registration and coordination requirements we adopt accomplish several key principles of the Joint Parties' proposal to protect AMT receive sites. First, an MBAN will not be allowed to operate in the 2360-2390 MHz band until the frequency coordinators determine the risk of interference between the two services and the MBAN coordinator notifies the health care facility whether the device can operate in the band and the terms and conditions of operation.[183] Second, the parties agree that MBAN operation within the line-of-sight of an AMT receive facility should serve as the baseline criteria that would trigger an analysis of interference risk and mitigation techniques.[184] The importance of this baseline is underscored in the Joint Parties' proposed rules which include an expectation that both MBAN and AMT licensees will avoid line-of-sight operations whenever possible. Finally, we expect that the MBAN and AMT coordinators will work cooperatively to evaluate potential interference situations and thus we will require that they reach mutually satisfactory coordination agreements before MBAN operation is allowed at any specific location. Nevertheless, we recognize that AMT operates under a primary allocation and is entitled to protection from MBAN operations that will occur on a secondary basis. We anticipate that the AMT coordinator will only enter into agreements that ensure an appropriate level of protection for the primary AMT operations.

60. We conclude that the use of frequency coordination procedures is an efficient and effective way for MBAN and AMT services to successfully share the 2360-2390 MHz band. Unlike exclusion zones, which would prohibit any MBAN operation within a specified distance of an AMT receive site, coordination provides the parties flexibility to determine whether and under what conditions both services could operate in the band at a given location. Because all MBAN operations in the band will be required to register and the information will be maintained in a database, a coordinator can readily identify those locations that are within line-of-sight of an AMT receive site and thus will require a coordination agreement with incumbent or new AMT receive sites.

61. The rules we adopt incorporate many but not all of the suggestions made by the Joint Parties, including their determination that the rules governing MBAN use of the 2360-2390 MHz band will be sufficient to protect AMT operations.[185] 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.

1. Registration Requirement

62. As indicated above, we are adopting a new rule, Section 95.1223, which requires health care facilities to register all MBAN devices they propose to operate in the 2360-2390 MHz band with a frequency coordinator designated by the Commission. MBAN operation in the 2360-2390 MHz band

[183] We note that the Joint Parties often describe the MBAN coordinator's function as "authorizing" MBAN use. MBAN operations are authorized by the Commission under the rules we adopt herein, and the frequency coordinator identifies those frequencies that are available for MBAN use at a given location.

[184] The Joint Parties stated that 94 percent of hospitals are not within line of sight to AMT receive locations. Joint Parties *ex parte,* filed January 14, 2011, Attachment A at slide 6.

[185] In the *NPRM*, we observed that the 2390-2395 MHz is "very sparsely used" by AMT. *NPRM* at 9592 footnote 22. AFTRCC has noted that its members "generally avoid use of [the band] due to the risk of interference from amateurs," and it had previously suggested that 2390-2395 MHz could be reallocated for MBAN use. Reply Comments of AFTRCC, filed November 4, 2009 at 6; *AFTRCC Comments* at 20-21.

prior to registration is prohibited.[186] We believe that registration of all MBAN operations in the band will create a regulatory environment that promotes MBAN use and protects AMT operations. To register MBAN devices whose scope of operations will include the 2360-2390 MHz frequency range, a health care facility must provide to the MBAN coordinator the following information:

- 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;
- 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 (*e.g.*, geographic coordinates, street address, building);
- Point of contact for the health care facility (*e.g.*, name, title, office, phone number, fax number, e-mail address). This would typically be an administrator or other official who has a high level of authority within the facility; and
- Contact information (*e.g.*, name, title, office, phone number, fax number, e-mail address) 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. This person would typically be an employee or contractor. 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.

63. To ensure that the registration data maintained by the MBAN coordinator is accurate and up to date, we are requiring heath care facilities to keep their registration information current and to notify the MBAN coordinator of any material changes to the location or operating parameters of a registered MBAN. Because changes in MBAN location or operation could place that MBAN within line-of-sight of an AMT receive site, we will prohibit the MBAN from operating under the changed parameters until the MBAN coordinator has determined if a new or revised coordination agreement with the AMT coordinator is required, and if so, coordination with the AMT coordinator is completed. We also require a health care facility to notify the MBAN coordinator whenever an MBAN programmer/controller 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.

64. We do not adopt a suggestion by the Joint Parties to require health care facilities to implement a "transition plan" that they must file with the MBAN coordinator in order to register an MBAN operating in the 2360-2390 MHz band. The Joint Parties define a transition plan as one that "…defines the responsibilities and execution process for the healthcare facility to vacate all or portions of the 2360-2390 MHz band…. The transition plan must specify the measures necessary to meet the transition requirements compliant with these rules [*sic*], and must expressly authorize the healthcare

[186] MBAN devices that will operate only in the 2390-2400 MHz band will not require registration or coordination. *See* para. 67, *infra*.

facility's MBANS equipment vendor to re-channel the healthcare facility's MBANS operations out of all or portions of the 2360-2390 MHz band if necessary to remain compliant with these rules. The healthcare facility and its equipment vendor shall be required to effect re-channeling in accordance with these Rules, which commitments shall be reflected in the transition plan."[187] The Joint Parties would require that transition plans be "re-validated annually by the healthcare facility, its MBANS equipment vendor, and the MBANS coordinator."[188] The Joint Parties argue that a transition plan would be an efficient way to respond to an interference situation if one should occur because it "creates a contractual outline of responsibilities … among the healthcare facility, equipment vendor, and MBANS coordinator" and would capture the "normal business practices" of warranty and service contracts whereby vendors manage hospitals' medical systems.[189] They also argue that, in the event a health care facility fails to take immediate action to correct interference, the transition plan assures AMT licensees that a mechanism exists to do so.[190] The Joint Parties envision that a transition plan would be unique for each health care facility in that it may identify various types of communications networks within the facility as back-ups for patient monitoring (*e.g.,* WMTS facilities), that the MBAN coordinator "would approve the transition plan if it describes a reasonable approach to eliminating potential interference for that particular hospital[,]" and that the "overall process is a product of normal vendor risk assessment that is required for medical devices and systems by the Food and Drug Administration."[191]

65. We are not persuaded that requiring a transition plan as suggested by the Joint Parties is necessary to ensure that interference with AMT operations, if it occurs, can be quickly resolved. Instead, we are adopting other requirements that would be less burdensome and provide some flexibility in accomplishing the same objective. In particular, we require a health care facility, as part of the registration process with the MBAN coordinator, to state whether its MBAN is capable of defaulting its operations to the 2390-2400 MHz band or to other hospital systems. We find that this approach effectively puts the facility on notice that it is responsible for taking whatever actions necessary to prevent or correct any harmful interference with AMT operations and also appropriately leaves the responsibility of defining and ensuring patient safety in the hands of medical professionals rather than the Commission or Commission designated frequency coordinators. Also, we are requiring that an MBAN transmitter not operate in the 2360-2390 MHz band unless it is able to receive and comply with a control message that notifies the device to limit or cease operations in the band.[192] This requirement should ensure that MBAN devices always operate in compliance with any coordination agreement and quickly respond to any interference situation. We also conclude that the rules we adopt will provide health care facilities with sufficient flexibility to decide how best to manage its communication and medical networks because, as the Joint Parties note, each situation is unique in terms of network capability and management capability.

66. Although we agree with the Joint Parties that integrating an MBAN into the existing network environment in a health care facility is important, we do not believe that a frequency coordinator should be responsible for approving a health care facility's plans for complying with the rules or its plans for managing its internal systems for communications or patient care. Although we appreciate the Joint Parties' argument that the overall process is a by-product of the risk assessment that a medical device manufacturer is required to conduct by the Food and Drug Administration (FDA) and thus may not be

[187] Joint Parties *ex parte,* filed January 30, 2012, Attachment § 95.1603(m).

[188] *Id*.

[189] *Id*. at 1-2.

[190] *Id*. at 2.

[191] *Id.*

[192] *See* § 95.628(c) in Appendix A and para. 49, *supra.*

burdensome to prepare, we believe that the FDA's risk assessment process serves a purpose that is fundamentally different than the Commission's in requiring health care facilities to register with a frequency coordinator. The transition plan as described by the Joint Parties goes beyond the scope of the registration and coordination functions we are requiring to ensure interference protection to AMT licensees, and those plans might overlap the risk assessment that is within the FDA's purview. We do not believe that a frequency coordinator is an appropriate party for approving such plans or that the Commission should confer such approval authority on a frequency coordinator. The approach we adopt will allow health care facilities to manage their own MBAN systems or enter agreements as they determine to be appropriate for their individual situation, rather than adopting an approach that would require a health care facility to enter into service agreements with MBAN vendors.[193] Finally, while we do not require health care facilities to file a transition plan with the MBAN coordinator, we anticipate that health care facilities will create such plans in routine practice. We encourage them to share such information with the MBAN coordinator to facilitate the coordination process.

67. Finally, we do not adopt the Joint Parties' suggestion that the registration (but not the coordination) requirement be expanded to include the 2390-2400 MHz band only for health care facilities that are classified as hospitals as defined at Section 1861 of the Social Security Act, 42 U.S.C. § 1395x(e) prior to their use of that band for MBAN equipment.[194] ASHE, which has expressed an interest in serving as the MBAN coordinator, advocated for this requirement because "hospitals treat patients with the most acute symptoms, they are the facilities that require the most protection from potential MBANS interference."[195] ASHE further argues that registration of all hospital deployments of MBAN equipment "will provide the MBANS frequency coordinator with better information to serve the facilities that are treating patients with the most critical needs."[196] We are not persuaded that registration of only certain types of health care facilities in a band not subject to coordination is needed or otherwise in the public interest. We are adopting a registration requirement for the 2360-2390 MHz band because it will facilitate coordination with AMT operations in that band; coordination is not needed and will not be required for an MBAN to operate in the 2390-2400 MHz band. Our rules recognize that some MBAN equipment may operate across the whole 2360-2400 MHz band, but some equipment may be designed to operate only in the 2390-2400 MHz band which can be used for indoor or outdoor use without coordination. In the latter case, a registration requirement would unnecessarily burden hospitals that do not need assistance from the MBAN coordinator. Even if we were persuaded that a registration requirement in the upper band would serve some useful purpose, we do not agree with ASHE that our rules should discriminate as to which facilities should be required to register. Our rules require that any facility that registers MBAN equipment that operates in the 2360-2390 MHz specify whether its equipment can default to the 2390-2400 MHz band since this information will enable the coordinator to help the facility manage its MBAN operations consistent with any coordination agreements.

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[193] In conjunction with this suggestion, the Joint Parties' also suggested that we expand the "Eligibility" rule (47 C.F.R. § 95.1201). *See* Joint Parties *ex parte,* filed January 30, 2012, Attachment § 95.1605. They argue that such authorization would allow vendors and coordinators to test equipment quickly with a minimum of paperwork and delay. *Id*. at 4. As we discussed above, because we have not adopted the Joint Parties "transition plan" concept, which would have obligated vendors and coordinators to operate MBAN equipment in some circumstances, we do not expand the eligibility rule. Again, we reiterate that a health care facility can enter agreements with third parties to operate MBAN equipment as it determines to be appropriate for their individual situation to facilitate the coordination process. *See also* paras. 33-34, *supra*.

[194] *See* Joint Parties *ex parte,* filed January 30, 2012, Attachment § 95.1615(e).

[195] The American Society for Healthcare Engineering of the American Hospital Association (ASHE) *ex parte*, filed September 26, 2011, at 2.

[196] *Id.*

2. Coordination Requirement

68. The Joint Parties have proposed using a coordination process that is based on the MBAN coordinator and the AMT coordinator agreeing to a set of technical specifications.[197] Under that proposal, it would first be necessary for the MBAN coordinator to determine whether the proposed MBAN location would be within the line-of-sight of an AMT receive site. The Joint Parties propose that the MBAN coordinator would notify the AMT coordinator of proposed MBAN operations that are beyond line-of-sight to AMT receiver locations so that the AMT coordinator could evaluate this determination. When MBAN operations are proposed for a location within line-of-sight of an AMT receiver location, the parties would initiate a coordination process that considers the proposed MBAN specifications and existing AMT operations. The Joint Parties propose using the technical parameters specified in ITU-R Recommendation M.1459 for determining protection criteria and technical parameters associated with AMT receivers.[198] Under this approach, the coordinators would agree to permit the MBAN to operate if an evaluation based on this standard indicates that MBAN operations can occur without causing harmful interference to AMT operations. The Joint Parties also propose the adoption of procedures that would cause an MBAN to automatically clear the band when the AMT stations require access to the spectrum.

69. We find that use of a coordination framework that is based on the Joint Parties' proposal will allow for the operation of MBAN devices in the 2360-2390 MHz band while also providing adequate interference protection for AMT receivers, and we codify these coordination procedures in new Section 95.1223(c) of our rules. As the first step in the coordination process, the MBAN coordinator will determine whether a proposed MBAN location is within line-of-sight of AMT operations. We will require that the MBAN coordinator provide the AMT coordinator with the MBAN registration information and get the AMT coordinator's concurrence that the MBAN is beyond line-of-sight prior to the MBAN beginning operations in the band. If the MBAN is within line-of-sight, the MBAN and AMT coordinators will assess the risk of interference between the two operations and determine the measures that may be needed to mitigate interference risk. In determining compatibility between proposed line-of-sight MBAN and AMT operations, the coordinators will use ITU-R M.1459, subject to accepted engineering practices and standards that are mutually agreeable to both coordinators and that take into account the local conditions and operating characteristics of the AMT and proposed MBAN facilities. The Joint Parties have proposed specific analytical techniques for determining whether proposed MBAN locations are within line-of-sight and how to determine actual path loss. We decline to specify these procedures in our rules. We recognize that the MBAN and AMT coordinators will have to agree to the procedures they will use to determine when coordination is required and how it is done, but we also are confident that the coordinators will be technically competent and will fully cooperate to develop mutually agreeable procedures to create coordination agreements. We are also convinced that codifying specific procedures would potentially reduce flexibility on the part of both coordinators to adapt the coordination procedures as MBAN technologies mature.

70. The Joint Parties have suggested procedures to follow when AMT users need to expand their operations beyond existing receiver locations. As a service operating on a primary basis in the 2360-2390 MHz band, AMT users are entitled to expand as necessary to provide for aeronautical testing purposes. Because health care facilities need levels of certainty and also need time to adapt to the

[197] Joint Parties *ex parte,* filed January 14, 2011, Appendix A at slide 7 (describing proposed criteria for MBAN protection of AMT operations).

[198] 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 MHz and 2 310-2 360 MHz, International Telecommunications Union/ITU Radiocommunications Sector, ITU-R Recommendation M.1459 (2002).

increased AMT requirements, the Joint Parties propose that an AMT licensee planning to expand its operations would first consider using locations that are not within line-of-sight to existing MBAN locations. If locations outside the line-of-sight to MBAN operations are not available, the AMT coordinator would give the MBAN coordinator at least seven days notice that MBAN users would have to cease or modify their operations.[199] Under this proposal, the MBAN operator would still be eligible to enter into a new or modified coordination agreement with the new AMT operator, but the MBAN operator would nevertheless be required to vacate its operations at the end of the seven-day period if no coordination agreement is reached. We adopt this proposal because we find that it provides for the continuing requirements of the AMT community and preserves their growth potential, while also providing adequate notice to MBAN operators to adapt to any new AMT requirements.

71. The Joint Parties have also suggested procedures to follow when AMT users experience interference from MBAN operations. We agree that it is important to consider the possibility that unexpected interference situations may occur, and we adopt rules that will aid MBAN users in identifying and resolving interference complaints. The channel use policy rule we adopt conditions MBAN use on not causing harmful interference to and accepting interference from authorized stations operating in the 2360-2400 MHz band.[200] As part of the registration process for operating MBAN devices in the 2360-2390 MHz band, we also require an MBAN user to provide an MBAN coordinator with a point of contact for the health care facility that is responsible for making changes to MBAN operating parameters (such as discontinuing operations or changing frequencies), to state whether its MBAN operation is capable of defaulting to the 2390-2400 MHz band, and to acknowledge that it is responsible for ceasing MBAN operations in the 2360-2390 MHz band or defaulting traffic to other hospital systems.[201] We require the MBAN coordinator, as part of its duties, to work with the health care facility to identify an interference source in response to a complaint from the AMT coordinator.[202] Together, these rules give MBAN users clear notice that they must be prepared to cease use of the 2360-2390 MHz band in the event of interference, require them to disclose the person who is able to modify or cut off MBAN use within a health care facility, and obligate the MBAN coordinator – the party who has a record of MBAN use and who will logically be contacted by the AMT coordinator about interference – to identify alternative frequencies for MBAN use or to direct the MBAN to cease operation. Under the procedures suggested by the Joint Parties, if a health care facility is notified of MBAN interference to an AMT receive antenna, the MBAN system should be required to immediately cease transmission.[203] We note that the Joint Parties' proposal does not clearly specify who is responsible for notifying the health care facility of interference and incorporates use of the transition plan concept, which we are not adopting. We conclude that the rules we describe above can accomplish the same overall goal of identifying and resolving interference to AMT from MBAN users in a way that also clearly sets forth the roles and responsibilities of the parties. We fully expect that licensees will work together to resolve any instances of harmful interference under the rules we adopt and the procedures described above.[204]

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[199] Joint Parties *ex parte*, filed January 14, 2011, Appendix C § 95.1615(g)(F).

[200] 47 C.F.R. § 95.1211(c). Although the secondary status of MBAN operations already indicates that MBAN licensees are responsible for resolving any harmful interference to primary AMT licensees, this rule serves to make the point explicitly.

[201] 47 C.F.R. §95.1223(a)(7).

[202] 47 C.F.R. §95.1225(b)(5).

[203] Joint Parties *ex parte*, filed January 30, 2012, Attachment § 95.1615(g)(E).

[204] In response to Commission staff inquiries, the Joint Parties acknowledged that in most services many, if not most, interference situations are resolved by the private parties involved, without FCC involvement or even knowledge. Joint Parties *ex parte*, filed January 30, 2012, at 6.

72. The Joint Parties have proposed additional rules for the coordination process that, although we are not codifying, we agree would be useful tools for the coordinators to use to achieve mutually agreeable coordination agreements. For example, the Joint Parties ask that the rules specify a priority order in which an MBAN would be permitted to use certain sub-bands within the 2360-2390 MHz band. We believe that this approach would likely provide some certainty to both MBAN and AMT users so they can avoid co-frequency operation. We prefer to provide coordinators with the flexibility to determine the appropriate operating parameters for band sharing, which may change over time, rather than codifying this approach. We also believe that our rules should offer the flexibility for health care facilities and MBAN coordinators to develop an interface for the delivery of MBAN operational parameters that is best suited to the health care facility's own internal communications network. Thus, the appropriate format and medium for delivering the information may vary in each case and may evolve over time. We recognize that the delivery of this information also must be consistent with the mutually agreeable coordination agreement the MBAN coordinator has reached with the AMT coordinator. The Joint Parties have addressed this issue by proposing rules that would specify two types of "electronic keys" and how they would be delivered by the MBAN coordinator to a facility's control point.[205] They suggest that in most cases "electronic keys" can be deployed using non-electronic means, *e.g.*, telephone or postal mail, but in certain cases – such as when MBAN operations can only be permitted during certain hours – it may be necessary to require a health care facility to receive this information electronically over a secure network to ensure effective band sharing. We believe that in the latter case, if a health care facility is not able to receive the operational parameter information on a secure link, the MBAN at that facility may not be successfully coordinated. While the specific architecture proposed by the Joint Parties may prove useful as MBAN devices are designed and deployed, we choose not to mandate their specific approach and we will instead provide the coordinators with flexibility to determine the appropriate format and medium for delivering MBAN operating parameters to a health care facility. Accordingly, we are not codifying the electronic key proposal into our rules.

3. Coordinator Functions

73. To implement the registration and coordination requirements that we describe above, the Commission will designate an MBAN coordinator(s) after resolution of the proceedings addressed in the Further Notice below.[206] We direct the staff to act expeditiously to prepare a decision in response to the Further Notice and to initiate the selection of an MBAN coordinator(s), with a target of completing the process by June 2013. We adopt a new rule, Section 95.1225, which sets forth the specific functions that the MBAN coordinator will perform. The MBAN coordinator must:

- 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;
- 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;
- 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; and
- Develop procedures to ensure that registered health care facilities operate an MBAN consistent with the coordination requirements.

[205] *See* footnote 37, *supra*.

[206] We will not permit MBAN operation in the 2360-2390 MHz band prior to the selection of a coordinator(s).

74. Regarding the AMT coordinator functions, in 1969 the Commission designated Aerospace & Flight Test Radio Coordinating Council (AFTRCC) as the AMT coordinator under its rules.[207] AFTRCC performs coordination for non-Federal Government licensees and coordinates with the Federal Government Area Frequency Coordinators for day-to-day scheduling of missions.[208] In the *NPRM,* we acknowledged AFTRCC's role as AMT coordinator and sought comment on the organization's involvement in MBAN and AMT spectrum-sharing.[209] We expect that AFTRCC will represent both Federal and non-Federal AMT interests when coordinating with the MBAN coordinator, thereby eliminating the need for MBAN licensees to separately coordinate with Federal AMT systems. This should significantly reduce the time needed to complete coordination and should facilitate timely deployment of MBAN operations.

IV. FURTHER NOTICE OF PROPOSED RULEMAKING

75. In this Further Notice we request comment on a number of issues related to designating the MBAN coordinator(s) for the 2360-2390 MHz band. As we discuss below, the Joint Parties have asked that only one MBAN coordinator be designated. American Society for Healthcare Engineering (ASHE), which is now the WMTS coordinator, has expressed its interest in being the MBAN coordinator as well.[210] Although the *NPRM* sought comment on coordination procedures and generated a record upon which we are adopting coordination requirements in the Report and Order herein, it did not address other issues that would guide the selection and designation of an MBAN coordinator. We raise those issues in this Further Notice.

A. MBAN Coordinator Criteria

76. In this section, we seek comment on whether we should designate one or more MBAN coordinators, the term of service for an MBAN coordinator, the qualifying criteria that should guide our selection of an MBAN coordinator, and fees to register with an MBAN coordinator and to coordinate MBAN and AMT operations.

77. *Number of coordinators*. The Joint Parties have asked that only one MBAN coordinator be designated, arguing that MBAN coordination should be viewed as an extension of WMTS coordination for health care facilities.[211] Philips and GEHC previously pointed out that the Commission has designated only one WMTS coordinator and one AMT coordinator, and a single MBAN coordinator would likewise simplify the coordination process, reduce costs and expedite deployment of MBAN

[207] *See* Request by Aerospace & Flight Test Radio Coordinating Council For Designation as a Recognized Frequency Advisory Committee, 17 F.C.C.2d 525 (1969); *see also* 47 C.F.R. § 87.305.

[208] *See* Letter from William K. Keane, counsel for AFTRCC, to Secretary, FCC, WT Docket No. 01-289 (January 27, 2005).

[209] *See NPRM* at 9606-9607 para. 60.

[210] ASHE is a part of the American Hospital Association, and represents a broad spectrum of professions involved in healthcare engineering and facilities management. ASHE *ex parte*, filed May 28, 2009, at 1. ASHE contracts with Comsearch as their technical partner in providing WMTS coordination services. ASHE *ex parte*, filed September 26, 2011, at 1. In this proceeding, ASHE has participated in discussions with the Joint Parties as evidenced by their co-signing their most recent filings. *See* Joint Parties *ex parte,* filed January 30, 2012, at 8; Joint Parties *ex parte,* filed September 13, 2011, at 2.

[211] Joint Parties *ex parte,* filed June 3, 2011, at 1.

equipment.[212] They assert that a process relying on multiple MBAN coordinators could delay coordination and compromise accuracy, as well as increase costs for users by, for example, maintaining multiple databases.[213]

78. We propose to select only one MBAN coordinator. Because the MBAN and AMT coordinators will have to mutually agree to coordination procedures, as discussed above, we believe that it will be easier for a single MBAN coordinator to work with the AMT coordinator to develop these coordination procedures. Use of a single MBAN coordinator will also provide both the health care community and the AMT coordinator a single point of contact for obtaining all the information needed regarding potential frequency conflicts. As with WMTS, a single MBAN coordinator will simplify the registration process for the health care community and provide a single database of all registered MBAN equipment in the 2360-2390 MHz band. We believe that using a model that is similar to WMTS will make it easier for the health care community to understand and comply with the MBAN rules that we are adopting. If we were to designate multiple coordinators, they all would have to agree to coordination procedures and share information on a regular and timely basis so that each has a complete registration database, provides consistent coordination results, and are able to provide coordination services without undue delay. This would likely add costs that would have to be shared among the relatively small and specialized health care user community, and we do not believe that the costs incurred by having multiple coordinators would spur a competitive environment that would provide sufficient benefits to offset these costs. We seek comment on this proposal.

79. *Term of Service*. We propose to require that the MBAN coordinator we designate agree to serve a ten-year term, which could be renewed by the Commission. Further, in the event that the MBAN coordinator cannot or does not want to continue to the end of its term, it will have to transfer its MBAN database to another entity designated by the Commission. We believe that a ten-year term is appropriate for several reasons. Because it will probably take several years for MBAN equipment to be deployed, a shorter term (*e.g.*, five years) may not provide enough time for the user communities and the coordinators to develop a working relationship to facilitate MBAN deployment while protecting AMT operations. A ten-year term also will provide a substantial time period for the Commission to evaluate the coordinator's performance. We seek comment on this proposal.

80. *Qualifying Criteria*. We propose to establish minimum qualifying criteria for selecting an MBAN coordinator. These minimum qualifying criteria are intended to ensure that the designated coordinator can successfully accomplish the functions required by our rules. We propose to require that parties interested in being designated an MBAN coordinator demonstrate that they meet the following criteria:

- Ability to register and maintain a database of MBAN transmitter locations and operational parameters;
- Knowledge of or experience with medical wireless systems in health care facilities (*e.g.*, WMTS);
- Knowledge of or experience with AMT operations;
- Ability to calculate and measure interference potential between MBAN and AMT operations

[212] Philips and GEHC *ex parte*, filed May 11, 2011, at 4. Although Philips and GEHC are the parties of record for this document, they noted that they "…provided a copy of this letter to AFTRCC for its review, and AFTRCC has advised that, in its view, the letter furthers adoption of the compromise approach for MBANS that the Joint Parties have submitted to the Commission." *Id.* at 1.

[213] *Id.* at 4.

and to enter into mutually satisfactory coordination agreements with the AMT coordinator based on the requirements in Section 95.1223(c);

- Ability to develop procedures to ensure that registered health care facilities operate an MBAN consistent with the requirements in Section 95.1223.

81. Philips and GEHC suggested additional requirements for an MBAN coordinator which emphasize, for example, experience working with hospitals and medical device vendors; institutional knowledge of the health care industry; and having an MBAN user community as its core constituency.[214] We believe that these types of requirements may have been useful had we adopted certain elements of the Joint Parties' coordination plan, *e.g*., the transition plan requirement, but they may not be necessary under the coordination rules we are adopting. We seek comment on the minimum qualifying criteria that should be established for selecting an MBAN coordinator, and whether those we propose above are sufficient. We also seek comment on whether we should require that service should be provided on a non-discriminatory basis.

82. Finally, as noted above, ASHE, the WMTS coordinator, has expressed an interest in being designated the MBAN coordinator. As indicated above, ASHE contracts with Comsearch as its technical partner in providing WMTS coordination services.[215] When the Commission designated ASHE as the WMTS coordinator, it noted that ASHE did not have frequency coordination experience and would contract with a third party to provide technical and administrative support for providing the service. Nonetheless, we concluded that this was not a significant factor arguing against ASHE's selection because the WMTS coordinator would not have to resolve frequency conflicts.[216] As we discuss above, the MBAN coordinator has broader responsibilities than the WMTS coordinator and will have to resolve frequency conflicts with the AMT coordinator. Because AMT is a primary service entitled to interference protection from MBAN operations, we believe it is important for us to be confident that the designated MBAN coordinator can perform the required functions under the rules and will be directly responsible to the Commission if it has to intervene in resolving any coordination disputes that may arise. We seek comment on whether third party contractual arrangements should be permitted to qualify an entity for designation as an MBAN coordinator and, if so, what amount of disclosure of a contractual arrangement should we require as part of the selection process.

83. *Fees for Service*. We do not propose to prescribe fees for MBAN registration and coordination services and instead propose to let an MBAN coordinator establish service fees. Nonetheless, we recognize that if we choose to designate only one MBAN coordinator, fees for service will not be disciplined by competition from several coordinators. Philips and GEHC have asked that, as a qualification for designation as an MBAN coordinator, an entity must be "willing to operate the coordination process and MBANS database at cost, ideally on a non-profit basis."[217] The Commission did not prescribe any service fees for WMTS coordination, but stated that it would allow the designated coordinator "to set the fee structure necessary to recoup costs."[218] We also seek comment on whether we

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[214] *Id.*

[215] *See* http://www.ashe.org/resources/WMTS/ and http://www.comsearch.com/interactive_solutions/WMTS/overview.jsp.

[216] Amendment of Parts 2 and 95 of the Commission's Rules to Create a Wireless Medical Telemetry Service, ET Docket 99-255, *Order*, 16 FCC Rcd 4543, 4550-51 para. 25 (WTB PSPWD 2001) (*WMTS Designation Order*).

[217] Philips and GEHC *ex parte,* filed May 11, 2011, at 5.

[218] Amendment of Parts 2 and 95 of the Commission's Rules to Create a Wireless Medical Telemetry Service, ET Docket No. 99-255, PR Docket No. 92-235, *Report and Order,*15 FCC Rcd 11206, 11218-19 at para. 36 (2000). (continued….)

should adopt any fee requirements for MBAN registration and coordination, including for example whether service fees should only recoup costs and how such a requirement should be evaluated and whether service fees should be reasonable and non-discriminatory.

84. AFTRCC has established service fees for FCC licensees in the aeronautical services.[219] The Joint Parties have asked that we codify as part of the coordination rules a requirement that health care facilities "bear responsibility for reasonable costs incurred by the aeronautical telemetry coordinator in effecting the coordination."[220] We seek comment on this request. We also seek comment on how "reasonable costs" should be evaluated, and if we were to codify this requirement, what oversight the Commission should exercise over AMT-MBAN coordination fees. Should we require that service should be provided on a non-discriminatory basis and that fees should be reasonable and non-discriminatory? We also seek comment on the procedures that would apply for health care facilities to pay these costs. For example, would a health care facility apply to AFTRCC for coordination or would it pay these fees to the MBAN coordinator who, in turn, would pass along the fees to AFTRCC? As discussed above, AFTRCC coordinates Federal AMT operations, in conjunction with the Federal Government Area Frequency Coordinators for day-to-day scheduling of missions. Should service fees for MBAN coordination exclude costs that AFTRCC may incur for coordinating Federal AMT operations?

B. MBAN Coordinator Selection

85. Under the Commission's rules, the Wireless Telecommunications Bureau (WTB) has delegated authority to certify frequency coordinators for the services that it administers, including the MedRadio Service under Part 95 of the Commission's rules.[221] We propose that, under its delegated authority, WTB would select the MBAN coordinator using the same procedures that were implemented for selecting the WMTS coordinator. The WTB would issue a Public Notice to announce procedures for interested parties to submit applications for consideration as an MBAN coordinator.[222] It would issue an Order to designate the MBAN coordinator, and execute a Memorandum of Understanding with the selected coordinator that will set forth the coordinator's authority and responsibilities.[223] The MBAN coordinator would assume its duties upon the execution of the Memorandum of Understanding. We seek comment on whether this process, which worked well for selecting the WMTS coordinator, would permit the Commission to complete the MBAN coordinator selection process in a timely and efficient manner.

V. PROCEDURAL MATTERS

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

87. *Initial Regulatory Flexibility Certification.* The Regulatory Flexibility Act of 1980, as

(Continued from previous page)
Interested parties were asked to provide their proposed fee structure as part of their request to be designated an WMTS coordinator. Wireless Telecommunications Bureau Opens Filing Window For Requests To Be a Frequency Coordinator In The Wireless Medical Telemetry Service, *Public Notice*, 15 FCC Rcd 19038 (2000).

[219] *See* http://www.aftrcc.org/pages/procedures.php.

[220] Joint Parties *ex parte,* filed January 30, 2012, Appendix § 95.1615 (g)(I).

[221] 47 C.F.R. § 0.131 (m) (WTB "[c]ertifies frequency coordinators; considers petitions seeking review of coordinator actions; and engages in oversight of coordinator actions and practices.").

[222] *See, e.g.,* Wireless Telecommunications Bureau Opens Filing Window for Requests to Be a Frequency Coordinator in the Wireless Medical Telemetry Service, *Public Notice*, 15 FCC Rcd 19038 (2000).

[223] *WMTS Designation Order* at 4551 para. 26.

amended (RFA),[224] requires that an initial regulatory flexibility analysis be prepared for notice and comment rulemaking proceedings, unless the agency certifies that "the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities."[225] The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction."[226] In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act.[227] 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 Small Business Administration (SBA).[228]

88. The Further Notice addresses a number of issues related to designating an MBAN coordinator for the 2360-2390 MHz band. The Joint Parties have asked that only one MBAN coordinator be designated. American Society for Healthcare Engineering (ASHE), who is now the WMTS coordinator, has expressed its interest in being the MBAN coordinator as well.[229] Although the NPRM sought comment on coordination procedures and generated a record upon which we are able to adopt coordination requirements in the Report and Order, the NPRM did not address other issues that would guide the selection and designation of an MBAN coordinator. We address those issues in the Further Notice. We seek comment on whether we should designate one or more MBAN coordinators, the terms of service for an MBAN coordinator, the qualifying criteria that should guide our selection of an MBAN coordinator, and fees to register with an MBAN coordinator and to coordinate MBAN and AMT operations.

89. Therefore, we certify that the proposals in this Further Notice of Proposed Rulemaking, if adopted will not have a significant economic impact on a substantial number of small entities. If commenters believe that the proposals discussed in the Further Notice require additional RFA analysis, they should include a discussion of these issues in their comments and additionally label them as RFA comments. The Commission will send a copy of the Further Notice, including a copy of this initial certification to the Chief Counsel for Advocacy of the SBA.[230] In addition, a copy of the Further Notice and this initial certification will be published in the Federal Register.[231]

90. *Congressional Review Act.* The Commission will send a copy of this Report & Order and Further Notice of Proposed Rulemaking to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

91. *Paperwork Reduction Act.* The Report and Order in this document contains new or

[224] 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).

[225] 5 U.S.C. § 605(b).

[226] 5 U.S.C. § 601(6).

[227] 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."

[228] 15 U.S.C. § 632.

[229] ASHE, part of the American Hospital Association, contracts with Comsearch as their technical partner in providing WMTS coordination services. *See* footnote 206, *supra*.

[230] *See* 5 U.S.C. § 605(b).

[231] *See* 5 U.S.C. § 605(b).

modified information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104-13.[232] The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public to comment on the information collection requirements contained in this Report and Order as required by the Paperwork Reduction Act. In addition, the Commission notes that pursuant to the "Small Business Paperwork Relief Act of 2002, Public Law 107-198, *see* 44 U.S.C. § 3506(c)(4), we previously sought specific comment on how the Commission might further reduce the information collection burden for small business concerns with fewer than 25 employees.

92. The Further Notice of Proposed Rule Making in this document does not contain proposed information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104-13. In addition, 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).

93. *Ex Parte Rules – Permit-But-Disclose Proceeding*. The Notice in this proceeding shall be treated as a "permit-but-disclose" proceeding in accordance with the Commission's *ex parte* rules.[233] Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule 1.1206(b). In proceedings governed by rule 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.*, .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

94. *Comments and Reply Comments.* Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR §§ 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS).[234]

- Electronic Filers: Comments may be filed electronically using the Internet by accessing the ECFS: http://fjallfoss.fcc.gov/ecfs2/.

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

[233] 47 C.F.R. §§ 1.1200 *et seq.*

[234] *See* Electronic Filing of Documents in Rulemaking Proceedings, GC Docket 97-113, *Report and* Order, 13 FCC Rcd 11322 (1998).

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

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

  - All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St., SW, Room TW-A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of before entering the building.

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

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

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

95. *Further Information*. For further information, contact Jamison Prime, Office of Engineering and Technology, at (202) 418-7474, or Brian Butler, Office of Engineering and Technology, at (202) 418-2702, Federal Communications Commission, 445 12th Street, SW, Washington, DC 20554; or via the Internet at Jamison.Prime@fcc.gov or Brian.Butler@fcc.gov, respectively.

VI. ORDERING CLAUSES

96. 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 B will become **[effective 30 days after date of publication in the Federal Register],** except for §§ 95.1215(c), 95.1217(a)(3), 95.1223 and 95.1225, which contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104-13, that are not effective until approved by the Office of Management and Budget. The Federal Communications Commission will publish a document in the Federal Register announcing OMB approval and the effective date of these rules.

97. IT IS FURTHER ORDERED, pursuant to sections 1.4(b)(1) and 1.103(a) of the Commission's rules, 47 C.F.R. §§ 1.4(b)(1) and 1.103(a), that the Further Notice of Proposed Rulemaking IS ADOPTED and comments will be sought on these proposals.

98. 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 C, to the Chief Counsel for Advocacy of the Small Business Administration.

99. IT IS FURTHER ORDERED that the Commission will send a copy of this Report & Order and Further Notice of Proposed Rulemaking to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

FEDERAL COMMUNICATIONS COMMISSION

Marlene H. Dortch
Secretary

APPENDIX A

Commenting Parties

Parties Filing Comments in ET Docket 08-59

Aerospace and Flight Test Radio Coordinating Council
American Society for Healthcare Engineering
American Telemedicine Association
Amy L. Bush
ARRL, the national association for Amateur Radio
A T and T Inc.
AdvaMed
Boeing Company
Comsearch
GE Healthcare
IEEE 802 Local and Metropolitan Area Networks Standards Committee
CHI Clinical Engineering
Lamont Yoder
Mike Foley
Philips Healthcare Systems
Telecommunications Industry Association
Texas Instruments Incorporated
Textron
Theresa Burdette
Toumaz Technology Ltd
Wi-Fi Alliance
Wireless Communications Association International, Inc.
Zarlink Semiconductor Inc.

Parties Filing Reply Comments in ET Docket 08-59

Aerospace and Flight Test Radio Coordinating Council
Boeing Company
GE Healthcare
Philips Healthcare Systems

APPENDIX B

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 C.F.R. 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 37 and 38 are revised.

b. In the list of United States (US) Footnotes, footnote US101 is added.

§ 2.106 Table of Frequency Allocations.

The revisions and addition read as follows:

* * * * *

International Table			United States Table		FCC Rule Part(s)
Region 1 Table	Region 2 Table	Region 3 Table	Federal Table	Non-Federal Table	
2200-2290 SPACE OPERATION (space-to-Earth) (space-to-space) EARTH EXPLORATION-SATELLITE (space-to-Earth) (space-to-space) FIXED MOBILE 5.391 SPACE RESEARCH (space-to-Earth) (space-to-space) 5.392			2200-2290 SPACE OPERATION (space-to-Earth) (space-to-space) EARTH EXPLORATION-SATELLITE (space-to-Earth) (space-to-space) FIXED (line-of-sight only) MOBILE (line-of-sight only including aeronautical telemetry, but excluding flight testing of manned aircraft) 5.391 SPACE RESEARCH (space-to-Earth) (space-to-space) 5.392 US303	2200-2290 US303	
2290-2300 FIXED MOBILE except aeronautical mobile SPACE RESEARCH (deep space) (space-to-Earth)			2290-2300 FIXED MOBILE except aeronautical mobile SPACE RESEARCH (deep space) (space-to-Earth)	2290-2300 SPACE RESEARCH (deep space) (space-to-Earth)	
2300-2450 FIXED MOBILE 5.384A Amateur Radiolocation	2300-2450 FIXED MOBILE 5.384A RADIOLOCATION Amateur		2300-2305 G122	2300-2305 Amateur	Amateur Radio (97)
			2305-2310 US338 G122	2305-2310 FIXED MOBILE except aeronautical mobile RADIOLOCATION Amateur US338	Wireless Communications (27) Amateur Radio (97)
			2310-2320 Fixed Mobile US339 Radiolocation G2 US327	2310-2320 FIXED MOBILE US339 BROADCASTING-SATELLITE RADIOLOCATION 5.396 US327	Wireless Communications (27) Aviation (87)
			2320-2345 Fixed Radiolocation G2 US327	2320-2345 BROADCASTING-SATELLITE 5.396 US327	Satellite Communications (25)
			2345-2360 Fixed Mobile US339 Radiolocation G2 US327	2345-2360 FIXED MOBILE US339 BROADCASTING-SATELLITE RADIOLOCATION 5.396 US327	Wireless Communications (27) Aviation (87)
			2360-2390 MOBILE US276 RADIOLOCATION G2 G120 Fixed US101	2360-2390 MOBILE US276 US101	Aviation (87) Personal Radio (95)
			2390-2395 MOBILE US276	2390-2395 AMATEUR	Aviation (87) Personal Radio (95)

			MOBILE US276 US101	MOBILE US276 US101	Amateur Radio (97)
			2395-2400 US101 G122	2395-2400 AMATEUR US101	Personal Radio (95) Amateur Radio (97)
			2400-2417 5.150 G122	2400-2417 AMATEUR 5.150 5.282	ISM Equipment (18) Amateur Radio (97)
			2417-2450 Radiolocation G2 5.150	2417-2450 Amateur 5.150 5.282	
2450-2483.5 FIXED MOBILE Radiolocation 5.150 5.397	2450-2483.5 FIXED MOBILE RADIOLOCATION 5.150		2450-2483.5 5.150 US41	2450-2483.5 FIXED MOBILE Radiolocation 5.150 US41	ISM Equipment (18) TV Auxiliary Broadcasting (74F) Private Land Mobile (90) Fixed Microwave (101)
2483.5-2500 FIXED MOBILE MOBILE-SATELLITE (space-to-Earth) 5.351A Radiolocation	2483.5-2500 FIXED MOBILE MOBILE-SATELLITE (space-to-Earth) 5.351A RADIODETERMINATION-SATELLITE (space-to-Earth) 5.398 RADIOLOCATION	2483.5-2500 FIXED MOBILE MOBILE-SATELLITE (space-to-Earth) 5.351A RADIOLOCATION Radiodetermination-satellite (space-to-Earth) 5.398	2483.5-2500 MOBILE-SATELLITE (space-to-Earth) US319 US380 US391 RADIODETERMINATION-SATELLITE (space-to-Earth) 5.398	2483.5-2495 MOBILE-SATELLITE (space-to-Earth) US380 RADIODETERMINATION-SATELLITE (space-to-Earth) 5.398 5.150 5.402 US41 US319 NG147	ISM Equipment (18) Satellite Communications (25)
				2495-2500 FIXED MOBILE except aeronautical mobile MOBILE-SATELLITE (space-to-Earth) US380 RADIODETERMINATION-SATELLITE (space-to-Earth) 5.398	ISM Equipment (18) Satellite Communications (25) Wireless Communications (27)
5.150 5.371 5.397 5.398 5.399 5.400 5.402	5.150 5.402	5.150 5.400 5.402	5.150 5.402 US41	5.150 5.402 US41 US319 US391 NG147	
2500-2520 FIXED 5.410 MOBILE except aeronautical mobile 5.384A	2500-2520 FIXED 5.410 FIXED-SATELLITE (space-to-Earth) 5.415 MOBILE except aeronautical mobile 5.384A	2500-2520 FIXED 5.410 FIXED-SATELLITE (space-to-Earth) 5.415 MOBILE except aeronautical mobile 5.384A MOBILE-SATELLITE (space-to-Earth) 5.351A 5.407 5.414 5.414A	2500-2655	2500-2655 FIXED US205 MOBILE except aeronautical mobile	Wireless Communications (27)
5.405 5.412	5.404	5.404 5.415A			
2520-2655 FIXED 5.410 MOBILE except aeronautical mobile 5.384A BROADCASTING-SATELLITE 5.413 5.416	2520-2655 FIXED 5.410 FIXED-SATELLITE (space-to-Earth) 5.415 MOBILE except aeronautical mobile 5.384A BROADCASTING-SATELLITE 5.413 5.416	2520-2535 FIXED 5.410 FIXED-SATELLITE (space-to-Earth) 5.415 MOBILE except aeronautical mobile 5.384A BROADCASTING-SATELLITE 5.413 5.416 5.403 5.414A 5.415A			
		2535-2655 FIXED 5.410 MOBILE except aeronautical mobile 5.384A BROADCASTING-SATELLITE 5.413 5.416			
5.339 5.405 5.412 5.417C 5.417D 5.418B 5.418C	5.339 5.417C 5.417D 5.418B 5.418C	5.339 5.417A 5.417B 5.417C 5.417D 5.418 5.418A 5.418B 5.418C	5.339 US205	5.339	Page 38

UNITED STATES (US) FOOTNOTES

* * * * *

US101 The band 2360-2400 MHz is 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.

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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 95.628 is amended by revising the heading and all text to read as follows:

§ 95.628 MedRadio transmitters in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz and 2360-2400 MHz bands.

The following provisions apply 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) and in the 2360-2400 MHz band as part of a Medical Body Area Network (MBAN).

(a) *Operating frequencies.* A MedRadio station authorized under this part must have out-of-band emissions that are attenuated in accordance with §95.635.

(1) 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.

(2) Only MedRadio stations that are part of an MBAN may operate in the 2360-2400 MHz frequency band

(b) *Requirements for a Medical Micropower Network*.

(1) *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.

(i) 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.

(ii) 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.

(iii) 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.

(2) 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.

(3) 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.

(4) *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.

(c) *Requirements for Medical Body Area Networks*. A MedRadio programmer/control transmitter shall not commence operating and shall automatically cease operating in the 2360-2390 MHz band if it does not receive, in accordance with the protocols specified by the manufacturer, a control message permitting such operation Additionally, a MedRadio programmer/control transmitter operating in the 2360-2390 MHz band shall comply with a control message that notifies the device to limit its transmissions to segments of the 2360-2390 MHz band or to cease operation in the band.

(d) *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 and Medical body-worn transmitters.

(e) *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.

(f) *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. 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).

5. Section 95.633 is amended by revising paragraph (e)(1) 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. For stations operating in 2360-2400 MHz, the maximum authorized emission bandwidth is 5 megahertz.

* * * * *

6. Section 95.635 is amended by adding paragraph (d)(1)(v); redesignating existing paragraph (d)(7) as paragraph (d)(8) and adding a new paragraph (d)(7) 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:

* * * * *

(v) Are more than 2.5 MHz outside of the 2360- 2400 MHz band (for devices designed to operate in the 2360-2400 MHz band).

* * * * *

(7) For devices designed to operate in the 2360-2400 MHz band: In the first 2.5 megahertz beyond any of the frequency bands authorized for MBAN 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.

(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*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*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 IFRA 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.

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[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.

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[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 operation[15] 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 heath 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*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*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 Micopower 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.