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

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

Adopted: June 29, 2009 **Released: June 29, 2009**

Comment Date: [60 days after date of publication in the Federal Register]
Reply Comment Date: [90 days after date of publication in the Federal Register]

By the Commission: Commissioner McDowell issuing separate statement.

I. INTRODUCTION

1. In this Notice of Proposed Rulemaking (Notice), the Commission seeks comment on allocating spectrum and establishing service and technical rules for the operation of Medical Body Area Network (or MBAN) systems using body sensor devices. We issue this Notice in response to a filing by GE Healthcare (GEHC), hereinafter referred to as the GEHC petition.[1] As envisioned, MBAN systems would provide a flexible platform for the wireless networking of multiple body sensors used for monitoring a patient's physiological data, primarily in health care facilities. Use of MBAN systems hold the promise of improved safety, quality, and efficiency of patient care by reducing or eliminating a wide array of hardwired, patient-attached cables used by present monitoring technologies.

2. This Notice reflects our continuing desire to foster the availability and use of advanced medical devices using wireless technologies, which, in turn, should help to improve the health and well-being of the American public. In this Notice, we consider the proposal in the GEHC petition to allocate up to 40 megahertz of spectrum in the 2360-2400 MHz band, which is used on a primary basis by Federal and non-Federal Aeronautical Mobile Telemetry (AMT), Federal Radiolocation, and non-Federal Amateur services. In addition, we seek comment on an alternative proposal by the Aerospace and Flight Test Radio Coordinating Council (AFTRCC) to accommodate MBAN operations in the 2300-2305 MHz and 2395-2400 MHz bands. In addition, we seek comment on whether other bands such as the 2400-2483.5 MHz or 5150-5250 MHz bands could be used to support MBAN operations.

3. We recognize the need to address the spectrum compatibility concerns with respect to incumbent operations in accommodating MBAN operations and therefore seek comment on the potential for interference caused either to incumbents, or to MBAN systems, and how any such concerns might be mitigated. In addition, we seek comment more generally on whether allocating spectrum and establishing

[1] *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*, DA 08-953 (Apr. 24, 2008). This Public Notice relates to document captioned as "Ex Parte Comments of GE Healthcare" filed by GEHC on December 27, 2007. ("GEHC petition")

rules to allow the operation of MBAN systems for the purposes described herein would serve the public interest.

II. BACKGROUND

4. The Commission has a long history of providing access to spectrum for wireless medical communications technologies. In 1973, for example, the Commission authorized the use of 18 frequencies in the 460-470 MHz band under Part 90 of its rules for low-power biomedical telemetry operations in hospitals, other medical facilities and convalescent centers.[2] In addition, medical radio device manufacturers have for many years been allowed to market products which operate on an unlicensed basis.[3]

5. As medical telemetry use increased and its spectrum needs expanded, the Commission in 2000 designated 14 megahertz of spectrum in the 608-614 MHz, 1395-1400 MHz, and 1429-1432 MHz bands for the Wireless Medical Telemetry Service (WMTS) under Part 95 of its Rules.[4] The WMTS is typically used for transmission of patient-related telemetric medical information to a central monitoring location in a hospital or other medical facility.[5] The Commission established the WMTS because existing medical telemetry devices operating in other frequency bands were receiving interference from incumbent users in those bands. In establishing that new service, the Commission also decided that it would no longer grant new equipment approvals for medical telemetry equipment operating on an unlicensed basis in the TV bands at 174-216 MHz, 512-608 MHz and 612-668 MHz bands under the provisions of Part 15 or for in-hospital medical telemetry equipment operating under Part 90 (except in the 1427-1432 MHz band).[6] Since that time, approvals for new medical telemetry equipment must be sought pursuant to the WMTS rules in Part 95.

6. With the development of increasing numbers and kinds of medical radio devices – particularly those of the implanted variety – the Commission in 1999 established the Medical Implant Communication Service (MICS) within Part 95 of its Rules.[7] For the MICS, the Commission set aside three megahertz of spectrum at 402-405 MHz, on a license-by-rule basis, expressly for very short-range wireless links between ultra-low power medical implant transmitters and associated programmer/control

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[2] "Amendment of Parts 2 and 91 of the Commission's Rules to Permit Medical Telemetry and Other Low-Power Uses of Offset Frequencies in the Business Radio Service," *First Report and Order,* Docket No. 19478 and RM-1842, 41 F.C.C.2d 8 (1973).

[3] 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. § 15.242 and 47 C.F.R. § 15.241.

[4] "Amendment of Parts 2 and 95 of the Commission's Rules to Create a Wireless Medical Telemetry Service," *Report and Order,* ET Docket No. 99-255 and PR Docket No. 92-235, 15 FCC Rcd 11206 (2000) (*WMTS Order*). 47 C.F.R. § 95.401(e). 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.

[5] "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 [. . .]." *See* 47 C.F.R. § 95.1103 (c).

[6] *See* 47 C.F.R. § 15.37(i), 90.203(a)(1) and 95.1101-1129. Furthermore, §15.37(j) eliminates all new equipment approvals for medical telemetry, in-hospital or not, under Sections 15.241 and 15.242.

[7] "Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band," *Report and Order,* WT Docket No. 99-66, 14 FCC Rcd 21040 (1999) (*MICS Order*); 47 C.F.R. Part 95, Subpart I (Medical Implant Communications), and Subpart E (Technical Regulations).

equipment.[8] Current examples of such implant devices include cardiac pacemakers and defibrillators that also monitor and report cardiac condition.

7. In 2006, the Commission initiated a proceeding to examine whether to establish the MedRadio Service in the 401-406 MHz band (*MedRadio Proceeding*) that would provide frequencies for implanted and body-worn medical devices used for diagnostic and therapeutic purposes in human patients.[9] On March 20, 2009, the Commission released an Order establishing the MedRadio Service. [10] Devices in the MedRadio Service typically include wireless cardiac pacemakers and glucose monitors, along with a variety of other anticipated uses. The MedRadio Service subsumes the former MICS core band frequencies at 402-405 MHz that remain designated for use only by implanted devices. In addition, the MedRadio Service accommodates the operation of both implanted and body-worn wireless medical devices under flexible rules in the adjacent 401-402 MHz and 405-406 MHz bands.

8. In the *MedRadio Proceeding*, the Commission also initiated a Notice of Inquiry (NOI) in 2006 seeking information in a broader context relating to future spectrum needs for wireless medical technologies.[11] On December 27, 2007, in response to this NOI, GEHC filed its petition (GEHC petition) which we are treating as the basis for this proceeding.[12] We have received numerous supportive comments in response to the GEHC petition. Several of those commenters focus on the need for

[8] *See MICS Order, supra,* at para. 3.

[9] *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 Radio Communications Service at 401-402 and 405-406 MHz, DexCom, Inc. Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules," ET Docket No. 06-135, RM-11271, *Notice of Proposed Rulemaking and Notice of Inquiry and Order,* (*MedRadio Notice*) 21 FCC Rcd 8164 (2006).

[10] *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 Radio Communications Service at 401-402 and 405-406 MHz, DexCom, Inc. Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules," ET Docket No. 06-135, RM-11271, *Report and Order,* (*MedRadio Order*), adopted March 19, 2009, released March 20, 2009, FCC 09-23.

[11] *See* n 10, *supra*.

[12] *See* n 1, *supra*. The Alfred Mann Foundation (Alfred Mann) also filed a petition for rulemaking in response to the NOI. *See* "Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Micropower Network Service in the 413-457 MHz band", Petition for Rulemaking, filed September 5, 2007 by Alfred Mann Foundation, placed on *Public Notice* for comment October 3, 2007, (Report No. 2835; RM-11404). In a Notice of Proposed Rulemaking released on March 20, 2009, the Commission proposed to designate up to 24 megahertz of spectrum in the 413-457 MHz range for a "medical micropower network" (or MMN) service to accommodate operation of wideband implanted microstimulator devices using functional electric stimulation (FES) techniques that could, among other uses, serve as an artificial nervous system to restore mobility and function to paralyzed/impaired limbs and organs. *See* "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, *Notice of Proposed Rulemaking*, adopted March17, 2009, released March 20, 2009, FCC 09-20. "Functional electric stimulation" - often abbreviated as FES - is the generic terminology commonly used in reference to techniques using electrical currents to either generate or suppress activity in the nervous system. Such techniques can produce and control the movement of otherwise paralyzed limbs, activate visceral body functions, create perceptions such as skin sensibility, arrest undesired pain or spasm, and facilitate natural recovery and accelerate motor relearning. *See, e.g.*, "FES Resource Info" and "FES Center Resource Guide" at http://fescenter.org/index.php.

additional spectrum allocations to support wireless medical devices.[13] Other commenters in the professional health care field focus their support on the potential benefits of networkable wireless patient monitoring technology and associated body area networks.[14]

9. The GEHC petition, which seeks to operate MBANs in the 2360-2400 MHz band on a secondary basis, is opposed by the Aerospace and Flight Test Radio Coordinating Council (AFTRCC), Aerospace Industries Association, Boeing Co., and several other entities in the aerospace industry who assert that MBAN and AMT operations are not compatible and will cause mutual interference.[15] 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. In addition, Broadcast Sports, Inc. (BSI) opposes the GEHC petition, stating that it and others have been periodically able to use the 2360-2395 MHz band on a non-interference basis under Special Temporary Authority (STA) granted by the Commission in order to provide video coverage of various short term events.[16] These STAs typically last only a few days and are coordinated with AFTRCC and with the American Radio Relay League (ARRL), where appropriate, for non-Federal use. These STAs are also coordinated with the Federal government in order to ensure that no Federal operations are adversely impacted. BSI believes that such continued use of the band might be precluded if MBAN operations are also allowed on these frequencies. BSI proposes that the 2360-2395 MHz band be allocated to an "Event Radio Service" that would allow video and audio of individual events for broadcast, cablecast, satellite transmission or webcast to use the band on a secondary basis to flight test telemetry operations.[17]

III. DISCUSSION

10. We undertake this proceeding to consider providing spectrum for the operation Medical Body Area Networks (MBANs) using wireless medical body sensors. We take due notice of the potential benefits of allowing such medical telemetry operations, particularly in light of the limitations and disadvantages of current wired patient monitoring technologies. More specifically, GEHC explains in its petition that current technologies, which rely heavily on wired connections to monitor patient vital signs and other physiological metrics, significantly complicate and increase the cost of medical care.[18] Particularly, GEHC notes that many of today's systems tether patients to monitoring devices by an array of hardwired cables. These cables inevitably result in reduced patient mobility, increased difficulty and delay in transporting patients and inordinate amounts of time being devoted to gathering patient data. For example, GEHC points to one industry survey indicating that 40 percent of patient care time for critical care beds in a standard hospital setting is spent manually recording patient monitor information. GEHC also indicates that these wired systems sometimes fail due to unintentional or improper disconnection,

[13] *See, e.g.*, comments of Medtronic, Inc., in ET Docket 06-135 at 17 (filed October 31, 2006) (appropriate to identify additional spectrum bands to support future advanced wireless medical uses, as need for medical devices will expand greatly in the future); comments of Partners Healthcare System, Inc., in ET Docket No. 06-135 at 2-3 (filed November 1, 2006) (WMTS systems are at maximum capacity, and unlicensed devices are facing capacity constraints as they proliferate in hospitals).

[14] *See, e.g.*, comments of Marilyn Rantz, Professor, Sinclair School of Nursing, University of Missouri at 1 (filed May 22, 2008) (allocation of spectrum is critical to support technological advances that will help address chronic medical needs of older adults); comments of Dr. David Pugliese at 1 (filed May 29, 2008) (body sensor networks would free patients from monitor cables that are "inconvenient, obtrusive and even unsafe at times" and enable provision of better health care).

[15] *See, e.g.,* comments filed by Bell Helicopter, Cessna Aircraft Co., General Aviation Manufacturers Assoc., and Gulfstream Aerospace Corp.

[16] *See* "Comments and Counterproposal" of Broadcast Sports Incorporated (BSI) (March 4, 2009) at 3.

[17] *See id*, at 7.

[18] *See* GEHC petition at 3.

which can result in increased risk of infection especially with respect to trans- or subcutaneous sensors. Preventing such outcomes often requires medical personnel to devote significant amounts of time and effort to managing and arranging monitor cables, thus increasing health care cost, risk and complexity. Patient care is further complicated if multiple monitoring functions need to be performed on a patient simultaneously.

11. Based upon the information provided by GEHC, a wireless body sensor technology could be integrated into a MBAN system in a manner that could address the medical care challenges mentioned above. For example, as described by GEHC, such a network could be created through attachment on the patient of multiple, inexpensive, wireless sensors or network nodes at different locations on or around a patient's body. These devices would take readings of key, patient-specific information, such as temperature, pulse, blood glucose level, blood pressure, respiratory function and a variety of other physiological metrics. Antenna components in the sensors would then wirelessly transmit this data the short distance to a hub device that is either worn by the patient or located nearby. The hub device, which might initially process the patient's information, could then relay the data or processed information to another station in the facility for further centralized processing, display and storage.

12. As suggested by GEHC, body sensor devices would perform primarily medical telemetry functions as that term is defined for the Wireless Medical Telemetry Service—*i.e.*, measurement and recording of physiological parameters and other patient related information via radiated bi- or uni-directional electromagnetic signals.[19] It is possible that MBAN systems could also include medical body-worn devices, as defined in the MedRadio Service, to collect medical diagnostic information and deliver medical therapy to the patient.[20] 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. In contrast, GEHC is proposing an approach whereby two or more of these monitoring, diagnostic and therapeutic devices are organized into an independent pico-network, or body sensor network (BSN), serving a single patient, and data from each monitoring function is relayed a short distance to a hub on or near the patient. The data from the hub, in turn, is transmitted through other wireless (*e.g.*, WMTS systems) or wired connections (*e.g.*, Ethernet) to a monitoring station. The body sensor network concept allows additional sensors for multiple functions to be added easily, thereby improving patient care and increasing spectrum efficiency by reducing the number of separate links needed for "backhaul" of data and allowing more frequency reuse within the health care facility.

13. Among other benefits, wireless MBAN systems could increase patient comfort and mobility, reduce risk of infection, improve caregiver effectiveness, and improve quality of medical decision making.[21] In light of all the foregoing, we seek comment on whether we should establish a mobile allocation of up to 40 megahertz of spectrum in the 2360-2400 MHz band for MBAN operation, as requested by GEHC, and also establish rules to allow such devices to operate in this band either on a licensed-by-rule basis under the Medical Device Radiocommunication Service (MedRadio Service) in Part 95 or on a licensed and non-exclusive basis under Part 90. At the same time, we request comment on AFTRCC's alternative suggestion that MBAN operations could be accommodated in 10 megahertz of spectrum in the 2300-2305 MHz and 2395-2400 MHz bands. We also seek comment on whether the 2390-2395 MHz portion of the band could also be used for MBAN operations without adversely

[19] 47 C.F.R. § 95.1103 (c).

[20] *See* Appendix 1 to Subpart E of Part 95.

[21] *See* GEHC comments (May 27, 2008) at 5.

impacting AMT operations.[22] We also seek comment on whether other bands such as the 2400-2483.5 MHz or 5150-5250 MHz bands could be used to support MBAN operations.

14. In the discussion that follows, we first address the issue of identifying the frequency band(s) in which MBAN operation should be permitted and the amount of spectrum that should be made available for their operation in each of the bands under consideration. Neither the 2400-2483.5 MHz nor 5150-5250 MHz band has been discussed as a potential band for MBAN operations in other comments received in response to GEHC's petition, and we have no information on whether MBAN systems could effectively operate in these bands or what operating parameters should apply. We request comment on all issues associated with the possible operation of MBAN systems on frequencies on those bands. We further seek comment on whether MBANs should operate on a licensed basis under Part 95 or an unlicensed basis under Part 15, as well as service and technical rules for MBAN operation in these bands. The Notice also addresses service and technical rules for MBAN operation in the 2360-2400 MHz band, which was proposed in GEHC's petition and addressed in comments submitted in response thereto.

A. Frequency Allocation

1. 2300-2305 MHz and 2360-2400 MHz Frequency Bands

15. The 2360-2395 MHz band is allocated for both Federal and non-Federal mobile operations limited to aeronautical telemetering and associated telecommand operations for flight testing of aircraft, missiles or major components thereof.[23] However, at present, most AMT operations occur in the 2360-2390 MHz portion of the band with limited AMT use of the 2390-2395 MHz segment.[24] The Federal Government uses this band to support telemetry in the flight testing of aircraft, spacecraft, and missiles at nine major military test ranges and numerous other test facilities.[25] The commercial aviation industry also uses this band for aeronautical flight testing at facilities across the United States. In order to relieve congestion experienced in other AMT bands, it is expected that the 2360-2395 MHz band will be used to support the growing need for wideband AMT systems.[26] Both military and commercial flight test operators contemplate adopting future technologies that would use high-power, omnidirectional, uplink and downlink transmissions.[27]

16. There is also a primary allocation for radiolocation service and a secondary allocation for fixed service in the 2360-2390 MHz band, both for Federal operations, along with a primary allocation for amateur radio service operations in the 2390-2400 MHz band. In addition, the 2370-2390 MHz band is allocated for and used by radio astronomy applications. Radio astronomy use of that band is limited to the S-band radar located in Arecibo, Puerto Rico. This radar is used to explore the surface of planets, explore other solar system bodies and to detect Near Earth Objects. The Arecibo S-band radar has a center frequency of 2380 MHz and operates in the 2370-2390 MHz band, with an instantaneous power of

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[22] The 2390-2395 MHz is very sparsely used by AMT. A search of our ULS licenses indicates that only 2 licenses are currently issued for AMT operation in this band, and both of those are located at Wichita, KS. A search of Federal authorizations indicates 24 total authorizations in 2390-2395 MHz at locations in AK, CA, FL, MD, and NM.

[23] *See* 47 C.F.R. §2.106, footnote US276.

[24] The following three frequencies are shared on a co-equal basis by Federal and non-Federal stations for telemetering and associated telecommand operations of expendable and reusable launch vehicles, whether or not such operations involve flight testing: 2364.5 MHz, 2370.5 MHz, and 2382.5 MHz. All other mobile telemetering uses shall not cause harmful interference to, or claim protection from interference from, the above uses. *See Id.* at Footnote US276.

[25] Although the allocation for AMT extends from 2360-2395 MHz, AMT operations typically do not extend beyond 2390 MHz.

[26] The 1432-1525 MHz is used in conjunction with the 2360-2390 MHz band for AMT operations.

[27] *See* AFTRCC *ex parte* comments (July 28, 2008) at 7.

up to 1 Megawatt, and is scheduled to operate according to science requirements. While the Arecibo radar's power is directed upwards, it may still be capable of interfering with and disrupting the operation of MBAN devices at a considerable distance from the radar.[28] The National Aeronautics and Space Administration has two test centers that use the 2360-2390 MHz band in conjunction with the Scientific Balloon Program and the Aeronautical Telemetry Program for unmanned aerial vehicles.[29] The Department of Energy also uses the 2360-2390 MHz band for an airborne ranging system that supports Sandia National Laboratory research and development in California, Hawaii and New Mexico.

17. GEHC argues that the 2360-2390 MHz band is sparsely utilized over the continental United States in terms of geography, time and frequency[30] and that high-power, long range AMT and amateur incumbent operations would coexist well with low-power, short-range MBAN devices. It also observes that operation of MBAN devices in the 2360-2400 MHz band would allow for use of off-the-shelf components having small, efficient antennas. GEHC additionally notes that the 2360-2400 MHz band is adjacent to the Industrial, Scientific and Medical (ISM) band at 2400-2500 MHz, and that manufacturers could leverage available technology to produce relatively low-cost MBAN devices.

18. GEHC claims that the existing and newly allocated spectrum for the MedRadio Service at 401-406 MHz and the WMTS at 608-614 MHz, 1395-1400 MHz, and 1429-1432 MHz is inadequate for use by MBAN systems.[31] For example, GEHC states that the duty cycle requirements of the existing 401-406 MHz MedRadio band would force MBAN devices to the MedRadio core band at 402-405 MHz, where the three megahertz allocation and the maximum emission bandwidth of 300 kilohertz would be insufficient for multiple body sensor networks operating in a full hospital patient population. It further states that the WMTS spectrum provides only limited and disjointed spectrum bands, which: 1) are already heavily used by hospitals for existing telemetry applications, 2) require command and control channel coordination, and 3) would prohibit use outside the hospital, in locations such as ambulance, home, and office settings. However, GEHC believes that legacy WMTS systems can be used in conjunction with new MBAN systems to "backhaul" data from a body sensor network hub to a monitoring station within the healthcare facility. Finally, GEHC asserts that the other current uses of available unlicensed spectrum would jeopardize the quality-of-service reliability needed for unprocessed, life-critical monitoring data, and is already fully utilized by hospital WLANs for mission-critical applications.[32]

[28] The operation of the S-band radar is often driven by targets of opportunity, e.g., the need to study a near Earth asteroid, and therefore time coordination is likely not option for the radar.

[29] The test areas cover a large, roughly rectangular, geographic region ranging from the Texas and Oklahoma area, and westward to the California coast.

[30] *See* GEHC *ex parte* comments (September 18, 2008) at 5-7.

[31] *See*, *e.g.,* GEHC *ex parte* comments (February 6, 2009) and GEHC *ex parte* comments (September 18, 2008).

[32] In the MedRadio rulemaking proceeding, NTIA expressed concern that medical devices can receive interference from the Federal systems resulting in disruption of operation for extended periods of time. *See* Letter from Karl B. Nebbia, Associate Administrator, Office of Spectrum Management, to Mr. Julius Knapp, Chief, Office of Engineering and Technology, Federal Communications Commission (February 27, 2009) (*NTIA MedRadio Letter*). In this letter, NTIA stated that given the implications for patient care if a Federal system interferes with a medical device it is in the public interest for NTIA and the FCC to take steps to ensure that manufacturers of medical devices take into account the Federal systems operating in the band particularly when developing medical devices used for time sensitive applications. *See NTIA MedRadio Letter* at 2.

19. AFTRCC, Aerospace Industries Association, Boeing Company, and several other aerospace entities oppose use of any frequencies in the 2360-2395 MHz range for MBAN purposes.[33] AFTRCC argues first and foremost that permitting MBAN use in the 2360-2395 MHz range would pose an unacceptable risk of harmful interference to AMT operations. It asserts that such interference can interrupt real-time links between the test pilot and the ground, risking the loss of information regarding dangerous conditions onboard the aircraft and, in some cases, re-starting a flight test sequence if the telemetry link cannot be re-established. GEHC and AFTRCC have each filed interference analyses using different modeling approaches that reach conflicting conclusions.[34] To support their position, AFTRCC submitted interference studies that purport to show the potential for deleterious impact of MBAN devices on AMT receivers. In response, GEHC submitted its own interference analyses and, further, modified its proposal for MBAN operations to reduce the likelihood of interference from MBAN operations to AMT operations. Specifically, GEHC suggests that MBAN operations in the 2360-2390 MHz band, which is the band used primarily by AMT, be limited to health care facilities and, in any event, not allowed within certain geographic distances of AMT flight test sites (exclusion zones).[35] GEHC also suggests that MBAN and AMT operations could be coordinated so that interference between operations could be avoided.[36] AFTRCC disputes the potential effectiveness of limiting MBAN operation to only certain specified locations, as well as the feasibility of specifying geographic exclusion zones around each flight test site – each requiring coordination and registration of MBAN devices. AFTRCC argues that no showing has been made by GEHC that exclusion zones are either practical or enforceable. More specifically, AFTRCC claims that any exclusion zone would have to be very large (radio line of sight), and that zones of this size would eliminate major metropolitan areas proximate to flight test centers as potential markets for MBAN devices. Thus, AFTRCC calls into question the enforceability of any such zones, as well as the ultimate feasibility of MBAN use of the 2360-2395 MHz range. As an alternative home for MBAN operations, AFTRCC suggests that a combination of the 2300-2305 MHz and 2395-2400 MHz bands would provide 10 megahertz of usable spectrum and offers that this would represent a major increase in the amount available for such medical device purposes and also ensure protection of AMT operations.[37] The 2300-2305 MHz band is allocated for Amateur radio service on a secondary basis.

20. Given the significant health care benefits offered by MBAN systems, we tentatively conclude that providing spectrum for MBAN operations would serve the public interest. We believe that fostering the development of MBAN technologies would afford significant benefits in terms of the improved quality of health care for all Americans. At the same time, we also recognize the necessity of affording interference protection to incumbent primary users, particularly AMT operations, if MBAN operations are to be permitted in the 2360-2400 MHz band. In addition, the potential for interference to MBAN devices and the attendant risk to patients must be considered. We seek comment on whether to allow MBAN operations on up to 40 megahertz of spectrum in the 2360-2400 MHz band on a secondary basis.

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[33] *See, e.g.,* AFTRCC *ex parte* (February 23, 2009). Comments filed by parties other than AFTRCC that oppose the GEHC petition are generally supportive of the concerns detailed by AFRTRCC. This includes comments filed by, among others, Boeing Company (June 11, 2008), Aerospace Industries Association (September 3, 2008), Bell Helicopter Textron (August 26, 2008), Aviation Spectrum Resources (August 14, 2008), Gulfstream Aerospace Corporation (August 27, 2008), and General Aviation Manufacturers Association (August 15, 2008).

[34] The GEHC and AFTRCC interference analyses are discussed in more detail in the discussion below on technical rules.

[35] *See* GEHC *ex parte* comments (March 18, 2009) at 2-3.

[36] *See* GEHC *ex parte* comments (March 18, 2009) at 8-9.

[37] *See, e.g.,* AFTRCC *ex parte* statement (March 16, 2009) at 12.

21. GEHC states that 40 megahertz of spectrum would allow MBAN devices to dynamically adjust operations to avoid interference to and from AMT operations. GEHC submits that the MBAN concept and its reliance on multiple independent body sensor networks require that sufficient spectrum be available either on a contiguous or close-proximity basis.[38] It estimates that at least 20 megahertz of spectrum will be needed to support multiple body sensor networks operating in a high density patient care facility. GEHC states that the full 40 megahertz of spectrum in the 2360-2400 MHz band would provide four contiguous blocks of 10-megahertz wide channel capacity, which, in turn, would afford good frequency diversity and flexibility for opportunistic secondary operations, even in the highest density hospital settings. It further submits that this amount of bandwidth would facilitate the use of wide (*e.g.*, 1 megahertz) device channels with high symbol rates, which it claims are necessary to maintain low duty cycles and limit power consumption. On the other hand, AFTRCC suggests that MBAN operations can be accommodated in 10 megahertz of spectrum. We seek comment on the amount of spectrum required to support MBAN operations, and what factors (including the number and types of incumbent users) should be taken into account in determining the amount of spectrum required.

22. Regarding the potential for interference from MBAN devices to incumbent operations, we believe that sharing between MBAN systems and incumbent AMT and radiolocation operations could be facilitated if we establish effective exclusion zones around AMT test flight sites in the 2360-2395 MHz band to protect those sites from harmful interference. We discuss this in more detail below. Further, sharing between MBAN systems and incumbent AMT and radiolocation operations could be facilitated if MBAN operations in the 2360-2390 MHz band, which is allocated for AMT operations, are limited to indoor use within health care facilities as defined in the WMTS.[39] We believe that this requirement would limit the incidence of MBAN operations and effectively reduce the likelihood that they would occur near AMT flight test sites. Because MBAN systems would be used indoors, building structures would attenuate MBAN signals and further reduce the likelihood of interference to AMT. We seek comment on whether to limit MBAN operations to indoor use within health care facilities. In addition to or in lieu of exclusion zones, MBAN operators and AMT licensees may be able to coordinate their operations. We discuss in more detail below the coordination approach. We seek comment on whether permitting MBAN systems to operate in 2360-2395 MHz band under the limitations proposed would provide interference protection to incumbent users.

23. Regarding interference from AMT to MBAN operations, GEHC states that MBAN devices can avoid receiving interference from AMT or other incumbent users by employing a contention-based protocol. Under this approach which is also discussed in detail below, MBAN devices could employ a variety of techniques to avoid operating on a frequency being used by an incumbent user if such use could be reliably detected. In addition, MBAN devices may be able to employ error detection and correction techniques, or re-transmission protocols, to overcome or recover from adverse effects due to AMT transmissions. We seek comment on whether transmissions from incumbent stations, as well as flight test stations using future technologies that could include the use of high-power, omnidirectional uplink and downlink transmissions, could adversely affect the operation of MBAN devices, possibly resulting in adverse effects to patients and what techniques such medical devices could effectively rely upon to avoid receiving interference from or constraining AMT and other incumbent users in the 2360-2400 MHz band.

24. We seek comment on the AFTRCC proposal that MBAN operations be limited to the 2300-2305 MHz and 2395-2400 MHz bands. We specifically seek comment on the ability of MBAN devices to utilize these two blocks of spectrum that are separated by 90 megahertz. We also seek comment on

[38] *See generally* GEHC petition.

[39] Rule section 95.1103 (b) 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).

whether we should consider a secondary allocation for MBAN operations in these two bands, or if allocating these bands on a primary basis would allow MBAN devices to more effectively use the spectrum since they would not have to avoid AMT users. Given that exclusion zones are not an option, it is crucial that MBANs can operate reliably without protection from co-channel Amateur users, with no risk of harm to patients. We seek comment as to whether MBAN operations can exist compatibly with the incumbent Amateur service users in the 2300-2305 MHz and 2390-2400 MHz bands. We further seek comment as to whether, in the 2390-2395 MHz band we should consider allowing MBAN and AMT operations to operate on a co-primary basis and what the sharing rules between them should be. Additionally, we seek comment on whether any additional MBAN spectrum would be needed if we were to reallocate the 2390-2395 MHz band to remove the AMT allocation in order to provide a total of up to 15 megahertz of spectrum for use by MBAN operations on a primary basis.

25. To the extent we provide for MBAN use in any portion of the 2300-2305 MHz or 2360-2400 MHz bands, we propose including a new U.S. footnote to the Table of Allocations in Part 2 of the Rules for the specific band. We would also require that MBANs not cause harmful interference to and accept interference from Federal and non-Federal stations operating in accordance with the Table of Frequency Allocations.[40] We seek comment on this approach.

2. 2400-2483.5 MHz Frequency Band

26. The 2400-2483.5 MHz band is used by Industrial, Scientific and Medical (ISM) equipment operating under Part 18 of the Commission's Rules. Any equipment or services operating in ISM bands are obliged to accept interference from ISM equipment.[41] GEHC has asserted that manufacturers could leverage available technology used for ISM equipment in this band to develop low-cost MBAN devices. We thus seek comment on whether MBAN devices could operate in this band.

27. In addition to the ISM use, various radio services are allocated in this band. The 2400-2417 MHz band is allocated to the Amateur service on a primary basis. Federal operations may be authorized on a non-interference basis, and shall not constrain the implementation of any non-Federal operations. The 2417-2450 MHz band is allocated to the Amateur service on a secondary basis, and to the Federal radiolocation service on a secondary basis. The 2450-2483.5 MHz band is allocated to the non-Federal fixed and mobile services on a primary basis, and to the non-Federal radiolocation service on a secondary basis. The Federal radiolocation service is also permitted in this band on condition that harmful interference is not caused to non-Federal services. The 2400-2483.5 MHz band is also used by unlicensed devices operating under Part 15 of the Commission's Rules.[42] These unlicensed devices include WiFi, cordless phones, and Bluetooth, among various other types of uses.

28. In light of the foregoing, we seek comment on the potential for MBAN devices to utilize the 2400-2483.5 MHz band. As a general proposition, could the widespread success of the unlicensed devices described in the preceding paragraph provide manufacturers the opportunity to leverage these technologies for the development of low cost MBAN devices within the 2400-2483.5 MHz band? More particularly, we seek comment as to whether MBAN devices could be certified and operate under the current Part 15 Rules, whether a new subpart under Part 15 might be required, or whether we should consider licensed operation of MBAN devices under Part 95 of the Commission's Rules. If it is determined that licensed operation is appropriate, would the technical and service rules discussed below for the 2360-2400 MHz band be applicable for MBAN operation in the 2400-2483.5 MHz band? If not, what technical and service rules would apply? What amount of bandwidth would MBAN devices require to operate in this band and in what portion of the band would they operate? We also seek comment regarding whether MBAN operations can exist compatibly with the incumbent Amateur service users who operate in this band, as we request with respect to the 2300-2305 MHz and 2390-2400 MHz bands.

[40] *See* 47 C.F.R. § 2.106.

[41] *See* 47 C.F.R. § 18.111.

[42] *See* 47 C.F.R. § 15.247.

29. We also note that in 2000, when the Commission created the Wireless Medical Telemetry Service (WMTS), it specifically did not propose to preclude medical telemetry equipment from operating in the ISM bands under Part 15 because only a small number of devices operated under those provisions. The Commission did, however, caution manufacturers and users that equipment operating in these bands has no protection from interference from ISM equipment operating under Part 18 of the rules or other low power transmitters operating under Part 15 of the rules.[43] We seek information as to whether the ISM bands are still used by medical telemetry devices, and comment as to whether MBAN operations would fit within this category of use.

3. Other Frequency Bands

30. We seek comment on whether there are other frequency bands where MBAN manufacturers can leverage existing technologies to implement such devices and achieve economies of scale. For example, we seek comment on whether the 5150-5250 MHz band offers similar opportunities for MBAN operation as may be achievable in or near the 2400 MHz band as described above. The 5150-5250 MHz band is allocated to the Federal and non-Federal aeronautical radionavigation service. The band is also allocated to the non-Federal fixed-satellite service. In addition to these allocated services, the band is also used by unlicensed national information infrastructure (U-NII) devices operating under Subpart E of the Commission's Part 15 rules.

31. U-NII devices use digital modulation techniques and provide a wide array of high data rate mobile and fixed communications applications.[44] U-NII devices operating in the 5250-5350 MHz and 5470-5725 MHz bands must employ Dynamic Frequency Selection (DFS) to avoid operating on the same channels as radars. However, the 5150-5250 MHz band does not require DFS and is limited to indoor operation only, which would appear to be consistent with GEHC's proposed MBAN devices.

32. We seek comment on the feasibility of using the 5150-5250 MHz band to accommodate MBAN device operations. Specifically, we request comment as to the potential for MBAN devices to utilize the 5150-5250 MHz band. We seek comment as to whether MBAN devices could be certified and operate under the current Part 15 Rules, whether a new subpart under Part 15 might be required, or whether we should consider licensed operation of MBAN devices under Part 95 of the Commission's Rules. If it is determined that licensed operation is appropriate, would the technical and service rules discussed below for the 2360-2400 MHz band be applicable for MBAN operation in the 5150-5250 MHz band? If not, what technical and service rules would apply? What amount of bandwidth would MBAN devices require to operate in this band and in what portion of the band would they operate? Can MBAN devices operate compatibly with the incumbent services in the 5150-5250 MHz band? Should MBAN operations be limited to indoor locations, similar to the indoor restriction to U-NII devices in Section 15.407(e)?

B. Service and Technical Rules

33. We discuss in this section the service and technical rules that we could apply to MBAN devices operating in the 2360-2400 MHz band. Similar service and technical rules would be required for MBAN operations in either the 2400-2483.5 MHz or the 5150-5250 MHz band. We discuss the 2360-2400 MHz band here because that band was specifically addressed in the GEHC petition and in both the comments and reply comments. Following our approach in the pending Alfred Mann proceeding, many of the service and technical rules discussed below follow the overall framework of the MedRadio Service in Part 95, but with modified power and emission bandwidth requirements to accommodate the anticipated bandwidth and EIRP needs of MBAN operations. We believe that this approach could be desirable as it would maintain general consistency with rules applicable to wireless medical devices,

[43] *See* WMTS Order at 23.

[44] Revision of Parts 2 and 15 of the Commission's Rules to Permit Unlicensed National Information Infrastructure (U-NII) devices in the 5 GHz band, *Memorandum Opinion and Order*, ET Docket No. 03-122 (rel. June 30, 2006). This is available on the http://www.fcc.gov/oet/ea/eameasurements.html.

particularly for body-worn and related diagnostic, therapeutic, and monitoring medical devices. Thus, the service and technical rules discussed below are essentially consistent with recommendations made by GEHC, which also follow the legacy MICS and new MedRadio models. We also note that the GEHC petition includes an appendix that sets forth one possible framework for the service and technical rules as a separate subpart of Part 95. To the extent that the possible approach discussed below deviates from GEHC's suggested approach for service and technical rules, we also invite comment on the suggestions in GEHC's petition.

34. Although the possible service and technical rules discussed below follow the overall framework of the MedRadio Service rules, we also intend to consider whether MBAN operations should be licensed under Part 90 and may ultimately decide to adopt such an approach. Except where we expressly seek comment on an approach consistent with licensing under Part 90, we seek comment on applying the service and technical rules addressed below. One of the primary issues in the 2360-2390 MHz band is the potential for interference between MBAN systems and AMT operations. Successful sharing between MBAN and incumbent services might best be accomplished if MBAN systems were individually licensed and coordinated. Thus, we hold open the possibility of authorizing MBAN systems under streamlined licensing procedures to minimize burdens on users.[45]

1. Service Rules

35. *Licensing*. We seek comment on whether medical device operations should be authorized in Part 95 of our Rules, thus providing for license-by-rule operation[46] pursuant to Section 307(e) of the Communications Act (Act).[47] Under this approach, medical devices would operate in the band on a shared, non-exclusive basis with respect to each other and without the need for MBAN systems to be individually licensed. As the Commission determined when it adopted the MedRadio Service rules, this approach minimizes regulatory burdens and facilitates the expeditious deployment of new generations of beneficial wireless medical devices that can improve the quality of life for countless Americans, thus serving the public interest, convenience and necessity. We seek comment on whether the rules for MBANs should be included in Subpart I of Part 95, which authorizes the MedRadio Service, or whether the rules for MBANs should be included in a new Subpart under Part 95.

36. Alternatively, we seek comment on whether MBAN operations should be licensed on a non-exclusive basis under Part 90. We are concerned that the use of exclusion zones could frustrate the widespread use of MBAN devices, particularly if it is determined in the course of this proceeding that such exclusion zones would be sufficiently large to encompass major metropolitan areas where MBAN operations might be prohibited. As we discuss further below, frequency coordination also could facilitate sharing between the incumbent operations and MBAN devices. Frequency coordination is required for WMTS operations authorized under Part 95,[48] but does not involve as many sites as could be required for MBAN and AMT coordination. Another licensing approach that we would consider for MBAN operation that includes coordination is non-exclusive licensing under Part 90. Under that approach, MBAN operations would be licensed on a non-exclusive basis with respect to each other for ten year license terms. We seek comment on whether we should consider using the same approach here as we do with wireless broadband services in the 3650-3700 MHz band, *i.e.*, eligible entities would apply for non-

[45] *See, e.g.,* Wireless Broadband Service in the 3650-3700 MHz Band, 47 C.F.R. § 90.1301 *et seq*.

[46] *See* 47 C.F.R.§ 95.401 (d).

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

[48] *See* 47 C.F.R.§ 95.1111.

exclusive nationwide licenses and subsequently register individual stations with the Commission.[49] If we were to adopt this approach, should we require that licensees register each individual MBAN system or, alternatively, require them to register the individual health care facility at which the licensee would be allowed to operate multiple MBAN systems? What type of licensing and registration information for MBAN operations would facilitate coordination with incumbent services? What would be the relative benefits and disadvantages of licensing under Part 90 compared with the license-by-rule approach under Part 95?

37. *Definitions*. We seek comment on the definitions to apply to MBAN systems and body sensor devices. Because MBAN systems may be comprised of sensors that perform not only monitoring functions but also diagnostic and therapeutic functions, definitions for MBAN and body sensor networks should be consistent with definitions already in the Com*miss*ion's Part 95 rules for wireless medical telemetry and body-worn devices.[50] We seek comment on the following proposed definitions:

- Medical body area device – a medical sensing device that is placed on or in close proximity to the human body for the purpose of measuring and recording physiological parameters and other patient information or performing diagnostic or therapeutic functions via radiated bi- or unidirectional electromagnetic signals. These devices may only communicate as part of a medical body area network.
- Medical body area network (MBAN) – a low-power independent network comprised of multiple medical body area devices that transmit or receive either non-voice me*dical data* of a patient or related device control commands. Transmissions to and from these multiple medical body area devices are routed through a hub, which is placed on or in close proximity to the patient's body, and which may communicate with a remote monitoring location.
- MBAN transmitter – A transmitter that operates as part of a Medical Body Area Network, and is located either on the human body or in close proximity to it.
- MBAN control transmitter – A MBAN transmitter, which is designed to placed on or in close proximity *t*o the patient's body, that serves as a hub to control and coordinate communications with body area devices, and which may also communicate with a remote monitoring location.

38. We request comment as to whether these definitions would be too broad or too narrow and whether alternative definitions should be used.[51] We ask whether other components of wireless MBAN systems should also be identified and defined. We are not proposing to include medical implant devices as part of MBAN systems, although we recognize that such devices could be used for monitoring, diagnostic or therapeutic purposes. Parties that believe medical implant devices should be allowed as part of MBAN operations should address how such devices would co-exist with body sensor devices and the technical rules that would apply to their operation. We also seek comment on whether any other current definitions included in the MedRadio Service rules need to be modified to accommodate wireless MBAN devices.

39. *Permissible Communications and Operator Eligibility.* We propose to establish requirements for permissible communications and operator eligibility that are generally the same as those in place for the MedRadio Service. The MedRadio rules provide that a MedRadio device may be used by persons for diagnostic and therapeutic purposes, but only to the extent that such devices have been provided to a

[49] *See* 47 C.F.R. § 90.1307.

[50] *See* 47 C.F.R. § 95.1103 (c), Appendix 1 to Subpart E of Part 95 – Glossary of Terms.

[51] We note that GEHC proposed different definitions in their appendix of recommended rules which is included with the GEHC petition, and parties may address those in their comments. The definitions proposed herein are based on the description GEHC provides in its petition and various ex parte comments of the typical use they envision for this spectrum, and that would be consistent with existing definitions for medical devices in Part 95 of our rules.

human patient under the direction of a duly authorized health care professional.[52] Furthermore, transmissions are limited to non-voice data signals.[53] We expect, based on GEHC's representations, that wireless body sensor devices configured as a MBAN would be used primarily for monitoring patient data. We believe it would be prudent to provide flexibility so that MBAN systems can also be used for performing diagnostic or therapeutic functions. We seek comment on whether these requirements would be appropriate for MBAN operations.

40. In the MedRadio proceeding, we declined to explicitly limit the use of some frequencies to life-critical and time-sensitive applications, as the comments of some parties suggested, while allowing other frequencies to be used for non-life-critical, non-time sensitive applications.[54] We concluded that the ultimate decision on which frequency band to use for each type of application was best left to health care professionals and medical device manufactures, in concert with FDA-required risk management processes, as it would result in better and more flexible use of this scarce spectrum resource. We seek comment on whether a similar approach is appropriate for MBAN devices—*i. e*., permitting health care professionals and medical device manufactures, in concert with FDA-required risk management processes, to decide whether MBAN devices should be used for life-critical and time-sensitive applications even though these devices would not receive interference protection from radiocommunication services with a higher allocation status. Commenters who believe that the Commission should not allow MBAN devices for life-critical and time-sensitive applications should suggest how the Commission should define these terms and types of applications.

41. We also note that the current MedRadio Service rules do not allow programmer/control transmitters to relay information to a receiver that is not included with a MedRadio implant or body-worn device.[55] However, the MedRadio Service rules do allow programmer/control transmitters to be interconnected with other telecommunications systems including the public switched telephone network. We seek comment on whether, and if so why, similar requirements should also apply here. We also seek comment on how spectrum might be used to perform backhaul from a single patient-based MBAN control transmitter to a monitoring station that receives and processes MBAN body sensor data from multiple patients and what spectrum should be used for that purpose.

42. We seek comment on whether communications between MBAN body sensors, or other intra-MBAN network communications, should be allowed, and whether there should be a requirement that each external MBAN control transmitter be limited to controlling the body sensor transmitters for a single patient. Alternatively, we ask whether we should permit groups of MBAN body sensors for multiple patients to be coordinated by one central MBAN control transmitter and if so, whether any special protocols or other requirements should be applied to such communications.

2. Technical rules

43. *Channelization.* We seek comment on adopting rules for MBAN operations that do not specify a particular channeling plan, thereby following the general approach used with the MedRadio Service.[56] Under this approach, the "channel" occupied by a MBAN transmitter or transmission would be

[52] *See* 47 C.F.R. §§ 95.1201, 95.1209 (a).

[53] *See* 47 C.F.R. § 95.401

[54] *MedRadio Order* at para. 36. Although we declined to limit the use of certain bands as discussed above, we noted that we were adopting certain technical rules that would effectively achieve much the same result—*i.e.,* implanted devices would likely be designed for use in the frequency bands that provided wider emission bandwidths and accommodate shorter transmissions with relatively higher data rates.

[55] *See* 47 C.F.R. § 95.1209 (e). Under this provision, wireless retransmission of information intended to be transmitted by a medical implant programmer/control transmitter shall be conducted using other radio services that operate in spectrum outside the MedRadio band.

[56] .*See* 47 C.F.R. § 95.628 (a) (6) (ii).

loosely defined as any continuous segment of spectrum that is equal to the largest bandwidth used by any MBAN transmitter that participates in a given single patient MBAN communications session. In this context, a MBAN "communication session" would be defined (analogous to the definition of a MedRadio communication session) as a collection of transmissions that may or may not be continuous and that take place between two or more MBAN devices in a single patient network.[57]

44. One benefit of this approach would be that networked MBAN devices could transmit on any center frequency within the MBAN band so long as the maximum emission bandwidth, out-of-band, and spurious emission limits adopted herein are met. This approach would also afford the flexibility for MBAN devices to subdivide the authorized frequency band(s) into ad-hoc device "channels" that could be tailored by manufacturers to meet device-specific spectrum requirements for a variety of medical monitoring, diagnostic and therapeutic functions. We seek comment on 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). In particular, we seek comment on whether the potential benefits described above might be outweighed by an increased risk of adverse mutual interactions between multiple MBAN devices or MBAN devices and incumbent users using differing center frequencies and bandwidths and whether there are other factors that should be considered under this option.

45. Alternatively, we seek comment on whether a specific channeling plan would be needed. If so, what form might it take and what are the advantages that it would obtain over the proposed approach?

46. *Exclusion Zones*. Under the GEHC proposal, in order to protect AMT receive sites in the 2360-2390 MHz range from interference, we should prohibit MBAN operations in geographic exclusion zones surrounding AMT test facilities.[58] Under GEHC's proposal, we would not extend the exclusion zones to MBAN use of the 2390-2400 MHz frequency range, that is, MBAN devices operating in the 2390-2400 MHz band segment would not be subject to exclusion zones. We note that the exclusion zones proposed by GEHC are not intended to provide protection to MBAN operations. MBAN devices would need to protect themselves by use of contention protocols, error correction, frequency monitoring, or other technical measures which are discussed more fully below.

47. We recognize that the current record contains conflicting information submitted by AFTRCC and GEHC relating to the appropriate models to be used for evaluating the potential for interference to AMT operations from MBAN devices and establishing the size of exclusion zones to protect those operations. Based on its analysis, GEHC recommends an exclusion zone with a radius of 11.5 km around each AMT test site.[59] GEHC provides a statistical analysis of the interference potential from MBANs to AMT using Monte Carlo techniques. Under this statistical approach, GEHC examined several different variables to determine how each variable affected the overall compatibility of the two services and the likelihood of interference occurring.

48. AFTRCC argues that any exclusion zones would have to be very large, so as to include all areas within the line of sight of the flight test facilities. It claims that a separation of 62 km would be needed to keep an interfering MBAN signal below a power-flux density (PFD) level of -180 dB Watts/m^2

[57] *See* 47 C.F.R. § 95.628 (a) (6) (iii) for the analogous definition of "MICS communications session" under the present rules.

[58] Because the AMT operations in this band are now one-way transmissions from the aircraft to receive sites on the ground, the exclusion zones as proposed by GEHC are intended to protect these receive sites from interference from MBAN operations. GEHC does not suggest that exclusion zones would protect MBAN operations from interference from AMT operations, even if in the future AMT operations were two-way with transmission from the terrestrial sites to the aircraft. GEHC has suggested that its devices would rely on frequency monitoring and agility to avoid co-channel operation with AMT, as discussed below.

[59] *See* GEHC *ex parte* (March 4, 2009) at 14.

in a bandwidth of 4 kHz.[60] AFTRCC contends that with such large exclusion zones, major metropolitan areas may not be available for the marketing and use of MBAN devices.[61] AFTRCC also questions the practicality of enforcing exclusion zones.[62]

49. GEHC refutes AFTRCC's claims, asserting that AFTRCC's interference studies are based upon worst-case, static modeling scenarios, resulting in severely unrealistic overestimates of the interference potential of MBAN devices to AMT receivers. AFTRCC responds that the probabilistic approach used by GEHC is wholly inappropriate for considering interference potential to flight-test telemetry operations that have safety-of-flight considerations.[63]

50. We note that GEHC's analytical approach considers MBAN system deployment parameters to simulate a "typical" sharing scenario between the AMT receivers and MBAN transmitters. This analysis predicts much less impact to AMT receivers than that predicted by the AFTRCC measurements and analyses. In addition, the GEHC analysis uses several assumptions regarding the operation of the MBAN system devices, including, for example, the suitability of using the Extended Hata propagation model.[64] Also, in its worst-case scenario, the GEHC analysis contends that only those MBAN system devices located near the face of the building that is oriented toward the receiver need to be considered because devices situated more interior to the building will have greater isolation due to interior walls, floors, or other building structures.[65] In addition, the GEHC analysis also uses several factors that could help to mitigate interference into AMT receivers, such as duty cycle limits and frequency hopping requirements. On the other hand, AFTRCC's original tests conducted by Learjet and Cessna examined potential interference to an aeronautical telemetry receiver from a device transmitting a 1 mW signal from an antenna attached to a test vehicle. This test vehicle was then taken to various locations to determine the impact to the received AMT signal. A further measurement program was carried out by Johns Hopkins University Applied Physic Laboratory (JHU-APL). The test scenarios investigated by JHU-APL examined the maximum possible power that could be coupled into the AMT receive antenna when pointed at a device simulating a MBANS transmitter, but did not evaluate the impact to a received AMT signal.

51. Another significant difference between the AFTRCC and GEHC analyses is the criteria used to determine when harmful interference might occur. GEHC uses an interference to noise ratio (I/N) of $\leq$ -3 dB.[66] This is significantly different than the criteria supported by AFTRCC, which examined a power-flux density (PFD) level of -180 dB Watts/m^2 in a bandwidth of 4 kHz.[67] We note that these criteria differ in that the I/N criteria examines the power of an interfering signal relative to the noise level of the receiver, while the PFD criteria measures power received at a given location (usually on the ground). We further note that both of these criteria are contained in an International Telecommunications Union recommendation that deals with aeronautical telemetry systems operating in the 1425-1525 and 2310-2360 MHz bands, specifically with respect to compatibility with the broadcasting-satellite and mobile-satellite services.[68]

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[60] *See* AFTRCC *ex parte* (May 27, 2008) at 15.

[61] *See* AFTRCC *ex parte* (February 23, 2009) at 1.

[62] *See id*.

[63] *See id* at 3.

[64] *See* GEHC *ex parte* (September 18, 2008) at 3.

[65] *See* GEHC *ex parte* (September 18, 2008) "Appendix A," at 5.

[66] *See id*. at 6.

[67] *See* AFTRCC Comments at "Exhibit C," at 2.

[68] ITU-R Recommendation M.1459.

52. More generally, we seek comment on the feasibility of using exclusion zones as a means to prevent interference to incumbent operations in the 2360-2390 MHz band and, if exclusions zones are to be used, the appropriate radius to use for such exclusion zones. We are not convinced at this time that either GEHC's or AFTRCC's analysis is appropriate for determining interference potential and the utility or size of exclusion zones. We seek comment on the analytic methodology that should be used and the assumptions that should be employed, including the methodologies and analyses used by AFTRCC and GEHC for determining an exclusion zone radius. We also invite comment on other methodologies and analyses, including assumptions on which they rely, that could be used. Commenters should describe in detail the methodology and assumptions and address whether their analyses are dependent on MBAN operations being limited to indoor use only. Commenters should also address whether assumptions that help show compatibility could be codified in our rules to provide greater certainty that interference does not occur. Studies should consider technical parameters of both the incumbent services, as well as the proposed MBAN operations. We also seek comment on whether it is appropriate to use either interference criteria described above, which are primarily intended for satellite and terrestrial sharing in the adjacent frequency band, for AMT and MBAN operations and invite suggestions for alternative approaches for determining the radius of potential exclusion zones. We provide in Appendix A additional parameters for MBAN and AMT systems that parties should address, as appropriate, to support further technical analyses.

53. We seek comment on whether exclusion zones could always preclude operation of MBAN devices at some locations. Is it in the public interest to make these technologies unavailable to certain health care facilities based on their location? Or should we permit health care facilities located within an exclusion zone to coordinate MBAN use with AMT operations in that zone?

54. If the Commission were to establish such exclusion zones, we seek comment on what criteria should be used to identify those AMT sites in need of protection.[69] Should we protect only AMT test sites that now actually use the 2360-2390 MHz band, or also protect those test sites that do not presently use the band but might prospectively do so? If we were to require protection of sites that AFTRCC claims are "entitled"[70] to, but do not currently use the 2360-2390 MHz band, how would we determine which sites are "entitled" to be protected? After we identify, at the conclusion of this rulemaking, test sites to be protected, how would future test sites be protected if MBAN devices are already operating within the area that will be designated as a new exclusion zone? With respect to making these determinations, we note that the Commission (for non-Federal users) and NTIA (for Federal users) maintain separate data bases containing geographic location and frequency information on users authorized to operate transmitters throughout the radio spectrum. Thus, if an exclusion zone approach permitting MBAN operation were to be adopted, we would anticipate relying, to the extent possible, upon the information contained in the relevant Commission and NTIA data bases as a baseline for identifying facilities that require protection. If we ultimately decide to protect sites that are not currently licensed to use the 2360-2390 MHz band, how would we maintain and timely update accurate information on exclusion zones in our rules? We seek comment on these matters.

55. Should we measure the distance for MBAN operations from the specified center point that establishes the incumbent's area of operation or should we measure from the edge of that area? How should we account for incumbent sites that are in close proximity to each other such that their areas of operation may overlap each other? Should we collect further information about incumbent operational locations and how we should gather that information? Regarding information about Federal sites, the Commission will consult with NTIA about how to identify this information and make it available. We

[69] There is a discrepancy in the record as to the number of AMT test sites that might need protection. GECH states that 157 existing AMT sites would be protected, whereas AFTRCC claims that 50 test sites use the band and 167 sites are "entitled" to use the band. *See GEHC ex parte* comments (Sept. 18, 2008) at 8; AFTRCC *ex parte* comments (July 28, 2008) at 3.

[70] *See id*., AFTRCC comments (July 28, 2008) at 3.

also seek comment on how we should account for future installations if a healthcare facility that is using MBANs is located in an area that would become part of an exclusion zone for the new site.

56. *Frequency Coordination.* GEHC has suggested that, in addition to protecting AMT flight test sites with exclusion zones, spectrum sharing might also be facilitated by allowing MBAN device users to coordinate their operations with AMT licensees. In particular, we recognize that coordination may be useful in the case of MBAN operations that would otherwise be excluded from a large geographic area that encompasses medical facilities; in such cases coordination would provide a means for the parties to work together on some type of sharing arrangement for given locations. We seek comment on whether coordination of MBAN systems is needed and should be required and, if so, under what circumstances. We also seek comment on whether we should require AMT or other incumbent licensees to participate in frequency coordination with operators of MBAN systems in any portions of the band. If so, what approaches would be feasible, and what parties would be responsible for ensuring that such coordination takes place?

57. GEHC, for example, contends that the Commission could require frequency coordination and device registration for MBAN operations such as is used for coordination of WMTS operation.[71] There, the Commission designated a private entity to serve as the WMTS frequency coordinator and that entity maintains a database of all WMTS equipment in operation. The database is used primarily by eligible users and manufacturers to plan for specific frequency use within a geographic area, especially where numerous WMTS operations may occur. The frequency coordinator also facilitates band-sharing between health care facilities and the limited government operations at specific sites. The Commission does not maintain any information on WMTS deployment or frequency use, but parties can bring disagreements to the Commission for resolution on a case-by-case basis.

58. In the case of MBAN systems, users may not need to coordinate their operations among themselves as do WMTS users, particularly if MBAN devices ultimately rely on a contention-based protocol as discussed below to promote intra-service sharing. Regarding coordination of MBAN operations with incumbent users, we note that MBAN devices would operate on a secondary basis, and a significantly large number of primary users must be accorded interference protection. Thus, we seek comment on whether the WMTS model would be feasible here. Parties supporting this approach should address what criteria would be used to determine if a MBAN system could operate without causing interference, what type of information should be contained in a database, who would have access to the database and on what terms, and how the Commission would designate a database administrator.

59. Alternatively, the Commission could license MBAN operations on a non-exclusive basis under Part 90, as discussed above, and would be responsible for facilitating coordination. For example, licensees in the Wireless Broadband Service in the 3650-3700 MHz band are permitted to operate anywhere outside of specified 150 km protection zones around incumbent non-Federal primary earth station facilities. Those wishing to operate within the protection zones must negotiate with the affected incumbents directly. To ensure compatibility with Federal stations, the Commission coordinates operations with NTIA through the Frequency Assignment Subcommittee of the Interdepartment Radio Advisory Committee for any station that requests registration of a site closer than 80 km from three specified radiolocation sites. We further note that our Universal Licensing System has the capability of screening for any terrestrial applications that might propose site coordinates located within the 80 km coordination zone and flag that application for any necessary coordination.

60. In the present case proposed by GEHC, the circumstances under which Federal and non-Federal AMT spectrum use is coordinated is substantially different than those at 3650-3700 MHz.[72] AFTRCC is the designated coordinator of all non-Federal AMT use, and is recognized as such by both the Commission and NTIA. Consequently, any Federal and non-Federal use of the 2360-2395 MHz band

[71] *See* GEHC *ex parte* (September 18, 2008) at 9. *See also* 47 C.F.R. §§ 95.1111, 95.1113.

[72] *See* 47 C.F.R. § 87.305.

is referred to AFTRCC and coordination with them must be completed prior to operation. In addition, the Commission coordinates non-Federal use of this spectrum with NTIA. If we were to follow this approach, any MBAN operation in the 2360-2395 MHz band segment would be referred to AFTRCC and to NTIA, which might delay deployment. At the same time, because the Commission would have the licensing and coordination information readily available, it could intercede in resolving disagreements more easily, as needed. Regarding spectrum sharing among MBAN operations, coordination under a non-exclusive licensing scheme does not appear to provide any additional benefits compared to the WMTS model. We seek comment on whether such an approach would be feasible here. Commenters should address the relative advantages and disadvantages of the approaches they support.

61. *Frequency Monitoring (Contention-based Spectrum Access Protocols)*. GEHC proposes that we apply contention protocols as a way for MBAN devices to successfully coexist within the band, and also as a way to protect MBAN devices from interference from the primary AMT systems.[73] We recognize that low power operation and spread spectrum or similar technology may enable MBAN devices to operate in very close proximity to one another without any mutual interference and mitigate the potential for one body sensor network to block another's access to the spectrum. We invite comment on this premise and whether any rules should be adopted to ensure such sharing. In particular, we seek comment on whether a contention-based protocol should be applied to MBAN transmitting devices, and if so, how such a protocol might be developed. If we were to adopt a requirement for a contention-based protocol, we invite comment as to whether we should rely upon the general definition of *contention-based protocol* recently adopted by the Commission for the operation of wireless devices under Part 90 of the rules in the 3650 MHz band, which reads as follows.[74]

> "*Contention-based protocol.* A protocol that allows multiple users to share the same spectrum by defining the events that must occur when two or more transmitters attempt to simultaneously access the same channel and establishing rules by which a transmitter provides reasonable opportunities for other transmitters to operate. Such a protocol may consist of procedures for initiating new transmissions, procedures for determining the state of the channel (available or unavailable), and procedures for managing retransmissions in the event of a busy channel."

62. Depending upon the transmit/receive reliability, or quality of service requirements of a particular use, contention-based protocols could take a variety of forms, such as listen-before-talk (LBT) frequency monitoring, time slot synchronization, or frequency hopping among others. GEHC does not specify the type of contention-based protocol that it envisions using for MBAN devices. One option would be to follow the existing approach of the MedRadio service whereby the medical transmitting device must incorporate a LBT frequency monitoring mechanism to monitor the channel or channels that the medical device transmitters intend to occupy.[75] One potential benefit of this latter approach would be that the LBT protocol of the MedRadio Service is already clearly defined in the rules and appears to be successful in allowing a number of uncoordinated devices to share the same spectrum.

63. GEHC asserts that a contention-based protocol would allow MBAN devices to avoid receiving interference from AMT operations.[76] For example, if MBAN devices relied on a LBT protocol, it is unlikely that the signal from an AMT transmitter on board an aircraft miles away would be received by the MBAN device using a small antenna with less gain than those used by the AMT receiver. Thus, the MBAN receiver would not be subjected to interference. GEHC and AFTRCC both assert that a contention-based protocol is not likely to prevent interference from MBAN devices to AMT receivers in situations where the medical device is located relatively close to the AMT receiver while the aircraft transmitting the AMT signal is located far from the MBAN device. AFTRCC further states that a

[73] *See* GEHC *ex parte* (September 18, 2008) at 10.

[74] *See* 47 C.F.R. § 90.7.

[75] *See* 47 C.F.R. §§ 95.628(a) and 95.1209 (b).

[76] *See* GEHC *ex parte* (September 18, 2008) at 9-10.

contention-based protocol using spectrum sensing is likely to increase the potential for interference because protocols that avoid frequencies used by nearby aircraft may cause the MBAN device to shift to frequencies used by aircraft that are farther away and thus not detectable by the MBAN device.[77] We agree with GEHC and AFTRCC that a contention protocol is not likely to protect AMT from MBAN interference, and that other measures, such as physical separation between MBANs and AMT systems, would be more effective means to avoid such interference.[78]

64. More generally, we encourage 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. How should such protocols be defined? Should the protocol be open-source or proprietary? Should more than one protocol be permitted? Should the same protocol be required for all devices, and how would this be accomplished? How should such protocols be established - by rule, by industry standard setting procedures, or other approaches?[79] Would any of these protocols be expected to interact either favorably or adversely with incumbent users?

65. *Transmitter Power, Emission Bandwidth, and Duty Cycle.* As recommended by GEHC, we would limit individual MBAN devices to a maximum transmit power of 1 mW equivalent isotropic radiated power (EIRP) measured in a 1 megahertz bandwidth, and a maximum emission bandwidth of 1 megahertz. In explaining this recommendation, GEHC indicates that, as presently conceived, a typical MBAN system would be comprised of a single network per patient/person with a gateway-hub device coordinating transmissions from multiple body worn sensors. It estimates that the suggested power and bandwidth limits would be sufficient to allow short burst messaging, which in turn would facilitate low power consumption from duty cycles less than 25 percent.

66. While GEHC emphasizes the use of MBAN systems for monitoring patient physiological data, we recognize that the definition that we propose for MBAN systems would also allow the operation of two or more networked medical devices to perform diagnostic and therapeutic functions. We seek comment on whether the power/bandwidth limits proposed above - which reflect GEHC's recommendations - are appropriate for such other purposes. We specifically ask whether another combination of power and duty cycle limits would provide a better balance between affording interference protection to incumbent users and achieving sufficiently reliable MBAN system performance. Commenters suggesting other bandwidths should fully discuss their relative benefits and potential disadvantages in light of the considerations discussed herein. With respect to transmitter duty cycles, we seek comment on whether GEHC's assumption of a 25 percent factor adequately characterizes operations that would be expected from real-world devices. For example, would the duty factor of MBAN transmitters used for diagnostic or therapeutic purposes, instead of patient monitoring, be more likely to require higher, lower, or the approximately the same duty cycles and, if so, should this be accounted for in the maximum duty cycle specification? What would be the relative advantages or disadvantages of specifying versus not specifying specific duty cycle limits for MBAN transmitters in the rules? Is a duty cycle limit needed to allow the functioning of a contention-based spectrum access protocol and, if so, what is the maximum duty cycle that should be allowed in order to support such a protocol? Should the duty cycle apply to individual MBAN transmitters, whether located in a medical body area device or the MBAN control transmitter, or to the aggregate duty cycle of all transmitters comprising an MBAN, as the terms are proposed to be defined above?

67. *Channel aggregation*. To the extent that device manufacturers might wish to aggregate multiple transmission channels in a single device, we seek comment on requiring only that the total

[77] *See* AFTRCC *ex parte* (August. 1, 2008) at 8.

[78] *See* GEHC *ex parte* (September 18, 2008) at 10.

[79] Alfred Mann indicates that it is exploring the establishment of an industry-led standards committee to define an appropriate communications protocol that could be used by all microstimulation devices to mitigate the risk of interference and to maximize use of spectrum. *See* AMF petition at 21.

emission bandwidth used by all devices in any single patient MBAN communication session not exceed the maximum authorized bandwidth of 1 megahertz. Thus, for example, a single MBAN body sensor could be designed to operate nominally on two channels, each occupying up to 500 kHz (*i.e.*, one half the maximum authorized emission). In essence, this would also carry forward the existing channel use provisions of the MedRadio Service. As an additional example, we further note that this provision would not preclude full duplex or half duplex communications; provided that the total amount of bandwidth utilized by all of the channels employed by collection of a single patient, networked MBAN devices during a communications session does not exceed the maximum authorized 1 megahertz emission bandwidth. We also request comment on allowing any lesser emission bandwidths may be employed so long as the device complies with all other EIRP and unwanted emission limits. We seek comment on all of these issues.

68. *Unwanted emissions*. The MedRadio rules under Part 95 set forth limits on unwanted emissions from medical transmitting devices operating in the 401-406 MHz band.[80] Those provisions include limits on both in-band and out-of-band radiation. Specifically, 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.[81] We seek comment on the appropriateness of applying the same general limits on MBAN operations in the 2300-2305 MHz and 2360-2400 MHz bands. If parties suggest other out of band emission limits for devices operating in this band, they should provide sufficient technical justification to support those limits. Under any approach, we seek to provide an RF environment that would be adequate to protect incumbent operations while fostering efficient spectrum use by MBAN devices.

69. *Frequency stability*. Following the MedRadio rules, we would require that MBAN transmitters maintain a frequency stability of +/- 100 ppm of the operating frequency over the 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.[82] We seek comment on these stability criteria.

70. *Antenna locations*. We seek comment on whether it would be appropriate to restrict the use of MBAN transmitting antennas to indoor locations in certain frequency bands. For example, in light of the concerns discussed above regarding the interference potential between AMT and MBAN systems, should MBAN operations that might be permitted in the 2360-2390 MHz band be limited to indoor use (within healthcare facilities)? This would be similar to the WMTS approach noted above, where transmitting antennas are restricted to indoor locations only. Alternatively, would it be more practical in other frequency bands to follow the approach of the present MedRadio rules by which temporary outdoor antennas are permitted?[83] We invite commenters to address the relative advantages and disadvantages of either approach for MBAN use in any of the frequency bands under consideration in this proceeding.

71. *RF safety*. We note that portable devices are subject to Section 2.1093 of the rules, pursuant to which an environmental assessment must be prepared under Section 1.1307. These rule sections also govern existing MedRadio devices. Devices covered by these rules are subject to routine environmental

[80] *See* 47 C.F.R. 95.635 (d).

[81] These limits generally reflect the same field strength limits presently specified in Section 95.635 (d) (1), 47 C.F.R. § 95.635(d)(1), for the MedRadio Service (formerly MICS).

[82] *See* 47 C.F.R. § 95.628 (e).

[83] *See* 47 C.F.R. § 95.1213. Under the MedRadio rules, temporary outdoor operation of a control transmitter is permitted so long as the antenna is not affixed to any structure for which the height of the tip of the antenna would exceed three (3) meters (9.8 feet) above ground. In any event, no antenna may be configured for permanent outdoor use.

evaluation for RF exposure prior to equipment authorization.[84] We further note, however, that in our ongoing RF safety proceeding (ET Docket No. 03-137) we anticipate dealing with proposed changes in our rules regarding human exposure to RF electromagnetic fields in a more comprehensive fashion.[85] Thus, for the purposes of the instant proceeding and the Commission's pending action in the RF safety proceeding in ET Docket 03-137, we only seek comment here on whether MBAN transmitters should be deemed as portable devices subject to Sections 2.1093 and 1.1307 of the existing rules.[86] To the extent that MBAN devices are deemed portable devices, they would then be subject to our RF exposure rules for such devices.

72. *Miscellaneous provisions*. We also seek comment on various rule provisions regarding equipment certification, authorized locations, station identification, station inspection, disclosure policy, labeling requirements and marketing limitations that mirror the existing MedRadio rules.

73. First, we seek comment on whether we should require that each authorized MBAN transmitter be certificated, except for such transmitters that are not marketed for use in the United States, but which otherwise comply with the applicable technical requirements and are operated in the United States by individuals who have traveled to the United States from abroad.[87]

74. We also seek comment on whether to specifically require that all non-implanted MBAN transmitter apparatus be made available for inspection upon request by an authorized FCC representative.[88] Under such a provision, persons operating MBAN transmitters would be required to cooperate reasonably with duly authorized FCC representatives in the resolution of interference.

75. We request comment on requiring that manufacturers of MBAN transmitters include an appropriate disclosure statement analogous to that for MedRadio transmitters with each MBAN transmitting device.[89] Such a statement would disclose the provision of the rules under which the device is authorized, along with a statement that the transmitter must not cause harmful interference to stations authorized to operate on a primary basis in the band, and must accept interference that may be caused by such stations, including interference that may cause undesired operation. Such a statement would also indicate that the transmitter shall be used only in accordance with the FCC Rules, and that analog and digital voice communications are prohibited. We seek comment on this proposal.

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[84] *See* §2.1093 (c). The limits to be used for evaluation are based generally on criteria published by the American National Standards Institute (ANSI) for localized specific absorption rate ("SAR") in Section 4.2 of "IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz," ANSI/IEEE C95.1–1992, Copyright 1992 by the Institute of Electrical and Electronics Engineers, Inc., New York, New York 10017. *See* §2.1093 (d).

[85] Proposed Changes in the Commission's Rules Regarding Human Exposure to Radiofrequency Electromagnetic Fields, ET Docket No. 03-137, *Notice of Proposed Rule Making*, 18 FCC Rcd 13187 (2003), available at http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC-03-132A1.doc.

[86] *See* 47 C.F.R. § 95.1221

[87] *See* 47 C.F.R. § 95.603.

[88] As proposed above, only non-implanted MBAN devices would be allowed. *See* 47 C.F.R. § 95.1207.

[89] For example, under the MedRadio rules, each transmitter must include a statement that "This transmitter is authorized by rule under the MedRadio Service. 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." *See* 47 C.F.R. § 95.1215.

76. We further seek comment on whether to require that MBAN control transmitters (if allocated on a secondary basis) be labeled[90] and bear the following statement in a conspicuous location on the device: "This device may not interfere with stations authorized to operate on a primary basis and must accept any interference received, including interference that may cause undesired operation ." Where a MBAN control transmitter is constructed in two or more sections connected by wire and marketed together, the statement specified in this section would be required to be affixed only to the main control unit. We also seek comment on whether to require that MBAN transmitters be identified with a serial number. Under that plan, we would allow the FCC ID number associated with the transmitter and the information required by 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.

77. Finally, with respect to marketing limitations, we seek comment on whether we should specify that MBAN transmitters may be marketed and sold only for those permissible uses described above.[91]

C. Other Matters and Conclusion

78. As noted in the *Background* discussion above, BSI (Broadcast Sports, Inc.) filed comments in which it proposes an "Event Radio Service" as an alternative to the GEHC proposal for use of the 2360-2400 MHz band. We find that BSI has not provided sufficient clarity to consider such an allocation or related service rules. On its face, the BSI proposal appears to be intended to preserve the ability to obtain access to additional spectrum for video coverage of sports events that can already be obtained under STAs. There is no evidence, however, to support the proposition that an allocation for MBANS would constrain the ability to obtain STAs for video coverage of sports events. Moreover, special temporary authority is precisely the proper instrument for authorizing temporary operations at specific locations. Furthermore, we are not persuaded that an allocation of spectrum and service rules limited to video coverage of sports events represents the most efficient use of this spectrum nor best serves the public interest as compared with devices that may have significant benefits for health care. Accordingly, we decline to propose BSI's alternative allocation for an Event Radio service.

79. We seek comment on all of the matters discussed in this Notice, and encourage commenters to address any other relevant matters of concern that might serve to illuminate the record in this proceeding.

IV. PROCEDURAL MATTERS

80. *Initial Regulatory Flexibility Analysis for the Notice of Proposed Rule Making.* As required by Section 603 of the Regulatory Flexibility Act, 5 U.S.C. § 603, the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities of the proposals suggested in this document. The IRFA is set forth in Appendix B.

81. *Initial Paperwork Reduction Analysis.* The *Notice of Proposed Rule Making* contains proposed new or modified information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995, Public Law 104-13. Public and agency comments are due [X] days after the date of publication in the Federal Register. Comments should address: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. In

[90] *See* 47 C.F.R. § 95.1217

[91] *See* 47 C.F.R. § 95.1218.

addition, pursuant to the Small Business Paperwork Relief Act of 2002,[92] we seek specific comment on how we might "further reduce the information collection burden for small business concerns with fewer than 25 employees."

82. In addition to filing comments with the Secretary, a copy of any comments on the Paperwork Reduction Act information collections requirements contained herein should be submitted to the Federal Communications Commission via email to PRA@fcc.gov and to Nicholas A. Fraser, Office of Management and Budget via email to Nicholas_A._Fraser@omb.eop.gov or via fax at (202) 395-5167.

83. *Comments.* Pursuant to Sections 1.415 and 1.419 of the Commission's rules, 47 C.F.R. §§ 1.415, 1.419, interested parties may file comments on or before the dates indicated on the first page of this document. Comments may be filed using: (1) the Commission's Electronic Comment Filing System (ECFS), (2) the Federal Government's eRulemaking Portal, or (3) by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings*, 63 Fed. Reg. 24121 (1998).

- Electronic Filers: Comments may be filed electronically using the Internet by accessing the ECFS: http://www.fcc.gov/cgb/ecfs/ or the Federal eRulemaking Portal: http://www.regulations.gov. Filers should follow the instructions provided on the website for submitting comments.

    - For ECFS filers, if multiple docket or rulemaking numbers appear in the caption of this proceeding, filers must transmit one electronic copy of the comments for each docket or rulemaking number referenced in the caption. In completing the transmittal screen, filers should include their full name, U.S. Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions, filers should send an e-mail to ecfs@fcc.gov, and include the following words in the body of the message, "get form." A sample form and directions will be sent in response.

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

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

    - The Commission's contractor will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE, Suite 110, Washington, DC 20002. The filing hours at this location are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building.

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

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

[92] Public Law 107-198, *see* 44 U.S.C. 3506(c) (4).

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).

84. *Further Information.* For further information, contact, Gary Thayer Office of Engineering and Technology, at (202) 418-2290, or via the Internet at gary.thayer@fcc.gov.

V. ORDERING CLAUSES

85. IT IS ORDERED that pursuant to Sections 4(i), 301, 302, 303(e), 303(f) and 303(r) of the Communications Act of 1934, as amended, 47 USC Sections 154(i), 301, 302, 303(e), 303(f) and 303(r), this *Notice of Proposed Rule Making* IS ADOPTED.

86. IT IS FURTHER ORDERED that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, SHALL SEND a copy of this *Notice of Proposed Rule Making,* including the Initial Regulatory Flexibility Analysis to the Chief Counsel for Advocacy of the Small Business Administration.

FEDERAL COMMUNICATIONS COMMISSION

Marlene H. Dortch
Secretary

APPENDIX A

Information Requested on Characteristics of MBAN and AMT Systems

Information on the following parameters for MBAN and AMT systems should be used, as appropriate, to address further technical analyses.

MBAN Characteristics

- What baseband data rate should be assumed for MBAN devices?
- What frequency reuse criteria will be employed?
- What modulation efficiency could be achieved (*e.g.*, bits per second per hertz)?
- What duty cycle limits are typically used for MBAN applications?
- What emission bandwidths are required for the medical applications envisioned?
- What maximum EIRP is required for the medical applications envisioned?
- What bandwidth, noise figure, antenna gain and gain pattern should be used in assessing interference into MBAN receivers?
- What interference criteria are appropriate for evaluating interference into MBAN receivers?

AMT Characteristics

- What emission bandwidths are used by the aeronautical telemetry services?
- What maximum EIRP is used by typical aeronautical telemetry systems?
- What bandwidth, noise figure, antenna gain and gain pattern should be used in assessing interference into AMT receivers?
- What interference criteria are appropriate for evaluating interference into AMT receivers?

APPENDIX B

Initial Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act (RFA),[1] the Commission has prepared this present Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities by the policies and rules proposed in this *Notice of Proposed Rule Making* (*NPRM*). Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments provided in this *NPRM*. The Commission will send a copy of this *NPRM*, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA).[2] In addition, the *NPRM* and IRFA (or summaries thereof) will be published in the Federal Register.[3]

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

The Commission seeks comment on the feasibility of allocating spectrum for the operation of Medical Body Area Network (or MBAN) systems using body sensor devices. Under the service and technical rules proposed herein, we envision that MBAN systems could provide a flexible platform for the wireless networking of multiple body sensors used for monitoring physiological patient data in health care facilities. Use of MBAN systems should result in improved safety, quality, and efficiency of patient care by reducing or eliminating a wide array of hardwired, patient-attached cables used by present monitoring technologies.

B. Legal Basis.

The proposed action is authorized under Sections 4(i), 301, 302, 303(e), 303(f), 303(r), 304 and 307 of the Communications Act of 1934, as amended, 47 U.S.C. Sections 154(i), 301, 302, 303(e), 303(f), 303(r), 304 and 307.

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

The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted.[4] The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction."[5] In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act.[6] A small business concern is one which:

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[1] *See* 5 U.S.C. § 603. The RFA, *see* 5 U.S.C. § 601 *et. seq.*, has been amended by the Contract With America Advancement Act of 1996, Pub. L. No. 104-121, 110 Stat. 847 (1996) (CWAAA). Title II of the CWAAA is the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

[2] *See* 5 U.S.C. § 603(a).

[3] *Id.*

[4] 5 U.S.C. § 603(b)(3).

[5] 5 U.S.C. § 601(6).

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

(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]

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

The 2300-2305 MHz, 2360-2400 MHz, 2400-2500 MHz and 5150-5250 MHz bands are used by various Federal and non-Federal radiocommunication services. Thus, we seek comment related to the potential for interference caused either to incumbents, or to MBAN systems, and how any such concerns might be mitigated.

We thus seek comment on allowing MBAN operations in any of the bands on a secondary basis, subject to the further condition that harmful interference is not caused to primary services allocated in the bands, or on allowing MBAN operations on a primary basis in the 2300-2305 MHz and 2390-2400 MHz bands. We would further propose to provide for such use by including a U.S. footnote to the Table of Allocations in Part 2 of the Rules for the specific band segments.[8]

We also seek comment on various provisions regarding equipment certification, authorized locations, station identification, station inspection, disclosure policy, labeling requirements and marketing limitations that mirror the existing MedRadio rules.

First, we seek comment on whether we should require that each MBAN transmitter must be certificated except for such transmitters that are not marketed for use in the United States, but which otherwise comply with the applicable technical requirements and are operated in the United States by individuals who have traveled to the United States from abroad.

We also seek comment on whether to provide that all non-implanted MBAN transmitter apparatus be made available for inspection upon request by an authorized FCC representative. Under such a provision, persons operating MBAN transmitters would be required to cooperate reasonably with duly authorized FCC representatives in the resolution of interference.

We seek comment on whether to require that manufacturers of MBAN transmitters include with each transmitting device (if allocated on a secondary basis) an appropriate disclosure statement analogous to that for MedRadio transmitters with each MBAN transmitting device.[9] Such a statement would disclose the provision of the rules under which the device is authorized, along with a statement that the transmitter must not cause harmful interference to stations authorized to operate on a primary basis in the band, and must accept interference that may be caused by such stations, including interference that may cause undesired operation. Such statement would also indicate that the transmitter shall be used only in accordance with the FCC Rules, and that analog and digital voice communications are prohibited.

We further seek comment on whether to require that MBAN control transmitters (if allocated on a secondary basis) be labeled and shall bear the following statement in a conspicuous location on the device: "This device may not interfere with stations authorized to operate on a primary basis and must accept any interference received, including interference that may cause undesired operation." Where a MBAN control transmitter is constructed in two or more sections connected by wire and marketed

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

[8] *See* 47 C.F.R. § 2.106.

[9] For example, under the MedRadio rules, each transmitter must include a statement that "This transmitter is authorized by rule under the MedRadio Service. 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."

together, the statement specified in this section would be required to be affixed only to the main control unit. We also seek comment on whether to require that MBAN transmitters be identified with a serial number. Under that plan, we would allow the FCC ID number associated with the transmitter and the information required by 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.

Finally, with respect to marketing limitations, we seek comment on requiring that MBAN transmitters intended for operation in any portions of the 2360-2400 MHz band may be marketed and sold only for those permissible uses

Licensing. We seek comment on whether medical device operations in any portion of the frequency bands under consideation should be authorized under the MedRadio Service in Part 95 of our Rules, thus providing for license-by-rule operation[10] pursuant to Section 307(e) of the Communications Act (Act).[11] Under this approach, medical devices would operate in the band on a shared, non-exclusive basis with respect to each other and without the need for MBAN systems to be individually licensed. As the Commission determined when it adopted the MedRadio Service rules, this approach minimizes regulatory burdens and facilitates the expeditious deployment of new generations of beneficial wireless medical devices that can improve the quality of life for countless Americans, thus serving the public interest, convenience and necessity.

Alternatively, we also seek comment on whether MBAN operations should be licensed on a non-exclusive basis under Part 90. Under that approach, MBAN operations would be licensed on a non-exclusive basis with respect to each other for ten year license terms. We seek comment on whether we should consider using the same approach here as we do with wireless broadband services in the 3650-3700 MHz band, *i.e.*, eligible entities would apply for non-exclusive nationwide licenses and subsequently register individual stations with the Commission.[12] If we were to adopt this approach, we also seek comment on whether we should require that licensees register each individual MBAN system or, alternatively, require them to register the individual health care facility at which the licensee would be allowed to operate multiple MBAN systems. In this regard, we seek comment on what type of licensing and registration information for MBAN operations would facilitate coordination with incumbent services; and what would be the relative benefits and disadvantages of licensing under Part 90 compared with the license-by-rule approach under Part 95.

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

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.[13]

[10] *See* 47 C.F.R.§ 95.401 (d).

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

[12] *See* 47 C.F.R. § 90.1307.

[13] *See* 5 U.S.C. § 603(c).

We also invite commenters to address the validity of the competing interference modeling studies that have already been placed into the record by GEHC and AFTRCC. Each party reaches opposite conclusions concerning whether MBAN operation would pose an undue interference risk to AMT operations in the 2360-2395 MHz band. We ask commenters to address which aspects of these interference models would be appropriate, or not, to be relied upon under the particular factual circumstances herein. For example, should interference potential be evaluated in this instance by reference to worst-case static models or by other statistical simulations such as the Monte-Carlo approach type relied upon by GEHC? Why or why not? Would some other interference modeling approaches give results providing a greater degree of confidence in their merit?

F. Federal Rules that May Duplicate, Overlap, or Conflict with the Proposed Rules.

None.

STATEMENT OF
COMMISSIONER ROBERT M. McDOWELL

RE: ***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***

I am delighted to vote to approve this notice of proposed rulemaking, the request for which was originally filed with the Commission in 2007. I thank Acting Chairman Copps for bringing this cutting edge proposal forward and giving it the attention it deserves. Our action today takes another step to improve the safety, efficiency and quality of care provided to millions of American hospital patients. I look forward to engaging with all interested parties to ensure that we complete our work in this proceeding as quickly as possible. Our fellow Americans living with chronic health conditions deserve no less.