energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. A preliminary environmental analysis checklist supporting this determination is available in the docket where indicated under **ADDRESSES**. We expect this proposed rule to be categorically excluded from requirements for further environmental documentation under figure 2–1, paragraph (34)(g), of the Instruction because the rule would establish a safety zone. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Public Law 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Add temporary § 165.T11–227 to read as follows:

§ 165.T11–227 Safety zone; Sea World Labor Day Fireworks, Mission Bay, San Diego, California.

(a) *Location.* The following area is a safety zone: All waters of Mission Bay, from surface to bottom, within a 600 foot radius around the fireworks launch barge in an approximate position of 32°46′03″ N, 117°13′11″ W (NAD 83).

(b) *Enforcement Period.* This section will be enforced from 8 p.m. to 10 p.m. on December 12, 2009. If the event concludes prior to the scheduled termination time, the Captain of the Port will cease enforcement of this safety zone and will announce that fact via Broadcast Notice to Mariners.

(c) *Definitions.* The following definition applies to this section: *Designated representative,* means any commissioned, warrant, or petty officers of the Coast Guard on board Coast Guard, Coast Guard Auxiliary, or local, state, or federal law enforcement vessels who have been authorized to act on the behalf of the Captain of the Port.

(d) *Regulations.* (1) Entry into, transit through or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port of San Diego or his designated on-scene representative.

(2) Mariners requesting permission to transit through the safety zone may request authorization to do so from the Sector San Diego Command Center. The Command Center may be contacted on VHF–FM Channel 16.

(3) All persons and vessels must comply with the instructions of the Coast Guard Captain of the Port or the designated representative.

(4) Upon being hailed by U.S. Coast Guard patrol personnel by siren, radio, flashing light, or other means, the operator of a vessel must proceed as directed.

(5) The Coast Guard may be assisted by other federal, state, or local agencies.

Dated: July 22, 2009.

T.H. Farris,

Captain, U.S. Coast Guard, Captain of the Port San Diego.

[FR Doc. E9–18755 Filed 8–5–09; 8:45 am]

BILLING CODE 4910–15–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2 and 95

[ET Docket No. 08–59; FCC 09–57]

Medical Body Area Network (MBAN)

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document 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. 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. This Notice of Proposed Rulemaking reflects the Commission's 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.

DATES: Comments must be filed on or before October 5, 2009, and reply comments must be filed on or before November 4, 2009.

ADDRESSES: You may submit comments, identified by ET Docket No. 08–59, by any of the following methods:

■ *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.

■ *Federal Communications Commission's Web Site: http://www.fcc.gov/cgb/ecfs/*. Follow the instructions for submitting comments.

■ *E-mail:* [Optional: Include the E-mail address only if you plan to accept comments from the general public.] Include the docket number(s) in the subject line of the message.

■ *Mail:* [Optional: Include the mailing address for paper, disk or CD–ROM submissions needed/requested by your Bureau or Office. Do not include the Office of the Secretary's mailing address here.]

■ *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Gary Thayer, Office of Engineering and Technology, (202) 418–2290, e-mail: *Gary.Thayer@fcc.gov*, TTY (202) 418–2989.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rule Making*, ET Docket No. 08–59, FCC 09–57, adopted June 29, 2009, and released June 29, 2009. The full text of this document is available for public inspection and copying during regular business hours in the Commission's Reference Information Center, Portals II, 445 12th Street, SW., (Room CY–A257), Washington, DC 20554. The complete text of this document also may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone (202) 488–5300, facsimile (202) 488–5563 or via e-mail *FCC@BCPIWEB.com*. The full text may also be downloaded at: *http://www.fcc.gov*.

Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using: (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 FR 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 Web site 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 a.m. to 7 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 should be addressed to 445 12th Street, SW., Washington, DC 20554.

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

Filings and comments are also available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. They may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone: (202) 488–5300, fax: (202) 488–5563, or via e-mail *http://www.bcpiweb.com*.

Summary of Notice of Proposed Rulemaking

1. In the Notice of Proposed Rulemaking (NPRM), 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. The NPRM reflects the Commission's continuing efforts 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.

2. MBAN systems, as contemplated by the NPRM, could 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 as well as in other health care monitoring situations. 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.

3. Given these significant health care benefits offered by MBAN systems, the Commission tentatively concludes that providing spectrum for MBAN operations would serve the public interest.

4. Against this backdrop, the Commission addresses a petition filed by GE Healthcare (hereinafter 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, the Commission seeks comment on an alternative recommendation by the Aerospace and Flight Test Radio Coordinating Council (AFTRCC) to accommodate MBAN operations in the 2300–2305 MHz and 2395–2400 MHz bands. Finally, the Commission seeks comment on whether other bands such as the 2400–2483.5 MHz or 5150–5250 MHz bands could be used to support MBAN operations.

5. The Commission also addresses several spectrum compatibility concerns with respect to incumbent operations in accommodating MBAN operations. Thus, the Commission seeks comment on the potential for interference caused either to incumbents, or to MBAN systems, and how any such concerns might be mitigated. In addition, the Commission seeks comment more generally on whether allocating spectrum and establishing rules to allow

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

6. Finally, the Commission seeks comment on what licensing approaches would be appropriate for MBAN operations in the various frequency bands under consideration, as well as service and technical rules for MBAN operation. This includes a discussion of whether MBANs should be authorized on a licensed basis under part 95, a ''licensing-lite'' approach under part 90, or an unlicensed basis under part 15. The tentative service and technical rules discussed in the NPRM follow the general framework of the recently adopted rules for the MedRadio Service.

A. Frequency Allocation

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

7. The Commission seeks comment on whether to allow MBAN operations on up to 40 megahertz of spectrum in the 2360–2400 MHz band on a secondary basis. This option reflects the initial recommendation set forth in the GEHC petition. In this context, the Commission recognizes the necessity of affording interference protection to incumbent primary users, particularly AMT operations. In addition, the NPRM considers the potential for interference to MBAN devices and the attendant risk to patients using MBAN systems.

8. The Commission also seeks additional 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.

9. Regarding the potential for interference from MBAN devices to incumbent operations, the Commission seeks comment on whether the potential for sharing between MBAN systems and incumbent AMT and radiolocation operations could be facilitated if geographic exclusion zones were to be established around AMT test flight sites in the 2360–2395 MHz band to protect those sites from harmful interference. In addition to or in lieu of exclusion zones, MBAN operators and AMT licensees may be able to coordinate their operations. The Commission further observes in the NPRM that sharing between MBAN systems and incumbents 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. The Commission believes 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. Thus, the Commission seeks comment on whether permitting MBAN systems to operate in the 2360–2395 MHz band under the limitations proposed would provide interference protection to incumbent users.

10. Regarding interference from AMT to MBAN operations, the Commission seeks comment on whether MBAN devices could avoid receiving interference from AMT or other incumbent users by employing a contention-based protocol or some other techniques. In this regard, the Commission seeks comment on whether transmissions from incumbent stations, as well as flight test stations using future technologies (which might 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.

11. To address recommendations made in comments filed by AFTRCC, the Commission seeks comment on limiting MBAN operations to the 2300–2305 MHz and 2395–2400 MHz bands. It specifically seeks comment on the ability of MBAN devices to utilize these two blocks of spectrum that are separated by 90 megahertz. The Commission also seeks comment on whether it 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. The Commission seeks 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. The Commission further seeks comment as to whether, in the 2390–2395 MHz band it should consider allowing MBAN and AMT operations to operate on a co-primary basis and what the sharing rules between them should be. Additionally, the Commission seeks comment on whether any additional MBAN spectrum would be needed if it 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.

12. To the extent that MBAN operation might ultimately be authorized in any portion of the 2300–2305 MHz or 2360–2400 MHz bands, the Commission proposes including a new U.S. footnote to the Table of Allocations in part 2 of the rules for the specific band. The Commission 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. The Commission seeks comment on this approach.

2. 2400–2483.5 MHz Frequency Band

13. The Commission seeks comment on whether MBAN devices could operate in the 2400–2483.5 MHz band. 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. In its petition, GEHC has asserted that manufacturers could leverage available technology used for ISM equipment in this band to develop low-cost MBAN devices.

14. In addition to present use by ISM, the Commission observes that various radio services are also allocated in this band. Among these, the 2400–2417 MHz band is allocated to the Amateur service on a primary basis. 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. Such Federal operations may be authorized on a non-interference basis, but may not constrain the implementation of any non-Federal operations. 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. These unlicensed devices include WiFi, cordless phones, and Bluetooth, among various other types of uses.

15. The Commission seeks comment on whether the widespread success of the unlicensed devices described in the preceding paragraph would 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, the Commission seeks 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 it 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 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? The Commission also seeks comment regarding whether MBAN operations can exist compatibly with the incumbent Amateur service users who operate in this band.

16. The Commission also cautions that any MBAN equipment operating in these bands would have 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. The Commission seeks 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

17. The Commission seeks comment on whether there are other frequency bands where MBAN manufacturers could leverage existing technologies to implement such devices and achieve economies of scale. For example, the Commission seeks 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. 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.

18. U–NII devices use digital modulation techniques and provide a wide array of high data rate mobile and fixed communications applications. 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.

19. With respect to the 5150–5250 MHz band, the Commission seeks 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 it 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 § 15.407(e)?

B. Service and Technical Rules

20. The tentative rules discussed in the NPRM focus upon 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 that might apply in the 2360–2400 MHz band. At the same time, the Commission seeks comment on other approaches, such as under part 90 or part 15, that might be feasible. The Commission takes this approach in the NPRM because the 2360–2400 MHz band was specifically addressed in the GEHC petition and in both the comments and reply comments, The Commission notes that, in any event, similar rules would also be required if MBAN operations were to be authorized in either the 2400–2483.5 MHz or the 5150–5250 MHz bands under consideration.

1. Service Rules

21. *Licensing.* The Commission seeks comment on whether medical device operations should be authorized in part 95 of our rules, thus providing for license-by-rule operation pursuant to Section 307(e) of the Communications Act (Act). 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. The Commission seeks 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.

22. Alternatively, the Commission seeks comment on whether MBAN operations should be licensed on a non-exclusive basis under part 90. In this context, the Commission also seeks comment on whether it would be feasible to establish geographic exclusion zones around AMT operational areas as an interference avoidance mechanism. At the same time, the Commission seeks comment on whether the use of such exclusion zones could frustrate the widespread use of MBAN devices—particularly, for example, if such exclusion zones were so large as to encompass major metropolitan areas where MBAN operations might be prohibited. As discussed elsewhere in the *NPRM*, frequency coordination also could facilitate sharing between the incumbent operations and MBAN devices. Frequency coordination is required for WMTS operations authorized under part 95, but does not involve as many sites as could be required for MBAN and AMT coordination. Another licensing approach that the Commission 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. The Commission seeks comment on whether it should consider using the same approach here as it does 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. If the Commission were to adopt this approach, should it 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?

23. *Definitions.* The Commission seeks 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 Commission's part 95 rules for wireless medical telemetry and body-worn devices. The Commission seeks 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 medical 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 be placed on or in close proximity to 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.

24. The Commission requests comment as to whether these definitions would be too broad or too narrow and whether alternative definitions should be used. The Commission asks whether other components of wireless MBAN systems should also be identified and defined. The Commission is not proposing to include medical implant devices as part of MBAN systems, although it recognizes 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. The Commission also seeks comment on whether any other current definitions included in the MedRadio Service rules need to be modified to accommodate wireless MBAN devices.

25. *Permissible Communications and Operator Eligibility.* The Commission proposes 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 human patient under the direction of a duly authorized health care professional. Furthermore, transmissions are limited to non-voice data signals. The Commission expects, based on representations made in the GEHC petition, that wireless body sensor devices configured as a MBAN would be used primarily for monitoring patient data. The Commission believes it would be prudent to provide flexibility so that MBAN systems can also be used for performing diagnostic or therapeutic functions. The Commission seeks comment on whether these requirements would be appropriate for MBAN operations.

26. In the MedRadio proceeding, the Commission 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. The Commission 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 manufacturers, in concert with FDA-required risk management processes, as it would result in better and more flexible use of this scarce spectrum resource. The Commission seeks comment on whether a similar approach is appropriate for MBAN devices—*i.e.*, permitting health care professionals and medical device manufacturers, 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.

27. The Commission also notes 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. However, the MedRadio Service rules do allow programmer/control transmitters to be interconnected with other telecommunications systems including the public switched telephone network. The Commission seeks comment on whether, and if so why, similar requirements should also apply here. The Commission also seeks 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.

28. The Commission seeks 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, the Commission asks whether it 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

29. *Channelization.* The Commission seeks 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. Under this approach, the ''channel'' occupied by a MBAN transmitter or transmission would be 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.

30. 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. The Commission seeks 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, the Commission seeks 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.

31. Alternatively, the Commission seeks 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?

32. *Exclusion Zones.* The Commission recognizes that the current record contains conflicting information 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. Therefore, the Commission seeks 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 exclusion zones are to be used, the appropriate radius to use for such exclusion zones. The Commission states that it is not convinced at this time that either the GEHC or AFTRCC analysis is appropriate for determining interference potential and the utility or size of exclusion zones. Thus, the Commission seeks 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. The Commission also invites comment on other methodologies and analyses, including assumptions on which they rely, that could be used. The Commission also seeks comment on whether it is appropriate to use either interference criteria described herein, 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. The Commission provides in Appendix A of the NPRM additional parameters for MBAN and AMT systems that parties should address, as appropriate, to support further technical analyses.

33. The Commission also seeks comment on whether exclusion zones could always preclude operation of MBAN devices at some locations. If so, would it be in the public interest to preclude these technologies from certain health care facilities based on their location? Or should health care facilities located within an exclusion zone be permitted to coordinate MBAN use with AMT operations in that zone?

34. If exclusion zones were to be established, what criteria should be used to identify those AMT sites in need of protection? Should only AMT test sites that now actually use the 2360–2390 MHz band be protected, or also those test sites that do not presently use the band but might prospectively do so? If protection were to be required of sites that AFTRCC claims are ''entitled'' to, but do not currently use the 2360–2390 MHz band, how would the sites which are ''entitled'' to be protected be determined? Once existing test sites were determined, 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, the NPRM notes 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, the Commission 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 the Commission ultimately decides to protect sites that are not currently licensed to use the 2360–2390 MHz band, how would information on exclusion zones be accurately maintained and timely updated in the Commission's rules? The Commission seeks comment on these matters.

35. The NPRM seeks comment on whether the distance for MBAN operations should be measured from the specified center point that establishes the incumbent's area of operation or whether it should be measured from the edge of that area? How should incumbent sites be accounted for that are in close proximity to each other such that their areas of operation may overlap each other? Should further information be collected about incumbent operational locations and how should it be gathered? Regarding information about Federal sites, the Commission notes that it would intend to consult with NTIA about how to identify this information and make it available. The Commission also seeks comment on how it 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.

36. *Frequency Coordination.* With respect to protecting AMT operations from MBAN interference in portions of the 2360–2400 MHz band, the Commission recognizes that coordination may be useful because MBAN operations might otherwise be excluded from large geographic areas that encompass 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. Thus, the Commission seeks comment on whether coordination of MBAN systems is needed and should be required and, if so, under what circumstances. The Commission also seeks comment on whether it 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?

37. For example, the Commission acknowledges the suggestion made in the GEHC petition that the Commission could require frequency coordination and device registration for MBAN operations such as is used for coordination of WMTS operation. 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.

38. However, 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, the Commission also notes that MBAN devices would operate on a secondary basis, and a significantly large number of primary users must be accorded interference protection. Thus, the Commission seeks 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.

39. Alternatively, the Commission could license MBAN operations on a non-exclusive basis under part 90, 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 radio location sites. The Commission further notes 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.

40. The Commission notes that, 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. 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 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 the Commission 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. The Commission seeks comment on whether such an approach would be feasible here. Commenters should address the relative advantages and disadvantages of the approaches they support.

41. *Frequency Monitoring (Contention-based Spectrum Access Protocols).* The Commission recognizes 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. The Commission also notes that GEHC claims that contention protocols could be applied 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. The Commission invites comment on these observations and whether any rules should be adopted to ensure such sharing. In particular, it seeks 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 the Commission were to adopt a requirement for a contention-based protocol, it invites comment as to whether it 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.

> ''*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.''

42. The Commission encourages 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? Would any of these protocols be expected to interact either favorably or adversely with incumbent users?

43. *Transmitter Power, Emission Bandwidth, and Duty Cycle.* As recommended by GEHC, the Commission 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.

44. While GEHC emphasizes the use of MBAN systems for monitoring patient physiological data, the Commission recognizes that the definition that it proposed for MBAN systems would also allow the operation of two or more networked medical devices to perform diagnostic and therapeutic functions. The Commission seeks comment on whether the power/bandwidth limits proposed above—which reflect GEHC's recommendations—would be appropriate for such other purposes. The Commission specifically asks 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. The Commission requests that 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, the Commission seeks 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?

45. *Channel aggregation.* To the extent that device manufacturers might wish to aggregate multiple transmission channels in a single device, the Commission seeks comment on requiring only that the total 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, the Commission further notes 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. The Commission also requests comment on allowing any lesser emission bandwidths to be employed so long as the device complies with all other EIRP and unwanted emission limits. The Commission seeks comment on all of these issues.

46. *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. 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. The Commission seeks 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, the Commission seeks to provide an RF environment that would be adequate to protect incumbent operations while fostering efficient spectrum use by MBAN devices.

47. *Frequency stability.* Following the MedRadio rules, the Commission 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. The Commission seeks comment on these stability criteria.

48. *Antenna locations.* The Commission seeks 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 herein, 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? The Commission invites 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.

49. *RF safety.* The Commission notes that portable devices are subject to § 2.1093 of the rules, pursuant to which an environmental assessment must be prepared under § 1.1307. These rule sections also govern existing MedRadio devices. Devices covered by these rules are subject to routine environmental evaluation for RF exposure prior to equipment authorization. The Commission further notes, however, that in our ongoing RF safety proceeding (ET Docket No. 03–137) it anticipates dealing with proposed changes in our rules regarding human exposure to RF electromagnetic fields in a more comprehensive fashion. Thus, for the purposes of the instant proceeding and the Commission's pending action in the RF safety proceeding in ET Docket No. 03–137, the Commission only seeks comment here on whether MBAN transmitters should be deemed as portable devices subject to §§ 2.1093 and 1.1307 of the Commission's existing rules. To the extent that MBAN devices are deemed portable devices, they would then be subject to our RF exposure rules for such devices.

50. *Miscellaneous provisions.* The Commission also seeks 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.

51. First, the Commission seeks comment on whether it 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.

52. The Commission also seeks 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. Under such a provision, persons operating MBAN transmitters would be required to cooperate reasonably with duly authorized FCC representatives in the resolution of interference.

53. The Commission 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. 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. The

Commission seeks comment on this proposal.

54. The Commission further seeks comment on whether to require that MBAN control transmitters (if allocated on a secondary basis) be labeled and bear the following statement in a conspicuous location on the device: ''This device may not interfere with stations authorized to operate on a primary basis 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. The Commission also seeks comment on whether to require that MBAN transmitters be identified with a serial number. Under that plan, the Commission would allow the FCC ID number associated with the transmitter and the information required by § 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.

55. Finally, with respect to marketing limitations, the Commission seeks comment on whether it should specify that MBAN transmitters may be marketed and sold only for those permissible uses described in the NPRM.

C. Other Matters and Conclusion

56. As noted in the *Background* discussion of the NPRM, 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. The Commission finds 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, the Commission is 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, the Commission declines to propose BSI's alternative allocation for an Event Radio service.

57. The Commission seeks comment on all of the matters discussed in this NPRM, and encourages commenters to address any other relevant matters of concern that might serve to illuminate the record in this proceeding.

Initial Regulatory Flexibility Analysis

58. 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]

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

59. 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, the Commission envisions 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

60. 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 Would Apply

61. 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.[3] The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.''[4] In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act.[5] A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.[6]

62. Nationwide, there are a total of approximately 27.2 million small businesses, according to the SBA.[7] A ''small organization'' is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.''[8] Nationwide, as of 2002, there were approximately 1.6 million small organizations.[9] The term ''small governmental jurisdiction'' is defined generally as ''governments of cities, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.''[10] Census Bureau data for 2002 indicate that there were 87,525 local governmental jurisdictions in the United States.[11] The Commission estimates that, of this total, 84,377 entities were ''small governmental jurisdictions.''[12] Thus, it estimates that

[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, Public Law 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] 5 U.S.C. 603(b)(3).

[4] 5 U.S.C. 601(6).

[5] 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).

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

[7] *See* SBA, Office of Advocacy, ''Frequently Asked Questions,'' *http://web.sba.gov/faqs* (accessed Jan. 2009).

[8] 5 U.S.C. 601(4).

[9] Independent Sector, The New Nonprofit Almanac & Desk Reference (2002).

[10] 5 U.S.C. 601(5).

[11] U.S. Census Bureau, Statistical Abstract of the United States: 2006, Section 8, page 272, Table 415.

[12] We assume that the villages, school districts, and special districts are small, and total 48,558. *See* U.S. Census Bureau, Statistical Abstract of the United States: 2006, section 8, page 273, Table 417. For 2002, Census Bureau data indicate that the total

Continued

most governmental jurisdictions are small.

63. *Wireless Telecommunications Carriers (except Satellite).* Since 2007, the Census Bureau has placed wireless firms within this new, broad, economic census category.[13] Prior to that time, such firms were within the now-superseded categories of ''Paging'' and ''Cellular and Other Wireless Telecommunications.'' [14] Under the present and prior categories, the SBA has deemed a wireless business to be small if it has 1,500 or fewer employees.[15] Because Census Bureau data are not yet available for the new category, we will estimate small business prevalence using the prior categories and associated data. For the category of Paging, data for 2002 show that there were 807 firms that operated for the entire year.[16] Of this total, 804 firms had employment of 999 or fewer employees, and three firms had employment of 1,000 employees or more.[17] For the category of Cellular and Other Wireless Telecommunications, data for 2002 show that there were 1,397 firms that operated for the entire year.[18] Of this total, 1,378 firms had employment of 999 or fewer employees, and 19 firms had employment of 1,000 employees or more.[19] Thus, we estimate that the majority of wireless firms are small.

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

64. 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, the Commission seeks comment related to the potential for interference caused either to incumbents, or to MBAN systems, and how any such concerns might be mitigated.

65. The Commission thus seeks 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.[20]

66. The Commission also seeks 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.

67. First, the Commission seeks comment on whether it 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.

68. The Commission also seeks 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.

69. The Commission seeks 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.[21] 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.

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

71. Finally, with respect to marketing limitations, the Commission seeks 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.

72. *Licensing.* The Commission seeks comment on whether medical device operations in any portion of the frequency bands under consideration should be authorized under the MedRadio Service in part 95 of our Rules, thus providing for license-by-rule

number of county, municipal, and township governments nationwide was 38,967, of which 35,819 were small. *Id.*

[13] U.S. Census Bureau, 2007 NAICS Definitions, ''517210 Wireless Telecommunications Categories (Except Satellite)''; *http://www.census.gov/naics/2007/def/ND517210.HTM#N517210.*

[14] U.S. Census Bureau, 2002 NAICS Definitions, ''517211 Paging''; *http://www.census.gov/epcd/naics02/def/NDEF517.HTM.*; U.S. Census Bureau, 2002 NAICS Definitions, ''517212 Cellular and Other Wireless Telecommunications''; *http://www.census.gov/epcd/naics02/def/NDEF517.HTM.*

[15] 13 CFR 121.201, NAICS code 517210 (2007 NAICS). The now-superseded, pre-2007 CFR citations were 13 CFR 121.201, NAICS codes 517211 and 517212 (referring to the 2002 NAICS).

[16] U.S. Census Bureau, 2002 Economic Census, Subject Series: Information, ''Establishment and Firm Size (Including Legal Form of Organization,'' Table 5, NAICS code 517211 (issued Nov. 2005).

[17] *Id.* The census data do not provide a more precise estimate of the number of firms that have employment of 1,500 or fewer employees; the largest category provided is for firms with ''1000 employees or more.''

[18] U.S. Census Bureau, 2002 Economic Census, Subject Series: Information, ''Establishment and Firm Size (Including Legal Form of Organization,'' Table 5, NAICS code 517212 (issued Nov. 2005).

[19] *Id.* The census data do not provide a more precise estimate of the number of firms that have employment of 1,500 or fewer employees; the largest category provided is for firms with ''1000 employees or more.''

[20] *See* 47 CFR 2.106.

[21] 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.''

operation [22] pursuant to section 307(e) of the Communications Act (Act).[23] 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.

73. Alternatively, the Commission also seeks 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. The Commission seeks comment on whether it 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.[24] If this approach were to be adopted, the Commission also seeks comment on whether it 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, the Commission seeks 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

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

75. The Commission also invites 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, alternative conclusions concerning whether MBAN operation would pose an undue interference risk to AMT operations in the 2360–2395 MHz band. The Commission asks 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

76. None.

Ordering Clauses

77. 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.*

78. 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.

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BILLING CODE 6712–01–P

[22] *See* 47 CFR 95.401 (d).

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

[24] *See* 47 CFR 90.1307.

[25] *See* 5 U.S.C. 603(c).

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 09–1532; MB Docket No. 08–153; RM–11477]

Television Broadcasting Services; Bangor, ME

AGENCY: Federal Communications Commission.

ACTION: Dismissal.

SUMMARY: The Commission dismisses the pending rulemaking petition filed by Community Broadcasting Service (''Community Broadcasting''), the licensee of WABI–DT, digital channel 19, Bangor, Maine, which requests the substitution of channel 12 for digital channel 19 at Bangor. Community Broadcasting's proposed channel substitution requires coordination and concurrence with the Canadian government because the proposed facility is located within the Canadian coordination zone. The Canadian government has indicated that Community Broadcasting's proposed channel substitution is not acceptable. Therefore, the Commission dismisses Community Broadcasting's petition for rulemaking.

FOR FURTHER INFORMATION CONTACT: Adrienne Y. Denysyk, Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Order,* MB Docket No. 08–153, adopted July 13, 2009, and released July 14, 2009. The full text of this document is available for public inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 12th Street, SW., Washington, DC 20554. This document will also be available via ECFS (*http://www.fcc.gov/cgb/ecfs/*). (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.) This document may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–478–3160 or via e-mail *http://www.BCPIWEB.com.* To request this document in accessible formats (computer diskettes, large print, audio recording, and Braille), send an e-mail to *fcc504@fcc.gov* or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). This document does not contain information collection requirements subject to the Paperwork Reduction Act