TABLE 1 TO SUBPART S OF PART 63—GENERAL PROVISIONS APPLICABILITY TO SUBPART S [a]—Continued

Reference	Applies to subpart S	Comment
63.8(e)	Yes	
63.8(f)(1)–(5)	Yes	
63.8(f)(6)	No	Subpart S does not specify relative accuracy test for CEMs.
63.8(g)	Yes	
63.9(a)	Yes	
63.9(b)(1)–(2)	Yes	Initial notifications must be submitted within one year after the source becomes subject to the relevant standard.
63.9(b)(3)	No	Section reserved.
63.9(b)(4)–(5)	Yes	
63.9(c)	Yes	
63.9(d)	No	Special compliance requirements are only applicable to kraft mills.
63.9(e)	Yes	
63.9(f)	No	Pertains to continuous opacity monitors that are not part of this standard.
63.9(g)(1)	Yes	
63.9(g)(2)	No	Pertains to continuous opacity monitors that are not part of this standard.
63.9(g)(3)	No	Subpart S does not specify relative accuracy tests, therefore no notification is required for an alternative.
63.9(h)(1)–(3)	Yes	
63.9(h)(4)	No	Section reserved.
63.9(h)(5)–(6)	Yes	
63.9(i)	Yes	
63.9(j)	Yes	
63.10(a)	Yes	
63.10(b)(1)	Yes	
63.10(b)(2)(i)	No	
63.10(b)(2)(ii)	No	See § 63.454(g) for recordkeeping of (1) occurrence and duration and (2) actions taken during malfunction.
63.10(b)(2)(iii)	Yes	
63.10(b)(2)(iv)–(v)	No	
63.10(b)(2)(vi)–(xiv)	Yes	
63.10(b)(3)	Yes	
63.10(c)(1)	Yes	
63.10(c)(2)–(4)	No	Sections reserved.
63.10(c)(5)–(8)	Yes	
63.10(c)(9)	No	Section reserved.
63.10(c)(10)–(11)	No	See § 63.454(g) for malfunction recordkeeping requirements.
63.10(c)(12)–(14)	Yes	
63.10(c)(15)	No	
63.10(d)(1)–(2)	Yes	
63.10(d)(3)	No	Pertains to continuous opacity monitors that are not part of this standard.
63.10(d)(4)	Yes	
63.10(d)(5)	No	See § 63.455(g) for malfunction reporting requirements.
63.10(e)(1)	Yes	
63.10(e)(2)(i)	Yes	
63.10(e)(2)(ii)	No	Pertains to continuous opacity monitors that are not part of this standard.
63.10(e)(3)	Yes	
63.10(e)(4)	No	Pertains to continuous opacity monitors that are not part of this standard.
63.10(f)	Yes	
63.11–63.15	Yes	

[a] Wherever subpart A specifies ''postmark'' dates, submittals may be sent by methods other than the U.S. Mail (e.g., by fax or courier). Submittals shall be sent by the specified dates, but a postmark is not required.

[FR Doc. 2012–20501 Filed 9–10–12; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2 and 95

[ET Docket No. 08–59; FCC 12–54]

Medical Area Body Network

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document expands the Commission's Medical Device Radiocommunications Service (MedRadio) rules to permit the development of new Medical Body Area Network (MBAN) devices in the 2360–2400 MHz band. The MBAN technology will provide a flexible platform for the wireless networking of multiple body transmitters used for the purpose of measuring and recording physiological parameters and other patient information or for performing diagnostic or therapeutic functions, primarily in health care facilities. This platform will enhance patient safety, care and comfort by reducing the need to physically connect sensors to essential monitoring equipment by cables and wires. This decision is the latest in a series of actions to expand the spectrum available for wireless medical use. The Commission finds that the risk of increased interference is minimal and is greatly outweighed by the benefits of the MBAN rules.

DATES: Effective October 11, 2012, except for §§ 95.1215(c), 95.1217(a)(3), 95.1223, and 95.1225, which contain information collection requirements that

are not effective until approved by the Office of Management and Budget. The Commission will publish a document in the **Federal Register** announcing the effective dates for those amendments. The Director of the Federal Register will approve the incorporation by reference in § 95.1223 concurrently with the published Office of Management and Budget approval of this section.

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SUPPLEMENTARY INFORMATION: This is a summary of the Commission's First Report and Order, ET Docket No. 08–59, FCC 12–54, adopted May 24, 2012 and released May 24, 2012. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY–A257), 445 12th Street SW., Washington, DC 20554. The complete text of this document also may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., 445 12th Street SW., Room, CY–B402, Washington, DC 20554. The full text may also be downloaded at: *www.fcc.gov.* People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

Summary of the First Report and Order

1. This First Report and Order (R&O) expands the Commission's part 95 MedRadio rules to permit the development of new Medical Body Area Network (MBAN) devices in the 2360–2400 MHz band. The MBAN technology will provide a flexible platform for the wireless networking of multiple body transmitters used for the purpose of measuring and recording physiological parameters and other patient information or for performing diagnostic or therapeutic functions, primarily in health care facilities. This platform will enhance patient safety, care and comfort by reducing the need to physically wire sensors to essential monitoring equipment. As the numbers and types of medical radio devices continue to expand, these technologies offer tremendous power to improve the state of health care in the United States. The specific MBAN technology that can be deployed under our revised rules promises to enhance patient care as well as to achieve efficiencies that can reduce overall health care costs.

2. The *Report and Order* adopts rules for MBAN operations on a secondary, non-interference basis under our ''license-by-rule'' framework. To address spectrum compatibility concerns with respect to incumbent operations under this approach, the Commission is establishing a process by which MBAN users will register and coordinate the use of certain equipment. In a concurrent Further Notice of Proposed Rulemaking, the Commission proposes the criteria for designating the frequency coordinator who will manage these activities. Notably, the Commission bases many of these procedures on a joint proposal (hereinafter the ''Joint Proposal'') submitted by representatives of incumbent Aeronautical Mobile Telemetry (AMT) licensees and the MBAN proponents—parties that, when the Commission issued the *Notice of Proposed Rulemaking* (NPRM) in this proceeding, strongly disagreed as to whether MBAN and AMT operations could successfully coexist in the same frequency band. Cooperative efforts such as this are beneficial in helping us realize the vital goal of promoting robust and efficient use of our limited spectrum resources.

3. The Commission concludes that there are significant public interest benefits associated with the development and deployment of new MBAN technologies. Existing wired technologies inevitably result in reduced patient mobility and increased difficulty and delay in transporting patients. Caregivers, in turn, can spend inordinate amounts of time managing and arranging monitor cables, as well as gathering patient data. The introduction of Wireless Medical Telemetry Service (WMTS) in health care facilities has overcome some of the obstacles presented by wired sensor networks. Nonetheless, the WMTS is restricted to in-building networks that are often used primarily for monitoring critical care patients in only certain patient care areas. The MBAN concept would allow medical professionals to place multiple inexpensive wireless sensors at different locations on or around a patient's body and to aggregate data from the sensors for backhaul to a monitoring station using a variety of communications media. The Commission concludes that an MBAN represents an improvement over traditional medical monitoring devices (both wired and wireless) in several ways, and will reduce the cost, risk and complexity associated with health care. The Commission also concludes that these benefits can be achieved with minimal cost. The only cost resulting from these new regulations is the risk of increased interference, and we are have minimizing that risk by adopting rules that permit an MBAN device to operate only over relatively short distances and as part of a low power networked system. This approach will permit us to provide frequencies where an MBAN can co-exist with existing spectrum users and engage in robust frequency re-use, which will result in greater spectral efficiency. As a result, the Commission believes that the risk of increased interference is low and is greatly outweighed by the substantial benefits of this new technology.

4. The rules adopted are based on and largely reflect the provisions of the *Joint Proposal* but differ from them in certain respects. The *Joint Proposal* is a comprehensive plan that draws from both the existing MedRadio and WMTS rules to specify MBAN operational requirements for body-worn sensors and hubs, but is drafted as a new subpart under part 95 of our Rules. It expands upon these rules, however, to include a detailed set of requirements for MBAN management within a health care facility. It also proposes that MBAN use in the 2360–2390 MHz band be limited mostly to indoor use and subject to specific coordination procedures and processes to protect AMT users in that band, whereas MBAN use in the 2390–2400 MHz band could occur at any location and without coordination. The *Joint Proposal* describes an MBAN as consisting of a master transmitter (hereinafter referred to as a ''hub''), which is included in a device close to the patient, and one or more client transmitters (hereinafter referred to as ''body-worn sensors'' or ''sensors''), which are worn on the body and only transmit while maintaining communication with the hub that controls its transmissions. The hub would convey data messages to the body-worn sensors to specify, for example, the transmit frequency that should be used. The hub and sensor devices would transmit in the 2360–2400 MHz band. The hub would aggregate patient data from the body-worn sensors under its control and, using the health care facility's local area network (LAN) (which could be, for example, Ethernet, WMTS or Wi-Fi links), transmit that information to locations where health care professionals monitor patient data. The hub also would be connected via the facility's LAN to a central control point that would be used to manage all MBAN operations within the health care facility. To protect AMT operations

from harmful interference, the *Joint Proposal* would have the Commission designate an MBAN frequency coordinator who would coordinate MBAN operations in the 2360–2390 MHz band with the AMT frequency coordinator. The control point would serve as the interface between the MBAN coordinator and the MBAN hub control operation in the 2360–2390 MHz band. The control point would receive an electronic key, which is a data message that specifies and enables use of specific frequencies by the MBAN devices. The control point, in turn, would generate a beacon or control message to convey a data message to the hub via the facility's LAN that specifies the authorized frequencies and other operational conditions for that MBAN.

5. The Commission's rules are based on the basic framework set forth in the *Joint Proposal,* particularly that an MBAN is comprised of two component devices—one that is worn on the body (sensor) and another that is located either on the body or in close proximity to it (hub)—that are used to monitor a patient's physiological functions and to communicate the data back to a monitoring station. Thus, the Commission will specify an MBAN to be a low power network of body sensors controlled on a localized basis by a single hub device, and use this framework as the context for our discussions. An MBAN shares many characteristics with other established medical radio services and applications. For example, MBAN devices would operate consistent with the definitions for body-worn devices in the MedRadio rules. Also, the data transmitted over the wireless link from the body-worn sensors to the nearby controlling hub would consist of physiological readings and other patient-related information that is transmitted via radiated electromagnetic signals, which follows the definition of medical telemetry in the WMTS rules. The Commission is therefore authorizing MBAN operations under our existing part 95 MedRadio rules, and the requirements adopted are limited to the operation of MBAN devices within the 2360–2400 MHz band.

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

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

Spectrum for MBAN Operation

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

9. The Commission also concludes that the 40 megahertz of spectrum in the 2360–2400 MHz band it proposed to allocate in the *NPRM* is an appropriate allocation for MBAN use. Both General Electric Healthcare (GEHC) and Philips Healthcare Systems (Philips) discuss how peak MBAN deployments would require as much as 20 megahertz of spectrum to be available if on an exclusive basis, and assert that a full 40 megahertz allocation would maximize the opportunity for MBAN devices that operate on a secondary basis to avoid interference to and from primary users. The Commission finds these arguments persuasive. Any MBAN device designed to operate in the 2360–2400 MHz band will also have to be designed to operate in a manner that will protect incumbent licensees, and a 40-megahertz allocation will provide sufficient spectrum flexibility to serve this goal. In addition, this allocation will enable greater frequency diversity and promote reliable MBAN performance. This is particularly true given the Commission's decision, to allow an MBAN device to operate with an emission bandwidth up to 5 megahertz. Additionally, the Commission finds that the 40-megahertz allocation is appropriate because it will allow for reliable MBAN operations in high-density settings, such as waiting rooms, elevator lobbies, and preparatory areas, where multiple MBAN-equipped patients will congregate. For example, AdvaMed notes that a smaller spectrum allocation might not allow for the use of devices by multiple vendors in the same hospital and thereby drive up costs, and also claims that more limited spectrum access would not support all of the currently conceived MBAN device applications. It is clear that such a scenario would increase costs by

reducing competition and effectively limiting the use of multiple MBAN devices; this, in turn, could deprive many patients of the health care and cost-saving benefits that MBAN operations are poised to deliver. For all of these reasons, the Commission agree that the 40 MHz of spectrum proposed in the *NPRM* ''will maximize opportunities to avoid interference through frequency separation, support the coexistence of multiple and competitive MBAN networks, and provide the spectrum needed for future innovation.''

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

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

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

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

14. Lastly, the Commission observes that, because MBAN operations will be permitted adjacent to other bands that host a variety of different services, MBAN users will have to take into account the operating characteristics of those adjacent-band services. The upper end of the band, 2400 MHz, is immediately adjacent to the spectrum used by unlicensed devices—such as Wi-Fi and wireless local area network (WLAN) devices—as well as industrial, scientific and medical (ISM) equipment operating under Part 18 of our Rules, both of which are widely used in health care settings. As MBAN users manage their facilities, they will need to consider the potential for adverse interaction between their MBAN, Wi-Fi, and ISM resources.

15. MBAN equipment will also operate immediately adjacent to the Wireless Communications Service (WCS) at 2360 MHz. As with any new service, it is incumbent on MBAN developers to evaluate and account for the operational characteristics of adjacent band services—in this case, WCS—when designing receivers and associated equipment. The Commission finds that it is unlikely WCS operations would preclude effective MBAN use given that MBAN operations near 2360 MHz will be in institutional settings under the control of a health care provider and because MBAN users will

have a large swath of spectrum in which to place their operations. Moreover, the record indicates that GEHC has already anticipated designing MBAN devices that use contention-based protocols and frequency agility to account for potential out of band emissions into the 2360–2400 MHz band. For these reasons, and notwithstanding filings made by the Wireless Communications Association, International (''WCAI''), the Commission finds no reason to adopt specific rules relating to adjacent-band WCS operations.

16. The Commission will add a new footnote US101 to the Table of Allocations to provide a secondary mobile, except aeronautical mobile, allocation in the 2360–2400 MHz band for use by the MedRadio Service. It is making this allocation through a unique footnote rather than a direct entry in the Table, or modification of the existing US276, in order to provide consistency across the entire band and to emphasize the limited nature of this allocation. It will place footnote US101 in both the Federal Table and non-Federal Table to facilitate MBAN use in a variety of settings such as in health care facilities operated by the Department of Veterans Affairs or the United States military, as well as non-Federal health care facilities. Because use of these frequencies will be on a secondary basis, MBAN stations will not be allowed to cause interference to and must accept interference from primary services, including AMT licensees operating under the primary mobile allocation in the 2360–2390 MHz and 2390–2395 MHz bands and Amateur Radio service licensees that operate on a primary basis in the 2390–2395 MHz and 2395–2400 MHz bands.

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

18. This action affirms the tentative conclusion from the *NPRM* that the Commission should allocate spectrum not currently used by existing medical radio services to support new MBAN operations. Although ARRL suggests that MBAN devices could make use of spectrum currently used by the WMTS, the Commission agrees with Philips that the WMTS bands are not suitable for MBAN devices because of the existing widespread use of WMTS applications in hospitals. The Commission does not believe that WMTS and MBAN devices would be able to successfully co-exist on the same frequencies simultaneously within the same facilities, leaving health care facilities with the dilemma of choosing between two valuable health care tools. A better course is to accommodate MBAN users in other frequencies. The Commission further notes that all of the other frequency bands identified in this proceeding for possible MBAN use have limitations that make them less desirable than the 2360–2400 MHz band. For example, Philips claims that the alternative bands are ''substantially inferior to the 2360–2400 MHz band'' for MBAN use, and predicts that ''devices would be unlikely to succeed for both cost and technical reasons, and the opportunity to benefit from better healthcare using these devices likely would be substantially delayed or lost.'' The Commission agrees, and briefly discusses each of the alternate band proposals.

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

A. Licensing Framework

20. The Commission concludes that authorizing MBAN use on a license-by-rule basis within its part 95 rules is the best approach. These devices share many characteristics with medical radiocommunications technologies that are already authorized under a license-by-rule approach, and the Commission finds that this framework can promote the rapid and robust development of MBAN devices without subjecting users to an unnecessarily burdensome individual licensing process. Moreover, the Commission is adopting appropriate technical rules and coordination procedures to ensure that MBAN devices can successfully operated on a secondary basis in the 2.3 GHz band without the need for individual licenses.

21. While an MBAN may be similar to WMTS in purpose—both involve the measurement and recording of physiological parameters and other patient-related information—the Commission finds that they are closer to MedRadio devices in their implementation. Like MedRadio devices, MBAN devices will be designed to operate at low power levels. Moreover, the two MBAN components—the body-worn sensor and the nearby hub—are functionally analogous to the medical body-worn device and associated MedRadio programmer/control transmitter that are provided for in our MedRadio rules. Although the Commission recognizes that it could codify the MBAN rules as a separate rule subpart, it concludes that the best course is to modify the existing MedRadio rules. This is the same approach the Commission recently took when providing for the development of new ultra-low power wideband networks consisting of multiple transmitters implanted in the body that use electric currents to activate and monitor nerves and muscles. Moreover this approach avoids duplicating existing rules that logically apply to both MBAN and existing MedRadio devices. This, in turn, will ensure that any future rules that affect MBAN and other MedRadio applications will be updated in a comprehensive and consistent manner. Also, because the MedRadio rules already distinguish

between each of the various types of MedRadio devices when necessary by, for example, setting forth particular operational rules and authorized frequencies, we will still be able to add MBAN-specific rules when and where appropriate.

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

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

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

Service and Technical Rules

23. The Commission now sets forth the specific service and technical parameters that will define an MBAN. Because it has chosen to regulate MBAN devices under the MedRadio rules, the Commission has analyzed those rules to determine which need to be modified for MBAN devices and which are already suitable for MBAN use. The Commission focuses primarily on those service and technical rules that require further modification.

Service Rules

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

25. The Joint Parties ask that the Commission expand MBAN eligibility to permit manufacturers and vendors (and their representatives) to operate MBAN transmitters for developing, demonstrating and testing purposes. Although the Joint Parties state that this would mirror analogous provisions in the WMTS rules, in fact the WMTS rules permit manufacturers and their representatives to operate such equipment only for purposes of ''demonstrating'' such equipment. There is similar language in the current MedRadio rules that permits operation of MedRadio equipment by manufacturers ''and their representatives.'' This language permits vendors to demonstrate MBAN equipment as representatives of a manufacturer. Thus, the Commission is not modifying the current rule to state this specifically. It further notes that the current rule would not preclude authorized healthcare professionals from contracting for the services of third parties to operate an MBAN. Additionally, for the reasons discussed regarding the frequency coordinators' roles, the Commission did not modify this rule to include frequency coordinators as eligible operators of MBAN equipment. With respect to expanding the MedRadio rule to permit equipment operation by manufacturers for developing and testing purposes, it is not persuaded that such a rule revision is necessary. The Commission's experimental licensing rules provide the appropriate process for granting non-licensees operational authority for developing and testing MedRadio devices, including MBAN devices.

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

27. As an initial matter, no commenter objected to allowing an MBAN to communicate both diagnostic and therapeutic information. The Commission will apply § 95.1209(a) of its rules, as written, to MBAN operations. While this rule provides considerable flexibility to provide data and visual information, it does not allow voice data, as requested by AT&T. The Commission believes that the current MedRadio and WMTS prohibitions regarding voice data are

part of a proven framework in which to base MBAN operations, and note that AT&T's suggestion relates to general speculation about potential future MBAN functionality as opposed to a specific application it intends to deploy.

28. The Commission will require an MBAN to consist of a single programmer/control transmitter (or hub) that controls multiple (*i.e.,* non-implanted) sensor devices. The intent of defining an MBAN in this way is to prevent direct communications between programmer/controllers which would facilitate mesh type networks using MBAN controllers to potentially extend the range of an MBAN beyond the confines of the medical facility. Consequently, it will not permit direct communications between body-worn sensors or direct communication between programmer/control transmitters. Under the existing § 95.1209(c), programmer/control transmitters will be able to interconnect with other telecommunications systems. This will allow backhaul from a single patient-based MBAN control transmitter to a monitoring station that receives and processes MBAN body sensor data from multiple patients using frequencies other than the 2360–2400 MHz band. The Commission recognizes that some commenters would have us allow one programmer/control transmitter to be controlled by a separate programmer/control transmitter or permit direct communications between body-worn sensor devices. It does not adopt these proposals. The Commission believes that the rules it adopted provide more certainty that an MBAN will operate in compliance with it rules or a coordination agreement because each programmer/control transmitter and its associated body-worn sensors will operate in response to a control message received over the facility's LAN. As the Commission gain further experience with MBAN operations, it may revisit these restrictions.

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

30. *Authorized Locations.* The Commission sought comment on whether it would be appropriate to restrict the use of MBAN transmitting antennas to indoor locations in certain frequency bands, and noted that its WMTS rules restrict antennas to indoor use only, while the MedRadio rules provide for the use of temporary outdoor antennas. The Commission modified §§ 95.1203 and 95.1213 of the MedRadio rules to provide for indoor-only MBAN operation in the 2360–2390 MHz band and MBAN operation at any location in the 2390–2400 MHz band.

31. The Commission's decision on this issue is consistent with the approach suggested in the *Joint Proposal.* It finds that limiting MBAN operation in the 2360–2390 MHz band to indoor locations within health care facilities is a reasonable and effective way to limit potential interference and promote sharing between MBAN and AMT users. It is also consistent with the coordination procedures being adopted. Although AT&T suggests that any rule restricting use to indoors would limit the usefulness of an MBAN, the Commission disagrees and notes that GEHC and other likely equipment developers have not been deterred by the prospect of indoor-only operation. Moreover, in the 2390–2400 MHz band, where there are fewer AMT interference concerns, the Commission is able to provide MBAN users with the added flexibility of operating in any location. The Commission rejected the suggestion by the Joint Parties that it modify the rules to permit outdoor operation in the 2360–2390 MHz band in cases of a ''medical emergency declared by duly authorized governmental authorities after emergency coordination with the AMT coordinator.'' The Commission finds that the suggested exception does not clearly define ''medical emergency'' or ''authorized governmental authorities'' and would essentially delegate authority to unnamed third parties to determine when outdoor MBAN operation is permitted. Instead, the Commission observed that there are other approaches that would as readily address this issue. Health care facilities can consider using MBAN devices that are capable of shifting to the 2390–2400 MHz band—where it is not necessary to receive prior approval to operate outdoors—in anticipation of situations where there may not be time to perform a quick coordination, such as an emergency in a part of the health care facility that requires some patients to be temporarily moved outdoors. For extraordinary circumstances involving outdoor use of the 2360–2390 MHz band, MBAN licensees will have to follow the same course of action as other licensees when emergencies occur, and ask the applicable licensing bureau (in this case, the Wireless Telecommunications Bureau) for a temporary waiver to permit such operation. The Commission expects that, in *bona fide* emergency situations, the MBAN and AMT licensees and the frequency coordinators will all cooperate to identify frequencies that can be made available for emergency MBAN operations as quickly as possible while ensuring flight safety.

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

33. Although no commenter specifically addressed this issue, the Commission notes that the certification requirement in § 95.603(f) of the rules does not apply to transmitters that are not marketed for use in the United States, but are being used in the United States by individuals who have traveled to the United States from abroad and comply with the applicable technical requirements. This provision will apply to MBAN devices. The disclosure statement and labeling requirements, which are similar to those suggested in the *Joint Proposal,* are based on requirements that have been in place

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

34. *Other Service Issues.* The Commission will also adopt the proposals in the *NPRM* that MBAN devices will not be required to transmit a station identification announcement, and that all MBAN transmitters are made available for inspection upon request by an authorized FCC representative. These requirements are the same as the existing MedRadio rules, and no commenters objected to applying these provisions to MBAN users. The Commission also updated § 95.1211 of its rules (''Channel Use Policy'') to reference the 2360–2400 MHz band.

Technical Rules

35. *Authorized Bandwidth and Channel* Aggregation. In the *NPRM,* the Commission sought 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). The record reflects broad support for this approach, and the Commission modified § 95.633 to specify a 5-megahertz maximum authorized bandwidth for MBAN devices. This approach is consistent with the existing MedRadio rules.

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

37. *Transmitter Operation and Power Limits.* In the *NPRM,* the Commission sought comment on the appropriate maximum transmitter power for MBAN devices. It proposed to limit individual MBAN devices to a maximum transmit power of 1 mW equivalent isotropic radiated power (EIRP) measured in a 1 megahertz bandwidth, which followed GEHC's proposal. The *Joint Proposal* suggested use of a maximum EIRP of 20 mW measured in a 5 megahertz bandwidth for the 2390–2400 MHz band, but maintained the original 1 mW EIRP maximum for the 2360–90 MHz band. Based on the information provided in the record and the Commission's decision to adopt a maximum bandwidth of 5 megahertz, the Commission will modify § 95.639 of its rules to specify the power limits in the *Joint Proposal.*

38. The need for a different power limit in the upper portion of the MBAN band was addressed by Philips. The 2390–2400 MHz portion of the MBAN spectrum will have no restrictions regarding location or mobile use, and thus all in-home MBAN use will occur in this band. Philips provides a detailed discussion of the differences between home and hospital MBAN use, and contends that there are unique circumstances—such as the possibility that an adverse health event could result in the patient falling on the MBAN transmitter and the need to provide patients with full mobility within their homes—that warrant a higher power level for this 10 megahertz band. It also notes that the upper band's proximity to the ISM band means that the MBAN may have to overcome excess noise in some instances to ensure a reliable link budget. AdvaMed echoes Philips in support of a 20 mW maximum EIRP in the 2390–2400 MHz band. The Commission finds that there is good reason to make a distinction in the maximum power it authorizes in the lower 2360–2390 MHz and in the upper 2390–2400 MHz bands.

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

40. Although the Commission generally agrees with the Joint Parties' suggestions, because each health care facility's communications infrastructure

and physical layout will present unique capabilities and challenges, it will not establish any requirements for how control messages are distributed within a health care facility. The Commission revised § 95.628 of the rules, which specifies the technical requirements for MedRadio transmitters, so that the MBAN programmer/controller transmitters must be capable of receiving and complying with a control message specifying its particular operating parameters within the band. Specifically, an MBAN programmer/control transmitter may not commence operation and must automatically cease operating in the 2360–2390 MHz band if it does not receive a control message. It must also comply with a control message that directs it to limit its transmissions to segments of the band or to cease operation in the band. The Commission notes that the Joint Parties did not propose a specific period of time within which the MBAN transmitter must receive a control message to begin or continue operating. The proposal also did not prescribe a specific format or protocol for the control message. It will require applicants for equipment certification to attest that they comply with the requirement that MBAN equipment receive the control message by describing the protocols that the devices employ including the expected periodicity for reception of control messages that will allow the MBAN transmitter to begin or continue operating in the band. Additionally, the Commission expects that the control message will be an electronic message since it is expected to be sent using the health care facility's LAN. This helps to ensure that the MBAN meets the requirement for operating indoors on the 2360–2390 MHz band, since it will have to be tethered to a wireline network or within signal range of a wireless network within the facility.

41. *Unwanted Emissions.* In the *NPRM,* the Commission noted that the part 95 MedRadio rules set forth limits on unwanted emissions from medical transmitting devices operating in the 401–406 MHz band and sought comment on the appropriateness of applying the same general limits to MBAN operations in the 2360–2400 MHz bands. The Commission finds that the provisions in § 95.635(d) of its rules, which specify limits on unwanted emissions, are appropriate. Accordingly, the Commission modified this rule to reflect the use of the 2360–2400 MHz band by MBAN devices. It notes that the Joint Parties' proposal supports using the proposed limits on unwanted radiation and no party objected to the use of these figures. In addition, use of the MedRadio limits is consistent with our approach of accommodating MBAN operations under the existing MedRadio rules where practical.

42. *Frequency Stability.* In the *NPRM,* the proposed to require that MBAN transmitters comply with the MedRadio rules and maintain a frequency stability of +/− 100 ppm of the operating frequency over the ambient environmental temperature range: (1) 25 °C to 45 °C in the case of MBAN transmitters; and (2) 0 °C to 55 °C in the case of MBAN control transmitters. GEHC states that +/− 100 ppm is an acceptable limit for MBAN devices, but does not discuss the temperature range over which that stability should be required. The Commission is using the existing MedRadio definitions to regulate the MBAN sensor and hub devices. Under this construction, the existing temperature range for MedRadio programmer/control transmitters set forth in § 95.628(d)(2) of the rules will apply to MBAN hub devices without modification. Because no MBAN sensor will be implanted, the Commission further concludes that the 25 °C to 45 °C range it has for implanted devices should not apply to sensors. Instead it will use the broader 0 °C to 55 °C specification.

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

44. *Frequency Monitoring.* In the *NPRM,* the Commission sought comment on whether a frequency monitoring requirement should be required for MBAN devices to promote inter- and intra-service sharing and, if so, how it should develop such a protocol. The Commission encouraged commenters supporting implementation of a contention based protocol to discuss what kinds of contention protocols (*i.e.,* listen-before-talk (LBT) frequency monitoring, time slot synchronization, and frequency hopping) should or should not be utilized, and to explain in detail why or why not.

45. The Commission, citing an evolving record, finds that it is not necessary to specify protocols to ensure spectrum sharing among MBAN systems. Initial filings by GEHC as well as the Joint Parties indicated a desire to codify a sharing protocol requirement. Several parties that support contention protocols nevertheless have urged us to avoid adopting specific rules. In more recent pleadings, the Joint Parties state that, while manufacturers believe that MBAN devices are likely to incorporate a mechanism to avoid interference when operating in close proximity (such as within medical facilities), they do not wish for us to adopt detailed procedures that might inadvertently inhibit the development of innovative methods that would allow them to make more intensive use of the spectrum. The Commission believes that the best course is to refrain from mandating a sharing protocol requirement, particularly because it appears that these matters are already being addressed within the standards setting process. In addition, it believes that the relatively low power levels used by MBAN transmitters make it possible that the use of sharing protocols might be unnecessary in many situations. The Commission further concludes that MBAN manufacturers will determine the appropriate level of communications reliability through the risk management activities involved with medical device design that is subject to oversight by the Food and Drug Administration (FDA), and that they should be given the flexibility to meet that level of communications reliability through whatever means they find appropriate. The Commission also finds that because it is requiring frequency coordination for MBAN and AMT sharing, it is not necessary to adopt frequency monitoring rules to promote spectrum sharing between these services.

46. *Duty Cycle.* In the *NPRM,* the Commission sought comment on whether it should adopt specific duty cycle limits for MBAN transmitters in our rules and whether such limits would be needed to allow the functioning of a contention-based protocol for achieving reliable MBAN system performance, or for other

reasons. The Commission finds that it is not necessary to specify a duty cycle in its rules. The record indicates that manufacturers are likely to employ duty cycles even without a specific requirement to do so because it will allow them to achieve important operational goals. The Commission believes that the ongoing efforts of standards setting bodies to address MBAN use are adequate to address any relevant duty cycle considerations.

Registration and Coordination for the 2360–2390 MHz Band

47. The Commission adopted registration and coordination rules for MBAN operations in the 2360–2390 MHz band. Registration and coordination are two separate but related processes. A health care facility that intends to operate an MBAN in the 2360–2390 MHz band must register the MBAN with a frequency coordinator (''the MBAN coordinator'') that the Commission will designate. The registration requirement will ensure that the locations of all MBAN operations in the 2360–2390 MHz band are recorded in a database. As part of the coordination process, the MBAN coordinator will first determine if a proposed MBAN in the 2360–2390 MHz band will be within line-of-sight of an AMT receiver. If the MBAN transmitter is within line-of-sight of an AMT receive site, the MBAN and AMT coordinators will work cooperatively to assess the risk of interference between the two operations and determine the measures that may be needed to mitigate interference risk. The MBAN coordinator will notify the health care facility when coordination is complete and the MBAN must operate consistent with the terms of any agreement reached by the coordinators. If no agreement is reached, the MBAN will not be permitted to operate in the band. The health care facility may not operate the MBAN in the band until it receives the appropriate operating parameters from the MBAN coordinator. The Commission also adopted procedures to accommodate new AMT receive sites as well as changes to MBAN deployment and operations.

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

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

50. The rules that the Commission is adopting incorporate many, but not all, of the suggestions made by the Joint Parties, including their determination that the rules governing MBAN use of the 2360–2390 MHz band will be sufficient to protect AMT operations. The rules adopted provide the flexibility manufacturers, licensees and coordinators need to accommodate changes in both AMT and MBAN operations and assurance to AMT users that their future access to the spectrum will not be hampered.

Registration Requirement

51. The Commission adopts a new rule, § 95.1223, which requires health care facilities to register all MBAN devices they propose to operate in the 2360–2390 MHz band with a frequency coordinator designated by the Commission. MBAN operation in the 2360–2390 MHz band prior to registration is prohibited. The Commission believes that registration of all MBAN operations in the band will create a regulatory environment that promotes MBAN use and protects AMT operations. In order to register MBAN devices that operate in 2360–2390 MHz frequency range, a health care facility must provide to the MBAN coordinator the following information:

- Specific frequencies or frequency range(s) within the 2360–2390 MHz band to be used, and the capabilities of the MBAN equipment to use the 2390–2400 MHz band;
- Effective isotropic radiated power;
- Number of programmer/controller transmitters in use at the health care facility as of the date of registration including manufacturer name(s) and model numbers and FCC identification number;
- Legal name of the health care facility;
- Location of programmer/controller transmitters (*e.g.,* geographic coordinates, street address, building);
- Point of contact for the health care facility (*e.g.,* name, title, office, phone number, fax number, email address). This would typically be an administrator or other official who has a high level of authority within the facility; and
- Contact information (*e.g.,* name, title, office, phone number, fax number, email address) for the party that is responsible for ensuring that MBAN operations within the health care facility are discontinued or modified in the event such devices have to cease operating in all or a portion of the 2360–2390 MHz band due to interference or because the terms of coordination have changed. This person would typically be an employee or contractor. The health care facility also must state whether, in such cases, its MBAN operation is capable of defaulting to the 2390–2400 MHz band and that it is responsible for ceasing MBAN operations in the 2360–2390 MHz band or defaulting traffic to other hospital systems.

52. To ensure that the registration data maintained by the MBAN coordinator is accurate and up to date, the Commission is requiring heath care facilities to keep their registration information current and to notify the MBAN coordinator of any material changes to the location or operating parameters of a registered MBAN.

Because changes in MBAN location or operation could place that MBAN within line-of-sight of an AMT receive site, the Commission will prohibit the MBAN from operating under the changed parameters until the MBAN coordinator has determined if a new or revised coordination agreement with the AMT coordinator is required, and if so, coordination with the AMT coordinator is completed. The Commission will also require a health care facility to notify the MBAN coordinator whenever an MBAN programmer/controller transmitter in the 2360–2390 MHz band is permanently taken out of service, unless it is replaced with transmitter(s) using the same technical characteristics as those reported on the health care facility's registration.

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

54. The Commission does not believe that a frequency coordinator should be responsible for approving a health care facility's plans for complying with the rules or its plans for managing its internal systems for communications or patient care. The transition plan as described by the Joint Parties goes beyond the scope of the registration and coordination functions the Commission is requiring to ensure interference protection to AMT licensees, and those plans might overlap the risk assessment that is within the FDA's purview. The Commission does not believe that a frequency coordinator is an appropriate party for approving such plans or that the Commission should confer such approval authority on a frequency coordinator. The approach it adopts will allow health care facilities to manage their own MBAN systems or enter agreements as they determine to be appropriate for their individual situation, rather than adopting an approach that would require a health care facility to enter into service agreements with MBAN vendors. Finally, while the Commission does not require health care facilities to file a transition plan with the MBAN coordinator, it anticipates that health care facilities will create such plans in routine practice. The Commission encourages them to share such information with the MBAN coordinator to facilitate the coordination process.

55. The Commission has adopted a registration requirement for the 2360–2390 MHz band because it will facilitate coordination with AMT operations in that band; coordination is not needed and will not be required for an MBAN to operate in the 2390–2400 MHz band. The Commission's rules recognize that some MBAN equipment may operate across the whole 2360–2400 MHz band, but some equipment may be designed to operate only in the 2390–2400 MHz band which can be used for indoor or outdoor use without coordination. In the latter case, a registration requirement would unnecessarily burden hospitals that do not need assistance from the MBAN coordinator. Even if the Commission was persuaded that a registration requirement in the upper band would serve some useful purpose, the Commission's rules should not discriminate as to which facilities should be required to register. The rules require that any facility that registers MBAN equipment that operates in the 2360–2390 MHz specify whether its equipment can default to the 2390–2400 MHz band since this information will enable the coordinator to help the facility manage its MBAN operations consistent with any coordination agreements.

Coordination Requirement

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

57. The Joint Parties have suggested procedures to follow when AMT users

need to expand their operations beyond existing receiver locations. Since they are authorized on a primary basis in the 2360–2390 MHz band, AMT users are entitled to expand as necessary to provide for aeronautical testing purposes. Because health care facilities need to be certain of their ability to rely on MBAN devices and also need time to adapt to the increased AMT requirements, the Joint Parties propose that an AMT licensee planning to expand its operations would first consider using locations that are not within line-of-sight to existing MBAN locations. If locations outside the line-of-sight to MBAN operations are not available, the AMT coordinator would give the MBAN coordinator at least seven days notice that MBAN users would have to cease or modify their operations. Under this proposal, the MBAN operator would still be eligible to enter into a new or modified coordination agreement with the new AMT operator, but the MBAN operator would nevertheless be required to vacate its operations at the end of the seven-day period if no coordination agreement is reached. The Commission adopts this proposal because it finds that it provides for the continuing requirements of the AMT community and preserves their growth potential, while also providing adequate notice to MBAN operators to adapt to any new AMT requirements.

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

Coordinator Functions

59. To implement the registration and coordination requirements, the Commission will designate an MBAN coordinator(s) after resolution of the proceedings addressed in the *Further Notice*. The Commission has directed the staff to act expeditiously to prepare a decision in response to the Further Notice and to initiate the selection of an MBAN coordinator(s), with a target of completing the process by June 2013. The Commission adopts a new rule, § 95.1225, which sets forth the specific functions that the MBAN coordinator will perform. The MBAN coordinator must:

- Register health care facilities that operate an MBAN in the 2360–2390 MHz band, maintain a database of these MBAN transmitter locations and operational parameters, and provide the Commission with information contained in the database upon request;
- Determine if an MBAN is within line-of-sight of an AMT receive facility in the 2360–2390 MHz band and coordinate MBAN operations with the designated AMT coordinator;
- Notify a registered health care facility when an MBAN has to change frequency within the 2360–2390 MHz band or to cease operating in the band consistent with a coordination agreement between the MBAN and the AMT coordinators; and
- Develop procedures to ensure that registered health care facilities operate an MBAN consistent with the coordination requirements.
- Regarding the AMT coordinator functions, in 1969 the Commission designated Aerospace & Flight Test Radio Coordinating Council (AFTRCC) as the AMT coordinator under its rules. AFTRCC performs coordination for non-Federal Government licensees and coordinates with the Federal Government Area Frequency Coordinators for day-to-day scheduling of missions. In the *NPRM,* the Commission acknowledged AFTRCC's role as AMT coordinator and sought comment on the organization's involvement in MBAN and AMT spectrum-sharing. The Commission expects that AFTRCC will represent both Federal and non-Federal AMT interests when coordinating with the MBAN coordinator, thereby eliminating the need for MBAN licensees to separately coordinate with Federal AMT systems. This should significantly reduce the time needed to complete coordination and should facilitate timely deployment of MBAN operations.

Final Regulatory Flexibility Analysis

60. As required by the Regulatory Flexibility Act of 1980, as amended (RFA),[1] an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the Notice of Proposed Rulemaking (NPRM).[2] The Commission sought written public comment on the proposals in the *NPRM,* including comment on the IRFA. No comments were received addressing the IRFA. This present Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.[3]

A. Need for and Objective of the Report and Order

61. The Report and Order (R&O) expands our part 95 Medical Device Radiocommunication Service (MedRadio) rules to permit the development of new Medical Body Area Network (MBAN) devices. MBAN

[1] *See* 5 U.S.C. 603. The RFA, *see* 5 U.S.C. 601–612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Public Law 104–121, Title II, 110 Stat. 857 (1996).

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

[3] *See* 5 U.S.C. 604.

devices will be linked into wireless networks of multiple body transmitters used for measuring and recording physiological parameters and other patient information or for performing diagnostic or therapeutic functions, primarily in health care facilities. By reducing the need to physically connect sensors to essential monitoring equipment by cables and wires, MBAN technology will enhance patient care and promote efficiencies that can in turn reduce overall health care costs.

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

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

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

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

64. Pursuant to the Small Business Jobs Act of 2010, the Commission is required to respond to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration (SBA), and to provide a detailed statement of any change made to the proposed rules as a result of those comments. The Chief Counsel did not file any comments in response to the proposed rules in this proceeding.

D. Description and Estimate of the Number of Small Entities to Which the Adopted Rules Will Apply

65. The RFA directs agencies to provide a description of, and, where feasible, an estimate of the number of small entities that may be affected by the rules and policies adopted herein.[4] The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' [5] In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act.[6] A ''small business concern'' is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.[7] Nationwide, there are a total of approximately 27.5 million small businesses, according to the SBA. As an initial matter, the Commission notes that its decision will permit MBAN use of the 2390–2400 MHz band, which is also allocated to the Amateur Radio Service on a primary basis. Individuals who are the control operators of amateur radio stations are not ''small entities,'' as defined in the RFA.

66. *Personal Radio Services.* The MBAN devices will be subject to part 95 of our rules (''Personal Radio Services''). The Commission has not developed a small business size standard specifically applicable to these services. Therefore, for purposes of this analysis, the Commission uses the SBA small business size standard for the category Wireless Telecommunications Carriers (except Satellite), which is 1,500 or fewer employees.[8] Census data for 2007 show that there were 1,383 firms that operated that year.[9] Of those, 1,368 had fewer than 100 employees. Personal radio services provide short-range, low power radio for personal communications, radio signaling, and business communications not provided for in other services. The Personal Radio Services include spectrum licensed under part 95 of our rules and cover a broad range of uses.[10] Many of the licensees in these services are individuals and thus are not small entities. In addition, due to the fact that licensing of operation under part 95 is accomplished by rule (rather than by issuance of individual license), and due to the shared nature of the spectrum utilized by some of these services, the Commission lacks direct information other than the census data above upon which to base an estimation of the number of small entities under an SBA definition that might be directly affected by the proposed rules adopted.

67. *Wireless Communications Equipment Manufacturers.* The Census Bureau does not have a category specific to medical device radiocommunication manufacturing. The appropriate category is that for wireless communications equipment manufacturers. The Census Bureau defines this category as follows: ''This industry comprises establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment. Examples of products made by these establishments are: Transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment.'' The SBA has developed a small business size standard for Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, which is: All such firms having 750 or fewer employees.[11] According to Census bureau data for 2007, there were a total of 919 firms in this category that operated for the entire year. Of this total, 771 had fewer than 100 employees and 148 had more than 100 employees.[12] Thus, under this size standard, the majority of firms can be considered small.

68. Aeronautical Mobile Telemetry (AMT). Currently there are 9 AMT licensees in the 2360–2395 MHz band. It is unclear how many of these will be affected by our new rules. The Commission has not yet defined a small business with respect to aeronautical mobile telemetry services. Therefore, for purposes of this analysis, the

[4] 5 U.S.C. 603(b)(3).

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

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

[7] 15 U.S.C. 632 (1996).

[8] *See* 13 CFR 121.201, NAICS code 517210.

[9] U.S. Census Bureau, 2007 Economic Census, Sector 51, 2007 NAICS code 517210 (rel. Oct. 20, 2009), *http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-fds_name=EC0700A1&-_skip=700&-ds_name=EC0751SSSZ5&-_lang=en.*

[10] 47 CFR part 90.

[11] 13 CFR 121.201 NAICS code 334220.

[12] *See http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-fds_name=EC0700A1&-_skip=4500&-ds_name=EC0731SG3&-_lang=en.*

Commission uses the SBA small business size standard for the category Wireless Telecommunications Carriers (except Satellite), which is 1,500 or fewer employees.[13] Census data for 2007 show that there were 1,383 firms that operated that year.[14] Of those 1,368 had fewer than 100 employees. Thus, under this size standard, the majority of firms can be considered small. The rules we adopt provide the flexibility manufacturers, licensees and coordinators need to accommodate changes in both AMT and MBAN operations and assurance to AMT users that their future access to the spectrum will not be hampered.

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

69. Under the adopted rules, MBAN operators will not require individual licenses but instead will qualify for license-by-rule operation [15] pursuant to Section 307(e) of the Communications Act (Act).[16] While there is no requirement to file with the Commission, parties seeking to utilize the 2360–2390 MHz band must register with a frequency coordinator. The Commission will designate the MBAN frequency coordinator(s). The frequency coordinator will require the following information from an entity that seeks to operate an MBAN in the 2360–2390 MHz band:

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

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

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

72. MBAN use shall be restricted for use by persons only for diagnostic and therapeutic purposes and only to the extent that such devices have been provided to a human patient under the direction of a duly authorized health care professional.[18] An MBAN consists of only body-worn devices. A single MBAN programmer/controller may direct more than one MBAN. MBAN programmer/controller devices may not directly communicate with each other and MBAN component devices may not directly communicate with each other.[19]

73. An MBAN may transmit in an authorized bandwidth of 5 megahertz.[20] MBAN transmitters may transmit in the 2360–2390 MHz band, the maximum EIRP over the frequency bands of operation shall not exceed the lesser of 1 mW or 10*log (B) dBm, where B is the 20 dB emission bandwidth in MHz. MBAN transmitters may transmit in the 2390–2400 MHz band, the maximum EIRP over the frequency bands of operation shall not exceed the lesser of 20 mW or 16+10*log (B) dBm, where B is the 20 dB emission bandwidth in MHz. The MBAN must meet specific limits on unwanted emissions.[21] MBAN transmitters will be required to maintain a frequency stability as specified in the current MedRadio rules of ± 100 ppm of the operating frequency over the range 0°C to 55°C.[22]

74. MBAN transmitters must be certificated except for such transmitters that are not marketed for use in the United States, are being used in the United States by individuals who have traveled to the United States from abroad, and comply with the applicable technical requirements. Manufacturers of MBAN transmitters must include with each transmitting device a disclosure statement and each MBAN programmer/controller must be labeled with a statement.[23] An MBAN may be operated anywhere that CB station operation is authorized under § 95.405,

[13] *See* 13 CFR 121.201, NAICS code 517210.

[14] U.S. Census Bureau, 2007 Economic Census, Sector 51, 2007 NAICS code 517210 (rel. Oct. 20, 2009), *http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-fds_name=EC0700A1&-_skip=700&-ds_name=EC0751SSSZ5&-_lang=en.*

[15] *See* 47 CFR 95.1201.

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

[17] Paras. 48–49, *supra.*

[18] Paras. 33–34, *supra.*

[19] Paras. 35–38, *supra.*

[20] Paras. 44–45, *supra.*

[21] Paras. 46–47, *supra.*

[22] Para. 51, *supra.*

[23] Paras 41–42, *supra.*

except in the 2360–2390 MHz band MBAN use is restricted to indoor operation within a health care facility registered with the MBAN coordinator, and an MBAN is not required to transmit a station identification announcement. All non-MBAN transmitters must be made available for inspection upon request by an authorized FCC representative.[24]

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

75. 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]

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

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

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

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

Report to Congress

80. The Commission will send a copy of the Report and Order, including this FRFA, in a report to Congress pursuant to the Congressional Review Act.[26] In addition, the Commission will send a copy of the Report and Order, including this FRFA, to the Chief Counsel for Advocacy of the SBA. A copy of the Report and Order and the FRFA (or summaries thereof) will also be published in the **Federal Register**.

81. Pursuant to the authority contained in Sections 4(i), 301, 302, 303(e), 303(f), 303(r), and 307(e) of the Communications Act of 1934, as amended, 47 U.S.C. Sections 154(i), 301, 302, 303(e), 303(f), 303(r), and 307(e), this Report and Order IS ADOPTED and parts 2 and 95 of the Commission's rules are amended as set forth in Final rules will become October 11, 2012, except for §§ 95.1215(c), 95.1217(a)(3), 95.1223 and 95.1225, which contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13, that are not effective until approved by the Office of Management and Budget. The Federal Communications Commission will publish a document in the **Federal Register** announcing OMB approval and the effective date of these rules.

82. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this Report and Order, including the Final Regulatory Flexibility Analysis in Appendix C, to the Chief Counsel for Advocacy of the Small Business Administration.

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

List of Subjects

47 CFR Part 2

Communications equipment, Reporting and recordkeeping.

47 CFR Part 95

Communications equipment, Incorporation by reference, Medical devices, Reporting and recordkeeping.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR parts 2 and 95 as follows:

PART 2—FREQUENCY ALLOCATIONS AND RADIO TREATY MATTERS; GENERAL RULES AND REGULATIONS

■ 1. The authority citation for part 2 continues to read as follows:

Authority: 47 U.S.C. 154, 302a, 303, and 336, unless otherwise noted.

■ 2. Section 2.106, the Table of Frequency Allocations, is amended as follows:

■ a. Pages 37 and 38 are revised.

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

The revisions and addition read as follows:

§ 2.106 Table of Frequency Allocations.

* * * * *

BILLING CODE 6712–01–P

[24] Para. 43, *supra.*

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

[26] *See* 5 U.S.C. 801(a)(1)(A).

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2520-2655 FIXED 5.410 MOBILE except aeronautical mobile 5.384A BROADCASTING-SATELLITE 5.413 5.416	2520-2655 FIXED 5.410 FIXED-SATELLITE (space-to-Earth) 5.415 MOBILE except aeronautical mobile 5.384A BROADCASTING-SATELLITE 5.413 5.416	2520-2535 FIXED 5.410 FIXED-SATELLITE (space-to-Earth) 5.415 MOBILE except aeronautical mobile 5.384A BROADCASTING-SATELLITE 5.413 5.416 5.403 5.414A 5.415A			
		2535-2655 FIXED 5.410 MOBILE except aeronautical mobile 5.384A BROADCASTING-SATELLITE 5.413 5.416			
5.339 5.405 5.412 5.417C 5.417D 5.418B 5.418C	5.339 5.417C 5.417D 5.418B 5.418C	5.339 5.417A 5.417B 5.417C 5.417D 5.418 5.418A 5.418B 5.418C	5.339 US205	5.339	

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United States (US) Footnotes

* * * * *

US101 The band 2360–2400 MHz is also allocated on a secondary basis to the mobile, except aeronautical mobile, service. The use of this allocation is limited to MedRadio operations. MedRadio stations are authorized by rule and operate in accordance with 47 CFR part 95.

* * * * *

PART 95—PERSONAL RADIO SERVICES

■ 3. The authority citation for part 95 continues to read as follows:

Authority: Secs. 4, 303, 48 Stat, 1066, 1082, as amended; 47 U.S.C. 154, 303.

Subpart E—Technical Regulations

■ 4. Section 95.628 is revised to read as follows:

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

The following provisions apply to MedRadio transmitters operating in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands as part of a Medical Micropower Network (MMN) and in the 2360–2400 MHz band as part of a Medical Body Area Network (MBAN).

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

(1) Only MedRadio stations that are part of an MMN may operate in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz frequency bands. Each MedRadio station that is part of an MMN must be capable of operating in each of the following frequency bands: 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz. All MedRadio stations that are part of a single MMN must operate in the same frequency band.

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

(b) *Requirements for a Medical Micropower Network.* (1) *Frequency monitoring.* MedRadio programmer/control transmitters must incorporate a mechanism for monitoring the authorized bandwidth of the frequency band that the MedRadio transmitters intend to occupy. The monitoring system antenna shall be the antenna used by the programmer/control transmitter for a communications session.

(i) The MedRadio programmer/control transmitter shall be capable of monitoring any occupied frequency band at least once every second and monitoring alternate frequency bands within two seconds prior to executing a change to an alternate frequency band.

(ii) The MedRadio programmer/control transmitter shall move to another frequency band within one second of detecting a persistent (*i.e.,* lasting more than 50 milliseconds in duration) signal level greater than −60 dBm as received by a 0 dBi gain antenna in any 12.5 kHz bandwidth within the authorized bandwidth.

(iii) The MedRadio programmer/control transmitter shall be capable of monitoring the authorized bandwidth of the occupied frequency band to determine whether either direction of the communications link is becoming degraded to the extent that communications is likely to be lost for more than 45 milliseconds. Upon making such a determination the MedRadio programmer/control transmitter shall move to another frequency band.

(2) *MedRadio transmitters.* MedRadio transmitters shall incorporate a programmable means to implement a system shutdown process in the event of communication failure, on command from the MedRadio programmer/control transmitter, or when no frequency band is available. The shutdown process shall commence within 45 milliseconds after loss of the communication link or receipt of the shutdown command from the MedRadio programmer/control transmitter.

(3) *MedRadio programmer/control transmitters.* MedRadio programmer/control transmitters shall have the ability to operate in the presence of other primary and secondary users in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands.

(4) *Authorized bandwidth.* The 20 dB authorized bandwidth of the emission from a MedRadio station operating in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands shall not exceed 6 MHz.

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

(d) *Frequency stability.* Each transmitter in the MedRadio service must maintain a frequency stability of ±100 ppm of the operating frequency over the range:

(1) 25 °C to 45 °C in the case of medical implant transmitters; and

(2) 0 °C to 55 °C in the case of MedRadio programmer/control transmitters and Medical body-worn transmitters.

(e) *Shared access.* The provisions of this section shall not be used to extend the range of spectrum occupied over space or time for the purpose of denying fair access to spectrum for other MedRadio systems.

(f) *Measurement procedures.* (1) MedRadio transmitters shall be tested for frequency stability, radiated emissions and EIRP limit compliance in accordance with paragraphs (f)(2) and (3) of this section.

(2) Frequency stability testing shall be performed over the temperature range set forth in (d) of this section.

(3) Radiated emissions and EIRP limit measurements may be determined by measuring the radiated field from the equipment under test at 3 meters and calculating the EIRP. The equivalent radiated field strength at 3 meters for 1 milliwatt, 25 microwatts, 250 nanowatts, and 100 nanowatts EIRP is 115.1, 18.2, 1.8, or 1.2 mV/meter, respectively, when measured on an open area test site; or 57.55, 9.1, 0.9, or 0.6 mV/meter, respectively, when measured on a test site equivalent to free space such as a fully anechoic test chamber. Compliance with the maximum transmitter power requirements set forth in § 95.639(f) shall be based on measurements using a peak detector function and measured over an interval of time when transmission is continuous and at its maximum power level. In lieu of using a peak detector function, measurement procedures that have been found to be acceptable to the Commission in accordance with § 2.947 of this chapter may be used to demonstrate compliance. For a transmitter intended to be implanted in a human body, radiated emissions and EIRP measurements for transmissions by stations authorized under this section may be made in accordance with a Commission-approved human body simulator and test technique. A formula for a suitable tissue substitute material is defined in OET Bulletin 65 Supplement C (01–01).

■ 5. Section 95.633 is amended by revising paragraph (e)(1) to read as follows:

§ 95.633 Emission bandwidth.

* * * * *

(e) * * *

(1) For stations operating in 402–405 MHz, the maximum authorized emission bandwidth is 300 kHz. For stations operating in 401–401.85 MHz or 405–406 MHz, the maximum authorized emission bandwidth is 100 kHz. For stations operating in 401.85–402 MHz, the maximum authorized emission bandwidth is 150 kHz. For stations operating in 413–419 MHz, 426–432 MHz, 438–444 MHz, or 451–457 MHz, the maximum authorized emission bandwidth is 6 megahertz. For stations operating in 2360–2400 MHz, the maximum authorized emission bandwidth is 5 megahertz.

* * * * *

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

§ 95.635 Unwanted radiation.

* * * * *

(d) * * *

(1) * * *

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

* * * * *

(7) For devices designed to operate in the 2360–2400 MHz band: In the first 2.5 megahertz beyond any of the frequency bands authorized for MBAN operation, the EIRP level associated with any unwanted emission must be attenuated within a 1 megahertz bandwidth by at least 20 dB relative to the maximum EIRP level within any 1 megahertz of the fundamental emission.

* * * * *

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

§ 95.639 Maximum transmitter power.

* * * * *

(f) * * *

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

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

* * * * *

■ 8. Appendix 1 is amended by adding a definition for ''Medical Body Area Network'' to the definitions list in alphabetical order:

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

* * * * *

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

* * * * *

Subpart I—Medical Device Radiocommunications Service (MedRadio)

■ 9. Section 95.1203 is revised to read as follows:

§ 95.1203 Authorized locations.

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

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

§ 95.1209 Permissible communications.

* * * * *

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

* * * * *

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

§ 95.1211 Channel use policy.

* * * * *

(c) MedRadio operation is subject to the condition that no harmful interference is caused to stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services, or to other authorized stations operating in the 413–419 MHz, 426–432 MHz, 438–444 MHz, 451–457, and 2360–2400 MHz bands. MedRadio stations must accept any interference from stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services, and from other authorized stations operating in the 413–419 MHz, 426–432 MHz, 438–444 MHz, 451–457, and 2360–2400 MHz bands.

■ 12. Section 95.1213 is revised to read as follows:

§ 95.1213 Antennas.

Except for the 2390–2400 MHz band, no antenna for a MedRadio transmitter shall be configured for permanent outdoor use. In addition, any MedRadio antenna used outdoors shall not be affixed to any structure for which the height to the tip of the antenna will exceed three (3) meters (9.8 feet) above ground.

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

§ 95.1215 Disclosure policies.

* * * * *

(c) Manufacturers of MedRadio transmitters operating in the 2360–2400 MHz band must include with each transmitting device the following statement:

''This transmitter is authorized by rule under the MedRadio Service (47 CFR part 95). This transmitter must not cause harmful interference to stations authorized to operate on a primary basis in the 2360–2400 MHz band, and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the MedRadio Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular

transmission from this transmitter will be free from interference.''

■ 14. Section 95.1217 is amended by adding paragraph (a)(3) and revising paragraph (c) to read as follows:

§ 95.1217 Labeling requirements.

* * * * *

(a) * * *

(3) MedRadio programmer/control transmitters operating in the 2360–2400 MHz band shall be labeled as provided in part 2 of this chapter and shall bear the following statement in a conspicuous location on the device:

''This device may not interfere with stations authorized to operate on a primary basis in the 2360–2400 MHz band, and must accept any interference received, including interference that may cause undesired operation.''

The statement may be placed in the instruction manual for the transmitter where it is not feasible to place the statement on the device.

* * * * *

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

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

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

(a) *Registration.* A health care facility must register all MBAN devices it proposes to operate in the 2360–2390 MHz band with a frequency coordinator designated under § 95.1225 of this chapter. Operation of these devices in the 2360–2390 MHz band is prohibited prior to the MBAN coordinator notifying the health care facility that registration and coordination (to the extent coordination is required under paragraph (c) of this section), is complete. The registration must include the following information:

(1) Specific frequencies or frequency range(s) within the 2360–2390 MHz band to be used, and the capabilities of the MBAN equipment to use the 2390–2400 MHz band;

(2) Effective isotropic radiated power;

(3) Number of control transmitters in use at the health care facility as of the date of registration including manufacturer name(s) and model numbers and FCC identification number;

(4) Legal name of the health care facility;

(5) Location of control transmitters (*e.g.,* geographic coordinates, street address, building);

(6) Point of contact for the health care facility (*e.g.,* name, title, office, phone number, fax number, email address); and

(7) In the event an MBAN has to cease operating in all or a portion of the 2360–2390 MHz band due to interference under § 95.1211 or changes in coordination under paragraph (c) of this section, a point of contact (including contractors) for the health care facility that is responsible for ensuring that this change is effected whenever it is required (*e.g.,* name, title, office, phone number, fax number, email address). The health care facility also must state whether, in such cases, its MBAN operation is capable of defaulting to the 2390–2400 MHz band and that it is responsible for ceasing MBAN operations in the 2360–2390 MHz band or defaulting traffic to other hospital systems.

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

(c) *Coordination procedures.* The frequency coordinator will determine if an MBAN is within the line of sight of an AMT receive facility in the 2360–2390 MHz band and notify the health care facility when it may begin MBAN operations under the applicable procedures in (c)(1) or (2) of this section.

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

(2) If the MBAN is within line of sight of an AMT receive facility, the MBAN frequency coordinator shall achieve a mutually satisfactory coordination agreement with the AMT frequency coordinator prior to the MBAN beginning operations in the band. Such coordination agreement shall provide protection to AMT receive stations consistent with International Telecommunication Union (ITU) Recommendation ITU–R M.1459, ''Protection criteria for telemetry systems in the aeronautical mobile service and mitigation techniques to facilitate sharing with geostationary broadcasting-satellite and mobile-satellite services in the frequency bands 1 452–1 525 and 2 310–2 360 MHz,'' May 2000, as adjusted using generally accepted engineering practices and standards that are mutually agreeable to both coordinators to take into account the local conditions and operating characteristics of the applicable AMT and MBAN facilities, and shall specify when the device shall limit its transmissions to segments of the 2360–2390 MHz band or shall cease operation in the band. This ITU document is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 and approved by the Director of Federal Register. Copies of the recommendation may be obtained from ITU, Place des Nations, 1211 Geneva 20, Switzerland, or online at *http://www.itu.int/en/publications/Pages/default.aspx.* You may inspect a copy at the Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* ''Generally accepted engineering practices and standards'' include, but are not limited to, engineering analyses and measurement data as well as limiting MBAN operations in the band by time or frequency.

(3) If an AMT operator plans to operate a receive site not previously analyzed by the MBAN coordinator to determine line of sight to an MBAN facility, the AMT operator shall consider using locations that are beyond the line of sight of a registered health care facility. If the AMT operator determines that non-line of sight locations are not practical for its

purposes, the AMT coordinator shall notify the MBAN coordinator upon no less than 7 days' notice that the registered health care facility must cease MBAN operations in the 2360–2390 MHz band unless the parties can achieve a mutually satisfactory coordination agreement under paragraph (c)(2) of this section.

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

§ 95.1225 Frequency coordinator.

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

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

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

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

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

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

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

[FR Doc. 2012–21984 Filed 9–10–12; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 111213751–2102–02]

RIN 0648–XC224

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod in the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; modification of a closure.

SUMMARY: NMFS is opening directed fishing for Pacific cod by catcher vessels less than 60 feet (18.3 meters) length overall (LOA) using hook-and-line or pot gear in the Bering Sea and Aleutian Islands Management Area (BSAI). This action is necessary to fully use the 2012 total allowable catch of Pacific cod allocated to catcher vessels less than 60 feet LOA using hook-and-line or pot gear in the BSAI.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), September 6, 2012, through 2400 hrs, A.l.t., December 31, 2012. Comments must be received at the following address no later than 4:30 p.m., A.l.t., September 21, 2012.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2012–0174, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal *www.regulations.gov.* To submit comments via the e-Rulemaking Portal, first click the ''submit a comment'' icon, then enter NOAA–NMFS–2012–0174 in the keyword search. Locate the document you wish to comment on from the resulting list and click on the ''Submit a Comment'' icon on that line.
- *Mail:* Address written comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Ellen Sebastian. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.
- *Fax:* Address written comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Ellen Sebastian. Fax comments to 907–586–7557.
- *Hand delivery to the Federal Building:* Address written comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Ellen Sebastian. Deliver comments to 709 West 9th Street, Room 420A, Juneau, AK.

Instructions: Comments must be submitted by one of the above methods to ensure that the comments are received, documented, and considered by NMFS. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (e.g., name, address) submitted voluntarily by the sender will be publicly accessible.

Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word or Excel, WordPerfect, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Obren Davis, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

NMFS closed directed fishing for Pacific cod by catcher vessels less than 60 feet LOA using hook-and-line or pot gear in the BSAI under § 679.20(d)(1)(iii) on February 17, 2012 (77 FR 10400, February 22, 2012).

NMFS has determined that as of September 5, 2012, approximately 1,134 metric tons of Pacific cod remain in the 2012 Pacific cod apportionment for catcher vessels less than 60 feet LOA using hook-and-line or pot gear in the BSAI. Therefore, in accordance with § 679.25(a)(1)(i), (a)(2)(i)(C), and (a)(2)(iii)(D), and to fully use the 2012 total allowable catch (TAC) of Pacific cod in the BSAI, NMFS is terminating the previous closure and is opening directed fishing for Pacific cod by catcher vessels less than 60 feet LOA using hook-and-line or pot gear in the BSAI. The Administrator, Alaska